UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 11,337,834 B2
APPLICATION NO. : 17/327673
DATED : May 24, 2022
INVENTOR(S) : Ali Shahriari

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

On Page 2:
Line 16 of Item (63) "Related U.S. Application Data", "9,339,399, which is a continuation of application No." should be replaced with --9,339,399, which is a division of application No.--

Signed and Sealed this
Twelfth Day of July, 2022

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office

Edwards v. Aortic Innovations
U.S. Patent 11,337,834
Edwards Ex. 1002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.	:	11,337,834	Confirmation No.:	1189
Application No.	:	17/327,673		
Patentee	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Issue Date	:	May 24, 2022		
TC/A.U.	:	3774		
Examiner	:	Tiffany P SHIPMON		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Patentee hereby requests pursuant to 35 U.S.C. §254 and 37 C.F.R. §1.322 that a Certificate of Correction be granted for the above-identified patent.

The requested correction to the coversheet on page 2 is as follows:

Line 16 of "Related U.S. Application Data", "9,339,399, which is a continuation of application No." should be replaced with --9,339,399, which is a division of application No.—

The correct continuity type was listed on the Application Data Sheet submitted on May 22, 2021 and on the official filing receipt mailed June 1, 2021. Therefore, the patentee believes that the mistake is the fault of the Office and that no fees are due at this time.

If there are any questions regarding this request, please call the attorney identified below.

Respectfully submitted,

Date: June 14, 2022

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

PTO/SB/44 (09-07)
Approved for use through 01/31/2020. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,337,834

APPLICATION NO.: 17/327,673

ISSUE DATE : May 24, 2022

INVENTOR(S) : Ali Shahriari

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On Page 2:

Line 16 of "Related U.S. Application Data", "9,339,399, which is a continuation of application No." should be replaced with --9,339,399, which is a division of application No.--

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

Justin R. Nifong, NK Patent Law, 4917 Waters Edge Drive, Suite 275, Raleigh, NC 27606

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	45946681
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	14-JUN-2022
Filing Date:	22-MAY-2021
Time Stamp:	09:12:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	426-2-23UTIL-20220614-Request-for-COC-TransLetter.pdf	19588 2d38df3d5b092cd922d48617db18ca06f7acdfc0	no	2

Warnings:

Information:					
2	Request for Certificate of Correction	426-2-23UTIL-20220614-Request-for-COC.pdf	153660 5a71599d1455b711f8fa3a98ad08923e90ac323b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	173248	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

	1	Inter Partes Review IPR2021-01584 dated April 1, 2022	
	2	Inter Partes Review IPR2022-00193 dated April 25, 2022	
	3	Inter Partes Review IPR2022-00034 dated April 1, 2022	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2022-05-09
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt	
EFS ID:	45659367
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	09-MAY-2022
Filing Date:	22-MAY-2021
Time Stamp:	06:42:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	426-2-23UTIL-ids-5-9-2022.pdf	1034338 27e53d0eae8661eb36842002166c5201511682e8	no	4

Warnings:

Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	426-npl-3-later-IPRs.pdf	3899640 def7a8000ed231e2ef3452a9b03e6dbeef8ef880	no	191
Warnings:					
Information:					
			Total Files Size (in bytes):	4933978	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/24/2022	11337834	426/2/23 UTIL	1189

175373 7590 05/04/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Ali Shahriari, Hillsboro Beach, FL;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Aortic Innovations, LLC, Hillsboro Beach, FL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

7590 05/02/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	
ART UNIT	**PAPER NUMBER**
3774	
NOTIFICATION DATE	**DELIVERY MODE**
05/02/2022	ELECTRONIC

NOTICE OF NON-COMPLIANT INFORMATION DISCLOSURE STATEMENT

An Information Disclosure Statement (IDS) filed 4-27-22 in the above-identified application fails to meet the requirements of 37 CFR 1.97(d) for the reason(s) specified below. Accordingly, the IDS will be placed in the file, but the information referred to therein has not been considered.

The IDS is not compliant with 37 CFR 1.97(d) because:

- ☐ The IDS lacks a statement as specified in 37 CFR 1.97(e).
- ☐ The IDS lacks the fee set forth in 37 CFR 1.17(p).
- ☑ The IDS was filed after the issue fee was paid. Applicant may wish to consider filing a petition to withdraw the application from issue under 37 CFR 1.313(c) to have the IDS considered. See MPEP 1308.

571-272-4200 or 1-888-786-0101
Application Assistance Unit
Office of Data Management

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 05/02/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
05/02/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Corrected ***Notice of Allowability***	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	**Art Unit** 3774	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the IDS filed 3/25/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 11 and 13-29 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S COMMENT

2. Applicants information disclosure statement (IDS) filed March 25th, 2022, was not considered at the time of the notice of allowance dated March 30, 2022, due to a cross in the mailing of the notice of allowance. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The allowability of claims 11 and 13-29 is confirmed. Nothing cited on the March 25,2022, IDS alters the previous determination of the allowable subject matter. Applicant cited correspondence from application 16/941,117, patent number 10,792,172 as well as a search report from a related application . Please refer to the Notice of Allowance mailed March 30,2022, for examiner amendments and a statement of reasons for allowance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/Jennifer Dieterle/
Supervisory Patent Examiner, Art Unit 3774

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	SHIPMON, TIFFANY P
Attorney Docket Number	426/2/23 UTIL

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

	1	Declaration and Response dated February 19, 2022 in US Application No. 16/941,117	
	2	Inter Partes Review IPR2021-01527 dated March 17, 2022	
	3	EP Examination report dated March 11, 2022 for EP Application No. 20172681.7	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	04/23/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

X The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

X A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2022-03-25
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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If you wish to add additional Foreign Patent Document citation information please click the Add button								Add

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	Application Number	17327673
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	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

	1	Inter Partes Review 2022-01584 of US Patent No. 10,857,011	
	2	Inter Partes Review 2022-00034 of US Patent No. 10,966,846	
	3	Inter Partes Review 2022-00193 of US Patent No. 10,881,538	

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2022-04-27
Name/Print	Justin R. Nifong	Registration Number	59389

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Electronic Patent Application Fee Transmittal					
Application Number:	17327673				
Filing Date:	22-May-2021				
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL				
First Named Inventor/Applicant Name:	Ali Shahriari				
Filer:	Justin Robert Nifong				
Attorney Docket Number:	426/2/23 UTIL				
Filed as Small Entity					
Filing Fees for Utility under 35 USC 111(a)					
Description		**Fee Code**	**Quantity**	**Amount**	**Sub-Total in USD($)**
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt	
EFS ID:	45580859
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	27-APR-2022
Filing Date:	22-MAY-2021
Time Stamp:	21:06:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	E20224QL08104162
Deposit Account	506191
Authorized User	Justin Nifong
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.21 (Miscellaneous fees and charges) 37 CFR 1.20 (Post Issuance fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	426-2-23UTIL-ids-4-27-2022.pdf	1034362 4e9a12b143d77055436de963877a5b243fb3ccc53	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	52df64d3-68ec-40ea-b5a7-fd9d00580002.pdf	927171 1ea1b74f6d5d1909f1ddd6581698cbfa03944c04	no	69
Warnings:					
Information:					
3	Non Patent Literature	ec21b29a-a4e4-4096-88fb-aa1d36190941.pdf	1716295 1fde6da5cd7e01a255f1990b22782dc6212a4787	no	63
Warnings:					
Information:					
4	Non Patent Literature	9cbf4e9f-8e55-4e91-8049-fa5a32badd1e.pdf	1501667 54a6a2346f7bba4062355599817aeae8472043a6	no	59
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	37844 dc210c661b79a6f803ff9f33199a1b8d8bcb091f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	5217339		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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Document Code:WFEE

User :C46472

Sale Adjustment Accounting Date:04/04/2022

Effective Date	Sale Accounting Date	Sale Item Reference Number
02/15/2022	04/04/2022	17327673

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I202244A04084904	2820	RCE- 2ND AND SUBSEQUENT REQUEST	$1,000.00	



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Document Code:WFEE

User :C46472

Refund Accounting Date:04/04/2022

Effective Date	Sale Item Reference Number	Refund Total
02/15/2022	17327673	$1,000.00

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method	Account Number
I202244A04084904	2820	RCE- 2ND AND SUBSEQUENT REQUEST	$1,000.00		**********0208

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 03/30/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
03/30/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Corrected ***Notice of Allowability***	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	**Art Unit** 3774	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the IDS filed 2/15/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 11 and 13-29 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	Date	Examiner
A61F 2/856,07,2418,82,962,24,86,89,90; 2002/061,067; 2210/00,0014,0057; 2220/008,0016,0025,0058,0075; 2230/001,0034,0067; 2250/0048,0069	07/22/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search	07/22/2021	T.S.
EAST Search	08/25/2021	T.S.
Updated EAST Search	12/02/2021	T.S.
IPR2021-01527 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
IPR2021-01584 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
IPR2022-00034 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
Consulted with Leslie Lopez	11/29/2021	T.S.
Updated IDS Search	03/11/2022	T.S.

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61F	2/856	07/22/2021	T.S.
A61F	2/856	12/02/2021	T.S.

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

CPC						
Symbol					**Type**	**Version**
A61F	/	2	/	856	F	2013-01-01
A61F	/	2	/	07	I	2013-01-01
A61F	/	2	/	2418	I	2013-01-01
A61F	/	2	/	962	I	2013-01-01
A61F	/	2	/	82	I	2013-01-01
A61F	/	2002	/	061	A	2013-01-01
A61F	/	2220	/	0025	A	2013-01-01
A61F	/	2230	/	0067	A	2013-01-01
A61F	/	2002	/	067	A	2013-01-01
A61F	/	2220	/	0008	A	2013-01-01
A61F	/	2220	/	0016	A	2013-01-01
A61F	/	2230	/	001	A	2013-01-01
A61F	/	2250	/	0048	A	2013-01-01
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A61F	/	2	/	90	A	2013-01-01
A61F	/	2220	/	0058	A	2013-01-01
A61F	/	2220	/	0075	A	2013-01-01
A61F	/	2230	/	0034	A	2013-01-01
A61F	/	2	/	24	A	2013-01-01
A61F	/	2	/	86	A	2013-01-01
A61F	/	2250	/	0069	A	2013-01-01
A61F	/	2210	/	0014	A	2013-01-01
A61F	/	2210	/	0057	A	2013-01-01
A61F	/	2210	/	00	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	11 March 2022	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	24 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

U.S. Patent and Trademark Office — Part of Paper No.: 20220311

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61F	/	2	/	856

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	11 March 2022	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	24 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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-	2	1	11	9	20	18	29								
-	3	-	12	10	21										
-	4	2	13	11	22										
-	5	3	14	12	23										
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/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	11 March 2022	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	24 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

U.S. Patent and Trademark Office — Part of Paper No.: 20220311

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	3	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/28 22:05
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S7	38	a61f2/2418	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S8	59	a61f2/2412	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S9	41	a61f2/2436	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S10	17	a61f2/2433	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S11	11	a61f2/2475	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
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S15	3	S13 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:12
S16	30	S13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:13
S17	74	623/1.13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:43
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S25	1	("7799072").PN.	USPAT; USOCR	OR	OFF	2014/07/14 09:28
S26	3	meretei.in.	USPAT	OR	OFF	2014/07/14 09:28
S27	14	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2014/07/14 09:28
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S40	3,379	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:47
S41	2	("13706869").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:49
S42	2	("13706896").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:51
S46	1	("14614628").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/03/20 19:27
S47	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/05/15 06:58
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S49	4	("20080132993" | "20140336749").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:29

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S52	18	("20050177222" | "20070067014" | "20100268318" | "6152956" | "20060276883" | "20070112411" | "20030220683" | "20040106981" | "20100094409").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:33
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S62	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/18 08:47

S63	1,461	carpentier.in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 08:54
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S65	3	"20050102018"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 09:39
S66	6	(US-20070168013-$ | US-20140172064-$ | US-20140316513-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:13
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S74	6,389	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
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S76	3,436	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
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S78	1,352	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
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S80	9,503	S74 S75 S76 S77 S78 S79	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S81	4,461	S80 and (artery arteries)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:06
S82	1,118	S80 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:09
S83	6,421	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S84	4,413	a61f2/2412.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/04/29 11:05

			EPO; JPO; DERWENT			
S85	3,462	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
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S87	1,354	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S88	9,549	S83 S84 S85 S86 S87	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S89	9,549	S83 S84 S85 S86 S87 S88	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S90	1,126	S89 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/29 11:05
S91	1	("20090254172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/05/14 15:40
S92	9	("20060155366" | "20100049313" | "6258117").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:09
S93	2	("20080262592").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S94	6	("20070168013" | "20140172064" | "20140316513").PN.	US-PGPUB; USPAT; USOCR;	OR	OFF	2019/07/21 10:10

			FPRS; EPO; JPO; DERWENT			
S95	6	("20020177890" | "5976179").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S96	3	"20140316513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:19
S97	2	"20070168013"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:20
S98	4	"20140172065"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:21
S99	6	"20100049313"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:26
S100	2	"20060155366"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:29
S101	6,666	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S102	4,593	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S103	3,601	a61f2/2436.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/07/21 10:35

			EPO; JPO; DERWENT			
S104	1,864	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S105	1,380	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S106	9,898	S101 S102 S103 S104 S105	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S107	9,898	S101 S102 S103 S104 S105 S106	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S108	1,179	S107 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 10:35
S109	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 11:44
S110	4	"14614628"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 12:36
S111	7,098	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S112	4,889	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S113	3,856	a61f2/2436.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/12/08 16:15

			EPO; JPO; DERWENT			
S114	1,965	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S115	1,422	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S116	10,508	S111 S112 S113 S114 S115	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S117	10,508	S111 S112 S113 S114 S115 S116	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S118	1,256	S117 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/12/08 16:15
S120	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S121	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S122	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S123	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S124	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S125	10,919	S120 S121 S122 S123 S124	US-PGPUB; USPAT;	OR	OFF	2020/03/13 11:45

			EPO; JPO; DERWENT			
S126	10,919	S120 S121 S122 S123 S124 S125	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S127	1,305	S126 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/03/13 11:45
S128	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S129	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S130	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S131	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S132	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S133	10,919	S128 S129 S130 S131 S132	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S134	10,919	S128 S129 S130 S131 S132 S133	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S135	966	S134 and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2020/03/13 14:56

			JPO; DERWENT			
S136	5,500	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11

S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ | US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$ | US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44

S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$ | US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

		3629739-$ | US-3652198-$ | US-3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05

		5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.				
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | NO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
S172	627	("20010039450" | "20020013571" | "20020026216" | "20020082630" | "20020107565" | "20020123802" | "20020151970" | "20020183835" | "20020183838" | "20020188348" | "20020198594" | "20030023303" | "20030050694" | "20030078652" | "20030130729" | "20030153943" | "20030163194" | "20030167071" | "20030171806" | "20030199975" | "20030229394" | "20030229395" | "20030233142" | "20030236568" | "20030236569" | "20040002719" | "20040003819" | "20040010305" | "20040015230" | "20040015232" | "20040015233" | "20040019374" | "20040019377" | "20040019378" | "20040024447" | "20040024451" | "20040024452" | "20040030321" | "20040030381" | "20040030382" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:31

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S195	10	(CN-102014805-$ | NO-2005087117-$ | NO-2006127412-$ | NO-2010006627-$ | NO-2010031060-$ | NO-2010105195-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | EP-2787925-$ | JS-2012068165-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:37
S196	50	(US-10034784-$ | US-10065824-$ | US-16736879-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2020/06/17 14:41

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S205	516	salahieh.in. and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48
S206	1	("20050137695").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:55
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S208	5,285	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S209	4,260	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S210	2,147	a61f2/2433.cpc.	US-PGPUB; USPAT;	OR	OFF	2020/07/20 11:59

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S211	1,470	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S212	11,433	S207 S208 S209 S210 S211	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S216	0	wo2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S217	0	(2006/124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:23
S218	0	(2006/0124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:24
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S220	1	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:55
S221	4	"20090125098"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:29
S222	7	"20030040771"	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/07/29 11:30

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S223	1,779	(cuff with (fiber barb))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:58
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S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17
S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20

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S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2020/09/27 23:02

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S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
S248	1	("4164046").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:09
S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 15:17
S258	0	("2006124649").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 15:17
S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03

S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
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S263	0	("2006018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S264	1	("20060018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S265	7	"20060018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$ | US-3992608-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:25
S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:22

			JPO; DERWENT			
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:25
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/01/16 10:27

			FPRS; EPO; JPO; DERWENT			
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:29

			JPO; DERWENT			
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:33
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/26 17:21

			JPO; DERWENT			
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:46
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48
S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51

S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
S320	5	"20060005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S321	96	"2006005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S322	5	"15876053"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:11
S323	2	("2018/0206982").URPN.	USPAT	OR	OFF	2021/02/13 09:12
S324	0	"20010049555"	USPAT	OR	OFF	2021/02/13 09:14
S325	4	"20010049555"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:14
S326	3	"20070233228"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S327	3	"20120296418"	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/02/13 09:16

			FPRS; EPO; JPO; DERWENT			
S328	822	("20010021872" | "20020026094" | "20020032481" | "20020138135" | "20020173842" | "20030050694" | "20030100939" | "20030158597" | "20030212454" | "20040039436" | "20040186563" | "20040186565" | "20050075728" | "20050096736" | "20050188525" | "20050203614" | "20050203617" | "20050234546" | "20060004469" | "20060025857" | "20060058872" | "20060149350" | "20060183383" | "20060229719" | "20060259137" | "20070005131" | "20070010876" | "20070010877" | "20070112422" | "20070162102" | "20070203503" | "20070203575" | "20070203576" | "20070213813" | "20070260305" | "20070265700" | "20080114442" | "20080125853" | "20080154355" | "20080183271" | "20090125118" | "20090157175" | "20090276040" | "20090281619" | "20090299452" | "20090319037" | "20100049313" | "20100168844" | "20100198347" | "20100204781" | "20110015729" | "20110319991" | "20120259409" | "20130023985" | "20130190857" | "20130274873" | "20130310926" | "20130317598" | "20130331929" | "20140194981" | "20140200661" | "20140209238" | "20140277417" | "20140277419" | "20140277424" | "20140330372" | "20140343671" | "20150073545" | "20150073546" | "3409013" | "3548417" | "3587115" | "3657744" | "3671979" | "3714671" | "3755823" | "4035849" | "4056854" | "4106129" | "4222126" | "4265694" | "4297749" | "4339831" | "4343048" | "4345340" | "4373216" | "4406022" | "4441216" | "4470157" | "4535483" | "4574803" | "4592340" | "4605407" | "4612011" | "4643732" | "4655771" | "4692164" | "4733665" | "4759758" | "4762128" | "4777951" | "4787899" | "4787901" | "4796629" | "4820299" | "4829990" | "4851001" | "4856516" | "4878495" | "4878906" | "4883458" | "4922905" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:25

		"4966604" | "4979939" | "4986830" | "4994077" | "5007896" | "5026366" | "5032128" | "5037434" | "5047041" | "5059177" | "5080668" | "5085635" | "5089015" | "5152771" | "5163953" | "5167628" | "5192297" | "5266073" | "5282847" | "5295958" | "5332402" | "5360444" | "5370685" | "5397351" | "5411055" | "5411552" | "5443446" | "5480424" | "5500014" | "5545209" | "5545214" | "5549665" | "5554185" | "5558644" | "5571175" | "5584803" | "5591185" | "5591195" | "5607464" | "5609626" | "5628792" | "5639274" | "5665115" | "5716417" | "5728068" | "5749890" | "5756476" | "5769812" | "5800508" | "5840081" | "5855597" | "5855601" | "5855602" | "5925063" | "5957949" | "6027525" | "6132473" | "6168614" | "6171335" | "6174327" | "6210408" | "6217585" | "6221091" | "6231602" | "6245102" | "6299637" | "6302906" | "6350277" | "6352547" | "6425916" | "6440764" | "6454799" | "6458153" | "6461382" | "6468660" | "6482228" | "6488704" | "6527979" | "6569196" | "6582462" | "6605112" | "6652578" | "6689123" | "6716244" | "6730118" | "6733525" | "6767362" | "6769161" | "6783542" | "6830584" | "6878162" | "6893460" | "6908481" | "6936067" | "7018406" | "7018408" | "7096554" | "7225518" | "7276078" | "7276084" | "7318278" | "7374571" | "7393360" | "7462191" | "7510575" | "7563280" | "7585321" | "7618446" | "7618447" | "7655034" | "7785366" | "7959672" | "7993394" | "8029556" | "8167932" | "8291570" | "8449606" | "8454685" | "8652203" | "8747463" | "9078781").PN.				
S329	4	("20130190862" | "20160317305").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:26
S330	4	("20070233228" | "20120296418").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/02/13 09:27

			JPO; DERWENT			
S331	835	("20020173842" | "20030100939" | "20040186563" | "20050203617" | "20070162102" | "20080183271" | "20100204781" | "20130274873" | "20140200661" | "20150073546" | "4222126" | "4733665" | "4759758" | "4777951" | "5026366" | "5032128" | "5332402" | "5411055" | "5558644" | "5571175" | "5609626" | "6231602" | "6425916" | "6440764" | "6689123" | "6893460" | "6936067" | "7655034" | "7993394" | "8652203" | "20030212454" | "20050075728" | "20070112422" | "20100168844" | "20100198347" | "4829990" | "5397351" | "5545214" | "5549665" | "5584803" | "5855602" | "6027525" | "6132473" | "6168614" | "6221091" | "6302906" | "6350277" | "6454799" | "6605112" | "6908481" | "7510575" | "7563280" | "20070233228" | "20020138135" | "20050203614" | "20050234546" | "20060149350" | "20070260305" | "3714671" | "4297749" | "4441216" | "4692164" | "4762128" | "4883458" | "4994077" | "5007896" | "5163953" | "5360444" | "5411552" | "5591185" | "5639274" | "5665115" | "5716417" | "5749890" | "5756476" | "5855601" | "6171335" | "6245102" | "6299637" | "6488704" | "6569196" | "6769161" | "7393360" | "7585321" | "7959672" | "8167932" | "8747463" | "9078781" | "20130190862" | "20010049555" | "20040186565" | "20060058872" | "20060229719" | "20070213813" | "20090299452" | "20120259409" | "20130023985" | "20130310926" | "20130317598" | "20130331929" | "20140209238" | "20140277417" | "20140343671" | "4265694" | "4339831" | "4373216" | "4470157" | "4592340" | "4643732" | "4796629" | "4820299" | "4856516" | "4966604" | "5047041" | "5089015" | "5266073" | "5295958" | "5591195" | "5607464" | "5957949" | "6716244" | "6767362" | "7018406" | "7096554" | "7276084" | "7374571" | "8029556" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27

		"20020026094" | "20050096736" | "20060259137" | "20070005131" | "20090125118" | "20090157175" | "20090319037" | "20110319991" | "20140194981" | "20140277424" | "3587115" | "3657744" | "3671979" | "4343048" | "4612011" | "4787899" | "4787901" | "4878495" | "4878906" | "4979939" | "4986830" | "5059177" | "5085635" | "5152771" | "5370685" | "5500014" | "5554185" | "5728068" | "6210408" | "6352547" | "6527979" | "6783542" | "7618446" | "20030050694" | "20030158597" | "20050188525" | "20060004469" | "20070203503" | "20080114442" | "20080154355" | "20100049313" | "20110015729" | "20140277419" | "20150073545" | "3409013" | "3548417" | "4035849" | "4056854" | "4106129" | "4406022" | "4535483" | "4922905" | "5037434" | "5080668" | "5282847" | "5769812" | "5840081" | "5855597" | "6174327" | "6458153" | "6468660" | "6652578" | "6830584" | "6878162" | "7018408" | "7225518" | "7785366" | "8454685" | "20120296418" | "20010021872" | "20040039436" | "20070010877" | "20070265700" | "20080125853" | "20090281619" | "20130190857" | "20140330372" | "4345340" | "4605407" | "5545209" | "5628792" | "6217585" | "6461382" | "6730118" | "7318278" | "7462191" | "7618447" | "8449606" | "20170014229" | "20020032481" | "20060025857" | "20060183383" | "20070010876" | "20070203575" | "20070203576" | "20090276040" | "3755823" | "4574803" | "4655771" | "4851001" | "5167628" | "5192297" | "5443446" | "5480424" | "5800508" | "5925063" | "6482228" | "6582462" | "6733525" | "7276078" | "8291570" | "20160317305").PN.				
S332	11	WO2006124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:13

S333	53	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:14
S334	0	"17131869"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S335	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S336	13	S328 and (outer$4 with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:49
S337	27	S328 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:00
S338	36,075	l11and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S339	27	S331 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S340	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:56

S341	12	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-3333075-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:57
S342	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 15:10
S343	1	("9333075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/17 05:33
S344	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/17 05:40
S345	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17007373-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 12:07
S346	10	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:38
S347	34	"10555823"	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/03/21 14:50

			FPRS; EPO; JPO; DERWENT			
S348	2	"16983196"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 15:15
S349	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/21 15:20
S350	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S351	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S352	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S353	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S354	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S355	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 18:03

			JPO; DERWENT			
S356	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S357	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S358	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S359	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S360	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S361	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S362	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S363	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 18:03

			JPO; DERWENT			
S364	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S365	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S366	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S367	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S368	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S369	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S370	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S371	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 18:03

			JPO; DERWENT			
S372	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S373	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S374	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S375	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S376	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S377	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S378	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S379	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S380	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S381	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S382	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S383	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S384	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S385	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S386	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S387	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/03/21 21:13

			FPRS; EPO; JPO; DERWENT			
S388	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S389	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S390	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S391	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S392	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S393	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S394	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S395	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S396	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S397	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S398	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S399	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S400	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S401	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S402	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S403	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S404	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S405	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S406	2,578	(S378 S379 S380 S381 S382 S383 S384 S385 S386 S387 S388 S389 S390 S391 S392 S393 S394 S395 S396 S397 S398 S399 S400 S401 S402 S403 S404 S405) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S407	15	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2021/03/25 16:13
S408	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S409	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S410	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S411	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13

S412	5,773	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S413	26,431	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S414	17,826	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S415	17,867	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S416	4,044	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S417	6,084	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S418	7,541	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S419	11,784	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13

S420	18,994	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S421	5,686	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S422	4,852	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S423	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S424	12,667	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S425	1,775	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S426	12,059	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S427	15,690	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13

S428	32,783	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S429	9,318	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S430	18,235	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S431	3,576	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S432	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S433	14,804	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S434	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S435	4,158	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13

S436	2,585	(S408 S409 S410 S411 S412 S413 S414 S415 S416 S417 S418 S419 S420 S421 S422 S423 S424 S425 S426 S427 S428 S429 S430 S431 S432 S433 S434 S435) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S438	0	("13706896").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:37
S439	34	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 09:37
S440	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:58
S441	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17170957-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:38
S442	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S443	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39

S444	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S445	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S446	5,776	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S447	26,437	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S448	17,841	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S449	17,872	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S450	4,046	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S451	6,089	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39

S452	7,542	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S453	11,785	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S454	18,999	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S455	5,689	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S456	4,854	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S457	555	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S458	12,674	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S459	1,777	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39

S460	12,063	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S461	15,695	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S462	32,786	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S463	9,323	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S464	18,239	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S465	3,579	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S466	3,175	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S467	14,810	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39

S468	1,657	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S469	4,160	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S470	2,587	(S442 S443 S444 S445 S446 S447 S448 S449 S450 S451 S452 S453 S454 S455 S456 S457 S458 S459 S460 S461 S462 S463 S464 S465 S466 S467 S468 S469) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S471	0	("16910189").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 16:49
S472	6	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 16:49
S473	11	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 17:22
S474	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 18:29
S475	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 18:36
S476	72	(US-10016271-$ | US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17006793-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48

		US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.				
S477	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | NO-2006005015-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110098802-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130304196-$ | NO-3829057-$ | IF-617622-$ | SO-0225223-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S478	54	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 09:42
S479	3	"20060259136"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 14:18
S480	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/09 16:30

		20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S481	28	S480 and (mitral)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 16:37
S482	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 11:44
S483	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 15:48
S484	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59
S485	5	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/04/24 09:59

			JPO; DERWENT			
S486	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 10:57
S487	55	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:15
S488	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 10:19
S489	39	S488 and (seal with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/04/27 10:19

			JPO; DERWENT			
S490	41	S488 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:23
S491	21	("2014/0316513").URPN.	USPAT	OR	OFF	2021/04/27 10:28
S492	0	"17006793"	USPAT	OR	OFF	2021/04/27 10:32
S493	1	"16792197"	USPAT	OR	OFF	2021/04/27 10:32
S494	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 11:19
S496	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 19:42

		20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S497	41	S496 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 19:42
S498	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/24 12:23
S499	15	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/05/25 08:57
S500	54	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/05/25 08:57
S503	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/30 17:02
S504	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 13:20

S505	3	"17007373"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 16:13
S506	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/06/03 13:29
S507	15	S506 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:29
S508	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55

		$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.				
S509	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S510	92	S508 S509	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S511	10	S510 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S512	232	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 14:01
S513	1	("7921678").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/06/03 14:08
S514	35	(US-17170957-$ | US-20030153974-$ | US-20060025857-$ | US-20060074484-$ | US-20070282436-$ | US-20100036484-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/18 10:36

		20120022633-$ | US-20120071969-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20140018915-$ | US-20140155997-$ | US-20170128209-$).DID.				
S518	6	(("20130018458") or ("20110125244") or ("20110166636") or ("20110098802") or ("20060074484") or ("20120310328")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/01 09:32
S520	102	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17327673-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060025857-$ | US-20060074484-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20070282436-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100036484-$ | US-20100204781-$ | US-20110009948-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20110218619-$ | US-20110319991-$ | US-20120022633-$ | US-20120071969-$ | US-20120123529-$ | US-20120296418-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20130304196-$ | US-20140018915-$ | US-20140155997-$ | US-20150335429-$ | US-20160022444-$ | US-20170128209-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 16:59
S521	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | AI-20060025857-$ | NO-2006005015-$ | AI-20060074484-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20070282436-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100036484-$ | AI-20100204781-$ | AI-20110009948-$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 17:17

		| AI-20110040367-$ | AI-20110098802-$ | AI-20110125244-$ | AI-20110166636-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120022633-$ | AI-20120071969-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20120310328-$ | NO-2012068175-$ | AI-20130018458-$ | AI-20130073030-$ | AI-20130304196-$ | AI-20140018915-$ | AI-20140155997-$ | AI-20150335429-$ | AI-20160022444-$ | AI-20170128209-$ | NO-3829057-$ | SO-0225223-$ | VA-223131450-$).DID.				
S522	0	"17327673"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:09
S523	4	"17096253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:10
S526	17	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/07/22 15:41
S527	58	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/07/22 15:41
S528	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/07/25 16:50

		or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S529	15	S528 and collagen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 16:50
S530	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:00
S531	23	"2005023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:16
S532	12	"20050023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:17
S533	0	("2005023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S534	1	("20050023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S535	1	("20060004442").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:19
S536	398	("2006/0004442").URPN.	USPAT	OR	OFF	2021/07/25 17:20

S537	1	("20130018458").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:28
S539	41	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/30 11:20
S542	22	"10299917"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/23 10:08
S545	234	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/25 14:20
S546	3	"20060276813"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/26 12:46
S547	25	"2011143263"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/26 12:47
S548	0	WO2005115275	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/19 09:38
S549	19	"2005115275"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/19 09:38
S550	3	"20050273155"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/10/19 09:39

			JPO; DERWENT			
S551	17	"2005112821"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/19 09:39
S552	9	("20030153974" | "20060276813" | "3365728" | "5411552" | "6893460" | "7393360" | "7510575" | "9393110" | "9829057").PN.	US-PGPUB; USPAT	OR	OFF	2021/10/19 09:56
S553	17	("20030153974" | "20060276813" | "3365728" | "5411552" | "6893460" | "7393360" | "7510575" | "9393110" | "9829057" | "10716662" | "20070288087" | "20090143855" | "20100217382" | "20100249916" | "20120123529" | "20200197199" | "8992608").PN.	US-PGPUB; USPAT	OR	OFF	2021/10/19 09:56
S554	8	("20030153974" | "3365728" | "5411552" | "6893460" | "7393360" | "7510575" | "9393110" | "9829057").PN.	US-PGPUB; USPAT	OR	OFF	2021/10/19 10:09
S555	385	"03047468"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/19 10:52
S556	17	WO03047468	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/19 10:53
S557	1	("8992608").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/19 11:07
S558	1	("10792172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/19 11:16
S559	1	("7510575").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/19 12:31
S560	108	"2006005015"	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/10/19 12:32

			FPRS; EPO; JPO; DERWENT			
S561	1	("8992608").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 09:25
S562	6	(("8645300") or ("7827487") or ("6615226") or ("6912505") or ("7865455") or ("6266649")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 10:07
S563	1	("20080235204").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 10:09
S564	1	("8032506").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 10:10
S565	76	(fibers adj (stent frame) same (attach$4 secur$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 11:14
S566	262	(fiber$4 adj (stent frame) same (attach$4 secur$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 11:16
S567	24	"2005023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 13:42
S568	12	"20050023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 13:42
S569	12	"10883575"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 13:44
S570	0	"35116043"	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/10/20 13:46

			FPRS; EPO; JPO; DERWENT			
S571	0	("35116043").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 13:46
S572	1	("20060004442").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 13:54
S573	17	"1641117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 16:23
S574	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/20 16:23
S575	1	("9393110").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 17:10
S576	2	(("7510575") or ("7510573")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/20 17:18
S577	58	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/10/23 14:38

		or US-20110208297-$ or US-20050273155-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$ or WO-2006005015-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$ or WO-2005112821-$ or WO-2005115275-$).did.				
S578	17	S577 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 14:39
S579	0	(("16808137") or ("16910189") or ("17096253")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/23 16:50
S580	17	"16808137" "16910189" "17096253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 16:50
S581	58	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/10/23 18:28

		or US-20110208297-$ or US-20050273155-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$ or WO-2006005015-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$ or WO-2005112821-$ or WO-2005115275-$).did.				
S582	1	(non adj2 porous) and S581	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 18:28
S583	97	(non adj2 porous) same graft and (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 18:29
S584	47	(non adj2 porous) same PET and (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 18:30
S585	29	(non adj2 porous) same (polyethylene adj2 terephthalate) and (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 18:31
S587	691,079	(graft wtih non adj2 porous)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 19:06
S588	1	("5152782").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/23 20:03
S589	699	(non$1porous with graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/10/23 20:04

			JPO; DERWENT			
S590	87	(non$1porous with graft) same (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 20:06
S591	14,252	(collagen with (fiber$3 fibril$4)) and graft	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 20:28
S592	1,597	(collagen with (fiber$3 fibril$4)) same graft	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 20:28
S593	1	("5171273").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/10/23 20:51
S594	178	(collagen with (fiber$3 fibril$4)) same graft and (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 20:53
S595	17	(collagen with (fiber$3 fibril$4)) same graft and (heart with valve) same seal$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 20:57
S596	12	(collagen adj2 (fiber$3)) same graft and (heart with valve) same seal$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:38
S597	1	(porous with nonporous) same graft same (heart adj2 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:48

S598	3	(porous with nonporous) same (graft covering material) same (heart adj2 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:49
S599	0	((polyethylene adj2 terephthalate) with nonporous) same (graft covering material) same (heart adj2 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:50
S600	98	((polyethylene adj2 terephthalate) with nonporous) same (graft covering material)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:51
S601	337	((polyethylene adj2 terephthalate) with (nonporous non adj2 porous)) same (graft covering material)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 21:53
S602	75,836	((nonporous non adj2 porous)) same (graft covering material) same (porous)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 22:12
S603	45	((nonporous non adj2 porous)) same (graft covering material) same (porous) same (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 22:12
S604	12	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/10/23 22:30
S605	3	"20060084927"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2022/01/10 08:51

S606	46	((nonporous non adj2 porous)) same (graft covering material) same (porous) same (heart with valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2022/01/10 10:01
S608	3	"20120143324"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2022/01/13 09:17
S609	13	("20020052649" | "20030153974" | "20090281619" | "20110098802" | "3365728" | "5411552" | "5957949" | "6730118" | "6893460" | "7393360" | "7510575" | "7585321" | "9393110").PN.	US-PGPUB; USPAT	OR	OFF	2022/01/13 10:37
S610	1	"17469391"	US-PGPUB; USPAT	OR	OFF	2022/01/13 18:52
S612	6	"20120123529"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2022/01/13 22:42

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	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

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	1	Inter Partes Review 2022-00549 of US Patent No. 11,129,735, and supporting declaration of Nigel Buller	☐
	2	Inter Partes Review 2022-00556 of US Patent No. 10,987,236, and supporting declaration of Nigel Buller	☐

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Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	03/10/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2022-02-15
Name/Print	Justin R. Nifong	Registration Number	59389

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

	1	Declaration and Response dated February 19, 2022 in US Application No. 16/941,117	
	2	Inter Partes Review IPR2021-01527 dated March 17, 2022	
	3	EP Examination report dated March 11, 2022 for EP Application No. 20172681.7	

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Name/Print	Justin R. Nifong	Registration Number	59389

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International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	25-MAR-2022
Filing Date:	22-MAY-2021
Time Stamp:	19:28:01
Application Type:	Utility under 35 USC 111(a)

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	Attorney Docket Number	426/2/23 UTIL

	1	Inter Partes Review 2022-00549 of US Patent No. 11,129,735, and supporting declaration of Nigel Buller	☐
	2	Inter Partes Review 2022-00556 of US Patent No. 10,987,236, and supporting declaration of Nigel Buller	☐

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC
Petitioners,

v.

Aortic Innovations, LLC
Patent Owner.

IPR2022-00556
Patent No. 10,987,236

DECLARATION OF NIGEL BULLER, M.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,987,236

Edwards v. Aortic Innovations
U.S. Patent 10,987,236
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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,792,172 B2 ("**'236 patent**")
1002	Excerpts from the prosecution history of the '236 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) ("**Walther**")
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. ("**Levi**")
1009	Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. ("**Spenser**")
1011	WO 2006/005015 A2 to Spenser et al. ("**Spenser II**")
1012	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009) ("**Cribier**")
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.

Exhibit No.	Description
1016	Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010) ("Alkashkari")
1017	Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020	Yuksel, Uygar, *Balloon-Expandable Transcatheter Aortic Valve Implantation,* Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) ("Walther II")
1022	Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) ("Zajarias")
1025	Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al. ("Spenser Parent")

Exhibit No.	Description
1027	Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., *Yarn structure and properties from different spinning techniques*, ("Tyagi")
1029	Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
1030	Cribier, Alain, et al., *Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis,* 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation,* edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)
1034	Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.

Exhibit No.	Description
1036	Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems,* Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., *In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry,* EuroIntervention 15:1240-1247 (2020)
1042	Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010)
1043	Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan,* General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations,* J. Endovasc. Ther. 14:347-351 (2007)
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. ("Cribier '321")
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020
1047	Piazza, Nicolo, et al., *Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve*, Cir Cardiovascular Intervention 1:74-81 (2008).
1048	WO 2011/051043 A1 to Essinger et al.

Exhibit No.	Description
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall ("Birdsall")
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD
1060	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (November 2011), obtained from the University of California Los Angeles Library
1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
1063	Library of Congress subject heading sh85099890
1064	Library of Congress subject heading sh85023143

Exhibit No.	Description
1065	Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009), obtained from the British Library
1067	Herz MARC Record from the British Library
1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD

I, Dr. Nigel Buller, M.D., do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, "Edwards" or "Petitioner") to provide my opinion regarding the patentability of claims 1-4 of U.S. Patent No. 10,987,236 ("the '236 patent"). For the reasons discussed herein, I have concluded that claims 1-4 of the '236 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Declaration supports Edwards' Petition for the above-captioned *inter partes* review ("IPR") of the '236 patent. I have reviewed the Petition and agree with the unpatentability arguments contained therein.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any expert declaration(s) submitted on behalf of the owner of the '236 patent, Aortic Innovations, LLC ("Aortic Innovations" or "Patent Owner").

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation

in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is included as Exhibit 1004.

6. I am a retired Consultant Cardiologist. Until January of 2008, I was Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham and the Lead Clinician for the Cardiac Catheterization Laboratories. The Cardiology Department at the Queen Elizabeth is one of the leading cardiology departments in the UK and one of only five centers in the UK that provides fully comprehensive adult cardiological services including interventional cardiology, electrophysiology, grown-up congenital heart disease and heart transplantation. I have conducted or directly supervised more than 8000 diagnostic and therapeutic non-surgical catheterization procedures since I was first appointed to a National Health Service consultant post in 1990.

7. During my medical training, I was awarded The John Mellanby Scholarship to fund an Intercalated Bachelor of Science degree. In 1977, I received a BSc (First Class Honours) in Physiology from the University of London. Modules included muscle physiology and biophysics at University College London (UCL), for which my tutor was the late Professor Andrew Huxley

FRS, and neurophysiology at the Sherrington School of Physiology, for which my tutor was Professor John Stephens.

8. Following my degree, I was awarded an MRC Training Fellowship to continue my research at UCL and submit a PhD thesis. However, I declined the offer and continued my clinical medical training. Nevertheless, during the three years of undergraduate clinical training I continued my research work in my spare time and, before qualifying in medicine, I had published some of the results of my research in both Nature and The Journal of Physiology. In 1980, I was awarded MB BS by St. Thomas's Hospital Medical School, University of London. In 1983, I became a member and, in 1996, I was elected a Fellow of the Royal College of Physicians in London.

9. I have held a number of positions within highly regarded cardiology departments in the UK.

10. From 1995 to 2010, I was Honoree Senior Lecturer in cardiovascular medicine at the University of Birmingham (UK).

11. From 1995 to 2008, I was employed full time at Queen Elizabeth Hospital, Birmingham.

12. From 1991 to 1995, I was Senior Lecturer in the Department of Interventional Cardiology and Cardiac Medicine at the National Heart and Lung

Institute in London, and Honorary Consultant Cardiologist at the Royal Brompton National Heart and Lung Hospital.

13. Before that, I was a Senior Registrar in Cardiology at Harefield Hospital, Middlesex, and the Royal Free Hospital, London and prior to that a Registrar at the National Heart Hospital, London.

14. From 1984 to 1986, I worked for Smith Kline & French Research Ltd, Philadelphia, USA, as a Research Physician and then as a project Chairman in Cardiovascular Drug Development.

15. My first formal postgraduate training in cardiology was at St. Thomas's Hospital and The Middlesex Hospital in 1981 and 1982, respectively.

16. During my years as a junior doctor I trained in all aspects of cardiology but my interest developed in cardiac catheterization and non-surgical interventional cardiology. My mentor was the late Dr. Anthony Rickards who had performed the first successful coronary artery angioplasty in the UK in 1980. By 1990, I was considered fully trained in catheterization techniques and interventional cardiology including angioplasty and valvuloplasty.

17. In 1990, I was appointed to and, in March 1991, I took up the position of Senior Lecturer in Interventional Cardiology at the National Heart and Lung Institute in London and was the third consultant interventional cardiologist to join

Dr. Anthony Rickards and Dr. Ulrich Sigwart at the Royal Brompton National Heart and Lung Hospital, London.

18. I have routinely assessed and investigated patients suffering from valvular heart disease. Such investigations typically include electrocardiogram (ECG), chest X-ray (CXR) and echocardiography (a sonar examination to obtain detailed anatomical images and functional assessment of the heart and heart valves). These three tests are non-invasive and typically provide confirmation of the clinical diagnosis and allow selection of those patients that require further invasive investigation by means of diagnostic catheterization of the heart (passing flexible tubes through the veins and/or arteries and into the chambers of the heart) for hemodynamic (pressure and flow) measurements and angiography (injection of a radiopaque contrast media into the chambers and blood vessels of the heart so as further to document detailed anatomical and functional information on X-ray imaging). With this information it is then usually possible to determine the cause, the severity and the options for treatment of a patients' heart valve disease.

19. My research interests have included the prevention, diagnosis and treatment of heart disease and the development and clinical application of stents and especially coronary artery stents. I have been an investigator for many national and international scientific clinical trials.

20. My earliest "hands on" clinical involvement with stent implantation was in 1987 when working with the late Dr. Anthony Rickards when I assisted him with the first insertions of stents into human coronary arteries in the UK. Stents were difficult to obtain at the time and initially were only for use in situations of acute or threatened closure after balloon angioplasty. This early work was experimental in nature. I have since conducted large numbers of stenting implantation procedures with stents made by many different manufacturers. During 1991 to 1993, I was an investigator for the Benestent Trial (the major international multicenter "proof of concept" trial designed to demonstrate the benefit of elective stent placement over simple balloon angioplasty in the treatment of coronary artery disease), the results of which were subsequently published in the New England Journal of Medicine in 1994.

21. In 1993, Ulrich Sigwart and I were the co-investigators for the "First-in-Man" study of Guidant Corporation's "Multilink Stent" that subsequently became the long standing market leader for bare metal stents.

22. In 1994, I implanted the first drug coated stent in a patient in the UK. In the same year I was approved by the U.S. Food and Drug Administration (FDA) to act as a proctor to supervise and oversee the first elective implantations of coronary artery stents in the U.S. (an FDA requirement) following the FDA

approval of the Johnson & Johnson Palmaz-Schatz coronary artery stent. In this latter role I worked at more than fifty of the leading U.S. cardiology departments.

23. In 2013, I received hands-on training on the use and implantation of transcatheter heart valve ("THV") technology at the New York Presbyterian Hospital.

24. Throughout my career I have had a close working relationship with the research and development departments in the medical device and pharmaceutical industries. I have served on the advisory boards for many of the major medical device manufacturers, including SCIMED, Boston Scientific, Medtronic, Cordis and Guidant/Abbott.

C. Topics of Opinions

25. I offer opinions in this Declaration on the following general topics:

- The subject matter described and claimed in the '236 patent;
- The level of ordinary skill in the art pertaining to the '236 patent;
- The teachings of the prior art; and
- Whether claims 1-4 of the '236 patent are anticipated and/or would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

26. I also provide background information on medical products and devices, including devices for replacing and repairing heart valves.

D. Materials Considered

27. In preparing this Declaration, I have considered the materials referenced in this Declaration and identified in the attached list of exhibits.

28. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '236 patent.

II. APPLICABLE LEGAL STANDARDS

29. I am a medical doctor by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training and technical knowledge and experience to the evaluation of certain prior art with respect to the '236 patent.

30. Although I have been previously involved as a technical expert in patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of patent law applicable in this matter, which I have used in arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

31. In determining whether a patent claim is unpatentable in view of the prior art, the Patent Office construes the claim by giving the claim its ordinary and customary (i.e., plain and ordinary) meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification and

prosecution history. For the purposes of my analysis and opinions, and to the extent necessary, I have construed each claim term in accordance with its ordinary and customary meaning under the required standard.

B. Anticipation

32. I have been instructed that a claim is "anticipated" if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention.

33. I understand that an element is "inherent in," and therefore taught by, the prior art, if it necessarily flows from the explicit disclosure of the prior art. The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed.

C. Obviousness

34. I have been instructed that a claim is "obvious" if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. An obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject

matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

35. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e., appropriate) prior art if it falls within the field of the inventor's endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

36. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '236 patent, e.g., minimally invasive devices for treating heart valves. The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic regurgitation or stenosis through a minimally invasive procedure.

37. To assess the differences between prior art and the claimed subject matter, I have been instructed that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have

selected the elements from the prior art and combined them in the claimed manner.

38. I am also informed that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include:

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

39. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose

the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

40. I have also been informed that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

41. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence that

would suggest that claims 1-4 of the '236 patent would have been non-obvious, as further explained in Section X below.

D. Person of Ordinary Skill in the Art

42. It is my understanding that when interpreting the claims of the '236 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the '236 patent is November 7, 2012. However, my opinions would not change if the relevant priority date were December 6, 2011 (the earliest filing date identified on the face of the '236 patent). I have been informed that all of the references relied upon in this Declaration qualify as prior art under either priority date.

43. I am informed that the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. This is a person of ordinary creativity, not an automaton.

44. I am informed that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person

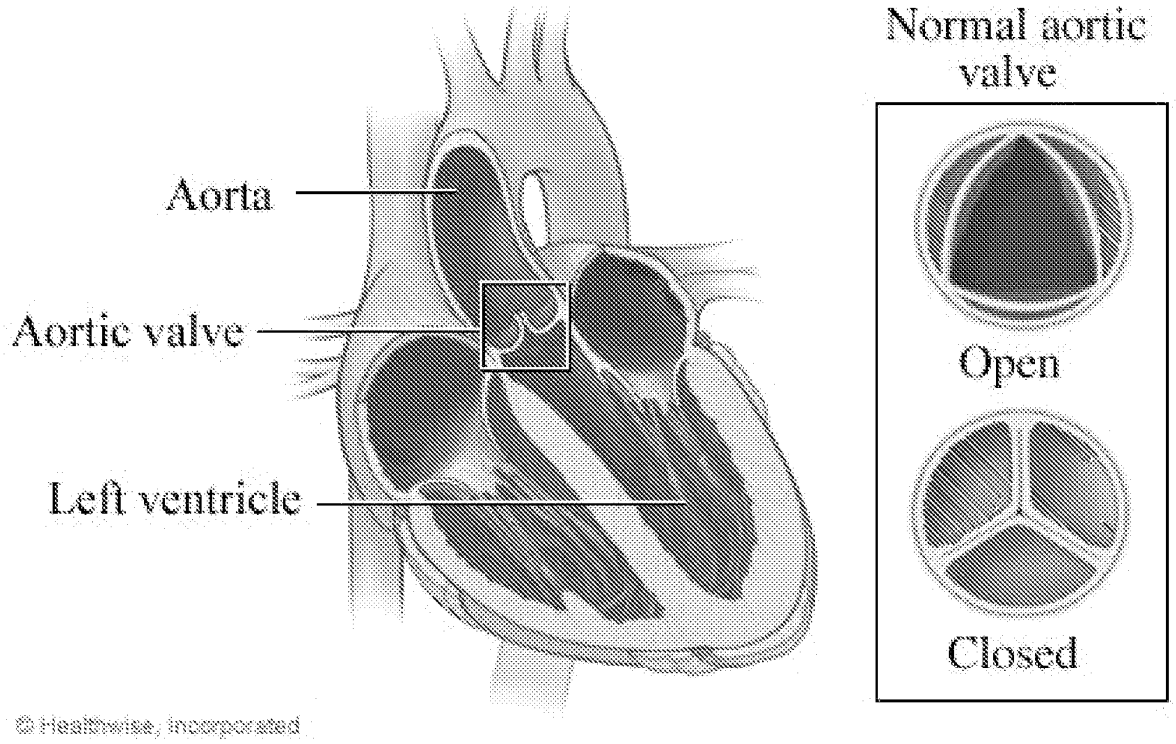
of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

45. Based on my review of the specification and claims of the '236 patent, it is my opinion that a person of ordinary skill in the art would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This person of ordinary skill in the art would, where necessary, work as a team in combination with a medical device engineer to experiment with or manufacture a prosthetic heart valve.

III. BACKGROUND OF HEART VALVE TECHNOLOGY

A. Anatomy of the Heart and Background of Aortic Stenosis and Regurgitation

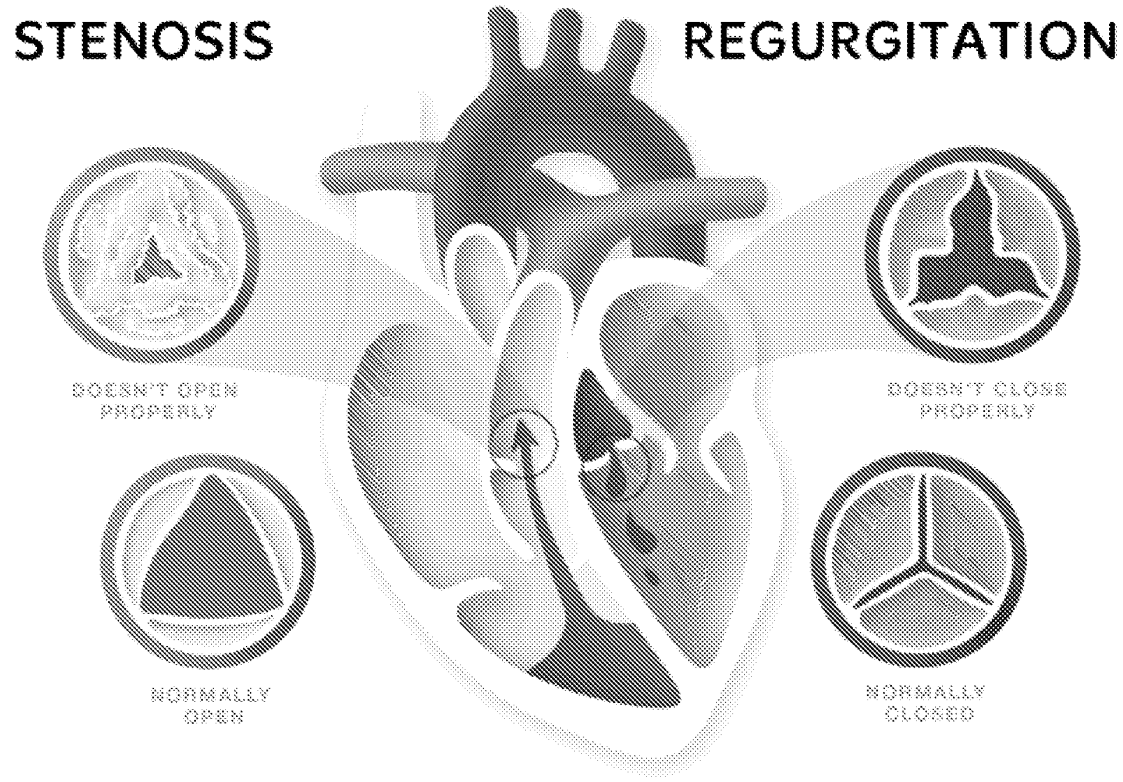
46. The human heart has two upper chambers, known as the left and right atriums, and two lower chambers, known as the left and right ventricles. The aortic valve connects the left ventricle with the aorta, the major artery that carries oxygenated blood from the heart to the rest of the body, on the left side of the heart. The aortic valve includes three leaflets that coapt and expand to operate as a one-way valve which regulates blood flow from the left ventricle into the aorta and prevents backflow of blood from the aorta to the left ventricle.



Available at: https://www.uofmhealth.org/conditions-treatments/aortic-valve-disease.

47. Aortic stenosis is a medical condition that occurs when the opening of the aortic valve is narrowed, often by excessive buildup of calcium deposits on the valve. This condition restricts the flow of blood through the aortic valve, which can have severe health consequences for the patient. Aortic regurgitation is another medical condition that occurs when the aortic leaflets fail to coapt properly, allowing blood to flow backward from the aorta into the left ventricle. Both aortic stenosis and regurgitation can cause the left ventricle to work harder to

pump the necessary amount of blood. Untreated, this can lead to cardiomyopathy (thickening of the heart muscle), irregular heartbeat, and even heart failure.



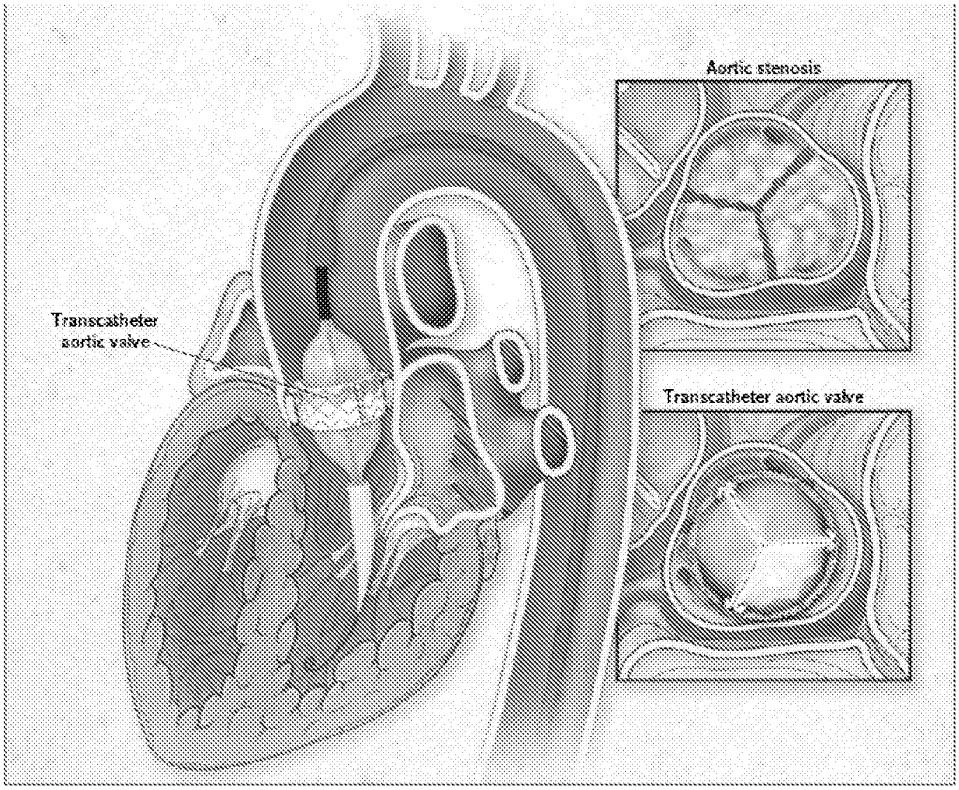
Available at https://www.heartfoundation.org.nz/your-heart/heart-conditions/heart-valve-disease. I note that the above image illustrates stenosis and regurgitation in two different heart valves. Persons of ordinary skill in the art, however, would have understood that both conditions could affect the aortic valve.

48. A common treatment for both aortic stenosis and aortic regurgitation is replacement of the diseased native aortic valve with a prosthetic heart valve. The prosthetic valve takes the place of the diseased native leaflets, and acts to

regulate blood flow in a similar manner as a healthy native aortic valve. One of the key considerations for prosthetic aortic valves is ensuring an effective seal is created between the valve and the patient's native aortic tissue. Without such a seal, blood can leak between the prosthetic valve and the native tissue, causing potentially harmful paravalvular leakage ("PVL").[1] Untreated PVL can lead to the same undesirable health conditions as aortic stenosis and regurgitation. Early prosthetic valves addressed PVL with sewing rings that were attached to the native tissue by sutures. However, implanting these valves required invasive open-heart surgery, limiting the availability of the valves for severely ill patients. *Infra* §III.C.

49. To avoid the risks of open-heart surgery, minimally invasive transcatheter heart valves ("THVs") were developed that could be implanted through the patient's vasculature via a catheter. *Infra* §III.D. Rather than sewing rings, which required open-heart surgery and suturing the ring to the native tissue, THVs created a seal by pressing the exterior of the THV against the diseased native leaflets and surrounding tissue, as shown in the illustration of Petitioner's SAPIEN THV below:

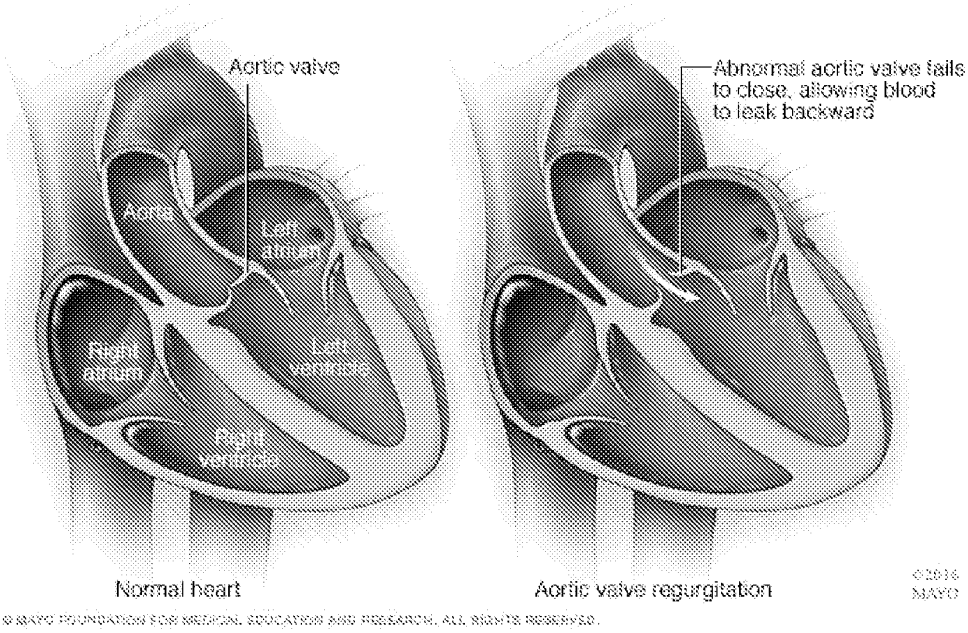
[1] "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



Ex. 1022 (Smith) at 2189, Fig. 1. Due to their minimally invasive implantation, THVs could be implanted in severely ill patients not eligible for open heart surgery, and they quickly became highly successful. Despite their success, however, the potential for PVL remained a major concern with THVs. As I discuss in detail below, this concern motivated those in the art, including Petitioner, to develop methods for minimizing PVL by creating more effective seals.

B. Anatomy of the Aortic Valve

50. The aortic valve lies between the left ventrical and the aorta. As shown below, the aortic valve leaflets extend distally (to use the terminology in the '236 patent) towards the aorta.



Available at: https://www.mayoclinic.org/diseases-conditions/aortic-valve-disease/symptoms-causes/syc-20355117#dialogId16413996.

51. The claims of the '236 patent state that the "first portion of fibers" is "configured to form a first sealing interface against the against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst." *See e.g.*, Ex. 1001 ('236 patent) at claim 1. The claims further state that the transcatheter aortic valve is "configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve

leaflets of the aorta to seal thereagainst." *Id.* As described below, persons of ordinary skill in the art would have understood that if the fibers radially overlap and press against the annulus of the aortic valve, they must also radially overlap and press against the leaflets.

52. The '236 patent identifies the annulus (identified by item #210) as the point where the aortic valve leaflets attach to the left ventricle:

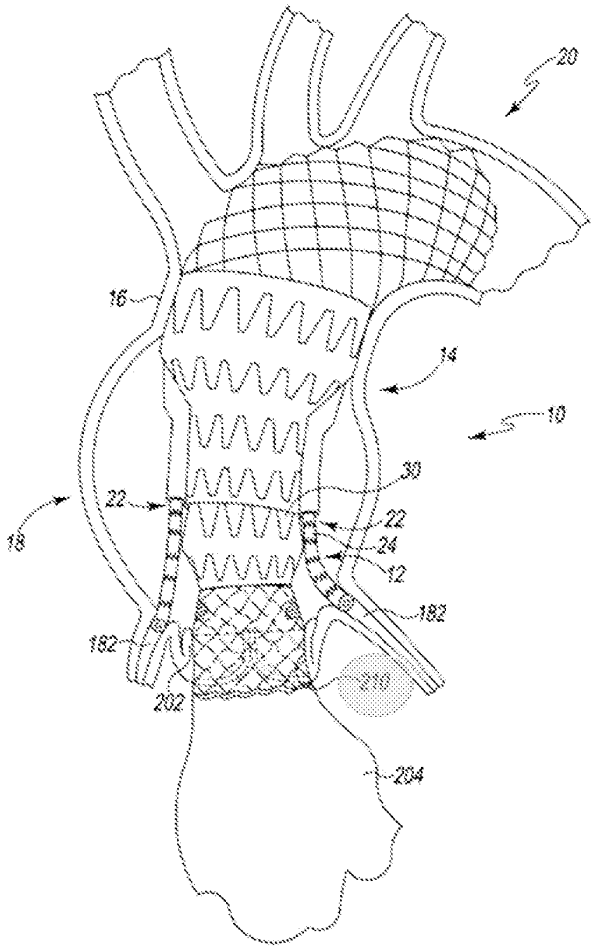
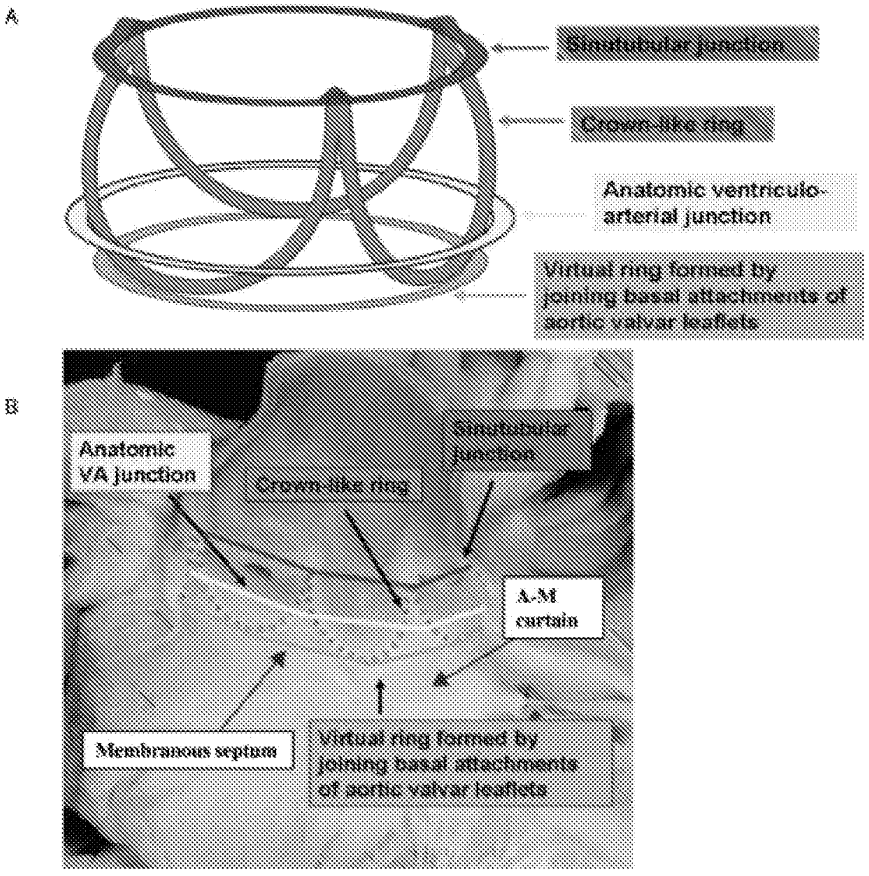


Fig. 2

See e.g., id. at Fig. 2. This is further confirmed by the '236 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valvsalve, the sinutubular junction, and the tubular portion." *Id.* at 1:58-60. The below image from a prior art journal article reflects the structure of the aortic valve. The '236 patent identifies the green line as the annulus.

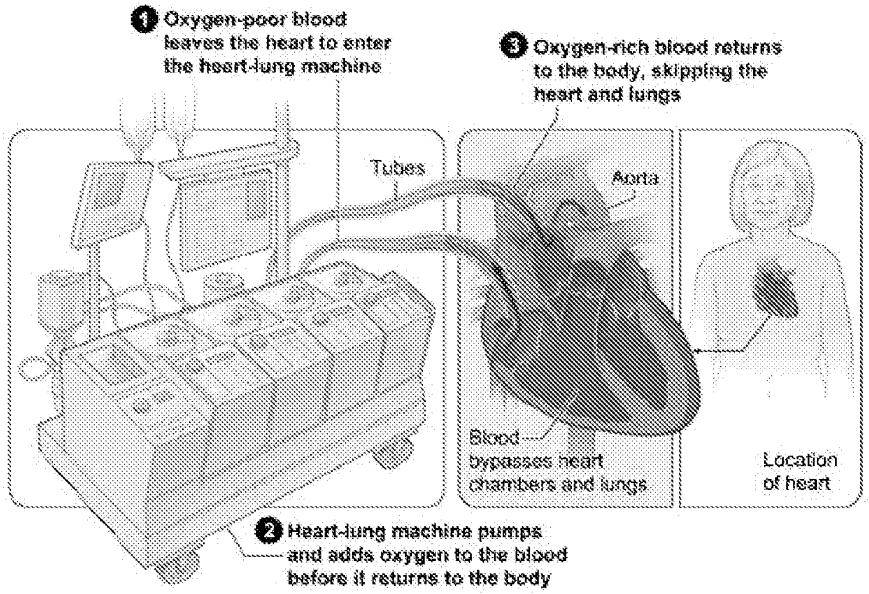


Ex. 1047 (Piazza) at Fig. 4. Because the "annulus" referred to in the '236 patent is the point where the leaflets begin, a person of ordinary skill in the art would have

recognized that fibers pressing against the annulus must also press against the valve leaflets. *Id.* at 76. The journal article confirms this to be the case. SAPIEN, the valve disclosed in the Cribier and Walther references relied upon herein, was positioned within the annulus (i.e., intra-annular) and "once deployed, crushes the leaflets of the native valve against the wall." *Id.* at 74.

C. Surgical Prosthetic Heart Valves

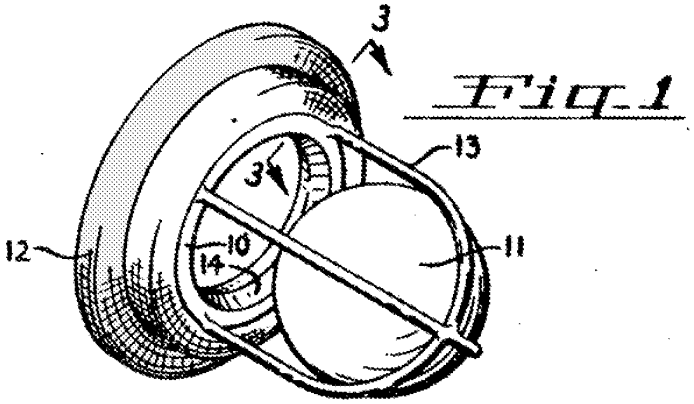
53. Petitioner Edwards was founded by Miles "Lowell" Edwards in 1958. Edwards' earliest work related to prosthetic heart valves that could be implanted surgically. Implantation of these devices involves an open surgical procedure that requires use of a heart-lung machine. In order to surgically implant a prosthetic heart valve, a surgeon opens a patient's chest and the patient is connected to a heart-lung bypass machine, after which the heart can be arrested. The surgeon then surgically removes the diseased native valve and sutures the prosthetic valve in place. A diagram detailing the operation of a heart-lung machine is pictured below:



Available at http://www.daviddarling.info/encyclopedia/H/heart_surgery.html. This procedure is used today for patients receiving a surgically implantable prosthetic heart valve.

54. One of Edwards' first commercially available surgical valves was a ball and cage valve called the Starr-Edwards valve. U.S. Patent No. 3,365,728 (the "'728 patent"), which issued on January 30, 1968, details the features of this valve. **Ex. 1013** ('728 patent). Notably, even this early valve prosthesis included a circumferentially oriented sewing ring that was adapted to extend into spaces in the tissue surrounding the implanted prosthesis to prevent leakage between the prosthetic valve and the surrounding tissue (*i.e.*, "paravalvular leak"). The '728 patent states:

Connected to the periphery of the valve ring is a suturable sewing ring [12] by which the valve may be connected by sutures with living tissue around the natural orifice in which the valve is implanted. The sewing ring is upholstered with a ring of compressible cushion material which will conform to irregularities in the bed in which the valve is placed whereby a good seal is established and leakage between the valve and the tissue is prevented.

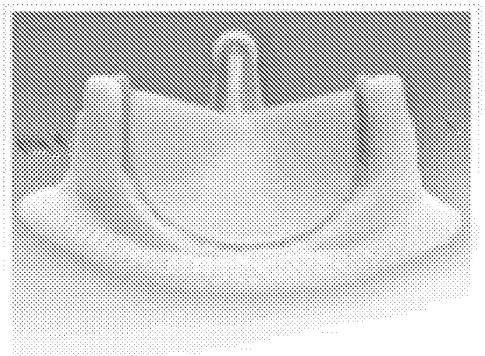


Id. at 1:38-46, 3:12-20, Figs. 1, 3.[2] Thus, paravalvular leak was a well-recognized complication of surgical valve replacement as early as the 1960s.

55. In addition to ball and cage valves, Edwards also developed surgically implantable valves with biological valve leaflets. The biological valve structure could be made with a whole excised valve or formed with pericardial tissue, primarily of bovine or porcine origin. Edwards' PERIMOUNT valve, for

[2] Highlighting and color has been added to all figures unless otherwise noted.

example, was first introduced in 1980 and included a tri-leaflet bovine pericardial valve and a frame having a fabric sewing ring akin to the Starr-Edwards valve:



See e.g., https://www.edwards.com/gb/devices/heart-valves/aortic-pericardial (describing Carpentier-Edwards PERIMOUNT valve).

D. Transcatheter Heart Valve ("THV") Technology

56. THV technology is aimed at providing a patient with a permanently implanted prosthetic heart valve that can be delivered via a catheter.

57. In 1989, Danish doctor Henning Rud Andersen conceived of the seminal invention of a permanently implanted transcatheter bioprosthetic heart valve. That year, Dr. Andersen and his colleagues, Drs. Michael Hasenkam and Lars Knudsen, built the first prototype by hand. The Danish team successfully implanted its prototype in pigs using a catheterization procedure.

58. The Danish team published their results in 1992. **Ex. 1034** (Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description*

of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs, European Heart Journal, 13:704-708 (1992)). There, Drs. Andersen, Hasenkam, and Knudsen described their hand-made THV, which included "a foldable biological cardiac valve inside a balloon expandable metalic stent." *Id.*, 704.

59. The Danish team's work also led to several patents, including U.S. Patent No. 5,411,552 ("Andersen patent"). (**Ex. 1014**).

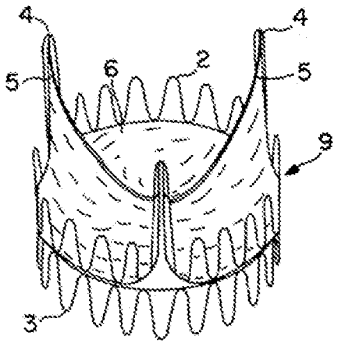


FIG. 2

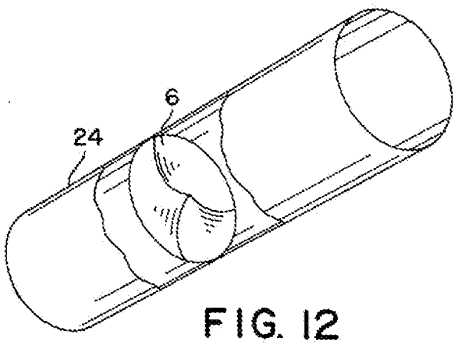


FIG. 12

Id. at Figs. 2, 12. The Andersen patent describes multiple THV embodiments that expand upon the inventors' early prototypes, including embodiments having additional tubular graft material that can be used along the external and internal surface of the THV. *Id.* at 2:21-27, 2:56-60, 4:3-16, 5:9-28, 7:17-29, Figs. 11-12.

60. The graft materials used on the external surface of early THVs were designed to conform to the surface of the surrounding tissue. These materials could be made with low-porosity woven fabrics. An early THV detailed in U.S. Patent No. 5,957,949 to Leonhardt et al. (**Ex. 1035**), which issued on September 28, 1999, details graft material to be used as an external cover on a THV:

> Graft material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE. It is capable of substantially conforming to the surface of the living tissue to which stent 26 coerces it.

Ex. 1035 at 5:53-59.

61. In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s. These designs provided the basis for a December 1996 patent application. A family of patents and patent applications stems from this 1996 application, including WO 98/29057 to Letac et al. ("Cribier patent publication", **Ex. 1018**).

62. This patent publication aims to improve upon the THV technology described in the Andersen patent discussed above. The Cribier patent publication notes that an "aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular in a stenosed aortic orifice, taking advantage of the strong structure made of the distorted stenosed valve and the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure." Ex. 1018 at 5:11-16.

63. Further aims of the Cribier patent publication include providing a THV frame structure capable of withstanding the recoil forces of the native aortic valve in treating aortic stenosis and providing a THV with a frame covering that "prevent[s] any passage of the body fluid through said frame." *Id.* at 5:6-10, 8:28-9:6; *see also id.* at 5:17-18, 20:26-21:3, 22:11-20.

64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then "rolled up to be applied to the external wall of the stent" to form an external cover [19"]:

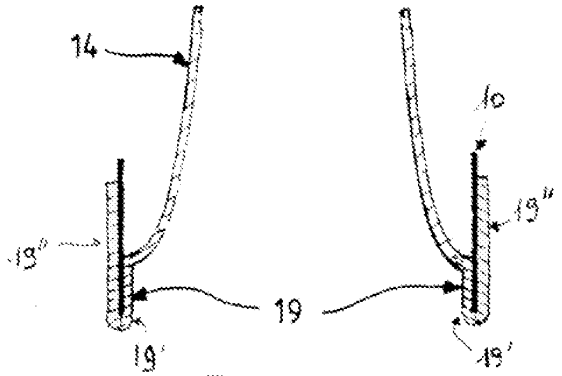
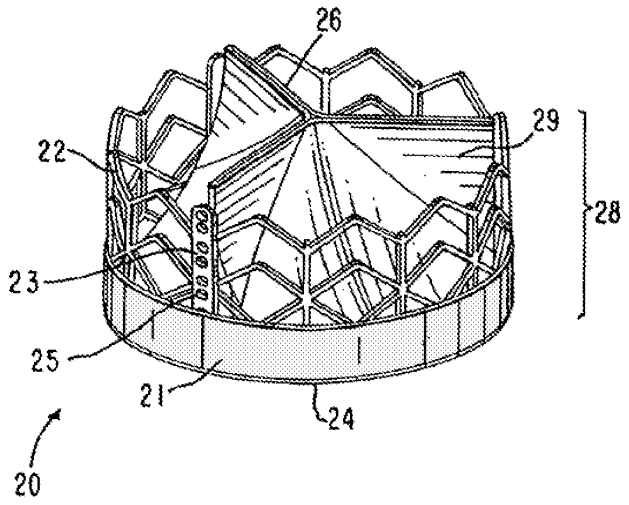


FIG_6d

Id. at 22:23-26, Fig. 6d. The single-piece cover is a tubular structure that can be made with any of the materials disclosed for making the valve structure, which include fabric (*e.g.*, Dacron), biological material (*e.g.*, pericardium), or other synthetic materials (*e.g.*, polyethylene). *Id.* at 8:16-23, 22:11-20. The Cribier patent publication discloses multiple ways of securing the cover to the frame. Specifically, the cover can be secured to the frame at "various points of attachment on various parts of the internal [and external] surface" by suturing, molding, gluing, or soldering the cover to the bars of the frame and, in its expanded state, would prevent blood from flowing between the cover and heart tissue. *Id.* at 22:23-26, 23:15-16, 24:24-27, Fig. 6d; *see also id.* at 23:12-24:23, Figs. 7, 8a-b.

65. In 2001, a company named Percutaneous Valve Technologies ("PVT"), which was co-founded by Dr. Cribier and three others (Stan Rowe, Stan

Rabinovich, and Dr. Martin Leon), filed a patent application on another THV design that included an external cover:

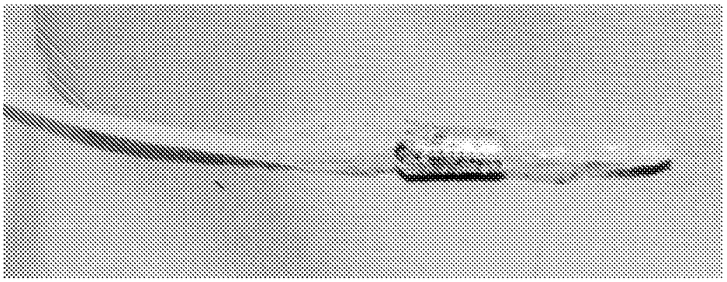


Ex. 1019 (U.S. Patent No. 6,893,460 B2 to Spenser *et al.* ("'460 patent")) at Fig. 1. The '460 patent discloses a THV having a tricuspid valve, a support stent including support beams for securing the commissures of the valve, and a cuff portion wrapped around the support stent at its inlet. *Id.* at 9:1-22, Fig. 1. The '460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a "sleeve-like" portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* ("To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet."). The cuff portion can be formed with PET (Dacron) fabric. *See id.* at 7:7-10, 10:57-11:10 ("Figs. 8*a* and 8*b* demonstrate a method of manufacturing a composite valve, which is based on

flexible PU 92 as the main body of the valve, rigid PU support beams 94 serving for the attachment area, and PET sleeve 96 portions for the valve inlet.").

66. Edwards's U.S. Patent No. 7,510,575 (referred to herein as **"Spenser," Ex. 1010**), claims priority to the '460 patent and includes the THV embodiment having an outer cuff. Ex. 1010 at 13:4-25, claim 31, Fig. 1.

67. In April 2002, using a THV developed by PVT, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. **Ex. 1025** (Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)).[3] The THV consisted of three bovine pericardial leaflets mounted within a tubular, slotted stainless steel balloon-expandable stent that was crimped onto a delivery balloon:



Id. at 3006, Fig. 1. Dr. Cribier implanted the THV using an antegrade approach from the right femoral vein. *Id.* at 3007. Dr. Cribier inserted a 24F sheath into the

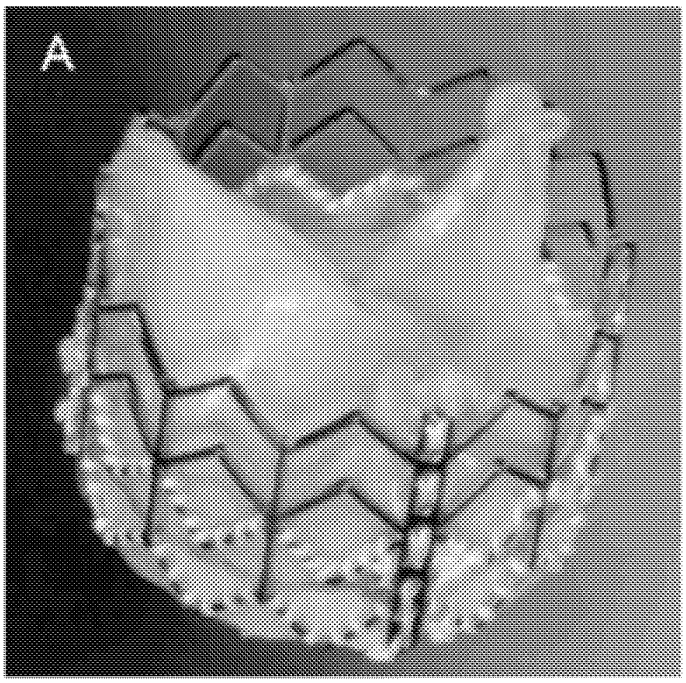
[3] Dr. Cribier uses the phrase "percutaneous heart valve" or "PHV" to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

right femoral vein. The THV was "easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic valve." *Id.* The balloon was then inflated to place the THV. *Id.* Dr. Cribier concluded that the implantation was successful and demonstrated "the feasibility of implanting a prosthetic heart valve percutaneously, with the use of standard interventional techniques, within the native diseased valve of a patient with calcific aortic stenosis." *Id.* at 3008.

68. Dr. Cribier continued to successfully use this implantation procedure in later patients. **Ex. 1030** (Cribier Early Experiences). From April 2002 to August 2003, Dr. Cribier attempted THV implantation in six patients. *Id.* at 699. The THV "was successfully and accurately delivered in the subcoronary position in all but one patient." *Id.* at 700. Dr. Cribier used the "anterograde trans-septal approach" for all cases. *Id.* at 701. Dr. Cribier's work confirmed "that a bioprosthetic valve can be implanted percutaneously within the native diseased stenotic aortic valve of patients with end-stage life-threatening calcific aortic stenosis, using standard interventional techniques under local anesthesia." *Id.*

69. In 2004, Edwards acquired PVT and began developing and testing the Cribier-Edwards THV. **Ex. 1023** (Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March

16, 2012)). The Cribier-Edwards THV "was constructed from a laser-cut stainless steel tubular frame within which was sewn valve leaflets constructed from equine pericardium, with the inflow covered with a fabric sealing cuff (Fig. 3A)." *Id.* at 154.



Id. at Fig. 3A.

70. In 2004, Edwards filed a patent application that formed the basis for PCT Patent Publication WO 2006/005015 A2, referred to herein as **Spenser II (Ex. 1011)**. Spenser II "provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself." *Id.* at [0014]. Figure 22 (below) "illustrates a valve device, in accordance with

another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve." *Id.* at [0085].

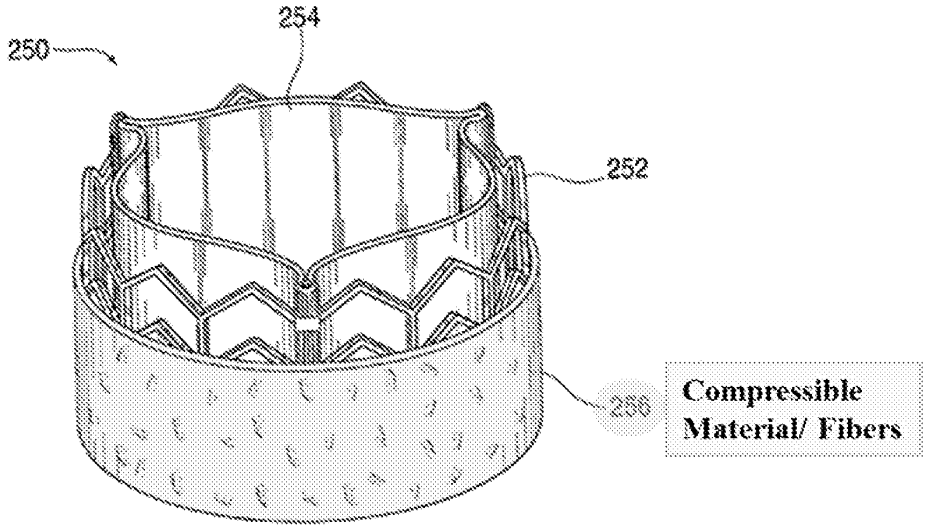


FIG. 22

Id. at Fig. 22. As shown, "a layer of compressible material 256 is disposed along an outer surface of the stent structure 252." *Id.* at [00145]. The material "may extend entirely around the stent structure, such as in the form of a sleeve." *Id.* "In one preferred embodiment, the compressible material is formed from polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.* "In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped." *Id.*

71. Spenser II explains that the purpose of the compressible material is "to reduce or prevent paravalvular leakage." *Id.* Spenser II states:

> The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps."

Id.

72. Edwards did not merely patent THVs having outer sealing materials. Edwards also worked with clinical groups on both sides of the Atlantic to add an outer cloth to the external surface of a THV frame. In 2008, Edwards collaborated with Dr. Anson Cheung and other physicians to develop and test "a cuffed, 26-mm Cribier Edwards transcatheter valve." **Ex. 1017** (Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009)) at e18.

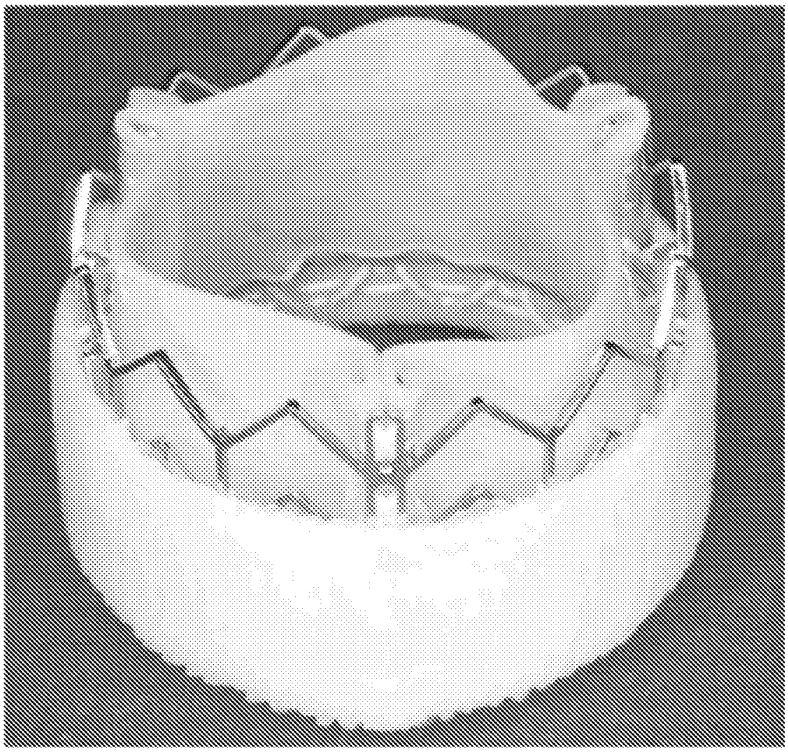


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

Id. at Fig.2. Dr. Cheung implanted the cuffed Cribier-Edwards valve within a patient's existing mitral bioprosthesis (Carpentier-Edwards PERIMOUNT Plus 6900P valve) using a transapical approach. *Id.* at e18. In the transapical approach, the valve is inserted through the patient's heart wall. Dr. Cheung and his team "used a cuffed device for the valve-in-valve implant to provide a better seal within the rigid support ring, minimizing paraprosthetic leak." *Id.* at e19.

73. By 2007, Edwards had modified the Cribier-Edwards valve to create SAPIEN, which included more durable bovine leaflets and a higher internal sealing

cuff. **Ex. 1023** (Webb) at 154. SAPIEN was the subject of a large clinical trial, referred to as the PATNER Trial. **Ex. 1022** (Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)). The results of the PARTNER Trial were published in The New England Journal of Medicine in 2011. *Id.* SAPIEN addressed a long-felt need in the industry for an aortic valve replacement device that did not require open-heart surgery. In view of its pioneering status, SAPIEN's development and progress were avidly followed in the industry and SAPIEN was discussed in numerous publications and textbooks. *See e.g.,* **Ex. 1009** (Conradi), **Ex. 1016** (Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010)), **Ex. 1031** (Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation,* edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114). For example, the **Cribier** publication, discussed in the grounds of unpatentability below, extensively discusses the transfemoral delivery of SAPIEN to a patient's heart valve. **Ex. 1012** (Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009)).

74. In 2010, Dr. Thomas Walther and several Edwards engineers conducted a valve-in-valve study "focused on the use of an Edwards SAPIEN™ trans-catheter heart valve (THV) cloth valve (see Fig. 1), which is identical to the SAPIEN, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve." **Ex. 1007** (Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011)) at 1120.

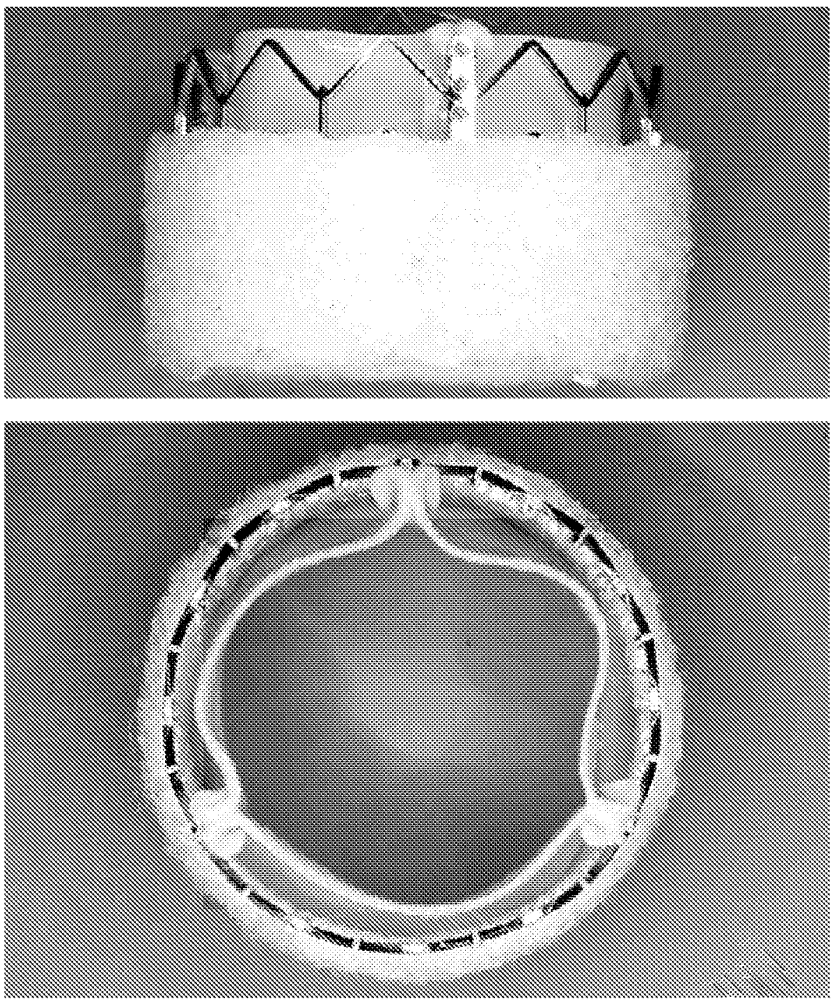
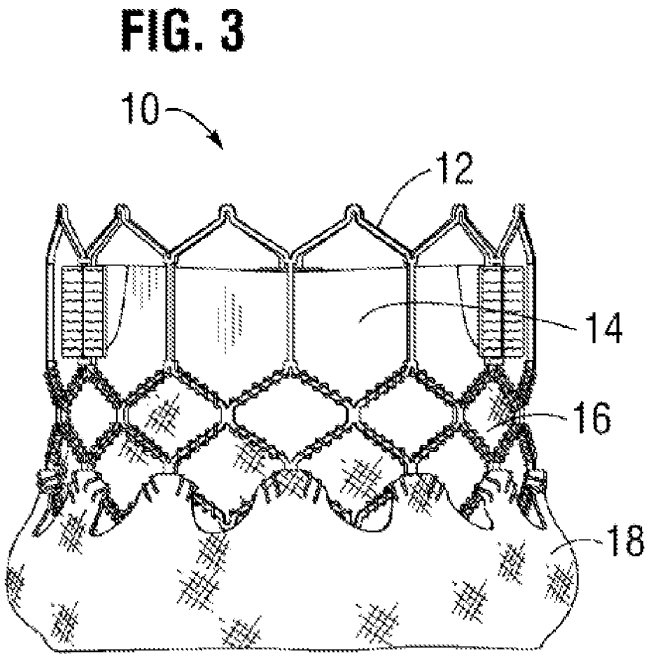


Fig. 1. Cloth valve.

Id. at Fig. 1. The team explained that the "addition of an outer cloth to the SAPIEN cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves." *Id.* at 1120. The team concluded that the "SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent

hydrodynamic performance." *Id.* at 1125. The team also concluded that an *in vivo* procedure "is feasible." *Id.*

75. In October 2010, Edwards filed a provisional patent application that matured into U.S. Patent No. 9,393,110 B2, referred to herein as "**Levi**" (**Ex. 1008**). Levi discloses a THV with "four main components: a stent, or frame, 12, a valvular structure 14, an inner skirt 16, and an outer skirt 18":



Id. at 5:52-58, 6:12-24, 9:7-35, 13:49-14:14, Figs. 1-3, 41-43. "The outer skirt 18 can be laser cut or otherwise formed from a strong, durable piece of material, such as woven PET, although other synthetic or natural materials can be used." *Id.* at 13:49-53. "[W]hen the valve 10 is deployed within the body, the excess material of the outer skirt 18 can fill in gaps between the frame 12 and the surrounding

native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." *Id.* at 14:3-7. "The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the valve 10." *Id.* at 14:7-9.

76. Persons of ordinary skill in the art had also used fibrous outer sealing materials to prevent paravalvular leakage when replacing valves other than the aortic valve. For example, Birdsall, a patent filed in 2006, discloses the use of a fibrous outer seal in a prosthetic valve implanted within a vascular conduit. Ex. 1057 (Birdsall) at Abstract. Birdsall teaches that its valve may be covered with a "barrier material 308" that "comprises directionally oriented microfibers . . . extending outward" that "contact the interior wall of the conduit and form a barrier that prevents blood from flowing around stented valve 310, between the outer surface of the stented valve and the inner wall of the conduit":

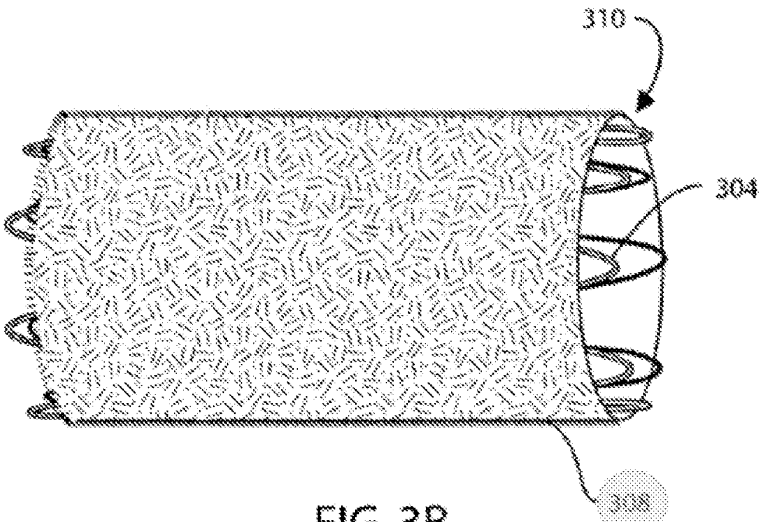


FIG. 3B

Id. at 6:9-33, Fig. 3B. While Birdsall discloses implanting this embodiment within a vascular conduit, Birdsall's disclosure of using a fibrous material to form a seal is not limited to this context. Persons of ordinary skill in the art would have understood that a fibrous material, like Birdsall's "barrier material," would perform a similar sealing function when implanted in a heart valve. Indeed, like the other THVs discussed above, Birdsall's valve is also designed for transcatheter, percutaneous implantation. *See id.* at 2:33-39.

77. The prior-art references identified above demonstrate that Petitioner invented and disclosed prosthetic heart valves, and specifically THVs, having fibers positioned outwardly of the valve frame for sealing against the patient's native aortic valve and preventing paravalvular leakage before November 2012.

Moreover, by 2012, Petitioner had advanced THV technology to the point that persons of ordinary skill in the art had a number of options they could balance when adding an outer fibrous material to a THV device. For example, the prior art demonstrates that persons of ordinary skill in the art had access to a wide range of suitable cloths and fabrics for use as the outer fibrous material. *See e.g.*, Ex. 1007 (Walther) at 1120-21; Ex. 1008 (Levi) at 13:49-53; Ex. 1010 (Spenser) at 13:4-25; Ex. 1011 (Spenser II) at [0085], [00145]; Ex. 1017 (Cheung) at e18-e19; Ex. 1018 (Cribier patent publication) at 8:16-23, 22:11-20. The cloths and fabrics had varying densities, thicknesses, and finishes. *Id.* A person of ordinary skill in the art would have had the option of selecting a cloth or fabric that best suited the specific heart valve assembly and met the necessary size requirements.

78. Additionally, by 2012, Petitioner had developed innovations for the heart valve frame and leaflets to further reduce the crimp profile of the heart valve assembly, thereby creating additional space for an outer fibrous sealing material. For example, well before November 2012, Edwards had developed SAPIEN XT, which replaced SAPIEN's stainless steel frame with a cobalt chromium alloy. Ex. 1023 (Webb) at 154; Ex. 1036 (Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems,* Catheterization and Cardiovascular Interventions, 75:295-300 (2010)) at 296. The cobalt chromium frame allowed "for a thinner, stronger, more open and compressible frame." Ex.

1023 (Webb) at 154; *see also* Ex. 1008 (Levi) at 6:31-6:49 (explaining that less material is needed with a cobalt chromium alloy frame). Edwards had also developed methods to reduce the diameter of the inlet portion of the heart valve frame and several other techniques for minimizing the valve's crimped diameter to accommodate an outer fibrous material. Ex. 1008 (Levi) at 16:51-17:18. Likewise, Edwards had disclosed innovative leaflet designs and several other features to reduce the crimp profile of the valve and offset or minimize any increase in diameter caused by adding additional components, like a plurality of fibers, to the outside of the valve. *Id.* at 16:24-16:50; *infra* ¶¶295-296.

79. Additionally, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. For example, the Retroflex 3 delivery system allowed the transfemoral introduction of SAPIEN 23 or 26 mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, the Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23 mm valve and 19 French for the 26mm valve. *Id.* The Novaflex incorporated an innovative feature where the heart valve was crimped on the inner catheter proximal to the inflatable balloon and then moved onto the balloon once the delivery system had been advanced into the aortic arch. *Id.*; *see also* Ex. 1037 (Le

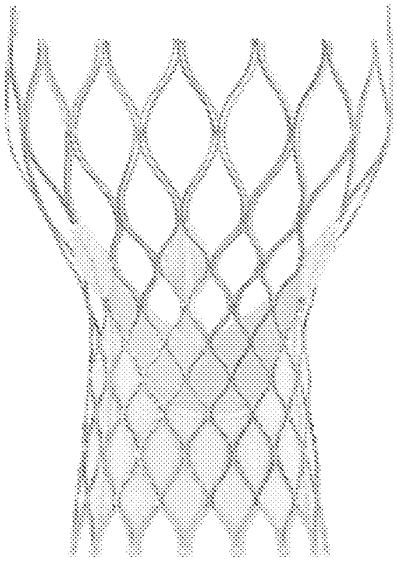
Patent Publication) at [0005]-[0006] (describing off balloon delivery). This unique feature enabled a reduction in sheath size.

80. In 2012, persons of ordinary skill in the art would have been familiar with the above innovations and understood that they could use one or more of the above options to optimize a THV having an outer fibrous material. Thus, the challenged claims are not novel or nonobvious, but merely describe the predictable use of prior art elements according to their established functions.

81. Moreover, by 2012, several THVs were commercially available. Edwards received regulatory approval to commercially sell SAPIEN in Europe in 2007. **Ex. 1038** (Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)). In 2011, the FDA approved the transfemoral delivery of SAPIEN for the treatment of inoperable patients with severe symptomatic aortic stenosis. **Ex 1032** (2011 FDA Approval). In 2012, the FDA approved the use of SAPIEN to treat high-risk aortic stenosis patients using the transfemoral and transapical delivery approaches. **Ex. 1033** (2012 FDA Approval). Further, Edwards received regulatory approval to commercially sell its second generation valve, SAPIEN XT, in Europe in March 2010. Ex 1042 (2010 FDA Approval).

82. Additionally, Edwards was not the only company to have commercialized a THV by 2012. Medtronic's Corevalve system also received

regulatory approval for commercial sales in Europe in 2007. (Ex. 1009, 514-515; 1027, 212-213).



Unlike SAPIEN, Corevalve included a self-expanding frame and further illustrates the diversity of innovations in the field by 2012. (*Id.*)

IV. THE '236 PATENT

A. Summary of the '236 Patent

83. The '236 patent describes endograft devices for repairing ascending aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments combine multiple components to form a structure that extends into the patient's ascending aorta and aortic arch.

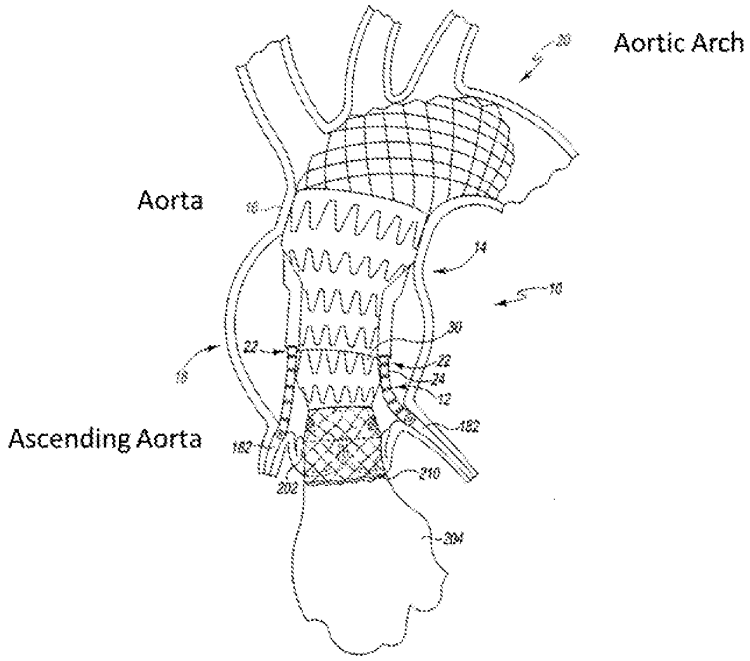


Fig. 2

84. However, the challenged claims of the '236 patent focus on a "transcatheter aortic valve assembly" for replacing an aortic heart valve. The '236 patent's specification describes a heart valve assembly that includes a "dual-frame" extending from a proximal end (i.e., nearest the left ventricle) to a distal end (i.e., furthest from the left ventricle). **Ex. 1001** ('236 patent) 11:61-12:21; 17:45-47. The "dual-frame" includes a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32":

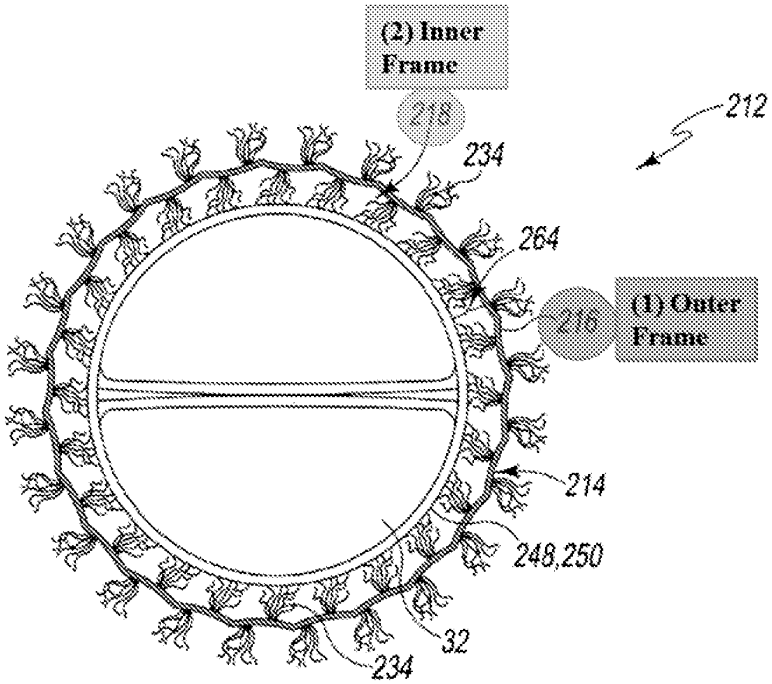


Fig. 13

Id. at 12:9-12, 17:56-59, Fig. 13.

85. The '236 patent states that the outer frame [red] is composed of a metallic or polymeric material that defines a gridded or "open-cell stent configuration." *Id.* at 12:12-18 13:17-20, 17:59-64, Fig. 9. The outer frame is self-expanding and may include a plurality of radially extending "collagen fibers" [green] attached to the exterior of the frame "to aid in preventing paravalvular leaks and migration of the [heart valve assembly] within the aortic walls." *Id.* at 12:43-46, 18:22-25. The inner frame [blue] is a "balloon-expandable tubular stent" constructed of metallic or polymeric material. *Id.* at 13:41-51. The inner

frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:6-8.

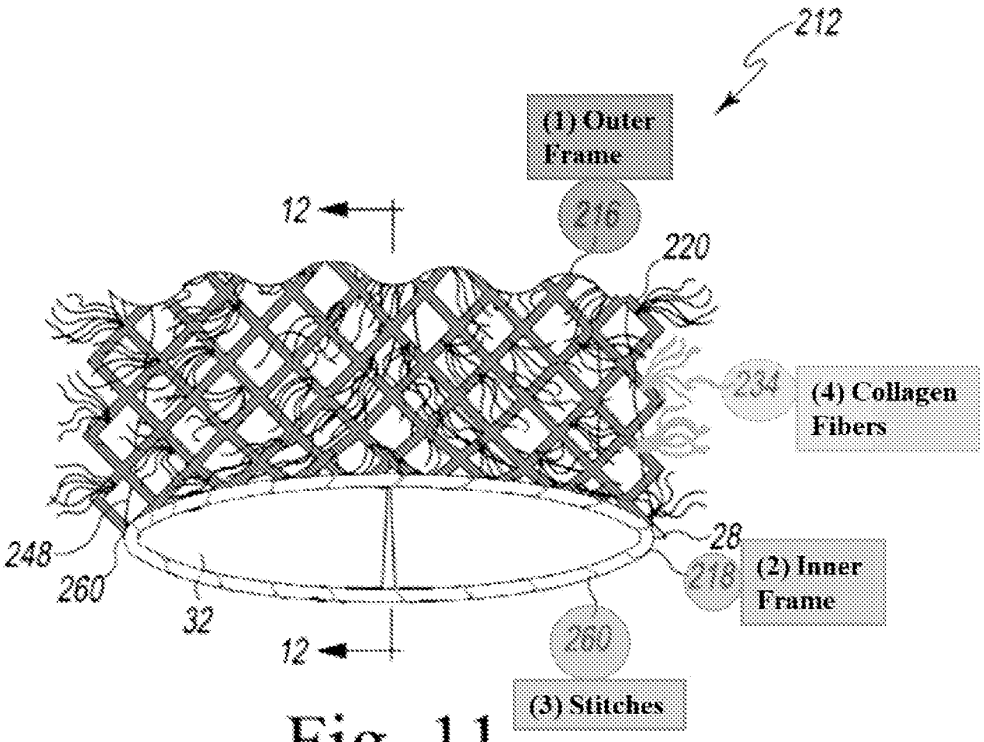


Fig. 11

86. The '236 specification discloses that the outer surfaces of the outer and inner frames may include a covering material, such as polyester, which prevents fluid from passing through the surface of the frame. *Id.* at 13:25-28, 13:51-55, 19:5-8.

B. The Challenged Claims

87. The challenged claims include claims 1-4 of the '236 patent. Claim 1 is the sole independent claim.

88. Claim 1 is illustrative (but not representative) of some of the limitations in the challenged claims. Claim 1 states:

> 1. A transcatheter aortic valve assembly comprising:
>
> an outer frame formed from a metallic material;
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
>
> wherein the outer frame is secured to the inner graft covering by stitching;
>
> a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,
>
> wherein the first portion of fibers is non-metallic; and
>
> a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst,
>
> wherein the second portion of fibers is non-metallic,
>
> wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,
>
> wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,
>
> wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,
>
> wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
>
> wherein the valve assembly is balloon expandable to the radially expanded orientation and,
>
> wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

C. Prosecution History

89. I have reviewed the '236 patent's prosecution history. I see that the Patent Examiner issued a single, non-final office action that included a single prior-art-based rejection. **Ex. 1002** ('236 Patent Prosecution History Excerpt) at 104-108. None of the references I discuss in connection to the grounds of unpatentability herein were asserted in the Examiner's rejection.

90. While the Patent Examiner did not discuss any of the prior art references included in the grounds of unpatentability discussed in this Declaration, I see that Patent Owner made representations about the prior art references Spenser II and Levi in a Preliminary Amendment during prosecution.

91. Regarding Spenser II, Patent Owner stated that Spenser II "appears to teach a band with fibers emanating therefrom in Fig. 22," but argued that "there is no graft forming the inner frame, thus the inner seal is missing." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 187. As explained more below, to the extent the valve in Figure 22 does not have an inner graft covering, a person of ordinary skill in the art would have found it obvious to combine Spenser II's compressible material with a valve having an inner graft covering, such as Spenser's Figure 44a.

92. Patent Owner also argued that persons of ordinary skill in the art would not add Spenser II's outer to a valve that included an inner seal due to

concerns about increasing the crimped profile of the valve, restricting expansion and foreshortening of the valve, and because Spenser II already provides a method for addressing PVL. *See id.* at 196. All of these concerns are unfounded, and none of them would have prevented a person of ordinary skill in the art from being motivated to add an outer seal such as Spenser II's to a valve having an inner seal. Indeed, Walther demonstrates that Patent Owner's concerns would not have deterred persons of ordinary skill in the art from doing so because Walther and colleagues did exactly what Patent Owner argues against. *See infra* §VI.A. Contrary to Patent Owner's arguments, Walther does not report any issues with the crimped profile, expansion, or foreshortening of its cloth-covered SAPIEN valve. Quite the opposite, Walther reports that its valve demonstrated "excellent hyrodynamic performance." Ex. 1007 (Walther) at 1125.

93. Patent Owner also argued that "Spenser [II] appears to include an outer graft covering between the fibers and the outer frame." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 196. As I explain below, Spenser II contains no such disclosure of an "outer graft covering between the fibers and the outer frame." *Infra* §VII.A.9.b. Rather, Spenser II discloses a compressible material that "may resemble a cloth or fabric having small fibers extending from the surface of the material . . . disposed along the outer surface" of the stent. Ex. 1011 (Spenser II) at [00145]. There is no disclosure of an "outer graft covering"

between the fibers and the stent, and no such "outer graft covering" is depicted in Spenser II's Figure 22. *See id.* at [00145], Fig. 22.

94. Regarding Levi, Patent Owner stated that Levi "appears to teach an inner and outer seal in Fig. 42," but argued that Levi's "seal . . . had a relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 194-195. Patent Owner's characterization of Levi is not supported by Levi's disclosure for multiple reasons. First, Levi's Figure 42 shows that Levi's outer skirt may cover the bottom two rows of open cells of the frame, contrary to Patent Owner's representations that it has a "relatively short height." *See* Ex. 1008 (Levi) at Fig. 42. Second, there is no teaching or suggestion in Levi that its outer skirt seals below the patient's native leaflets. Rather, Levi expressly teaches that its outer skirt "fill[s] in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." *Id.* at 14:4-7. As I explained previously, the annulus is the point where the native aortic leaflets attach to the left ventricle, *supra* §III.B, and thus a person of ordinary skill in the art would have understood Levi to teach that its outer skirt seals against the native leaflets. Patent Owner appears to agree with this, as it stated that Levi's outer seal

"extend[s] into crevices created by the native leaflets." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 194-195. Patent Owner's argument that Levi's outer seal does "not radially overlap[] with the leaflets at a most narrow spot of the ascending aorta" has no support in Levi's disclosure, and in any event, is irrelevant, as no claim of the '236 patent requires the outer seal to overlap or press against the native leaflets "at a most narrow spot of the ascending aorta." *Id.*

V. SUMMARY OF IPR GROUNDS

95. I have identified the following grounds of unpatentability in this Declaration:

Ground	Claims Challenged	Unpatentability Basis	References
1	1-4	Obvious	Cribier + Walther
2	1-4	Obvious	Spenser + Walther
3	1-4	Obvious	Spenser + Spenser II
4	1-4	Anticipated	Levi
5	1-4	Obvious	Levi
6	1-4	Obvious	Levi + Walther
7	1-4	Obvious	Levi + Spenser II

VI. GROUND 1: CLAIMS 1-4 OBVIOUS OVER CRIBIER AND WALTHER

96. Cribier is one of the many prior art publications describing SAPIEN. **Ex. 1012** (Cribier). Cribier explains that SAPIEN "consists of a balloon-expandable stent with an integrated bovine pericardial valve." *Id.* at 347. Cribier states that SAPIEN "can be implanted within the diseased aortic valve using either the retrograde transfemoral or antegrade transapical routes," and it describes endovascularly delivering SAPIEN through the transfemoral route. *Id.*

97. Walther, as discussed above in my section covering "Transcatheter Heart Valve ("THV") Technology," discloses a modified SAPIEN having an added outer cloth:

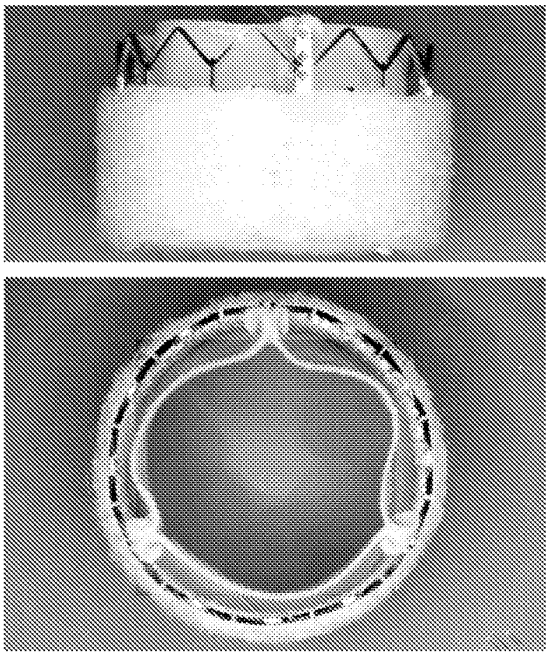


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at 1120-21, Figs. 1-3. Walther's modified SAPIEN is "identical" to SAPIEN except for the added outer cloth. *Id.* at 1120. Walther generally describes SAPIEN but does not include some of the details discussed in Cribier. Thus, I have combined the teachings of Cribier and Walther to provide a more comprehensive review of the features of the cloth-covered SAPIEN disclosed in Walther. Based on my review of these references, I believe that the combination of Cribier and Walther renders claims 1-4 of the '236 patent obvious.

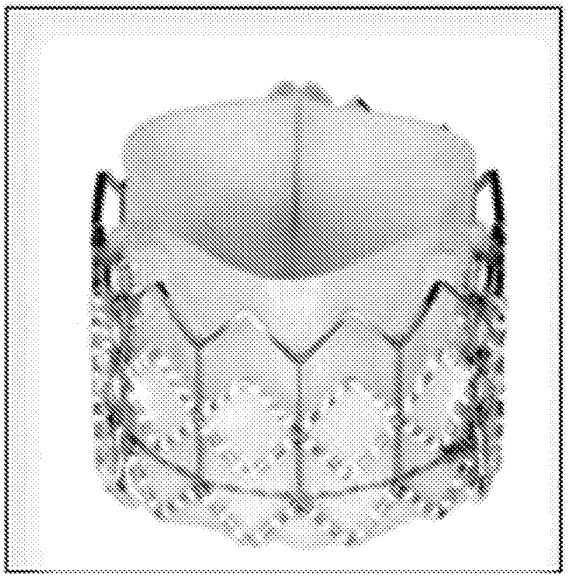
A. Claim 1

98. Based on my review of the prior art, it is my opinion that Cribier in combination with Walther renders claim 1 obvious.

1. Preamble

99. The preamble of claim 1 recites: "A transcatheter aortic valve assembly comprising."

100. Cribier discloses SAPIEN, which is a transcatheter aortic valve assembly. Cribier states that SAPIEN "consists of a tubular slotted stainless-steel balloon-expandable stent with an integrated unidirectional trileaflet bovine tissue valve with a polyethylene terephthalate (PET) fabric cuff." Ex. 1012 (Cribier) at 348. Cribier Figure 1 (below) provides a picture of SAPIEN:



Edwards SAPIEN® THV
23 mm, 26 mm

Id. at Fig. 1. Cribier further discloses that SAPIEN is a "Transcatheter Heart Valve" that can be implanted within a patient's native aortic valve. *Id.* at 347. Cribier specifically describes methods of "transcatheter aortic valve implantation with the Edwards-Sapien® heart valve using the transfemoral approach." *Id.* at 348.

101. As shown in the figure above, SAPIEN's fabric cuff is stitched to the inside of the balloon-expandable stent and also attached to the heart valve leaflets. The green suture line in Figure 1 above is one point of attachment between the fabric cuff and the heart valve leaflets.

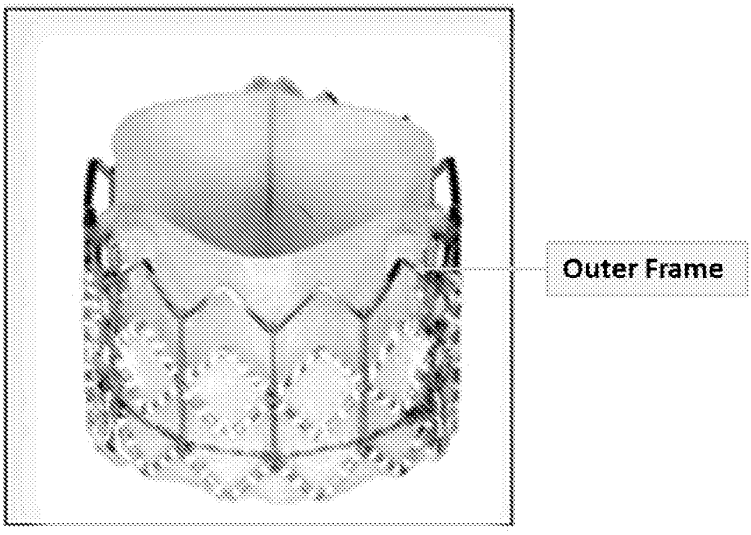
102. Walther similarly discloses SAPIEN with an outer PET cloth stitched to its perimeter. Ex. 1007 (Walther) at 1120-21, Fig. 1. Walther discloses that its

cloth-covered SAPIEN was "identical" to SAPIEN except for the added outer cloth. *Id.* at 1120. Walther also discloses delivering the cloth-covered SAPIENs through a catheter using Edwards' Ascendra system, and thus Walther also discloses a "transcatheter aortic valve assembly." *Id.* at 1121; *see also* Ex. 1031 (Akin) at 110. A person of ordinary skill in the art would have understood the term "transcatheter" to mean through a catheter; however, persons of ordinary skill in the art would not have understood "transcatheter" delivery to require delivery through a specific route within the body. For example, the '236 patent discloses a transcatheter valve that "may be introduced transfemorally or through the subclavian artery or the apex of the heart." Ex. 1001 ('236 Patent) at 6:43-47. And while the '236 patent discloses that the valve is compressible and expandable, which is necessary for transcatheter deployment, the '236 patent does not disclose any dimensions or sizing for the catheter or the compressed valve. The Ascendra system used to deliver Walther's valves was typically introduced into the patient through the apex of the heart via the transapical approach. Ex. 1031 (Akin) at 110.

2. Outer Frame

103. Claim 1 next recites: "an outer frame formed from a metallic material." Cribier discloses this limitation.

104. Cribier discloses that SAPIEN includes "a tubular slotted stainless-steel balloon-expandable stent." Ex. 1012 (Cribier) at 348. As shown in Figure 1 below, the stent surrounds the other valve components, such as the heart valve leaflets, making it an "outer frame":



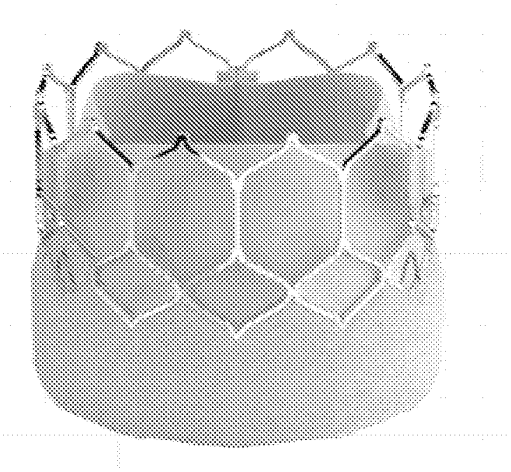
Id. at Fig. 1.

3. Inner Frame

105. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Cribier also discloses this limitation.

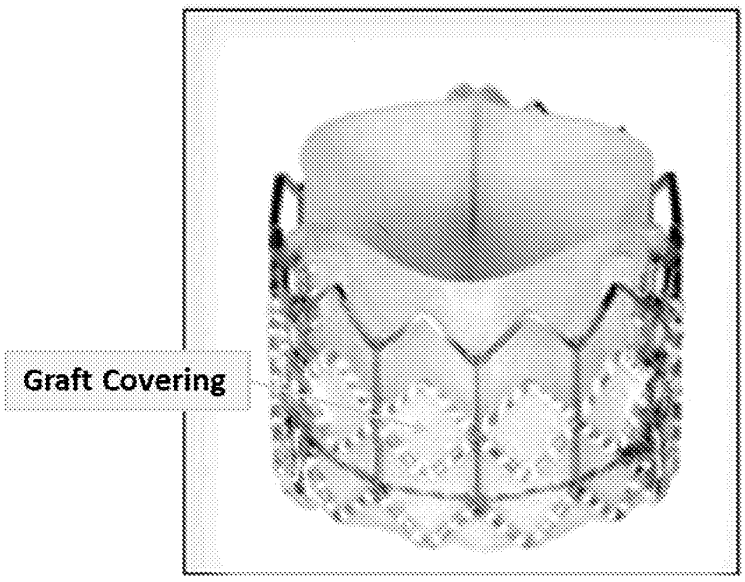
106. The claim states, "the inner frame ***includes*** a cylindrically extending polymeric inner graft covering." I understand that during prosecution of the '236 patent , Patent Owner argued the "includes" language requires only an inner frame that ***is*** a graft covering. Specifically, Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a "graft forming the inner frame." Ex. Ex. 1002 ('236 Patent Prosecution History Excerpt) at 187. Similarly, during prosecution of a related patent – U.S. Patent No. 10,966,846 (the "'846 patent") – Patent Owner argued the "includes" language is met by Petitioner's SAPIEN 3 Ultra product because it "includes an inner frame that is a graft." Ex. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 21-22.

107. I am aware that the SAPIEN 3 Ultra THV (pictured below) has only one frame:



108. Cribier discloses that SAPIEN includes a "unidirectional trileaflet bovine tissue valve." Ex. 1012 (Cribier) at 348. A person of ordinary skill in the art would therefore have understood that SAPIEN includes three "prosthetic leaflets" constructed from bovine tissue.

109. Cribier also discloses that SAPIEN includes "a polyethylene terephthalate (PET) fabric cuff." *Id.* at 348, Fig. 1. PET is a type of polyester and also a polymer and is a "polymeric graft covering." Figure 1 below shows the fabric cuff, which is the whiter material that extends around the prosthetic heart valve, at the lower end of the outer frame. As shown in the figure, the fabric cuff is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame:



Edwards SAPIEN® THV
23 mm, 26 mm

SAPIEN's PET fabric cuff covers the inside surface of SAPIEN's outer frame. Based on Patent Owner's statements during prosecution, SAPIEN's inner fabric cuff is an inner frame that includes a graft covering, as required by claim 1. SAPIEN's fabric cuff is stitched to the prosthetic leaflets along the green suture line in the figure above, and thus the fabric cuff "engages" the prosthetic heart valve.

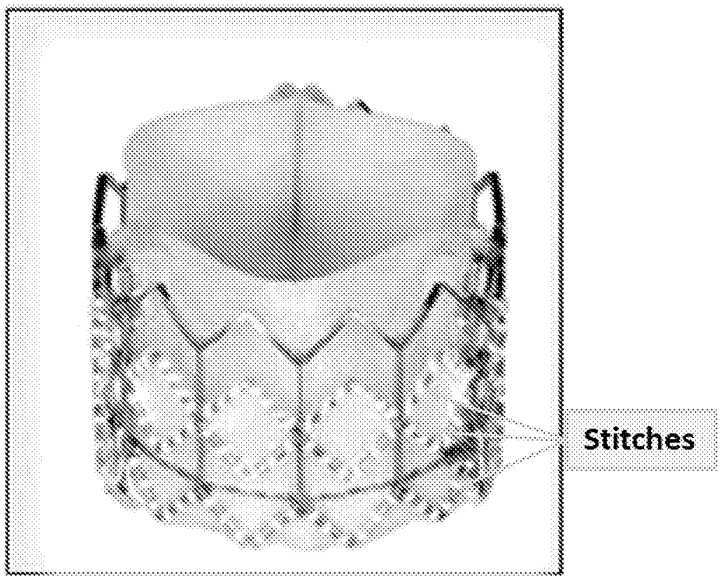
110. A person of ordinary skill in the art would have understood that the SAPIEN's PET fabric cuff provides sealing to the heart valve. Importantly, if the PET fabric cuff did not provide sealing to the heart valve, blood could leak around the valve and undermine the efficacy of the assembly. Further, many prior art publications recognized the sealing capabilities of SAPIEN's PET fabric cuff. *See e.g.,* Ex. 1009 (Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)) at 514 (describing "polyester fabric sealing cuff"); Ex. 1023 (Smith) at 154 (SAPIEN included a "higher sealing cuff…to reduce paravalvular leaks."); Ex. 1025 (Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009)) at 1830 ("The stent has a polyethylene terephthalate fabric skirt that decreases perivalvular leaks."); Ex. 1028 (Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine,

207-219 (Mar. 1, 2011)) at 213 (SAPIEN "includes both the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize the paravalvular leak").

4. Stitching

111. Claim 1 next recites: "wherein the outer frame is secured to the inner graft covering by stitching." Cribier also discloses this limitation.

112. As shown in Cribier's Figure 1 (below), a plurality of white stitches secure SAPIEN's fabric cuff to the outer frame along the three lower rows of the frame:



Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 at 348, Fig. 1; *see also* Ex. 1027 (Roselli) at 213 ("The pericardial tissue is sewn to the frame using polytetrafluorethylene (PTFE) suture and includes both

the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize paravalvular leak.").

5. First Portion of Fibers

113. Claim 1 next recites: "a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic." Cribier in combination with Walther renders this limitation obvious.

114. Walther's PET outer cloth, pictured in Figure 1 below, is positioned radially outwardly of the outer frame:

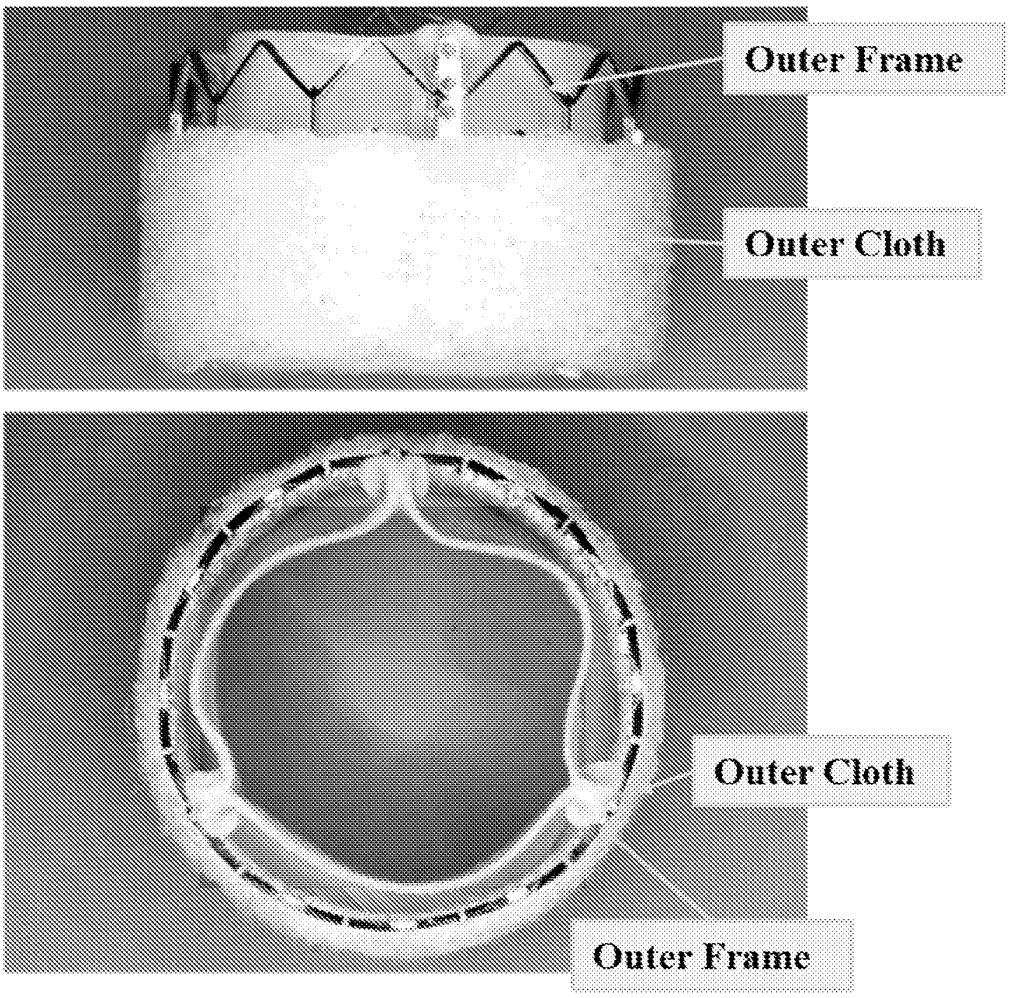
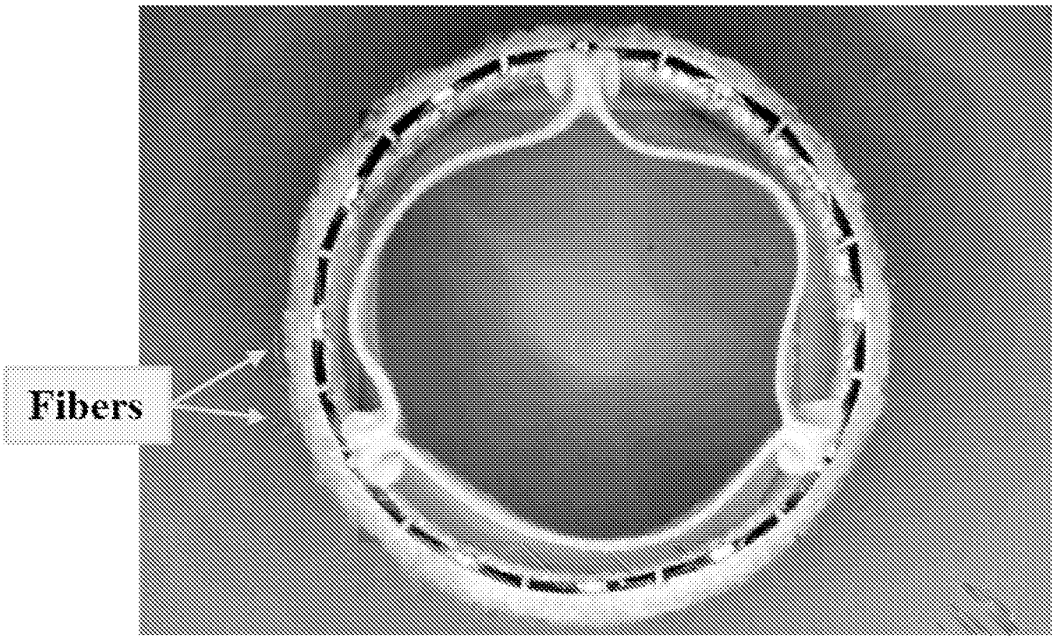


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at Fig. 1. Walther states that the outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves." *Id.* at 1120. Based upon the tests, Walther concluded that "the Edwards SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent

hydrodynamic performance," indicating that the valve performed its sealing function well. *Id.* at 1125.

115. Walther's outer cloth is comprised of PET fibers that extend radially outwardly of the outer frame. The PET fibers are "non-metallic," as required by claim 1. In the figure below, one can see the fibers extending radially outwardly from the outer frame all around the circumference of the valve. Additionally, several particularly long fibers are visible that extend outwardly of the outer frame illustrating that the fibers have different lengths:



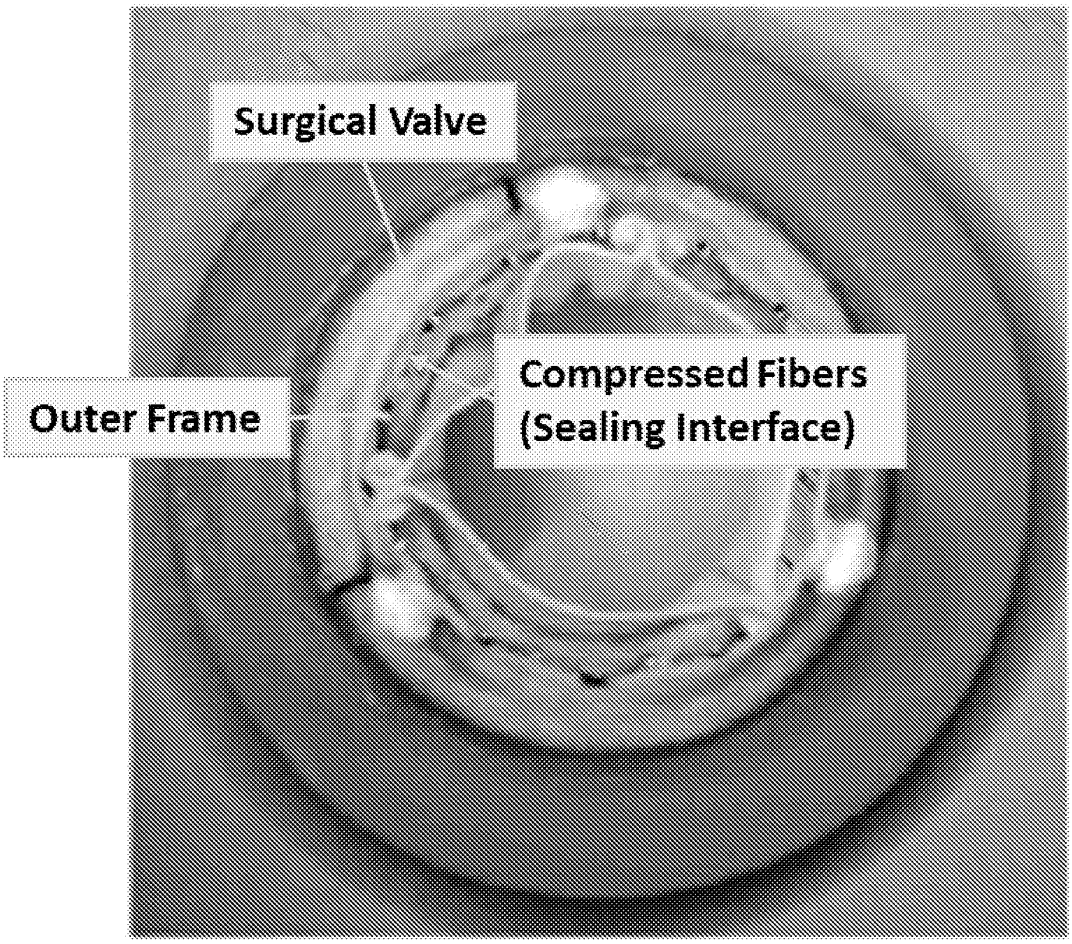
Id. at 1121, Fig. 1. The above figure depicting fibers extending radially outwardly from the outer frame is consistent with what a person of ordinary skill in the art would have expected from a cloth. A person of ordinary skill in the art would have expected outwardly extending fibers (like those shown above) because cloths

are known to be made of woven fibers and have some amount of "hairiness." *See e.g.*, Ex. 1028 (Tyagi, G.K., *Chapter 5: Yarn structure and properties from different spinning techniques*, Advances in Yarn Spinning Technology (2010)); Ex. 1029 (Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004)). Additionally, Merriam-Webster defines "cloth" as "a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments." *Available at:* https://www.merriam-webster.com/dictionary/cloth.

116. Moreover, the fibrous exterior of Walther's outer cloth is not surprising. As demonstrated by Walther's PET outer cloth and SAPIEN's PET fabric cuff, PET can have a range of finishes. Here, Walther discloses that the PET outer cloth is required to "reduce paravalvular leaks" and "increase 'fit' within [Edwards's] surgical Perimount valves." Ex. 1007 (Walther) at 1120. A person of ordinary skill in the art would have been motivated to select an outer cloth having a fibrous finish, like the outer cloth shown in Figure 1 above, so that the radially extending fibers that extend outwardly of the outer frame fill the gaps between the SAPIEN and surgical valve. *See also id.* at 1126 (explaining that the outer cloth fills little gaps).

117. A person of ordinary skill in the art would have understood that the outwardly extending fibers of Walther's outer cloth constitute the "first portion" of fibers required by claim 1.

118. The outwardly extending fibers of Walther's outer cloth (i.e., the first portion) are configured to form a sealing interface against the patient's annulus and native valve leaflets when compressed thereagainst. Walther's cloth-covered SAPIEN is implanted within a surgical valve made by Petitioner. Ex. 1007 (Walther) at 1020, 1121. Walther discloses that the outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves…." *Id.* at 1120. The outer cloth creates a seal by compressing the radially extending fibers against the surgical valve, as shown in Walther's Figure 2 below:

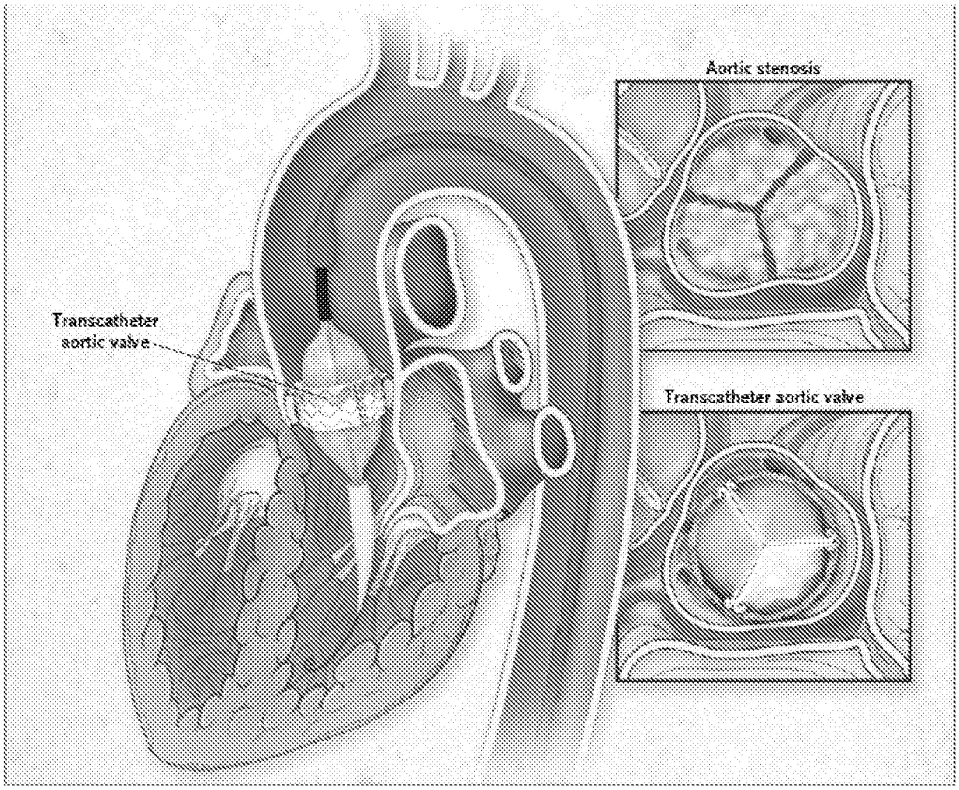


Id. at Fig. 2. A person of ordinary skill in the art would therefore have understood that expanding Walther's cloth-covered SAPIEN in a patient's native aortic valve would compress the outer cloth's outwardly extending fibers (i.e., the first portion) against the patient's annulus and native leaflets to form a sealing interface therewith.

119. This understanding of Walther would have been informed by a person of ordinary skill in the art's knowledge of the standard procedure for implanting

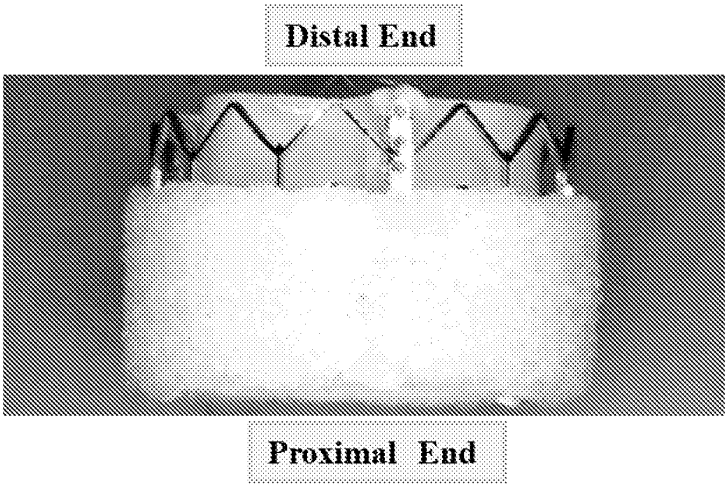
SAPIEN. Cribier discloses that SAPIEN "can be implanted within the diseased native aortic valve using either the retrograde transfemoral or antegrade transapical routes." Ex. 1012 (Cribier) at 347; *see also id.* (disclosing that SAPIEN is "positioned across the aortic annulus"). When implanted, SAPIEN provides sealing between the outer frame and the patient's anatomical wall to "minimize perivalvular leaks." *Id.*, 353; Ex. 1009 (Conradi) at 516-517, Fig. 4A; Ex. 1022 (Smith) at 156-158; Ex. 1012, Abstract, 350-355; Ex. 1027 (Roselli) at 208-210, 214; Ex. 1047 (Piazza) at 74. SAPIEN's outer frame presses against, and forms a seal with, the annulus and the native valve leaflets of the patient's native aortic valve. *See, e.g.,* Ex. 1047 (Piazza) at 74 (disclosing that SAPIEN "is positioned within the aortic root and, once deployed, crushes the leaflets of the native valve against the wall"); Ex. 1009 (Conradi) at 516-517, Fig. 4A; *supra* §III.B. Cribier instructs that "before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion." Ex. 1012 (Cribier) at 353. Consistent with the understanding in the art, the '236 patent identifies the annulus as the point where the leaflets begin. Ex. 1001 ('236 patent) at 1:58-60, Fig. 2; *see also* Ex. 1047 (Piazza) at 76 ("[T]he annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the [aortic] leaflets."). When

positioned and expanded as described in Cribier , SAPIEN presses against and replaces the patient's native aortic leaflets, as illustrated below:

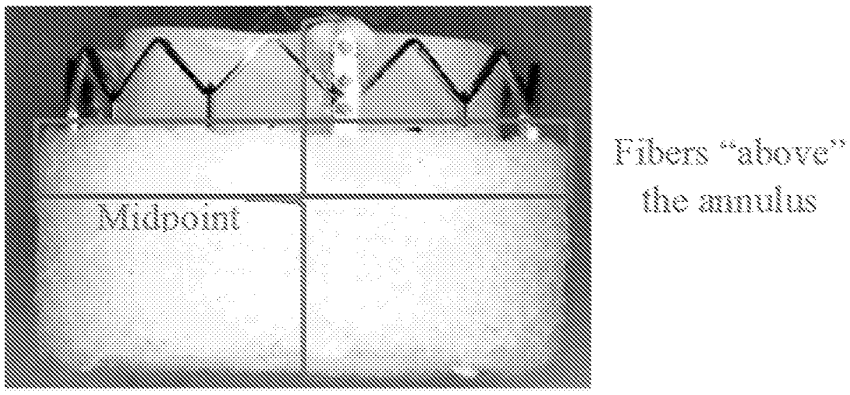


Ex. 1022 (Smith) at 2189, Fig. 1. The prior art even describes SAPIEN as "crush[ing] the leaflets of the native valve against the wall" when it is implanted. Ex. 1047 (Piazza) at 74.

120. Expanding Walther's cloth-covered SAPIEN in a native aortic valve would press Walther's fibers against the patient's annulus and native leaflets to form a sealing interface. Walther's outer cloth covers approximately two-thirds of SAPIEN's frame, as shown below:



Ex. 1007 (Walther) at Fig. 1 (excerpt). If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, as taught by Cribier, the central fibers would press against the annulus and the fibers "above the annulus" would press against the leaflets:



Id.; *see also* Ex. 1047 (Piazza) at 74.

121. A person of ordinary skill in the art would have been motivated to combine SAPIEN, as described in Cribier, with Walther's outer cloth because

Walther expressly discloses this combination. Ex. 1007 (Walther) at 1120-1121. A person of ordinary skill in the art would have had a reasonable expectation of success in adding an outer cloth (as described in Walther) with SAPIEN (as described in Cribier) because Walther describes how to make the combination, provides images of the combination, and concludes that the cloth-covered SAPIEN "demonstrated excellent hydrodynamic performance." *Id.* at 1125. Additionally, Walther also discloses that the cloth-covered SAPIEN "has demonstrated acceptable *in vitro* central regurgitation performance in previous verification studies, meeting minimum performance requirements standard per ISO 5840:2005 section 7.2.3." *Id.* at 1124.

122. A person of ordinary skill in the art would have found it obvious to deploy Walther's cloth-covered SAPIEN within a patient's native valve. Notably, claim 1 does not require endovascular delivery of the heart valve. Thus, a person of ordinary skill in the art would have understood that the size of the valve would not be an issue for delivery. *See e.g.,* Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007)) at I-244 ("With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients"). Dr. Walther recognized size would not be an issue during the

Conference Discussion accompanying his publication stating that he hoped the valve would be available soon, "at least for the trans-apical approach, where tight crimping is not an issue." Ex. 1007 (Walther) at 1126.

123. As explained previously, Walther describes deploying the cloth-covered SAPIEN within an Edwards surgical valve "to reduce paravalvular leak by creating a seal between the two valves." Ex. 1007 (Walther) at 1120. Walther's outer cloth creates a seal by pressing against the surgical valve. *See e.g., id.*, Fig. 2.

124. Persons of ordinary skill in the art well understood that paravalvular leaks could occur between SAPIEN's outer frame and the patient's anatomical wall by November 2012. *See e.g.,* Ex. 1012 (Cribier) at 354 (disclosing that the "vast majority of aortic insufficiency seen on post implantation angiography" with the SAPIEN valve "is perivalvular"; Ex. 1022 (Smith) at 2194 (reporting that 12.2% of patients who received transcatheter implantation of the SAPIEN valve experienced moderate or severe paravalvular leakage at 30 days). This well-known problem would have motivated a person of ordinary skill in the art to apply Walther's known technique for reducing paravalvular leakage (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement. The performance of the cloth-covered SAPIEN would have been

predictable because, for example, Walther describes how the device performed in testing. Ex. 1007 (Walther) at 1124-25.

125. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying the cloth-covered SAPIEN in a patient's native aortic valve because Walther discloses that the valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." Ex. 1007 at 1125. Walther also discloses that the cloth-covered SAPIEN "demonstrated acceptable *in vitro* central regurgitation performance in previous verification studies." *Id.* at 1124. Moreover, persons of ordinary skill in the art had studied implantation of SAPIEN within a patient's native aortic valve using multiple delivery approaches, including transapical and transfemoral delivery and delivery through the common iliac artery, and deemed the procedure safe by November 2012. *See e.g.,* Ex. 1012 (Cribier) at 355 ("Transcatheter valve implantation with the Edwards-Sapien® Heart Valve can be done safely and efficiently using the transfemoral retrograde approach."); *id.,* 347 (recognizing that SAPIEN can be implanted using "antegrade transapical routes"); Ex. 1009 (Conradi) at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively); Ex. 1043 (Kainuma) at 273-276 (describing successful delivery through the common iliac artery). Additionally, the surgical valves described in Walther are designed

to replace and simulate the native aortic valve and POSITAs would have expected Walther's cloth-covered SAPIEN to perform similarly in either environment.A person of ordinary skill in the art would therefore have reasonably expected success in implanting the cloth-covered SAPIEN valve within a patient's native aortic valve.

126. I am aware that Patent Owner has made representations about Walther during the prosecution of a related application (U.S. Patent Application 17/213,251). During that prosecution, Patent Owner admitted that Walther describes a SAPIEN "where a graft may form part of the inner frame." Ex. 1039 (Patent Owner Amendment with RCE) at 6. However, Patent Owner also argued that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." *Id.* at 9. There is no support in Walther for this statement. Walther merely states that an "added poly(ethylene terephthalate) (PET) cloth was stitched onto the perimeter of each SAPIEN valve." Ex. 1007 (Walther) at 1121. Walther does not describe a "cloth base or outer graft" and a "fiber portion." Likewise, the figures do not show a "cloth base or outer graft" and a "fiber portion":

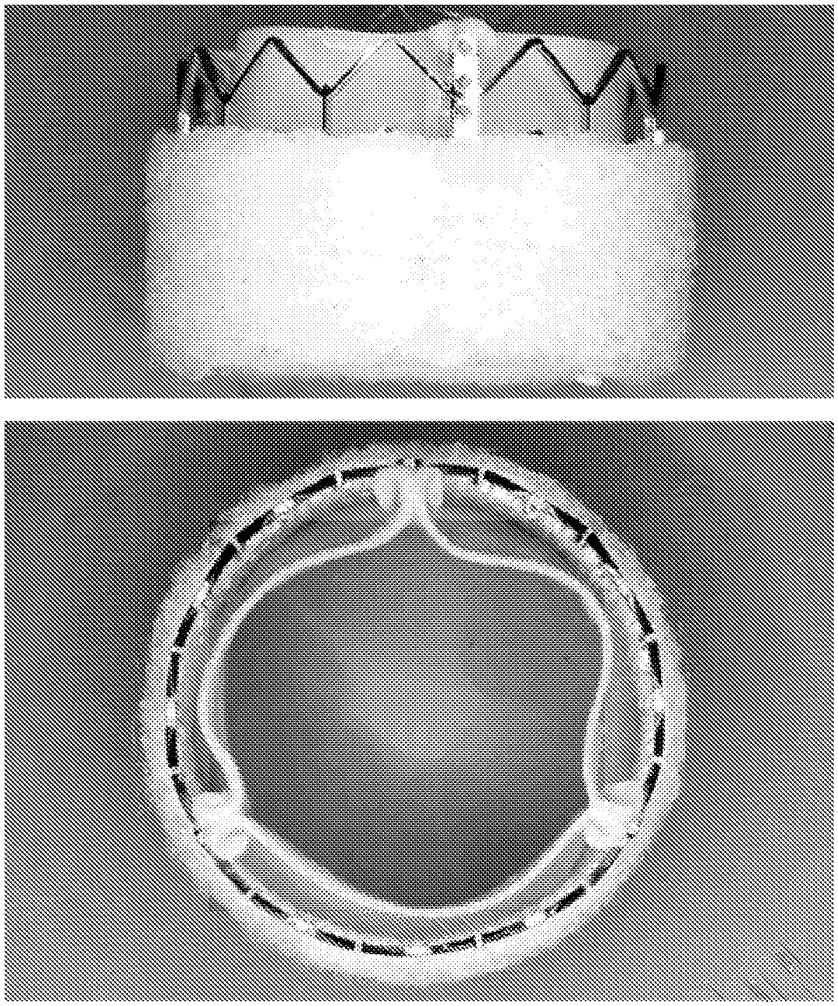


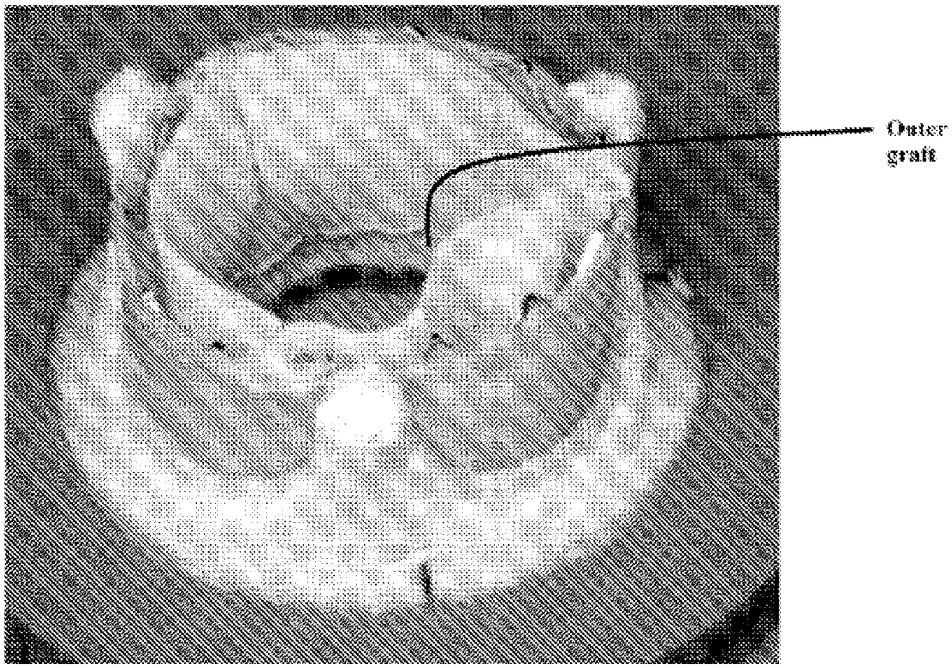
Fig. 1. Cloth valve.

The figures depict a single piece of PET. For this reason, a person of ordinary skill in the art would not have understood Walther to disclose "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft," as argued by Patent Owner. Ex. 1039 at 9.

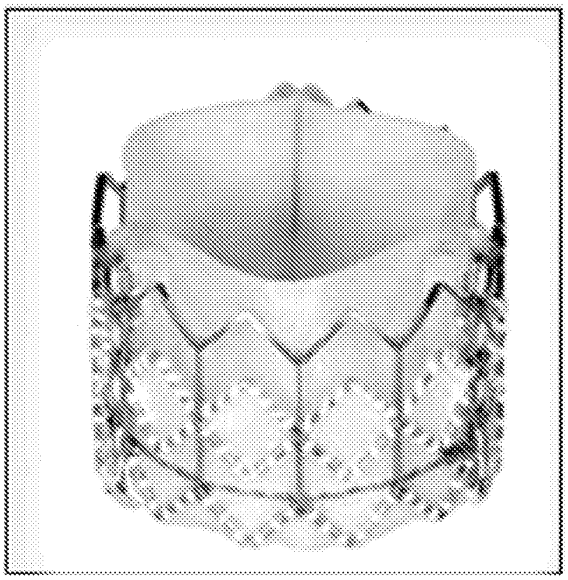
127. Patent Owner also argued that Walther's outer cloth is "wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets" and

thereby constricts the orifice area and impacts hemodynamics. Ex. 1039 (Patent Owner Amendment with RCE) at 9-10. Again, there is no support in Walther for this statement. Walther never states that its outer cloth is wrapped around the inflow end. To the contrary, Walther states that an "added poly(ethylene terephthalate) (PET) cloth was stitched onto the ***perimeter*** of each SAPIEN valve." Ex. 1007 at 1121 (emphasis added). There is no reason to doubt Walther's description.

128. Patent Owner argues that the below figure shows the outer cloth (labeled "Outer graft") "flipped towards the prosthetic leaflets where the base/outer graft is then stitched to the metallic frame." *Id.* at 9.



Patent Owner misunderstands the figure. In the above figure, Patent Owner's line labelled "Outer graft" points to a polytetrafluoroethylene (PTFE) suture that attaches the valve leaflets and inner fabric cuff to the frame. Ex. 1027 (Roselli) at 213. This same suture (green) is also visible on the outside of SAPIEN (with no outer cloth) as shown in the below figure from Cribier:



Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 (Cribier) at Fig. 1.

129. The below enlarged and color photograph from Walther shows that the outer cloth is not wrapped around the inflow end of the valve and sutured to the inside of the valve as Patent Owner argues. If the outer cloth was wrapped around and sutured, as Patent Owner argued, it would be visible in the below figure, but it is not.

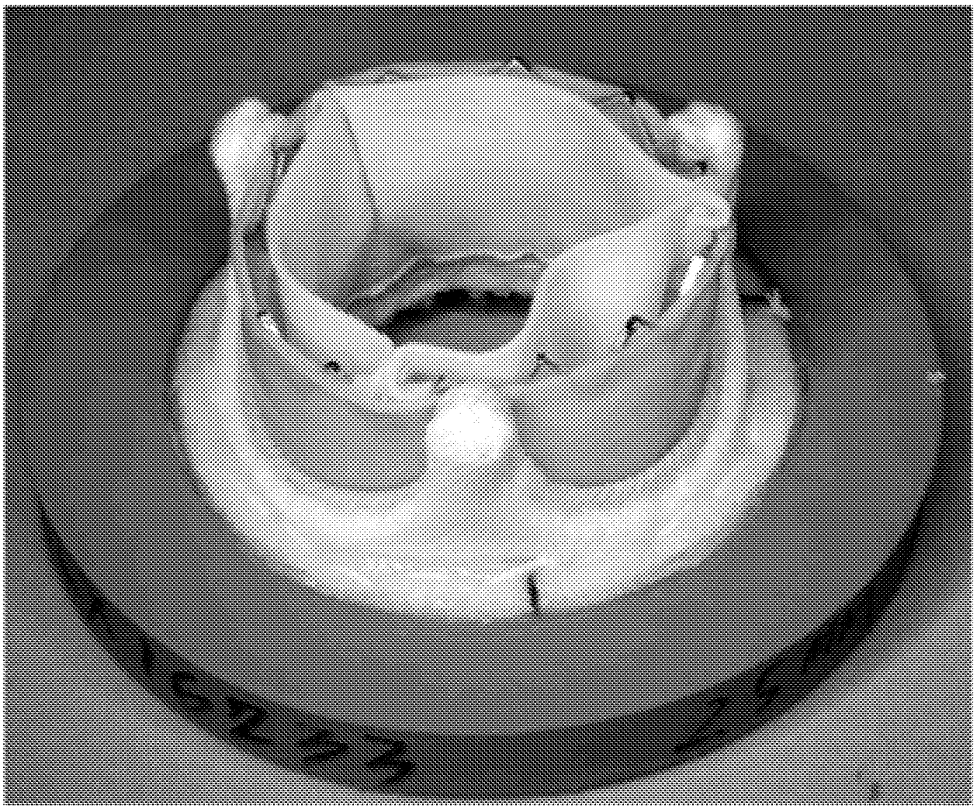


Fig. 2. Cloth THV valve deployed in surgical valve.

Ex. 1007 (Walther) at Fig. 2.

130. Further, because the outer cloth is not "wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets," a person of ordinary skill in the art would not have been concerned that the outer cloth would constrict the orifice area or impact hemodynamics. Dr. Walther was asked about this potential issue during a Conference Discussion occurring in conjunction with his paper and did not express any concern about this issue, stating: "I am not sure whether it changes the effective orifice area that much and I am pretty sure you just squeeze

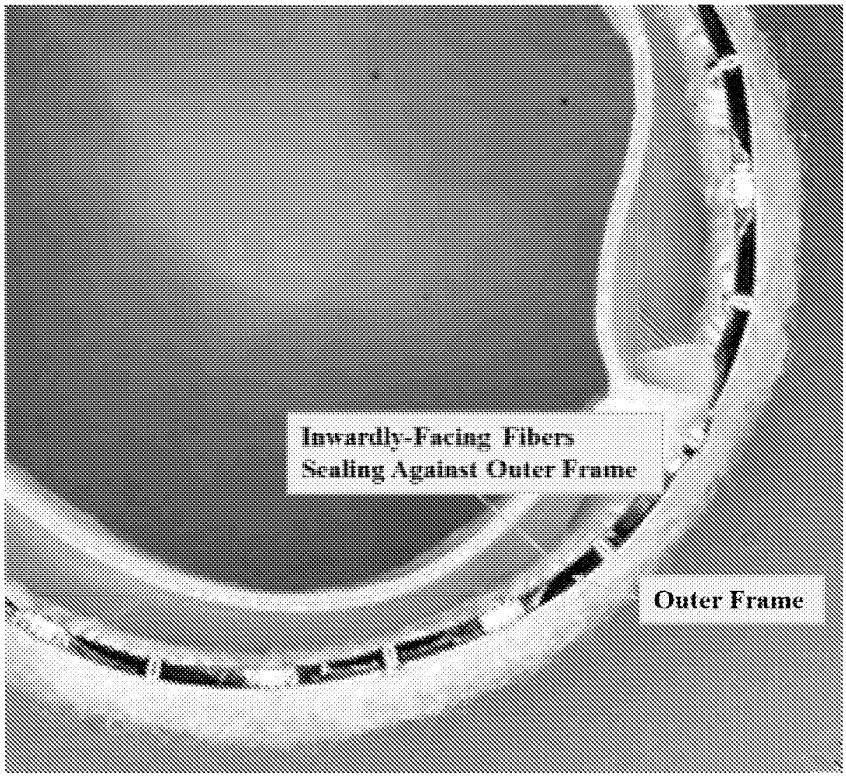
it in. You have four atmospheres and really it is just filling little gaps there." Ex. 1007 (Walther) at 1126. Further, Walther concludes that the valve "demonstrated excellent hydrodynamic performance," further eliminating any concerns that the outer cloth somehow disadvantageously impacts the orifice area or hemodynamics. *Id.* at 1125-1126. For these reasons, a person of ordinary skill in the art would not have understood Walther's outer cloth to wrap around the inflow end of the valve or negatively impact hemodynamics.

6. <u>Second Portion of Fibers</u>

131. Claim 1 next recites: "a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second portion of fibers is non-metallic." Cribier in combination with Walther renders this limitation obvious.

132. As I explained in the preceding section, Walther discloses a SAPIEN with an outer cloth sutured to the exterior of the stent frame that includes a plurality of PET fibers that extend outwardly from the outer frame (i.e., the first portion). *Supra* §VI.A.5. In addition to the outwardly extending fibers on the outward-facing surface of the outer cloth, a person of ordinary skill in the art would have understood that Walther's outer cloth also includes a plurality of PET fibers on the opposite side of the cloth on the inward-facing surface that press

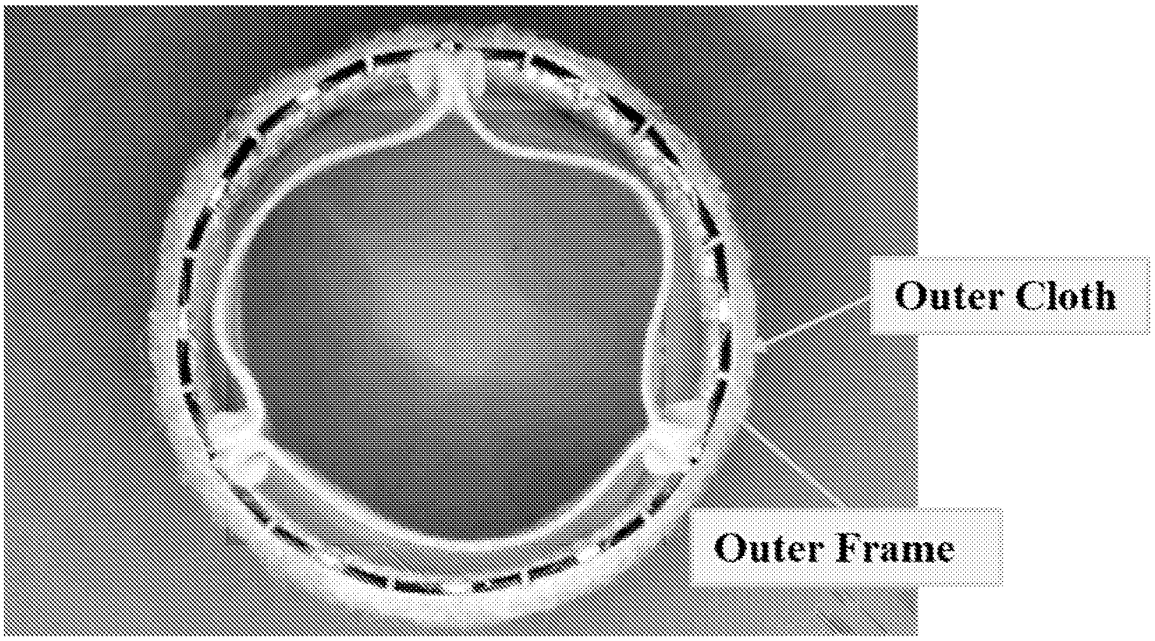
against the outer frame. These fibers pressing the outer frame are visible in Walther's Figure 1 below:



Ex. 1007 (Walther) at Fig 1 (excerpt). As shown above, some of the inwardly-facing fibers extend radially inwardly through the open cells of the outer frame. *Id.* A person of ordinary skill in the art would have understood that many of the inwardly-facing fibers do not pass through the open cells, but instead press against and form a sealing interface with the outer frame. As I explained above, cloths, including Walther's PET cloth, are generally made by weaving or knitting a plurality of fibers together to form a single piece of material. *Supra* §VI.A.5. Therefore, a person of ordinary skill in the art would expect Walther's PET cloth to

have fibers on both its outwardly-facing surface and its inwardly-facing surface because the entire cloth is formed from woven fibers. The inwardly-facing surface of the outer cloth, which presses against the outer frame, is the "second portion of fibers" required by claim 1. The fibers are PET and, therefore, "non-metallic." *Supra* §VI.A.5.

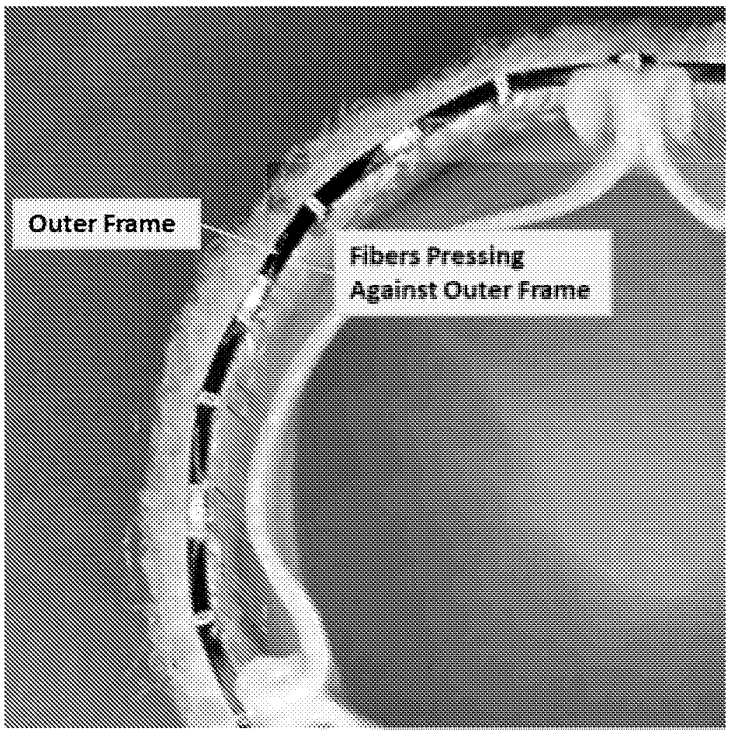
133. Walther discloses that the outer cloth is "stitched onto the perimeter of each SAPIEN valve." Ex. 1007 (Walther) at 1121. The perimeter of the SAPIEN valve is the outer frame, as shown in Walther's Figure 1 below:



Ex. 1007 (Walther) at Fig. 1 (excerpt). Therefore, the second portion of fibers, which press against the outer frame, are "carried by the outer frame."

134. A person of ordinary skill in the art would also have understood that the PET fibers pressing against the outer frame (i.e., second portion) are

"configured to form a second sealing interface against the outer frame when . . . compressed thereagainst." Because the fibers are stitched to the exterior surface of the outer frame, they would press against the outer frame when the valve is expanded, forming a "second sealing interface thereagainst." *See e.g., id.* at Fig. 2. Again, this is visible in Walther's Figure 1, which shows the cloth-covered SAPIEN in the expanded state:



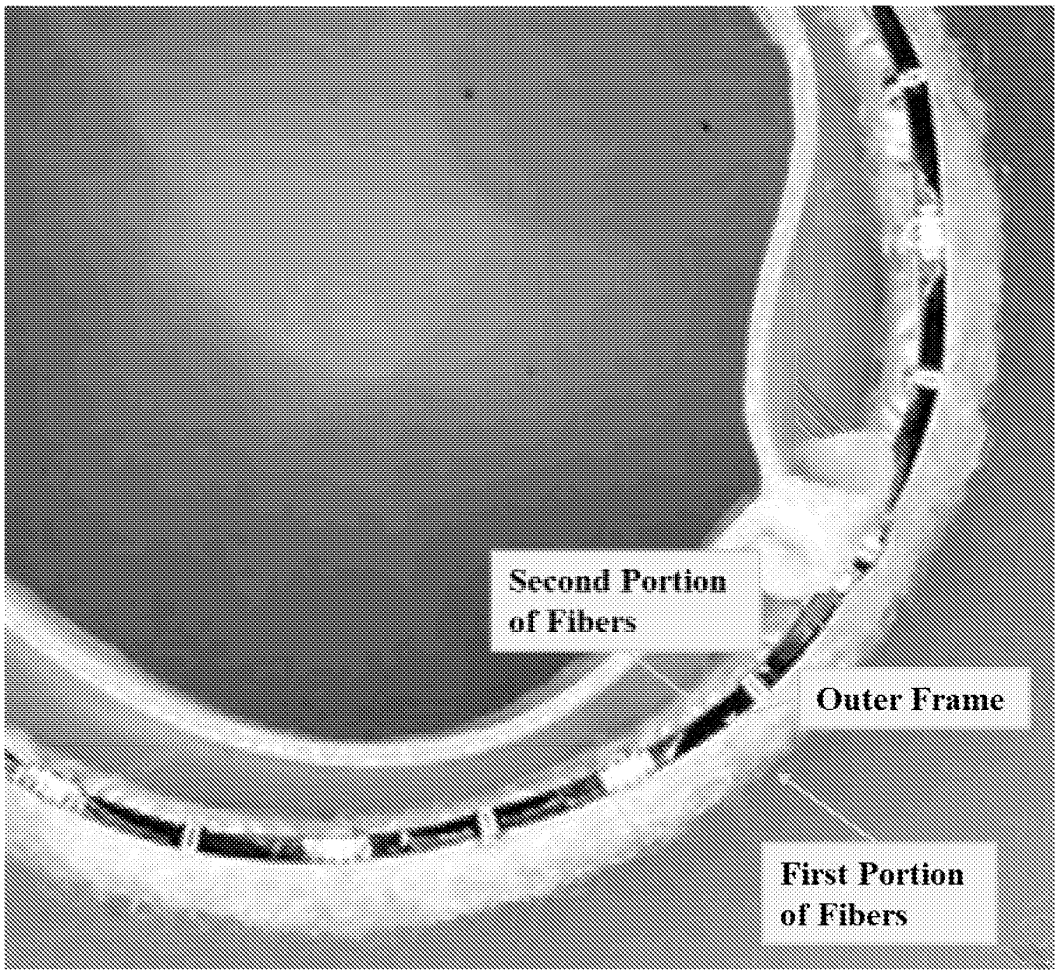
Id. at Fig. 1 (excerpt). The sealing interface formed between the second portion and the outer frame helps the outer cloth "reduce paravalvular leak." *Id.* at 1120. The radially extending fibers of the outward-facing surface of the cloth (i.e., the first portion) would press against and seal the native tissue of the patient's aortic

valve, preventing blood from leaking between the cloth and the native tissue. On the opposite side of the cloth, the fibers of the inward-facing surface of the cloth press against and seal the outer frame, preventing blood from leaking between the cloth and the outer frame. In this way, the two fiber portions of the outer cloth work together to reduce PVL.

7. First and Second Portion in Overlapping Radial Alignment

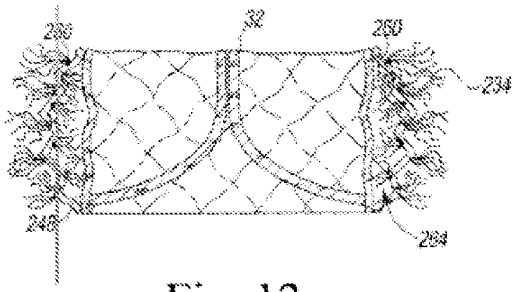
135. Claim 1 next recites: "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment." Cribier in combination with Walther renders this limitation obvious.

136. The outwardly extending fibers extending from the outward-facing surface of Walther's outer cloth (i.e., first portion) and the inwardly-facing fibers extending from the inward-facing surface Walther's outer cloth (i.e., second portion) are in "overlapping radial alignment" as shown in Walther's Figure 1:



Ex. 1007 (Walther) at Fig. 1 (excerpt). Because Walther's outer cloth encircles the entire perimeter of the SAPIEN valve, a person of ordinary skill in the art would have understood that the outwardly facing fibers (i.e., first portion) and the inwardly facing fibers (i.e., second portion) radially overlap along the entire perimeter of the SAPIEN. In addition, because Walther's first portion of fibers and second portion of fibers are part of a single woven PET cloth, the first portion and the second portion would necessarily be in radially overlapping alignment.

137. This understanding is further confirmed by Patent Owner's representations during prosecution of the '236 patent. During prosecution, of the '236 patent, Patent Owner relied on Figure 12 to support originally filed claim 13, which recited that the "first portion of fibers and the second portion of fibers radially overlap":

13. (New) The valve assembly according to claim 11, wherein the first portion of fibers and the second portion of fibers radially overlap.	See added line to FIG. 12 (Applicant added):  Fig. 12

Ex. 1002 ('236 Patent Prosecution History Excerpt) at 241. The fibers in Walther's outer cloth are arranged the same way. *See, e.g.*, Ex. 1007 (Walther) at Fig. 1. Therefore, Walther's first portion of fibers is in "overlapping radial alignment" with the second portion of fibers.

8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets

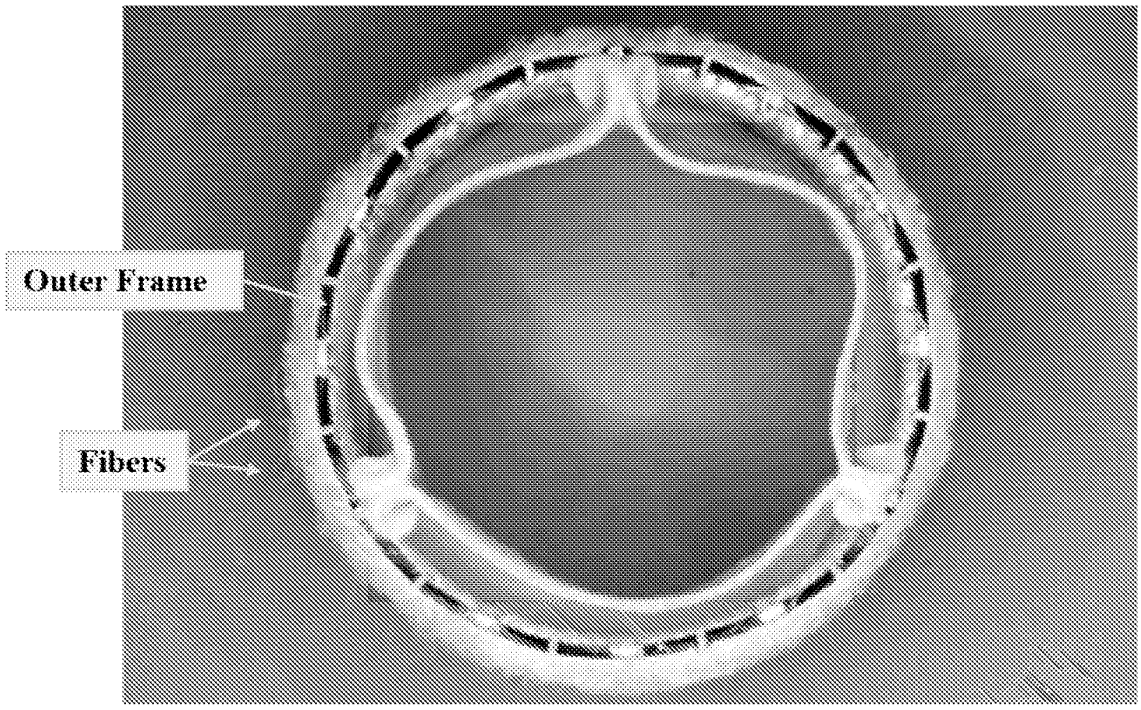
138. Claim 1 next recites: "wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst." Cribier in combination with Walther renders this limitation obvious.

As I explained above, when Walther's cloth-covered SAPIEN is implanted in a patient's native aortic valve, the fibers of the first portion would be in overlapping radial alignment with, and seal against, the patient's native aortic leaflets. *Supra* §VI.A.5. A person of ordinary skill in the art would have been motivated to implant Walther's cloth-covered SAPIEN in a patient's native aortic valve, and would have reasonably expected success in doing so, for the reasons I previously provided. *Id.*

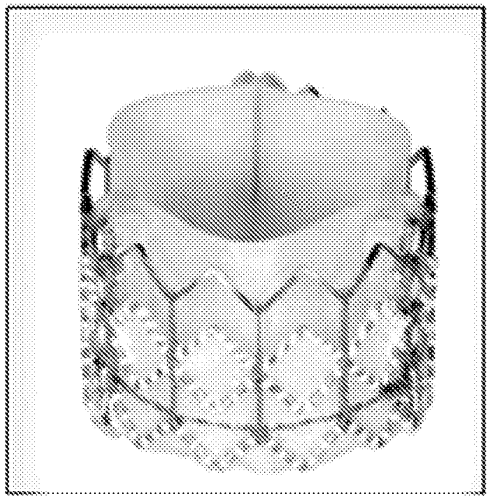
9. Free of an Outer Graft Covering Between First Portion of Fibers and Outer Frame

139. Claim 1 next recites: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Cribier in combination with Walther renders this limitation obvious.

140. As shown below, the fibers of Walther's outer cloth are directly stitched to the metal bars of the outer frame:



Ex. 1007 (Walther) at Fig. 1. Walther does not state that there is any "outer graft covering" between the fibers and SAPIEN's frame and no such "outer graft covering" is visible in the figures. *See id.* at 1120-1121, Figs. 1-2. Additionally, Walther discloses that the outer cloth was stitched to the perimeter of SAPIEN valves that were "identical" to the existing SAPIEN except for the outer cloth. *Id.* at 1120. A person of ordinary skill in the art would have understood that SAPIEN did not include any "outer graft covering" on the exterior of the outer frame, as shown in Cribier's Figure 1 below:



Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 (Cribier) at Fig. 1. As shown above, there is no graft covering, or other material, on the exterior of SAPIEN's outer frame. Therefore, a person of ordinary skill in the art would have understood that when Walther's outer cloth was added to SAPIEN's outer frame, there was no "outer graft covering" between the outwardly extending fibers of the outer cloth (i.e., first portion) and the outer frame.

141. As I discussed above, I am aware that Patent Owner has made arguments about Walther during prosecution of a related patent application, asserting that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." Ex. 1039 (Patent Owner Amendment with RCE) at 9. Patent Owner's arguments about

Walther are unsupported and incorrect for the reasons I provided previously. *Supra* §VI.A.5.

10. Radially Compressed Orientation and Radially Expanded Orientation

142. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Both Cribier and Walther disclose this limitation.

143. Cribier discloses that the SAPIEN is "***compressed*** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its ***expanded size*** to its 'mounted' size.'" Ex. 1012 (Cribier) at 348 (emphasis added). A person of ordinary skill in the art would have understood that SAPIEN's "mounted size" is a compressed orientation. Similarly, Walther discloses that the cloth-covered SAPIEN valves were crimped and then expanded within various surgical valves by a balloon catheter. Ex. 1007 (Walther) at 1122, Fig. 4.

11. Balloon Expandable

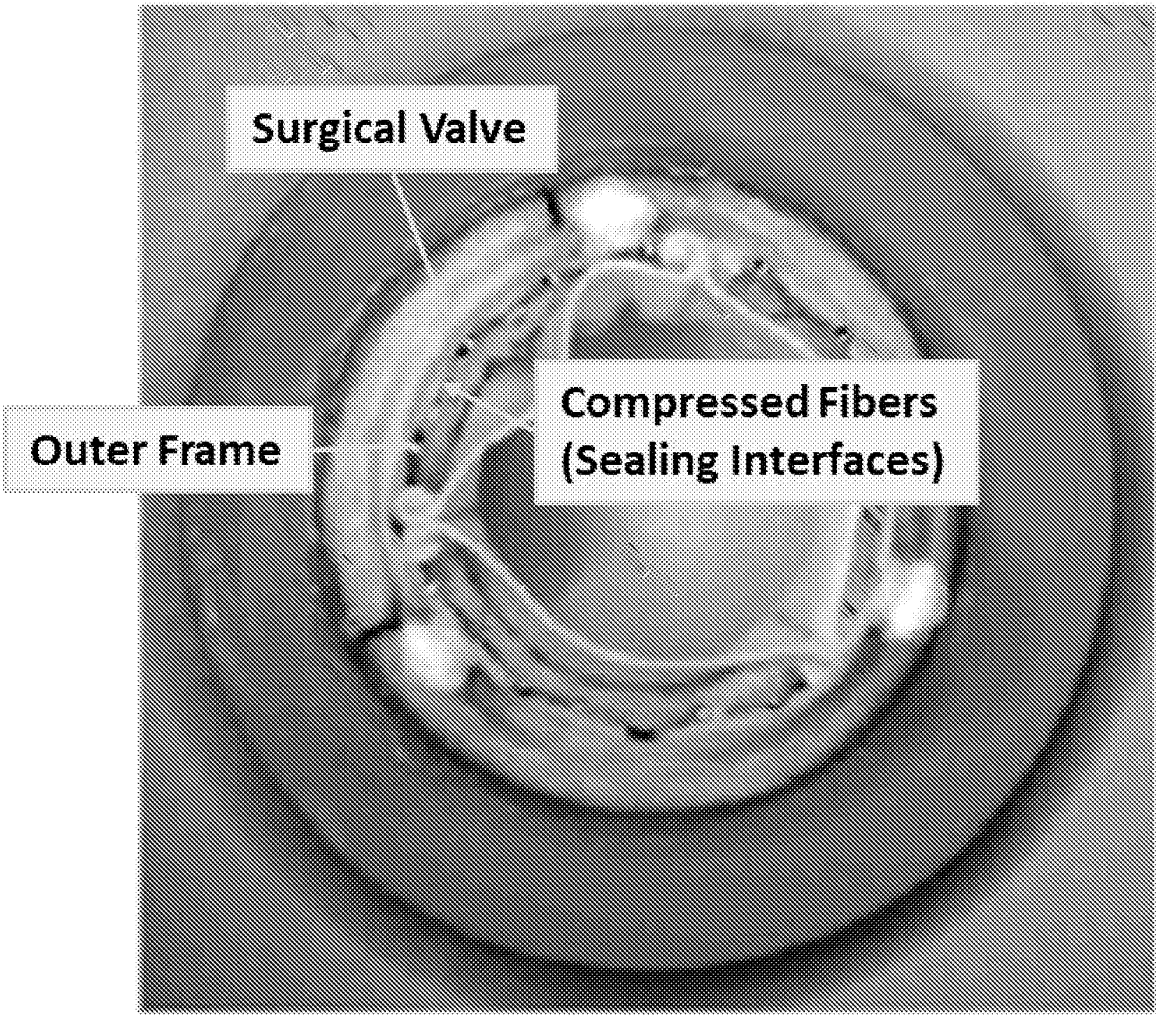
144. Claim 1 next recites: "wherein the valve assembly is balloon expandable to the radially expanded orientation." Cribier and Walther both discloses this limitation.

145. Cribier discloses that SAPIEN consists of a "balloon-expandable stent." Ex. 1012 (Cribier) at 348. Walther also discloses that SAPIEN includes a balloon-expandable stent. Ex. 1007 (Walther) at 1122.

12. Compress Fibers to Form a Sealing Interface

146. Claim 1 concludes by reciting: "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface." Cribier in combination with Walther renders this limitation obvious.

147. Walther discloses implanting the cloth-covered SAPIEN in a surgical valve, and that the outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves…." Ex. 1007 (Walther) at 1120. Walther's valve creates a seal by pressing the outer cloth against the surgical valve, compressing the fibers of the outer cloth against the surgical valve and SAPIEN's outer frame to form sealing interfaces thereagainst:



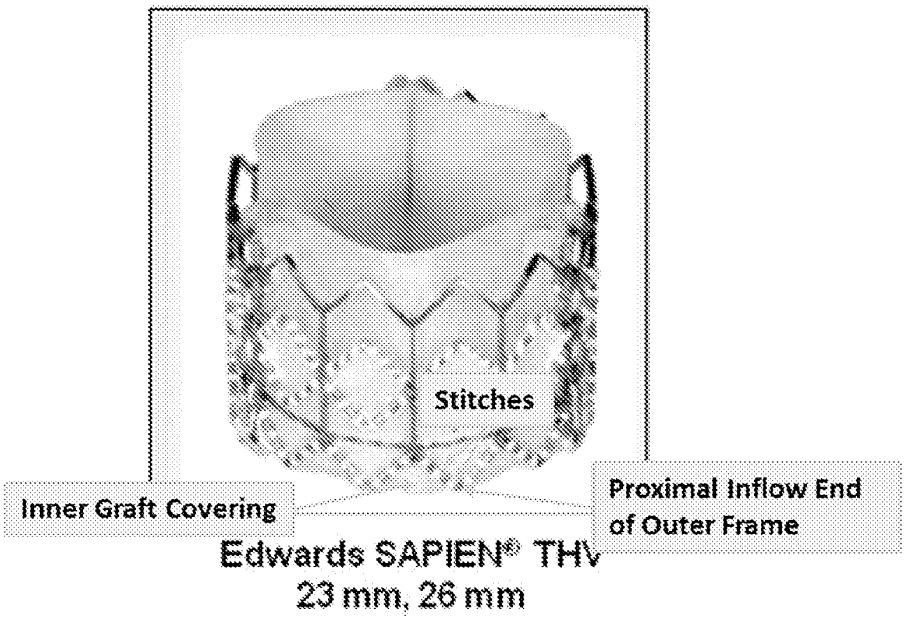
Id. at Fig. 2. Expansion of Walther's cloth-covered SAPIEN within a patient's native aortic valve would similarly compress the outwardly extending fibers of the outward-facing surface of the cloth (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and the inwardly extending fibers of the inward-facing surface of the cloth (i.e., second portion) against SAPIEN's outer frame to form a second sealing interface. As I explained above,

these sealing interfaces prevent blood from leaking around the outside of the valve or between the outer cloth and the stent. *Supra* §§VI.A.5-6.

B. Claim 2

148. Claim 2 recites: "The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." Cribier in combination with Walther renders this claim obvious.

149. As I explained in claim 1, Cribier discloses that SAPIEN includes an inner PET fabric cuff (i.e., inner graft covering) that extends to the proximal inflow end of SAPIEN's outer frame:



Ex. 1012 (Cribier) at 348, Fig. 1. As shown in the figure above, a plurality of white stitches extend between the fabric cuff (i.e., inner graft covering) and through the outer frame to secure the fabric cuff to the proximal inflow end of the outer frame. (*See* Ex. 1012, Fig. 1.

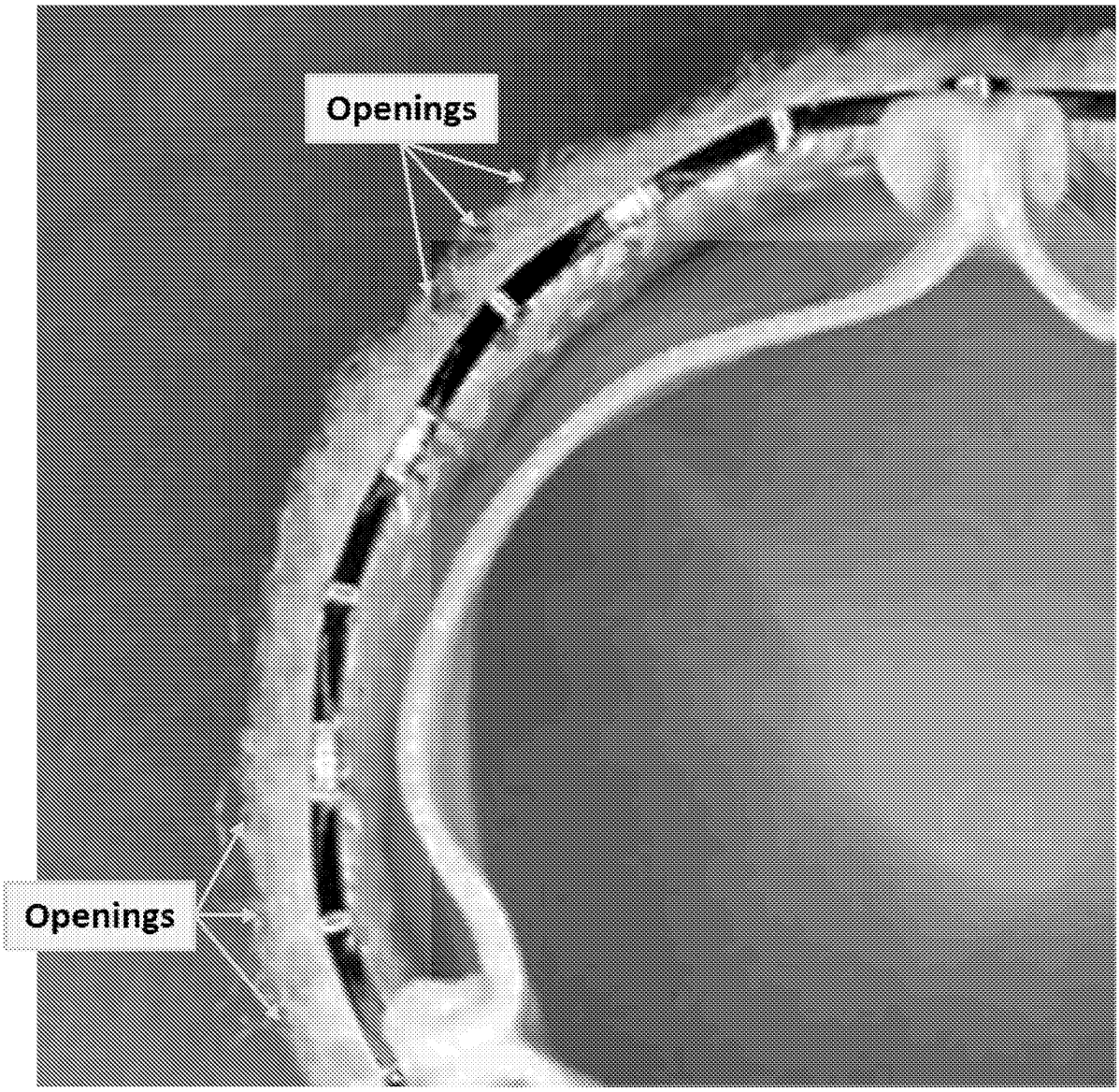
C. Claim 3

150. Claim 3 recites: "The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." Cribier in combination with Walther renders this claim obvious.

151. First, I note that the '236 patent does not claim or disclose how to size or arrange the fibers to provide "an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." *See* Ex. 1001. For example, the '236 patent never discloses the length or width of the fibers, the density of the fibers, or any particular arrangement of the fibers. *Id.* The '236 patent also does not disclose the size of the "opening." I note that the figures of the '236 patent illustrate relatively large openings between the groups of collagen fibers. *See, e.g.*, Ex. 1001 ('236 Patent) at Figs. 8-9, 11-14. A person of ordinary skill in the art would have understood that fibers with such large openings between them would not be able to form a sufficient seal against the patient's native tissue to prevent PVL. Therefore, persons of ordinary skill in the art would

have understood that the '236 patent's figures are merely schematic or conceptual, and do not accurately reflect the dimensions, density, or placement of the collagen fibers on the frame.

152. As I explained in claim 1, Walther discloses a SAPIEN with an added outer cloth that includes a plurality of radially extending fibers on the outward-facing surface of the cloth (i.e., first portion of fibers). *Supra* §VI.A.5. A person of ordinary skill in the art would have understood that Walther's outer cloth includes openings between the outwardly extending fibers created by spacing formed between adjacent fibers. *See* Ex. 1007 (Walther) at Fig. 1. These openings are the "opening[s] extending through a thickness" of the outwardly extending fibers required by claim 3, and are visible in the below excerpt of Walther's Figure 1:



Id. at Fig. 1 (excerpt). A person of ordinary skill in the art would have understood that any cloth or fabric that is composed of interwoven fibers, such as Walther's outer cloth pictured above, would necessarily include small openings between adjacent woven fibers. *See e.g.,* Ex. 1008, 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). The openings between fibers may be smaller in

densely-woven cloths/fabrics than in a loosely-woven cloth/fabrics, but a person of ordinary skill in the art would have understood that the openings exist.

153. As shown above, the fibers of Walther's outer cloth are sufficiently dense to prevent blood from flowing through the fibers, but loose enough to create small openings between the adjacent fibers. Ex. 1007 (Walther) at Fig. 1. Persons of ordinary skill in the art would have understood that the openings between the fibers must be small to enable the first portion of fibers to form an effective sealing interface with the native tissue. If the openings were too wide, blood may disadvantageously leak through the openings.

154. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of radially extending fibers such that even larger openings existed between the fibers. *Supra* §III.D; *see also e.g.,* Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. The exchange of Walther's cloth for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in

substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.,* Ex. 1007 (Walther) at 1120-1121.

D. Claim 4

155. Claim 4 recites: "The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame." Cribier in combination with Walther renders this claim obvious.

156. Like claim 3, I note that the '236 patent does not claim or disclose how to size or arrange the fibers to provide "an opening extending through a thickness [of the second portion of fibers] that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame." *See* Ex. 1001. For example, the '236 patent never discloses the length or width of the fibers, the density of the fibers, or any particular arrangement of the fibers. *Id.* The '236 patent also does not disclose the size of the "opening." As I noted in the preceding section, persons of ordinary skill in the art would have understood that the '236 patent's figures are merely schematic or conceptual, and do not accurately represent the dimensions, density, or placement of the collagen fibers

on the frame because the openings shown between the groups of collagen fibers would be too large for the fibers to form a sufficient seal against the outer frame to prevent PVL.

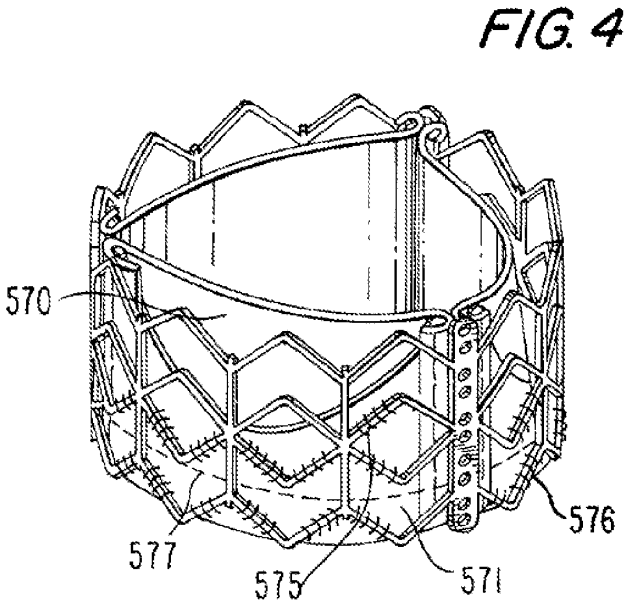
157. As I explained in claim 1, Walther discloses a SAPIEN with an added outer cloth that includes a plurality of radially extending PET fibers on its outward-facing surface (i.e., first portion) and a plurality of inwardly-facing PET fibers abutting SAPIEN's outer frame (i.e., second portion of fibers). *Supra* §VI.A.6. As I explained in the preceding section, a person of ordinary skill in the art would have understood that any woven fabric, including Walther's outer cloth, would include some openings between the interwoven fibers of the fabric. *See supra* §VI.C; *see also e.g.,* Ex. 1008, 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). A person of ordinary skill in the art would therefore have understood that openings necessarily exist between the woven PET fibers of the second portion of Walther's outer cloth that are the "opening[s] extending through a thickness" of the second portion required by claim 4. As I explained for claim 3, the fibers of Walther's cloth are sufficiently dense to prevent leakage of blood, but loose enough to create small openings between the adjacent fibers. *Supra* §VI.C. A person of ordinary skill in the art would have understood that these openings in the second portion extend to the outer frame because the second

portion abuts the exterior surface of the outer frame and is sutured thereto. *Supra* §VI.A.6.

158. Moreover, as I explained in the preceding section, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of woven PET fibers such that even larger openings existed between the fibers. *Supra* §III.C; *see also e.g.,* Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. The exchange of Walther's cloth for a less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.,* Ex. 1007 (Walther) at 1120-1121.

VII. GROUNDS 2-3: CLAIMS 1-4 OBVIOUS OVER SPENSER AND WALTHER OR SPENSER II

159. Spenser describes heart valve assemblies similar to SAPIEN including the below embodiment, which is shown in Figure 44a of Spenser:



Ex. 1010, Fig. 44a.

160. Embodiments of the Spenser patent were commercialized by Edwards and sold as the SAPIEN device. The SAPIEN Instructions for Use ("IFU") identify Spenser as a patent that may cover SAPIEN. Ex. 1040, 6.

161. As I explained in Ground 1, Walther discloses a modified SAPIEN that includes an added outer cloth. *Supra* §VI.A. Walther's modified SAPIEN is shown in Figure 1 of the article, below:

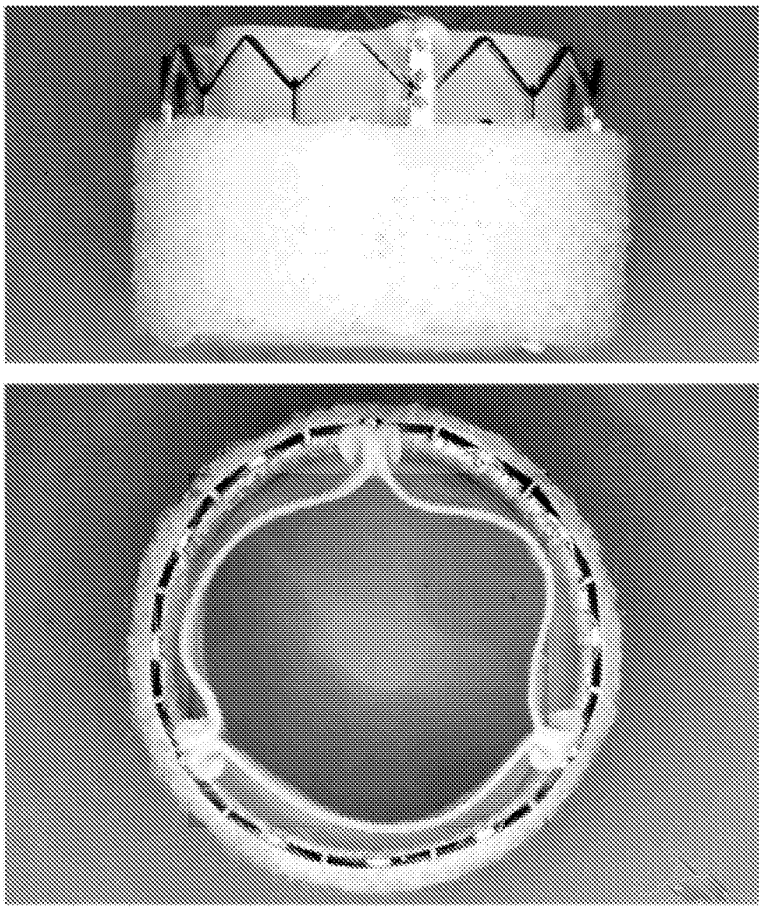


Fig. 1. Cloth valve.

162. Similar to Walther, Spenser II discloses a prosthetic stented valve that includes a layer of "compressible material" [i.e., sealing material] disposed along the "outer surface of the stent structure" to reduce paravalvular leaks:

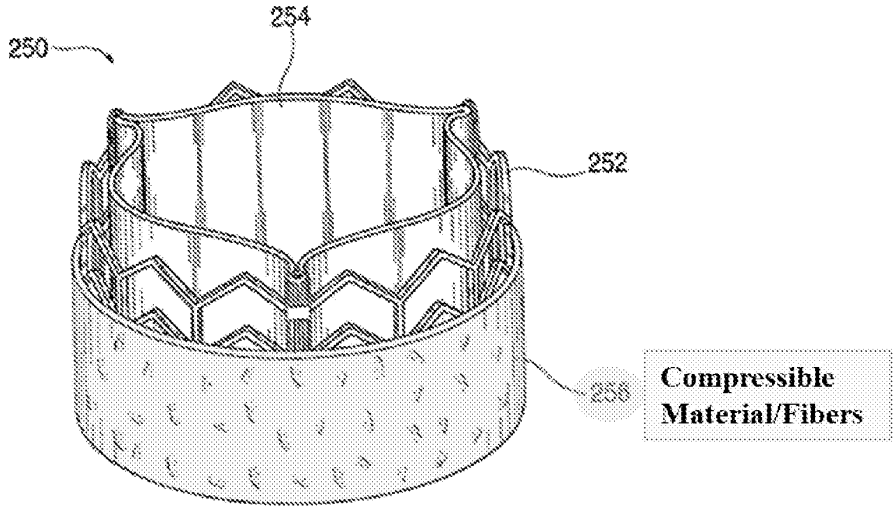


FIG. 22

Ex. 1011 at [00144]-[00145], Fig. 22. Spenser II explains that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material" (i.e., a plurality of radially extending fibers). *Id.* at [00145].

163. For the reasons below, I believe that that a person of ordinary skill would have been motivated to combine Walther's outer cloth or Spenser II's outer compressible material with the heart valve assemblies in Spenser, including the assembly shown in Figure 44a. Based on my review of these references, I believe that the combination of Spenser and Walther or Spenser II renders claims 1-4 obvious.

A. Claim 1

164. Based on my review of the prior art, it is my opinion that the combination of Spenser and Walther or Spenser II renders claim 1 obvious.

1. Preamble

165. The preamble of claim 1 recites: "A transcatheter aortic valve assembly comprising."

166. Spenser discloses that "[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously*** … ***via a large blood vessel such as the femoral artery***[.]" Ex. 1010 (Spenser) at 2:6-12 (emphases added). Spenser discloses that its valve may be implanted "at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient." *Id.* at 1:13-15, 5:17-25, 5:65-6:3, 17:19-18:43. Spenser further discloses that its valve may be implanted by "inserting the valve assembly on a delivery device similar to a catheter." *Id.* at 2:6-12.

167. Walther also discloses a "transcatheter aortic valve assembly" for the reasons I provided previously. *Supra* §VI.A.1. Likewise, Spenser II discloses a "transcatheter aortic valve assembly." Spenser II discloses that its invention "is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve." Ex. 1011 (Spenser II) at [0087]. Thus, a person of ordinary skill in the art would have understood that the stented valve 250 disclosed in Figure 22 is an

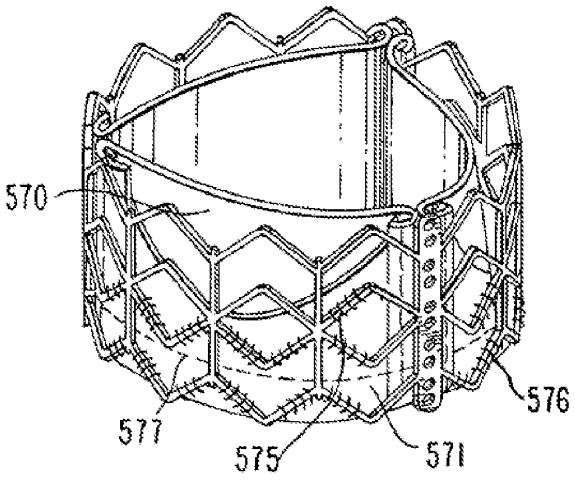
"aortic valve assembly." *See id.* at [00144]. Spenser II further teaches that this valve is designed for implantation using a balloon catheter. *Id.* A person of ordinary skill in the art would have recognized that where an expandable valve is implanted using a balloon catheter, both the valve and the balloon would be advanced to the patient's heart via a sheath or catheter, as was standard practiced in the art. Indeed, Spenser II confirms that percutaneous delivery of prosthetic valves involved delivery through a catheter. *See, e.g., id.* at [0033]-[0035], [0040]. Thus, a person of ordinary skill in the art would have understood that Spenser II's stented valve 250 is a "transcatheter aortic valve assembly."

2. Outer Frame

168. Claim 1 next recites: "an outer frame formed from a metallic material." Spenser also discloses this limitation.

169. Figure 44a of Spenser illustrates "an implantable prosthetic valve in accordance with [a] preferred embodiment of the present invention" that includes "frame 575":

FIG. 44a



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame).

170. As shown in Figure 44a above, frame 575 surrounds the other valve features, making it an "outer frame." *Id.* at Fig. 44a-44b. Spenser further discloses that the frame may be made from metallic materials such as "nickel titanium." *Id.* at 12:28-31.

3. Inner Frame

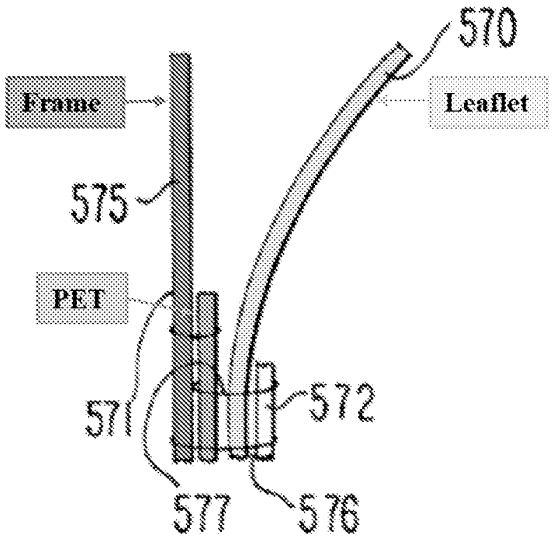
171. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Spenser also discloses this limitation.

172. The embodiment in Figure 44a of Spenser includes an "additional piece of PET" 571 for "sealing and protecting the pericardium." Ex. 1010 (Spenser) at 26:30-34, Figs. 44a-44c; *see also id.* claims 10, 30 ("including a fabric layer interposed between the valve assembly and support stent"). The "pericardium" is the prosthetic pericardial leaflets 570 (*see e.g.,* Figures 44a-b below). *Id.* at 26:30-54. PET is a type of polyester and is a "polymeric…graft covering."

173. As shown in Figure 44b of Spenser below, the PET 571 [blue] is positioned "between the leaflets [570 yellow] and the frame [575 red]"[4]:

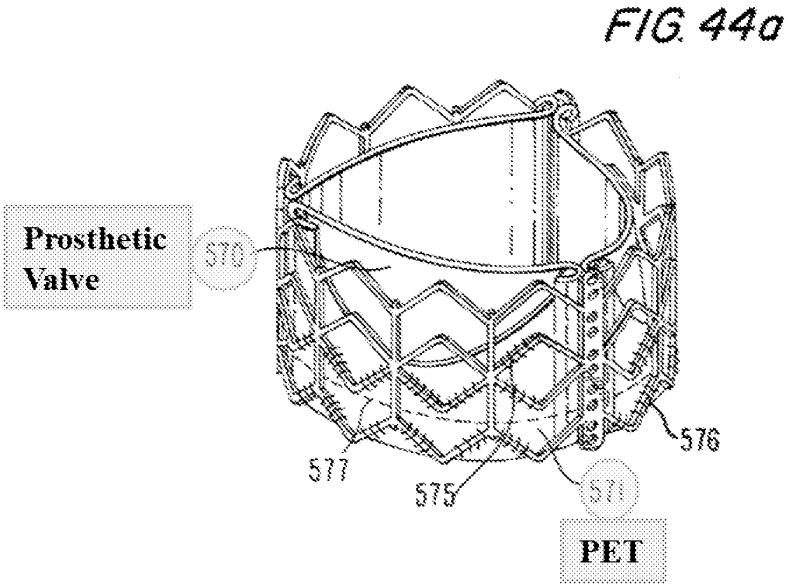
[4] In Fig. 44b, the lead lines for 571 and 575 both point to the outer frame [red]. *See* Ex. 1010 (Spenser) at Fig. 44b. I believe this is a drafter's error. As explained in Spenser's written disclosure, the lead line for the outer PET layer 571 should point to the middle layer [blue] because PET 571 is described as being positioned "between the leaflets [570] and the frame [575]." *Id.* at 26:40-42.

FIG. 44b



Id. at 26:30-54, Fig. 44b. Spenser teaches that the PET 571 is stitched to the prosthetic valve using at least suture 576. *Id.* at 26:45-47. PET 571 thus "engages" the prosthetic heart valve.

174. As shown in Figure 44b above and Figure 44a below, the PET 571 is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:



Id. at 26:30-34, Fig. 44a. Thus, based on Patent Owner's statements during prosecution of related patents, *supra* §VI.A.3, and if an inner frame can be a graft covering, PET 571 is an "inner frame [that] includes a cylindrically extending polymeric inner graft covering."

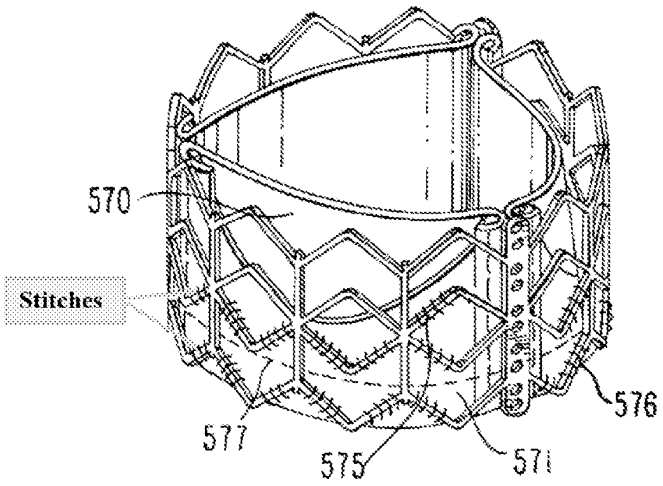
4. Stitching

175. Claim 1 next recites: "wherein the outer frame is secured to the inner graft covering by stitching." Spenser also discloses this limitation.

176. Spenser discloses that a "[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a strong sealing line." Ex. 1010 (Spenser) at 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30. Additionally, an "upper suture 578 connects the outer PET layer 571 to frame 575." *Id.* at 26:47-48.

177. Figure 44a illustrates that the top and bottom sutures secure the PET (graft covering) to the outer frame with a plurality of stitches:

FIG. 44a



Id., Fig. 44a; *see also id.*, Fig. 44b (showing sutures).

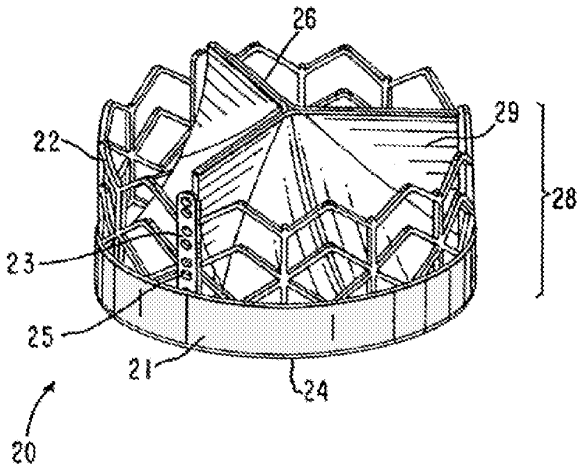
5. First Portion of Fibers

178. Claim 1 next recites: "a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic." Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

179. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.5.

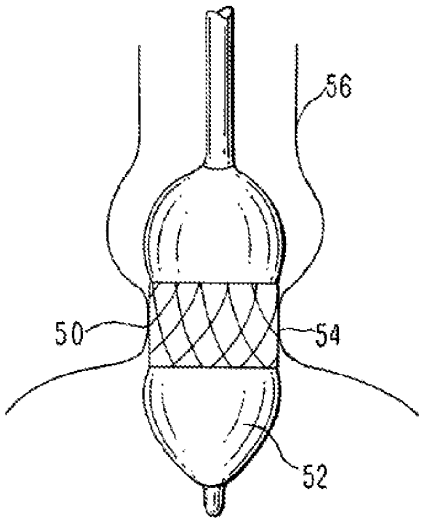
180. A person of ordinary skill would have been motivated by Walther to add an outer cloth, like Walther's outer cloth or a similar outer cloth, to Spenser's Figure 44a because Walther expressly discloses combining an outer cloth with SAPIEN, a heart valve having features similar (if not identical) to Figure 44a. Ex. 1007 (Walther) at 1120-1121. Moreover, Spenser suggests the combination by disclosing a valve similar to Figure 44a having an outer cuff portion 21 for sealing around the valve:



Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. A person of ordinary skill in the art would have had a reasonable expectation of success in combining an outer cloth with Figure 44a because Walther discloses how to combine a cloth with a similar

heart valve, provides images of the combination, and concludes that the cloth-covered valve "demonstrated excellent hydrodynamic performance." *See* Ex. 1007 (Walther) at 1125.

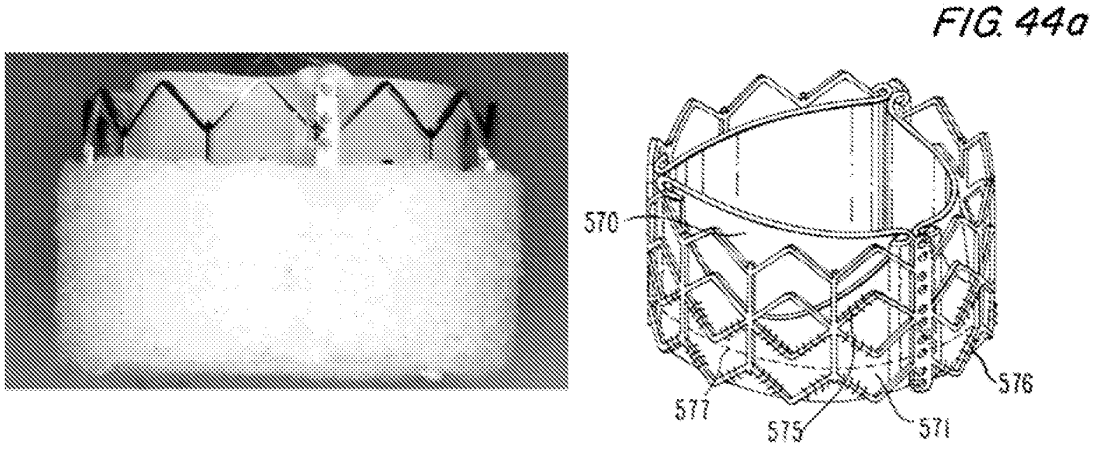
181. A person of ordinary skill in the art would have understood that when Walther's outer cloth is added to Spenser's Figure 44a, the outer cloth's radially extending fibers (i.e., first portion) would be "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst." Spenser's Figure 4 (below) shows Spenser's valve deployed "in a natural aortic valve position in accordance with the present invention":



Ex. 1010 (Spenser) at 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b. As shown in Figure 4, Spenser's valve presses against the patient's aortic annulus. Although not shown in Figure 4, persons of ordinary skill

in the art would have understood that the valve also presses against the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. *Supra* §III.B.

182. When added to Spenser's Figure 44a, Walther's outer cloth would cover at least the two proximal rows of Figure 44's outer frame, as illustrated by the comparison of Walther's Figure 1 (left) and Spenser's Figure 44a(right) below:



Compar Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1010 (Spenser) at Fig. 44a. As illustrated by Spenser's Figure 4 and understood by a person of ordinary skill in the art, expanding Figure 44a would cause at least a portion of the proximal two rows to press against the patient's annulus and native aortic leaflets. Thus, expansion of Figure 44a would press the outwardly extending fibers of Walther's outer cloth against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst.

183. A person of ordinary skill would have found it obvious to deploy Spenser's Figure 44a combined with Walther's outer cloth within a patient's native valve. Spenser discloses methods of implanting the described valves, such as Figure 44a, at the native aortic valve. *See e.g.,* Ex. 1010 (Spenser) at 5:17-6:36 (listing delivery steps). A person of ordinary skill would have been motivated to apply Walther's known technique for reducing paravalvular leakage (adding an outer cloth to a valve frame) to Spenser's known prosthetic heart valves (*e.g.,* Figure 44a) for the same reasons I provided for Walther and SAPIEN. *Supra* §VI.A.5.

184. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying Figure 44a with an outer cloth, like Walther's, in a patient's native aortic valve because Walther discloses that the cloth-covered valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." Ex. 1007 (Walther) at 1125. Additionally, Walther's cloth-covered valve was deployed within a surgical valve designed to emulate the native valve. Therefore, a person of ordinary skill in the art would have expected Walther's cloth-covered valve to function similarly in either environment. Moreover, Spenser describes endovascular implantation of its described valves, including Figure 44a, within the aortic valve and persons of ordinary skill in the art had successfully implanted SAPIEN, which is similar to

Figure 44a, within a patient's native aortic valve many times by November 2012. Ex. 1010, 2:6-12, 12:8-36, 13:26-54, 14:12-14; *see also e.g.,* Ex. 1012 at 355 ("Transcatheter valve implantation with the Edwards-Sapien® Heart Valve can be done safely and efficiently using the transfemoral retrograde approach."); Ex. 1009 at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively).

185. Additionally, claim 1 does not require endovascular delivery of the heart valve. Thus, a person of ordinary skill in the art would have understood that the size of the valve would not be an issue for delivery. *See e.g.,* Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007)) at I-244 ("With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients"). Dr. Walther recognized the size of his cloth-covered valve would not inhibit delivery during the Conference Discussion accompanying his publication stating that he hoped the valve would be available soon, "at least for the trans-apical approach, where tight crimping is not an issue." Ex. 1007 (Walther) at 1126. Therefore, a person of ordinary skill in the art would have reasonably expected success in implanting Figure 44a with Walther's cloth cover within a patient's native aortic valve.

186. I also note that during prosecution of a related patent application (U.S. Patent Application No. 17/213,251), Patent Owner suggested, without further explanation, that foreshortening could be an issue in combining an outer cloth, like Walther's, with a stent frame. Here, a person of ordinary skill in the art would not have been concerned by the combination of an outer cloth, like Walther's, with the frame in Spenser's Figure 44a because the frame in Figure 44a is almost identical to SAPIEN. Walther already establishes that Walther's outer cloth could be successfully added to SAPIEN. Additionally, by 2012, persons of ordinary skill in the art would have understood how to adjust and attach the outer cloth to a frame to account for foreshortening of the stent frame during expansion. For example, Levi describes methods of constructing and arranging the outer cloth or skirt to account for foreshortening. Ex. 1008 (Levi) at 13:32-14:14. For these reasons, any foreshortening of the stent would not have discouraged a person of ordinary skill in the art from adding an outer sealing material to a heart valve frame or led the person to believe that the combination would not be successful.

b. Spenser II

187. Spenser II discloses this limitation. Spenser II discloses that "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252":

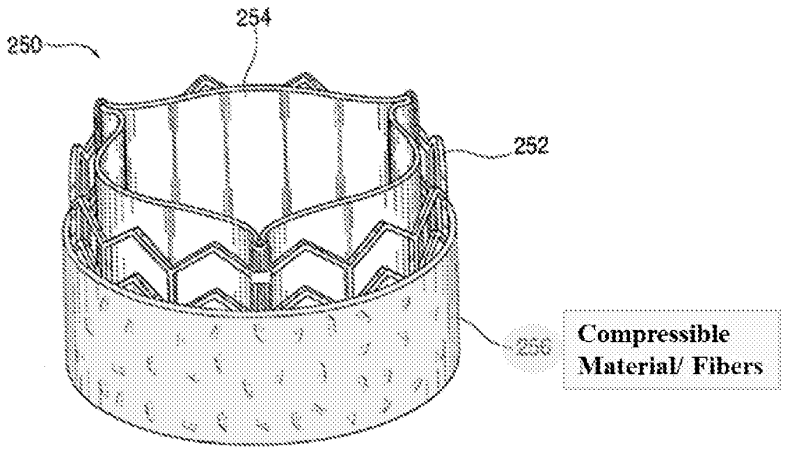


FIG. 22

Ex. 1011 (Spenser II) at [00145], Fig. 22. As shown, the compressible material is positioned externally to the outer frame. The compressible material also includes a plurality of outwardly extending fibers. Spenser II explains that the compressible material "***may resemble a cloth or fabric having small fibers extending from the surface of the material***." *Id.* (emphasis added). A person of ordinary skill in the art would have understood that the fibers extending outwardly from outward-facing surface of the compressible material are a "first portion of fibers [that] extend radially outwardly of the outer frame." Spenser II teaches that in a preferred embodiment, the compressible material is formed of PET. *Id.* PET fibers are "non-metallic." Moreover, as in the case of Walther, Spenser II does not contain any disclosure that the compressible material is made of a cloth base or outer graft and a fiber portion. Rather, Spenser II consistently describes the compressible material as a "layer" or single piece of cloth or fabric.

188. Spenser II further discloses that the compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* Therefore, a person of ordinary skill in the art would have understood that the fibers extending from the outward-facing surface of Spenser II's compressible material (i.e., first portion) are "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst." Moreover, when added to the exterior of the stent in Spenser's Figure 44a, the compressible material would cover the bottom two rows of grids formed by the stent frame. A side-by-side comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right) confirms the compressible material would cover two rows of Figure 44a:

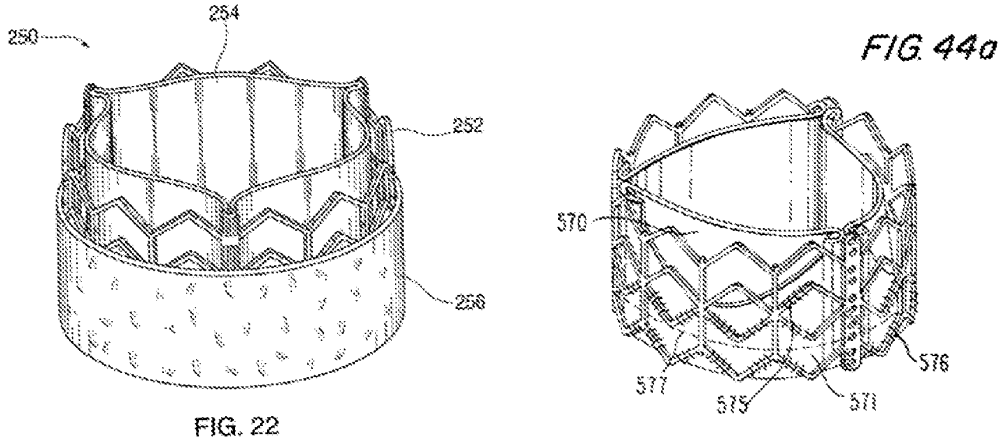


Fig. 1011 (Spenser II) at Fig. 22; Ex. 1010 (Spenser) at Fig. 44a. As I explained in the preceding section, expanding Spenser's Figure 44a within a patient's native

aortic valve would cause at least a portion of the proximal two rows of the frame to press against the native annulus and aortic leaflets. *Supra* §VII.A.5.a. Thus, expansion of Figure 44a would press the radially extending fibers of Spenser II's compressible material against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst.

189. A person of ordinary skill in the art would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a for a number of reasons. First, Spenser and Spenser II are from the same field of endeavor and share the same objective of providing a prosthetic valve suitable for transcatheter delivery. *See, e.g.*, Ex. 1010 (Spenser) at Abstract, 2:5-15; Ex. 1011 (Spenser II) at Abstract, [0001], [0011]-[0014]. Second, the references share three common inventors, and Spenser II explicitly references U.S. Publication No. 2003/0153974 (Ex. 1015), which is a parent application of Spenser. Ex. 1011 (Spenser II) at [0009]; *see also* Ex. 1010 (Spenser) at 1 (claiming priority as a continuation-in-part to application No. 09/975,750); Ex. 1015 (publication of Application No. 09/975,750) at 1.

190. Also, as I explained previously, PVL was known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. *Supra* §VI.A.5. A person of ordinary skill in the art would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a to "address leaks that can

occur around the implanted valve" and "to encourage coagulation of blood to further fill the gaps and prevent leakage," as suggested by Spenser II. Ex. 1011 (Spenser II) at [0010], [0145]. Moreover, adding the compressible material to Figure 44a would merely entail the combination of known elements (Spenser's prosthetic valve and Spenser II's fibers) according to known methods (stitching the devices together) to yield the predictable result of reducing paravalvular leakage.

191. A person of ordinary skill would have had a reasonable expectation of success in combining Spenser II's compressible material with Figure 44a because the valve assemblies in Spenser and Spenser II share many common features, including a balloon-expandable metallic stent having a gridded configuration that is configured for endovascular delivery. *See, e.g.,* Ex. 1010 (Spenser) at 2:5-15; 12:28-36, 13:26-54, 19:5-13; *see also, e.g.,* Ex. 1011 (Spenser II) at [0011]-[0015], [00144]. Moreover, Spenser already discloses valves having a sealing material positioned around the inlet, for example in Figure 1, which would have given persons of ordinary skill confidence that other sealing structures, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. Additionally, Claim 1 is not limited to endovascular delivery, so a person of ordinary skill in the art would not have foreseen any potential issues stemming

from the valve diameter. Also, a person of ordinary skill in the art would not have had any concerns about stent foreshortening for the reasons provided in the previous section. *Supra* §VII.A.5.a.

6. Second Portion of Fibers

192. Claim 1 next recites: "a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second portion of fibers is non-metallic." Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

193. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.6. A person of ordinary skill in the art would have been motivated to combine Walther's outer cloth with Spenser's Figure 44a with a reasonable expectation of success for the reasons I provided in the previous section. *Supra* §VII.A.5.a.

194. As I explained in Ground 1, Walther's outer cloth is stitched to and carried by SAPIEN's outer frame. *Supra* §VI.A.6. A person of ordinary skill in the art would have been motivated to stitch Walther's outer cloth to Figure 44a's frame in the same way because Walther describes this method of attachment, stitching is simple, and stitching would have been known to persons of ordinary

skill in the art. The combination of Walther's outer cloth with Figure 44a would therefore include a second portion of fibers carried by the outer frame. The second portion of fibers of Walther's outer cloth would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" for the reasons I provided in Ground 1. *Supra* §VI.A.6.

b. Spenser II

195. Spenser II also discloses this limitation. As I explained in the preceding section, Spenser II discloses a compressible material disposed along the exterior of an expandable valve stent that "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that a PET cloth or fabric would be constructed of a plurality of woven PET fibers. For example, Merriam-Webster defines "cloth" as "a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments." *Available at:* https://www.merriam-webster.com/dictionary/cloth. Therefore, a person of ordinary skill would have understood that the PET cloth or fabric of Spenser II's compressible material would include radially extending PET fibers on both its outward-facing surface (i.e., a first portion of fibers) and radially extending fibers on its inward-facing surface that would press against the bars of the outer frame

when disposed along the exterior thereof. A person of ordinary skill in the art would have understood that the PET fibers on the inward-facing surface of the compressible material abutting the outer frame are the "second portion of fibers" required by claim 1. A person of ordinary skill in the art would have understood that the compressible material's second portion of fibers are "carried by" the outer frame because Spenser II discloses that the compressible material "is disposed along an outer surface of the stent structure 252," as shown in Figure 22 below:

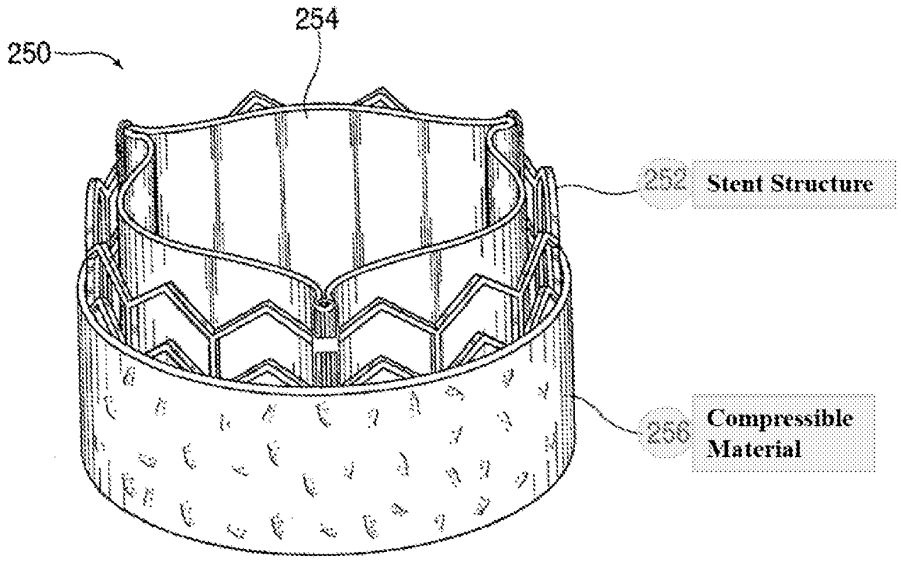


FIG. 22

Id. at [00145], Fig.22. Additionally, because the fibers are disposed along the exterior surface of the outer frame, a person of ordinary skill in the art would have understood that the woven PET fibers of the second portion are "configured to form a second sealing interface against the outer frame when . . . compressed thereagainst," as shown in Figure 22 above. *See id.* at Fig. 22.

7. First and Second Portion in Overlapping Radial Alignment

196. Claim 1 next recites: "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment." Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

197. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.7.

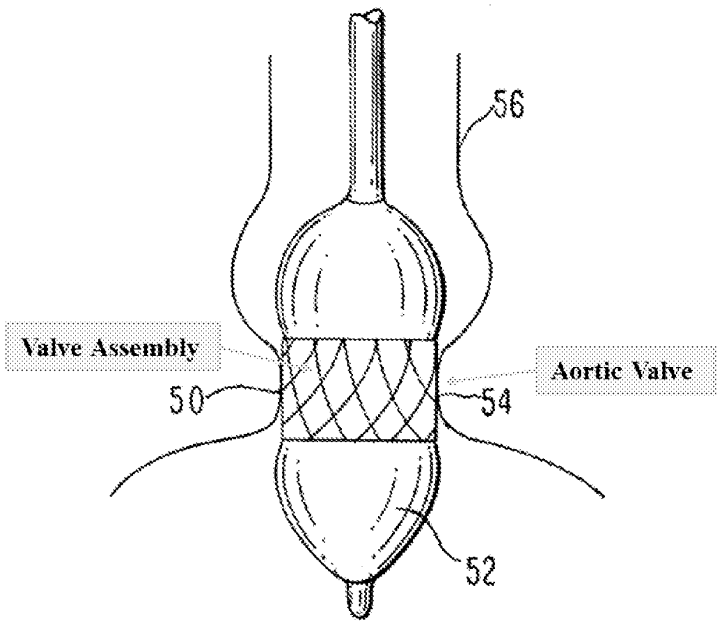
b. Spenser II

198. Spenser II also discloses this limitation. Spenser II discloses that its compressible material "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." Ex. 1011 (Spenser II) at [00145]. As I explained above, a person of ordinary skill in the art would have understood that such a PET cloth or fabric would include radially fibers extending from both its outward-facing surface (a first portion) and its inward-facing surface (a second portion). *Supra* §§VII.A.5-6. Because the two portions of fibers are part of a single PET cloth disposed along the exterior of the outer frame, a person of ordinary skill in the art would have understood that the two portions of fibers, located on opposite surfaces of the compressible material, are in overlapping radial alignment for the same reasons I discussed in Ground 1 with respect to Walther's outer cloth. *See supra* §VI.A.7.

8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets

199. Claim 1 next recites: "wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst." Spenser in combination with Walther or Spenser II renders this limitation obvious.

200. Spenser's Figure 4 (below) "depicts deployable valve deployment in a natural aortic valve position in accordance with the present invention":



Ex. 1010 (Spenser) at 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b (disclosing placement at the aortic valve). As shown in Figure 4, the valve radially overlaps with the patient's aortic annulus. *Id.* at Fig. 4.

Although not pictured in Fig. 4, a person of ordinary skill in the art would have understood that the valve also radially overlaps with the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. A person of ordinary skill in the art would have understood Figure 4 to illustrate the placement of Figure 44a because Figure 4 describes "the present invention" and Figure 44a is referred to as a "preferred embodiment of the present invention." Ex. 1010, 8:66-67, 26:30-34.

201. As I explained previously, when added to the exterior of Spenser's Figure 44a, both Walther's outer cloth and Spenser II's compressible material would cover the proximal two rows of grids formed by the frame. *Supra* §VII.A.5. As illustrated by Spenser's Figure 4 and understood by a person of ordinary skill in the art, positioning Spenser's Figure 44a across the patient's native aortic valve as taught in Spenser would cause at least a portion of the proximal two rows of the outer frame to radially overlap the patient's annulus and native aortic leaflets. Thus, the combination of Spenser's Figure 44a and Walther's outer cloth or Spenser II's compressible material results in a valve "configured to be positioned in a patient" so that the radially extending fibers of the outward-facing surface of the outer cloth/compressible material (i.e., first portion) radially overlap with the patient's native aortic leaflets to seal thereagainst.

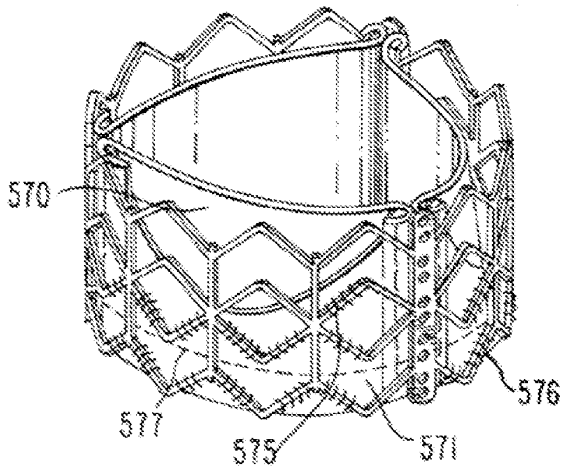
9. Free of an Outer Graft Covering Between the First Portion of Fibers and Outer Frame

202. Claim 1 next recites: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Spenser and Walther or Spenser II render this limitation obvious.

a. Walther

203. Walther's outer cloth is "free of an outer graft covering between the first portion of fibers and the outer frame" for the reasons I provided in Ground 1. *Supra* §VI.A.9. Additionally, Spenser's Figure 44a does not include any "outer graft covering" on the exterior of the outer frame 575:

FIG. 44a



Ex. 1010, Fig. 44a. As shown in Figure 44a, there is no graft covering on the exterior of the frame, and Spenser does not disclose any such material in the embodiment in Figure 44a. *See id.* at 26:30-54, Fig. 44a-c. Therefore, a person of

ordinary skill in the art would have understood that when Walther's outer cloth is added to the exterior of Figure 44a's outer frame, there would be no "outer graft covering" between the outwardly extending fibers of the outward-facing surface of the outer cloth (i.e., the first portion) and the outer frame.

204. Additionally, as I explained in Ground 1, I am aware that Patent Owner has made arguments about Walther during prosecution of a related patent application, asserting that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." Ex. 1039 (Patent Owner Amendment with RCE) at 9. Patent Owner's arguments about Walther are unsupported and incorrect for the reasons I provided previously. *Supra* §VI.A.9.

b. Spenser II

205. Spenser II's compressible material is also "free of an outer graft covering between the first portion of fibers and the outer frame." Spenser II discloses that the compressible material, which "may resemble a cloth or fabric having small fibers extending from the surface of the material," is "disposed along the outer surface" of the stent. Ex. 1011 (Spenser II) at [00145]. Spenser II does not disclose or suggest any "outer graft covering" between the radially extending fibers of the compressible material (i.e., first portion) and the stent. Therefore, a person of ordinary skill in the art would have understood that there is no such

"outer graft covering" between the fibers of the compressible material and the outer frame. Moreover, as I explained in the preceding section, Spenser's Figure 44a does not include any "outer graft covering" on the exterior of the outer frame 575. *Supra* §VII.A.9.a. Therefore, a person of ordinary skill in the art would have understood that when Spenser II's compressible material is added to the exterior of Figure 44a's outer frame, there would be no "outer graft covering" between the radially extending fibers of the compressible material (i.e., first portion) and the outer frame.

206. I am aware that in a preliminary amendment during prosecution of the '236 patent, Patent Owner argued that "Spenser [II] appears to include an outer graft covering between the fibers and the outer frame." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 196. Patent Owner provided no support or explanation for this assertion, however, and Patent Owner's argument is not supported by Spenser II's disclosure. As I explained above, Spenser II does not include any teaching or disclosure suggesting any "outer graft covering" between the fibers of the compressible material and the outer frame. *See* Ex. 1011 (Spenser II) at [00145]. On the contrary, Spenser II describes the compressible material as a single PET cloth or fabric that is disposed along the exterior of the stent. *See id.* Therefore, a person of ordinary skill in the art would have understood that there is

no "outer graft covering" between the fibers of Spenser II's compressible material and the outer frame.

10. Radially Compressed Orientation and Radially Expanded Orientation

207. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Spenser, Walther, and Spenser II all disclose this limitation.

208. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.10. Spenser teaches that its prosthetic valve "has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation]." Ex. 1010 (Spenser) at 27:67-28:2. A person of ordinary skill in the art would have understood that Spenser's 4 mm diameter corresponds to the valve's compressed orientation and the 25 mm diameter corresponds to the valve's expanded orientation. Spenser II discloses a stented valve that comprises "an expandable stent structure" that may be "adapted for radial expansion using a balloon catheter." Ex. 1011 (Spenser II) at [00144]. A person of ordinary skill in the art would have understood that a balloon expandable stent structure, as disclosed in Spenser II, would include a radially compressed and a radially expanded configuration. Indeed, by definition, a balloon expandable stent is capable of being expanded from a narrower, compressed orientation to an expanded orientation by inflation of the balloon.

11. Balloon Expandable

209. Claim 1 next recites: "wherein the valve assembly is balloon expandable to the radially expanded orientation." Spenser in combination with Walther or Spenser II renders this limitation obvious.

210. Spenser discloses that the valve assembly depicted in Figure 44a "resembles the valve shown in Fig. 43." Ex. 1010 (Spenser) at 26:34-35. The valve shown in Figure 43 may be "inflated by a balloon . . . [such that] the frame is expanded to the full diameter." *Id.* at 26:19-22; *see also id.* at 12:4-8, 14:10-14, 17:19-18:43 (balloon-expandable assemblies). A person of ordinary skill in the art would therefore have understood that Figure 44a is balloon expandable. A person of ordinary skill in the art would have further understood that Figure 44a would remain balloon expandable after adding either Walther's outer PET cloth or Spenser II's outer compressible material, as both references explicitly disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. *See* Ex. 1007 (Walther) at 1122 (cloth-covered SAPIEN was balloon-expandable); Ex. 1011 (Spenser II) at [00144] (valve "adapted for radial expansion using a balloon catheter").

12. Compress Fibers to Form a Sealing Interface

211. Claim 1 concludes by reciting: "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second

portion of fibers to form the respective first sealing interface and second sealing interface." Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

212. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.12. Walther's outer cloth would behave in the same way if it were added to Figure 44a because Figure 44a and SAPIEN are similar, if not identical. Therefore, when Walther's outer cloth is added to Spenser's Figure 44a, expansion of the valve within a patient's native aortic valve would be configured to (1) compress the outwardly extending fibers on the outward-facing surface of the compressible material (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and (2) compress the PET fibers on the inward-facing surface of the compressible material (i.e., second portion) against Figure 44a's outer frame to form a second sealing interface.

b. Spenser II

213. Spenser II also discloses this limitation. Spenser II teaches that the compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that the

compressible material "creates a mechanical seal" (i.e., sealing interface) by (1) compressing the radially extending fibers of the compressible material (i.e., first portion) against the patient's annulus and native leaflets and (2) compressing the woven PET fibers of the inward-facing surface (i.e., second portion) against the stent's outer frame. Similar to Walther, these two sealing interfaces would work cooperatively to seal around the exterior of the valve and reduce paravalvular leakage. For example, the first sealing interface prevents blood from leaking between the outward-facing surface of the compressible material and the native tissue of the patient's aortic valve. The second sealing interface prevents blood from leaking between the inward-facing surface of the compressible material and the exterior of the outer stent frame.

B. Claim 2

214. Claim 2 recites: "The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." Spenser discloses the limitations in claim 2 and, in combination with Walther or Spenser II, renders claim 2 obvious.

215. Spenser discloses that a "[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a

strong sealing line." Ex. 1010 (Spenser) 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30. Figures 44a and 44b illustrate that PET 571 (i.e., inner graft covering) extends to the proximal inflow end of the outer frame, and that bottom sutures 576 extend between PET 571 and through the outer frame to secure PET 571 to the proximal inflow end of the outer frame:

FIG. 44a

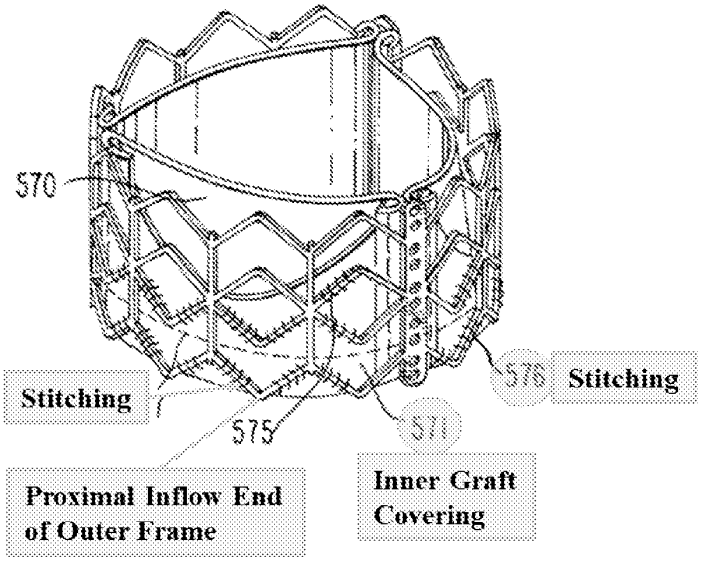
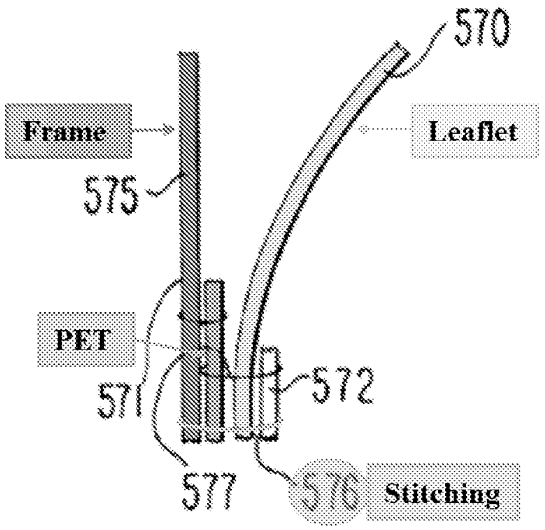


FIG. 44b



Id., Figs. 44a, 44b.

C. Claim 3

216. Claim 3 recites: "The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." Spenser in combination with Walther or Spenser II renders this claim obvious.

1. Walther

217. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.C.

2. Spenser II

218. Spenser II also discloses this limitation or renders it obvious. Spenser II discloses that the compressible material "may resemble a cloth or fabric having

small fibers extending from the surface of the material." Ex. 1011 (Spenser II) [00145]. A person of ordinary skill in the art would have understood that the radially extending fibers would extend from various different locations along the material and would thus have understood that the compressible material would include openings between the radially extending fibers formed by spacing between the adjacent fibers. Indeed, a person of ordinary skill in the art would have understood that such "openings" would exist in any cloth or fabric material with radially extending fibers such as Spenser II's compressible material. *Supra* §VI.C. A person of ordinary skill in the art would have further understood that the openings define a plurality of "opening[s] extending through a thickness" of the radially extending fibers for the same reasons I explained previously with respect to Walther. *Id.*

219. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of outwardly extending fibers such that even larger openings existed between the fibers. *Supra* §III.D. The exchange of Spenser II's compressible material for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the

crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.,* Ex. 1007 (Walther) at 1120-1121.

D. Claim 4

220. Claim 4 recites: "The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame." Spenser in combination with Walther or Spenser II renders this claim obvious.

1. Walther

221. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.D.

2. Spenser II

222. Spenser II also discloses this limitation. As I explained in claim 1, a person of ordinary skill in the art would have understood that Spenser II's compressible material, which may be a PET cloth or fabric, includes a plurality of

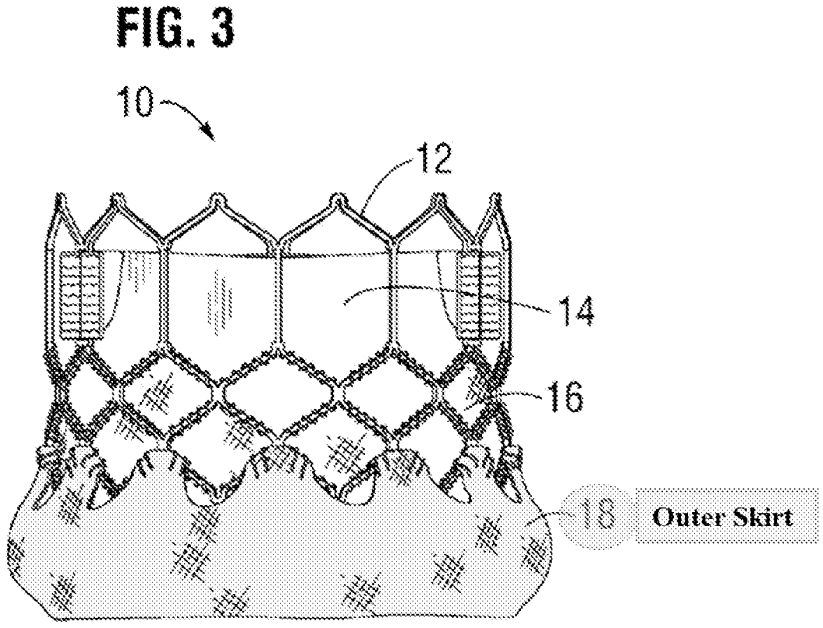
PET fibers on the inward-facing surface of the compressible material that define a "second portion of fibers." *Supra* §VII.A.6.b. A person of ordinary skill in the art would have further understood that any woven fabric, including Spenser II's PET cloth/fabric, would include at least some gaps between the interwoven fibers of the fabric. *See supra* §VI.C; *see also e.g.*, Ex. 1008 (Levi) 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). A person of ordinary skill in the art would therefore have understood that openings exist between the PET fibers of the second portion of Spenser II's compressible material which define "opening[s] extending through a thickness" of the second portion. Similar to Walther's outer cloth, the fibers of Spenser II's fabric/cloth would be sufficiently dense to prevent blood from leaking through the cloth/fabric, but loose enough to include small openings between the adjacent fibers. A person of ordinary skill in the art would have further understood that at least some of these openings extend to the outer frame because the compressible material is disposed along the exterior of the outer frame, and the fibers of the inward-facing surface of the compressible material (i.e., second portion) directly abut and are compressed against the outer frame.

223. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of fibers such that even larger

openings existed between the fibers. *Supra* §III.D. The exchange of Spenser II's compressible material for a less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.,* Ex. 1007 (Walther) at 1120-1121.

VIII. GROUNDS 4-7: CLAIMS 1-4 ANTICIPATED OR OBVIOUS IN VIEW OF LEVI ALONE OR WITH WALTHER OR SPENSER II

224. Levi discloses a prosthetic heart valve assembly having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame, as shown in Figure 3 below:



Ex. 1008 (Levi) at 13:50-53, 13:62-66, Fig. 3. As I explain in detail below, Levi's outer skirt of woven PET fabric is a sealing material that includes a first and second portion of fibers, as required by the claims of the '236 patent. Therefore, based on my review of the prior art, I believe Levi discloses or suggests every limitation of claims 1-4 and anticipates or renders the claims obvious.

225. However, even if Levi does not disclose or suggest a first and second portion of fibers, Walther and Spenser II do, as I explained previously. I believe that a person of ordinary skill in the art would have found it obvious to combine Levi with Walther or Spenser II for the reasons I provide in detail below. In fact, Levi expressly discloses methods of adapting the outer frame to accommodate sealing materials, like the sealing materials in Walther and Spenser II. Ex. 1008

(Levi) at 14:26-35. Therefore, I believe that Levi in combination with Walther or Spenser II renders obvious claims 1-4.

A. Claim 1

226. Based on my review of the prior art, it is my opinion that Levi anticipates claim 1 or renders it obvious alone or in combination with Walther or Spenser II.

1. Preamble

227. The preamble of claim 1 recites: "A transcatheter aortic valve assembly comprising."

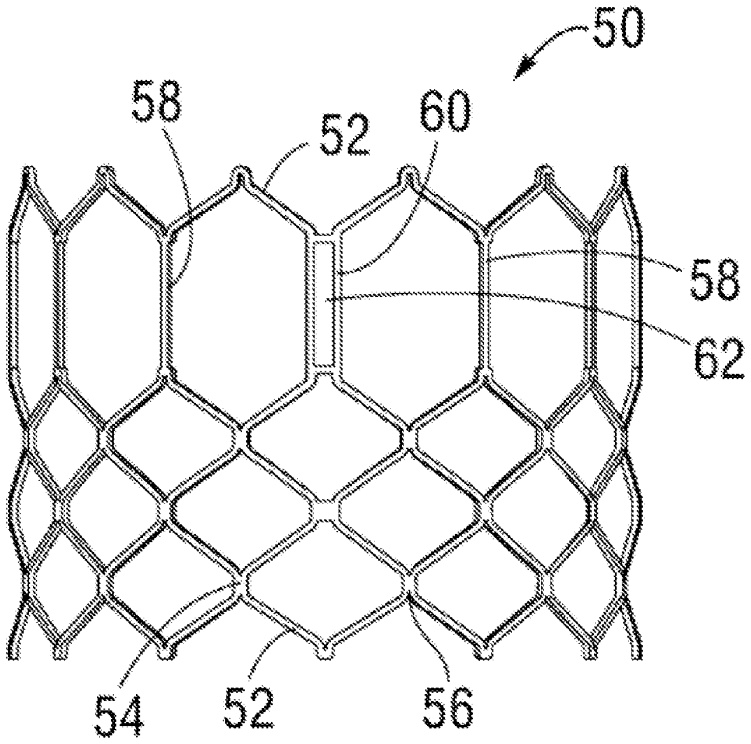
228. Levi discloses a "transcatheter aortic valve assembly." Levi discloses "embodiments of a prosthetic heart valve, and delivery systems for implanting heart valves." Ex. 1008, 1:16-17. Levi teaches that its valve is "adapted to be implanted in the native aortic annulus." *Id.* at 5:53-54. Levi further discloses that due to known "drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches" were developed in which "collapsible transcatheter heart valves . . . can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent." *Id.*, 1:57-67.

2. Outer Frame

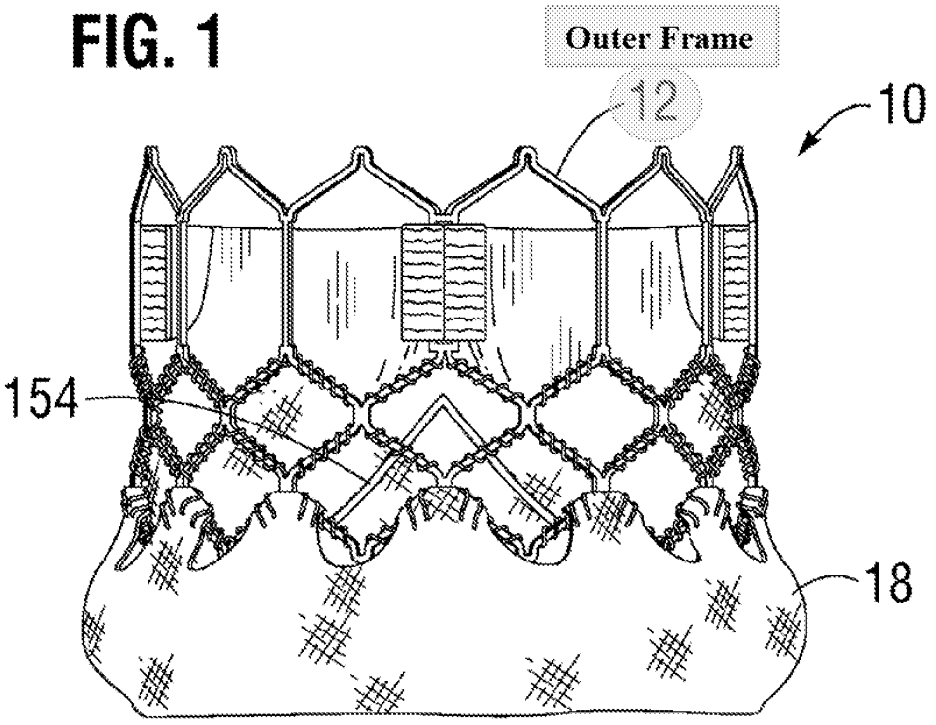
229. Claim 1 next recites: "an outer frame formed from a metallic material." Levi also discloses this limitation.

230. Levi discloses an expandable frame formed from metal (e.g., stainless steel) as shown in Figure 11 below:

FIG. 11



Ex. 1008 (Levi) at 6:17-24, Fig. 11. As shown in Figure 42 below, the frame 12 surrounds the other components of the valve and is thus an "outer frame":



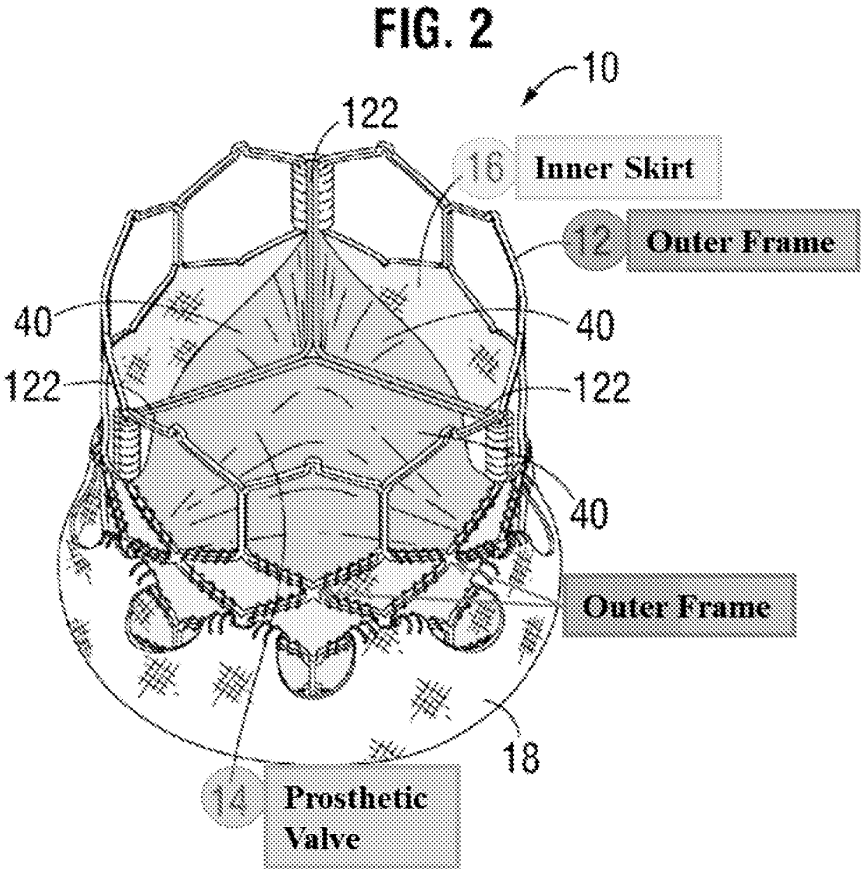
Id. at Fig. 42.

3. Inner Frame

231. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Levi also discloses this limitation.

232. Levi discloses an "inner skirt 16 … to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through

the open cells of frame 12 below the lower edge of the leaflets." Ex. 1008 (Levi) at 9:7-11. The inner PET skirt therefore provides sealing to the heart valve. The inner skirt is constructed of "a tough, tear resistant material such as polyethylene terephthalate (PET)." *Id.* at 9:11-16. PET is a type of polyester and also a polymer and is a "polymeric…graft covering." The inner skirt is engaged to the valvular structure "via one or more thin PET reinforcing strips. *Id.* At 9:25-29. The "valvular structure 14 can comprise three leaflets 40, collectively forming a leaflet structure." *Id.* at 5:59-62, Fig. 2. The three leaflets of the valvular structure are "prosthetic leaflets." Levi's inner skirt 16 [yellow] is cylindrically extending and extends radially outwardly of prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red] as illustrated in Figure 2 below:



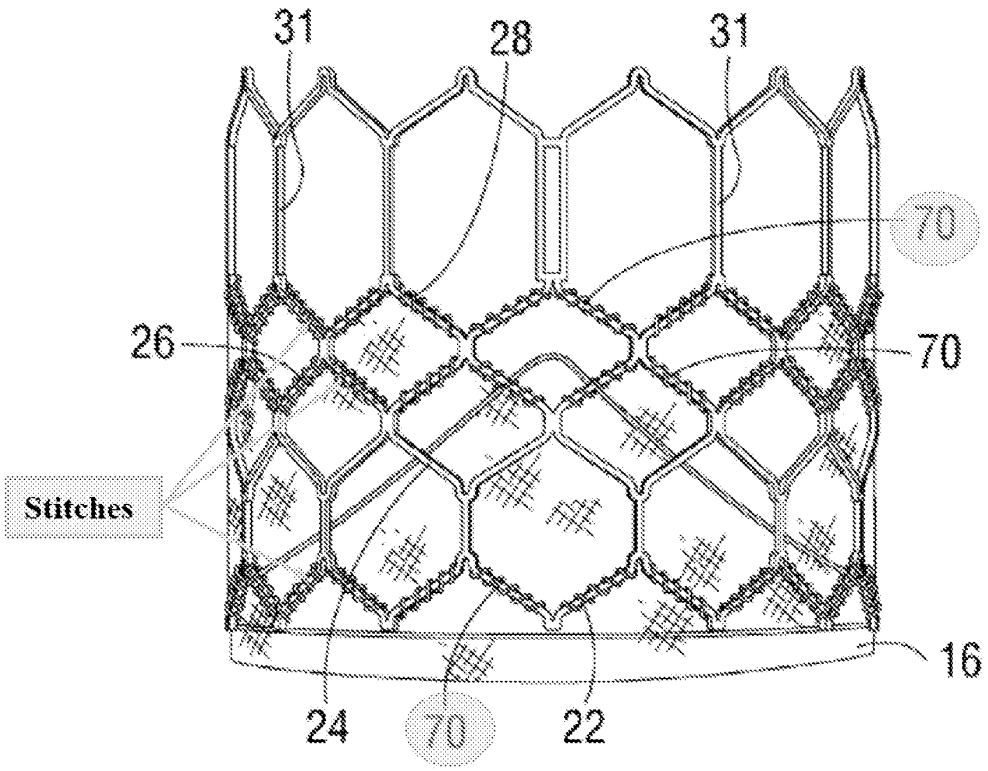
Id. at Fig. 2. Therefore, based on Patent Owner's statements during prosecution, and if a graft covering can be an inner frame, Levi's inner skirt satisfies this limitation. In fact, during prosecution, Patent Owner admitted that Levi includes an inner seal. Ex. 1002 ('236 Patent Prosecution History Excerpt) at 186.

4. Stitching

233. Claim 1 next recites: "wherein the outer frame is secured to the inner graft covering by stitching." Levi also discloses this limitation.

234. Levi's inner skirt 16 is secured to the frame 12 via a plurality of sutures 70 at the top and bottom of the skirt, as shown in Figure 20 below:

FIG. 20



Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39.

5. First Portion of Fibers

235. Claim 1 next recites: "a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend

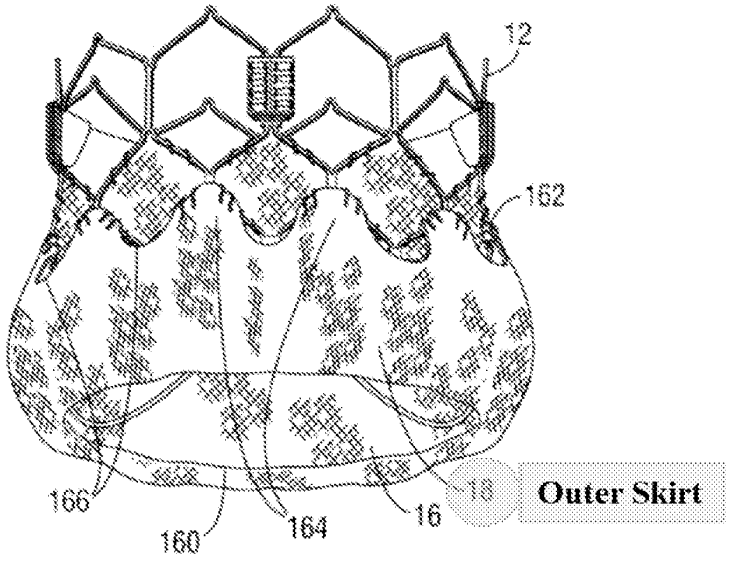
radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic." Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

a. Levi

236. Levi discloses this limitation or renders it obvious.

237. Levi discloses this limitation in two ways. Levi discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame. Ex. 1008 (Levi) at 13:50-53, 13:62-66. The outer skirt is thus positioned radially outwardly of the outer frame. Levi teaches that the outer skirt is constructed with excess material that "does not lie flat against the outer surface of the frame 12," but bulges radially outwardly as the frame expands and foreshortens. *Id.* at 13:62-14:2. The excess material allows the outer skirt to "fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." *Id.* at 14:3-7. The bulging outer skirt [yellow] is shown in Figure 3 below:

FIG. 42



Id. at Fig. 42. A person of ordinary skill in the art would have understood that the PET fibers, which are non-metallic, form Levi's outer skirt constitute a "first portion" of fibers. *See id* at 9:52-56, 13:62-14:2. As shown in Figure 3 above, the outer skirt "does not lie flat against," but "bulge[s] outwardly" from the outer frame. Therefore, the plurality of woven PET fibers that make up Levi's outer skirt (i.e., first portion) "extend radially outwardly from the outer frame." Additionally, the skirt "fill gaps" in the surrounding tissue and becomes folded or pinched by the tissue in those locations causing the fibers to extend radially outwardly of the outer frame. *Id.* at 14:3-7.

238. Alternatively, a person of ordinary skill in the art would have understood that the outer surface of the woven PET fabric of Levi's outer skirt would not be entirely smooth, but would necessarily have fibers, or strands, that extend radially outwardly from the surface of the fabric. A person of ordinary skill in the art would have known that textile polyester yarn, such as PET yarn, exhibits a property known as "hairiness," which describes the "amount and length of fibre ends and loops protruding from the body of the yarn." Ex. 1028 (Tyagi) at 124. The hairiness of yarn can be influenced by a number of factors, and a person of ordinary skill in the art would have understood that polyester fabrics, such as PET, would exhibit at least some level of hairiness. *See id.*; *see also* Ex. 1029 (Kothari) at 32 (disclosing that 100% polyester yarn included between 50 and 150 hairs per meter). Therefore, even if the woven PET fabric of the outer skirt does not itself constitute a "first portion of fibers," a person of ordinary skill would have nonetheless understood that Levi's outer skirt includes a "first portion of fibers" extending radially outwardly from the surface of the outer skirt.

239. As I noted above, Levi teaches that the outer skirt is constructed with excess material that "does not lie flat against the outer surface of the frame 12," but bulges radially outwardly as the frame expands and foreshortens. *Id.* at 13:62-14:2. The excess material allows the outer skirt to "fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal

between the valve and the native annulus." *Id.* at 14:3-7. A person of ordinary skill in the art would have understood that when the outer skirt "form[s] a good fluid-tight seal between the valve and the native annulus," the fibers of the outer skirt would also seal against the native aortic leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.B. Indeed, during prosecution, Patent Owner admitted that Levi's outer skirt would "extend[] into crevices created by the native leaflets." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 194. Therefore, Levi's outer skirt (i.e., first portion of fibers) is "configured to form a first sealing interface against the annulus and native valve leaflets of the patient" when the outer skirt is pressed thereagainst.

b. Walther

240. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.5.

241. It is my opinion that a person of ordinary skill in the art would have found it obvious to replace Levi's bulging outer PET skirt with Walther's outer cloth. A person of ordinary skill would have been motivated by Walther's disclosure that its outer cloth prevents paravalvular leakage, increases the fit between the implanted prosthetic valve and the existing valve, and promotes tissue ingrowth. *See* Ex. 1007 (Walther) at 1120. Moreover, the combination of Walther's outer cloth and Levi would merely entail substitution of one known

element (Walther's outer cloth) for another (Levi's bulging PET) to yield the predictable results of reducing paravalvular leakage.

242. The field of heart valves had a finite number of options to address paravalvular leakage in November 2012. Walther and Levi disclose two such methods. A person of ordinary skill would have found it obvious to select either of these finite, predictable options and, as I explain below, would have had a reasonable expectation of success in doing so.

243. A person of ordinary skill would have had a reasonable expectation of success in substituting Walther's outer cloth (or a similar cloth) for Levi's PET skirt. Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that *in vivo* implantation of the valve "is feasible." Ex. 1007 (Walther) at 1125. Claim 1 does not require endovascular delivery so a person of ordinary skill in the art would not have expected the size of the valve to impact deliverability. *See e.g.,* Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007)) at I-244 ("With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients").

244. Moreover, Levi suggests adding other components, like Walther's outer cloth, to its valve by disclosing that the inflow portion of the outer frame has a narrower crimped diameter so that "if ***additional components*** are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component." Ex. 1008 (Levi) at 16:41-45 (emphasis added). A person of ordinary skill would have understood that Walther's outer cloth would be a potential "additional component."

245. Levi additionally discloses several other features that minimize the crimped profile of the valve to accommodate a fibrous outer sealing material. Levi teaches that the configuration of its outer frame enables a "reduction in the frame wall thickness to achieve a smaller crimped diameter of the valve." *Id.* at 7:10-12. Levi's outer frame is also formed with relatively larger open cells in the uppermost row, which allow portions of the prosthetic leaflets to protrude from the frame when the valve is crimped, again reducing the minimum crimped profile of the valve. *Id.* at 7:36-42, 15:17-24. The frame may also be formed with a "thickness that varies along its length to optimize strength where needed, yet minimize material (and therefore crimp profile) at selected regions of the frame," such as the inflow end that is covered by the outer skirt. *Id.* at 16:54-17:18. The frame may also include window frame portions which are depressed radially

inwardly relative to the other portions of the frame, which also minimizes the crimp profile of the valve. *Id.* at 14:40-45. The shape of Levi's prosthetic leaflets also minimize the valve's profile. Levi teaches that the leaflets may be tapered or "V-shaped" instead of the traditional "U-shaped leaflets." *Id.* at 14:26-30, 16:24-40. The tapered shape of the leaflets results in less leaflet material at the inflow end of the valve, which further minimizes the crimped profile of the inflow end that is covered by the outer skirt or some other "additional component." *Id.* Even Levi's inner skirt is designed to help minimize the crimp profile. Levi teaches that its skirt is woven with fibers that are non-perpendicular to the upper and lower edges of the skirt, which enables the skirt to undergo greater axial elongation when the valve is crimped, resulting in a more uniform crimping profile and a smaller crimped diameter. *Id.* at 9:36-11:2. A person of ordinary skill in the art would have found it obvious to use any or all of Levi's methods to minimize the crimped profile of the valve, which would enable addition of a fibrous outer seal without disadvantageously increasing the valve's crimped profile.

246. Additionally, the valve frames in Walther and Levi share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. *See supra* §VI.A.2,11, VIII.A.2. Further, Walther discloses that the cloth-covered SAPIEN valves

displayed "excellent hydrodynamic performance" and that in-patient implantation of the valve "is feasible," suggesting that other cloth-covered valves would achieve similar success. Ex. 1007 (Walther) at 1125. For all of these reasons, a person of ordinary skill would have reasonably expected success in using Walther's outer cloth on Levi's valve.

c. Spenser II

247. Spenser II discloses this limitation for the reasons I provided in Grounds 2-3. *Supra* §VII.A.5.b.

248. In my opinion, a person of ordinary skill in the art would have found it obvious to replace Levi's bulging outer PET skirt with Spenser II's compressible material. A person of ordinary skill would have been motivated by Spenser II's teachings that its radially extending fibers reduce or prevent paravalvular leakage and "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." Ex. 1011 (Spenser II) at [00145]. In addition, the combination of Spenser II's compressible material and Levi would merely entail substitution of one known element (Levi's bulging PET) for another (compressible material) to yield the predictable results of reducing paravalvular leakage.

249. Moreover, as I discussed in the prior section, the field of heart valves had a finite number of options to address paravalvular leakage in November 2012.

Supra §VIII.A.5.b. Spenser II and Levi disclose two such ways. A person of ordinary skill would have found it obvious to select either of these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in doing so. Spenser II's compressible material may "encourage coagulation of blood," which would have motivated a person of ordinary skill in the art to try replacing Levi's PET skirt with Spenser II's compressible material. Ex. 1011 (Spenser II) at [0055].

250. A person of ordinary skill would have had a reasonable expectation of success in substituting Spenser II's compressible material for Levi's outer skirt. The stent frames in Levi and Spenser II have many similar features, including being metallic and balloon-expandable. *Supra* §§VII.11, VIII.A.2. Moreover, Levi and Spenser II are from the same field of endeavor and share the same objective of providing a prosthetic valve suitable for minimally invasive procedures. *See, e.g.*, Ex. 1008, Abstract, 2:1-7; Ex. 1011 (Spenser II) at Ex. 1008, 1:57-67, 6:46-49. Further, the references specifically relate to prosthetic heart valves developed by Edwards. Levi and Spenser II also share a common inventor (Benichou). *See* Ex. 1008 (Levi) at 1; Ex. 1011 (Spenser II) at 1. A person of ordinary skill in the art would therefore have found it obvious to combine the features among these closely tied references. Additionally, claim 1 does not require endovascular delivery so a person of ordinary skill in the art

would not have expected the size of the valve to impact deliverability. *See e.g.,* Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007)) at I-244 ("With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients").

251. Moreover, Levi suggests mounting "***additional components***" to Levi's valve. Ex. 1008 (Levi) at 16:41-45 (emphasis added.) A person of ordinary skill in the art would have understood that Spenser II's compressible material would be a potential "additional component." Moreover, as I explained in the preceding section, Levi discloses several features of its valve that enable the addition of an additional fibrous component on the exterior of the valve without disadvantageously increasing the valve's minimum crimped diameter. *Supra* §VIII.A.5.b. For all of these reasons, a person of ordinary skill in the art would have reasonably expected success in using Spenser II's compressible material on Levi's valve.

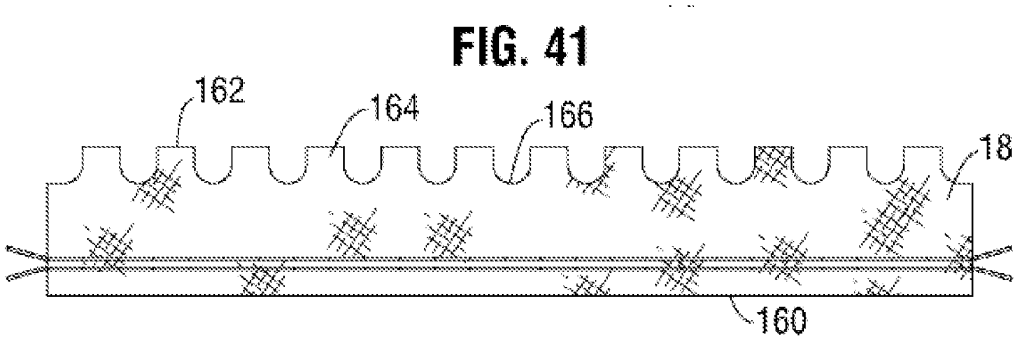
6. <u>Second Portion of Fibers</u>

252. Claim 1 next recites: "a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second

portion of fibers is non-metallic." Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

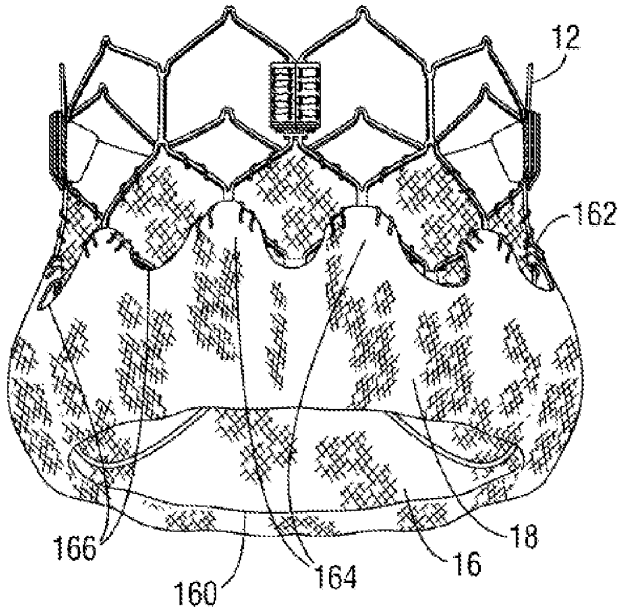
a. Levi

253. Levi discloses this limitation in two ways. First, as I explained previously, Levi discloses an inner skirt of woven PET fabric secured to the interior surface of the outer frame. *Supra* §VIII.A.5.a. Levi's outer skirt includes "an upper edge 162 defining a plurality of alternating projections 164 and notches 166" shown in Figure 41 below:



Ex. 1008 (Levi) at 13:53-55, Fig. 41. Levi further teaches that "[a]s shown in Figure 43, each projection 164 can be sutured to the second rung II of struts 24 of the frame 12." *Id.*, at 13:58-59. Levi also explains that "[t]he corners 162 of the projections 164 can be folded over the respective struts of rung II and secured with sutures 168." *Id.*, 13:60-61. Figure 42 of Levi shows the projections folded over the struts and secured with sutures:

FIG. 42



Id. at Fig. 42.

254. The non-metallic fibers that comprise the corners 162 that are wrapped around the struts and reside on the interior of the frame are the "second portion of fibers" required by claim 1. As shown in Figure 42, the corners are sutured to and "carried by" the outer frame. *Id.* Likewise, the corners are configured to "form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst." As the outer skirt bulges outward, the outer skirt pulls upon the corners and compresses the fibers forming the corners against the outer frame. This compression creates a sealing interface between the corners of the outer skirt and frame. By wrapping the corners around the struts before they are sutured, the outer skirt is attached more securely to the

outer frame. Thus, the compression between Levi's second portion and the outer frame also helps create the sealing interface between the outer skirt and the patient's native tissue by holding the skirt against the frame.

255. Alternatively, a person of ordinary skill in the art would have understood that Levi's outer skirt would include small fibers extending from its surface due to the hairiness of the fabric. *Supra* §VIII.A.5.a. A person of ordinary skill in the art would have understood that these small fibers would extend both from the outward-facing surface of outer skirt, and the inward-facing surface of the skirt. As I explained previously, the outer skirt is "carried by" the frame and forms a seal between the valve and native tissue. *Supra* §VIII.A.5.a. When the valve is expanded to form the seal against the native tissue, the interior surface of the outer skirt presses against and is compressed against the outer frame. The small fibers extending from the interior surface of the outer skirt therefore "form a second sealing surface against the outer frame when the second portion of fibers is compressed thereagainst."

b. Walther and Spenser II

256. Alternatively, Walther and Spenser II disclose this limitation as for the reasons I provided in Grounds 1-3. *Supra* §§VI.A.6, VII.A.6.b. A person of ordinary skill in the art would have been motivated to combine Walther's outer cloth or Spenser II's compressible material with Levi's valve with a reasonable

expectation of success for the reasons I provided in the previous section. *Supra* §VIII.A.5.

257. Levi's outer skirt is stitched to and carried by Levi's outer frame. *Supra* §VIII.A.6.a. A person of ordinary skill in the art would have been motivated to stitch Walther's outer cloth or Spenser II's compressible material to Levi's frame because Levi describes this method of attachment and stitching is simple and would have been known to persons of ordinary skill. The combination of Walther's outer cloth or Spenser II's compressible material with Levi's valve would therefore include a second portion of fibers "carried by" the outer frame. The second portion of fibers of Walther's outer cloth or Spenser II's compressible material would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" for the same reasons I provided in Grounds 1-3. *Supra* §§VI.A.6, VII.A.6.

7. <u>First and Second Portion in Overlapping Radial Alignment</u>

258. Claim 1 next recites: "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment." Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

259. Levi discloses this limitation in two ways. First, as described above, the fibers that comprise the corners are wrapped around the struts and oppose the fibers in the rest of the outer skirt. *Supra* §VIII.A.6.a. Thus, the fibers in the

corners and the outer skirt are in overlapping radial alignment. Alternatively, the small fibers extending from the outward-facing and inward-facing surfaces of the outer skirt are in overlapping radial alignment with each other because they are located on opposite sides of the outer skirt and are both part of the same PET fabric. *See supra* §VI.A.7.

260. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.A.7, VII.A.7.

8. First Sealing Interface in Overlapping Radial Alignment with Leaflets

261. Claim 1 next recites: "wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst." Levi discloses this limitation and renders it obvious in combination with Walther or Spenser II.

262. Levi's valve "is adapted to be implanted in the native aortic annulus" and, when the frame is expanded, the outer skirt will "fill gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." Ex. 1008 (Levi) at 5:52-54, 14:3-7. A person of ordinary skill in the art would have understood that to "fill in gaps between the frame 12 and the surrounding native annulus," the fibers of the outer skirt (i.e., first portion) would be positioned in radially overlapping alignment with

the patient's native valve leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.B.

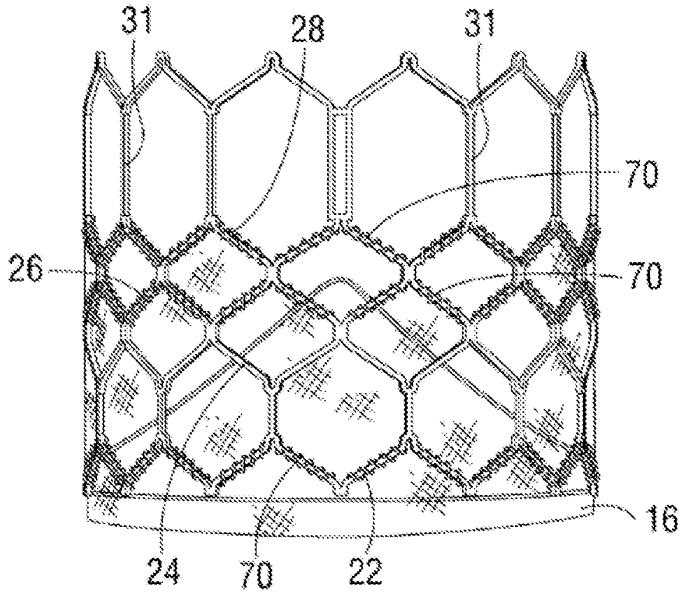
263. Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's compressible material, a person of ordinary skill in the art would have understood that the fibers of the outer cloth/compressible material, rather than the outer skirt, would be positioned to radially overlap with the patient's native leaflets.

9. Free of an Outer Graft Covering

264. Claim 1 next recites: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Levi discloses this limitation and renders it obvious in combination with Walther or Spenser II.

265. Levi's valve is free of an "outer graft covering" between the fibers of the outer skirt and the outer frame. Levi teaches that the outer skirt is sutured to the exterior of the outer frame. Ex. 1008 (Levi) 13:58-61. Levi does not include any "outer graft covering" on the exterior of the outer frame, as shown in Figure 20 below, which illustrates the valve without the outer skirt attached:

FIG. 20



Id. at Fig. 20. Therefore, a person of ordinary skill in the art would have understood that when the outer skirt is stitched to the exterior of the outer frame, there would be no "outer graft covering" between the fibers of the outer skirt (i.e., first portion) and the outer frame.

266. Alternatively, Levi in combination with Walther or Spenser II render this limitation obvious. A person of ordinary skill in the art would have understood that when Levi's outer skirt is replaced with Walther's outer cloth or Spenser II's compressible material, there would be no "outer graft covering" between the radially extending fibers of the outer cloth/compressible material (i.e.,

first portion) and the outer frame because Levi does not include any "outer graft covering" on the exterior of the outer frame.

10. Radially Compressed Orientation and Radially Expanded Orientation

267. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Levi, Walther, and Spenser II all disclose this limitation.

268. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.8. Spenser II discloses this limitation for the reasons I provided in Grounds 3-4. *Supra* §VII.A.8. Levi teaches that "[w]hen constructed of a plastically-expandable material, the frame 12 (and thus the valve 10) ***can be crimped to a radially compressed*** state on a delivery catheter and then ***expanded*** inside a patient by an inflatable balloon or equivalent expansion mechanism." Ex. 1008 (Levi) at 6:20-24 (emphasis added).

11. Balloon Expandable

269. Claim 1 next recites: "wherein the valve assembly is balloon expandable to the radially expanded orientation." Levi discloses this limitation or renders it obvious in combination with Walther or Spenser II.

270. Levi discloses that "the frame 12 (and thus the valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon." Ex. 1008 (Levi) at 6:17-28. Thus, a

person of ordinary skill in the art would have understood that Levi's valve is balloon expandable.

271. Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's outer compressible material, a person of ordinary skill in the art would have understood that the resulting valve would remain balloon expandable because both Walther and Spenser II disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. *See* Ex. 1007 (Walther) at 1122; Ex. 1011 (Spenser II) at [00144].

12. Compress Fibers to Form a Sealing Interface

272. Claim 1 concludes by reciting: "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface." Levi discloses this limitation or renders it obvious alone or in combination with Walther or Spenser II.

273. Levi discloses that its outer skirt (i.e., first portion of fibers) "fill gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." Ex. 1008 (Levi) at 14:3-7. A person of ordinary skill in the art would have understood that Levi's valve "form[s] a good fluid-tight seal" by compressing the fibers of the outer skirt against the patient's annulus and native valve leaflets to form a sealing interface

thereagainst. Also as I explained previously, the second portion of fibers of the outer skirt's corners, which are wrapped around the struts of the frame, are pulled against and form a seal with the outer frame when the valve is expanded. *Supra* §VIII.A.6.a.

274. Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. *Supra* §§VI.A.12, VII.A.12. Therefore, when Walther's outer cloth or Spenser II's compressible material is added to Levi's valve, expansion of the valve within a patient's native aortic valve would be configured to (1) compress the outwardly extending fibers of the outward-facing surface of the outer cloth/compressible material (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and (2) compress the PET fibers of the inward-facing surface (i.e., second portion) against the valve's outer frame to form a second sealing interface.

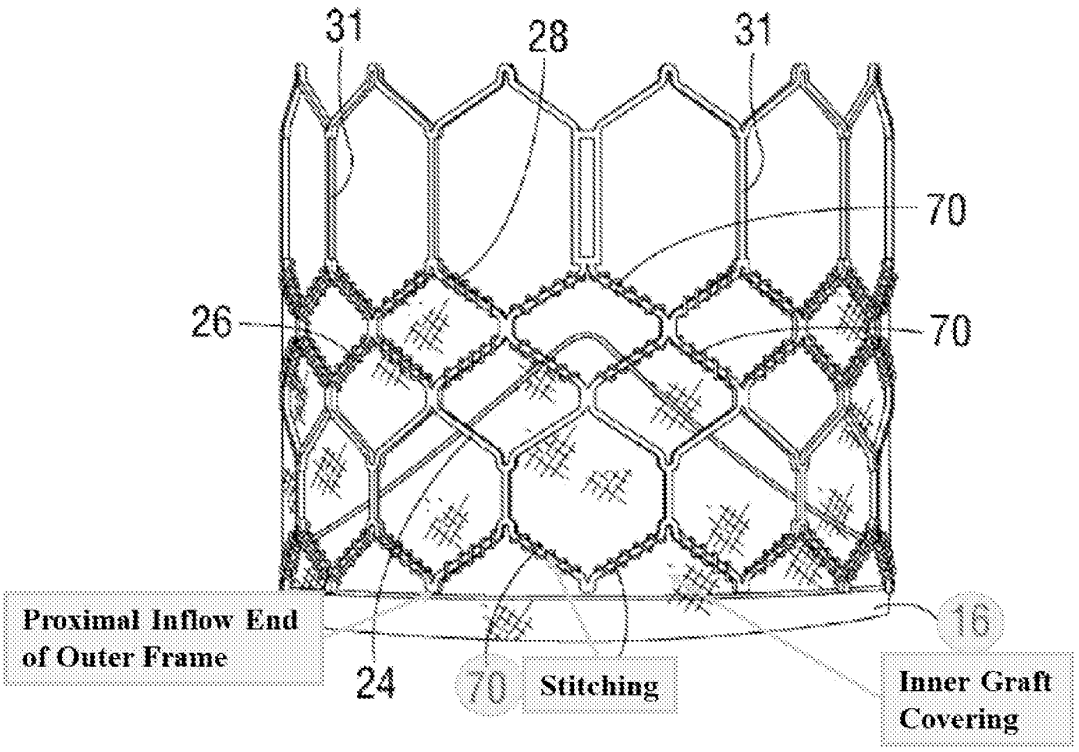
B. Claim 2

275. Claim 2 recites: "The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." Levi discloses the limitations in claim 2. And based on claim 1,

Levi anticipates claim 2 or renders it obvious alone or in combination with Walther or Spenser II.

276. Levi's inner skirt (i.e., inner graft covering) extends to the proximal inflow end of the outer frame, as shown in Figure 20 below:

FIG. 20



Ex. 1008 (Levi) at Fig. 20. As shown in the figure above, a plurality of sutures 70 extend between the inner skirt and through the outer frame, securing the inner skirt to the proximal inflow end of the outer frame. *See id.*

C. Claim 3

277. Claim 3 recites: "The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." Levi discloses the limitations in claim 3 and anticipates claim 3 or renders claim 3 obvious alone or in combination with Walther or Spenser II.

278. Levi's outer skirt (i.e., first portion of fibers) may be constructed of "woven PET" fabric. Ex. 1008 (Levi) at 13:50-53. A person of ordinary skill in the art would have understood that woven PET fabric, including Levi's outer skirt, would include openings between the interwoven fibers of the fabric. *See, e.g., id.* at 10:48-57 (discussing spacing between the woven fibers of the inner PET skirt). A person of ordinary skill in the art would therefore have understood that openings existed between the woven PET fibers of the Levi's outer skirt which define "opening[s] extending through a thickness" of the outer skirt.

279. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable PET fabrics having varying thicknesses and densities and could have selected a fabric with a lower density of woven fibers such that even larger openings existed between the fibers. *See id.* at 10:48-57. A person of ordinary skill in the art would have been motivated to do so to facilitate further axial elongation of the outer skirt as the valve is expanded to provide a more

uniform and predictable crimping profile. *Id.* at 10:35-57 (explaining that "the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction" which helps ensure a uniform crimped profile). Additionally, the exchange of Levi's outer skirt for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.,* Ex. 1007 (Walther) at 1120-1121.

280. Alternatively, a person of ordinary skill in the art would have understood that small fibers would extend from the outer surface of the outer skirt as I explained above. *Supra* §VIII.A.5.a. A person of ordinary skill in the art would have understood that the small fibers would occur at spaced intervals, thereby defining openings between the small fibers, similar to the openings between the fibers of Walther's outer cloth discussed in Ground 1. *Supra* §VI.C.

These openings would extend through a thickness of the small fibers extending from the surface of the outer skirt.

281. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.C, VII.C.

D. Claim 4

282. Claim 4 recites: Claim 4 recites: "The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame." Levi discloses the limitations in claim 3 and anticipates claim 3 or renders claim 3 obvious alone or in combination with Walther or Spenser II.

283. Just as Levi's outer skirt (first portion of fibers) would have defined openings between the adjacent woven fibers, the corners of the outer skirt (second portion of fibers), which are made from the same PET and carried by the frame, would define an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers. Likewise, the fibers extending from the inwardly-facing surface of the outer skirt would also define such openings for the same reasons as the small fibers extending from the outwardly-facing surface. At least some of these openings would extend to the outer frame because the second

portion of fibers in the outer skirt directly abuts, and is compressed against, the outer frame when the valve is expanded.

284. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable PET fabrics having varying thicknesses and densities and could have selected a fabric with a lower density of woven fibers such that even larger openings existed between the fibers. *See id.* at 10:48-57. A person of ordinary skill in the art would have been motivated to do so to facilitate further axial elongation of the outer skirt as the valve is expanded to provide a more uniform and predictable crimping profile. *Id.* at 10:35-57 (explaining that "the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction" which helps ensure a uniform crimped profile). Additionally, the exchange of Levi's outer skirt for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths

could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

285. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.D, VII.D.

IX. SECONDARY CONSIDERATIONS

286. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '236 patent. For example, I am not aware of any products sold by Patent Owner that would be covered by the '236 patent and, therefore, I am not aware of any commercial success.

287. Further, given that the devices claimed in the '236 patent are not new, and were invented long before November 2012, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

X. CONCLUSION

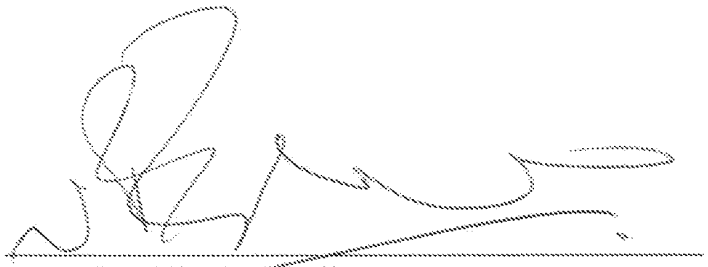
288. For the foregoing reasons, it is my opinion that claims 1-4 of the '236 patent are anticipated and/or rendered obvious by the prior art discussed above in

view of the knowledge of one of ordinary skill in the art at the time of the alleged invention.

289. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Patent Owner may raise, as well as new information, including, but not limited to, any claim constructions advanced by Patent Owner or adopted by the Board in the Institution Decision, and respond to any alleged secondary considerations as they become available to me.

290. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: February 4th 2022.



Dr. Nigel P. Buller

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC
Petitioners,

v.

AORTIC INNOVATIONS, LLC
Patent Owner.

IPR2022-00549
Patent No. 11,129,735

DECLARATION OF NIGEL BULLER, M.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,129,735

Edwards v. Aortic Innovations
U.S. Patent 11,129,735
Edwards Ex. 1003

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Exhibit No.	Description
1001	U.S. Patent No. 11,129,735 B2 ("**'735 patent**")
1002	Excerpts from the prosecution history of the '735 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) ("**Walther**")
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. ("**Levi**")
1009	Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. ("**Spenser**")
1011	WO 2006/005015 A2 to Spenser et al. ("**Spenser II**")
1012	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009) ("**Cribier**")
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.

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1016	Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010) ("Alkashkari")
1017	Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020	Yuksel, Uygar, *Balloon-Expandable Transcatheter Aortic Valve Implantation,* Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) ("Walther II")
1022	Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) ("Zajarias")
1025	Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al. ("Spenser Parent")

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Exhibit No.	Description
1027	Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., *Yarn structure and properties from different spinning techniques*, ("Tyagi")
1029	Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
1030	Cribier, Alain, et al., *Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis,* 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation,* edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)
1034	Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.

Exhibit No.	Description
1036	Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems,* Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., *In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry,* EuroIntervention 15:1240-1247 (2020)
1042	Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010)
1043	Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan,* General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations,* J. Endovasc. Ther. 14:347-351 (2007)
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. ("**Cribier '321**")
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020
1047	Piazza, Nicolo, et al., *Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve*, Cir Cardiovascular Intervention 1:74-81 (2008).

Exhibit No.	Description
1048	WO 2011/051043 A1 to Essinger et al.
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD
1060	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (November 2011), obtained from the University of California Los Angeles Library
1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
1063	Library of Congress subject heading sh85099890
1064	Library of Congress subject heading sh85023143

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1065	Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009), obtained from the British Library
1067	Herz MARC Record from the British Library
1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD

I, Dr. Nigel Buller, M.D., do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, "Edwards" or "Petitioner") to provide my opinion regarding the patentability of claims 1-9, 11-12 of U.S. Patent No. 11,129,735 ("the '735 patent"). For the reasons discussed herein, I have concluded that claims 1-9 and 11-12 of the '735 patent are unpatentable because the prior art references render them obvious.

2. I understand that this Declaration supports Edwards' Petition for the above-captioned *inter partes* review ("IPR") of the '735 patent. I have reviewed the Petition and agree with the unpatentability arguments contained therein.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any expert declaration(s) submitted on behalf of the owner of the '735 patent, Aortic Innovations, LLC ("Aortic Innovations" or "Patent Owner").

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation

in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is included as Exhibit 1004.

6. I am a retired Consultant Cardiologist. Until January of 2008, I was Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham and the Lead Clinician for the Cardiac Catheterization Laboratories. The Cardiology Department at the Queen Elizabeth is one of the leading cardiology departments in the UK and one of only five centers in the UK that provides fully comprehensive adult cardiological services including interventional cardiology, electrophysiology, grown-up congenital heart disease and heart transplantation. I have conducted or directly supervised more than 8000 diagnostic and therapeutic non-surgical catheterization procedures since I was first appointed to a National Health Service consultant post in 1990.

7. During my medical training, I was awarded The John Mellanby Scholarship to fund an Intercalated Bachelor of Science degree. In 1977, I received a BSc (First Class Honours) in Physiology from the University of London. Modules included muscle physiology and biophysics at University College London (UCL), for which my tutor was the late Professor Andrew Huxley

FRS, and neurophysiology at the Sherrington School of Physiology, for which my tutor was Professor John Stephens.

8. Following my degree, I was awarded an MRC Training Fellowship to continue my research at UCL and submit a PhD thesis. However, I declined the offer and continued my clinical medical training. Nevertheless, during the three years of undergraduate clinical training I continued my research work in my spare time and, before qualifying in medicine, I had published some of the results of my research in both Nature and The Journal of Physiology. In 1980, I was awarded MB BS by St. Thomas's Hospital Medical School, University of London. In 1983, I became a member and, in 1996, I was elected a Fellow of the Royal College of Physicians in London.

9. I have held a number of positions within highly regarded cardiology departments in the UK.

10. From 1995 to 2010, I was Honoree Senior Lecturer in cardiovascular medicine at the University of Birmingham (UK).

11. From 1995 to 2008, I was employed full time at Queen Elizabeth Hospital, Birmingham.

12. From 1991 to 1995, I was Senior Lecturer in the Department of Interventional Cardiology and Cardiac Medicine at the National Heart and Lung

Institute in London, and Honorary Consultant Cardiologist at the Royal Brompton National Heart and Lung Hospital.

13. Before that, I was a Senior Registrar in Cardiology at Harefield Hospital, Middlesex, and the Royal Free Hospital, London and prior to that a Registrar at the National Heart Hospital, London.

14. From 1984 to 1986, I worked for Smith Kline & French Research Ltd, Philadelphia, USA, as a Research Physician and then as a project Chairman in Cardiovascular Drug Development.

15. My first formal postgraduate training in cardiology was at St. Thomas's Hospital and The Middlesex Hospital in 1981 and 1982, respectively.

16. During my years as a junior doctor I trained in all aspects of cardiology but my interest developed in cardiac catheterization and non-surgical interventional cardiology. My mentor was the late Dr. Anthony Rickards who had performed the first successful coronary artery angioplasty in the UK in 1980. By 1990, I was considered fully trained in catheterization techniques and interventional cardiology including angioplasty and valvuloplasty.

17. In 1990, I was appointed to and, in March 1991, I took up the position of Senior Lecturer in Interventional Cardiology at the National Heart and Lung Institute in London and was the third consultant interventional cardiologist to join

Dr. Anthony Rickards and Dr. Ulrich Sigwart at the Royal Brompton National Heart and Lung Hospital, London.

18. I have routinely assessed and investigated patients suffering from valvular heart disease. Such investigations typically include electrocardiogram (ECG), chest X-ray (CXR) and echocardiography (a sonar examination to obtain detailed anatomical images and functional assessment of the heart and heart valves). These three tests are non-invasive and typically provide confirmation of the clinical diagnosis and allow selection of those patients that require further invasive investigation by means of diagnostic catheterization of the heart (passing flexible tubes through the veins and/or arteries and into the chambers of the heart) for hemodynamic (pressure and flow) measurements and angiography (injection of a radiopaque contrast media into the chambers and blood vessels of the heart so as further to document detailed anatomical and functional information on X-ray imaging). With this information it is then usually possible to determine the cause, the severity and the options for treatment of a patients' heart valve disease.

19. My research interests have included the prevention, diagnosis and treatment of heart disease and the development and clinical application of stents and especially coronary artery stents. I have been an investigator for many national and international scientific clinical trials.

20. My earliest "hands on" clinical involvement with stent implantation was in 1987 when working with the late Dr. Anthony Rickards when I assisted him with the first insertions of stents into human coronary arteries in the UK. Stents were difficult to obtain at the time and initially were only for use in situations of acute or threatened closure after balloon angioplasty. This early work was experimental in nature. I have since conducted large numbers of stenting implantation procedures with stents made by many different manufacturers. During 1991 to 1993, I was an investigator for the Benestent Trial (the major international multicenter "proof of concept" trial designed to demonstrate the benefit of elective stent placement over simple balloon angioplasty in the treatment of coronary artery disease), the results of which were subsequently published in the New England Journal of Medicine in 1994.

21. In 1993, Ulrich Sigwart and I were the co-investigators for the "First-in-Man" study of Guidant Corporation's "Multilink Stent" that subsequently became the long standing market leader for bare metal stents.

22. In 1994, I implanted the first drug coated stent in a patient in the UK. In the same year I was approved by the U.S. Food and Drug Administration (FDA) to act as a proctor to supervise and oversee the first elective implantations of coronary artery stents in the U.S. (an FDA requirement) following the FDA

approval of the Johnson & Johnson Palmaz-Schatz coronary artery stent. In this latter role I worked at more than fifty of the leading U.S. cardiology departments.

23. In 2013, I received hands-on training on the use and implantation of transcatheter heart valve ("THV") technology at the New York Presbyterian Hospital.

24. Throughout my career I have had a close working relationship with the research and development departments in the medical device and pharmaceutical industries. I have served on the advisory boards for many of the major medical device manufacturers, including SCIMED, Boston Scientific, Medtronic, Cordis and Guidant/Abbott.

C. Topics of Opinions

25. I offer opinions in this Declaration on the following general topics:

- The subject matter described and claimed in the '735 patent;
- The level of ordinary skill in the art pertaining to the '735 patent;
- The teachings of the prior art; and
- Whether claims 1-9 and 11-12 of the '735 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

26. I also provide background information on medical products and devices, including devices for replacing and repairing heart valves.

D. Materials Considered

27. In preparing this Declaration, I have considered the materials referenced in this Declaration and identified in the attached list of exhibits.

28. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '735 patent.

II. APPLICABLE LEGAL STANDARDS

29. I am a medical doctor by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training and technical knowledge and experience to the evaluation of certain prior art with respect to the '735 patent.

30. Although I have been previously involved as a technical expert in patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of patent law applicable in this matter, which I have used in arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

31. In determining whether a patent claim is unpatentable in view of the prior art, the Patent Office construes the claim by giving the claim its ordinary and customary (i.e., plain and ordinary) meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification and

prosecution history. For the purposes of my analysis and opinions, and to the extent necessary, I have construed each claim term in accordance with its ordinary and customary meaning under the required standard.

B. Anticipation

32. I have been instructed that a claim is "anticipated" if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention.

33. I understand that an element is "inherent in," and therefore taught by, the prior art, if it necessarily flows from the explicit disclosure of the prior art. The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed.

C. Obviousness

34. I have been instructed that a claim is "obvious" if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. An obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject

matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

35. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e., appropriate) prior art if it falls within the field of the inventor's endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

36. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '735 patent, e.g., minimally invasive devices for treating heart valves. The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic regurgitation or stenosis through a minimally invasive procedure.

37. To assess the differences between prior art and the claimed subject matter, I have been instructed that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems

as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

38. I am also informed that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include:

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

39. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

40. I have also been informed that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

41. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a

teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence that would suggest that claims 1-9 and 11-12 of the '735 patent would have been non-obvious, as further explained in Section X below.

D. Person of Ordinary Skill in the Art

42. It is my understanding that when interpreting the claims of the '735 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the '735 patent is November 7, 2012. However, my opinions would not change if the relevant priority date were December 6, 2011 (the earliest filing date identified on the face of the '735 patent). I have been informed that all of the references relied upon in this Declaration qualify as prior art under either priority date.

43. I am informed that the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. This is a person of ordinary creativity, not an automaton.

44. I am informed that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and

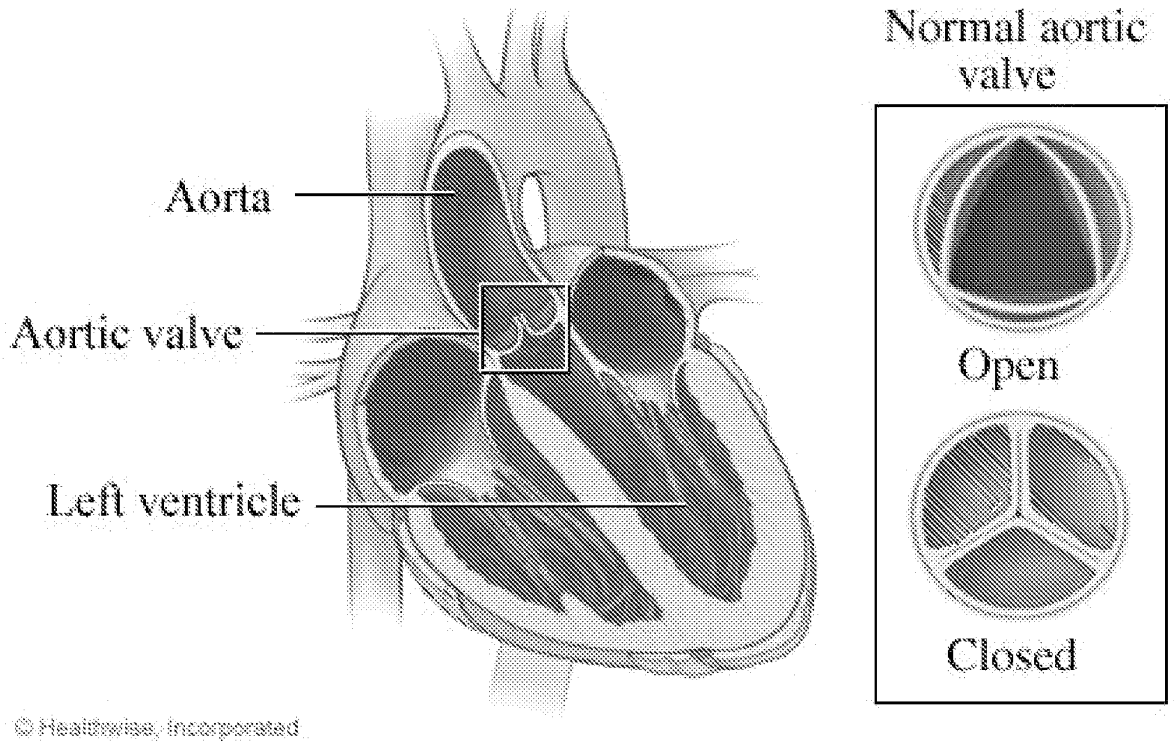
(v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

45. Based on my review of the specification and claims of the '735 patent, it is my opinion that a person of ordinary skill in the art would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This person of ordinary skill in the art would, where necessary, work as a team in combination with a medical device engineer to experiment with or manufacture a prosthetic heart valve.

III. BACKGROUND OF HEART VALVE TECHNOLOGY

A. Anatomy of the Heart and Background of Aortic Stenosis and Regurgitation

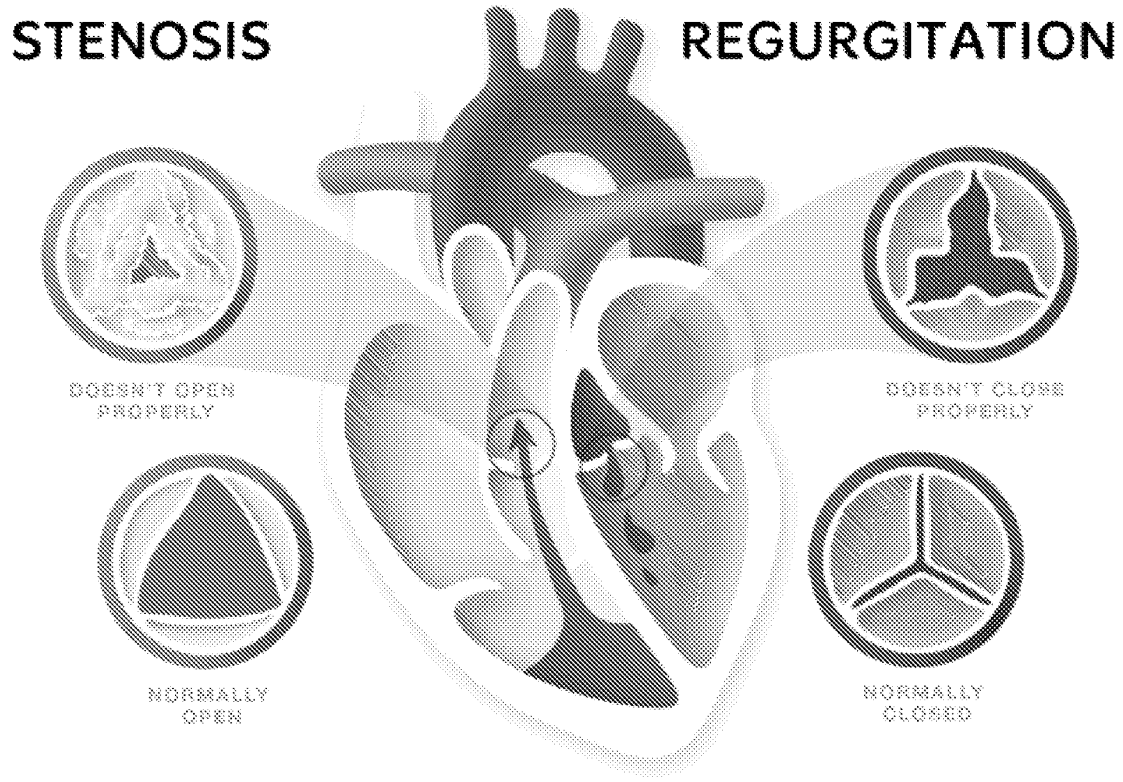
46. The human heart has two upper chambers, known as the left and right atriums, and two lower chambers, known as the left and right ventricles. The aortic valve connects the left ventricle with the aorta, the major artery that carries oxygenated blood from the heart to the rest of the body, on the left side of the heart. The aortic valve includes three leaflets that coapt and expand to operate as a one-way valve which regulates blood flow from the left ventricle into the aorta and prevents backflow of blood from the aorta to the left ventricle.



Available at: https://www.uofmhealth.org/conditions-treatments/aortic-valve-disease.

47. Aortic stenosis is a medical condition that occurs when the opening of the aortic valve is narrowed, often by excessive buildup of calcium deposits on the valve. This condition restricts the flow of blood through the aortic valve, which can have severe health consequences for the patient. Aortic regurgitation is another medical condition that occurs when the aortic leaflets fail to coapt properly, allowing blood to flow backward from the aorta into the left ventricle. Both aortic stenosis and regurgitation can cause the left ventricle to work harder to

pump the necessary amount of blood. Untreated, this can lead to cardiomyopathy (thickening of the heart muscle), irregular heartbeat, and even heart failure.



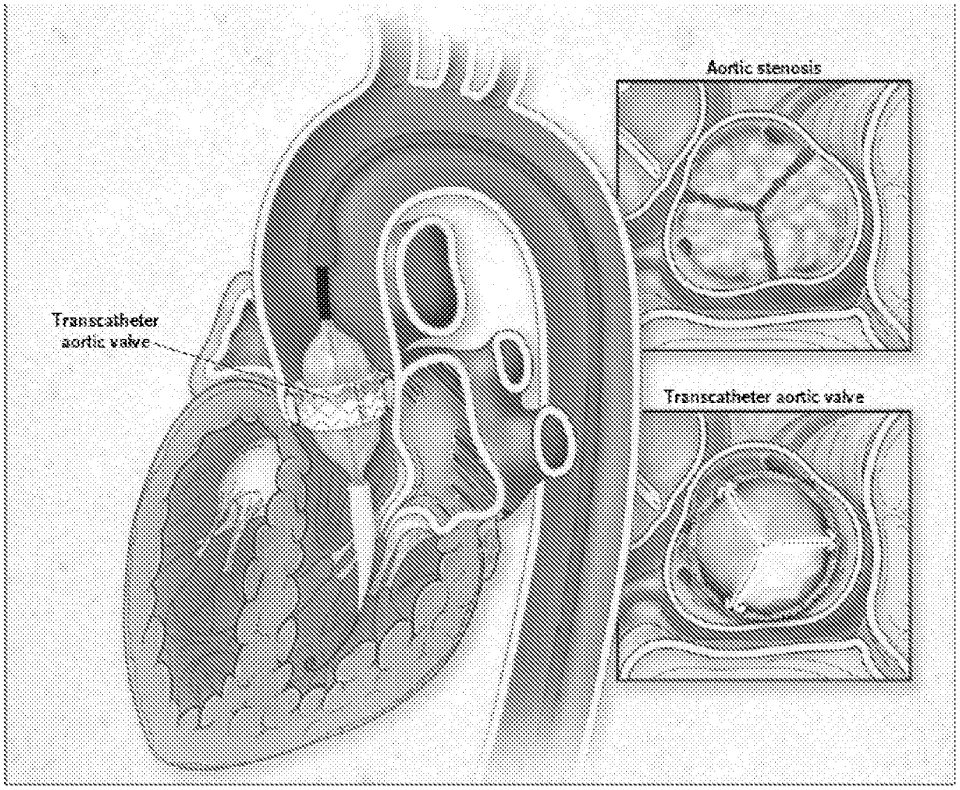
Available at https://www.heartfoundation.org.nz/your-heart/heart-conditions/heart-valve-disease. Although the above image illustrates stenosis and regurgitation on different heart valves, persons of ordinary skill in the art would understand that both conditions can occur on the aortic valve.

48. A common treatment for both aortic stenosis and aortic regurgitation is replacement of the diseased native aortic valve with a prosthetic heart valve. The prosthetic valve takes the place of the diseased native leaflets, and acts to

regulate blood flow in a similar manner as a healthy native aortic valve. One of the key considerations for prosthetic aortic valves is ensuring an effective seal is created between the valve and the patient's native aortic tissue. Without such a seal, blood can leak between the prosthetic valve and the native tissue, causing potentially harmful paravalvular leakage ("PVL").[1] Untreated PVL can lead to the same undesirable health conditions as aortic stenosis and regurgitation. Early prosthetic valves addressed PVL with sewing rings that were attached to the native tissue by sutures. However, implanting these valves required invasive open-heart surgery, limiting the availability of the valves for severely ill patients. *Infra* §III.C.

49. To avoid the risks of open-heart surgery, minimally invasive transcatheter heart valves ("THVs") were developed that could be implanted through the patient's vasculature via a catheter. *Infra* §III.D. Rather than sewing rings, which required open-heart surgery and suturing the ring to the native tissue, THVs created a seal by pressing the exterior of the THV against the diseased native leaflets and surrounding tissue, as shown in the illustration of Petitioner's SAPIEN THV below:

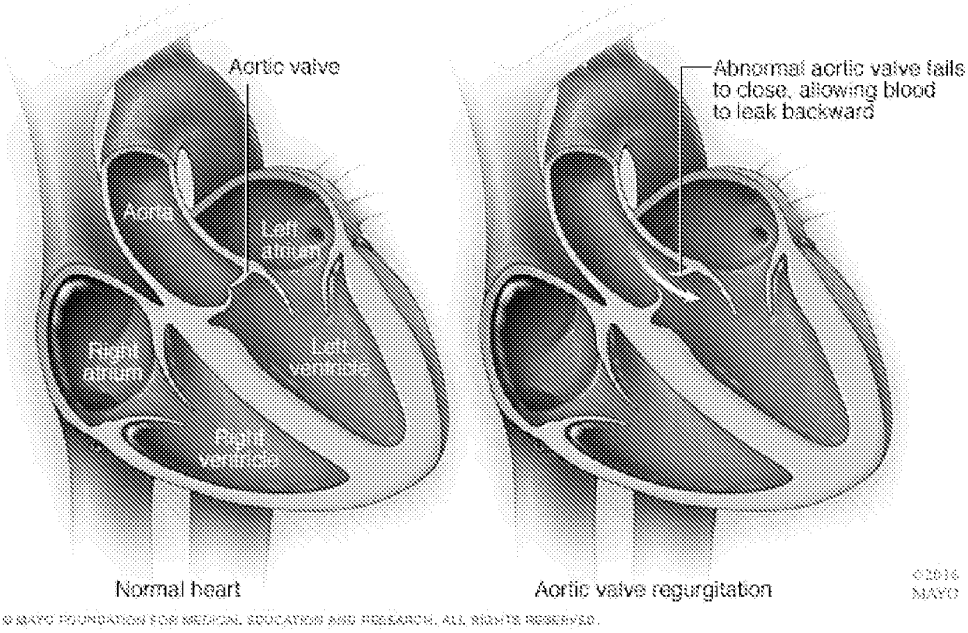
[1] "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



Ex. 1022 (Smith) at 2189, Fig. 1. Due to their minimally invasive implantation, THVs could be implanted in severely ill patients not eligible for open heart surgery, and they quickly became highly successful. Despite their success, however, the potential for PVL remained a major concern with THVs. As I discuss in detail below, this concern motivated those in the art, including Petitioner, to develop methods for minimizing PVL by creating more effective seals.

B. Anatomy of the Aortic Valve

50. As I noted in the prior section, the aortic valve lies between the left ventrical and the aorta. As shown below, the aortic valve leaflets extend distally (to use the terminology in the '735 patent) towards the aorta.



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Available at: https://www.mayoclinic.org/diseases-conditions/aortic-valve-disease/symptoms-causes/syc-20355117#dialogId16413996.

51. The claims of the '735 patent state that "the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient." *See e.g.*, Ex. 1001 ('735 patent) at claim 1. As described below, persons of ordinary skill in the art would have understood that if the fibers press against the annulus of the aortic valve, they must also press against the leaflets.

52. The '735 patent identifies the annulus (identified by item #210) as the point where the aortic valve leaflets attach to the left ventricle:

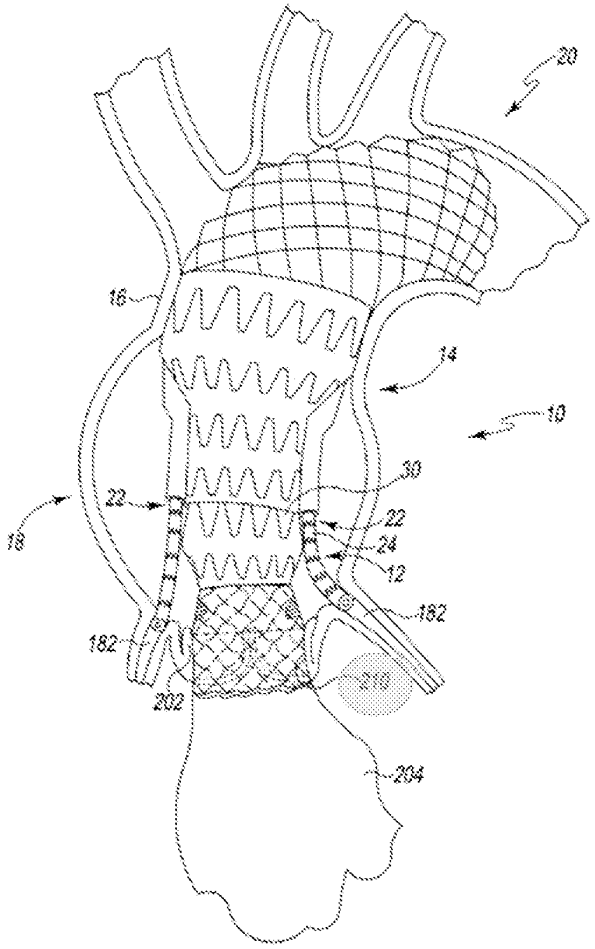
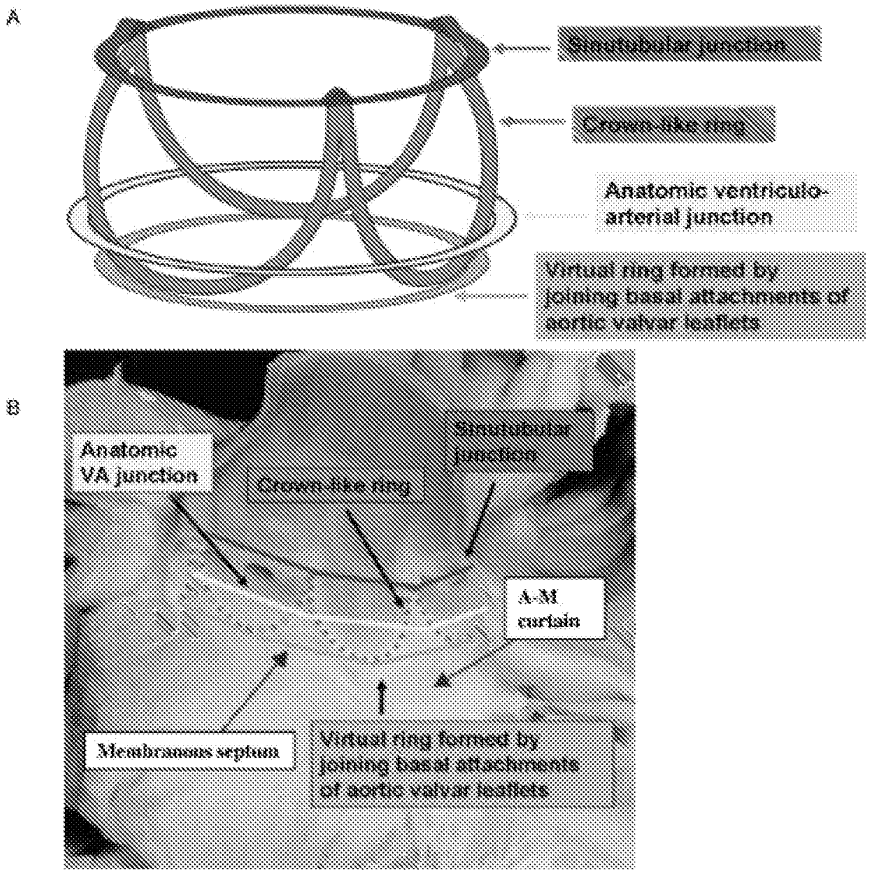


Fig. 2

See e.g., id. at Fig. 2. This is further confirmed by the '735 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valvsalve, the sinutubular junction, and the tubular portion." *Id.* at 1:62-64. The below image from a prior art journal article reflects

the structure of the aortic valve. The '735 patent identifies the green line as the annulus.

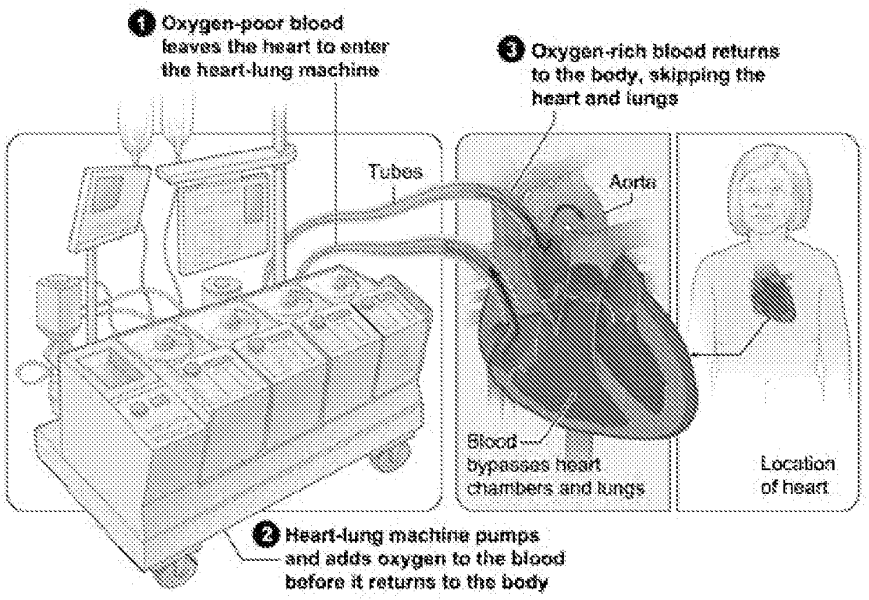


Ex. 1047 (Piazza) at Fig. 4. Because the "annulus" referred to in the '735 patent is the point where the leaflets begin, a person of ordinary skill in the art would have recognized that fibers pressing against the annulus must also press against the valve leaflets. *Id.* at 76. The journal article confirms this to be the case. SAPIEN, the valve disclosed in the Cribier and Walther references relied upon herein, was

positioned within the annulus (i.e., intra-annular) and "once deployed, crushes the leaflets of the native valve against the wall." *Id.* at 74.

C. Surgical Prosthetic Heart Valves

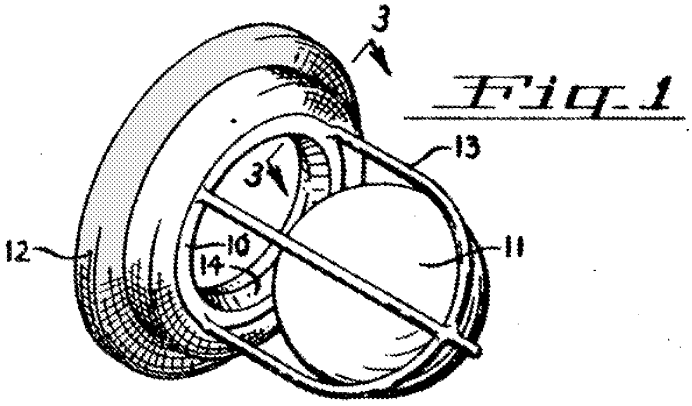
53. Petitioner Edwards was founded by Miles "Lowell" Edwards in 1958. Edwards' earliest work related to prosthetic heart valves that could be implanted surgically. Implantation of these devices involves an open surgical procedure that requires use of a heart-lung machine. In order to surgically implant a prosthetic heart valve, a surgeon opens a patient's chest and the patient is connected to a heart-lung bypass machine, after which the heart can be arrested. The surgeon then surgically removes the diseased native valve and sutures the prosthetic valve in place. A diagram detailing the operation of a heart-lung machine is pictured below:



Available at http://www.daviddarling.info/encyclopedia/H/heart_surgery.html. This procedure is used today for patients receiving a surgically implantable prosthetic heart valve.

54. One of Edwards' first commercially available surgical valves was a ball and cage valve called the Starr-Edwards valve. U.S. Patent No. 3,365,728 (the "'728 patent"), which issued on January 30, 1968, details the features of this valve. **Ex. 1014** ('728 patent). Notably, even this early valve prosthesis included a circumferentially oriented sewing ring that was adapted to extend into spaces in the tissue surrounding the implanted prosthesis to prevent leakage between the prosthetic valve and the surrounding tissue (*i.e.*, "paravalvular leak"). The '728 patent states:

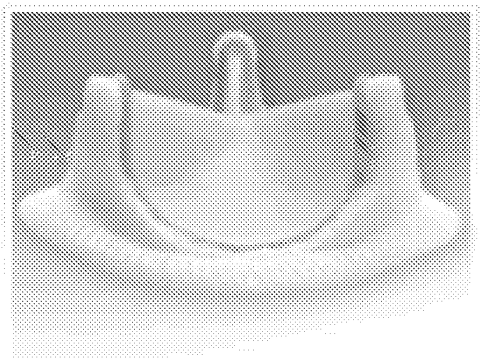
> Connected to the periphery of the valve ring is a suturable sewing ring [12] by which the valve may be connected by sutures with living tissue around the natural orifice in which the valve is implanted. The sewing ring is upholstered with a ring of compressible cushion material which will conform to irregularities in the bed in which the valve is placed whereby a good seal is established and leakage between the valve and the tissue is prevented.



Id. at 1:38-46, 3:12-20, Figs. 1, 3.[2] Thus, paravalvular leak was a well-recognized complication of surgical valve replacement as early as the 1960s.

55. In addition to ball and cage valves, Edwards also developed surgically implantable valves with biological valve leaflets. The biological valve structure could be made with a whole excised valve or formed with pericardial tissue, primarily of bovine or porcine origin. Edwards' PERIMOUNT valve, for example, was first introduced in 1980 and included a tri-leaflet bovine pericardial valve and a frame having a fabric sewing ring akin to the Starr-Edwards valve:

[2] Highlighting and color has been added to all figures unless otherwise noted.



Carpentier-Edwards PERIMOUNT
aortic valve

See e.g., https://www.edwards.com/gb/devices/heart-valves/aortic-pericardial (describing Carpentier-Edwards PERIMOUNT valve).

D. Transcatheter Heart Valve ("THV") Technology

56. THV technology is aimed at providing a patient with a permanently implanted prosthetic heart valve that can be delivered via a catheter.

57. In 1989, Danish doctor Henning Rud Andersen conceived of the seminal invention of a permanently implanted transcatheter bioprosthetic heart valve. That year, Dr. Andersen and his colleagues, Drs. Michael Hasenkam and Lars Knudsen, built the first prototype by hand. The Danish team successfully implanted its prototype in pigs using a catheterization procedure.

58. The Danish team published their results in 1992. **Ex. 1034** (Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)). There,

Drs. Andersen, Hasenkam, and Knudsen described their hand-made THV, which included "a foldable biological cardiac valve inside a balloon expandable metallic stent." *Id.*

59. The Danish team's work also led to several patents, including U.S. Patent No. 5,411,552 ("Andersen patent"). (**Ex. 1014**).

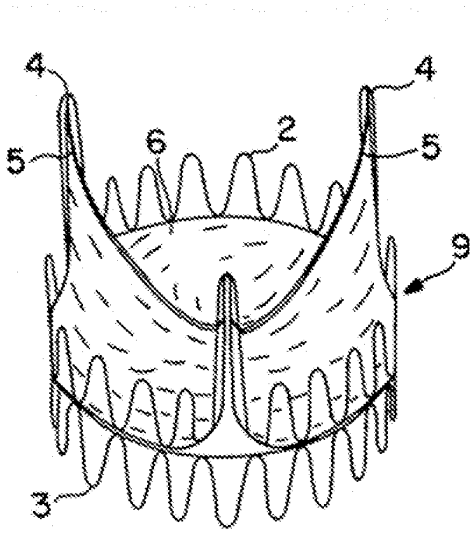


FIG. 2

Id. at Fig. 2. The Andersen patent describes multiple THV embodiments that expand upon the inventors' early prototypes, including embodiments having additional tubular graft material that can be used along the surface of the THV. *Id.* at 2:21-27, 2:56-60, 4:3-17, 5:9-28, 7:17-29, Figs. 11-12 ("[T]he stent may be made with a relatively great height and with a cylinder surface which is closed by a

suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted.").

60. The graft materials used on the external surface of early THVs were designed to conform to the surface of the surrounding tissue. These materials could be made with low-porosity woven fabrics. An early THV detailed in U.S. Patent No. 5,957,949 to Leonhardt et al. (**Ex. 1035**), which issued on September 28, 1999, details graft material to be used as an external cover on a THV:

> Graft material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE. It is capable of substantially conforming to the surface of the living tissue to which stent 26 coerces it.

Ex. 1035 at 5:53-59.

61. In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s. These designs provided the basis for a December 1996 patent application. A family of patents and patent applications stems from this 1996 application, including WO 98/29057 to Letac et al. ("Cribier patent publication", **Ex. 1018**).

62. This patent publication aims to improve upon the THV technology described in the Andersen patent discussed above. The Cribier patent publication notes that an "aim of the present invention is to provide an efficient prosthesis

valve which can be implanted by a catheterization technique, in particular in a stenosed aortic orifice, taking advantage of the strong structure made of the distorted stenosed valve and the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure." *Id.* at 5:11-16.

63. Further aims of the Cribier patent publication include providing a THV frame structure capable of withstanding the recoil forces of the native aortic valve in treating aortic stenosis and providing a THV with a frame covering that "prevent[s] any passage of the body fluid through said frame." *Id.* at 5:6-10, 8:28-9:6; *see also id.* at 5:17-18, 20:26-21:3, 22:11-20.

64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then "rolled up to be applied to the external wall of the stent" to form an external cover [19"]:

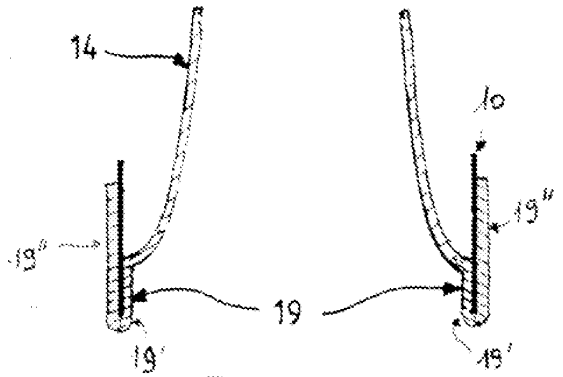
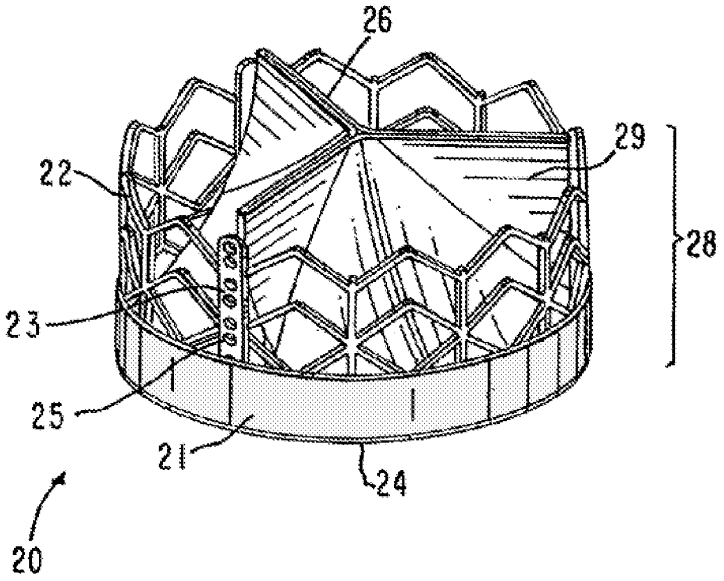


FIG_6d

Id. at 22:23-26, Fig. 6d. The single-piece cover is a tubular structure that can be made with any of the materials disclosed for making the valve structure, which include fabric (*e.g.*, Dacron), biological material (*e.g.*, pericardium), or other synthetic materials (*e.g.*, polyethylene). *Id.* at 8:16-23, 22:11-20. The Cribier patent publication discloses multiple ways of securing the cover to the frame. Specifically, the cover can be secured to the frame "at various points of attachment on various parts of the internal [and external] surface" by suturing, molding, gluing, or soldering the cover to the bars of the frame and, in its expanded state, would prevent blood from flowing between the cover and heart tissue. *Id.* at 22:23-26, 23:15-16, 24:24-27, Fig. 6d; *see also id.* at 23:12-24:23, Figs. 7, 8a-b.

65. In 2001, a company named Percutaneous Valve Technologies ("PVT"), which was co-founded by Dr. Cribier and three others (Stan Rowe, Stan Rabinovich, and Dr. Martin Leon), filed a patent application on another THV design that included an external cover:

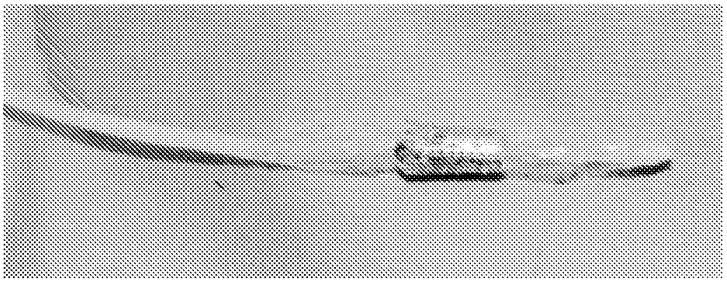


Ex. 1019 (U.S. Patent No. 6,893,460 B2 to Spenser *et al.* ("'460 patent")) at Fig. 1. The '460 patent discloses a THV having a tricuspid valve, a support stent including support beams for securing the commissures of the valve, and a cuff portion wrapped around the support stent at its inlet. *Id.* at 9:1-22, Fig. 1. The '460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a "sleeve-like" portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* ("To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet."). The cuff portion can be formed with PET (Dacron) fabric. *See id.* at 7:7-10, 10:57-11:10 ("Figs. 8*a* and 8*b* demonstrate a method of manufacturing a composite valve, which is based on flexible PU 92 as

the main body of the valve, rigid PU support beams 94 serving for the attachment area, and PET sleeve 96 portions for the valve inlet.").

66. Edwards's U.S. Patent No. 7,510,575 (referred to herein as **"Spenser," Ex. 1010**), claims priority to the '460 patent and includes the THV embodiment having an outer cuff. Ex. 1010 at 13:4-25, claim 31, Fig. 1.

67. In April 2002, using a THV developed by PVT, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. **Ex. 1025** (Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)).[3] The THV consisted of three bovine pericardial leaflets mounted within a tubular, slotted stainless steel balloon-expandable stent that was crimped onto a delivery balloon:



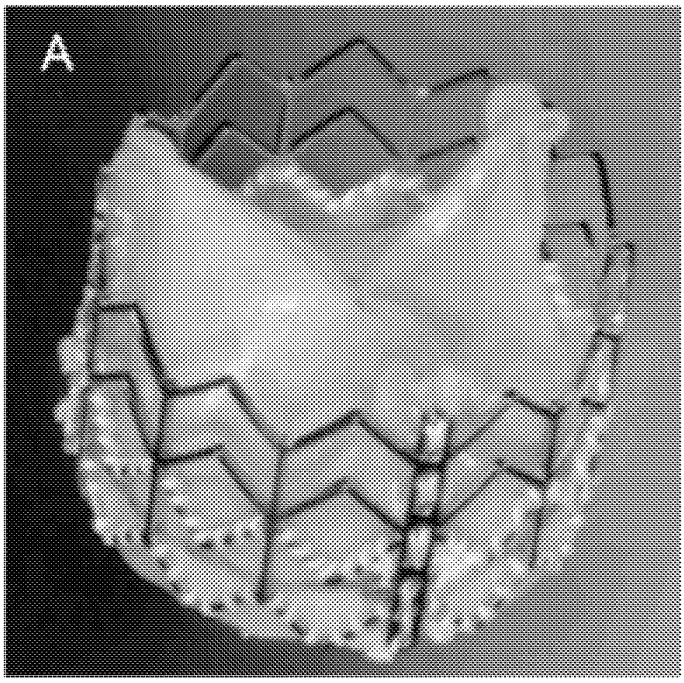
Id. at 3006, Fig. 1. Dr. Cribier implanted the THV using an antegrade approach from the right femoral vein. *Id.* at 3007. Dr. Cribier inserted a 24F sheath into the

[3] Dr. Cribier uses the phrase "percutaneous heart valve" or "PHV" to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

right femoral vein. The THV was "easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic valve." *Id.* The balloon was then inflated to place the THV. *Id.* Dr. Cribier concluded that the implantation was successful and demonstrated "the feasibility of implanting a prosthetic heart valve percutaneously, with the use of standard interventional techniques, within the native diseased valve of a patient with calcific aortic stenosis." *Id.* at 3008. Dr. Cribier continued to successfully use this implantation procedure in later patients. **Ex. 1030** (Cribier Early Experiences). From April 2002 to August 2003, Dr. Cribier attempted THV implantation in six patients. *Id.* at 699. The THV "was successfully and accurately delivered in the subcoronary position in all but one patient." *Id.* at 700. Dr. Cribier used the "anterograde trans-septal approach" for all cases. *Id.* at 701. Dr. Cribier's work confirmed "that a bioprosthetic valve can be implanted percutaneously within the native diseased stenotic aortic valve of patients with end-stage life-threatening calcific aortic stenosis, using standard interventional techniques under local anesthesia." *Id.*

68. In 2004, Edwards acquired PVT and began developing and testing the Cribier-Edwards THV. **Ex. 1023** (Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)). The Cribier-Edwards THV "was constructed from a laser-cut stainless

steel tubular frame within which was sewn valve leaflets constructed from equine pericardium, with the inflow covered with a fabric sealing cuff (Fig. 3A)." *Id.* at 154.



Id. at Fig. 3A.

69. In 2004, Edwards filed a patent application that formed the basis for PCT Patent Publication WO 2006/005015 A2, referred to herein as **Spenser II (Ex. 1011)**. Spenser II "provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis itself." *Id.* at [0014]. Figure 22 (below) "illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible

material, such as a cloth material, is provided along an exterior surface of a stented valve." *Id.* at [0085].

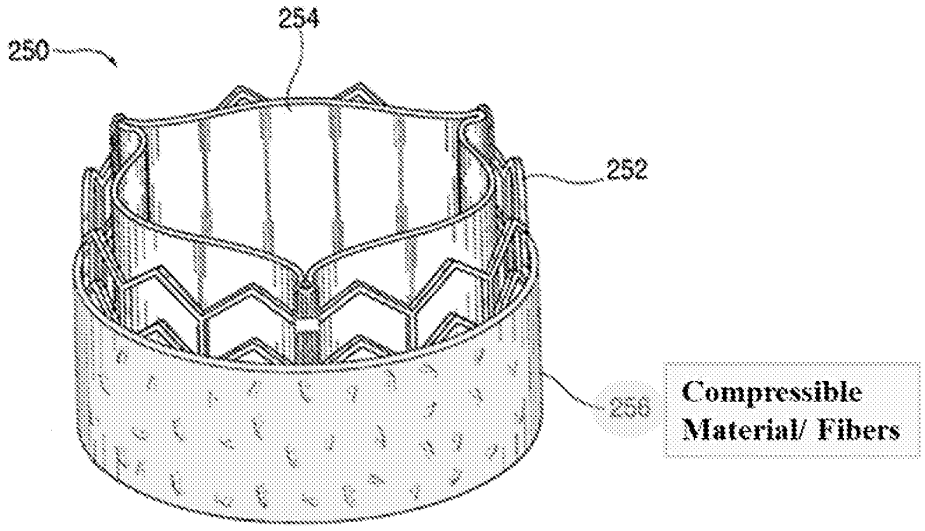


FIG. 22

Id. at Fig. 22. As shown, "a layer of compressible material 256 is disposed along an outer surface of the stent structure 252." *Id.* at [00145]. The material "may extend entirely around the stent structure, such as in the form of a sleeve." *Id.* "In one preferred embodiment, the compressible material is formed from polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.* "In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped." *Id.*

70. Spenser II explains that the purpose of the compressible material is "to reduce or prevent paravalvular leakage." *Id.* Spenser II states:

> The compressible material expands after deployment at the treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps."

Id.

71. Edwards did not merely patent THVs having outer sealing materials. Edwards also worked with clinical groups on both sides of the Atlantic to add an outer cloth to the external surface of a THV frame. In 2008, Edwards collaborated with Dr. Anson Cheung and other physicians to develop and test "a cuffed, 26-mm Cribier Edwards transcatheter valve." **Ex. 1017** (Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009)) at e18.

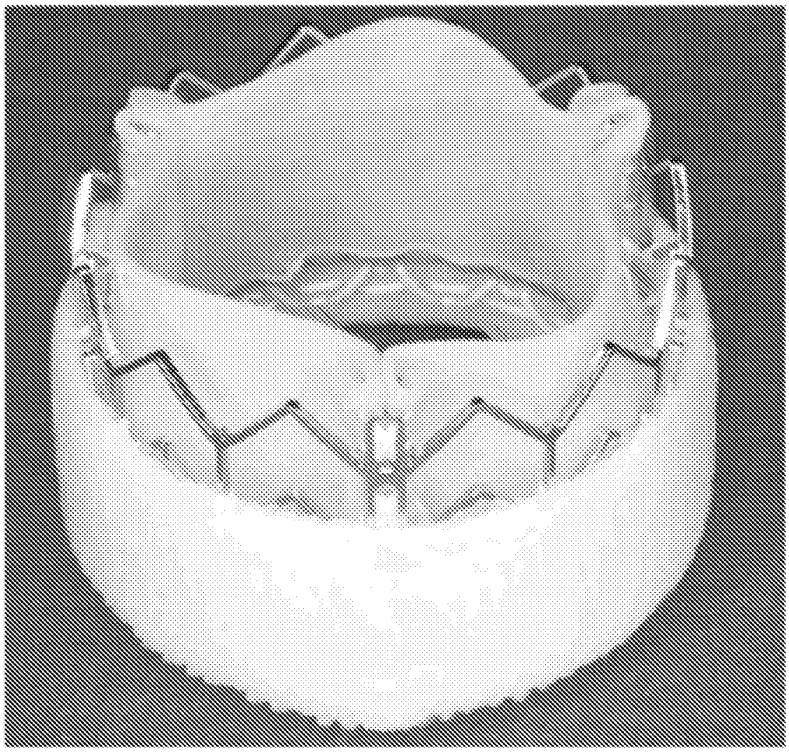


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

Id. at Fig.2. Dr. Cheung implanted the cuffed Cribier-Edwards valve within a patient's existing mitral bioprosthesis (Carpentier-Edwards PERIMOUNT Plus 6900P valve) using a transapical approach. *Id.* at e18. In the transapical approach, the valve is inserted through the patient's heart wall. Dr. Cheung and his team "used a cuffed device for the valve-in-valve implant to provide a better seal within the rigid support ring, minimizing paraprosthetic leak."[4] *Id.* at e19.

[4] "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.

72. By 2007, Edwards had modified the Cribier-Edwards valve to create SAPIEN, which included more durable bovine leaflets and a higher internal sealing cuff. **Ex. 1023** (Webb) at 154. SAPIEN was the subject of a large clinical trial, referred to as the PATNER Trial. **Ex. 1022** (Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)). The results of the PARTNER Trial were published in The New England Journal of Medicine in 2010. *Id.* SAPIEN addressed a long-felt need in the industry for an aortic valve replacement device that did not require open-heart surgery. In view of its pioneering status, SAPIEN's development and progress were avidly followed in the industry and SAPIEN was discussed in numerous publications and textbooks. *See e.g.,* **Ex. 1009** (Conradi), **Ex. 1016** (Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010)), **Ex. 1031** (Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation,* edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114). For example, the **Cribier** publication extensively discusses the transfemoral delivery of SAPIEN to a patient's heart valve. **Ex. 1012** (Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009)). Edwards received

regulatory approval to commercially sell SAPIEN in Europe in 2007. **Ex. 1038** (Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)). In 2011, the FDA approved the transfemoral delivery of SAPIEN for the treatment of inoperable patients with severe symptomatic aortic stenosis. **Ex 1032** (2011 FDA Approval). In 2012, the FDA approved the use of SAPIEN to treat high-risk aortic stenosis patients using the transfemoral and transapical delivery approaches. **Ex. 1033** (2012 FDA Approval).

73. In 2010, Dr. Thomas Walther and several Edwards engineers conducted a valve-in-valve study "focused on the use of an Edwards SAPIEN trans-catheter heart valve (THV) cloth valve (see Fig. 1), which is identical to the SAPIEN, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve." **Ex. 1007** (Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011)) at 1120.

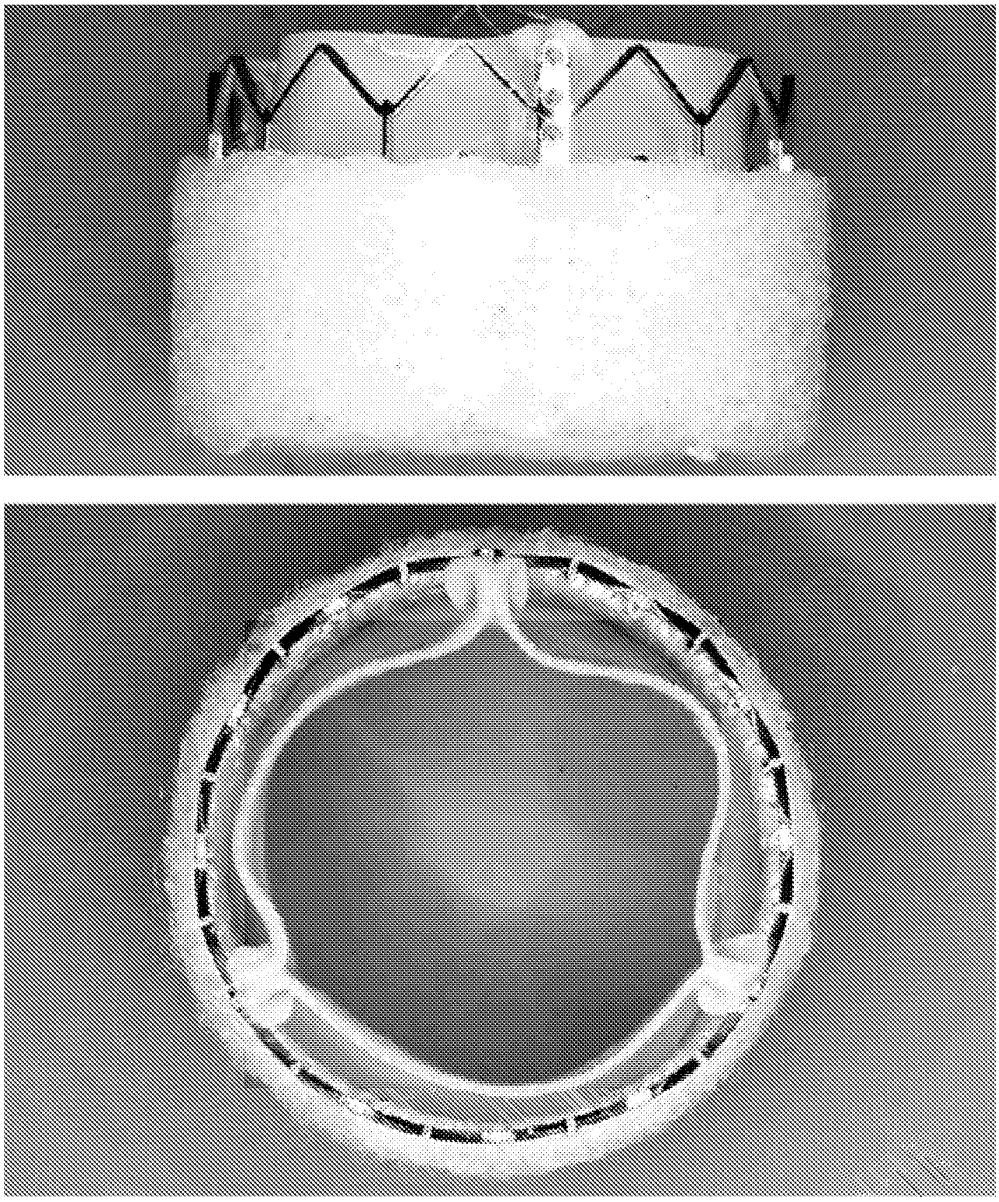


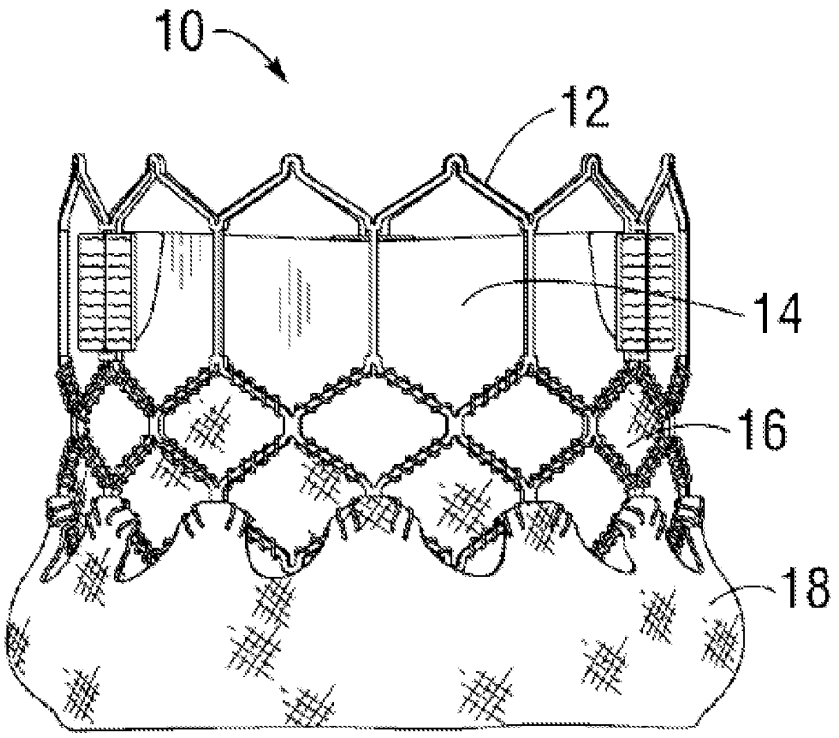
Fig. 1. Cloth valve.

Id. at Fig. 1. The team explained that the "addition of an outer cloth to the SAPIEN cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within

surgical Perimount valves." *Id.* at 1120. The team concluded that the "SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent hydrodynamic performance." *Id.* at 1125. The team also concluded that an *in vivo* procedure "is feasible." *Id.*

74. In October 2010, Edwards filed a provisional patent application that matured into U.S. Patent No. 9,393,110 B2, referred to herein as "**Levi**" (**Ex. 1008**). Levi discloses a THV with "four main components: a stent, or frame, 12, a valvular structure 14, an inner skirt 16, and an outer skirt 18":

FIG. 3



Id. at 5:52-58, 6:12-24, 9:7-35, 13:49-14:14, Figs. 1-3, 41-43. "The outer skirt 18 can be laser cut or otherwise formed from a strong, durable piece of material such as woven PET, although other synthetic or natural materials can be used." *Id.* at 13:49-53. "[W]hen the valve 10 is deployed within the body, the excess material of the outer skirt 18 can fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." *Id.* at 14:3-7. "The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the valve 10." *Id.* at 14:7-9.

75. Persons of ordinary skill in the art were also aware of fibrous outer sealing materials to prevent paravalvular leakage when replacing valves other than the aortic valve. For example, Birdsall, a patent filed in 2006 discloses the use of a fibrous outer seal in a prosthetic valve implanted within a vascular conduit. Ex. 1057 (Birdsall) at Abstract. Birdsall teaches that its valve may be covered with a "barrier material 308" that "comprises directionally oriented microfibers . . . extending outward" that "contact the interior wall of the conduit and form a barrier that prevents blood from flowing around stented valve 310, between the outer surface of the stented valve and the inner wall of the conduit":

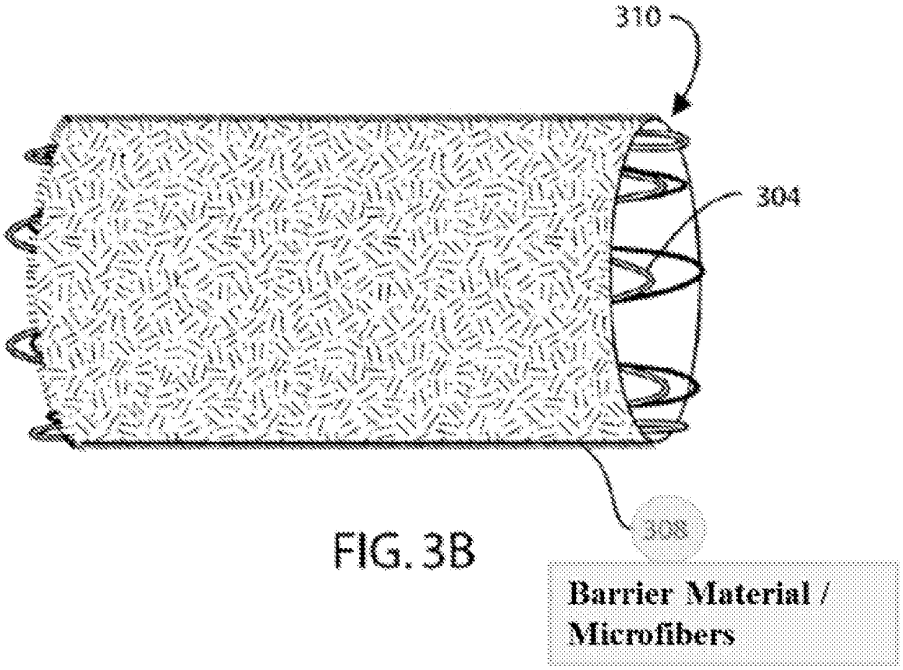


FIG. 3B

Id. at 6:9-33, Fig. 3B. While Birdsall teaches that this embodiment is intended to be implanted within a vascular conduit, Birdsall's teaching of extending fibers to form a seal is broader and is not limited to this context. Therefore, persons of ordinary skill in the art would have understood that a fibrous material like Birdsall's "barrier material" would perform a similar sealing function when implanted in a native tissue valve. Indeed, like the other THVs discussed above, Birdsall's valve is also designed for transcatheter, percutaneous implantation. *See id.* at 2:33-39.

76. The prior-art references identified above demonstrate that Petitioner invented and disclosed prosthetic heart valves, and specifically THVs, having an outer sealing material to reduce paravalvular leakage before November 2012.

Moreover, by 2012, Petitioner had advanced THV technology to the point that persons of ordinary skill in the art had a number of options they could balance when adding an outer sealing material to a THV device. For example, the prior art demonstrates that persons of ordinary skill in the art had access to a wide range of suitable cloths and fabrics for use as a sealing material. *See e.g.*, Ex. 1007 (Walther) at 1120-21; Ex. 1008 (Levi) at 13:49-53; Ex. 1010 (Spenser) at 13:4-25; Ex. 1011 (Spenser II) at [0085], [00145]; Ex. 1017 (Cheung) at e18-e19; Ex. 1018 (Cribier patent publication) at 8:16-23, 22:11-20. The cloths and fabrics had varying densities, thicknesses, and finishes. *Id.* A person of ordinary skill in the art would have had the option of selecting a cloth or fabric that best suited the specific heart valve assembly and met the necessary size requirements.

77. Additionally, by 2012, Petitioner had developed innovations for the heart valve frame and leaflets to further reduce the size of the heart valve assembly, thereby creating additional space for an outer sealing material. For example, well before November 2012, Edwards had developed SAPIEN XT, which replaced SAPIEN's stainless steel frame with a cobalt chromium alloy. Ex. 1023 (Webb) at 154; Ex. 1036 (Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems,* Catheterization and Cardiovascular Interventions, 75:295-300 (2010)) at 296. The cobalt chromium frame allowed "for a thinner, stronger, more open and compressible frame." *Id.*;

see also Ex. 1008 (Levi) at 6:31-6:49 (explaining that less material is needed with a cobalt chromium alloy frame). Edwards had also developed methods to reduce the diameter of the inlet portion of the heart valve frame to accommodate a sealing material. Ex. 1008 (Levi) at 16:51-17:18. Likewise, Edwards had disclosed innovative leaflet designs to reduce the crimp profile of the valve and offset or minimize any increase in diameter caused by adding additional components, like a sealing material, to the outside of the valve. *Id.* at 16:24-16:50.

78. Additionally, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. For example, the Retroflex 3 allowed the transfemoral introduction of SAPIEN 23 or 26 mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, the Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23 mm valve and 19 French for the 26mm valve. *Id.* The Novaflex incorporated an innovative feature where the heart valve was crimped on the inner catheter proximal to the inflatable balloon and then moved onto the balloon once the delivery system had been advanced into the aortic arch. *Id.*; *see also* Ex. 1037 (Le Patent Publication) at [0005]-[0006] (describing off balloon delivery). This unique feature enabled a reduction in sheath size.

79. In 2012, persons of ordinary skill in the art would have been familiar with the above innovations and understood that they could use one or more of the above options to optimize a THV having an outer seal. Thus, the challenged claims are not novel or nonobvious, but merely describe the predictable use of prior art elements according to their established functions.

IV. THE '735 PATENT

A. Summary of the '735 Patent

80. The '735 patent describes endograft devices for repairing ascending aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments combine multiple components to form a structure that extends into the patient's ascending aorta and aortic arch.

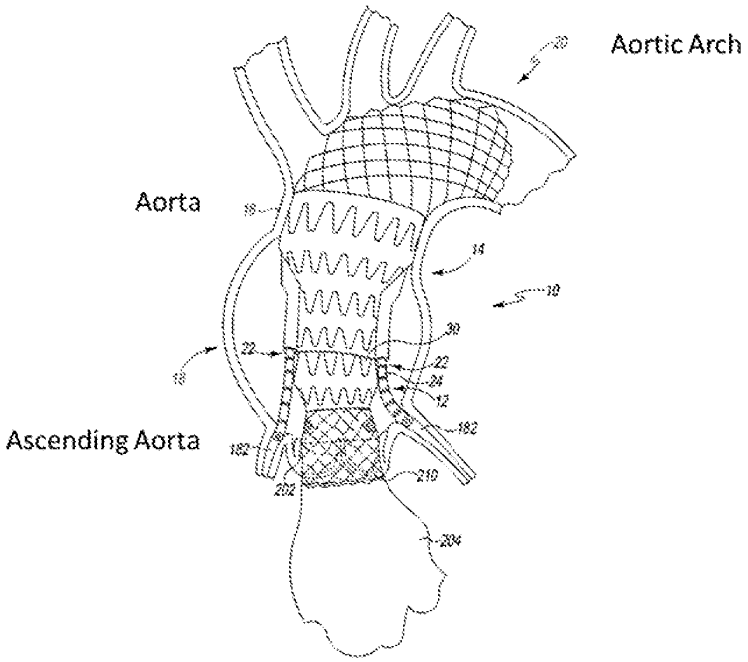


Fig. 2

81. However, the challenged claims of the '735 patent focus on a "heart valve assembly" for replacing an aortic heart valve. The '735 patent's specification describes a heart valve assembly that includes a "dual-frame" extending from a proximal end (i.e., nearest the left ventricle) to a distal end (i.e., furthest from the left ventricle). **Ex. 1001** ('735 patent) 11:63-65; 17:47-49. The "dual-frame" includes a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32":

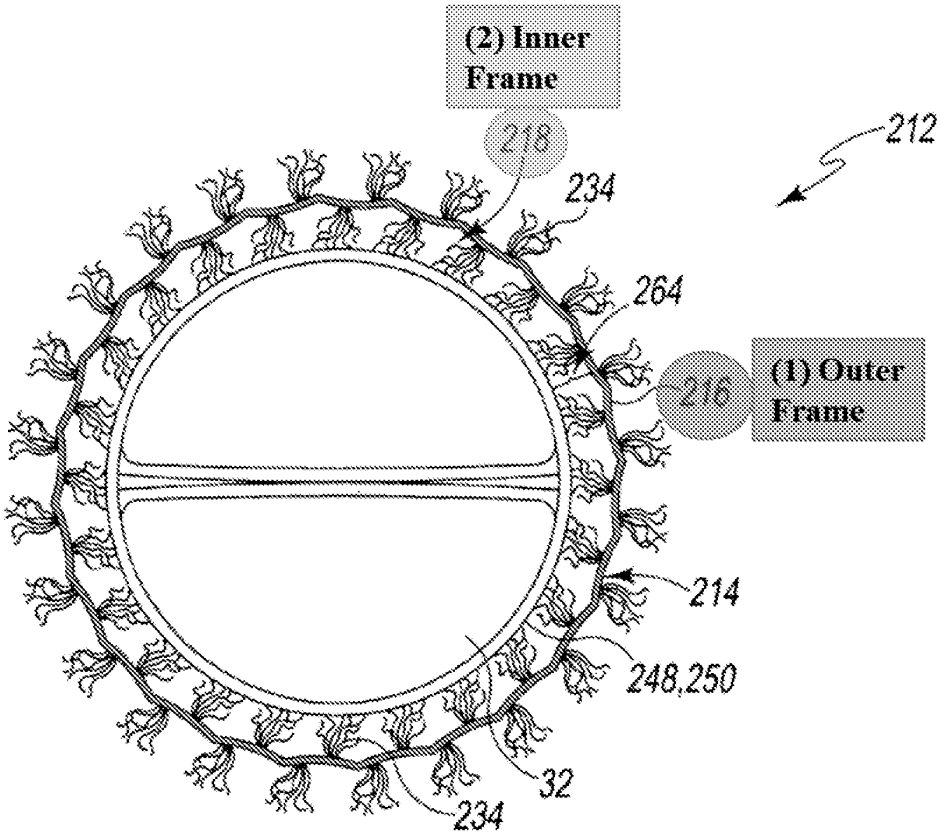


Fig. 13

Id. at 12:11-14, 17:58-61, Fig. 13.

82. The '735 patent states that the outer frame [red] is composed of a metallic or polymeric material that defines a gridded or "open-cell stent configuration." *Id.* at 12:14-20, 13:19-22, 17:61-66, Fig. 9. The outer frame is self-expanding and may include a plurality of radially extending "collagen fibers" [green] attached to the exterior of the frame "to aid in preventing paravalvular leaks and migration of the [heart valve assembly] within the aortic walls." *Id.* at

12:45-48, 18:24-27. The inner frame [blue] is a "balloon-expandable tubular stent" constructed of metallic or polymeric material. *Id.* at 13:43-50. The inner frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:8-10.

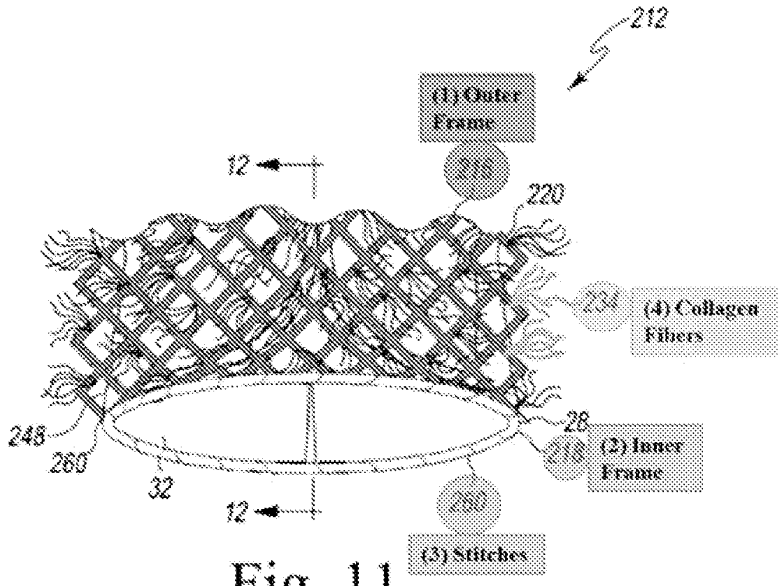


Fig. 11

83. The '735 specification discloses that the outer surfaces of the outer and inner frames may include a covering material, such as polyester, which prevents fluid from passing through the surface of the frame. *Id.* at 13:27-30, 13:53-59, 19:7-10.

84. The claims of the '735 patent additionally recite that "an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering" and that "the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." *Id.* at claim 1. Based on my review of the specification of the '735 patent, the specification

does not describe such an embodiment. The specification does not contain any description of the placement or arrangement of the collagen fibers on the outer frame other than stating that the collagen fibers are "attached" to the outer frame. *See id.* at 12:45-48, 18:24-27. The figures of the '735 patent, however, show that the collagen fibers of the "outer seal" extend proximally further than the most proximal end of the proximal apices of the outer frame. For example, Figure 11 below shows that the collagen fibers extend proximally further than the proximal ends of the most proximal apices of the outer frame:

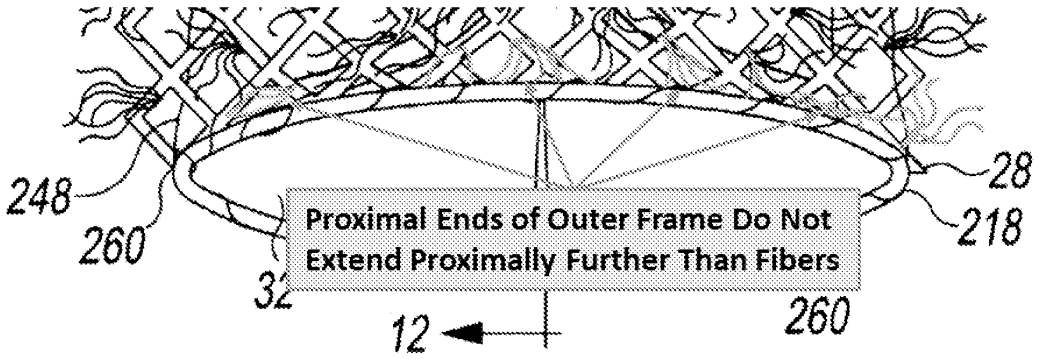


Fig. 11

Id. at Fig. 11 (excerpt). This is also illustrated in Figure 20 of the '735 patent, which shows that some of the collagen fibers extend proximally further than the proximal ends of the outer frame:

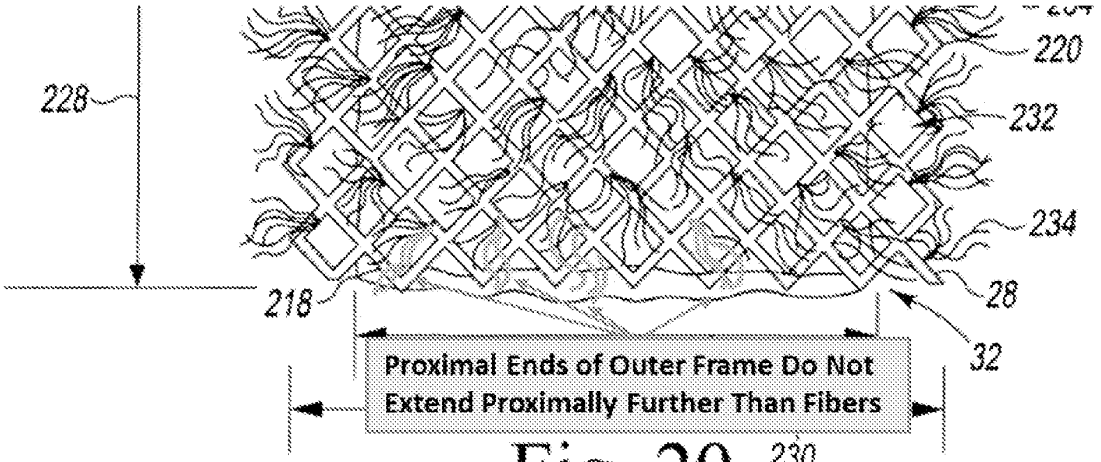


Fig. 20

Id. at Fig. 20 (excerpt).

85. During prosecution of the '735 patent, Patent Owner identified Figure 12 as allegedly providing support for these limitations. I disagree that Figure 12 provides supporting disclosure for these limitations. Patent Owner stated that Figure 12 depicts a different embodiment from Figure 11 that "differ[s] in construction of the inner graft covering and outer seal." Ex. 1002 ('735 patent prosecution history excerpt) at 272. Patent Owner's statement is not supported by the specification of the '735 patent, which teaches that Figure 12 "is a cross-sectional elevation view of the proximal prosthetic component of Fig. 8 taken along the line 12-12 in Fig. 11." Ex. 1001 ('735 Patent) at 5:55-57. Thus, contrary to Patent Owner's argument, Figure 12 does not depict a separate embodiment that differs in construction from Figure 11. Figure 12 merely shows a different perspective view of the same embodiment depicted in Figure 11, which is the

proximal component of Figure 8. Like Figure 20 above, Figure 8 clearly shows that the collagen fibers extend proximally further than the the proximal ends of the outer frame:

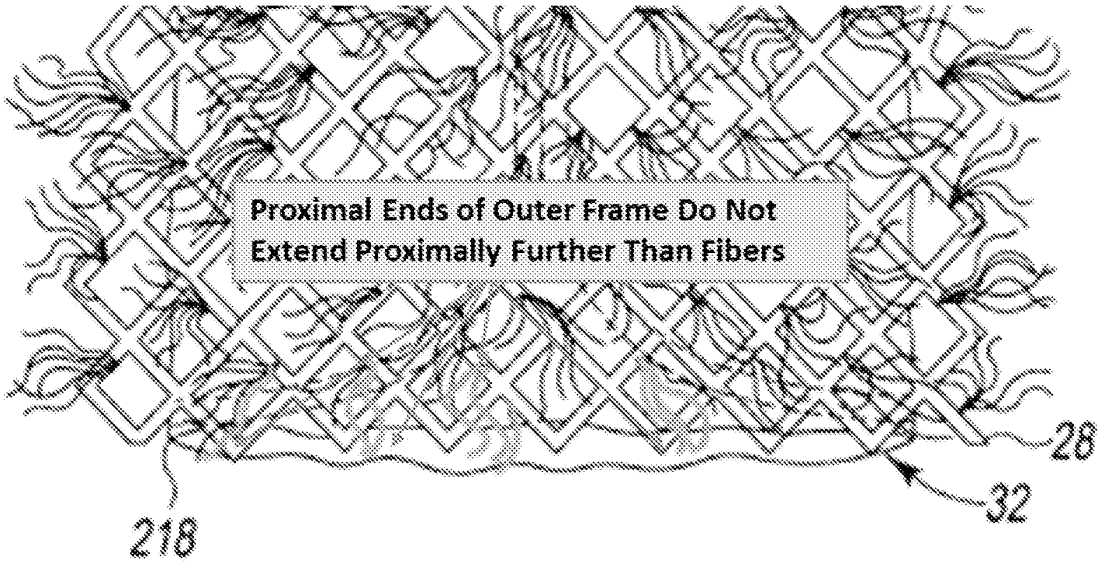


Fig. 8

Id. at Fig. 8 (excerpt). In addition, according to Patent Owner's own arguments during prosecution, Figure 11 shows that "the inner graft covering 248/inner frame 218 extends over apices of the stent frame." Ex. 1002 ('735 patent prosecution history excerpt) at 272. Therefore, because Figure 12 merely discloses a different perspective view of the same embodiment shown in Figures 8 and 11, Figure 12 cannot provide support for an embodiment wherein the proximal apices of the outer frame are uncovered by both the graft covering and collagen fibers (i.e., outer seal).

B. The Challenged Claims

86. The challenged claims include claims 1-9 and 11-12 of the '735 patent. Claim 1 is the sole independent claim.

87. Claim 1 is illustrative (but not representative) of some of the limitations in the challenged claims. Claim 1 states:

> "1. An endovascular transcatheter valve assembly comprising:
> an outer frame,
> wherein the outer frame is formed from a metallic material and defines an open cell configuration
> wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof,
> wherein the outer frame is formed by a plurality of struts that adjoin each other at the inflow end to form apices:
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
> wherein the outer frame is secured to the inner graft covering by stitching a proximal portion of the outer frame;
> an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the outer frame,
> wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame,
> wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
> wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient
> wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering,
> wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal."

C. Prosecution History

88. I have reviewed the '735 patent's prosecution history. I see that the Patent Examiner issued a single, non-final office action that included a single prior-art based rejections. **Ex. 1002** ('735 patent prosecution history excerpt) at 292-302. None of the prior art references included in the grounds of unpatentability discussed in this Declaration were asserted by the Examiner's rejection. *Id.* I also understand that Cribier and Spenser were not cited during prosecution.

89. While the Patent Examiner did not discuss any of the prior art references included in the grounds of unpatentability discussed in this Declaration, I see that Patent Owner made about the prior art and statement concerning the scope of the claims in two Amendments during prosecution.

90. For example, Patent Owner made arguments about Spenser II in a May 5, 2021 Amendment, arguing that Spenser II "teaches a variety of outer seal designs such as Fig. 21" but "appears not to teach that the seal extends partially over at least two most proximal rows of cells." Ex. 1002 ('735 patent prosecution history excerpt) at 273. Because Patent Owner's arguments are directed at the embodiment of Fig. 21 in Spenser II, which is not the embodiment relied on in the grounds of unpatentability discussed in this Declaration, Patent Owner's arguments are irrelevant to my analysis. Patent Owner omitted discussion of the most

relevant embodiment from Spenser II, the embodiment shown in Figure 22, which discloses a valve having a seal that extends over the proximal two rows of cells as I explain below. *Infra* §VII.A.5.b. Patent Owner also argued that Spenser II "appears to be missing an inner graft, though it is not clear." Ex. 1002 ('735 patent prosecution history excerpt) at 273. As explained more below, to the extent the valve in Figure 22 does not have an inner graft covering, a person of ordinary skill in the art would have found it obvious to combine Spenser II's compressible material with a valve having an inner graft covering, such as Spenser's Figure 44a.

91. Patent Owner also argued that Levi's outer skirt "covers the end of the apices [of the frame] and attempts to solve the same problem as the claimed invention by providing slack to the skirt to allow elongation of the frame." *Id.* at 275. As explained more below, the slack provided in Levi's outer skirt was just one known way of addressing shortening and elongation of the stent frame. However, a person of ordinary skill in the art would have found it obvious to adjust the positioning of Levi's outer skirt such that the proximal end is attached to the exterior of the outer frame and does not cover the end of the proximal apices. Moreover, as also explained more below, a person of ordinary skill in the art would have found it obvious to combine Levi with Walther or Spenser II, and the resulting device would not include an outer seal covering the proximal ends of the apices.

92. Patent Owner also made representations about Walther in a July 27, 2021 Amendment. Patent Owner Argued that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." Ex. 1002 ('735 prosecution history excerpt) at 29. There is no support in Walther for this statement. Walther merely states that an "added poly(ethylene terephthalate) (PET) cloth was stitched onto the perimeter of each SAPIEN valve." Ex. 1007 (Walther) at 1121. Walther does not describe a "cloth base or outer graft" and a "fiber portion." Likewise, the figures do not show a "cloth base or outer graft" and a "fiber portion":

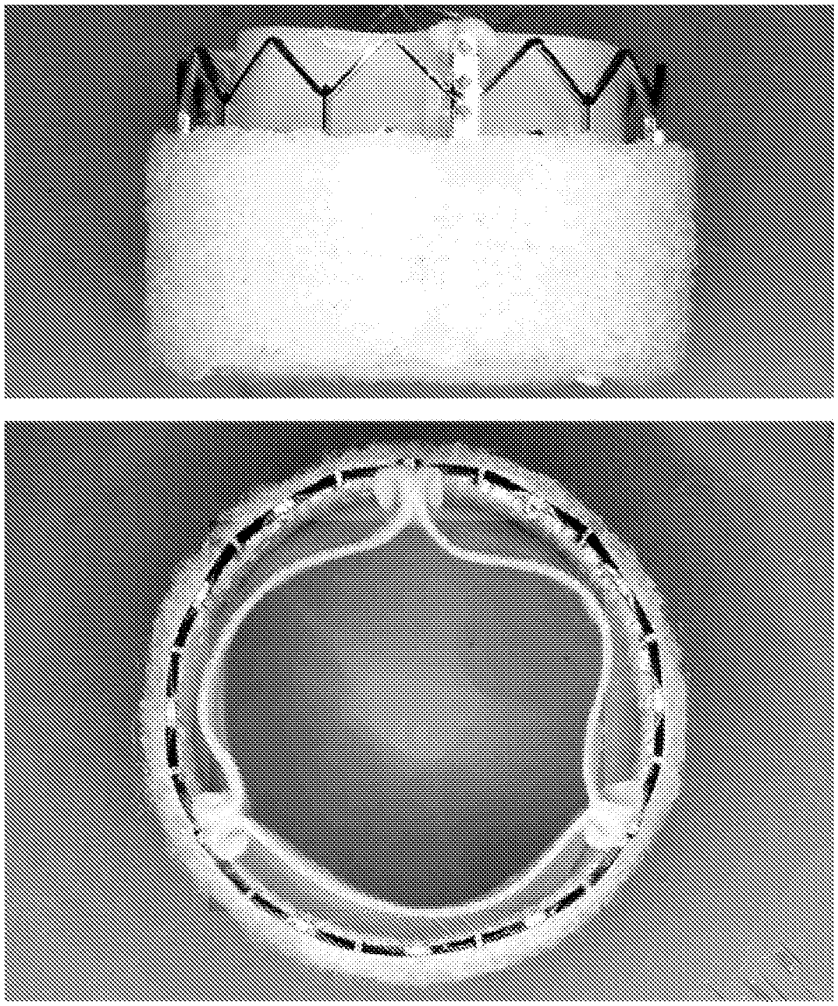


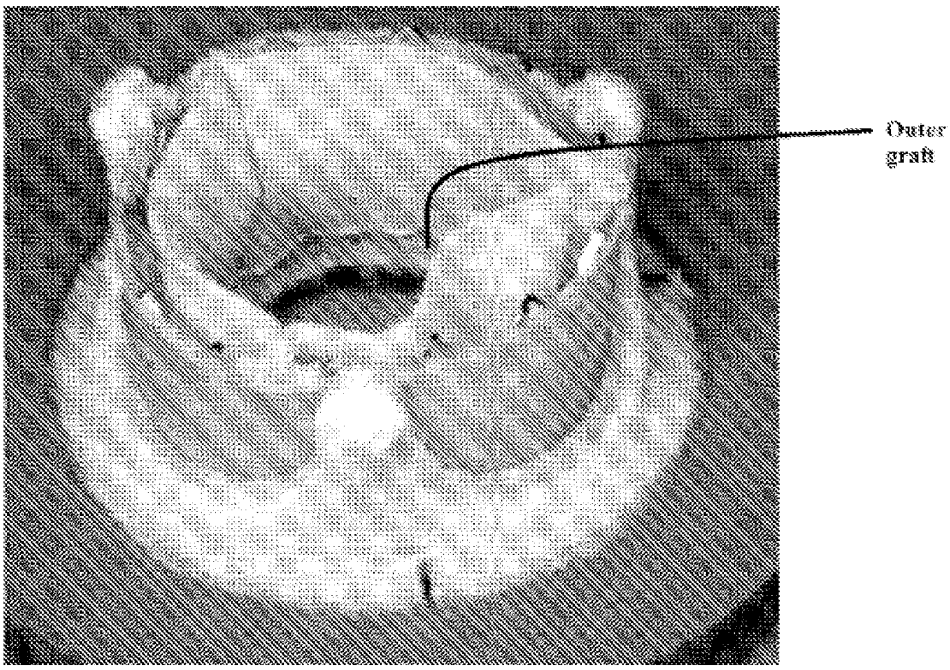
Fig. 1. Cloth valve.

The figures depict a single piece of PET. For this reason, a person of ordinary skill in the art would not have understood Walther to disclose "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft," as argued by Patent Owner.

93. Patent Owner also argued that Walther's outer cloth is "wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets" and

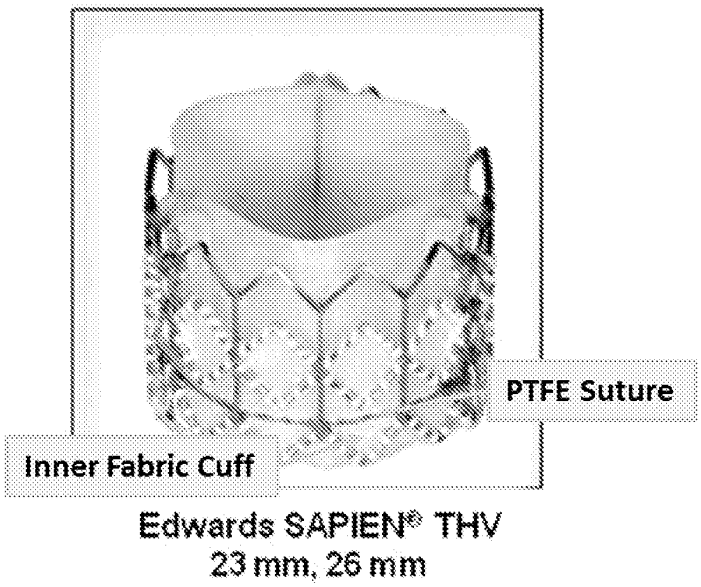
thereby constricts the orifice area and impacts hemodynamics. Ex. 1002 ('735 prosecution history excerpt) at 30. Again, there is no support in Walther for this statement. Walther never states that its outer cloth is wrapped around the inflow end. To the contrary, Walther teaches that the outer cloth was stitched to the "perimeter" of the SAPIEN valve. Ex. 1007 (Walther) at 1121.

94. Patent Owner argues that the below figure shows the outer cloth (labeled "Outer graft") "flipped towards the prosthetic leaflets where the base/outer graft is then stitched to the metallic frame." Ex. 1002 ('735 prosecution history excerpt) at 29-30.



Patent Owner misunderstands the figure. In the above figure, Patent Owner's line labelled "Outer graft" points to a polytetrafluoroethylene (PTFE) suture that

attaches the valve leaflets and inner fabric cuff to the frame. Ex. 1028 (Roselli) at 213. This same suture (green) is also visible on the outside of SAPIEN (with no outer cloth) as shown in the below figure from Cribier:



Ex. 1012 (Cribier) at Fig. 1.

95. The below enlarged and color photograph from Walther shows that the outer cloth is not wrapped around the inflow end of the valve and sutured to the inside of the valve as Patent Owner argues. If the outer cloth was wrapped around and sutured, as Patent Owner argued, it would be visible in the below figure, but it is not.

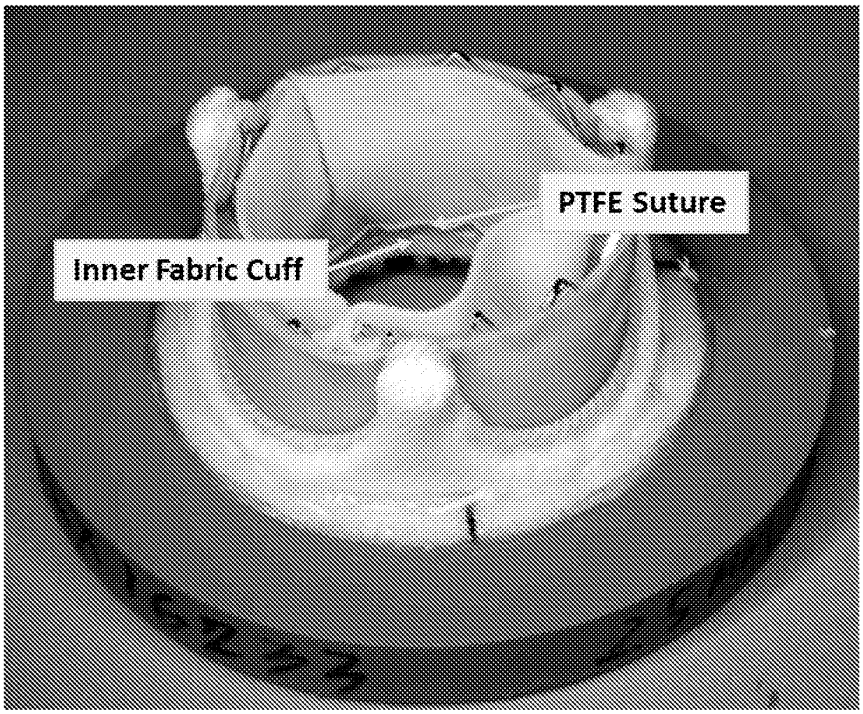


Fig. 2. Cloth THV valve deployed in surgical valve.

Ex. 1007 (Walther) at Fig. 2.

96. Further, because the outer cloth is not "wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets," a person of ordinary skill in the art would not have been concerned that the outer cloth would constrict the orifice area or impact hemodynamics. Dr. Walther was asked about this potential issue during a Conference Discussion occurring in conjunction with his paper and did not express any concern about this issue, stating: "I am not sure whether it changes the effective orifice area that much and I am pretty sure you just squeeze it in. You have four atmospheres and really it is just filling little gaps there." Ex. 1007 (Walther) at 1126. Further, Walther concludes that the valve "demonstrated

excellent hydrodynamic performance," further eliminating any concerns that the outer cloth somehow disadvantageously impacts the orifice area or hemodynamics. *Id.* at 1125-1126. For these reasons, a person of ordinary skill in the art would not have understood Walther's outer cloth to wrap around the inflow end of the valve or negatively impact hemodynamics.

V. SUMMARY OF IPR GROUNDS

97. I have identified the following grounds of unpatentability in this Declaration:

Ground	Claims Challenged	Unpatentability Basis	References
1	1, 3-6, 8-9, 11-12	Obviousness	Cribier + Walther
2	1-9, 11-12	Obviousness	Spenser + Walther
3	1-9, 11-12	Obviousness	Spenser + Spenser II
4	1-9, 12	Obviousness	Levi + Walther
5	1-9, 12	Obviousness	Levi + Spenser II

VI. GROUND 1: CLAIMS 1, 3-6, 8-9, 11-12 OBVIOUS OVER CRIBIER AND WALTHER

98. Cribier is one of the many prior art publications describing SAPIEN. **Ex. 1012** (Cribier). Cribier explains that SAPIEN "consists of a balloon-expandable stent with an integrated bovine pericardial valve." *Id.* at 347. Cribier

states that SAPIEN "can be implanted within the diseased aortic valve using either the retrograde transfemoral or antegrade transapical routes." *Id.*

99. Walther, as discussed above in my section covering "Transcatheter Heart Valve ("THV") Technology," discloses a modified SAPIEN having an added outer cloth:

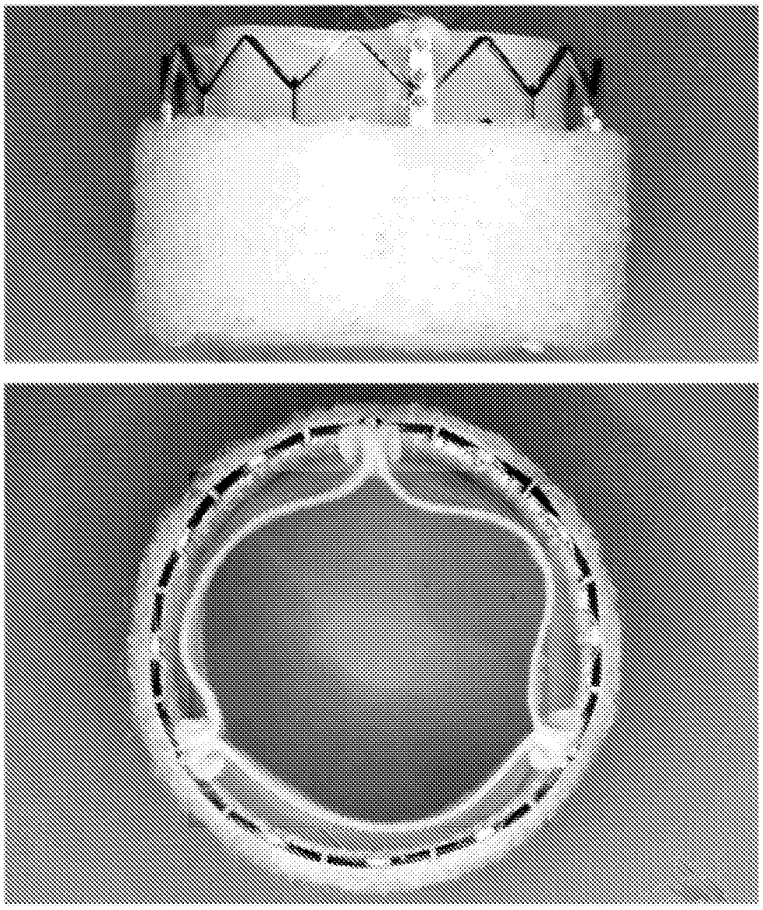


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at 1120-21, Figs. 1-3. Walther explicitly discloses that the modified SAPIENs were "identical" to SAPIEN except for the outer cloth. *Id.* at

1120. SAPIEN would have been well known to a person of ordinary skill in the art by November 2012. Walther generally describes SAPIEN but does not include some of the details about SAPIEN that are discussed in Cribier. Thus, I have combined the teachings of Cribier and Walther to provide a more comprehensive review of the features of the cloth-covered SAPIEN disclosed in Walther. Based on my review of these references, I believe that the combination of Cribier and Walther renders claims 1, 3-6, 8-9, and 11-12 of the '735 patent obvious.

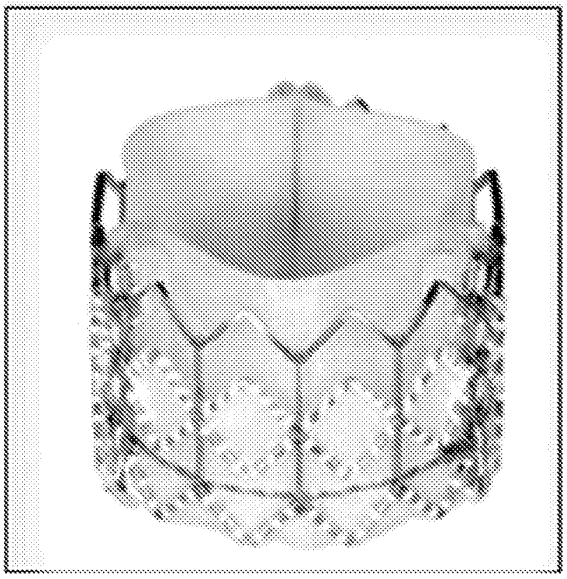
A. Claim 1

100. Based on my review of the prior art, it is my opinion that Cribier in combination with Walther renders claim 1 obvious.

1. Preamble

101. The preamble of claim 1 recites: "An endovascular transcatheter valve assembly comprising." If this preamble is limiting, Cribier in combination with Walther renders this limitation obvious.

102. Cribier discloses SAPIEN, which is a transcatheter valve assembly. Ex. 1012 (Cribier) at 348. Cribier states that SAPIEN "consists of a tubular slotted stainless-steel balloon-expandable stent with an integrated unidirectional trileaflet bovine tissue valve with a polyethylene terephthalate (PET) fabric cuff." *Id.* at 348. Cribier Figure 1 (below) provides a picture of SAPIEN:



Edwards SAPIEN® THV
23 mm, 26 mm

Id. at Fig. 1.

103. As shown in the figure above, SAPIEN's fabric cuff is stitched to the inside of the balloon-expandable stent and also attached to the heart valve leaflets. The green suture line in Figure 1 above is one point of attachment between the fabric cuff and the heart valve leaflets.

104. I note that despite claiming an endovascular valve assembly, the '735 patent does not contain any disclosure regarding how to size the disclosed valves for endovascular delivery. For example, the '735 patent never discloses the length, thickness, or width of the sealing material and fibers, the density of the fibers, or the crimp profile of the valve assembly. In my opinion, the dual-frame concept must rely on the prior art for all of the dimensional teaching.

105. By 2012, persons of ordinary skill in the art would have been aware that SAPIEN could be endovascularly delivered through different blood vessels. For example, persons of ordinary skill had successfully delivered SAPIEN through the common iliac artery, which is a larger artery than the femoral artery and can, therefore, accommodate bigger devices or achieve endovascular delivery in patients with diseased femoral arteries. Ex. 1043 (Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan,* General Thoracic Cardiovascular Surgery 59:273-276 (2011); *see also* Ex. 1044 (Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations,* J. Endovasc. Ther. 14:347-351 (2007) (describing endovascular access through the common iliac artery). The common iliac artery also provide an alternative route for endovascular delivery when the femoral artery was too diseased or tortuous. *Id.* Delivery through the common iliac artery is endovascular delivery.

106. Additionally, Cribier describes the successful delivery of SAPIEN using the "retrograde transfemoral" approach. Ex. 1012 (Cribier) at 347-356; *see also* Ex. 1009 (Conradi) at 515-517 (disclosing transfemoral and transapical approaches); Ex. 1023 (Webb) at 156-158 (same). In the transfemoral approach, SAPIEN is "introduced within the femoral artery, advanced to the native aortic valve under X-ray control, positioned across the aortic annulus, and delivered by

balloon inflation under rapid heart pacing." Ex. 1012 (Cribier) at 347; *see also* Ex. 1009 (Conradi) at 514-517, Fig. 4A; Ex. 1027 (Roselli) at 209, 213. Delivery of SAPIEN using the transfemoral approach is "endovascular" delivery. Cribier also mentions the antegrade transseptal approach in which a SAPIEN was delivered through the femoral vein. Ex. 1012 (Cribier) at 348; *see also* Ex. 1030 (describing antegrade transsepatal approach). The antegrade transseptal approach is yet another type of endovascular delivery. Therefore, SAPIEN, as confirmed by Cribier, is an "endovascular transcatheter valve assembly."

107. Walther discloses SAPIEN with an outer cloth stitched to its perimeter. Ex. 1007 (Walther) at 1120-21, Fig. 1. Walther's cloth-covered valve is identical to SAPIEN except for the outer cloth. *Id.* As confirmed by Cribier, SAPIEN is an "endovascular transcatheter valve assembly" and, thus, Walther discloses such an assembly as well.

108. Walther discloses implanting the cloth-covered SAPIEN *in vitro* using Edwards' transapical delivery system (the Ascendra). Ex. 1007 (Walther) at 1121. Transapical delivery is a method for implanting prosthetic heart valves that includes inserting the valve between the ribs and through the heart wall.

109. In my opinion, a person of ordinary skill in the art would have found it obvious, and been motivated, to endovascularly deliver a cloth-covered SAPIEN, similar to the one disclosed in Walther, in 2012. The purpose of Walther's bench-

top testing was to confirm that the cloth-covered valve would work in a patient. Ex. 1007 (Walther) at 1120-21. Based on the testing, Walther concluded that an in-patient procedure "is feasible." *Id.*, 1125. Thus, POSITAs would have been motivated, and expected success, in implanting the valve in a patient. POSITAs would have motivated to endovascularly deliver the Walther valve through the common iliac artery because the artery is large and would not have required any modifications to Walther's valve.

110. Persons of ordinary skill in the art also would have been motivated to endovascularly deliver the Walther valve through the femoral artery. Many persons of ordinary skill in the art considered the transfemoral approach "as the technique of first choice" and safer than the transapical approach, which was associated with "more adverse events and higher mortality rates." Ex. 1009 (Conradi) at 515-516; Ex. 1020 (Yuksel, Uygar, *Balloon-Expandable Transcatheter Aortic Valve Implantation,* Cardiac Interventions Today (Aug./Sept. 2009) at 52; Ex. 1043 (Kainuma) at 275.

111. A person of ordinary skill in the art would have possessed the skills necessary to adapt a cloth-covered SAPIEN, like the one in Walther, for transfemoral delivery. *Supra* §III.C. First, persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected an appropriately dimensioned cloth for

endovascular delivery through, for example, the femoral artery. *Id.*; *see also e.g.,* Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. Second, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. *Supra* §III.C; Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. These delivery systems permitted POSITAs to crimp valves to smaller diameters and thus endovascularly deliver valves having additional components, such as an outer seal. Third, by 2012, Petitioner had developed a variety of ways to adapt a heart valve's outer frame and leaflets to create additional space for an outer seal. *Supra* §III.C; *see e.g.,* Ex. 1008 (Levi) at 6:31-49, 16:24-17:18; *infra* §VIII.A.5. Persons of ordinary skill in the art would have found it obvious to utilize one or more of these known strategies to make the cloth-covered SAPIEN suitable for endovascular delivery, and particularly for transfemoral delivery.

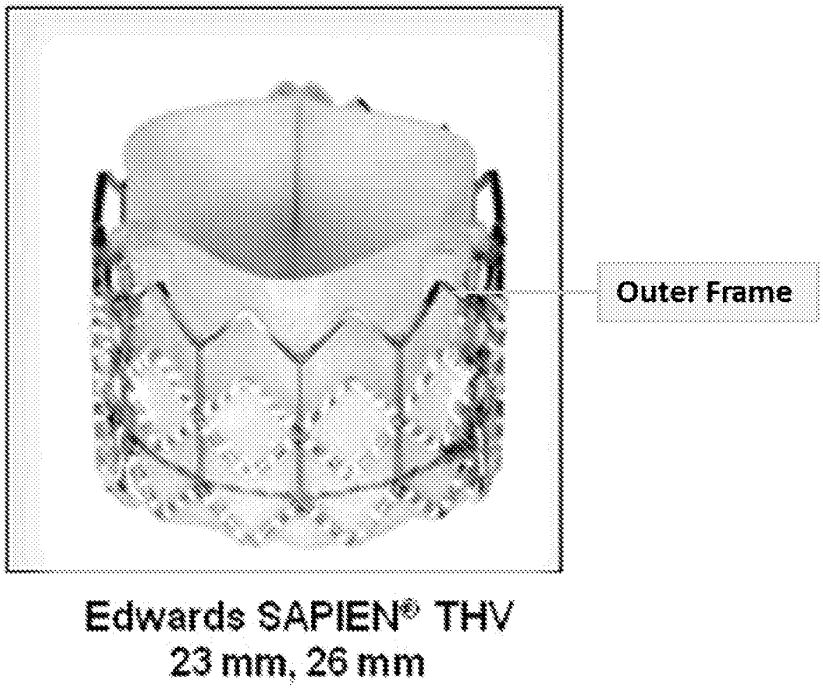
112. A person of ordinary skill in the art would have had a reasonable expectation of success in endovascularly delivering the cloth-covered SAPIEN for several reasons. First, Walther concludes that *in vivo* (i.e., in a patient) implantation of the cloth-covered valve "is feasible." Ex. 1007 at 1125. Second, many references reported the successful transfemoral delivery of SAPIEN and, by 2012, SAPIEN was widely used globally and had been approved by the FDA. *See e.g.,* Ex. 1009 (Conradi) at 517; Ex. 1012 (Cribier) at 355; Ex. 1032 (2011 FDA

Approval). Third, persons of ordinary skill in the art had successfully implanted SAPIEN through the common iliac artery, which could accommodate the delivery of larger devices. Ex. 1043 (Kainuma). In view of these factors, a person of ordinary skill in the art would have reasonably expected success in endovascularly delivering a cloth-covered SAPIEN.

2. Outer Frame

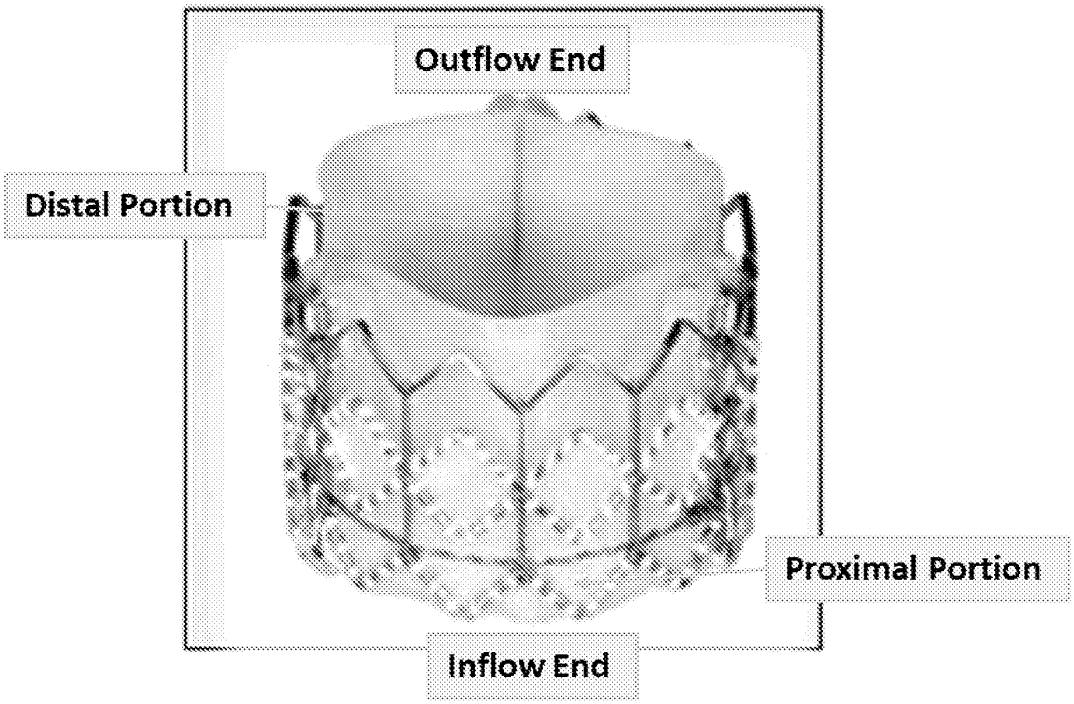
113. Claim 1 next recites: "an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof, wherein the outer frame is formed by a plurality of struts that ajoin each other at the inflow end to form apices." Cribier discloses these limitations.

114. Cribier discloses that SAPIEN includes "a tubular slotted stainless-steel balloon-expandable stent." Ex. 1012 (Cribier) at 348. As shown in Figure 1 below, the stent defines an open cell configuration and surrounds the other valve features, such as the heart valve leaflets, making it an "outer frame":

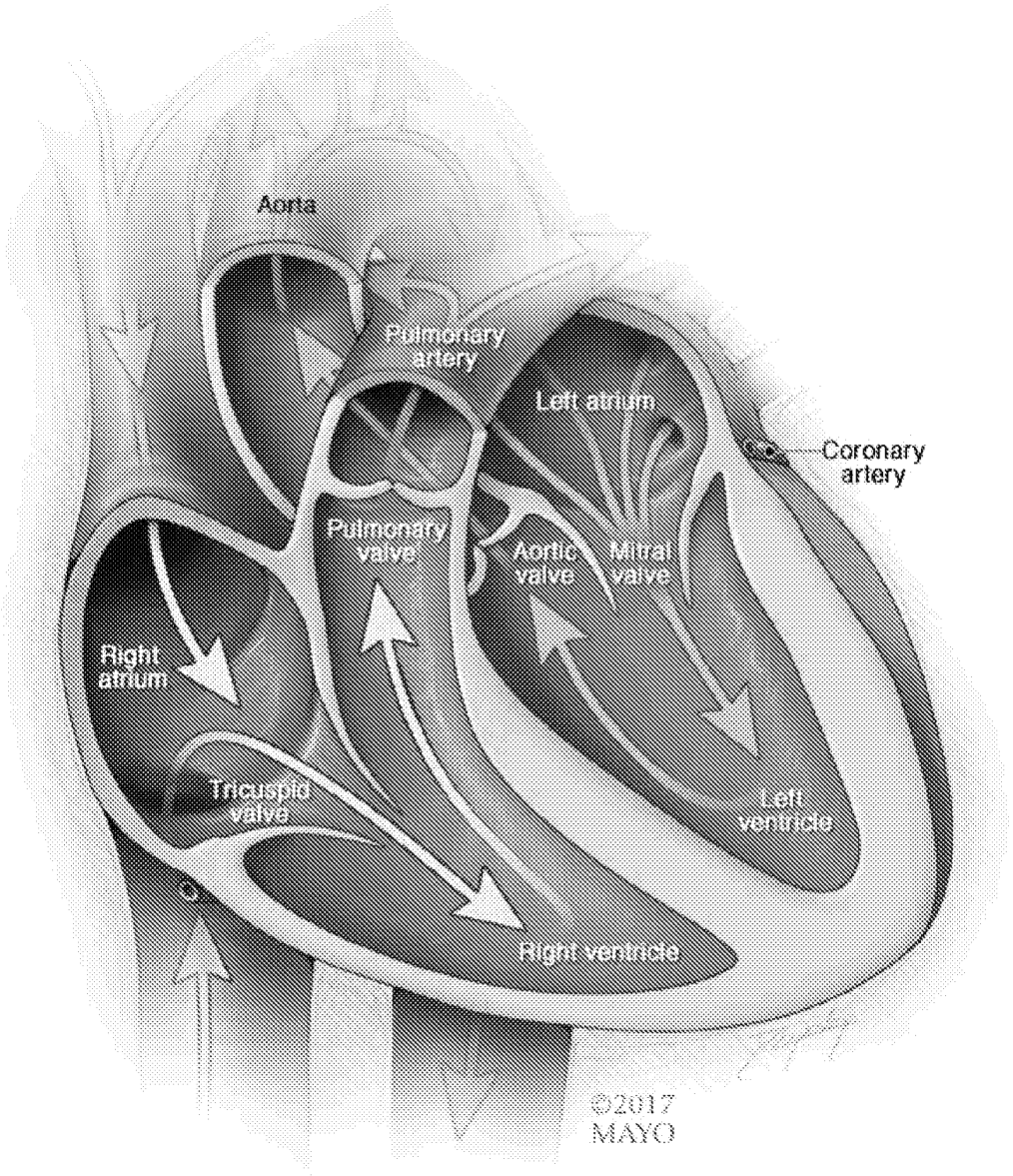


Id. at Fig. 1.

115. SAPIEN's outer frame includes an inflow end a proximal portion of the valve and an outflow end at a distal end of the valve, as shown in Figure 1 below:



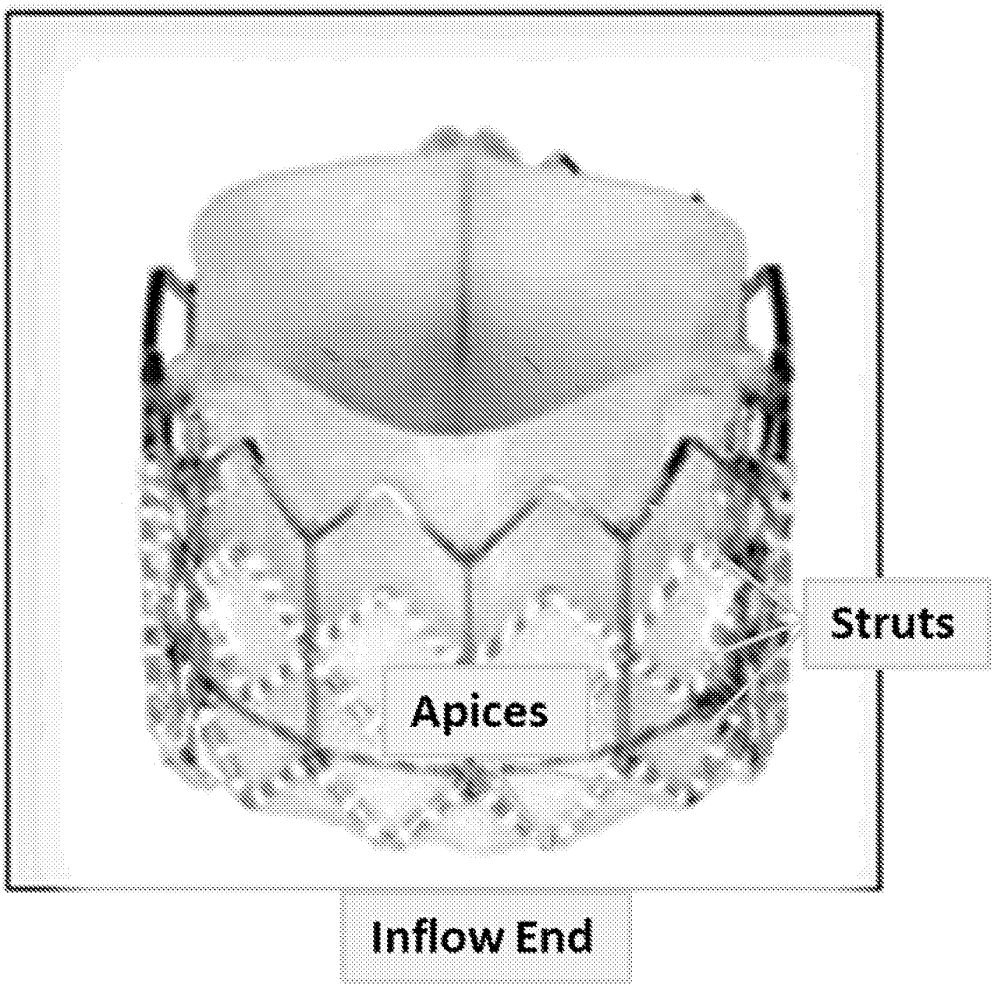
Id. A person of ordinary skill in the art would understand that the outflow end of the frame is necessarily located at a distal portion of the valve (i.e., furthest from the heart), and the inflow end of the frame is necessarily located at a proximal portion of the valve (i.e., closest to the heart) because the direction of blood flow through the aortic valve carries blood from the left ventricle, through the aortic valve, and away from the heart through the aorta:



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Available at: https://www.mayoclinic.org/diseases-conditions/aortic-valve-disease/symptoms-causes/syc-20355117#dialogId16413996.

116. In addition, as can be seen from Cribier's Figure 1, SAPIEN's outer frame is formed from a plurality of interconnected metallic struts that adjoin each other at the inflow end of the valve to form a plurality of apices:



Ex. 1012 (Cribier) at Fig. 1.

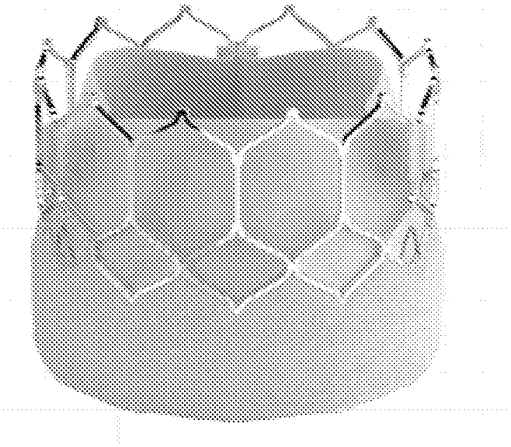
3. Inner Frame

117. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically

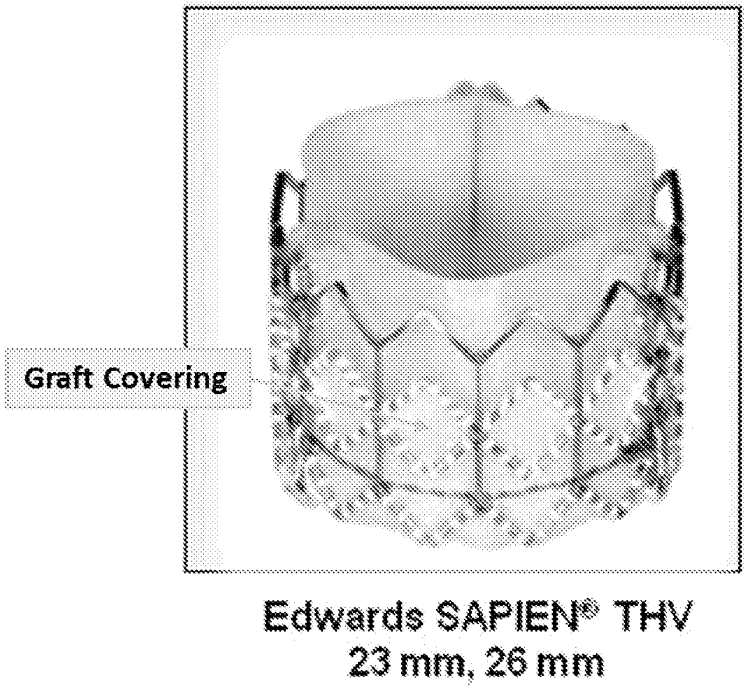
extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Cribier also discloses this limitation.

118. The claim states, "the inner frame ***includes*** a cylindrically extending inner graft covering." I understand that during prosecution of a related patent – U.S. Patent No. 10,966,846 (the "'846 patent") – Patent Owner argued the "includes" language in claim 12 requires only an inner frame that ***is*** a graft covering. Specifically, Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a "graft forming the inner frame." Ex. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 14. Patent Owner also argued that Petitioner's SAPIEN 3 Ultra product is "covered by the claimed invention" because it "includes an inner frame that is a graft." *Id.* at 21-22.

119. I am aware that the SAPIEN 3 Ultra THV (pictured below) has only one frame:



120. Cribier discloses that SAPIEN includes "a polyethylene terephthalate (PET) fabric cuff." Ex. 1012 (Cribier) at 348, Fig. 1. The PET fabric cuff is a "graft covering." Figure 1 below shows the fabric cuff, which is the whiter material that extends around the prosthetic heart valve at the lower end of the outer frame. As shown in the figure, the fabric cuff is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame:



Id. at Fig. 1.

121. SAPIEN's PET fabric cuff covers the inside surface of SAPIEN's outer frame. Based on Patent Owner's statements during prosecution of the related '846 patent, and to the extent an "inner frame" can be a graft covering, SAPIEN's PET fabric cuff satisfies this limitation.

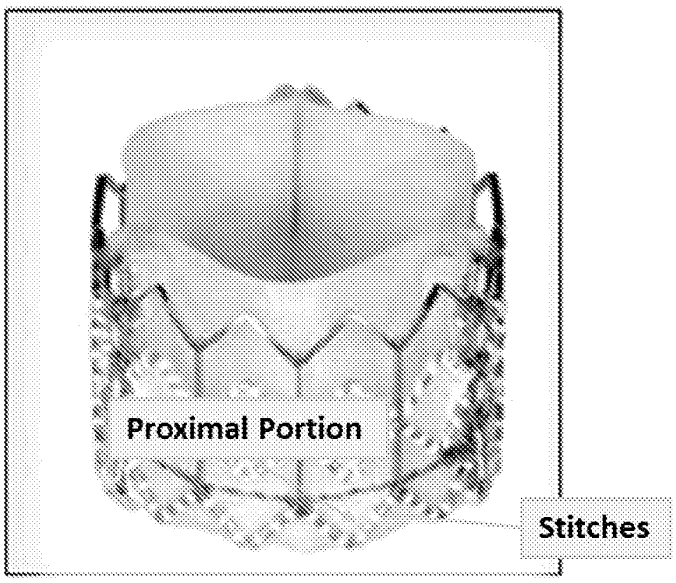
122. Cribier also discloses that SAPIEN includes a "unidirectional trileaflet bovine tissue valve." Ex. 1012 (Cribier) at 348. A person of ordinary skill in the art would therefore have understood that SAPIEN includes three "prosthetic leaflets" constructed from bovine tissue. SAPIEN's fabric cuff is stitched to the prosthetic leaflets along the blue suture line in the figure above, and thus the fabric cuff "engages" the prosthetic heart valve.

123. A person of ordinary skill in the art would have understood that the SAPIEN's PET fabric cuff provides sealing to the heart valve. Importantly, if the PET fabric cuff did not provide sealing to the heart valve, blood could leak around the valve and undermine the efficacy of the assembly. Further, many prior art publications recognized the sealing capabilities of the PET fabric cuff. *See e.g.,* Ex. 1009 (Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)) at 514 (describing "polyester fabric sealing cuff"); Ex. 1023 (Smith) at 154 (SAPIEN included a "higher sealing cuff…to reduce paravalvular leaks."); Ex. 1025 (Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009)) at 1830 ("The stent has a polyethylene terephthalate fabric skirt that decreases perivalvular leaks."); Ex. 1028 (Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011)) at 213 (SAPIEN "includes both the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize the paravalvular leak").

4. Stitching

124. Claim 1 next recites: "wherein the outer frame is secured to the inner graft overing by stitching a proximal portion of the outer frame." Cribier also discloses this limitation.

125. As shown in Cribier's Figure 1 (below), a plurality of white stitches secure SAPIEN's fabric cuff to the outer frame along the three lower rows of the frame. The stitches along the lowermost (i.e., proximal) row secure the fabric cuff to a proximal portion of the frame:



Ex. 1012 (Cribier) at 348, Fig. 1; *see also* Ex. 1028 (Roselli) at 213 ("The pericardial tissue is sewn to the frame using polytetrafluorethylene (PTFE) suture

and includes both the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize paravalvular leak.").

5. Outer Seal

126. Claim 1 next recites: "an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the outer frame, wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame." Cribier in combination with Walther renders the limitations of the outer seal obvious.

127. Walther's outer cloth, pictured in Figure 1 below, is positioned externally to the outer frame:

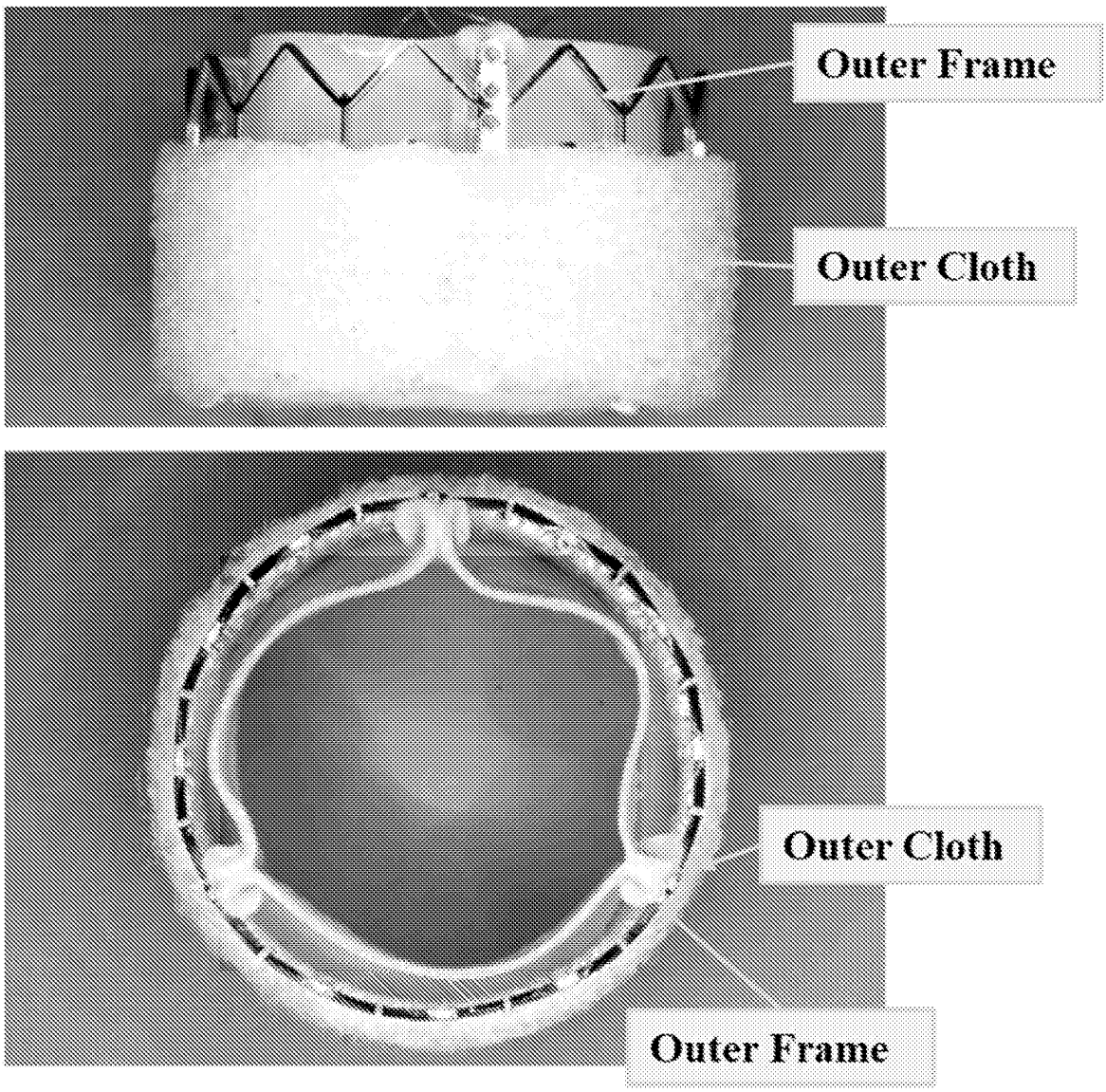
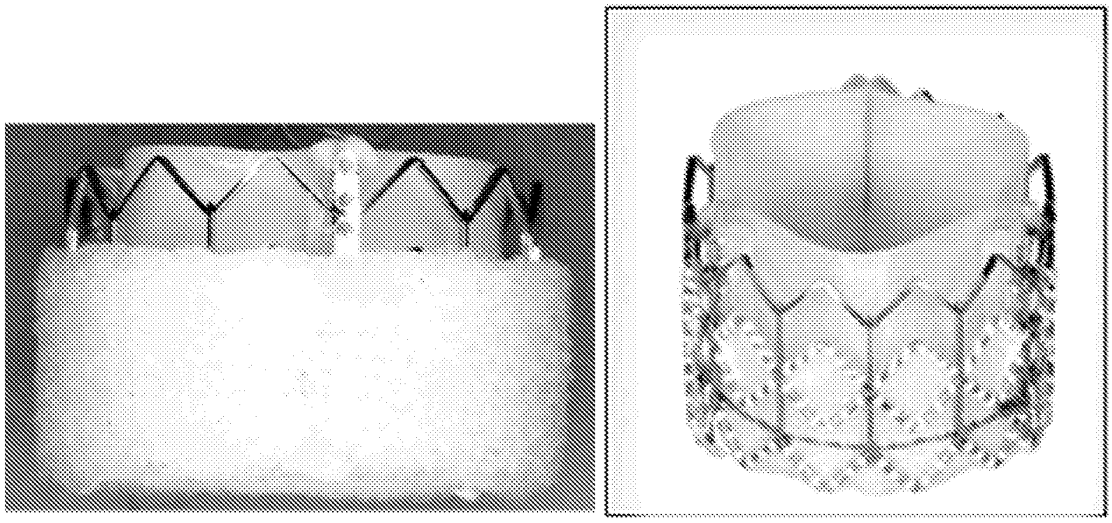


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at Fig. 1. The outer cloth is an outer seal for preventing paravalvular leaks. Walther states that the outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves." *Id.* at 1120. Based

upon the tests, Walther concluded that "the Edwards SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent hydrodynamic performance," indicating that the valve performed its sealing function well. *Id.* at 1125.

128. Walther's outer cloth partially extends over at least two most proximal rows of cells in SAPIEN's outer frame. *Id.* at 1121, Fig. 1. A side-by-side comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right) illustrates that Walther's outer cloth partially extends over the two proximal rows of SAPIEN's frame:

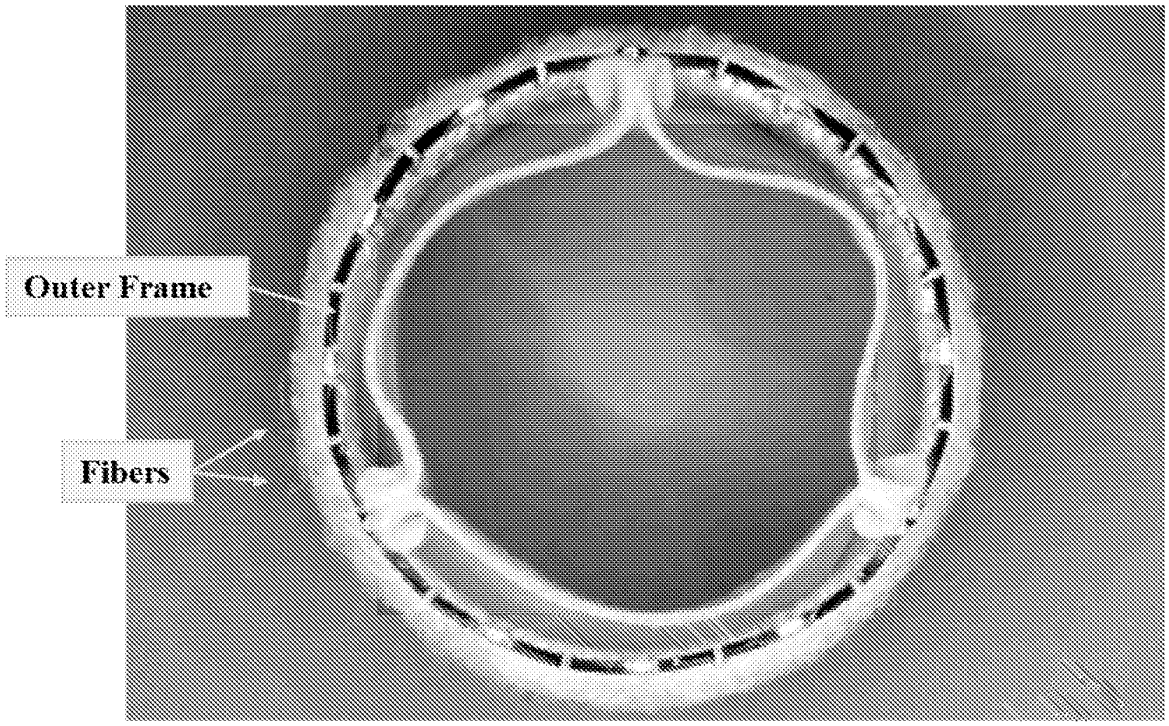


Compare id. at Fig. 1 *with* Ex. 1012 (Cribier) at Fig. 1.

129. During prosecution of the related '846 patent which similarly recites an outer seal "formed of outwardly extending fibers positioned externally to the outer frame," Patent Owner argued that an outer seal that ***includes*** outwardly

extending fibers satisfies this limitation. For example, Patent Owner argued that Petitioner's SAPIEN 3 Ultra product is "covered by the claimed invention" because it "includes . . . an outer seal that includes outwardly extending fibers." Ex. 1046, (Preliminary Amendment for Patent Application No. 17,096,253) at 21-22.

130. Walther's outer cloth includes a plurality of outwardly extending fibers that are positioned externally to the outer frame. In the figure below, one can see the fibers extending outwardly from the outer frame all around the external circumference of the valve. Moreover, many of the fibers are shown terminating outwardly of the valve:



Id. at 1121, Fig. 1. Therefore, based on Patent Owner's statements during the related prosecution, Walther's outer cloth is an outer seal "formed of outwardly extending fibers."

131. The above figure depicting fibers extending outwardly from the outer cloth is consistent with what a person of ordinary skill in the art would have expected from a cloth. A person of ordinary skill in the art would have expected radially extending fibers (like those shown above) because cloths are known to be made of woven fibers and have some amount of "hairiness." *See e.g.*, Ex. 1029 (Tyagi, G.K., *Chapter 5: Yarn structure and properties from different spinning techniques*, Advances in Yarn Spinning Technology (2010)); Ex. 1029 (Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004)). Additionally, Merriam-Webster defines "cloth" as "a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments." *Available at:* https://www.merriam-webster.com/dictionary/cloth.

132. Moreover, the fibrous exterior of Walther's outer cloth is not surprising. As demonstrated by Walther's PET outer cloth and SAPIEN's PET fabric cuff, PET can have a range of finishes. Here, Walther discloses that the PET outer cloth is required to "reduce paravalvular leaks" and "increase 'fit' within [Edwards's] surgical Perimount valves." Ex. 1007 (Walther) at 1120. A person of

ordinary skill in the art would have been motivated to select an outer cloth having fibrous finish, like the outer cloth shown in Figure 1 above, so that the radially extending fibers that extend outwardly of the outer frame fill the gaps between the SAPIEN and surgical valve. *See also id.* at 1126 (explaining that the outer cloth fills little gaps).

133. I am aware that Patent Owner has made representations about Walther during the prosecution of the '735 patent. Patent Owner's statements during prosecution misrepresent Walther's disclosure for the reasons I previously provided in my section discussing the '735 patent's prosecution history. *Supra* §IV.C.

134. A person of ordinary skill in the art would have been motivated to combine SAPIEN, as described in Cribier, with Walther's outer cloth because Walther expressly discloses this combination. Ex. 1007 (Walther) at 1020-1021. A person of ordinary skill in the art would have had a reasonable expectation of success in adding an outer cloth (as described in Walther) with SAPIEN (as described in Cribier) because Walther describes how to make the combination, provides images of the combination, and concludes that the cloth-covered SAPIEN "demonstrated excellent hydrodynamic performance." *Id.* at 1125. Additionally, Walther also discloses that the cloth-covered SAPIEN "has demonstrated acceptable *in vitro* central regurgitation performance in previous verification

studies, meeting minimum performance requirement standard per ISO 5840:2005 section 7.2.3." *Id.* at 1124.

6. Radially Compressed Orientation and Radially Expanded Orientation

135. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Cribier and Walther both disclose this limitation.

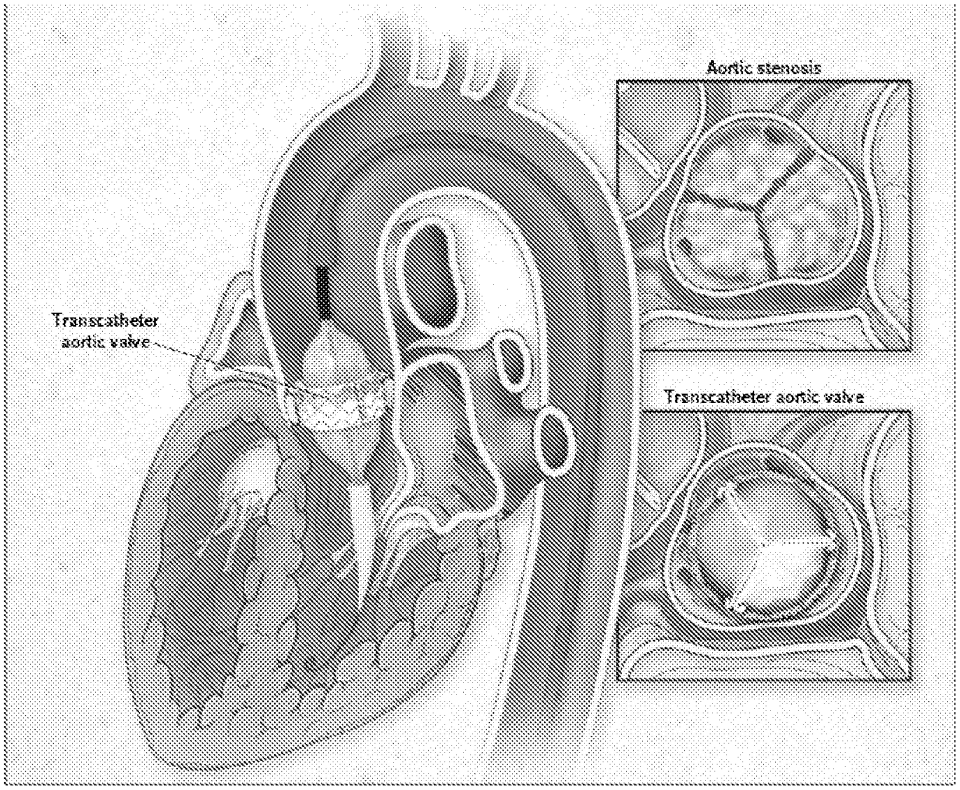
136. Cribier discloses that the SAPIEN is "***compressed*** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its ***expanded size*** to its 'mounted' size.'" Ex. 1012 (Cribier) at 348 (emphasis added). A person of ordinary skill in the art would have understood that SAPIEN's "mounted size" is a radially compressed orientation. Similarly, Walther discloses that the cloth-covered SAPIEN valves were crimped and then expanded within various surgical valves by a balloon catheter. Ex. 1007 (Walther) at 1122, Fig. 4. A person of ordinary skill in the art would have understood that SAPIEN is in a radially expanded position when, for example, it is expanded in the surgical valves (as in Walther) or a patient's native aortic valve (as in Cribier).

7. Fibers Press Against Native Leaflets

137. Claim next recites: "wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient." Cribier and Walther render this limitation obvious.

138. Cribier describes the "retrograde transfemoral" approach for implanting SAPIEN. Ex. 1012 (Cribier) at 347-355; *see also* Ex. 1009 (Conradi) at 515-516 (disclosing transfemoral and transapical approaches); Ex. 1024 (Webb) at 156-158 (same). In the transfemoral approach, SAPIEN is "introduced within the femoral artery, advanced to the native aortic valve under X-ray control, positioned across the aortic annulus, and delivered by balloon inflation under rapid heart pacing." Ex. 1012 (Cribier) at 347; *see also* Ex. 1009 (Conradi) at 514-517, Fig. 4A; Ex. 1028 (Roselli) at 209, 213. Consistent with the understanding in the art, the '735 patent identifies the annulus as the point where the leaflets begin. Ex. 1001 ('735 patent) at 1:58-60, Fig. 2; *see also* Ex. 1047 (Piazza) at 76 ("[T]he annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the [aortic] leaflets.").

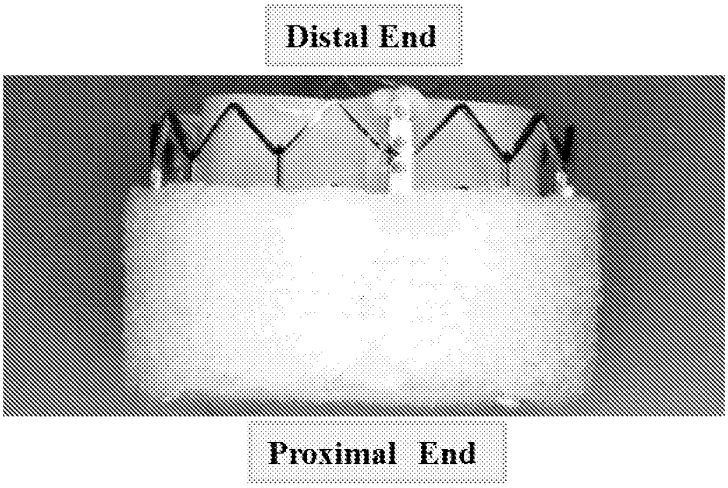
139. A person of ordinary skill in the art would have understood that balloon expansion of SAPIEN presses SAPIEN's frame against the native leaflets of the aortic valve. Cribier discloses that "one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT in order to minimize perivalvular leaks and avoid coronary occlusion." Ex. 1012 (Cribier) at 353-354. When expanded in this position, SAPIEN presses against and replaces the patient's native aortic leaflets, as illustrated in Figure 1 of the New England Journal of Medicine publication below:



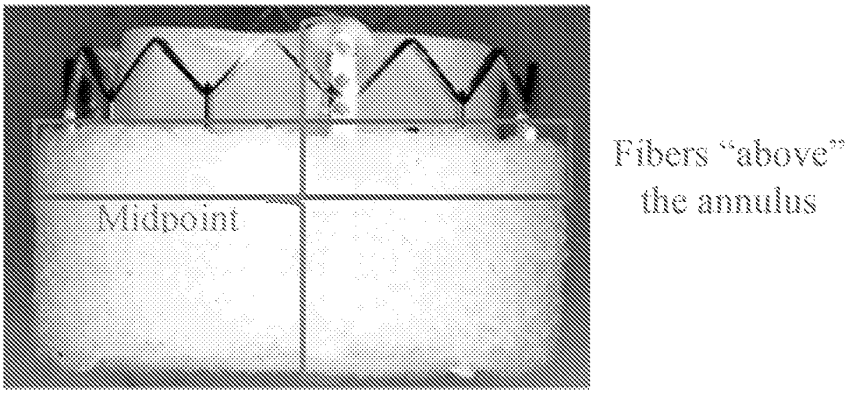
Ex. 1022 (Smith) 2189, Fig. 1; *see also* Ex. 1047 (Piazza) at 74 (disclosing that SAPIEN "is positioned within the aortic root and, once deployed, crushes the leaflets of the native valve against the wall").

140. Walther discloses the expansion of a cloth-covered SAPIEN within a surgical valve made by Petitioner. Ex. 1007 (Walther) at 1121, Fig. 2. Expansion of the valve presses the outer cloth (i.e., outer seal) against the surgical valve's prosthetic leaflets. *Id.* at Fig. 2; *see also id.,* 1120-1121. A person of ordinary skill in the art would have understood that expanding the cloth-covered SAPIEN in a native aortic valve, as described in Cribier, would press the outer cloth (i.e., outer

seal) against the patient's native leaflets. As I explained previously, Walther's outer cloth covers the two proximal rows of SAPIEN's outer frame:



Id. at Fig. 1. If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, the fibers "above the annulus" would press against the leaflets, as illustrated below:



See also supra §III.B (discussing the anatomy of the aortic valve and the location of the annulus and leaflets). In fact, Patent Owner admitted this was the case

during prosecution of the related '846 patent. Patent Owner stated that the "limitation of the fibers covering at least two rows of open cells provides an improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets." Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 25.

141. A person of ordinary skill in the art would have found it obvious to deploy Walther's cloth-covered SAPIEN within a patient's native valve. A person of ordinary skill in the art would have been motivated to do so to reduce paravalvular leaks. (*Id.*) As explained previously, Walther describes deploying the cloth-covered SAPIEN within an Edwards surgical valve "to reduce paravalvular leak by creating a seal between the two valves." *Id.* at 1120. Walther's outer cloth creates a seal by pressing against the surgical valve. *See e.g., id.*, Fig. 2.

142. Cribier discloses that SAPIEN "can be implanted within the diseased native aortic valve using either the retrograde transfemoral or antegrade transapical routes." Ex. 1012 (Cribier) at 347; *see also id.* (SAPIEN is "positioned across the aortic annulus"). The implanted SAPIEN provides sealing between the outer frame and the patient's anatomical wall to "minimize perivalvular leaks." *Id.* at 353; *see also id.* at 354 (describing issues that may cause "perivalvular insufficiency"); *see also* Ex. 1009 (Conradi) at 516-517, Fig. 4A; Ex. 1024 (Webb)

at 156-158; Ex. 1012 (Cribier) at Abstract, 350-355; Ex. 1028 (Roselli) at 208-210, 214.

143. However, despite the success of SAPIEN, persons of ordinary skill in the art in November 2012 understood that paravalvular leaks could still occur between SAPIEN's outer frame and the patient's native valve. *See e.g.*, Ex. 1012 (Cribier) at 354 (disclosing that the "vast majority of aortic insufficiency seen on post implantation angiography" with the SAPIEN valve "is perivalvular"; Ex. 1023 (Smith) at 2194 (reporting that 12.2% of patients who received transcatheter implantation of the SAPIEN valve experienced moderate or severe paravalvular leakage at 30 days). This well-known problem would have motivated a person of ordinary skill in the art to apply Walther's known technique for reducing paravalvular leakage (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement. The performance of the cloth-covered SAPIEN would have been predictable because, for example, Walther explains that the cloth-covered valve performed well in testing. Ex. 1007 (Walther) at 1124-25.

144. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying the cloth-covered SAPIEN in a patient's native aortic valve. Walther discloses that the cloth-covered SAPIEN "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation

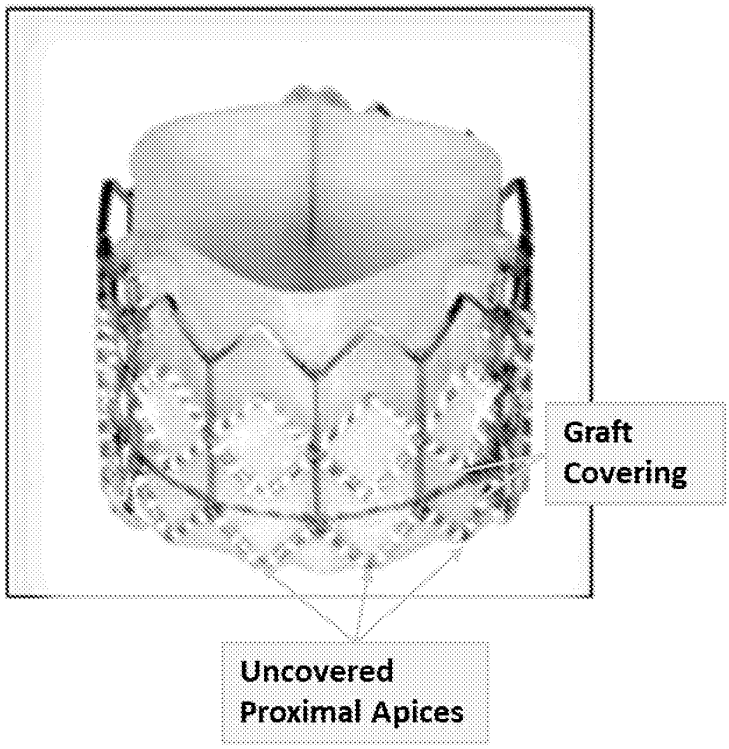
procedure "is feasible." Ex. 1007 at 1125. Walther also discloses that the cloth-covered SAPIEN "demonstrated acceptable *in vitro* central regurgitation performance in previous verification studies. *Id.* at 1124. Moreover, persons of ordinary skill in the art had studied implantation of SAPIEN within a patient's native aortic valve using both the transfemoral and transapical approaches and deemed the procedures safe by November 2012. *See e.g.,* Ex. 1012 (Cribier) at 355 ("Transcatheter valve implantation with the Edwards-Sapien Heart Valve can be done safely and efficiently using the transfemoral retrograde approach."); *id.,* 347 (recognizing that SAPIEN can be implanted using "antegrade transapical routes"); Ex. 1009 (Conradi) at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively). A person of ordinary skill in the art would therefore have reasonably expected success in implanting the cloth-covered SAPIEN valve within a patient's native aortic valve.

8. <u>Uncovered Proximal Apices</u>

145. Claim 1 next recites: "wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering." Cribier in combination with Walther renders this limitation obvious.

146. As I explained previously, Cribier discloses that SAPIEN includes an inner PET fabric cuff stitched to the interior surface of the outer frame. *Supra*

§VI.A.3. As shown below, an end of the most proximal apices of SAPIEN's outer frame are uncovered by the fabric cuff, which is the whiter material in the figure:



Ex. 1012 (Cribier) Fig. 1.

147. As I explained above, Walther discloses a modified SAPIEN with an outer PET cloth stitched to the exterior of the valve. *Supra* §VI.A.5. Walther discloses that the outer cloth is stitched to the "perimeter" of the SAPIEN valves, and there is no teaching or suggestion that the outer cloth wraps around or covers the proximal apices of the valve. Ex. 1007 (Walther) at 1121. Additionally, the outer cloth is not sutured to the inside of the valve or visible inside the valve:

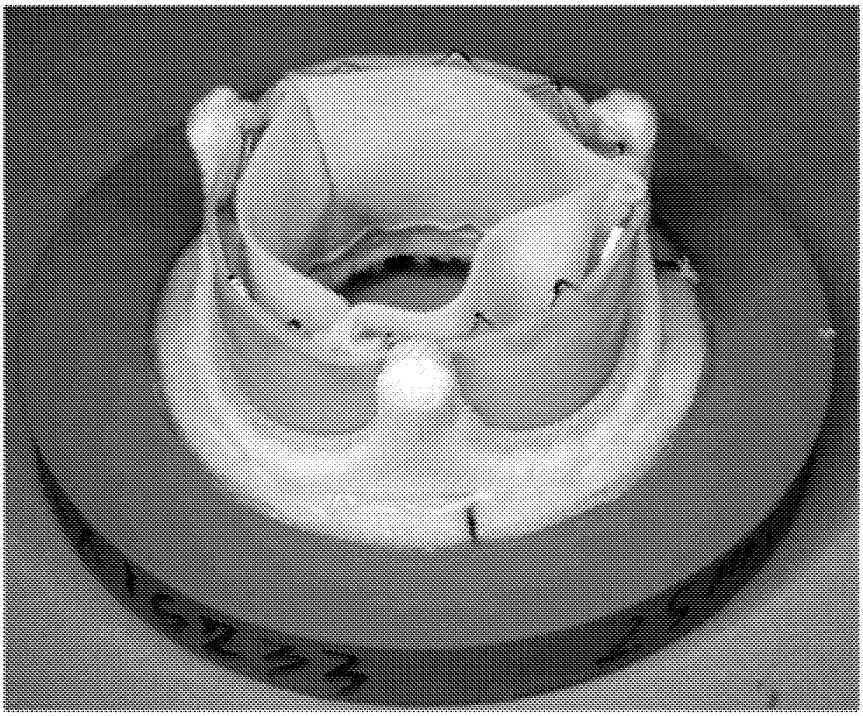


Fig. 2. Cloth THV valve deployed in surgical valve.

Id. at Fig. 2 (excerpt). Therefore, a person of ordinary skill in the art would understand that Walther's outer cloth does not cover the ends of the proximal apices. However, even if Walther's outer cloth extends over the ends of the most proximal apices, a person of ordinary skill in the art would have found it obvious to adjust the size and placement of the outer cloth such that the outer cloth does not extend beyond and over the ends of the most proximal apices. A person of ordinary skill in the art would have been motivated to do so to accommodate the lengthening and shortening of the stent frame that occurs when the valve is compressed and expanded, ensuring a more uniform crimped profile. *See* Ex. 1008 (Levi) at 9:39-44. A person of ordinary skill in the art would understand that

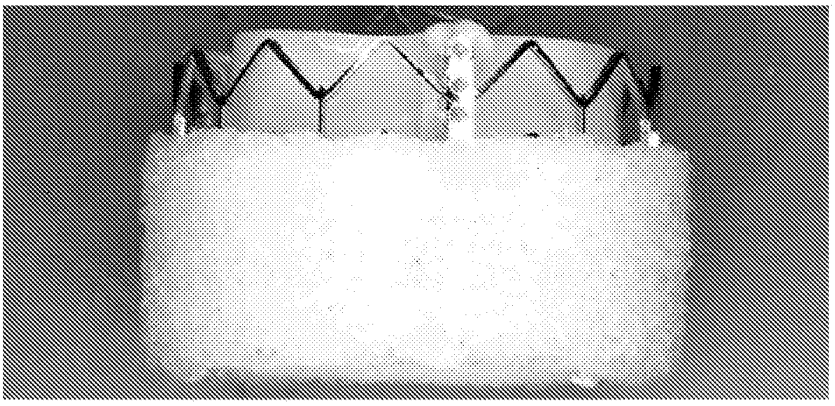
leaving the proximal ends of the outer frame uncovered would help ensure that the outer cloth does not restrict the lengthening or shortening of the valve.

148. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so because the resulting PET cloth would still cover most of the proximal two rows of the frame, providing ample surface area to seal the patient's native tissue and prevent paravalvular leaks.

9. <u>Proximal Apices Extend More Proximally than Outer Seal</u>

149. Claim 1 concludes by reciting: "wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." Cribier in combination with Walther renders this limitation obvious.

150. As I explained above, Walther discloses a modified SAPIEN with an outer PET cloth stitched to the exterior of the valve. *Supra* §VI.A.8. Walther's figures illustrate that in its expanded configuration, Walther's outer seal extends roughly the same distance proximally as the most proximal apices:



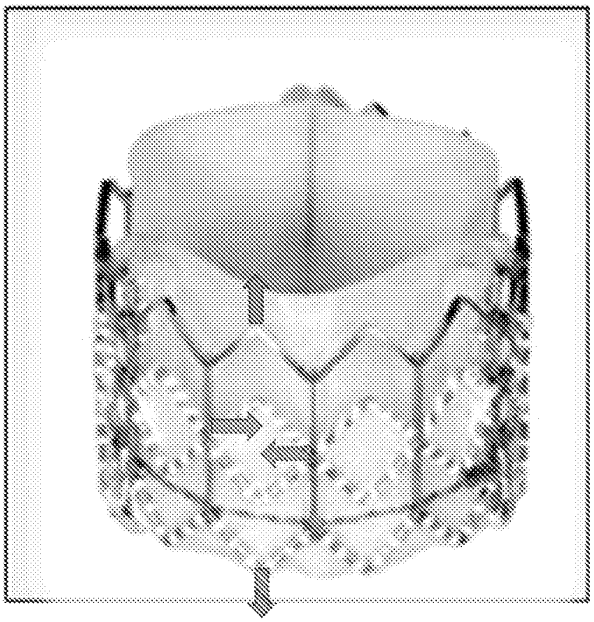
Ex. 1007 (Walther) at Fig. 1. However, Walther teaches that its fibrous outer cloth does not need to cover the entire exterior of the SAPIEN valve, as illustrated by the uppermost row of cells that are uncovered in Figure 1. *See id.* Instead, Walther teaches that the fibrous outer cloth must cover SAPIEN over the area that will press against and seal with the existing annulus and leaflets to form a seal with the existing valve. *Id.* at 1120. The proximal apices of the proximal cells would lie below the annulus when a SAPIEN valve is correctly positioned. *See supra* §VI.A.7. Indeed, Walther teaches that its cloth-covered SAPIENs were positioned within the surgical valves such that the "bottom of the frame of the cloth valve is 2 ± 2 mm below the bottom of the surgical valve." Ex. 1007 (Walther) at 1122. Accordingly, a person of ordinary skill in the art would understand that the most proximal ends of the proximal apices of Walther's cloth-covered SAPIEN would lie below the annulus and native leaflets when implanted in a patient's native valve. Because the proximal ends of the frame do not press against the annulus or native tissue, a person of ordinary skill in the art would understand that they do not need to be covered by the outer cloth.

151. A person of ordinary skill in the art would have therefore found it obvious to adjust the size and placement of the outer cloth such that the most proximal apices of the outer frame extend proximally further than the outer cloth. Persons of ordinary skill in the art were motivated to routinely adjust the size and

shape of outer cloths to maximize sealing while minimizing the profile of the cloth. The variety of outer seals disclosed in Spenser II, for example, illustrates this point. *See e.g.*, Ex. 1011 (Spenser II) at Figs. 20a-22. As I previously explained, persons of ordinary skill in the art had access to many suitable cloths having varying thicknesses and densities and naturally tried different cloths having different dimensions and placements. *Supra* §VI.A.1. Walther, Spenser II, and Levi reflect that persons of ordinary skill in the art knew how to attach different types and shapes of outer cloths to heart valves. *See e.g.*, Ex. 1007 (Walther) at Fig. 1; Ex. 1011 (Spenser II) at Fig. 22; Ex. 1008 (Levi) at Figs. 1, 42-43. Persons of ordinary skill in the art would have been motivated to position Walther's outer cloth so that the apices extend more proximally because such placement would reduce the amount of cloth material on the outside of the valve, minimizing the crimped profile. Additionally, such placement would help ensure that the outer cloth does not restrict expansion of the proximal apices of the frame when the device is implanted in patients.

152. Walther does not picture the valve in the crimped (i.e., compressed) configuration. However, a person of ordinary skill in the art would have expected that when crimped, the ends of the outer frame's most proximal apices would elongate in the proximal direction. SAPIEN's frame elongates when crimped and foreshortens when expanded. *See* Ex. 1012 (Cribier) at Fig. 2 (illustrating

foreshortening of SAPIEN when expanded). When the device is crimped and the vertical frame struts move towards each other (green arrows), the ends of the frame move away from each other (red arrows):



When this happens, the ends of the most proximal apices of the outer frame would extend proximally further than they do in the expanded configuration. Thus, a person of ordinary skill in the art would understand that even without any modification, the proximal apices of Walther's outer frame may extend proximally further than the outer cloth when the valve is crimped. And where the positioning of Walther's outer cloth is modified as I propose above, the proximal apices would

continue to extend proximally further than the outer cloth when the valve is crimped.[5]

153. A person of ordinary skill in the art would have had a reasonable expectation of success in slightly adjusting the position or size of Walther's outer cloth so that the proximal apices extended further proximally than the cloth. The necessary adjustments to expose the proximal apices would be minimal and the cloth would still provide ample surface area to seal against the patient's native tissue and prevent PVL. Indeed, because thee proximal end of Walther's cloth-covered valve is positioned below the existing valve, as I explained above, repositioning the outer cloth slightly higher on the valve would not impede the

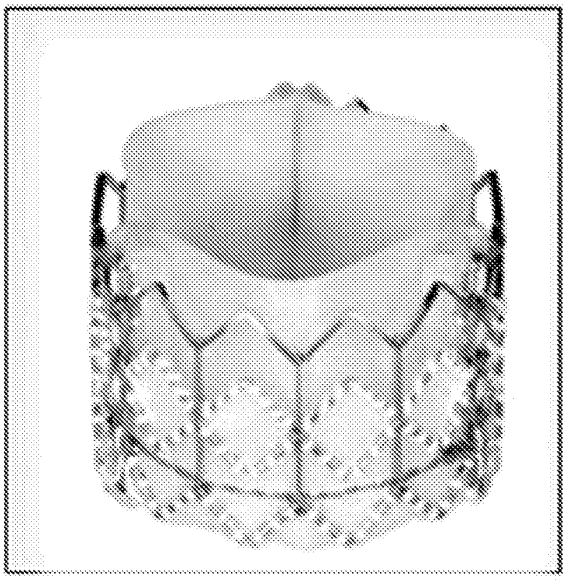
[5] A person of ordinary skill in the art would understand that claim 1 requires the outer frame's proximal apices to extend proximally further than the outer seal both when the valve is in its compressed configuration, and when the valve is in its expanded configuration. As noted above, claim 1 requires the valve to include both a compressed and an expanded configuration. *Supra* §VI.A.6. There is no teaching or suggestion in the '735 patent that the positioning of the proximal apices relative to the outer seal changes when the valve is compressed or expanded. A person of ordinary skill in the art would therefore understand that the plain and ordinary meaning of claim 1 requires the valve to practice the "proximal apices" limitations in both the expanded and compressed configurations.

fibers from sealing against the patient's native leaflets to prevent paravalvular leaks.

B. Claim 3

154. Claim 3 recites: "The valve assembly of claim 1, wherein the outer frame is a singular, integral component." Cribier discloses the limitation in claim 3, and, based on claim 1, Cribier and Walther render claim 3 obvious.

155. Cribier discloses that SAPIEN's frame is a "tubular slotted stainless-steel balloon-expandable stent." Ex. 1012 (Cribier) at 348. SAPIEN's frame was laser cut from a single stainless-steel tube. As shown below, SAPIEN's stent (i.e., outer frame) comprises a "singular, integral component":



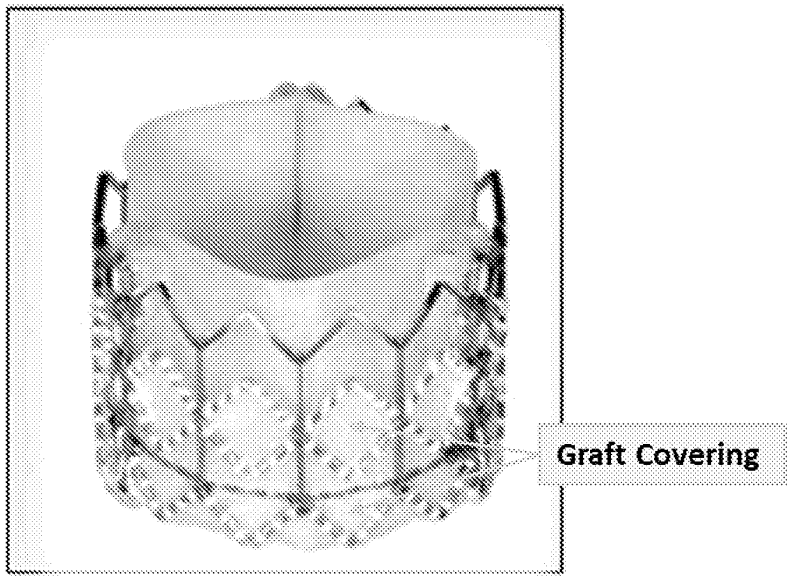
Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 at 348, Fig. 1.

C. Claim 4

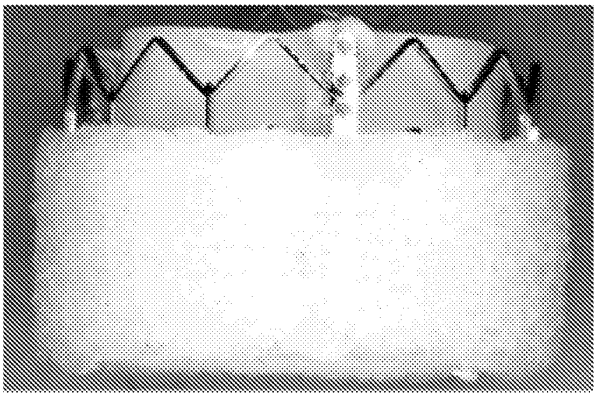
156. Claim 4 recites: "The valve assembly of claim 1, wherein the inner graft covering and the fibers are distinct elements." Cribier and Walther render this claim obvious.

157. Cribier discloses that SAPIEN includes an internal fabric cuff at the base of the device (i.e., inner graft covering) that is stitched to the inner surface of the stent frame. Ex. 1012 (Cribier) at 348. The whiter material in the below figure is the fabric cuff:



Id. at Fig. 1.

158. Walther's outer PET cloth (i.e., fibers) "was stitched to the perimeter of each SAPIEN valve":



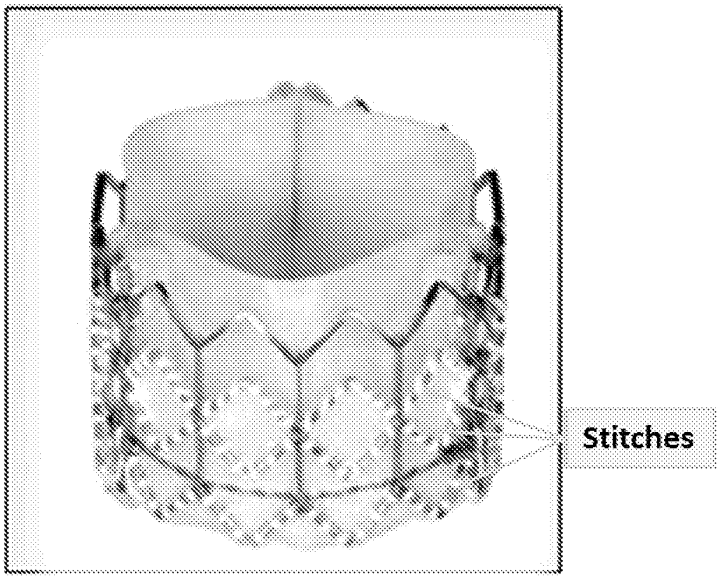
Ex. 1007 at 1121, Fig. 1 (excerpt). A person of ordinary skill in the art would have understood that the fibers comprising Walther's outer cloth are a "distinct element" from SAPIEN's internal fabric cuff because the outer cloth and internal cuff reside on opposite sides of the frame and are separately stitched to the frame. The above figures illustrate that the outer cloth and fabric cuff are "distinct elements."

D. Claim 5

159. Claim 5 recites: "The valve assembly of claim 1, wherein a seal is created between the inner frame and the outer frame." Cribier in combination with Walther renders this claim obvious.

160. Cribier discloses that SAPIEN includes a "fabric cuff." Ex. 1012 (Cribier) at 348, Fig. 1. As explained in claim 1, if an "inner frame" can be a "graft covering," SAPIEN's fabric cuff is an inner frame. A seal is created between the inner frame and the outer frame to prevent blood from leaking through or around the device (i.e., paravalvular leakage). *See e.g.*, Ex. 1016 (Alkashkari) at 23 (SAPIEN includes a "fabric-sealing cuff covering the lower portion of the stent

[that] facilitates a seal with the calcified conduit and prevents paravalvular leaks"). A person of ordinary skill in the art would have understood that a seal is created between the sealing cuff and SAPIEN's stainless steel stent because a plurality of sutures securely attach the cuff to the stent, as shown below:



Edwards SAPIEN® THV
23 mm, 26 mm

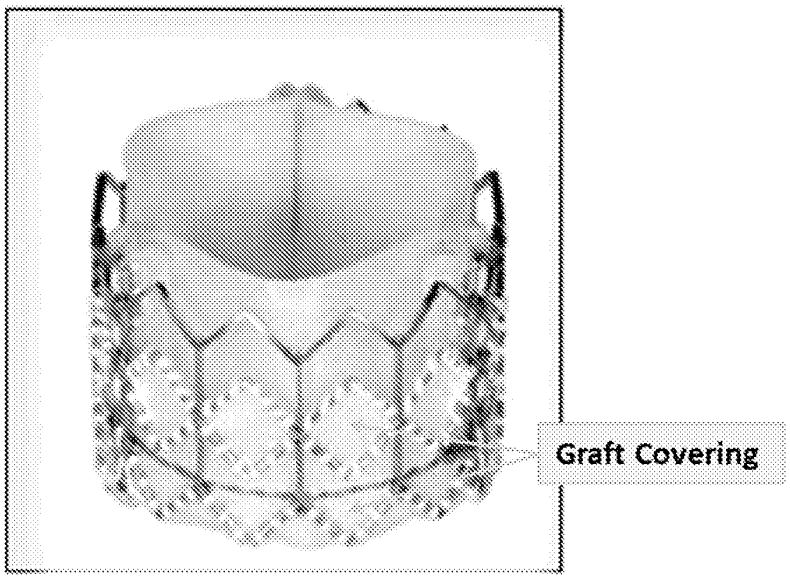
Ex. 1012 at Fig. 1. Additionally, a person of ordinary skill in the art would have understood that SAPIEN would not work if a seal did not exist between the cuff and stent because blood could disadvantageously leak between the cuff and stent.

E. Claim 6

161. Claim 6 recites: "The valve assembly of claim 1, wherein a portion of the outer frame is uncovered by the graft covering and the outer seal." Cribier in combination with Walther renders this claim obvious.

162. First, I note that Claim 1 requires that an end of the most proximal apices of the outer frame, which are a "portion of the outer frame," are uncovered by the inner graft covering and the outer seal. Therefore, Cribier and Walther render this claim obvious for the reasons I provided in claim 1. *Supra* §VI.A.8.

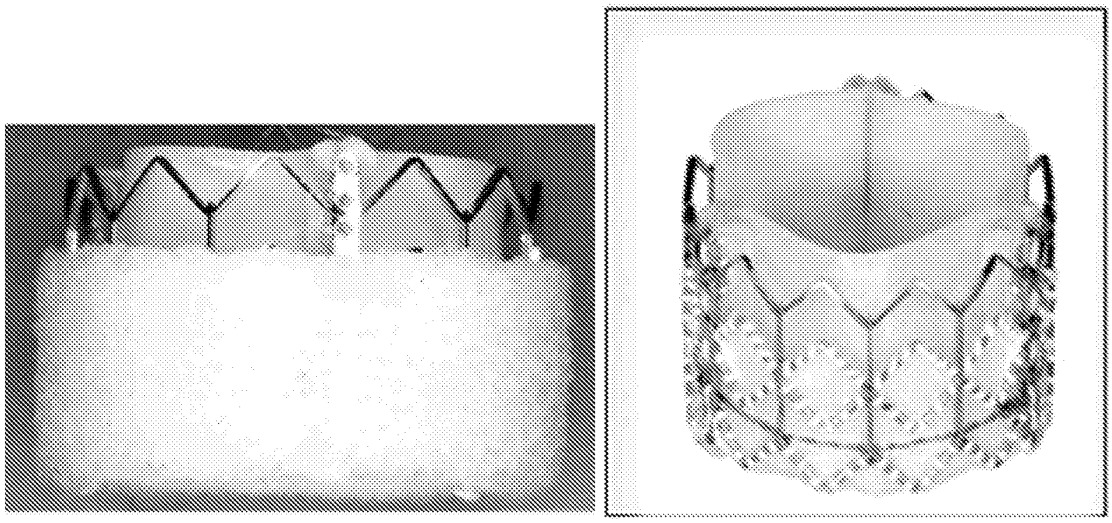
163. As I explained in claim 1, Cribier discloses that SAPIEN includes an internal fabric cuff at the proximal end (lower end in the picture below) of the device (i.e., inner graft covering) that is stitched to the inner surface of the stent frame. *Supra* §VI.A.3-4; Ex. 1012 (Cribier) at 348. SAPIEN's inner graft covering, which is the whiter material in the figure below, covers the proximal two rows of cells of SAPIEN's outer frame but ***does not*** cover the uppermost row of cells, as shown in Cribier's Figure 1 below:



Edwards SAPIEN® THV
23 mm, 26 mm

Id. at Fig. 1.

164. As further explained in claim 1, Walther's outer cloth (i.e., outer seal) covers the bottom two rows of cells of SAPIEN's outer frame. *Supra* §VI.A.5. Walther's outer cloth does not cover the uppermost row of cells of SAPIEN's frame, as illustrated in the side-by-side comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right):



Compare Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1012 (Cribier) at Fig. 1.

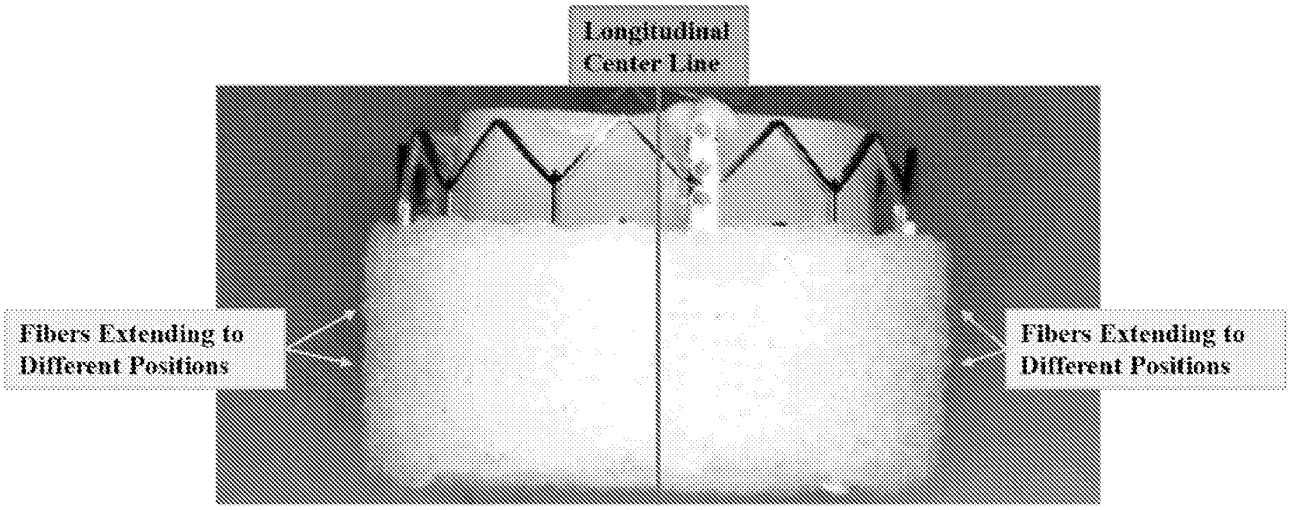
165. Therefore, the uppermost row of cells in Walther's cloth-covered SAPIEN valve, which is a "portion of the outer frame," is uncovered by both the inner fabric cuff (inner graft covering) and the outer cloth (outer seal).

F. <u>Claim 8</u>

166. Claim 8 recites: "The valve assembly of claim 1, wherein the outwardly extending fibers extend outwardly to different positions relative to a

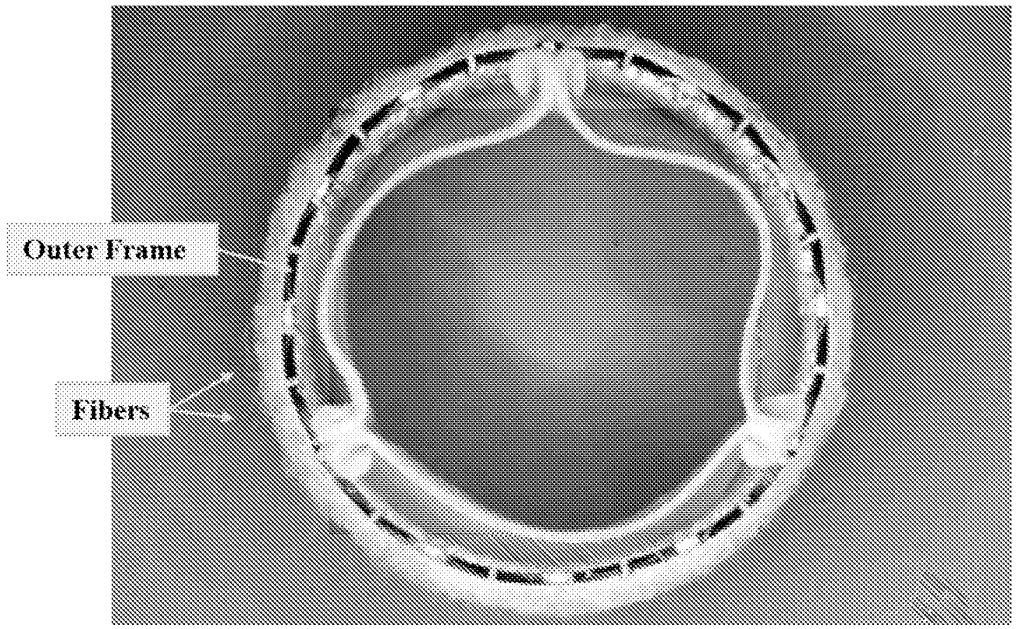
centerline run through a longitudinal of the valve assembly." Cribier in combination with Walther renders this claim obvious.

167. As I explained in claim 1, Walther discloses a modified SAPIEN valve with PET cloth sutured to the exterior of the outer frame, and Walther's outer cloth is formed from a plurality of outwardly extending fibers. *Supra* §VI.A.5. Walther's outer cloths surrounds the valve and, therefore, the fibers extend to the left and right of a longitudinal centerline. Thus, Walther's outer cloth includes outwardly extending fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly":



Ex. 1007 (Walther) at Fig. 1 (excerpt).

168. Additionally, Walther's outer cloth is not uniform. As shown below, some fibers extend further out from the frame than others:



Thus, even the fibers on the same side of the valve (relative to the centerline) "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly."

G. Claim 9

169. Claim 9 recites: "The valve assembly of claim 1, wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping." Cribier in combination with Walther renders this claim obvious.

170. The '735 patent does not use the term "radially overlapping" outside of the claims; however, I understand that in a Preliminary Amendment during prosecution of a related patent that shares a specification with the '735 patent, U.S. Patent No. 10,881,538 (the "'538 patent"), Patent Owner relied on Figure 11 of the '538 patent as providing support for the limitation requiring that the two rows of

grids covered by the fibers of the outer seal "radially overlap with the prosthetic leaflets." Ex. 1056 ('538 Prosecution History Excerpt) at 149-150.[6] Figure 11 below illustrates the collagen fibers 234 the prosthetic leaflets 32, which Patent Owner has described as radially overlapping:

[6] Patent Owner's representations in the Preliminary Amendment related to what was then claim 15, which recited: "The method of claim 2, wherein the fibers cover at least two circumferentially extending rows of grids formed in the open cell configuration and the at least two circumferentially extending rows radially overlap with the prosthetic leaflets." Ex. 1056 ('538 Prosecution History Excerpt) at 149-150. Patent Owner subsequently amended claim 15 to recite the language that ultimately became claim 3 in the issued '538 patent. The differences in the language between originally filed claim 15 and claim 3 of the '538 patent do not impact my analysis here.

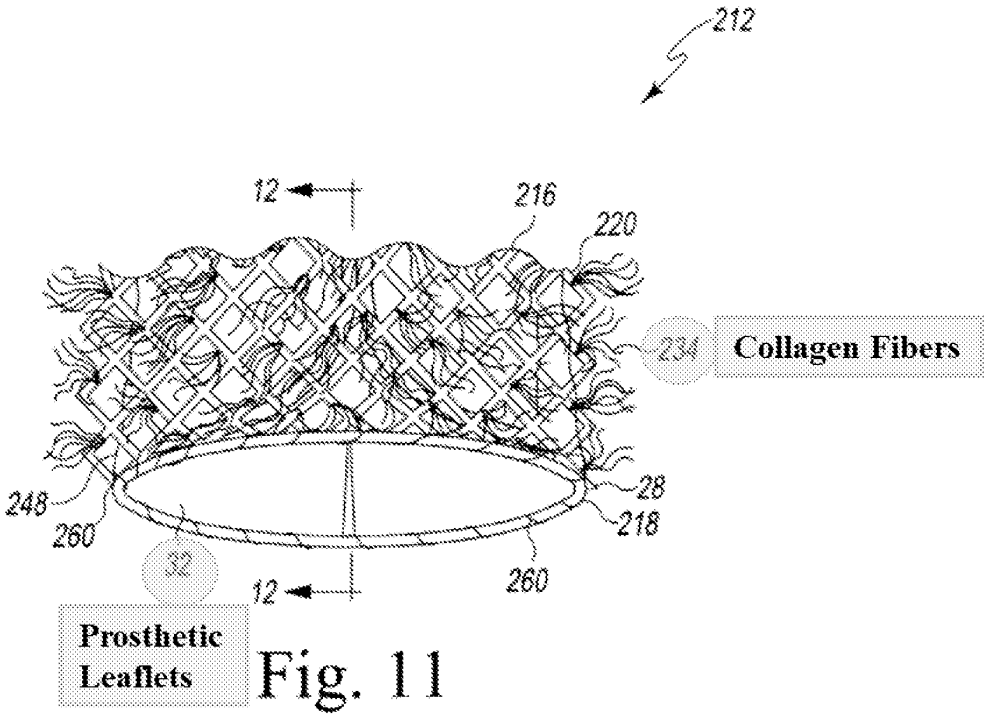
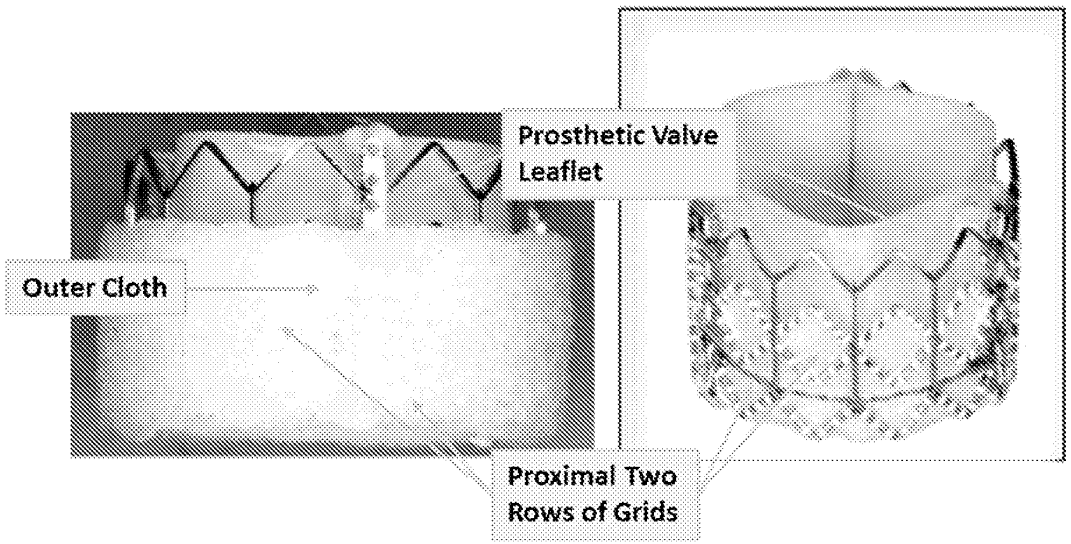


Fig. 11

Ex. 1001 at Fig. 11.

171. Walther's outer cloth, inner PET fabric cuff, and leaflets are positioned in the same way as the collagen fibers, graft covering, and leaflets in Figure 11 above. As I explained in claim 1, Walther's outer cloth (i.e., fibrous network) covers the two most proximal rows of cells in SAPIEN's outer frame. *Supra* §VI.A.5. SAPIEN's leaflets are sutured to the inner graft covering at the green suture line visible in Cribier's Figure 1 (below right). As shown below, the green suture line is located within the proximal row of cells. Thus, the two proximal rows of cells covered by Walther's outer cloth radially overlap with

SAPIEN's prosthetic leaflets and inner fabric cuff, as illustrated in the side-by-side comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right) below:

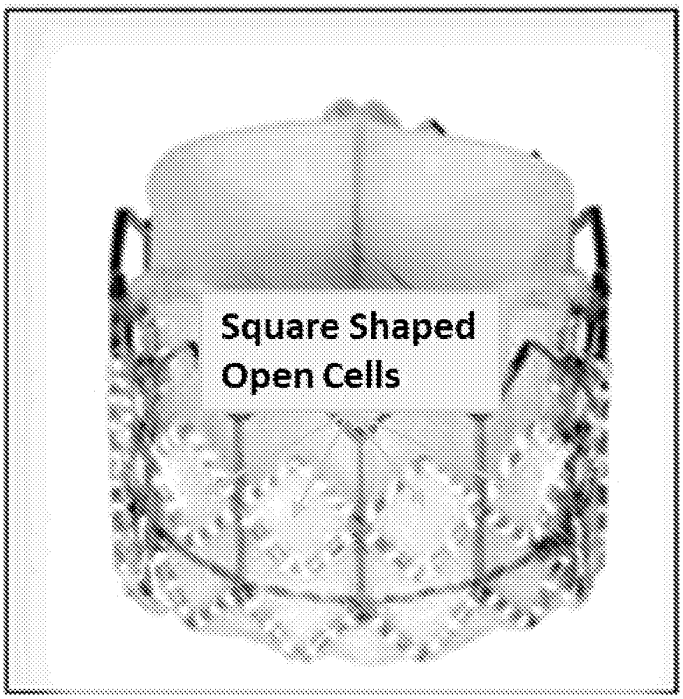


Supra §§VI.A.5, VI.E; *compare* Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1012 (Cribier) at Fig. 1. Therefore, the outer cloth (outer seal), inner fabric cuff (graft covering), and prosthetic leaflets are radially overlapping at least along the two proximal rows of the device.

H. Claim 11

172. Claim 11 recites: "The valve assembly of claim 1, wherein open cells of the open cell configuration area are a square shape." Cribier discloses the limitation in claim 11, and, based on claim 1, Cribier and Walther render claim 11 obvious.

173. SAPIEN's outer frame comprises three rows of open cells, and as shown in Cribier's Figure 1 below, the cells of the middle row each form a square shape:



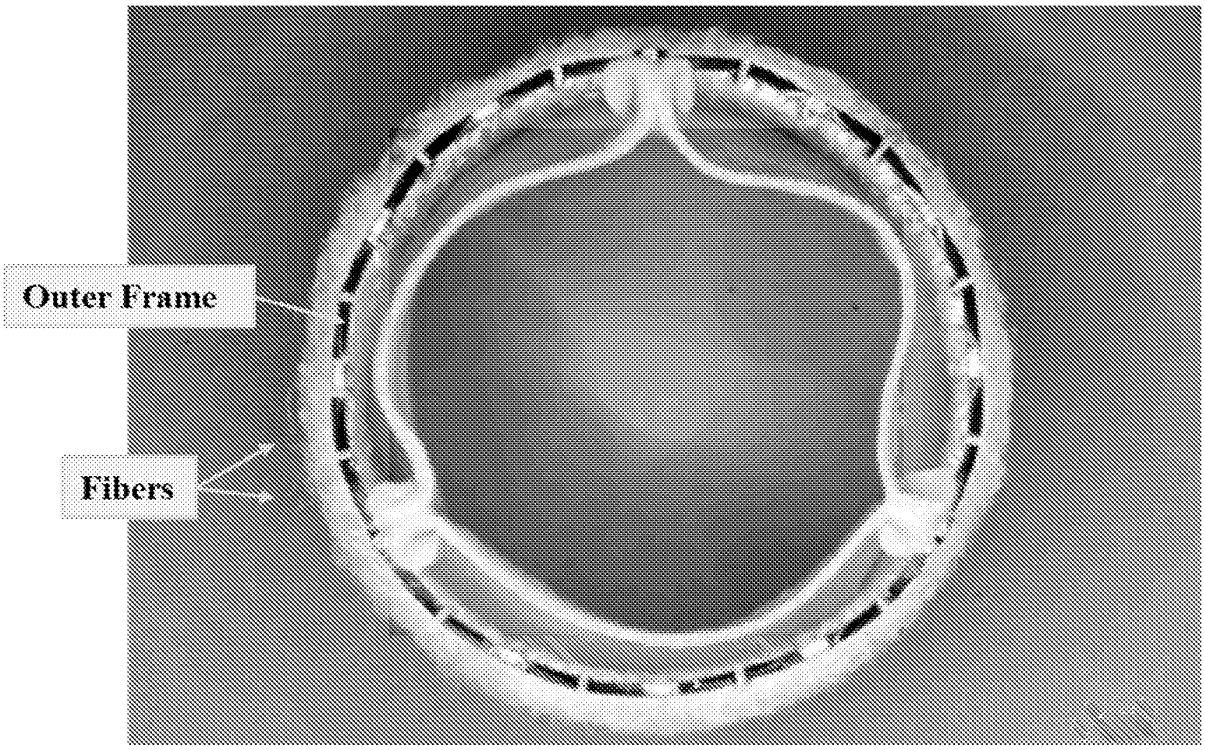
Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 (Cribier) at Fig. 1.

I. Claim 12

174. Claim 12 recites: "The valve assembly of claim 1, wherein the outer seal is free of a non-porous graft covering." Cribier in combination with Walther renders this claim obvious.

175. Walther's outer cloth (i.e., "outer seal") is "free of a non-porous graft covering." As shown in figure 1 below, the fibers of the outer cloth are directly attached to the metal bars of the outer frame:



Id. at Fig. 1. Walther discloses that the outer cloth was stitched to the perimeter of SAPIEN valves that were "identical" to the existing SAPIEN except for the outer cloth. *Id.* at 1120. Walther never states that any graft covering was positioned between the outer cloth and outer frame, and no such graft covering is visible in the figure above. *See id.* at Fig. 1. As shown in Cribier's Figure 1 below, SAPIEN does not include any "non-porous graft covering" on the exterior surface of the outer frame:



Edwards SAPIEN® THV
23 mm, 26 mm

Ex. 1012 (Cribier) at Fig. 1. Therefore, a person of ordinary skill in the art would understand that when Walther's outer cloth was added and stitched to the exterior of SAPIEN's outer frame, there would be no "non-porous graft covering" between the outer cloth and the outer frame.

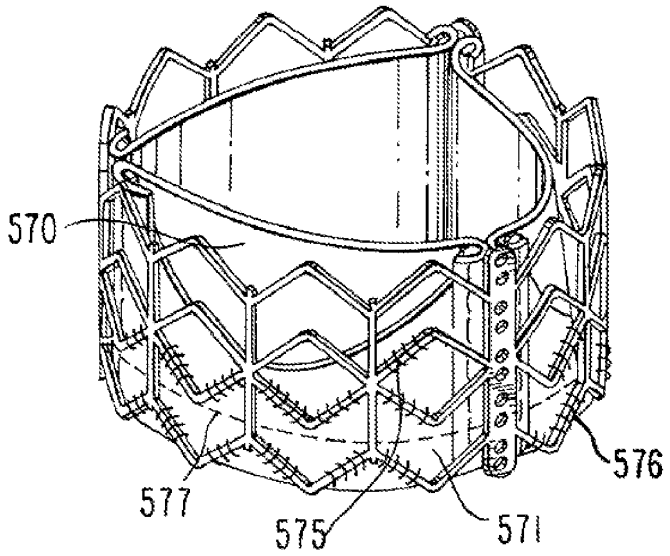
176. In addition, as I explained above in the section discussing the '735 patent's prosecution history, a person of ordinary skill in the art would not have understood Walther to disclose "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft," as argued by Patent Owner during prosecution of the '735 patent. *Supra* §IV.C. Instead, a person of

ordinary skill in the art would understand that Walther's outer cloth is simply a PET cloth, as Walther clearly states, that is free of a "non-porous graft covering."

VII. GROUNDS 2-3: CLAIMS 1-9, 11-12 OBVIOUS OVER SPENSER AND WALTHER OR SPENSER II

177. Spenser describes heart valve assemblies similar to SAPIEN including the below embodiment, which is shown in Figure 44a of Spenser:

FIG. 44a



Ex. 1010, Fig. 44a. Figure 44a is very similar (if not identical) to SAPIEN. The SAPIEN Instructions for Use ("IFU") identify Spenser as potentially covering SAPIEN. Ex. 1040 at 8.

178. As I explained in Ground 1, Walther discloses a modified SAPIEN that includes an added outer cloth. *Supra* §VI.A.5. Similarly, Spenser II discloses

a prosthetic stented valve that includes a layer of "compressible material" disposed along the outer surface of the stent structure" to reduce paravalvular leaks:

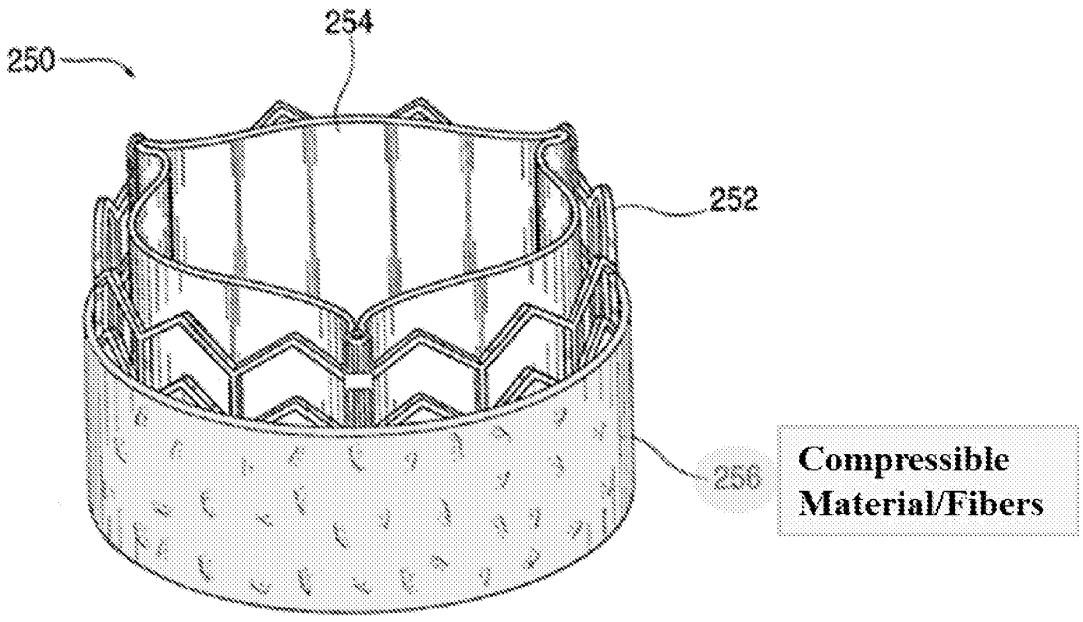


FIG. 22

Ex. 1011 at [00144]-[00145], Fig. 22. Spenser II explains that the compressible material "may resemble a cloth or fabric having ***small fibers*** extending from the surface of the material." *Id.* at [00145] (emphasis added). During prosecution of the related '846 patent, Patent Owner admitted that Spenser II teaches "a thick band of fibers emanating therefrom in FIG. 22." Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 14. Patent Owner tried to distinguish Spenser II by arguing that "there is no graft forming the inner frame, thus the inner sealing is missing." *Id.* However, to the extent the valve in Figure 22 does not have an inner graft covering, a person of ordinary skill in the art would

have found it obvious to combine Spenser II's compressible material with a valve having an inner graft covering, such as Spenser Figure 44a.

179. For the reasons I provide in detail below, it is my opinion that that a person of ordinary skill would have been motivated to combine Walther's outer cloth or Spenser II's outer compressible material with the heart valve assemblies in Spenser, including the assembly shown in Figure 44a. Based on my review of these references, I believe that the combination of Spenser and Walther or Spenser II renders claims 1-9 and 11-12 obvious.

A. Claim 1

180. Based on my review of the prior art, it is my opinion that the combination of Spenser and Walther or Spenser II renders claim 1 obvious.

1. Preamble

181. The preamble of claim 1 recites: "An endovascular transcatheter valve assembly comprising." If this preamble is limiting, Spenser in combination with Walther or Spenser II renders this limitation obvious.

182. Spenser discloses that "[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously***, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location ***via a large blood vessel such as the femoral artery***, in a procedure similar to other known interventional cardiovascular procedures." Ex. 1010

(Spenser) at 2:6-12 (emphasis added). Spenser explains that the prosthetic valve may be crimped to a narrow configuration that is "suitable for percutaneous catheterization and deployment." *Id.* at 14:12-14; *see also id.* at 12:8-17, 12:28-36, 13:26-54. Spenser also discloses a method of endovascularly implanting the prosthetic valve in a patient's native aortic valve using a balloon catheter that is guided through the patient's vasculature to the patient's native aortic valve. *Id.* at 5:17-6:36, 17:19-18:43.

183. According to Spenser, Figure 44a illustrates a "preferred embodiment of the ***present invention***." Ex. 1010 (Spenser) at 26:30-34. A person of ordinary skill in the art would have therefore understood that Spenser's disclosure of endovascular delivery applies to the embodiment in Figure 44a. *See id.* at 2:6-12, 26:30-34. Spenser's Figure 44a is thus an "endovascular transcatheter valve assembly."

184. A person of ordinary skill in the art would have been motivated to add Walther's outer cloth or Spenser II's compressible material to Spenser's Figure 44a for the reasons I provide below. *Infra* §VII.A.5.

185. Spenser II also discloses endovascular delivery. Spenser II states that "[t]he present invention provides a series of new ***percutaneous*** concepts of paravalvular repairs including . . . built-in means for leak prevention." Ex. 1011 (Spenser II) at Abstract (emphasis added); *see also id.* at [0014]. Spenser II

teaches that "[p]ercutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation." *Id.* at [0012]. Percutaneous delivery as described in Spenser II is endovascular delivery.

186. A person of ordinary skill in the art would have been motivated to endovascularly deliver Figure 44a with Walther's outer cloth or Spenser II's compressible for the same reasons a person would have been motivated to deliver the Walther valve endovascularly. *Supra* §VI.A.1. By 2012, persons of ordinary skill in the art had demonstrated that devices not suitable for delivery through smaller blood vessels could still be endovascularly delivered through the common iliac artery. Ex. 1043 (Kainuma) at 273-276; Ex. 1044 (Craido). Thus, a person of ordinary skill in the art would have reasonably expected that Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material would have been deliverable through this route.

187. Moreover, if persons of ordinary skill in the art wanted to deliver the combined valve through smaller blood vessels, they would have possessed the skills and equipment necessary to adapt the outer seal or valve for the particular vessel, including the femoral artery, as discussed in Ground 1. *Supra* §VI.A.1. A person of ordinary skill in the art would have found it obvious to utilize one or more of the known techniques discussed in Ground 1 to combine Walther's outer

cloth or Spenser II's compressible material with Spenser's Figure 44a for endovascular delivery. Persons of ordinary skill in the art would have reasonably expected success in combining Walther's outer cloth with Spenser's Figure 44a because Figure 44a is similar, if not identical, to SAPIEN and for the reasons provided in Ground 1. *Supra* §VI.A.5.

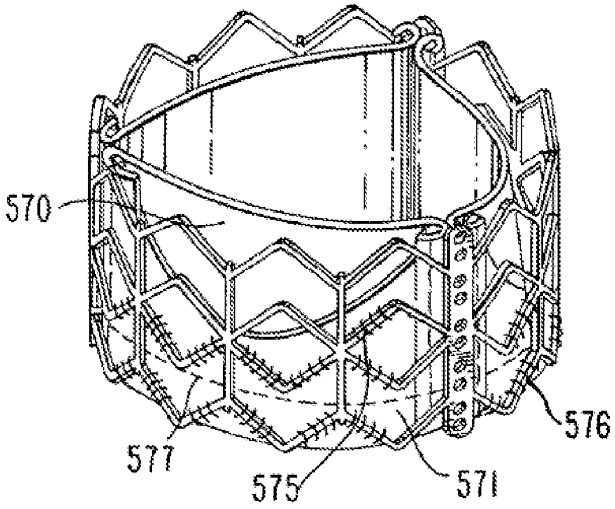
188. Moreover, Spenser discloses that the "maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter." Ex. 1010 (Spenser) at 27:65-67. Spenser's prosthetic valve "has the ability to change its diameter from about 4 mm to about 25 mm." *Id.* at 27:67-28:2. Spenser II's compressible material can have "a thickness ranging from about 1 to 5 mm." Ex. 1011 at [00145]. POSITAs would have reasonably expected that adding a compressible material 1 mm thick to Spenser's 4-mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery because the device's diameter would have been no more than 8 mm. Additionally, a person of ordinary skill in the art would have recognized the availability of even thinner compressible materials that could be used to further reduce the profile. Thus, a person of ordinary skill in the art would have reasonably expected the combination of Spenser II's compressible material, or a similar but thinner material, and Figure 44a to be suitable for transfemoral delivery.

2. Outer Frame

189. Claim 1 next recites: "an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof, wherein the outer frame is formed by a plurality of struts that ajoin each other at the inflow end to form apices." Spenser also discloses these limitations.

190. Figure 44a of Spenser illustrates "an implantable prosthetic valve in accordance with [a] preferred embodiment of the present invention" that includes "frame 575":

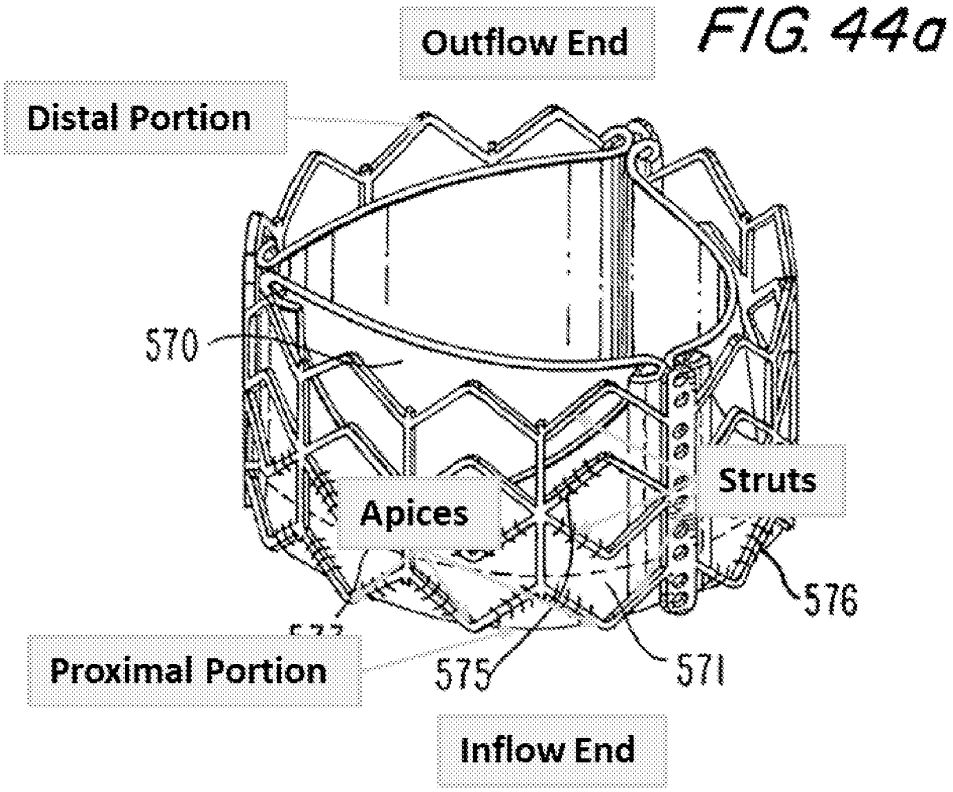
FIG. 44a



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame).

191. As shown in Figure 44a above, frame 575 defines an open cell configuration and surrounds the other valve features, including the leaflets and inner graft covering, making it an "outer frame." *Id.* at Fig. 44a-44b. Spenser further discloses that the frame may be made from metallic materials such as "nickel titanium." *Id.* at 12:28-31.

192. As shown in Figure 44a below, frame 575 includes an inflow end at its proximal portion and an outflow end at its distal portion. *See id.*, Fig. 44a. Indeed, as I explained previously, a person of ordinary skill in the art would understand that the outflow end of the frame is necessarily located at a distal portion of the valve (i.e., furthest from the heart), and the inflow end of the frame is necessarily located at a proximal portion of the valve (i.e., closest to the heart) because the direction of blood flow through the aortic valve carries blood from the left ventricle, through the aortic valve, and away from the heart through the aorta. *Supra* §VI.A.2. Also as shown below, frame 575 is formed from a plurality of struts that adjoin at the inflow end of the frame to form apices:



Ex. 1010 (Spenser) at Fig. 44a.

3. Inner Frame

193. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Spenser also discloses this limitation.

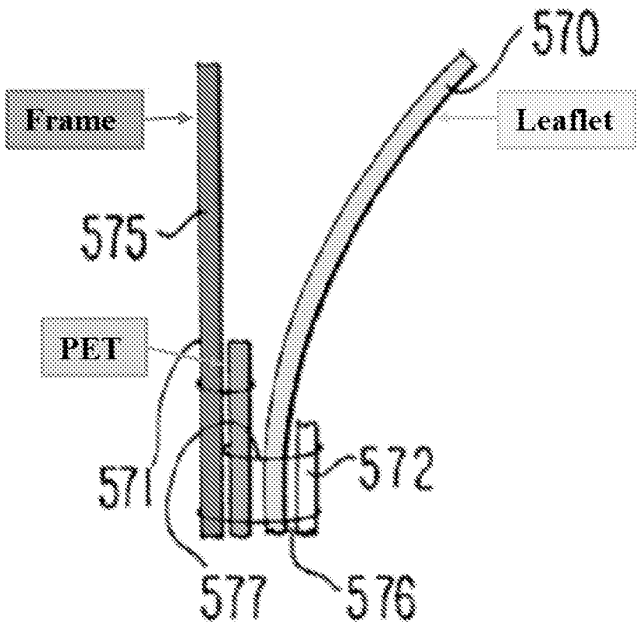
194. The embodiment in Figure 44a of Spenser includes an "additional piece of PET" 571 for "sealing and protecting the pericardium." Ex. 1010

(Spenser) at 26:30-34, Figs. 44a-44c; *see also id.* claims 10, 30 ("including a fabric layer interposed between the valve assembly and support stent"). The "pericardium" is the prosthetic pericardial leaflets 570 (*see e.g.,* Figures 44a-b below). *Id.* at 26:30-54. The PET 571 is a "graft covering."

195. As shown in Figure 44b of Spenser below, the PET 571 [blue] is positioned "between the leaflets [570 yellow] and the frame [575 red]"[7]:

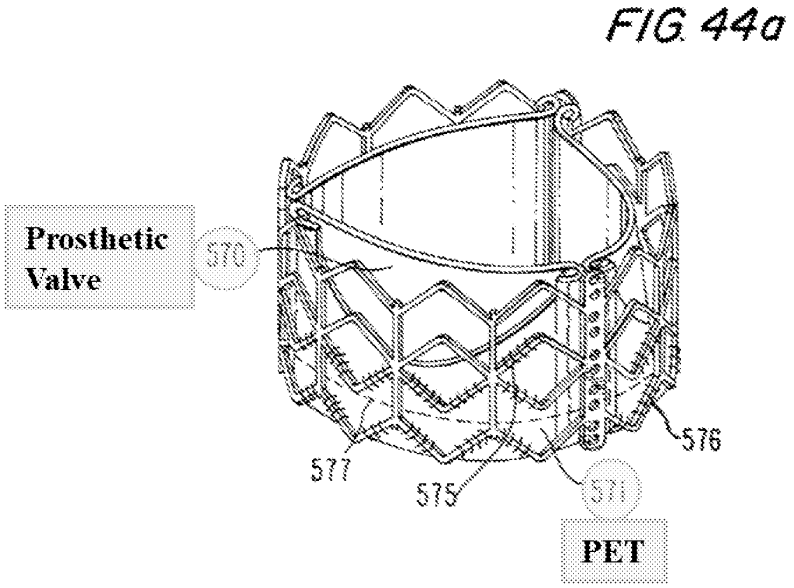
[7] In Fig. 44b, the lead lines for 571 and 575 both point to the outer frame [red]. *See* Ex. 1010 (Spenser) at Fig. 44b. I believe this is a drafter's error. As explained in Spenser's written disclosure, the lead line for the outer PET layer 571 should point to the middle layer [blue] because PET 571 is described as being positioned "between the leaflets [570] and the frame [575]." *Id.* at 26:40-42.

FIG. 44b



Id. at 26:30-54, Fig. 44b. Spenser teaches that the PET 571 is stitched to the prosthetic valve using at least suture 576. *Id.* at 26:45-47. PET 571 thus "engages" the prosthetic heart valve.

196. As shown in Figure 44b above and Figure 44a below, the PET 571 is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:



Id. at 26:30-34, Fig. 44a. Thus, based on Patent Owner's statements during prosecution of related patents, *supra* §VI.A.3, and if an inner frame can be a graft covering, PET 571 is an inner frame that includes a graft covering.

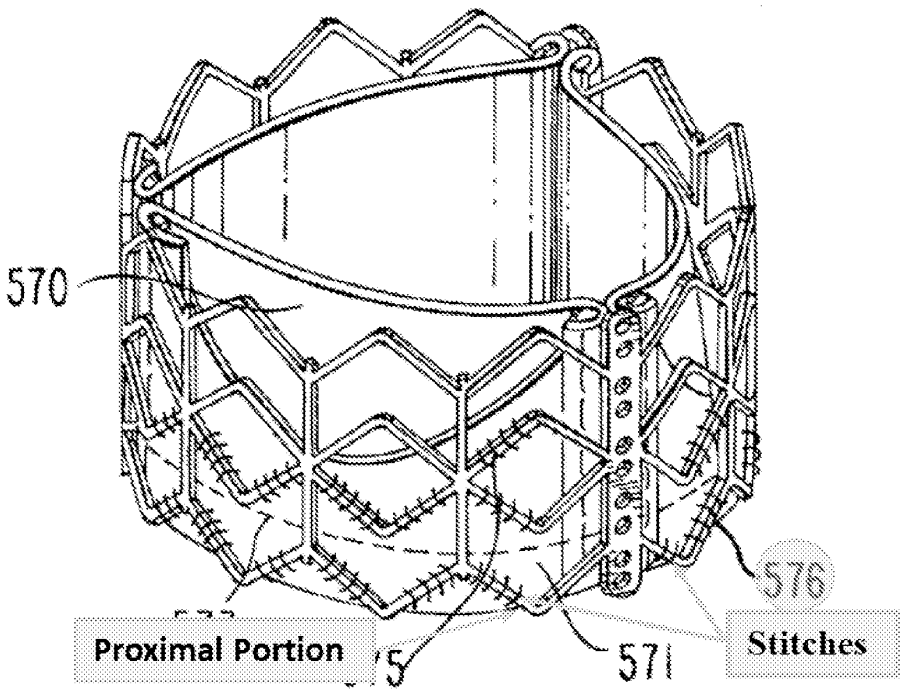
4. Stitching

197. Claim 1 next recites: "wherein the outer frame is secured to the inner graft covering by stitching at a proximal portion of the outer frame." Spenser also discloses this limitation.

198. Spenser discloses that a "[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a strong sealing line." Ex. 1010 (Spenser) at 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30.

199. Figure 44a illustrates that the bottom suture 576 secures the inner PET layer (inner graft covering) by stitching at the proximal end of the outer frame:

FIG. 44a



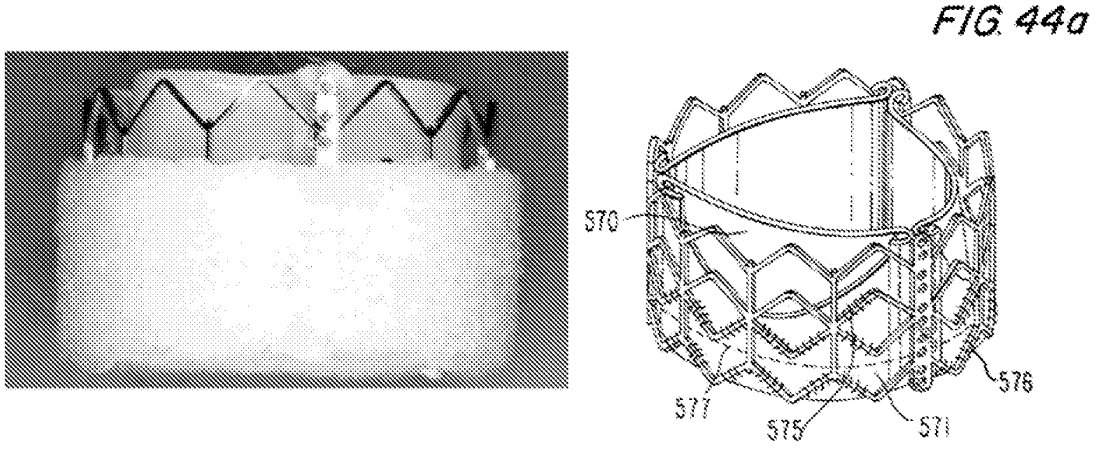
Id., Fig. 44a; *see also id.* at Fig. 44b (showing sutures).

5. Outer Seal

200. Claim 1 next recites: "an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the outer frame, wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame." Spenser in combination with Walther or Spenser II renders the limitations of the outer seal obvious.

a. Walther

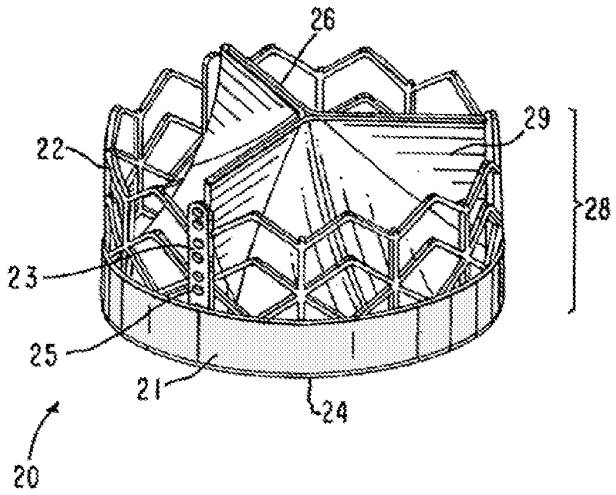
201. Walther discloses an outer cloth formed of outwardly extending fibers that is attached to the exterior of SAPIEN's outer frame for preventing paravalvular leaks as discussed in Ground 1. *Supra* §VI.A.5. If Walther's outer cloth were added to Figure 44a, the combined valve would also include outwardly extending fibers positioned externally to the outer frame. Walther's outer cloth covers the proximal two rows of cells formed from SAPIEN's outer frame. *Id.* If Walther's outer cloth were added to Spenser's Figure 44a, the cloth would cover the proximal two rows of cells of the support stent. A side-by-side comparison of Walther's Figure 1 (left) and Spenser's Figure 44a (right) illustrates that Walther's outer cloth would cover the two bottom rows:



Compare Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1010 (Spenser) at Fig. 44a.

202. A person of ordinary skill in the art would have been motivated to combine Walther's outer cloth with Spenser's Figure 44a because Walther

expressly discloses combining an outer cloth with a similar (if not identical) heart valve (SAPIEN). Ex. 1007 (Walther) at 1020-1021. Additionally, Spenser suggests adding an outer cloth to Figure 44a by disclosing a similar valve with an outer cuff portion 21 for sealing around the valve:



Ex. 1010 (Spenser) at 13:22-25, Fig. 1. Adding Walther's outer cloth to Figure 44a would have merely entailed applying a known technique (attaching an outer cloth) to a known device (Figure 44a) ready for improvement (enhanced sealing).

203. A person of ordinary skill would have had a reasonable expectation of success in combining an outer cloth with Figure 44a because Walther discloses how to combine a cloth with a similar (if not identical) heart valve, provides images of the combination, and concludes that the cloth-covered valve "demonstrated excellent hydrodynamic performance." *See* Ex. 1007 (Walther) at 1125.

204. I note that during prosecution of a related patent application (U.S. Patent Application No. 17/213,251), Patent Owner suggests, although does not explain, that foreshortening could be an issue in combining an outer cloth, like the one in Walther, with a stent frame. Here, a person of ordinary skill in the art would not have been concerned by the combination of an outer cloth, like Walther's, with the frame in Spenser's Figure 44a because the frame in Figure 44a is almost identical to SAPIEN. Walther already establishes Walther's outer cloth could be successfully added to SAPIEN. Additionally, by 2012, persons of ordinary skill in the art would have understood how to adjust and attach the outer cloth to respond to the foreshortening of the stent frame during expansion. For example, Levi describes methods of building some slack into the outer cloth or skirt to allow for the foreshortening. Ex. 1008 (Levi) at 13:32-14:14. For these reasons, any foreshortening of the stent would not have discouraged a person of ordinary skill in the art from adding an outer sealing material to a heart valve frame or led the person to believe that the combination would not be successful.

b. Spenser II

205. Spenser II discloses this limitation. Spenser II discloses that "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252":

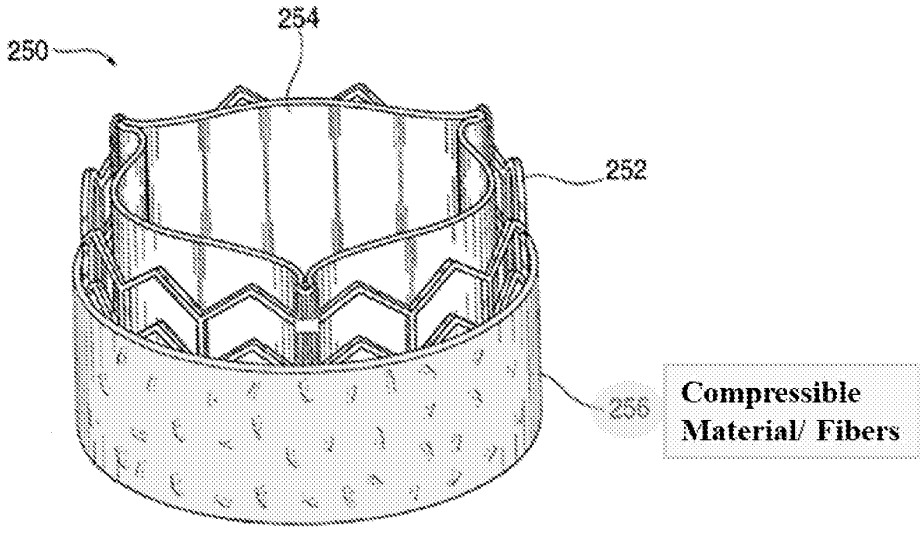


FIG. 22

Ex. 1011 (Spenser II) at [00145], Fig. 22. As shown, the compressible material is positioned externally to the outer frame. Spenser II explains that the compressible material "***may resemble a cloth or fabric having small fibers extending from the surface of the material***." *Id.* (emphasis added). Spenser II further discloses that the compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* The compressible material is therefore an "outer seal for preventing paravalvular leaks" that is formed of outwardly extending fibers positioned externally to the outer frame based on Patent Owner's statements during prosecution of related patents, *supra* §VI.A.5. In fact, during prosecution of the related '846 patent, Patent

Owner admitted that Spenser II includes an "outer seal." Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 23.

206. Spenser II's compressible material covers the proximal two rows of cells formed by stent structure 252, as shown in Spenser II's Figure 22 below:

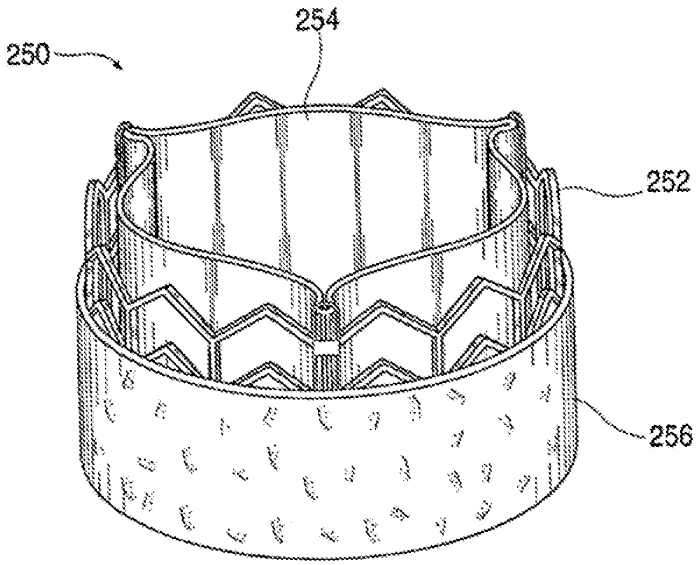


FIG. 22

Ex. 1011, Fig. 22.

207. A person of ordinary skill in the art would have understood that when added to the exterior of the frame in Spenser's Figure 44a, the compressible material would cover the proximal two rows of cells formed by the outer frame. The side-by-side comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right) below confirms the compressible material would cover a portion of the two proximal rows of Figure 44a:

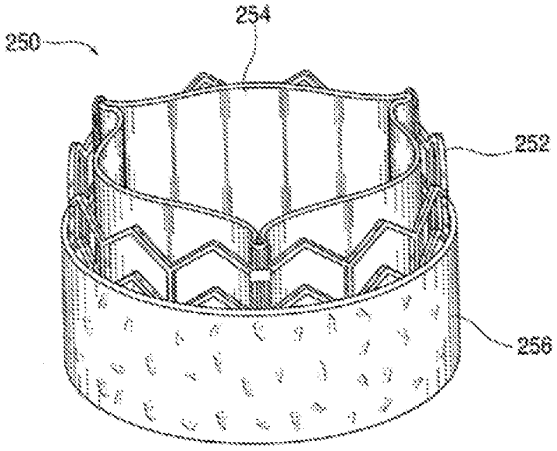
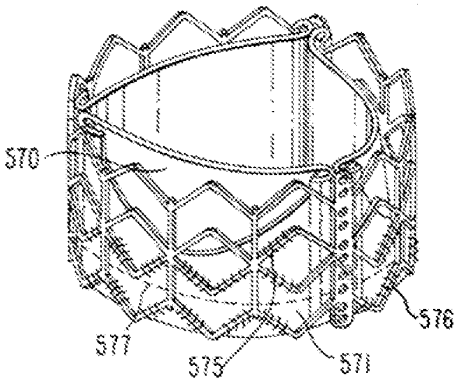


FIG. 22

FIG. 44a



Compare Ex. 1011 (Spenser II) at Fig. 22 *with* Ex. 1010 (Spenser) at Fig. 44a. The cell shape and orientation are the same in Figures 22 and 44a.

208. A person of ordinary skill in the art would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a for a number of reasons. First, Spenser and Spenser II describe similar valves, share three common inventors, and Spenser II explicitly references Spenser's parent application: U.S. Publication No. 2003/0153974 (Ex. 1015). *See, e.g.*, Ex. 1010 (Spenser) at Abstract, 2:5-15; Ex. 1011 (Spenser II) at [0001], [0009]-[0014].

209. Also, as I explained in Ground 1, paravalvular leaks were known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. *Supra* §VI.A.e. A person of ordinary skill in the art would have been motivated to combine Spenser II's compressible material with Figure 44a to "address leaks that can occur around the implanted valve" and "to encourage coagulation of blood to

further fill the gaps and prevent leakage." Ex. 1011 (Spenser II) at [0010], [0145]. Moreover, adding the compressible material to Figure 44a would have merely entailed the combination of known elements (Figure 44a and compressible material) according to known methods (stitching or otherwise attaching) to yield the predictable result of reducing paravalvular leakage.

210. A person of ordinary skill would have had a reasonable expectation of success in combining Spenser II's compressible material with Figure 44a because the valve assemblies share many common features, including a balloon-expandable metallic stent having a gridded configuration that supports prosthetic leaflets, and inner graft covering, and being radially compressible for endovascular delivery. *See, e.g.,* Ex. 1010 (Spenser) at 2:5-15; 12:28-36, 13:26-54, 19:5-13; *see also, e.g.,* Ex. 1011 (Spenser II) at [0011]-[0015], [00144]. Moreover, Spenser already discloses valves having a sealing material positioned around the inlet, for example in Figure 1. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. A person of ordinary skill in the art would thus have been confident that other sealing structures with superior sealing capabilities, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. Also, a person of ordinary skill in the art would not have had any concerns about stent foreshortening because the valve in Spenser II, which is very similar to Spenser's

Figure 44a, is a balloon expandable valve and Spenser II does not describe any problems with foreshortening. *Supra* §VII.A.5.a.

6. Radially Compressed Orientation and Radially Expanded Orientation

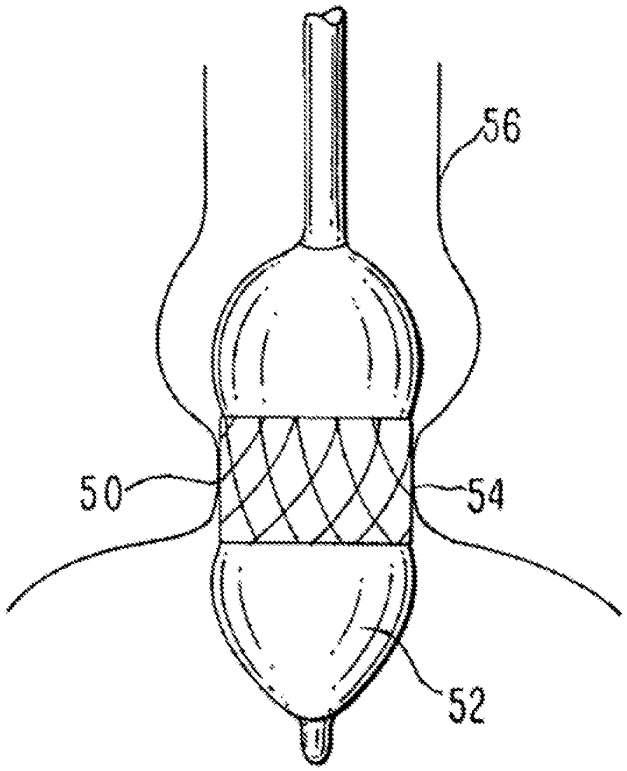
211. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Spenser, Walther, and Spenser II all disclose this limitation.

212. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.6. Spenser discloses that its prosthetic valve "has the ability to change its diameter from about 4 mm [radially compressed orientation] to about 25 mm [radially expanded orientation]." Ex. 1010 (Spenser) at 27:67-28:2. Likewise, Spenser II discloses a stented valve that comprises "an expandable stent structure" that may be "adapted for radial expansion using a balloon catheter." Ex. 1011 (Spenser II) at [00144]. A person of ordinary skill in the art would have understood that a balloon expandable stent structure, as disclosed in Spenser II, would include a radially compressed and a radially expanded configuration.

7. Fibers Press Against Native Leaflets

213. Claim 1 next recites: "wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient." Spenser in combination with Walther or Spenser II render this limitation obvious.

214. Spenser's Figure 4 (below) "depicts deployable valve deployment in a natural aortic valve position in accordance with the present invention":



Ex. 1010 (Spenser) at 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b. As shown above, the valve presses against the patient's aortic annulus. *Id.* at Fig. 4. Although not pictured in Fig. 4, a person of ordinary skill in the art would understand that the valve also presses against the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. *Supra* §III.B. A person of ordinary skill in the art would have understood Figure 4 to illustrate the placement of Spenser's Figure 44a because

Figure 4 describes "the present invention" and Figure 44a is described as a "preferred embodiment of the present invention." Ex. 1010 (Spenser) at 8:66-67, 26:30-34.

215. As I explained previously, Walther's outer cloth and Spenser II's compressible material would cover at least the two proximal rows of Figure 44a's outer frame. *Supra* §VII.A.5. As illustrated by Figure 4 and understood by a person of ordinary skill in the art, expanding Figure 44a would cause at least a portion of the proximal two rows of the outer frame to press against the patient's native aortic leaflets. *Supra* §VI.A.7. Thus, expansion of Figure 44a would press some of the fibers of Walther's outer cloth and Spenser II's compressible material against the patient's native aortic leaflets. In fact, Patent Owner admitted this was the case during prosecution of the related '846 patent. Patent Owner stated that the "limitation of the fibers covering at least two rows of open cells provides an improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets." Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 25.

216. A person of ordinary skill in the art would have found it obvious to deploy Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material within a patient's native valve. Spenser discloses methods of implanting the described valves, such as Figure 44a, at the natural aortic valve.

See e.g., Ex. 1010 (Spenser) at 5:17-6:36 (listing delivery steps). A person of ordinary skill would have been motivated to apply Walther's and Spenser II's known techniques for reducing paravalvular leakage (adding an outer cloth to a valve frame) to Spenser's known prosthetic heart valves (*e.g.*, Figure 44a) for the same reasons I provided for Walther and SAPIEN. *Supra* §VI.A.7. My discussion of SAPIEN is relevant here because Figure 44a is very similar, if not identical, to SAPIEN.

217. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying Figure 44a with an outer cloth or compressible material, like Walther's or Spenser II's, in a patient's native aortic valve. Walther discloses that the cloth-covered valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." Ex. 1007 (Walther) at 1125. Likewise, Spenser II describes the implantation of a valve with a compressible material in a native valve and, given the similarities between the stents in Spenser's Figure 44a and Spenser II's Figure 22, POSITAs would have expected implantation in a native valve to work equally well if the compressible material were added to Spenser's Figure 44a. Ex. 1011 at [0144]-[0145].

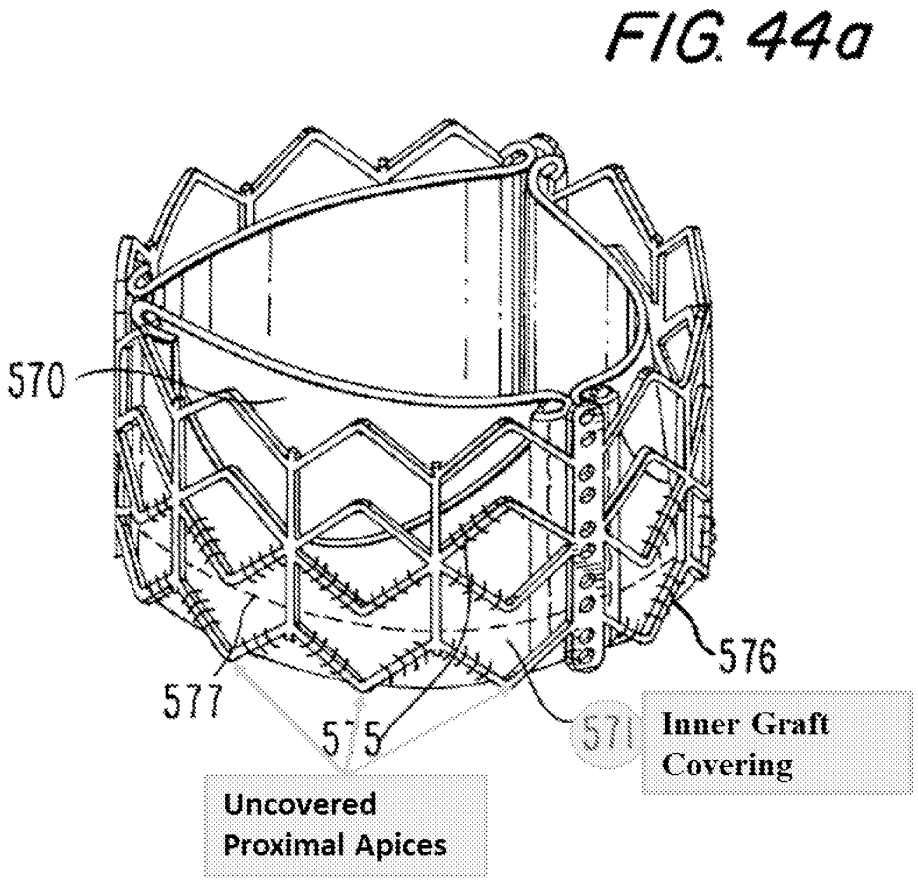
218. Moreover, Spenser describes endovascular implantation of its described valves, including Figure 44a, within the aortic valve and persons of

ordinary skill in the art had successfully implanted SAPIEN, which is similar (if not identical) to Figure 44a, within a patient's native aortic valve countless times by November 2012. Ex. 1010, 2:6-12, 12:8-36, 13:26-54, 14:12-14; *see also e.g.*, Ex. 1012 at 355 ("Transcatheter valve implantation with the Edwards-Sapien Heart Valve can be done safely and efficiently using the transfemoral retrograde approach."); Ex. 1009 at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively). Thus, a person of ordinary skill in the art would have been confident in implanting Figure 44a with Walther's outer cloth or Spenser II's compressible material within a patient's native aortic valve.

8. Uncovered Proximal Apices

219. Claim 1 next recites: "wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering." Spenser in combination with Walther or Spenser II renders this limitation obvious.

220. As I explained above, Spenser's Figure 44a includes an inner layer of PET sutured to the interior surface of the outer frame. *Supra* §VII.A.3-4. As shown in Figure 44a, PET layer 571 extends only on the interior of the outer frame, leaving the ends of the most proximal apices uncovered:



Ex. 1010 (Spenser) at Fig. 44a.

a. Walther

221. Walther's outer cloth does not extend over the ends of the most proximal apices of SAPIEN's outer frame for the reasons I provided in Ground 1. *Supra* §VI.A.8. A person of ordinary skill in the art would have been motivated to arrange Walther's outer cloth on Figure 44a's frame in the same way with a reasonable expectation of success because Walther discloses that such an arrangement was successful for the SAPIEN valve, which has features similar (if

not identical) to Figure 44a. Therefore, a person of ordinary skill in the art would understand that Walther's outer cloth would not cover the ends of the most proximal apices of Figure 44a's outer frame.

b. Spenser II

222. As I explained above, Spenser II discloses a fibrous compressible material disposed along the exterior of the valve. *Supra* §VII.A.5. Because the compressible material is only disposed along the outer surface of the stent, a person of ordinary skill in the art would understand that the compressible material does not extend over or cover the ends of the most proximal apices of the stent:

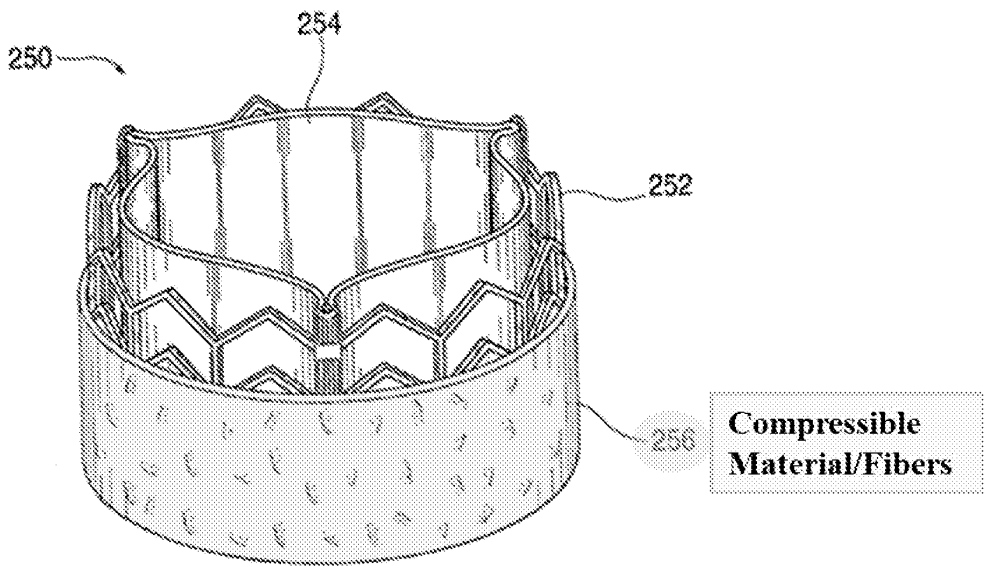


FIG. 22

Ex. 1011 (Spenser II) at [00145], Fig. 22. There is no teaching or suggestion in Spenser II that the compressible material wraps over or covers the proximal end of

the stent. *See* Ex. 1011, [00145]. Therefore, a person of ordinary skill in the art would understand that if the compressible material is disposed along the exterior of Figure 44a's frame, the compressible would not cover the ends of the most proximal apices.

9. Proximal Apices Extend More Proximally than Outer Seal

223. Claim 1 concludes by reciting: "wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

224. A person of ordinary skill in the art would have found it obvious to adjust the size and placement of the compressible material such that the most proximal apices of Figure 44a's outer frame extend proximally further than the compressible for the same reasons I provided in Ground 1 with respect to Walther's outer cloth. *Supra* §VI.A.9.

b. Spenser II

225. Spenser II discloses that the compressible material is disposed along the outer surface of the stent. *Supra* §VII.A.5. Spenser II's Figure 22 does not clearly show whether the proximal apices of the outer frame extend proximally further than the compressible material:

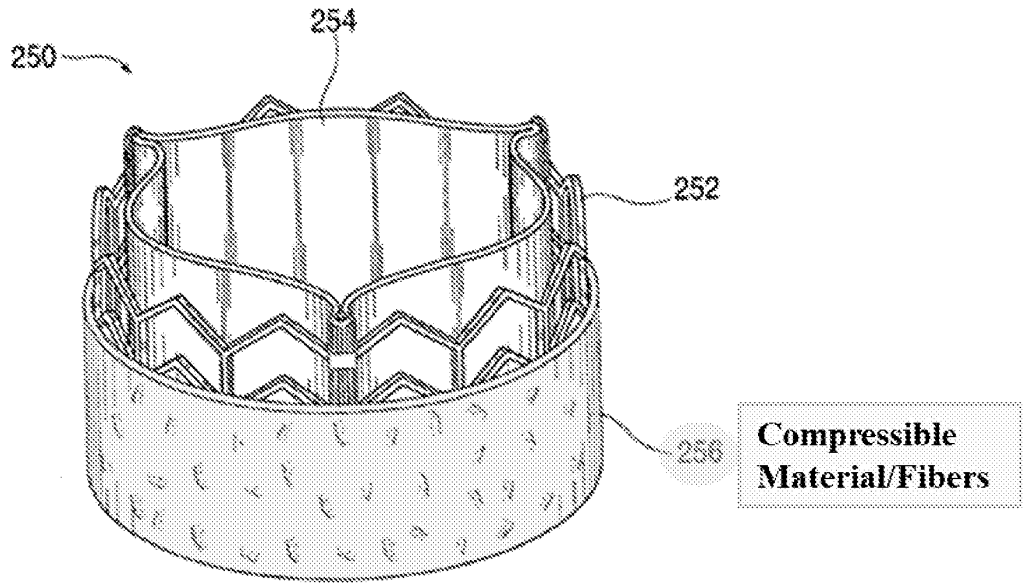


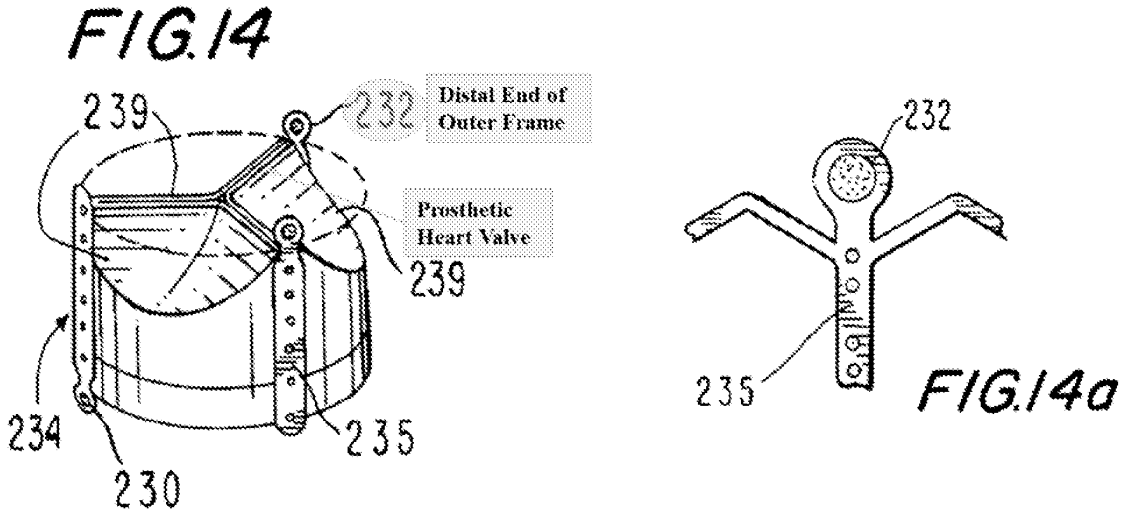
FIG. 22

Ex. 1011 (Spenser II) at Fig. 22. Regardless, a person of ordinary skill in the art would have found it obvious to adjust the size and placement of the compressible material such that the most proximal apices of Figure 44a's outer frame extend proximally further than the compressible for the same reasons explained in Ground 1 with respect to Walther's outer cloth. *Supra* §VI.A.9.

B. Claim 2

226. Claim 2 recites: "The valve assembly of claim 1, wherein the outer frame extends distally further than the prosthetic heart valve." Spenser discloses the limitations in claim 2 and, in combination with Walther or Spenser II, renders claim 2 obvious.

227. Spenser discloses the limitations in claim 2 in at least two ways. First, Spenser discloses heart valves having "heavy metal markers [232] on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location":



Ex. 1010 (Spenser) at 16:27-51, Figs. 14-14a. As shown in Figure 14 (above left), the portion of the outer frame having the marker extends distally further than the prosthetic heart valve. A person of ordinary skill in the art would have been motivated to add the markers to the stent in Spenser's Figure 44a to better visualize the stent during deployment. A person of ordinary skill in the art would have reasonably expected success in adding the marker because Spenser describes using the marker with a stent similar to Figure 44a and metal markers were commonly used in the field by 2012.

228. Second, Spenser illustrates a method of attaching the leaflets 430 to a metallic frame 420:

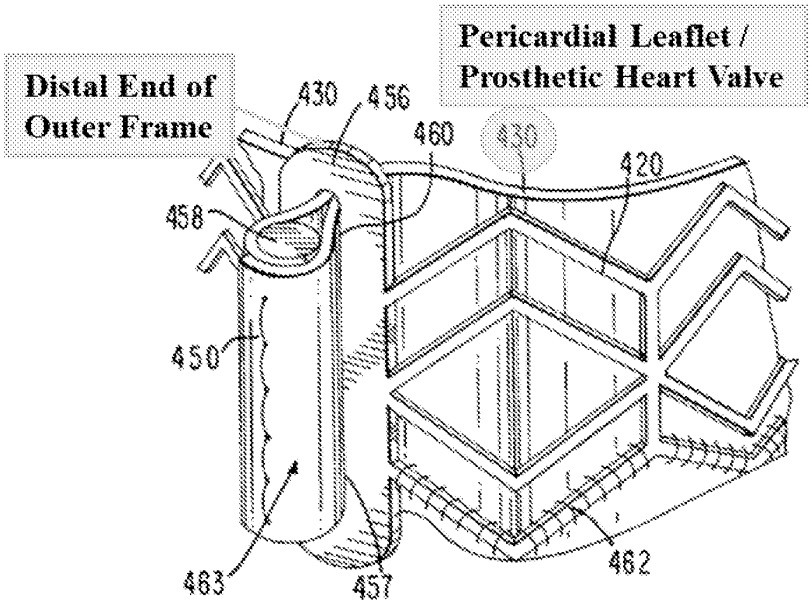


FIG. 28

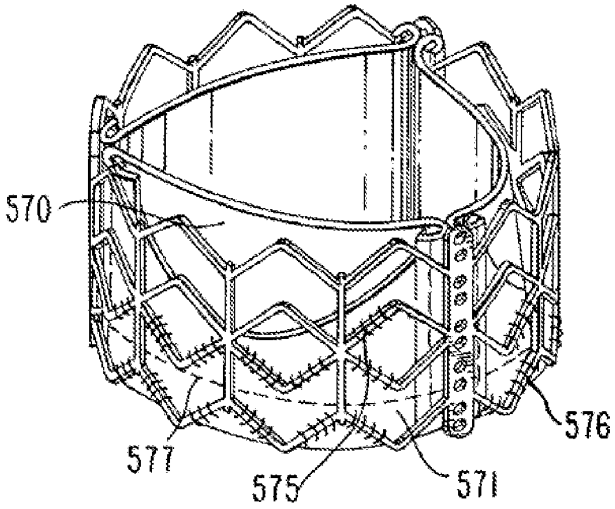
Id. at 21:46-67, Fig. 28. As shown, the outer frame portion 456 extends distally further than the prosthetic heart valve 430. A person of ordinary skill in the art would have been motivated to use this method of attachment in Spenser's Figure 44a to reduce stress points and abrasion on the leaflets. *Id.* at 20:60-67. A person of ordinary skill in the art would have reasonably expected success in using this method with Figure 44a because Spenser already discloses using the method in conjunction with a stent like Figure 44a.

C. Claim 3

229. Claim 3 recites: "The valve assembly of claim 1, wherein the outer frame is a singular, integral component." Spenser discloses the limitations in claim 5 and, in combination with Walther or Spenser II, renders claim 5 obvious.

230. Figure 44a includes "frame 575":

FIG. 44a



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame). As shown in figure 44a above, the vertically straight bars of the frame are each connected by four rows of interconnected, angular struts that form the gridded shape of the frame. *See id.* Thus, frame 575 is a singular, integral component. *Id.* at Fig. 44a-44b.

D. Claim 4

231. Claim 4 recites: "The valve assembly of claim 1, wherein the inner graft covering and the fibers are distinct elements." Spenser in combination with Walther or Spenser II renders claim 4 obvious.

232. As I explained in claim 1, Figure 44a of Spenser discloses a layer of PET fabric stitched to the interior surface of the outer frame. *Supra* §§VII.A.3-4. A person of ordinary skill in the art would have understood that Walther's outer cloth and Spenser II's outer compressible are separate materials from the inner layer of PET fabric and, therefore, "distinct elements."

E. Claim 5

233. Claim 5 recites: "The valve assembly of claim 1, wherein a seal is created between the inner frame and the outer frame." Spenser discloses this limitation. Thus, Spenser in combination with Walther or Spenser II renders claim 5 obvious.

234. Spenser's Figure 44a includes a layer of PET positioned between the valve leaflets and the support frame "***for sealing*** and protecting the pericardium." Ex. 1010 (Spenser) at 26:30-54 (emphasis added). Spenser further discloses that the "[b]ottom attachment suture 576, connects . . . the leaflet and both PET layers to the frame and ***forms a strong sealing line***." *Id.* at 26:45-47 (emphasis added).

From these disclosures, a person of ordinary skill would have understood that a seal is created between Spenser's inner PET layer and outer frame.

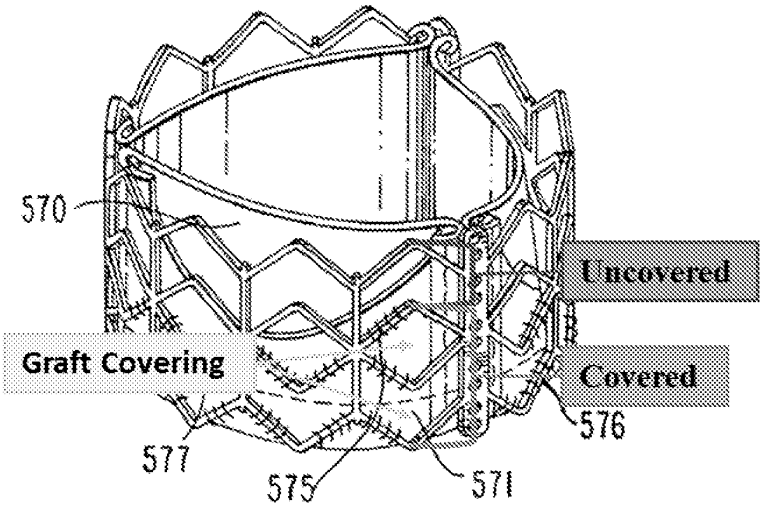
F. Claim 6

235. Claim 6 recites: "The valve assembly of claim 1, wherein a portion of the outer frame is uncovered by the graft covering and the outer seal." Spenser in combination with Walther or Spenser II renders this claim obvious.

236. First, I note that Claim 1 requires that an end of the most proximal apices of the outer frame, which are a "portion of the outer frame," are uncovered by the inner graft covering and the outer seal. Therefore, Spenser and Walther or Spenser II render this claim obvious for the reasons I provided in claim 1. *Supra* §VII.A.8.

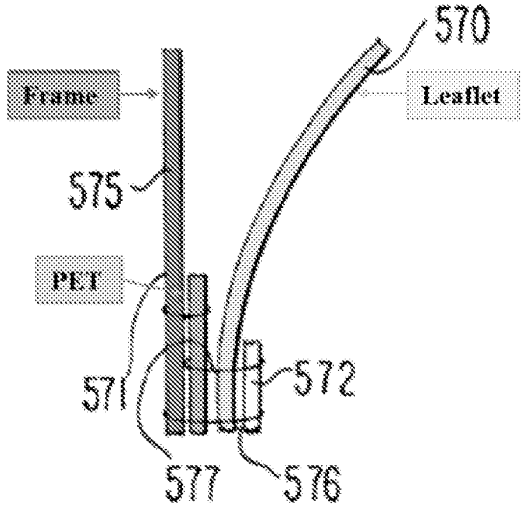
237. Additionally, as shown in Spenser's Figure 44a below, the inner PET fabric covers the bottom two rows of cells of Figure 44a's outer frame but ***does not*** cover the uppermost row of cells:

FIG. 44a



Ex. 1010 (Spenser) at Fig. 44a. Figure 44b (below) confirms that the inner PET layer 571 [blue] does not cover the entire frame 575 [red].

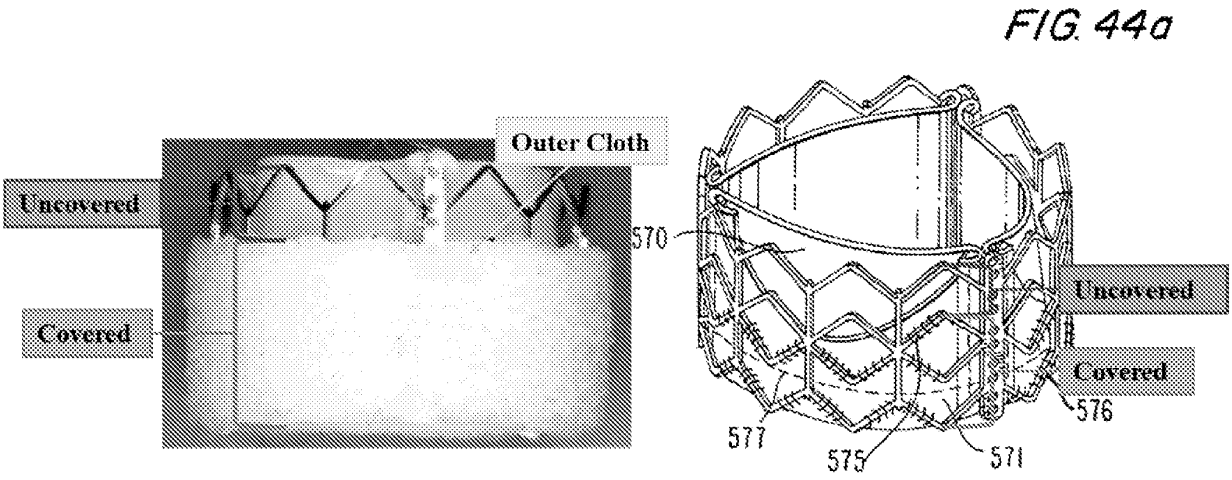
FIG. 44b



Id. at Fig. 44b.

1. Walther

238. As I explained previously, Walther's outer cloth covers the two most proximal circumferentially extending rows of cells formed in SAPIEN's open cell configuration. *Supra* VII.A.5. If Walther's outer cloth were added to Spenser's Figure 44a, the cloth would cover the bottom two rows of cells of the support stent but ***would not*** cover the uppermost row of cells, as illustrated in the side-by-side comparison of Walther's Figure 1 (left) and Spenser's Figure 44a (right):



Compare Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1010 (Spenser) at Fig. 44a.

239. Therefore, when Walther's outer cloth is added to Spenser's Figure 44a, the uppermost row of cells, which are a "portion of the outer frame," would be uncovered by the both the inner PET fabric (graft covering) and the outer cloth (outer seal).

2. Spenser II

240. Figure 22 of Spenser II (below) shows the compressible material covering the bottom two rows of grids formed by stent structure 252, leaving the uppermost (i.e., distal) third row uncovered:

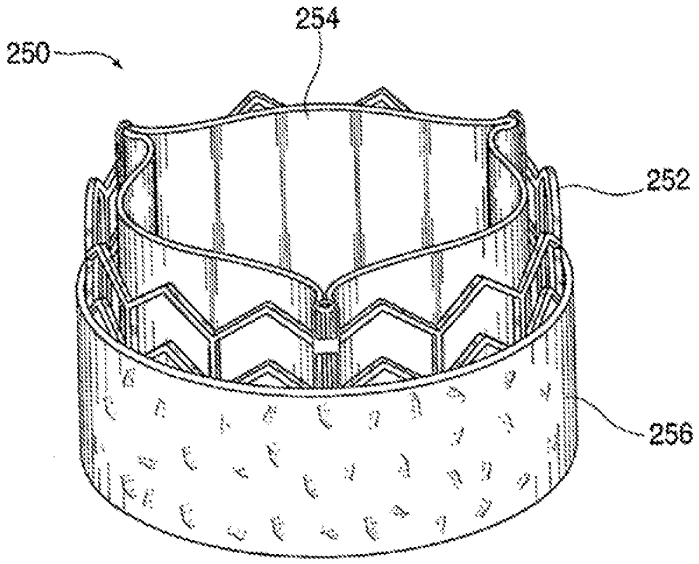
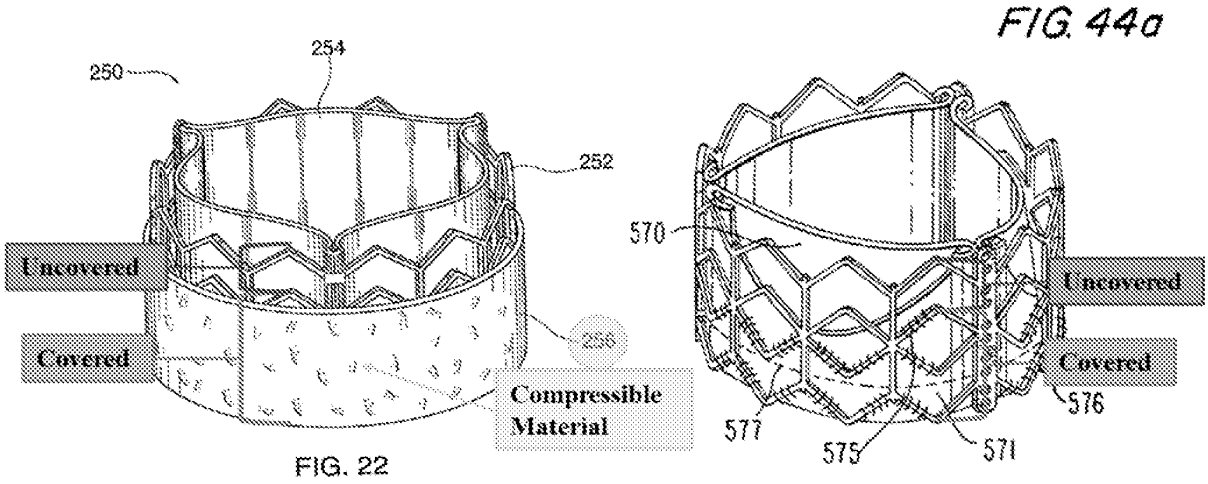


FIG. 22

Ex. 1011 (Spenser II) at Fig. 22.

241. When added to the exterior of the stent in Spenser's Figure 44a, the compressible material would cover the bottom two rows of cells formed by the stent frame but ***would not*** cover the uppermost row of cells, as illustrated in the side-by-side comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



Compare id. at Fig. 22 *with* Ex. 1010 (Spenser) at Fig. 44a. Therefore, when Spenser II's compressible material is added to Spenser's Figure 44a, the uppermost row of cells, which are a "portion of the outer frame," would be uncovered by both the inner PET fabric (graft covering) and the compressible material (outer seal).

G. Claim 7

242. Claim 7 recites: "The valve assembly of claim 1, wherein a distal end of the outer frame extends distally beyond the prosthetic leaflets." Spenser discloses the limitations in claim 7 and, in combination with Walther or Spenser II, renders claim 7 obvious.

243. This claim is substantially similar to claim 2, which recites: "The valve assembly of claim 1, wherein the outer frame extends distally further than the prosthetic heart valve." In both claims, the outer frame extends distally further than, or beyond, the prosthetic heart valve (or prosthetic leaflets).

244. Thus, Spenser discloses this limitation and Spenser combined with Walther or Spenser II renders claim 7 obvious for the same reasons the references render claim 2 obvious. *Supra* §VII.B.

H. Claim 8

245. Claim 8 recites: "The valve assembly of claim 1, wherein the outwardly extending fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly." Spenser in combination with Walther or Spenser II renders this claim obvious.

246. Walther's outer cloth discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.F.

247. Spenser II's compressible material also discloses this limitation. Spenser II's compressible material extends around the outer frame so fibers extend to the left and right of the "centerline." Thus, the compressible material includes fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly":

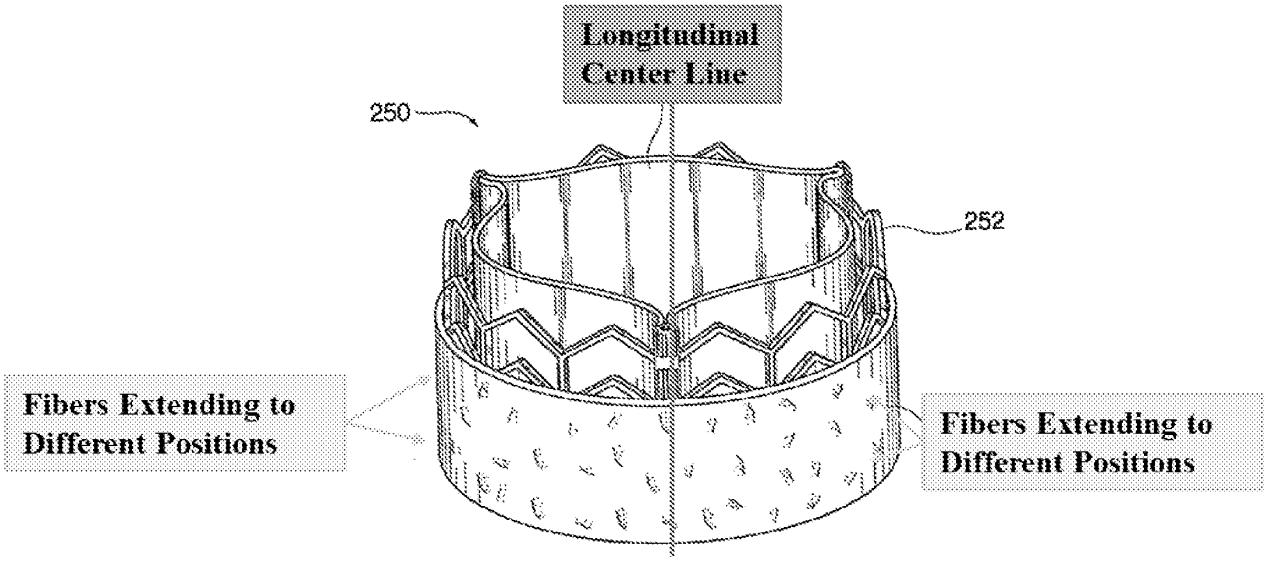


FIG. 22

Ex. 1011 (Spenser II) at Fig. 22.

248. Additionally, Spenser II's compressible material does not have a uniform surface. Spenser II discloses that the fibers of the compressible material "may be straight, curved, or hook shaped." Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood the speckled markings on the compressible material 256 in Figure 22 below to indicate that some of the fibers extend further out from the frame than others:

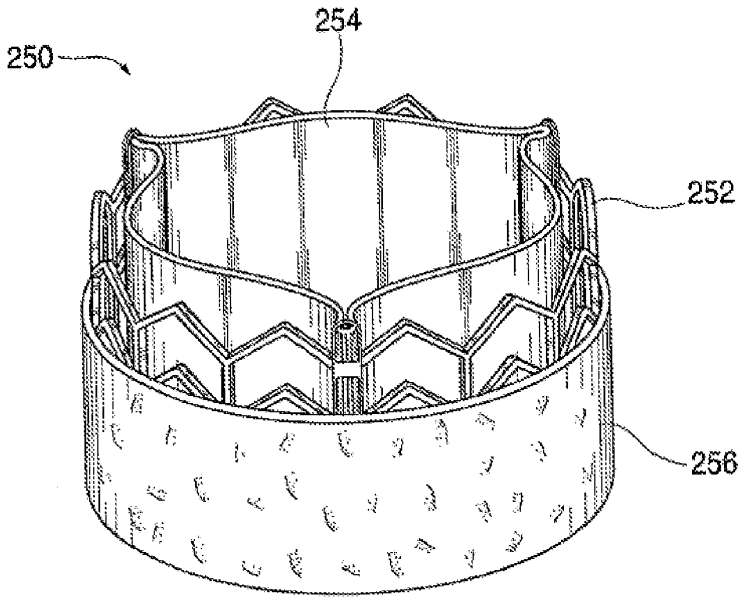


FIG. 22

Id. Fig. 22. Thus, even the fibers on one side of the valve "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly."

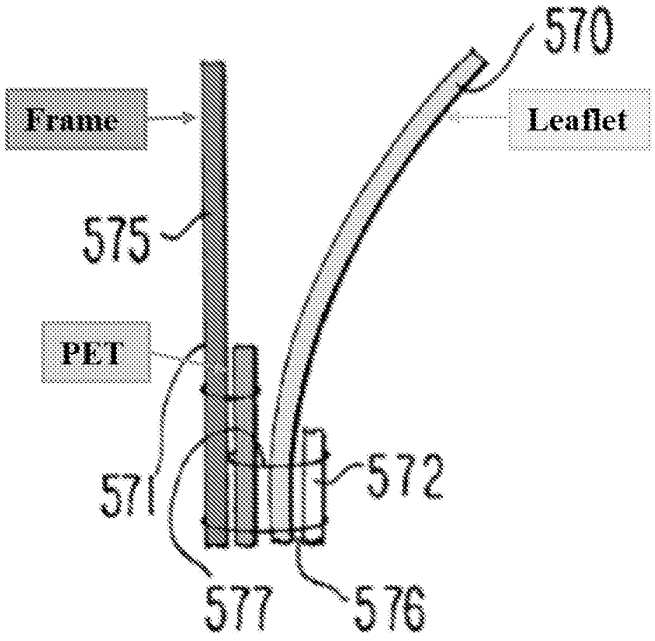
I. Claim 9

249. Claim 9 recites: "The valve assembly of claim 1, wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping." Spenser in combination with Walther or Spenser II renders this claim obvious.

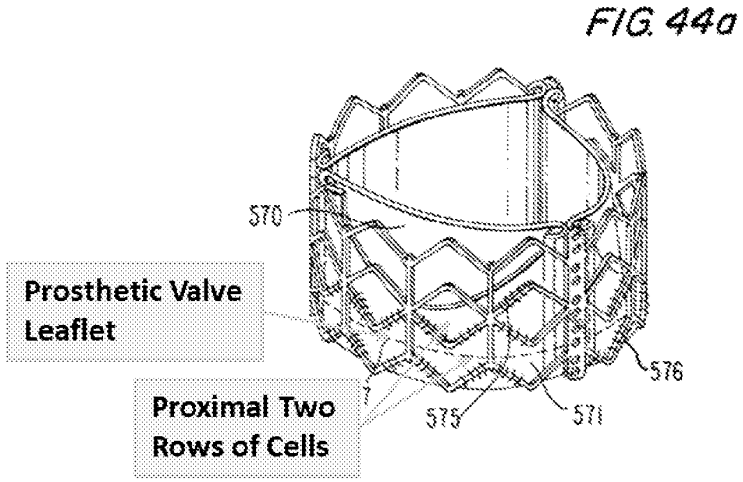
250. As I explained in claim 1, Spenser's Figure 44a includes an inner PET fabric 571 (inner graft covering) that is secured to the interior surface of the outer frame and extends around the prosthetic heart valve at the lower end of the outer frame. *Supra* §VII.A.3. Spenser discloses that PET 571 is positioned "between

the leaflets and the frame." Ex. 1010 (Spenser) at 26:40-42. A person of ordinary skill in the art would have understood that PET 571 radially overlaps with the leaflets 570, as illustrated below:

FIG. 44b



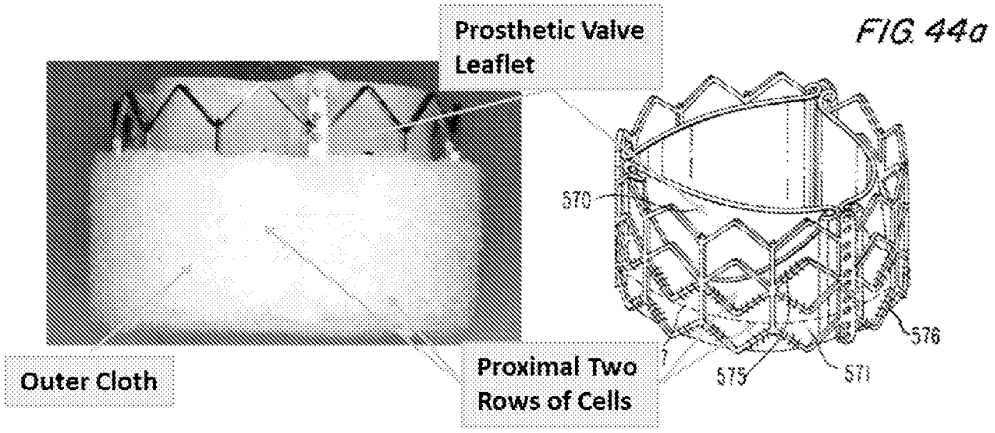
Id. at Fig. 44b. Figure 44a (below) depicts the sealing line where the prosthetic leaflets are sutured to the inner PET layer:



Id. at Fig. 44a.

1. Walther

251. As I explained in claim 1, if Walther's outer cloth were added to Spenser's Figure 44a, the cloth would cover the proximal two rows of cells of the support stent. *Supra* §VII.A.5.a. A side-by-side comparison of Walther's Figure 1 (left) and Spenser's Figure 44a (right) illustrates that the two proximal rows of cells covered by the outer cloth would "radially overlap" with the prosthetic leaflets 570 of Spenser's Figure 44a:

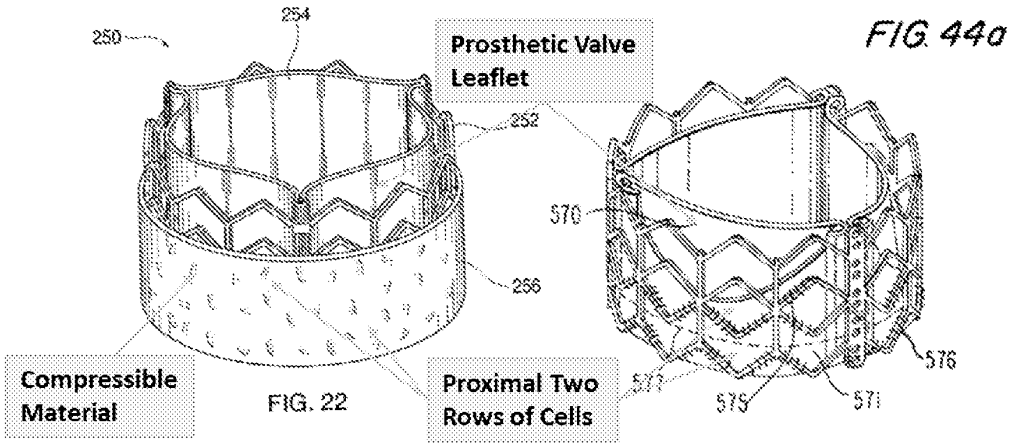


Compare Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1010 (Spenser) at Fig. 44a.

252. Therefore, the combination of Spenser and Walther would include an inner graft covering, an outer cloth (outer seal), and prosthetic leaflets that are radially overlapping based on Patent Owner's arguments regarding Figure 11 and "radially overlaps" during prosecution of the related '538 patent.

2. Spenser II

253. As I explained in claim 1, when added to the exterior of the stent in Spenser's Figure 44a, Spenser II's compressible material would cover the proximal two rows of cells formed by the stent frame. *Supra* §VII.A.5.b. A side-by-side comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right) illustrates that the compressible material would radially overlap with the prosthetic leaflets of Figure 44a:



Compare Ex. 1011 (Spenser II) at Fig. 22 *with* Ex. 1010 (Spenser) at Fig. 44a.

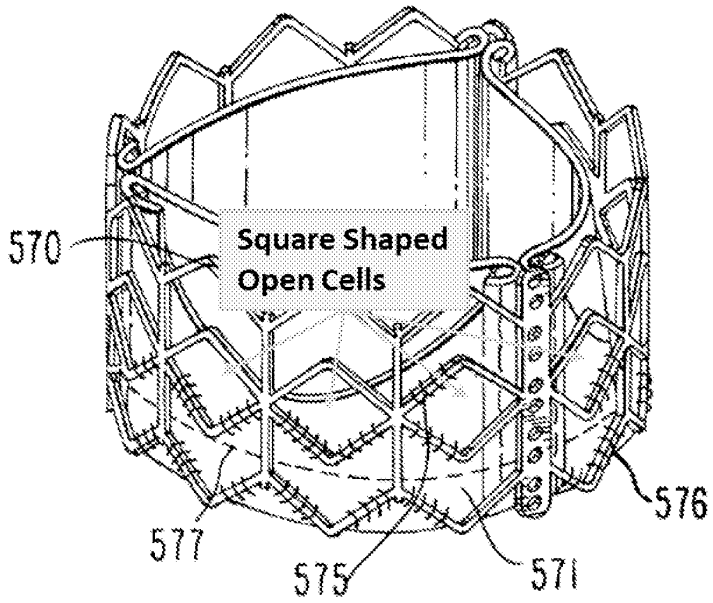
254. Therefore, the combination of Spenser and Spenser II would include an inner graft covering, an outer compressible material (outer seal), and prosthetic leaflets that are radially overlapping based on Patent Owner's arguments regarding Figure 11 and "radially overlaps" during prosecution of the related '538 patent.

J. Claim 11

255. Claim 11 recites: "The valve assembly of claim 1, wherein open cells of the open cell configuration area are a square shape." Spenser discloses the limitation in claim 11, and, based on claim 1, Spensr in combination with Walther or Spenser II render claim 11 obvious.

256. Figure 44a's outer frame comprises three rows of open cells, and as shown below, the cells of the middle each form a square shape:

FIG. 44a



Ex. 1010 (Spenser) at Fig. 44a.

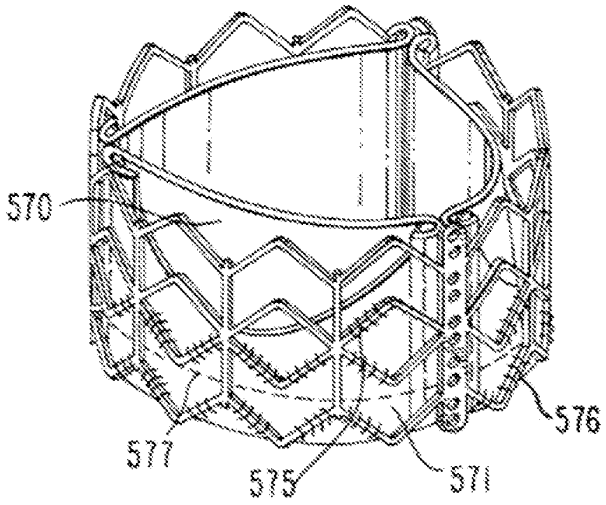
K. Claim 12

257. Claim 12 recites: "The valve assembly of claim 1, wherein the outer seal is free of a non-porous graft covering." Spenser in combination with Walther or Spenser II renders this claim obvious.

1. Walther

258. Walther's outer cloth is "free of non-porous graft covering" for the reasons I provided in Ground 1. *Supra* §VI.I. Likewise, Spenser's Figure 44a does not depict any "non-porous graft covering" on the exterior of frame 575 and Spenser's specification does not describe frame 575 as having an outer graft covering:

FIG. 44a



Ex. 1010 (Spenser) at Fig. 44a. Therefore, a person of ordinary skill in the art would have understood that when Walther's outer cloth is added to the exterior of Figure 44a's outer frame, there would be no "non-porous graft covering" between the outer cloth and the outer frame.

2. Spenser II

259. Spenser II's compressible material is also "free of a non-porous graft covering." Spenser II discloses that the compressible material, which "may resemble a cloth or fabric having small fibers extending from the surface of the material," is "disposed along the outer surface" of the stent. Ex. 1011 (Spenser II) at [00145]. Spenser II does not disclose or picture any additional "non-porous graft covering" as part of the compressible material. Therefore, a person of ordinary skill in the art would have understood that there is no such "non-porous

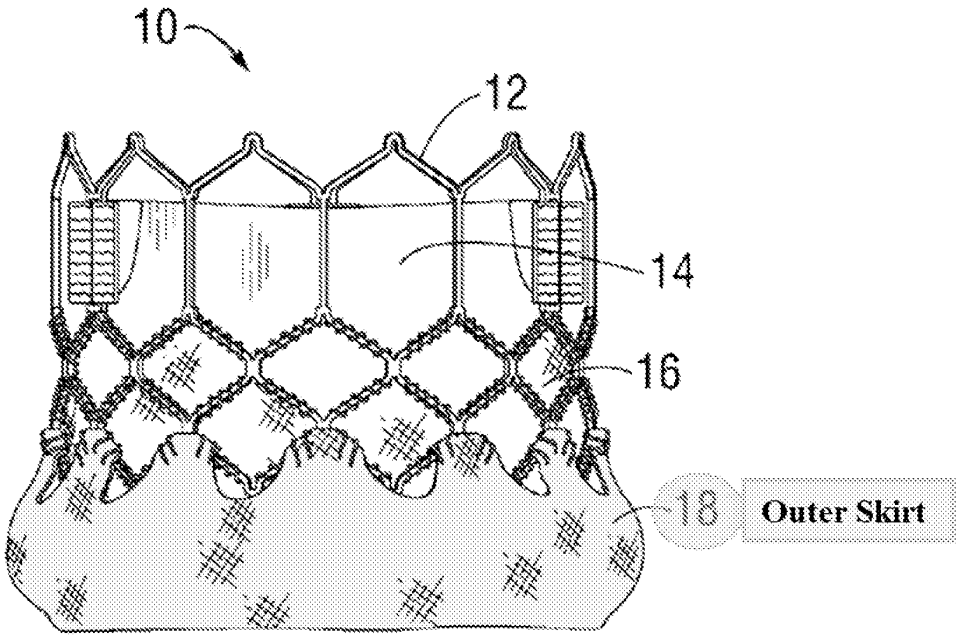
graft covering" that is part of the compressible material. Moreover, Spenser II does not contain any disclosure that the compressible material is made of a cloth base or outer graft and a fiber portion. Rather, Spenser II consistently describes the compressible material as a "layer" or single piece of cloth or fabric. *Id.*

260. As I explained in the previous section, Spenser's Figure 44a does not include any "non-porous graft covering" on the exterior of the outer frame 575. *Supra* §VII.K.a. Therefore, a person of ordinary skill in the art would understand that when Spenser II's compressible material is added to the exterior of Figure 44a's outer frame, there would be no "outer graft covering" between the fibers of the compressible material and the outer frame.

VIII. GROUNDS 4-5: CLAIMS 1-9, 12 OBVIOUS IN VIEW OF LEVI AND WALTHER OR SPENSER II

261. Levi discloses a prosthetic heart valve assembly having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame, as shown in Figure 3 below:

FIG. 3



Ex. 1008 (Levi) at 13:50-53, 13:62-66, Fig. 3. Levi's outer skirt extends beyond and over the proximal apices of the outer frame; however, as I explained above and below, Walther and Spenser II each describe an outer seal that does not cover the ends of the proximal apices. It is my opinion that a person of ordinary skill in the art would have found it obvious to combine Levi with Walther or Spenser II for the reasons I provide in detail below. In fact, Levi expressly discloses methods of adapting the outer frame to accommodate a sealing material. Ex. 1008 (Levi) at 14:26-35. Therefore, I believe that Levi combination with Walther ***or*** Spenser II renders obvious claims 1-9 and 12.

A. Claim 1

262. Based on my review of the prior art, it is my opinion that Levi in combination with Walther or Spenser II renders claim 1 obvious.

1. Preamble

263. The preamble of claim 1 recites: "An endovascular transcatheter valve assembly comprising." If this preamble is limiting, Levi in combination with Walther or Spenser II renders this limitation obvious.

264. Levi discloses a "transcatheter aortic valve assembly." Ex. 1008 (Levi) at 1:16-17, 5:52-56. Levi discloses that due to known "drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches" were developed in which "collapsible transcatheter heart valves . . . can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent." Ex. 1008 (Levi) at 1:57-67. Percutaneous delivery is endovascular delivery. Levi discloses several features to enable such percutaneous (i.e., endovascular) delivery. *See id.* at 6:46-49.

265. For example, Levi discloses that its frame is preferably constructed of nickel-cobalt-chromium-molybdenum alloy, which allows for less material to be used so that "the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly ***for percutaneous delivery to the treatment location***

in the body." Ex. 1008 (Levi) at 6:31-49 (emphasis added); *see also id.* at 7:10-12. Levi discloses that "[b]y minimizing the diameter of the valve when mounted on the delivery shaft, the assembly can ***[be] contained within a smaller diameter catheter and thus can be passed through smaller vessels in the body*** and can be less invasive in general." *Id.* at 14:60-64 (emphasis added). A person of ordinary skill in the art would have understood that Levi's valve is delivered endovascularly.

266. Additionally, Levi discloses a number of features to accommodate additional graft or sealing material at the proximal end of the device. *Infra* §VIII.A.5. For example, Levi discloses methods to reduce the diameter of the valve frame at the inlet, or to modify the leaflets to reduce the frame size, to create room for additional components. Ex. 1008 (Levi) at 16:24-17:18. Thus, a person of ordinary skill in the art would have expected success in delivering Levi's valve endovascularly.

267. A person of ordinary skill in the art would have found it obvious to replace Levi's outer skirt with Walther's outer cloth or Spenser II's compressible material for the reasons I provide below. *Infra* §VIII.A.5. A person of ordinary skill in the art would have understood that after replacing Levi's outer skirt with Walther's outer cloth or Spenser II's compressible material, the resulting device would remain suitable for endovascular deployment. For example, even if the

addition of Walther's outer cloth or Spenser II's compressible material resulted in some small increase in the valve diameter, a person of ordinary skill in the art would have recognized that the valve could still be endovascularly delivered through the patient's common iliac artery. Ex. 1043 (Kainuma).

268. Additionally, Levi teaches that "[w]hen crimped, the frame 12 has a reduced diameter region extending along a portion of the frame . . . that generally corresponds to the region of the frame covered by the outer skirt 18" so that the outer skirt "does not increase the overall crimp profile of the valve." Ex. 1008 (Levi) at 8:46-54; *see also id.* at 2:22-35, 14:22-35, 16:38-45, 17:14-18. Walther's outer cloth or Spenser II's compressible material would also cover the reduced diameter region, which would reduce any risk that the outer cloth/compressible material would disadvantageously increase the crimp profile. *Id.* at 8:46-54.

269. Levi additionally discloses several other features that minimize the crimped profile of the valve and would enable endovascular delivery of a valve equipped with Walther's outer cloth or Spenser II's compressible material. Levi teaches that the configuration of its outer frame enables a "reduction in the frame wall thickness to achieve a smaller crimped diameter of the valve." *Id.* at 7:10-12. Levi's outer frame is also formed with relatively larger open cells in the uppermost row, which allow portions of the prosthetic leaflets to protrude from the frame when the valve is crimped, again reducing the minimum crimped profile of the

valve. *Id.* at 7:36-42, 15:17-24. The frame may also be formed with a "thickness that varies along its length to optimize strength where needed, yet minimize material (and therefore crimp profile) at selected regions of the frame," such as the inflow end that is covered by the outer skirt. *Id.* at 16:54-17:18. The frame may also include window frame portions which are depressed radially inwardly relative to the other portions of the frame, which also minimizes the crimp profile of the valve. *Id.* at 14:40-45. The shape of Levi's prosthetic leaflets also minimize the valve's profile. Levi teaches that the leaflets may be tapered or "V-shaped" instead of the traditional "U-shaped leaflets." *Id.* at 14:26-30, 16:24-40. The tapered shape of the leaflets results in less leaflet material at the inflow end of the valve, which further minimizes the crimped profile of the inflow end that is covered by the outer skirt or some other "additional component." *Id.* Even Levi's inner skirt is designed to help minimize the crimp profile. Levi teaches that its skirt is woven with fibers that are non-perpendicular to the upper and lower edges of the skirt, which enables the skirt to undergo greater axial elongation when the valve is crimped, resulting in a more uniform crimping profile and a smaller crimped diameter. *Id.* at 9:36-11:2. A person of ordinary skill in the art would have found it obvious to use any or all of Levi's methods to minimize the crimped profile of the valve, which would enable endovascular delivery of a valve with a fibrous outer seal.

270. Levi discloses that "[i]n one example, the frame of a 26-mm valve, when crimped, had a diameter D_1 of 14 French at the outflow end of the valve and a diameter D_2 of 12 French at the inflow end of the valve." *Id.* at 8:56-59. A person of ordinary skill in the art would have understood that adding Walther's outer cloth or Spenser II's compressible material (which is described as being 1 mm think in some embodiments) to Levi's valve would result in a device suitable for endovascular delivery through, for example, the common iliac artery or a smaller artery such as the femoral artery. In addition, as discussed in Ground 1, a person of ordinary skill in the art would have had access to a range of suitable cloths and materials having varying thicknesses and densities and could have selected an appropriately dimensioned cloth/material for endovascular delivery. *Supra* §VI.A.1.

271. Levi also expressly suggests adding other components, like Walther's outer cloth or Spenser II's compressible material, to the inflow portion of the outer frame, stating "if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component." Ex. 1008 (Levi) at 16:41-45. A person of ordinary skill in the art would have understood that Walther's outer cloth or Spenser II's compressible material would be a potential "additional component." For these reasons, a person of ordinary

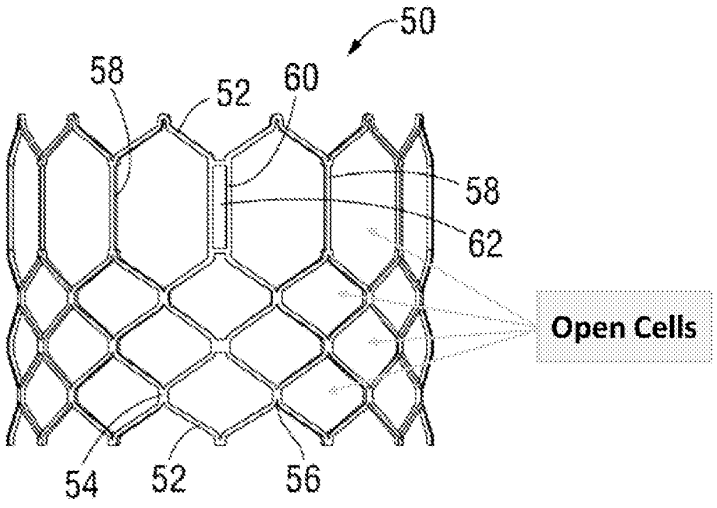
skill in the art would have reasonably expected success in adding materials like Walther's outer cloth or Levi's compressible material to Levi's valve.

2. Outer Frame

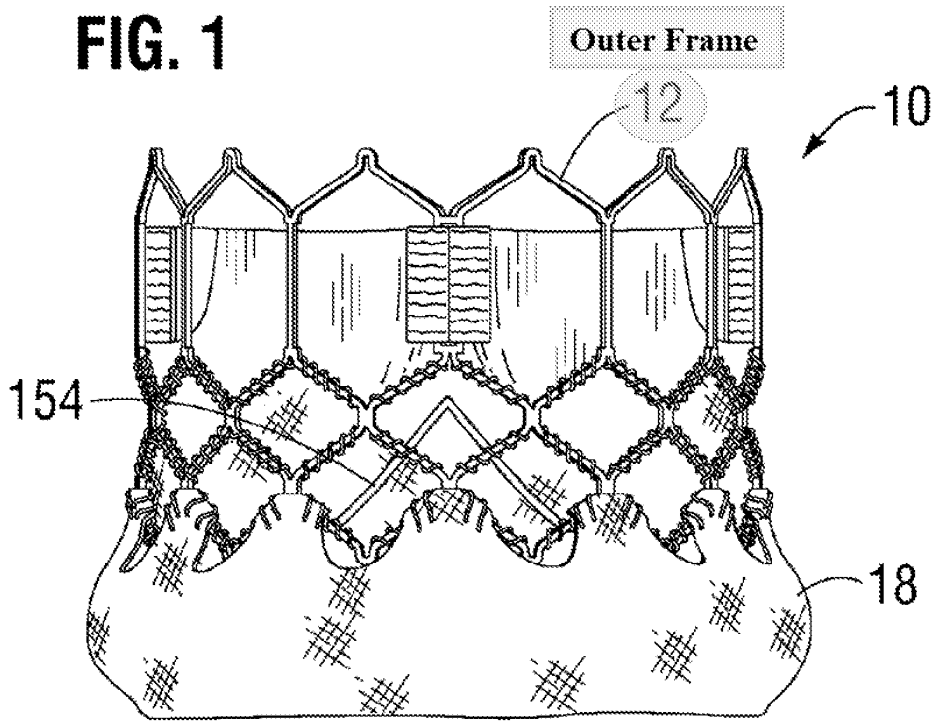
272. Claim 1 next recites: "an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof, wherein the outer frame is formed by a plurality of struts that ajoin each other at the inflow end to form apices." Levi also discloses these limitations.

273. Levi discloses an expandable frame formed from metal (e.g., stainless steel, cobalt-chromium, etc.) that defines an open cell structure, as shown in Figure 11 below:

FIG. 11



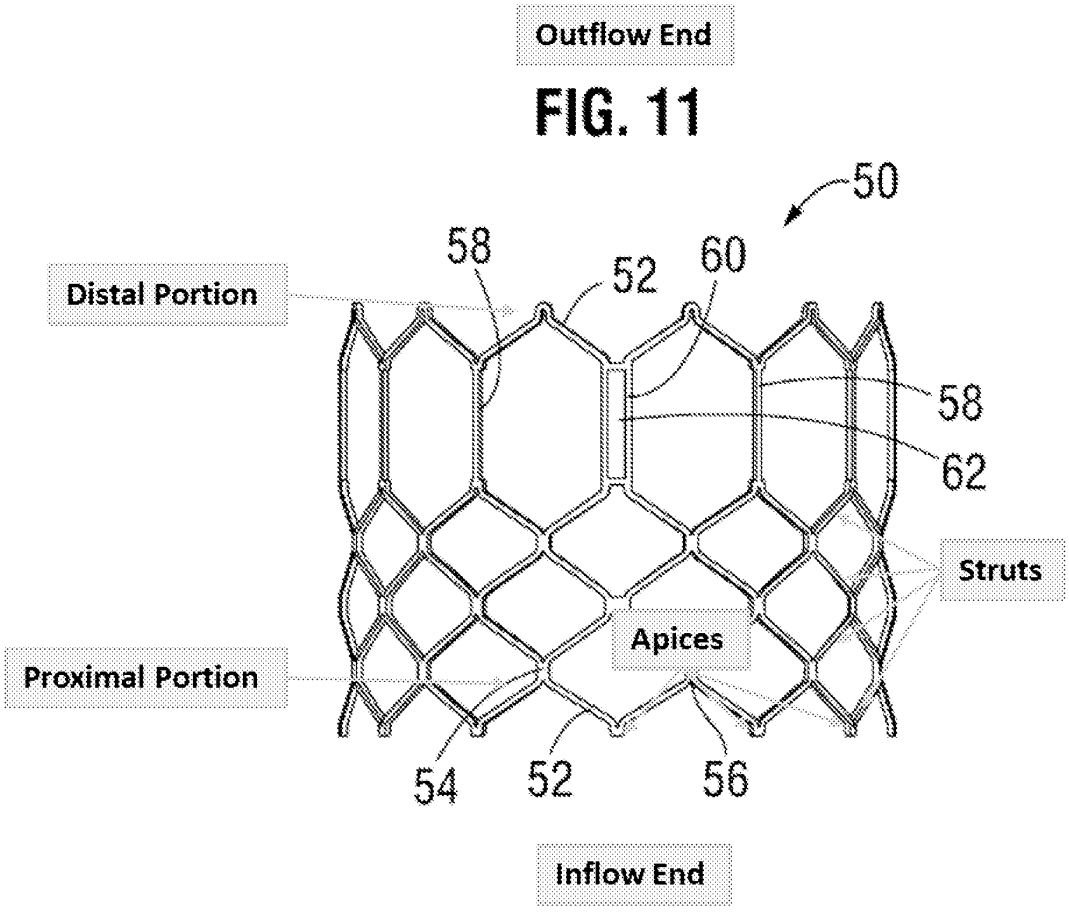
Ex. 1008 (Levi) at 6:17-24, Fig. 11. As shown in Figure 1 below, the frame 12 surrounds the other components of the valve and is thus an "outer frame":



Id. at Fig. 1.

274. As shown below, Levi's frame includes an inflow end at its proximal portion and an outflow end at its distal portion. *See id.*, 6:50-58, Fig. 11. Indeed, as I explained previously, a person of ordinary skill in the art would understand that the outflow end of the frame is necessarily located at a distal portion of the valve (i.e., furthest from the heart), and the inflow end of the frame is necessarily located at a proximal portion of the valve (i.e., closest to the heart) because the direction of blood flow through the aortic valve carries blood from the left

ventricle, through the aortic valve, and away from the heart through the aorta. *Supra* §VI.A.2.

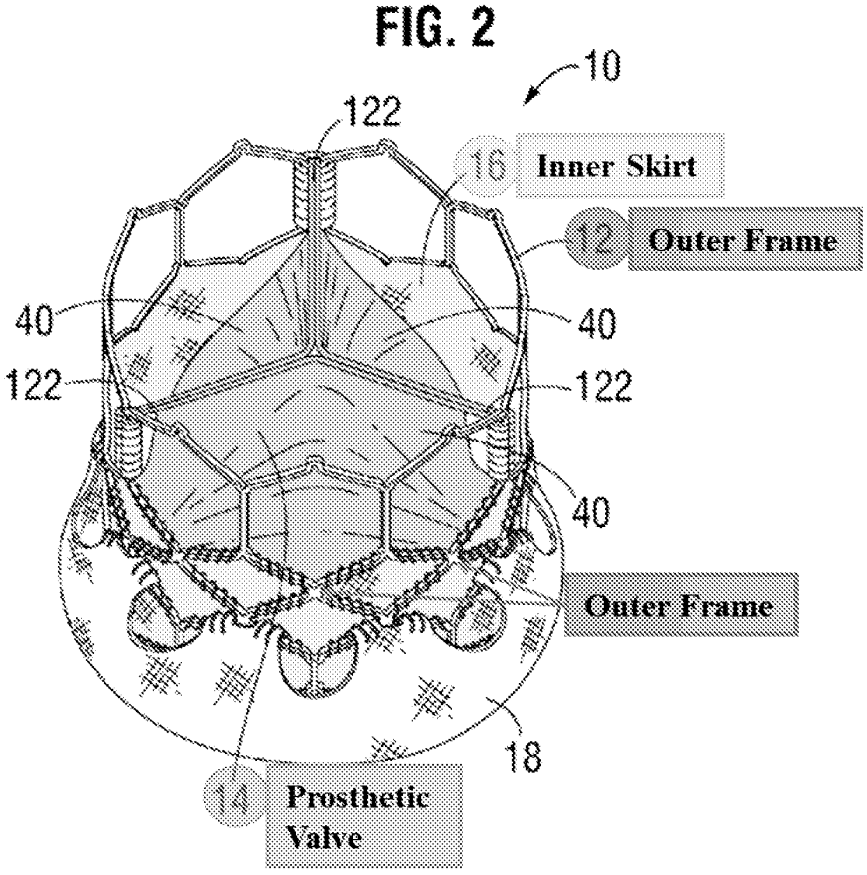


Ex. 1008 (Levi) at Fig. 8. Levi discloses that its outer frame "comprises multiple rows of circumferentially extending, angled struts 52 that are connected to each other at nodes, or connecting portions, 54 and 56." Ex. 1008 (Levi) at 8:61-64. As shown in Figure 11 above, the struts 52 connect (adjoin) at the inflow end of the frame to form a plurality of apices. *See id.* at Fig. 11.

3. Inner Frame

275. Claim 1 next recites: "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." Levi also discloses this limitation.

276. Levi discloses an "inner skirt 16 … to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets." Ex. 1008 (Levi) at 9:7-11. The inner PET skirt therefore provides sealing to the prosthetic heart valve. The inner skirt is constructed of "a tough, tear resistant material such as polyethylene terephthalate (PET)." *Id.* at 9:11-16. PET, for example, is a "graft covering." The inner skirt is engaged to the valvular structure "via one or more thin PET reinforcing strips. *Id.* at 9:25-29. The "valvular structure 14 can comprise three leaflets 40, collectively forming a leaflet structure." *Id.* at 5:59-62, Fig. 2. The three leaflets of the valvular structure are "prosthetic leaflets." Levi's inner skirt 16 [yellow] is cylindrically extending and extends at least partially radially outwardly of prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red] as illustrated in Figure 2 below:



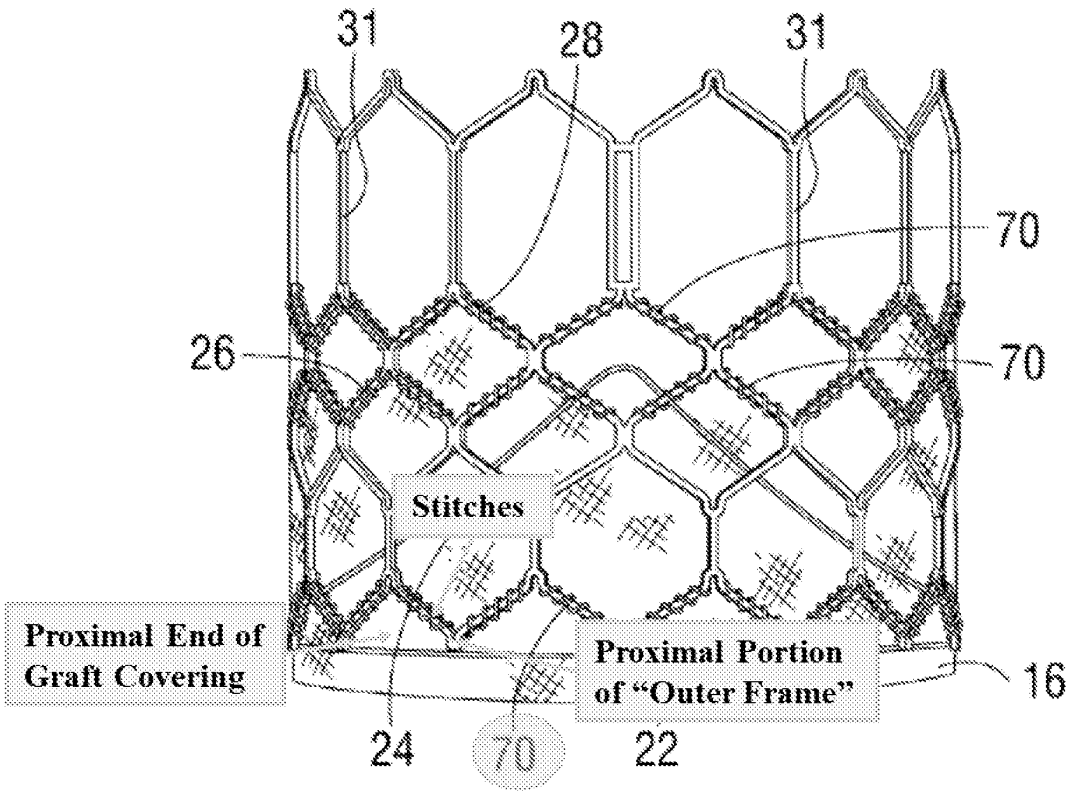
Id. at Fig. 2. Therefore, based on Patent Owner's statements during prosecution of related patents, and if a graft covering can be an inner frame, Levi's inner skirt satisfies this limitation. In fact, during prosecution of the related '846 patent, Patent Owner admitted that Levi includes an inner seal. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 13-14, 21.

4. Stitching

277. Claim 1 next recites: "wherein the outer frame is secured to the inner graft covering by stitching a proximal portion of the outer frame." Levi also discloses this limitation.

278. Levi's inner skirt is secured to the frame via a plurality of sutures 70 at the proximal portion of the outer frame, as shown in Figure 20 below:

FIG. 20

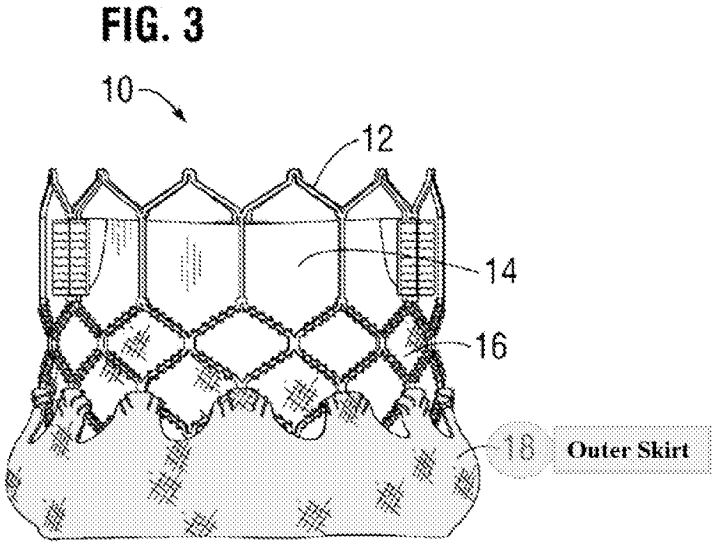


Ex. 1008 (Levi) at 9:24-25, 10:11-30, Figs. 20, 39.

5. Outer Seal

279. Claim 1 next recites: "an outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows of cells formed in the outer frame, wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame."

280. Levi discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame for preventing paravalvular leaks. Ex. 1008 (Levi) at 13:50-53, 13:62-66. The outer skirt is thus positioned externally to the outer frame.



Id. at Fig. 3.

a. Levi and Walther

281. Walther's outer cloth satisfies the "outer seal" limitations for the reasons presented in Ground 1. *Supra* §VI.A.5. A person of ordinary skill in the

art would have been motivated to attach Walther's outer cloth to Levi's frame in the same way that the cloth is attached to SAPIEN. Specifically, person of ordinary skill in the art would have been motivated to suture the outer cloth to the valve frame beginning at the proximal end of the frame such that the outer cloth covers at least two rows of cells in the frame. A person of ordinary skill in the art would have been motivated to attach the outer cloth in this way because Walther discloses that the orientation provided good results and Levi suggests a similar orientation for its outer skirt. Moreover, suturing is a simple procedure that would have been well known to person of ordinary skill in the art.

282. It is my opinion that a person of ordinary skill in the art would have found it obvious to replace Levi's bulging outer PET skirt with Walther's outer cloth. A person of ordinary skill would have been motivated by Walther's disclosure that its outer cloth prevents paravalvular leakage, increases the fit between the implanted prosthetic valve and the existing valve, and promotes tissue ingrowth. *See* Ex. 1007 (Walther) at 1120. The substitution of Walther's outer cloth for Levi's outer skirt would have merely entailed substitution of one known element (Walther's outer cloth) for another (Levi's bulging PET) to yield the predictable results of reducing paravalvular leakage.

283. Moreover, the field of heart valves had a finite number of options to address paravalvular leakage in November 2012. Walther and Levi disclose two

such methods. A person of ordinary skill would have found it obvious to select one of these finite, predictable options and, as I explain below, would have had a reasonable expectation of success in doing so.

284. A person of ordinary skill would have had a reasonable expectation of success in substituting Walther's outer cloth for Levi's outer skirt. The valve frames in Walther and Levi share many common features, including being balloon-expandable and formed of interconnected metal struts. Thus, a person of ordinary skill in the art would have reasonably expected the teachings of one patent to apply to another. Additionally, Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that *in vivo* implantation of the valve "is feasible," suggesting to persons of ordinary skill in the art that other cloth-covered valves would enjoy similar success. Ex. 1007 (Walther) at 1125.

285. Moreover, Levi suggests adding other components, like Walther's outer cloth, to the inflow portion of the outer frame. Ex. 1008 (Levi) at 16:41-45. Levi discloses that the inflow portion of the frame has a narrower crimped diameter so that "if ***additional components*** are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component." Ex. 1008 (Levi) at 16:41-45 (emphasis added). A person of ordinary

skill would have understood that Walther's outer cloth would be a potential "additional component."

286. Levi also discloses alternative frame materials and methods for modifying the leaflets to reduce the valve size to create more room for an outer seal. *Id.* at 6:31-49, 16:24-17:18. Persons of ordinary skill in the art would have understood they could utilize one or more of these strategies to add Walther's outer cloth to Levi's frame if the access vessel required a smaller valve. For all of these reasons, a person of ordinary skill would have reasonably expected success in using Walther's outer cloth on Levi's valve.

b. Levi and Spenser II

287. Spenser II's outer compressible material satisfies the "outer seal" limitations for the reasons presented in Grounds 2-3. *Supra* §VII.A.5.b. A person of ordinary skill in the art would have been motivated to attach Spenser II's compressible material to Levi's frame in the same way that the material is attached in Spenser II. Specifically, person of ordinary skill in the art would have been motivated to attach the compressible material to Levi's valve such that the compressible material covers at least the two proximal rows of cell in the frame. A person of ordinary skill in the art would have been motivated to attach the compressible material in this way because Spenser II discloses that the compressible material "creates a mechanical seal that prevents paravalvular

leakage" and Levi discloses a similar orientation for the outer skirt. Ex. 1011 (Spenser II) at [00145].

288. In my opinion, a person of ordinary skill in the art would have found it obvious to replace Levi's bulging outer PET skirt with Spenser II's compressible material. A person of ordinary skill would have been motivated by Spenser II's teachings that its radially extending fibers reduce or prevent paravalvular leakage and "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." Ex. 1011 (Spenser II) at [00145]. The substitution of Spenser II's compressible material for Levi's outer skirt would have merely entailed substitution of one known element (Spenser II's compressible material) for another (Levi's bulging PET) to yield the predictable results of reducing paravalvular leakage.

289. Moreover, as I discussed in the prior section, the field of heart valves had a finite number of options to address paravalvular leakage in November 2012. *Supra* §VIII.A.5.b. Spenser II and Levi disclose two such ways. A person of ordinary skill would have found it obvious to select either of these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in doing so.

290. A person of ordinary skill would have had a reasonable expectation of success in substituting Spenser II's compressible material for Levi's outer skirt.

The valve frames in Spenser II and Levi share many common features, including being balloon-expandable and formed of interconnected metal struts. Additionally, the references specifically relate to prosthetic heart valves developed by Edwards and share a common inventor (Benichou). *See* Ex. 1008 (Levi) at 1; Ex. 1011 (Spenser II) at 1. Thus, a person of ordinary skill in the art would have reasonably expected the teachings of one patent to apply to another. Additionally, Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that *in vivo* implantation of the valve "is feasible," suggesting to persons of ordinary skill in the art that other cloth-covered valves would enjoy similar success. Ex. 1007 (Walther) at 1125.

291. Moreover, as discussed in the previous section, Levi discloses a number of ways to accommodate an outer seal on its outer frame, which would have encouraged a person of ordinary skill in the art to add Spenser II's compressible material to Levi's frame. *Supra* §VIII.A.5.b.

6. Radially Compressed Orientation and Radially Expanded Orientation

292. Claim 1 next recites: "wherein the valve assembly has a radially compressed orientation and a radially expanded orientation." Levi, Walther, and Spenser II all disclose this limitation.

293. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.6. Spenser II discloses this limitation for the reasons I provided in Grounds 2-3. *Supra* §VII.A.6.

294. Levi also discloses this limitation. Levi teaches that "[w]hen constructed of a plastically-expandable material, the frame 12 (and thus the valve 10) ***can be crimped to a radially compressed*** state on a delivery catheter and then ***expanded*** inside a patient by an inflatable balloon or equivalent expansion mechanism." Ex. 1008 (Levi) at 6:20-24 (emphasis added). Thus, Levi discloses a valve assembly having a radially compressed orientation and a radially expanded orientation.

7. Fibers Press Against Native Leaflets

295. Claim 1 next recites: "wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient." Levi in combination with Walther or Spenser II renders this limitation obvious.

296. Levi discloses that the valve illustrated in Figures 1-3 "is adapted to be implanted in the native aortic annulus" and that when the frame is expanded, the skirt will "fill gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." Ex. 1008 (Levi) 5:52-54, 14:3-7. A person of ordinary skill in the art would have understood when the outer skirt "fills gaps between the frame 12 and the

surrounding native annulus," the outer skirt would press against the patient's native aortic leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.B.

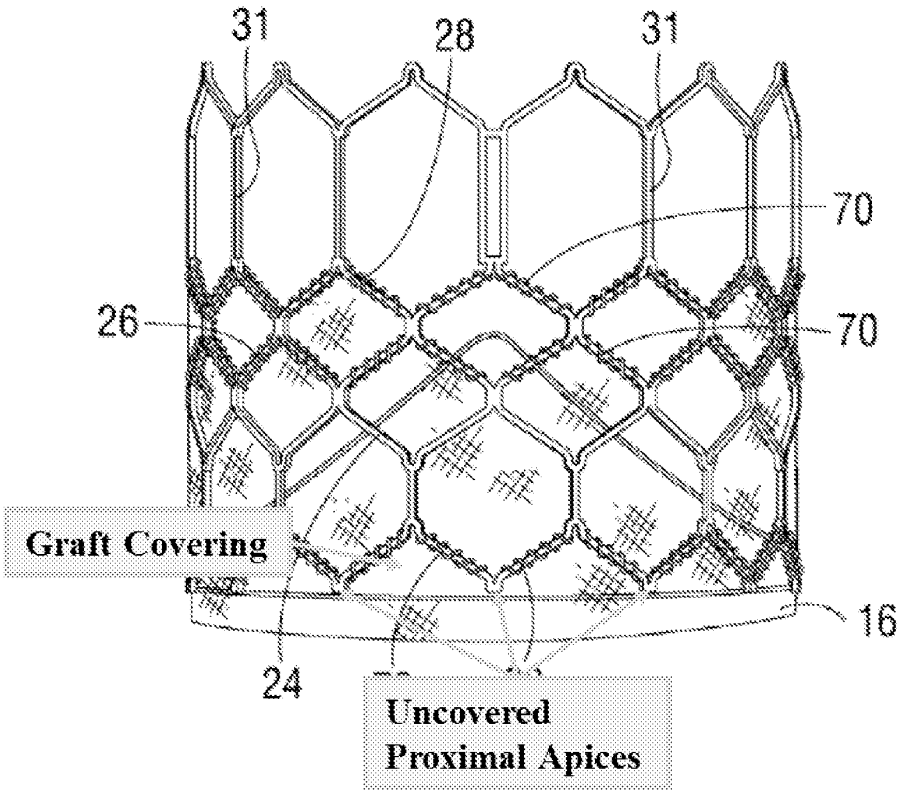
297. If Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's outer compressible material, a person of ordinary skill in the art would understand that the fibers of the outer cloth/compressible material, rather than the outer skirt, would press against the native leaflets. As explained previously, a person of ordinary skill in the art would have been motivated to simply attach the outer cloth/compressible material to Levi's outer frame in the same way and orientation that the components were attached to their prior valves. *Supra* §VIII.A.5.b-c. Thus, the outer cloth/compressible material would press against the annulus and leaflets just like Levi's outer skirt. *Supra* §§VI.A.7, VII.A.7.

8. <u>Uncovered Proximal Apices</u>

298. Claim 1 next recites: "wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering." Levi in combination with Walther or Spenser II renders this limitation obvious.

299. As I explained above, Levi discloses an inner PET skirt stitched to the interior surface of the outer frame. *Supra* §VIII.A.3. As shown in Figure 20 below, the inner skirt extends beyond, but does not expressly cover, the most proximal apices of the frame:

FIG. 20



Ex. 1008 (Levi) at Fig. 20.

300. Walther and Spenser II disclose an outer seal that does not cover the ends of the most proximal apices of their outer frames as I explained previously. *Supra* §§VI.A.8, VII.A.8. A person of ordinary skill in the art would have been motivated to position the outer cloth/compressible material on Levi's valve in the same way because Walther and Spenser II teach that such positioning is effective for creating a seal. Moreover, Levi discloses methods of reducing the diameter of

the valve at the inflow end to make space for an outer seal like the ones disclosed in Walther and Spenser II. *Supra* §§VIII.A.1-5.

9. Proximal Apices Extend More Proximally than Outer Seal

301. Claim 1 concludes by reciting: Claim 1 concludes by reciting: "wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." Levi in combination with Walther or Spenser II renders this limitation obvious.

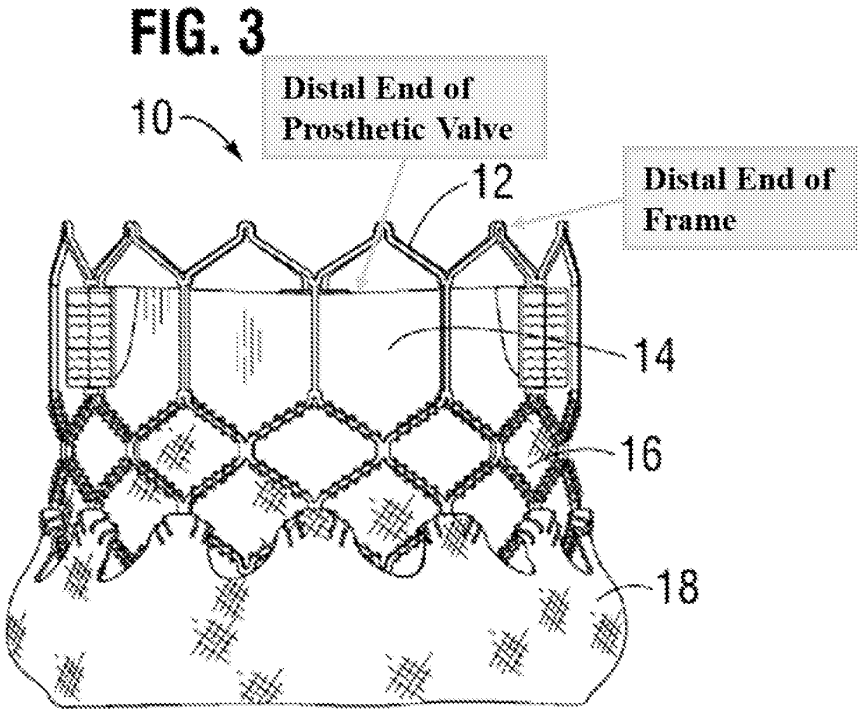
302. Persons of ordinary skill in the art would have found it obvious to adjust the size and placement of the Walther's outer cloth or Spenser II's compressible material such that the most proximal apices of Levi's outer frame extend proximally further than the outer cloth for the same reasons explained in the previous section and Grounds 1-3. *Supra* §§VI.A.9, VII.A.9.

B. Claim 2

303. Claim 2 recites: "The heart valve assembly of claim 1, wherein the outer frame extends distally further than the prosthetic heart valve." Levi discloses the limitations in claim 2 and based on claim 1, Levi renders claim 2 obvious in combination with Walther or Spenser II.

304. Levi discloses a prosthetic heart valve having a radially compressible and expandable stent frame. Ex. 1008 (Levi) at 6:17-20, 6:31-40. Levi discloses that "the inflow and outflow ends of a frame generally tend to over-expand more

so than the middle portion of the frame due to the 'dog boning' effect of the balloon used to expand the valve." *Id.* at 8:8-11. "To protect against over-expansion of the leaflet structure 14," Levi teaches that the "***leaflet structure desirably is secured to the frame 12 below the upper row of struts 32***." *Id.* at 8:11-13 (emphasis added). Levi teaches that this configuration helps ensure that the leaflets do not "protrude outwardly beyond the outflow end of the frame when the valve is crimped," protecting the leaflets from damage that may be caused by a "pushing mechanism or stop member [of the balloon catheter] that pushes against or abuts the outflow end of the valve." *Id.* at 8:21-39. When the leaflet structure is secured to the frame below the upper row of struts, as in Figure 3 below, the frame 12 extends distally further than the prosthetic valve 14:



Id. at Fig. 3.

C. Claim 3

305. Claim 3 recites: "The valve assembly of claim 1, wherein the outer frame is a singular, integral component." Levi discloses the limitations in claim 3 and renders claim 3 obvious in combination with Walther or Spenser II.

306. Levi discloses that its outer frame "comprises multiple rows of circumferentially extending, angled struts 52 [yellow] that are connected to each other at nodes, or connecting portions, 54 and 56 [blue]." Ex. 1008 (Levi) at 8:61-64. Levi further discloses that "[t]he uppermost row of struts 52 are connected to an adjacent row of struts by a plurality of axially extending struts 58 [red] and

commissure window frame portions 60 [red]." *Id.* at 8:64-67. Levi's Figures 11-12 illustrate the outer frame:

FIG. 11

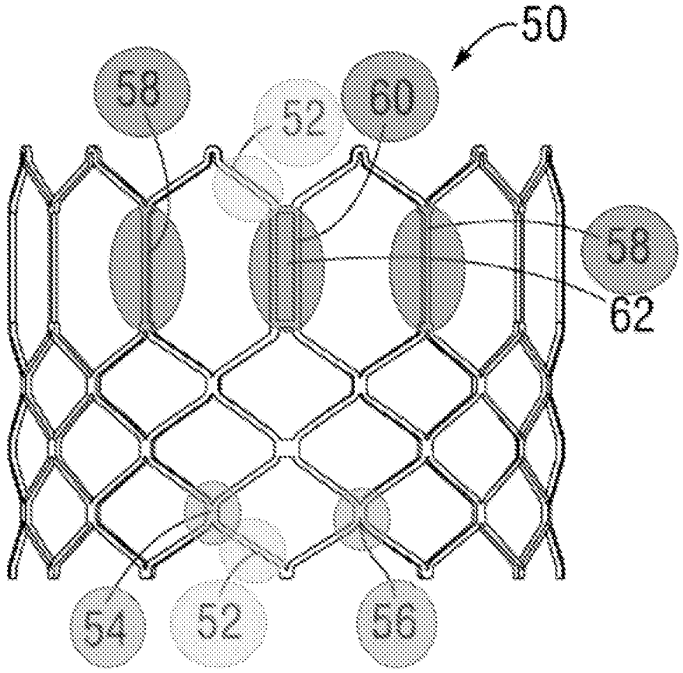
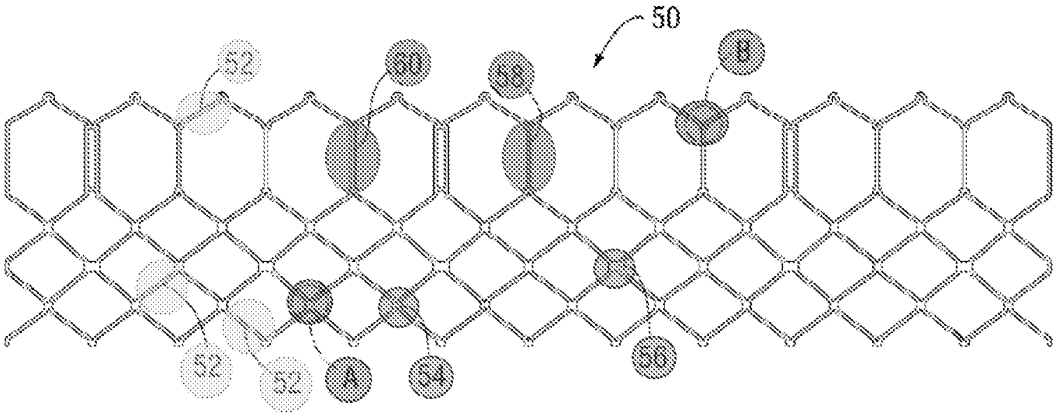


FIG. 12



Id. at Figs. 11, 12.

307. Because all of the metallic bars of the outer frame are interconnected, as shown in the figures above, the outer frame is a singular, integral component. *See id.* at 6:50-7:17, 9:4-6, Figs. 4-10, 13-14.

D. Claim 4

308. Claim 4 recites: "The valve assembly of claim 1, wherein the inner graft covering and the fibers are distinct elements." Levi discloses the limitations in claim 4 and renders claim 4 obvious in combination with Walther or Spenser II.

309. Levi discloses an inner PET skirt that is secured to the inner surface of the outer frame, and an outer PET skirt that is separately secured to the outer surface of the outer frame. Ex. 1008 (Levi) at 9:24-25, 10:11-30, 13:49-61, 16:51-54, Figs. 3, 20, 39.

310. If Levi's outer skirt was replaced with Walther's outer PET cloth or Spenser II's outer compressible material, a person of ordinary skill in the art would have understood that the outer cloth/compressible material and Levi's inner skirt would be "distinct elements" for at least the reasons that the elements would be positioned on opposite sides of the outer frame and separately attached thereto. The inner skirt would be positioned on the interior surface of the outer frame and secured thereto by a plurality of stitches. *Supra* §VIII.A.3-4. The outer cloth/compressible material would be positioned around the exterior surface of the outer frame and separately secured thereto. *Supra* §VIII.A.4-5.

E. Claim 5

311. Claim 5 recites: "The valve assembly of claim 1, wherein a seal is created between the inner frame and the outer frame." Levi discloses the limitations in claim 5 and renders claim 5 obvious in combination with Walther or Spenser II.

312. Levi discloses its inner skirt assists "in ***forming a good seal*** between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets." Ex. 1008 (Levi) at 9:7-11 (emphasis added). A person of ordinary skill in the art would have understood that "blocking the flow of blood through the open cells" means that a seal is created between Levi's inner skirt and frame. If a seal was not created, the inner skirt would not be able to block the flow of blood.

F. Claim 6

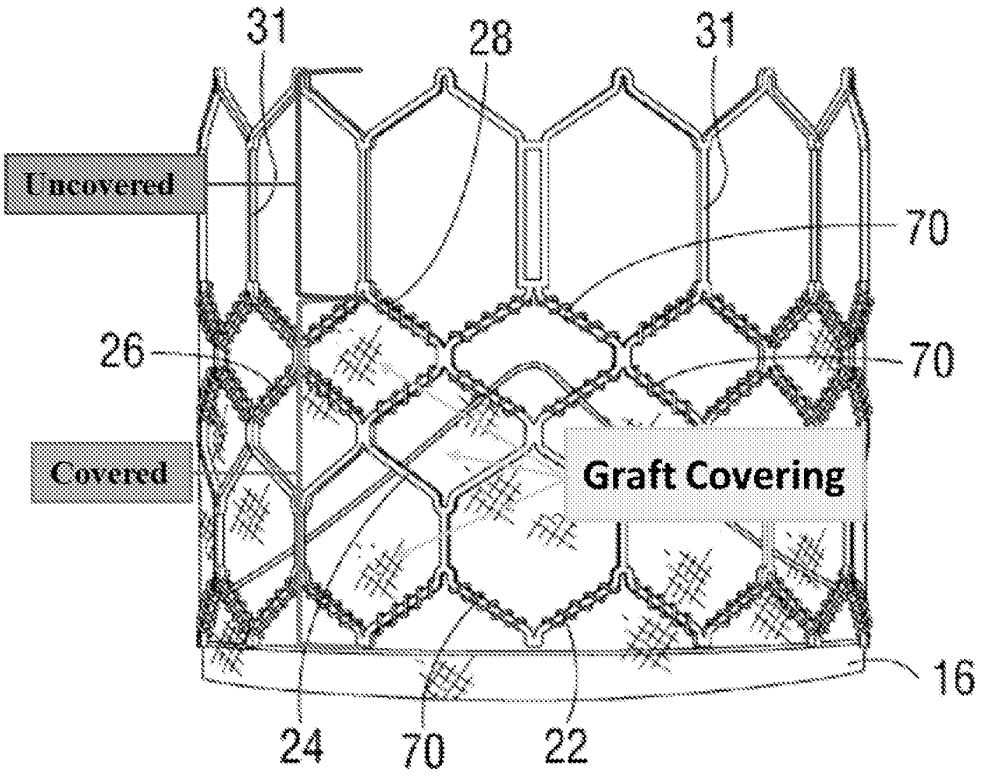
313. Claim 6 recites: "The valve assembly of claim 1, wherein a portion of the outer frame is uncovered by the graft covering and the outer seal." Levi discloses the limitations in claim 6 and renders claim 6 obvious in combination with Walther or Spenser II.

314. First, I note that Claim 1 requires that an end of the most proximal apices of the outer frame, which are a "portion of the outer frame," are uncovered by the inner graft covering and the outer seal. Therefore, Levi renders this claim

obvious alone and in combination with Walther or Spenser II for the reasons I provided in claim 1. *Supra* §VIII.A.8.

315. As I explained in claim 1, Levi discloses an inner PET skirt (inner graft covering) stitched to the interior surface of the outer frame. *Supra* §VIII.A.3. As shown in Figure 20 below, Levi's inner skirt 16 covers the bottom (i.e., proximal) three rows of cells in the outer frame but does not cover the uppermost row of cells:

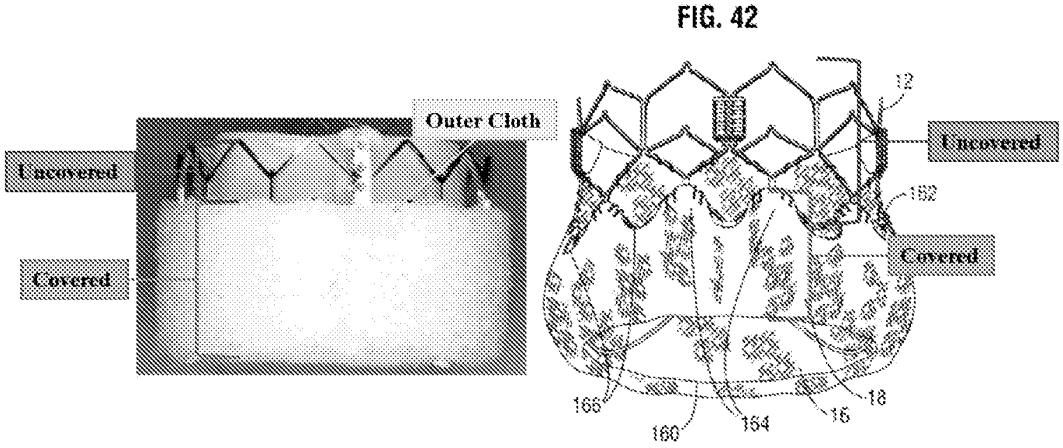
FIG. 20



Ex. 1008 (Levi) at Fig. 20.

1. Walther

316. As I explained in Ground 1, Walther's outer cloth covers two circumferentially extending rows of cells formed from SAPIEN's open cell configuration but does not cover the distal portion of the frame. *Supra* §VI.E. If Walther's outer cloth were substituted for Levi's outer skirt, the outer cloth would cover the bottom two rows of cells of the support stent but ***would not*** cover the uppermost row of cells, as illustrated in the side-by-side comparison of Walther's Figure 1 (left) and Levi's Figure 42 (right) below:



Compare Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1008 (Levi) at Fig. 42. Persons of ordinary skill in the art would have been motivated to position the outer cloth as to not cover at least the uppermost row of cells to minimize the risk of blocking the patient's coronary arteries, which are located distally from the aortic valve. Leaving the uppermost row of cells uncovered ensures that even if the uppermost row overlaps with the coronary arteries, blood is not blocked from flowing into the

arteries by the outer seal. This also ensures the coronary arteries are accessible for future intervention in cases where patients also suffer from conditions affecting the coronary arteries.

317. Therefore, the combination of Levi and Walther would result in a valve wherein a portion of the outer frame is uncovered by the graft covering and the outer seal.

2. Spenser II

318. As I explained in Grounds 2-3, Spenser II's compressible material covers the bottom two rows of cells formed by stent structure 252, but does not cover the upper portion of the stent structure. *Supra* §VII.F. When added to the exterior of the stent in Levi's valve, the compressible material would cover the bottom two rows of cells formed by the stent frame but ***would not*** cover the uppermost two rows, as illustrated in the side-by-side comparison of Spenser II's Figure 22 (left) and Levi's Figure 42 (right) below:

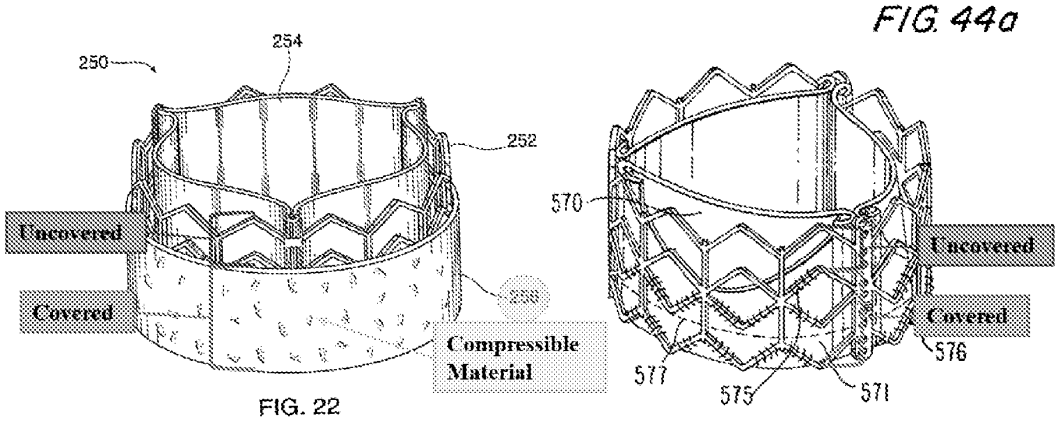


FIG. 22

Compare Ex. 1011 (Spenser II) at Fig. 22 *with* Ex. 1008 (Levi) at Fig. 42. Persons of ordinary skill in the art would have been motivated to position the compressible material this way to avoid blocking the patient's coronary arteries for the reasons I explained in the preceding section. *Supra* §VIII.F.1.

319. Therefore, the combination of Levi and Spenser II would result in a valve wherein a portion of the outer frame is uncovered by the graft covering and the outer seal.

G. Claim 7

320. Claim 7 recites: "The valve assembly of claim 1, wherein a distal end of the outer frame extends distally beyond the prosthetic leaflets." As explained in Grounds 2-3, claim 7 is substantially similar to claim 2. Therefore, Levi discloses the limitations in claim 7 for the same reasons presented in claim 2. *Supra* §VIII.B. Thus, Levi renders claim 7 obvious in combination with Walther or Spenser II.

H. Claim 8

321. Claim 8 recites: "The valve assembly of claim 1, wherein the outwardly extending fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly." Levi in combination with Walther or Spenser II renders claim 8 obvious.

322. If Walther's outer cloth or Spenser II's compressible material were substituted for Levi's outer skirt, the resulting valve would include fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve" for the reasons I previously stated in Grounds 1-3. *Supra* §§VI.F, VII.H.

I. Claim 9

323. Claim 9 recites: "The valve assembly of claim 1, wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping." Levi in combination with Walther or Spenser II renders claim 9 obvious.

324. As I explained in claim 1, Levi discloses an inner skirt comprised of a PET fabric graft covering that extends around the prosthetic valve leaflets. *Supra* §VIII.A.3. Levi's inner skirt 16 [yellow] "extends in radially overlapping alignment with the leaflets of the prosthetic heart valve" 14 [blue]:

FIG. 2

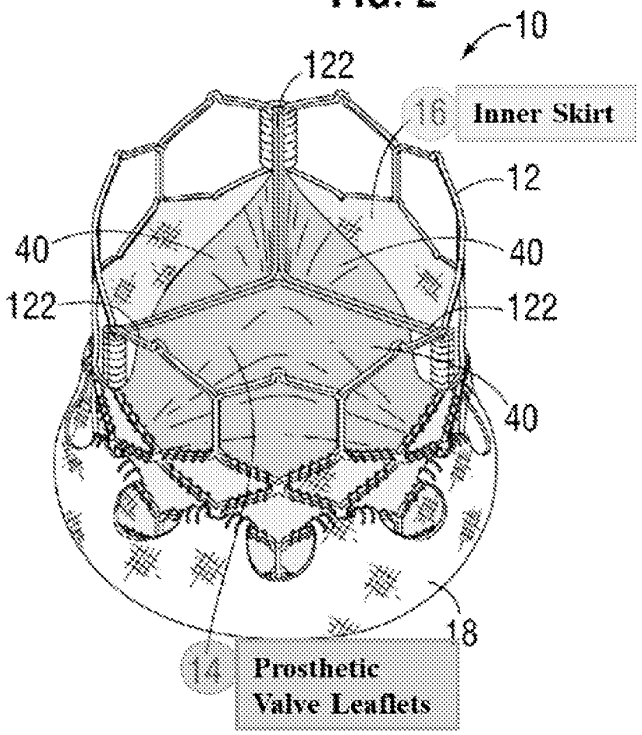
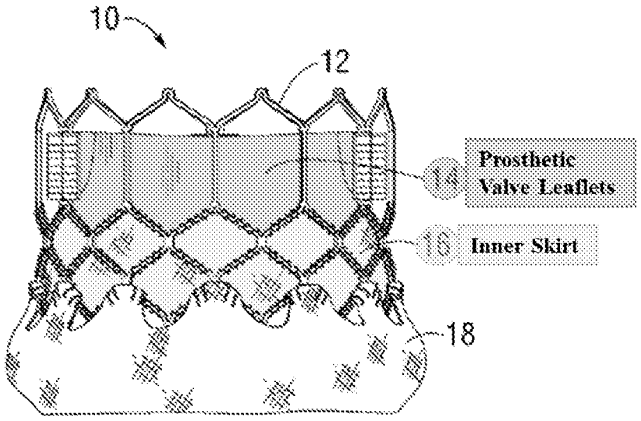


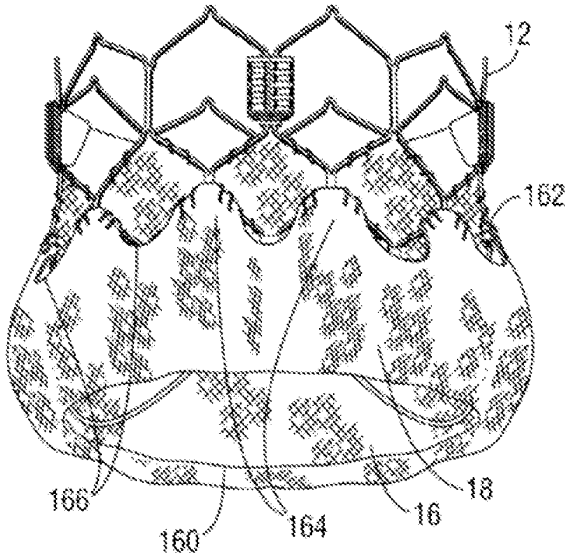
FIG. 3



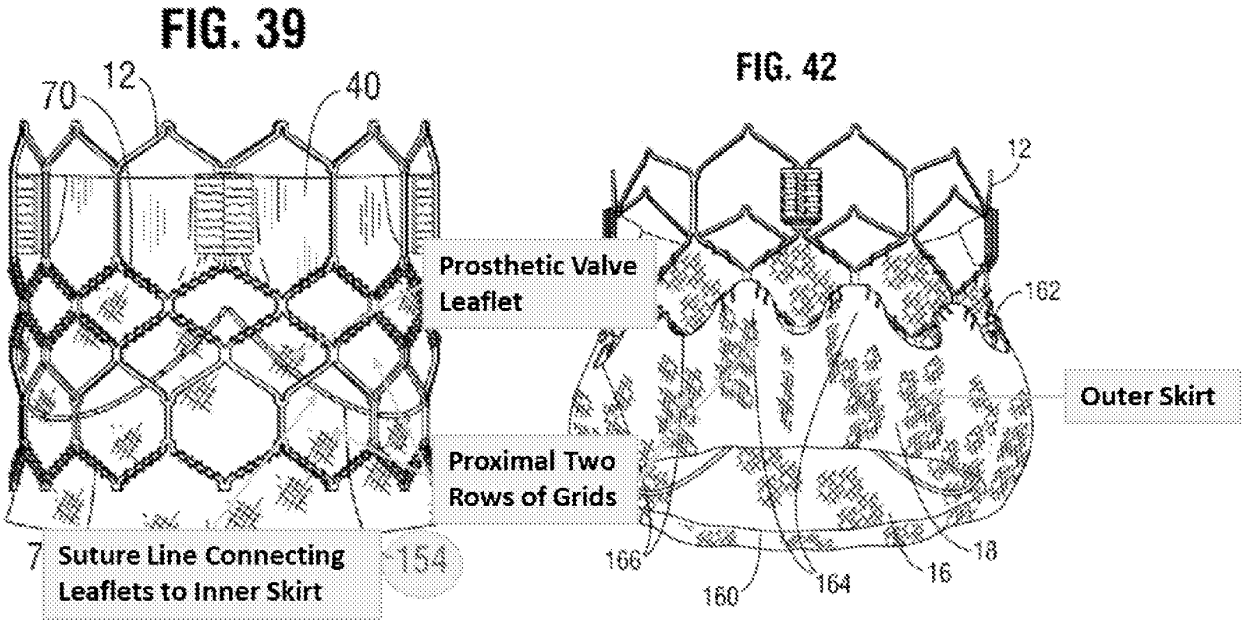
Ex. 1008 (Levi) at Figs. 2-3.

325. Levi's Figure 42 (below) shows that the outer skirt may cover the bottom (i.e., proximal) two rows of open cells formed by the outer frame:

FIG. 42



Id. at Fig. 42. A side-by-side comparison of Figures 39 and 42 confirms that the proximal two rows of cells covered by the outer skirt in Figure 42 radially overlap with the prosthetic valve leaflets:



Compare id. at Fig. 39 *with id.* at Fig. 42.

326. Walther and Spenser II disclose an outer seal that covers the bottom two rows of cells formed by the stent frame, which radially overlap with the prosthetic leaflets. Ex. 1007 (Walther) at 1121, Fig. 1; Ex. 1011 (Spenser II) at [00145], Fig.22; *supra* §§VI.G, VII.I. A person of ordinary skill in the art would have been motivated to attach Walther's outer cloth or Spenser II's compressible material to Levi's outer frame in the same way, and would have expected success in doing so, because the references demonstrate that covering the bottom two rows is effective at creating a seal. The combined device would thus include an outer seal covering the bottom two rows of cells formed by Levi's outer frame, which

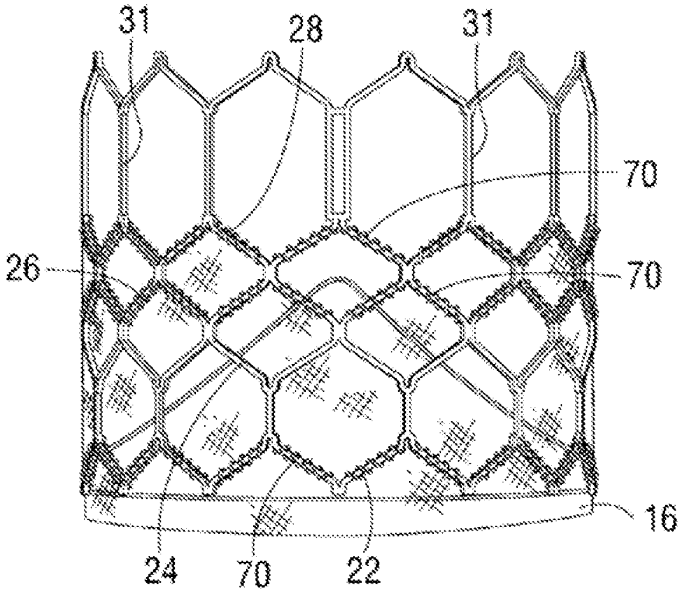
radially overlap with the prosthetic leaflets and the inner skirt (graft covering) for the reasons I provided above.

J. Claim 12

327. Claim 12 recites: "The valve assembly of claim 1, wherein the outer seal is free of a non-porous graft covering." Levi in combination with Walther and Spenser II renders claim 12 obvious.

328. A person of ordinary skill in the art would understand that when Levi's outer skirt is replaced with Walther's outer cloth or Spenser II's compressible material, there would be no "non-porous graft covering" between the outer cloth/compressible material. Levi does not include any "non-porous graft covering" on the exterior of the outer frame between the skirt and the frame, as shown in Figure 20, which depicts the valve without the outer skirt attached:

FIG. 20



Ex. 1008 (Levi) at Fig. 20. Similarly, neither Walther's outer cloth nor Spenser II's compressible material includes such a graft covering. *Supra* §§VI.I, VII.K.

IX. SECONDARY CONSIDERATIONS

329. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '735 patent. For example, I am not aware of any products sold by Patent Owner that would be covered by the '735 patent and, therefore, I am not aware of any commercial success.

330. Further, given that the devices claimed in the '735 patent are not new, and were invented long before November 2012, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged

inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

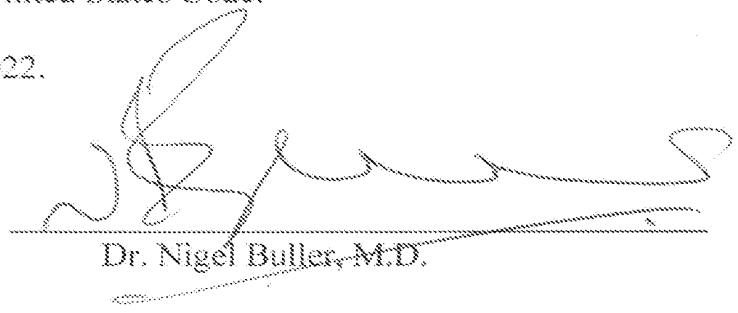
X. CONCLUSION

331. For the foregoing reasons, it is my opinion that claims 1-9, 11-12 of the '735 patent are rendered obvious by the prior art discussed above in view of the knowledge of one of ordinary skill in the art at the time of the alleged invention.

332. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Patent Owner may raise, as well as new information, including, but not limited to, any claim constructions advanced by Patent Owner or adopted by the Board in the Institution Decision, and respond to any alleged secondary considerations as they become available to me.

333. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on January 3, 2022.



Dr. Nigel Buller, M.D.

Filed: February 7, 2022

On behalf of **Edwards Lifesciences Corporation and Edwards Lifesciences LLC**
By: Craig S. Summers
Joshua J. Stowell
Brian C. Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxEdwards21-5@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC
Petitioners,

v.

AORTIC INNOVATIONS, LLC
Patent Owner.

IPR2022-00556
Patent No. 10,987,236

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,987,236

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Exhibit No.	Description
1001	U.S. Patent No. 10,792,172 B2 ("**'236 patent**")
1002	Excerpts from the prosecution history of the '236 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) ("**Walther**")
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. ("**Levi**")
1009	Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. ("**Spenser**")
1011	WO 2006/005015 A2 to Spenser et al. ("**Spenser II**")
1012	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009) ("**Cribier**")
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.

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1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.
1016	Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010) ("Alkashkari")
1017	Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020	Yuksel, Uygar, *Balloon-Expandable Transcatheter Aortic Valve Implantation,* Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) ("Walther II")
1022	Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) ("Zajarias")
1025	Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)

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1026	U.S. Patent No. 7,393,360 B2 to Spenser et al. ("Spenser Parent")
1027	Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., *Yarn structure and properties from different spinning techniques*, ("Tyagi")
1029	Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
1030	Cribier, Alain, et al., *Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis*, 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation*, edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)
1034	Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)

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1035	U.S. Patent No. 5,957,949 to Leonhardt et al.
1036	Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems*, Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., *In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry*, EuroIntervention 15:1240-1247 (2020)
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1043	Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan*, General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations*, J. Endovasc. Ther. 14:347-351 (2007)
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. ("Cribier '321")
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020

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1048	WO 2011/051043 A1 to Essinger et al.
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall ("Birdsall")
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD

Exhibit No.	Description
1060	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (November 2011), obtained from the University of California Los Angeles Library
1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
1063	Library of Congress subject heading sh85099890
1064	Library of Congress subject heading sh85023143
1065	Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009), obtained from the British Library
1067	Herz MARC Record from the British Library
1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD

Petitioners Edwards Lifesciences Corp. and Edwards Lifesciences LLC ("Petitioner") request *inter partes* review ("IPR") of claims 1-4 ("the challenged claims") of U.S. Patent No. 10,987,236 ("the '236 patent"), purportedly assigned to Aortic Innovations, LLC ("Patent Owner").

I. SUMMARY OF THE ARGUMENT

The '236 patent describes endograft devices for repairing aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments comprise multi-component structures extending into the patient's ascending aorta and aortic arch.[1]

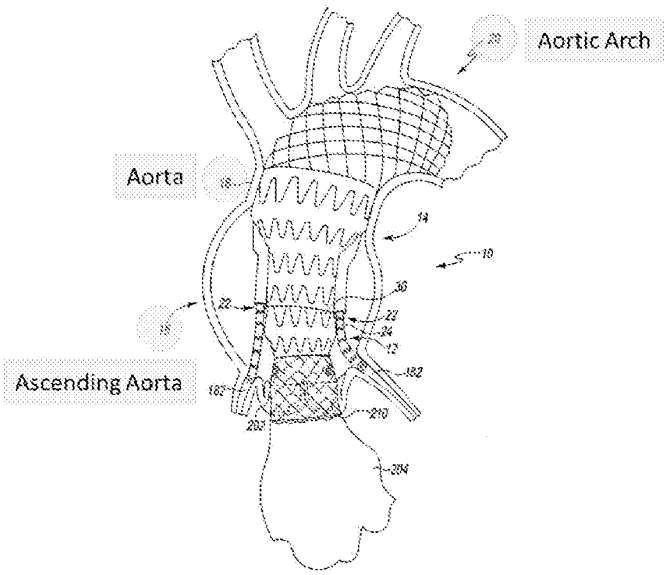


Fig. 2

[1] Color and labels added to figures unless otherwise noted.

The challenged claims, however, describe only the heart-valve component. Petitioner recently filed IPR Petitions against Patent Owner's U.S. Patent Nos. 10,792,172, 10,857,011, 10,966,846, 10,881,538, and 11,129,735 ("IPR Patents"). The '236 patent shares a common specification with the IPR patents. Like the IPR patents, the '236 patent claims a valve assembly having four principal elements: (1) a metallic outer frame [red], (2) an inner frame that includes a polymeric graft covering [blue], (3) stitches securing the inner frame to the outer frame [orange], and (4) non-metallic fibers positioned radially outwardly of the outer frame [green].

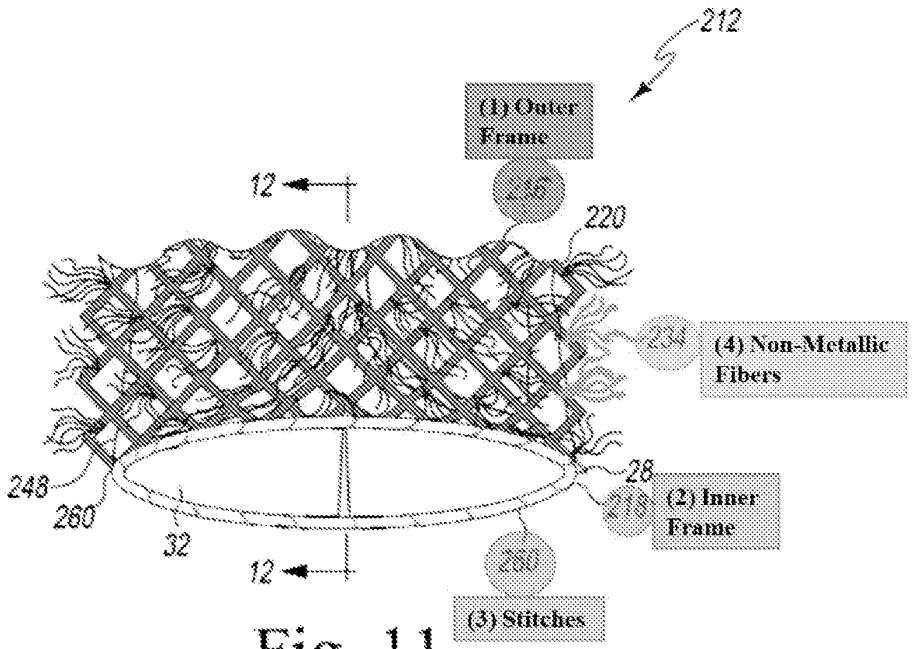


Fig. 11

The prior art discussed below discloses and renders obvious all of the claimed limitations, which were well known in the field by November 2012, the '236 patent's priority date ("Critical Date").

Patent Owner does not make or sell heart valves that practice the '236 patent. Rather, the '236 patent is part of a calculated attempt by Patent Owner to secure claims covering Petitioner's commercially successful SAPIEN 3 Ultra transcatheter heart valve. During prosecution of several related patents, Patent Owner argued that Petitioner's SAPIEN 3 Ultra was covered by the claims. Patent Owner also recently filed suit against Petitioner asserting that the SAPIEN 3 Ultra infringes the '236 patent ("the Litigation"). However, in its effort to snare SAPIEN 3 Ultra, Patent Owner broadened its patent claims so far that they cover the prior art.

The '236 patent claims a dual-frame valve that must include a metallic "outer frame" [red] and an "inner frame" [blue]:

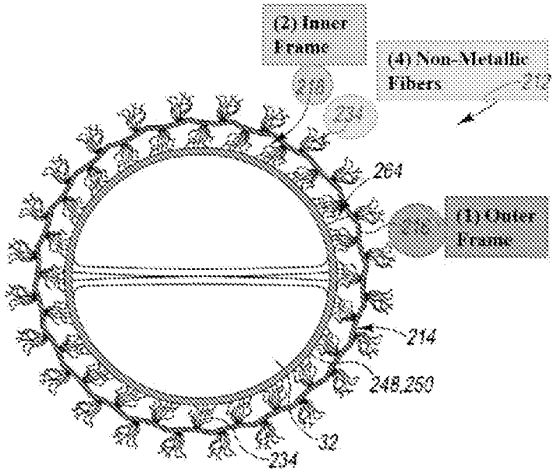
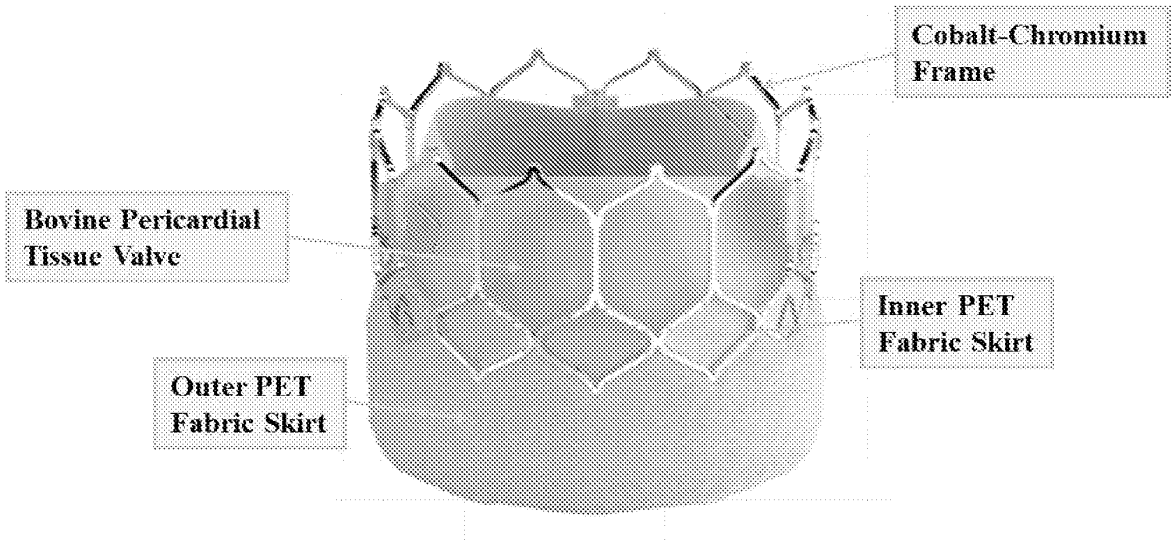


Fig. 13

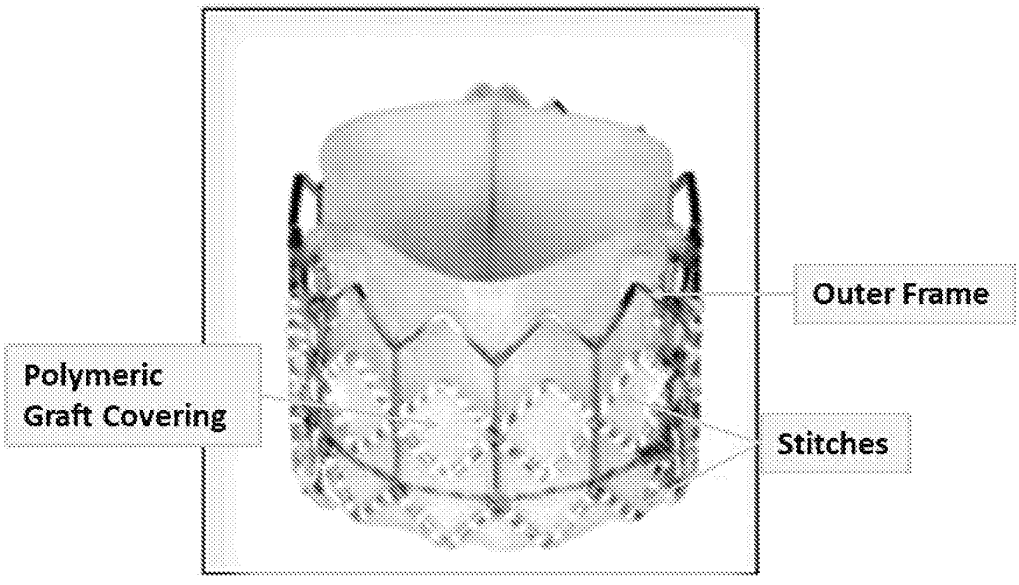
In contrast, SAPIEN 3 Ultra has only one frame, not inner and outer frames:



In an attempt to capture SAPIEN 3 Ultra, Patent Owner argued during prosecution of the '236 patent family that the limitations in claim 1 requiring "an outer frame" and "inner frame" that includes a polymeric "graft covering" are satisfied by a valve

that has ***only*** one frame and a polymeric graft covering. Patent Owner also argued that an outer skirt satisfied the limitation requiring non-metallic fibers positioned radially outwardly of the outer frame. But Petitioner's prior-art publications and patents describe earlier SAPIEN heart valves having precisely these features.

For example, Petitioner's SAPIEN Transcatheter Heart Valve (a predecessor to SAPIEN 3 Ultra) was one of the world's first THVs. Petitioner received regulatory approval for SAPIEN in Europe in 2007 and the United States in 2011, both before the Critical Date. **Cribier**, a publication relied on herein, discloses that SAPIEN includes: (1) a metallic "outer" frame, (2) a "polymeric graft covering," and (3) stitches securing the graft covering to the outer frame.



Edwards SAPIEN® THV
23 mm, 26 mm

Petitioner also modified SAPIEN to include an outer cloth comprising (4) an outer seal including non-metallic fibers positioned radially outwardly of the outer frame. **Walther** describes and pictures this modified SAPIEN.

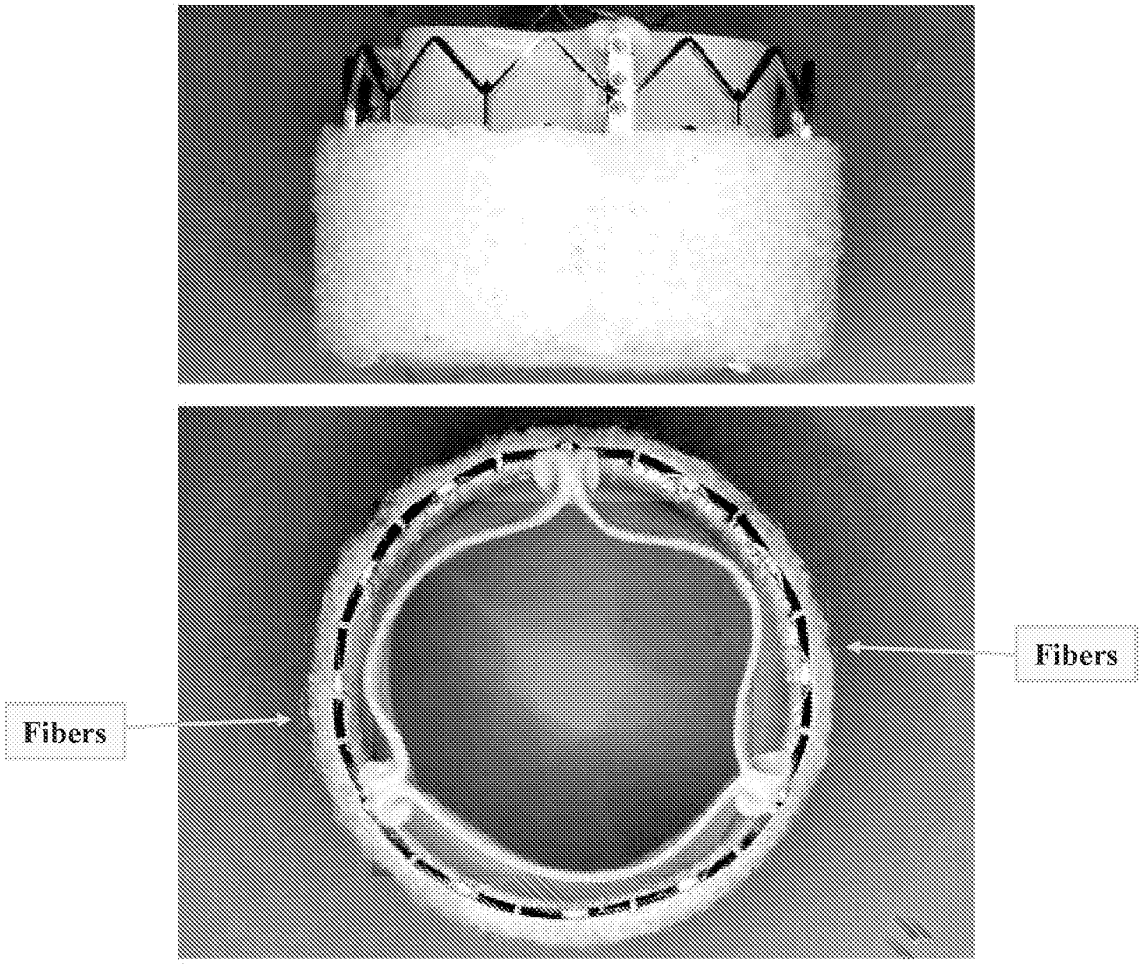
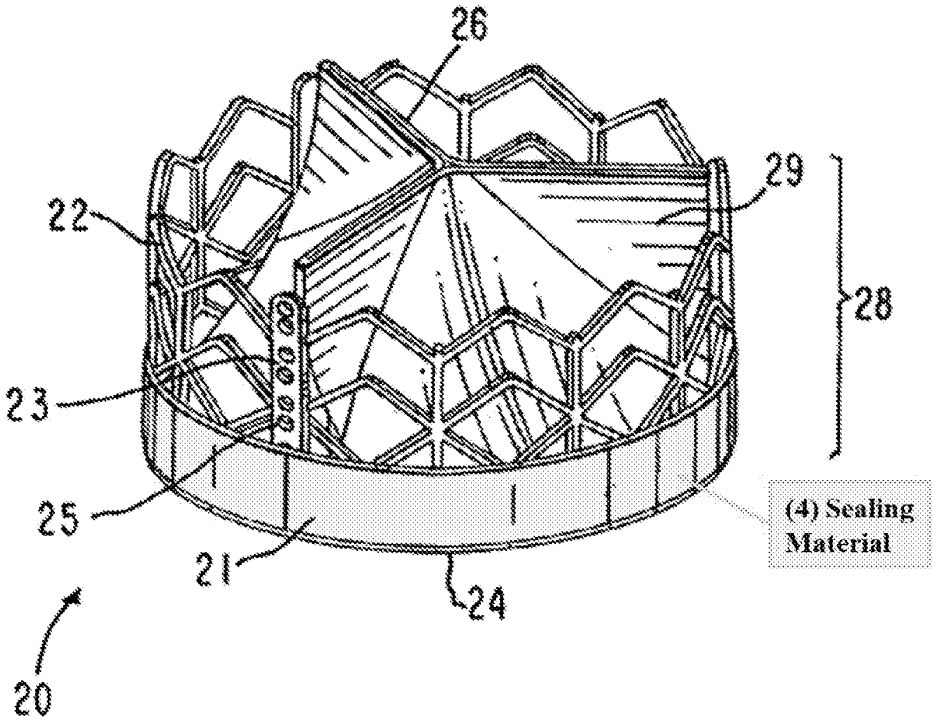


Fig. 1. Cloth valve.

Walther discloses implanting the modified SAPIEN within a surgical valve where the fibrous outer cloth reduces leaks around the SAPIEN, known as paravalvular leakage ("PVL"), and increases fit between SAPIEN and the surgical valve.

Petitioner also filed patent applications in the early 2000s disclosing THVs like SAPIEN having an outer seal for reducing PVL. **Spenser** discloses a heart valve configured for endovascular delivery that includes a sealing material, or cuff portion, positioned externally to the outer frame.



Spenser II also discloses a heart valve having a "compressible material" that "may resemble a cloth or fabric having small fibers extending from the surface of the material." In fact, during prosecution of the '236 patent, Patent Owner admitted that Spenser II "appears to teach a band with fibers emanating therefrom in FIG 22."

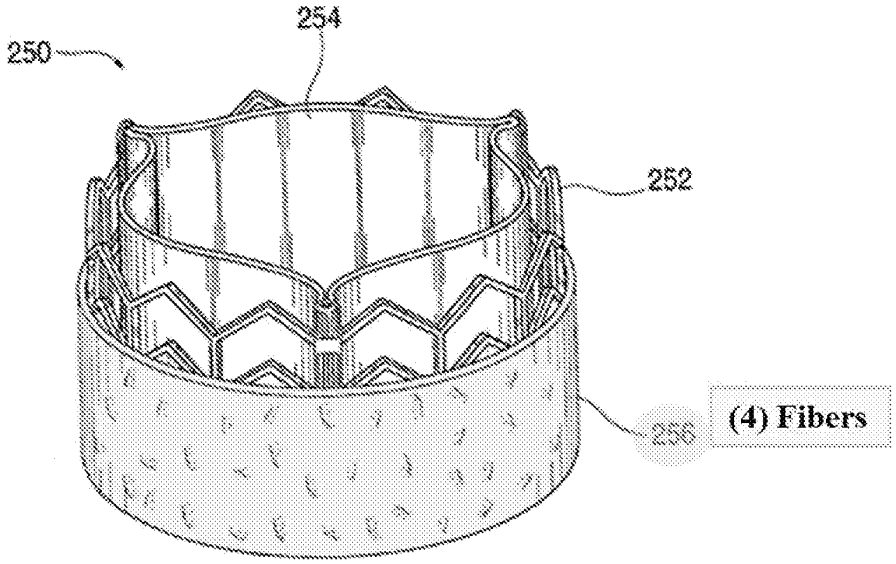
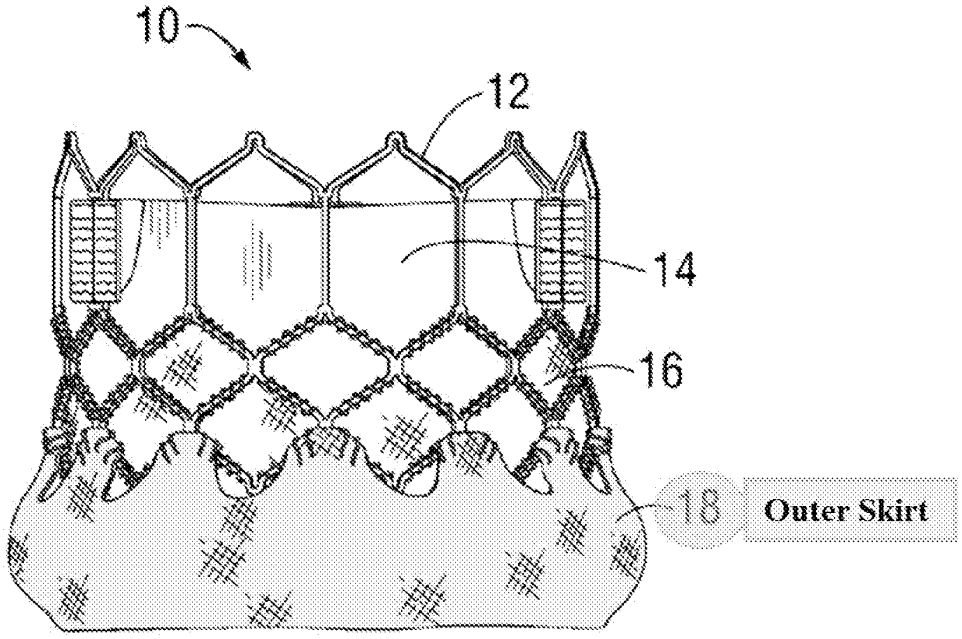


FIG. 22

Spenser II's compressible material prevents PVL by sealing against the patient's native tissue.

Likewise, **Levi** discloses a heart valve having a "polymeric graft covering" and fibrous outer skirt for sealing against the native annulus and leaflets to reduce PVL.

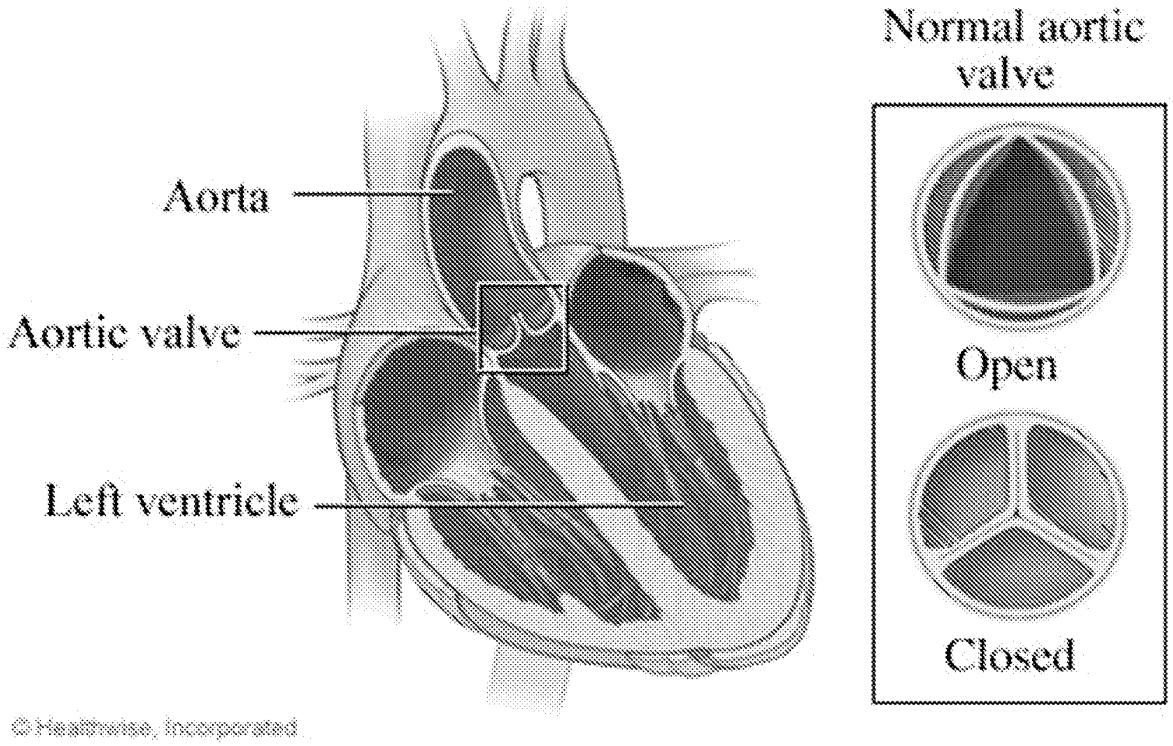
FIG. 3



This prior art demonstrates that Petitioner and persons of ordinary skill in the art (POSITAs) disclosed the claimed heart valves before the Critical Date. Unfortunately, the Examiner of the '236 patent did not apply any of the prior art references relied on herein during prosecution, nor was she aware of all of the prior art. Cribier, Walther, and Spenser were not of record during prosecution. Because Petitioner's prior inventions and disclosures anticipate or render obvious the challenged claims, the Board should institute this IPR and cancel the challenged claims.

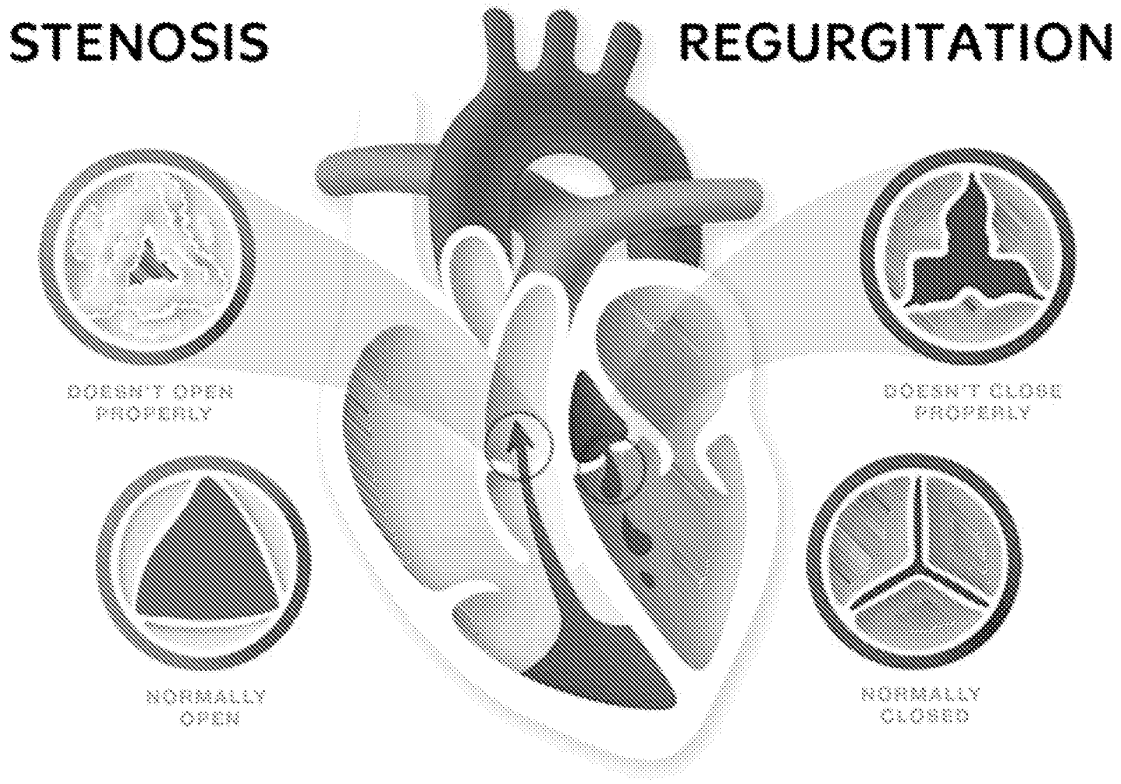
II. ANATOMY AND BACKGROUND

The human heart has two upper chambers (left and right atriums) and two lower chambers (left and right ventricles). (Ex. 1003, ¶46.) The aortic valve connects the left ventricle with the aorta on the left side of the heart. (*Id.*) The aortic valve includes three leaflets that coapt and expand to operate as a one-way valve that regulates blood flow from the left ventricle into the aorta and prevents backflow of blood from the aorta to the left ventricle. (*Id.*)



Aortic stenosis occurs when the aortic valve's opening narrows, often by excessive buildup of calcium deposits on the valve. (*Id.*, ¶47) Aortic regurgitation

occurs when the aortic leaflets fail to coapt properly, allowing blood to flow backward from the aorta into the left ventricle.[2] (*Id.*)



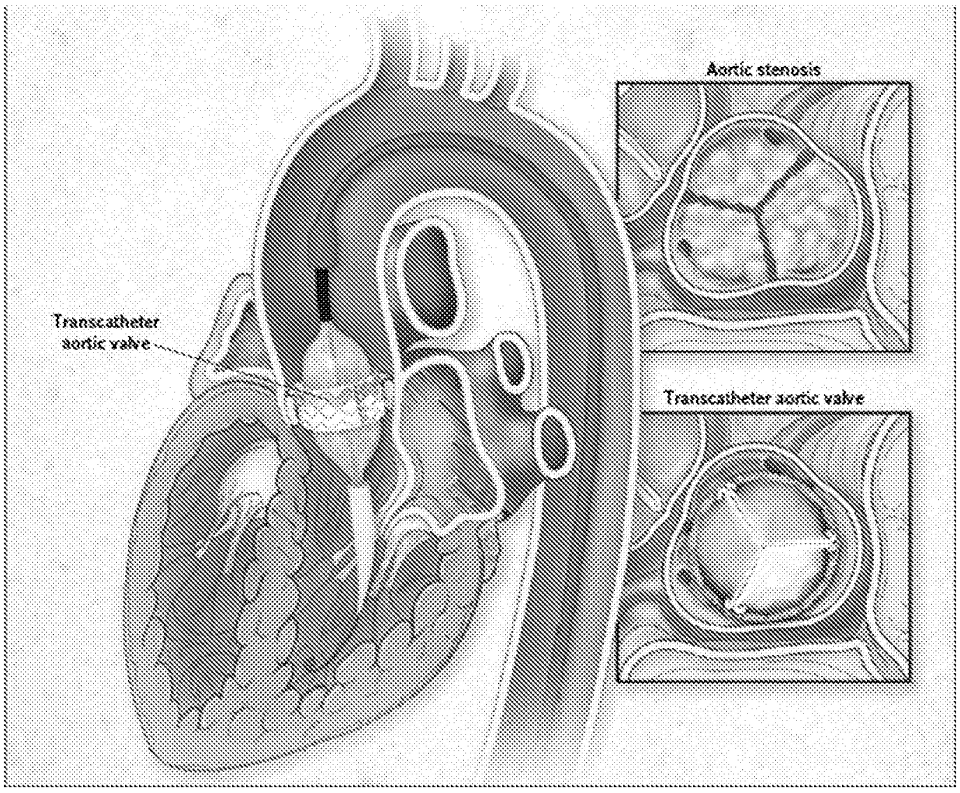
A common treatment for aortic stenosis and regurgitation is replacement of the diseased native valve with a prosthetic valve. (*Id.*, ¶48.) An effective prosthetic

[2] The image provided illustrates stenosis and regurgitation in two different heart valves; however, POSITAs would understand that both conditions could affect the aortic valve. (Ex. 1003, ¶47.)

aortic valve must create an effective seal between the valve and the patient's native aortic tissue. (*Id.*) Without such a seal, blood can leak between the prosthetic valve and native tissue, causing PVL.[3] (*Id.*)

To avoid the risks of open-heart surgery, Petitioner developed minimally invasive transcatheter heart valves ("THVs") that could be implanted through the patient's vasculature via a catheter. (*Id.*, ¶49.) Unlike surgical valves, which required a surgeon to suture a sewing ring to the patient's tissue, THVs sealed against the patient's tissue by pressing the exterior of the THV against the diseased native leaflets and surrounding tissue, as shown in the illustration of Petitioner's SAPIEN THV below:

[3] "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve. (Ex. 1003, ¶48, n.1.)

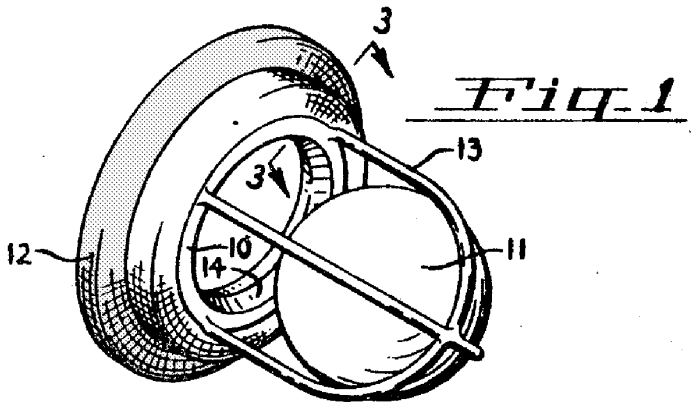


(*Id.*; Ex. 1022, 2189, Fig. 1.) Physicians could implant THVs in severely ill patients not eligible for open-heart surgery, and THVs quickly became highly successful. (Ex. 1003, ¶49.) Despite their success, however, the potential for PVL remained a concern. (*Id.*) As discussed in detail below, this concern motivated those in the art, including Petitioner, to develop methods for minimizing PVL by creating more effective outer seals.

III. STATE OF THE ART

Petitioner was founded in 1958. Petitioner's earliest work related to surgically implantable heart valves. One of Petitioner's first commercial valves, the Starr-

Edwards valve, included a sewing ring 12 that formed a seal between the valve and tissue to prevent PVL:



(Ex. 1013, 1:38-46 Fig. 1; Ex. 1003, ¶54.)

In 1989, Dr. Henning Andersen conceived of the first THV. The balloon-expandable valve included a wire stent and was implanted with a catheter. Dr. Andersen's work led to U.S. Patent 5,411,552, which was filed in 1994, and discloses a THV having a metallic outer frame (2, 3) and graft covering (24):

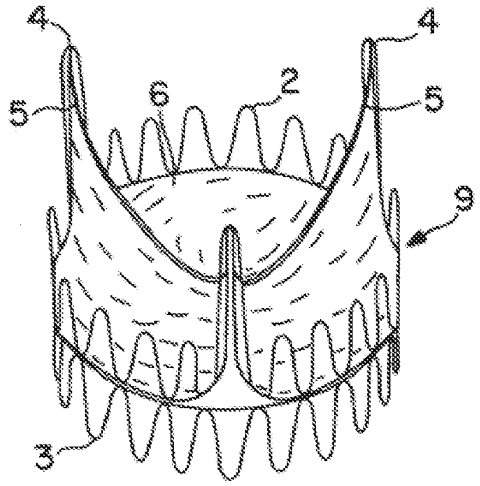


FIG. 2

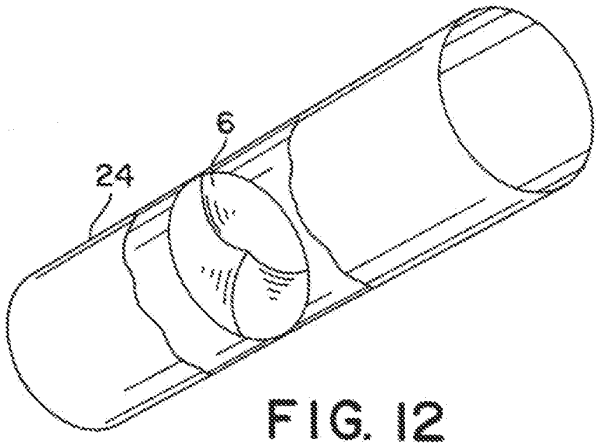


FIG. 12

(Ex. 1014, 4:3-17, 5:9-28, Figs. 2, 11-12; Ex. 1003, ¶¶58-59.)

Shortly thereafter, POSITAs began adding outer seals to THVs to reduce PVL. In 1996, Dr. Alain Cribier filed a patent application on a THV having an internal cover (19′) that is "rolled up to be applied to the external wall of the stent" to form an outer seal (19″) [yellow]:

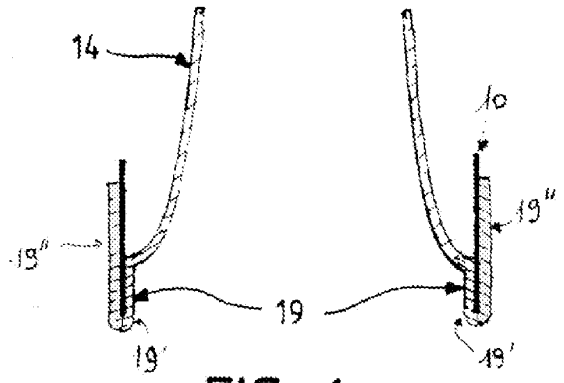
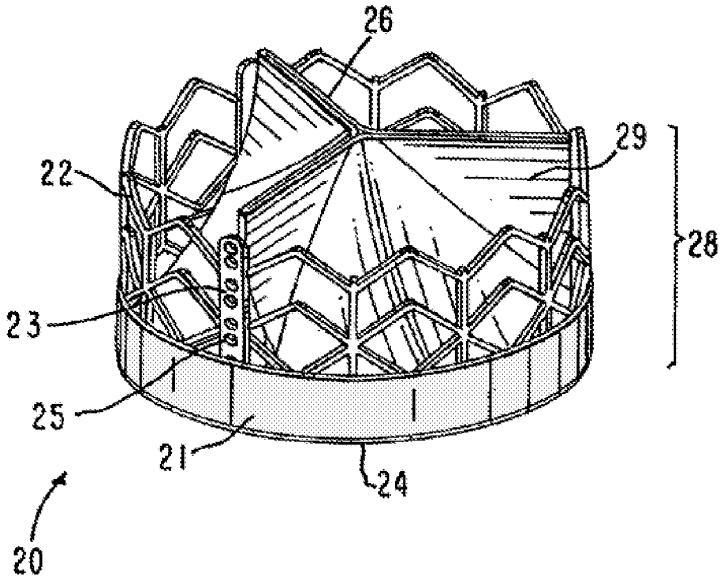


FIG_6d

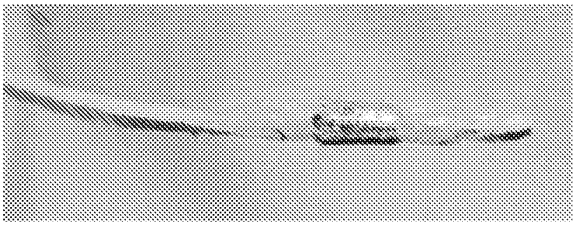
(Ex. 1018, 22:11-26, Fig. 6d.) The sealing material (19″) presses against the patient's native diseased tissue and prevents blood from leaking through and around the device. (*Id.*)

Similarly, in 2001, Percutaneous Valve Technologies ("PVT"), a company founded by Dr. Cribier, filed a patent application on a THV that disclosed an outer seal, or "cuff portion," highlighted in yellow below, and wrapped around the support stent's inlet:



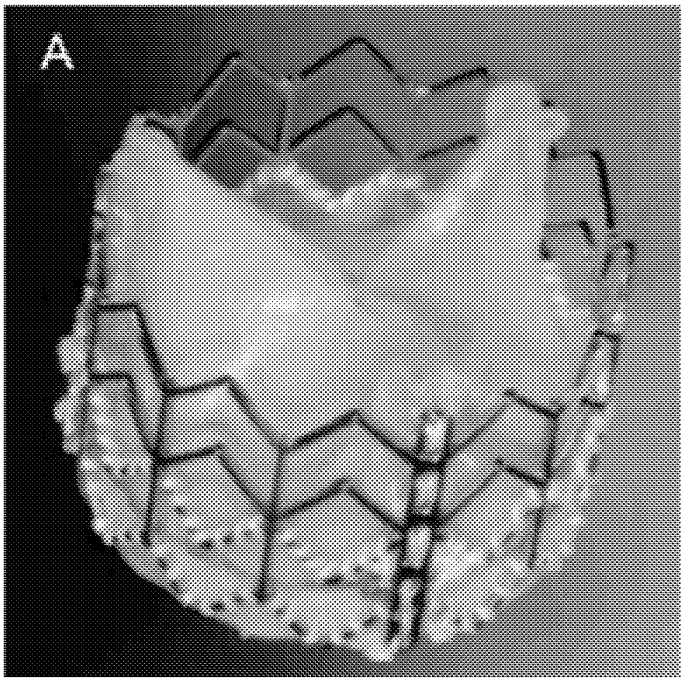
(Ex. 1019, 9:19-22, Fig. 1.) The cuff portion helped prevent PVL. (*Id.*, 8:47-50; Ex. 1003, ¶65.) **Spenser**, relied on herein, is a continuation-in-part of the 2001 patent application and includes the above embodiment. (Ex. 1010, 13:22-25, Fig. 1.)

In April 2002, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. (Ex. 1025, 3006.) The THV included a metallic balloon-expandable stent that was crimped onto a delivery balloon and endovascularly delivered through the right femoral vein:



(*Id.*, 3006-3007, Fig. 1.)

In 2004, Petitioner acquired PVT and began developing the Cribier-Edwards THV, which included (1) a metallic "outer" frame, (2) a polymeric graft covering, and (3) stitches securing the graft covering to the outer frame:



(Ex. 1023, 154, Fig. 3A (excerpt); Ex. 1003, ¶69.)

Petitioner also collaborated with physicians to modify the Cribier-Edwards THV to include an external fabric cuff designed "to provide a better seal…[and] minimize[e] paraprosthetic leak." (Ex. 1017, 2, Fig. 2.)

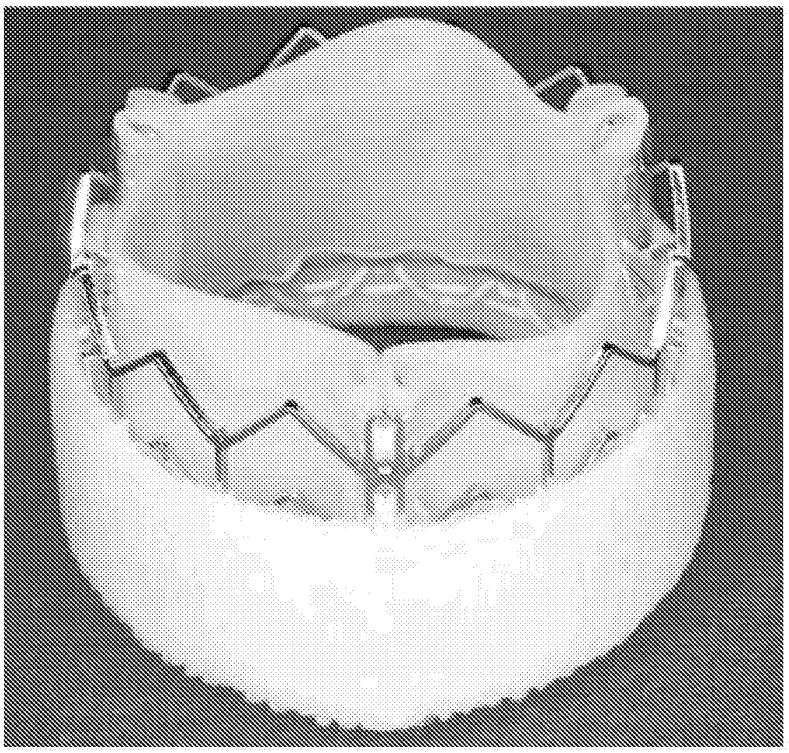


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

In 2004, Petitioner filed **Spenser II**, which discloses a THV having "a layer of compressible material 256 … disposed along an outer surface of the stent structure 252" to prevent PVL:

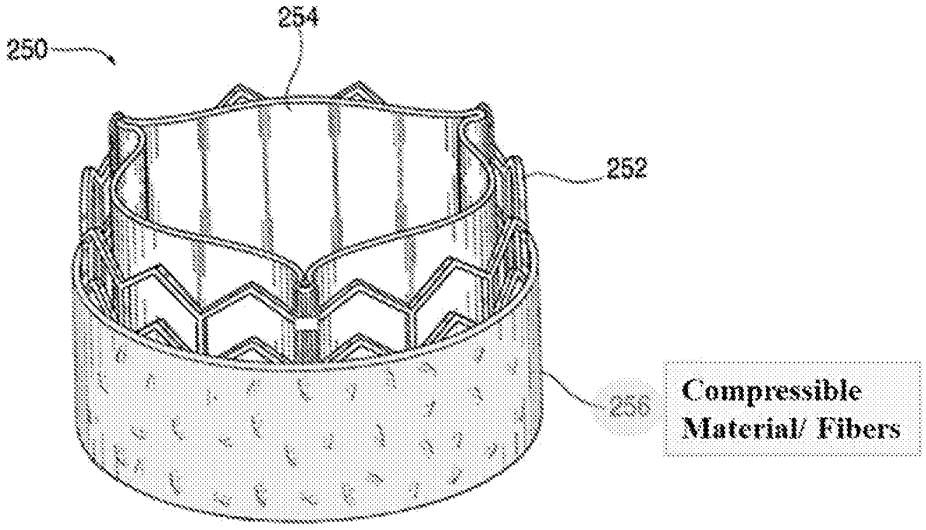


FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶70.) The compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material" and formed a mechanical seal with the native tissue to prevent PVL. (*Id.*)

By 2007, Petitioner had modified the Cribier-Edwards valve to create SAPIEN. SAPIEN was one of the world's first commercially available THVs and the subject of a large clinical trial, the results of which were published in The New England Journal of Medicine in 2010. (Ex. 1022.). SAPIEN addressed a long-felt need in the industry for an aortic replacement valve that did not require open-heart surgery. (Ex. 1003, ¶73; *see e.g.*, Ex. 1012, 355-56; Ex. 1022, 2188; Ex. 1027, 207-208.) The FDA approved SAPIEN for use in patients in 2011. (Exs. 1032-1033.)

Walther, a 2011 publication referenced herein, discloses implanting SAPIENs having a fibrous outer cloth into existing surgical valves:

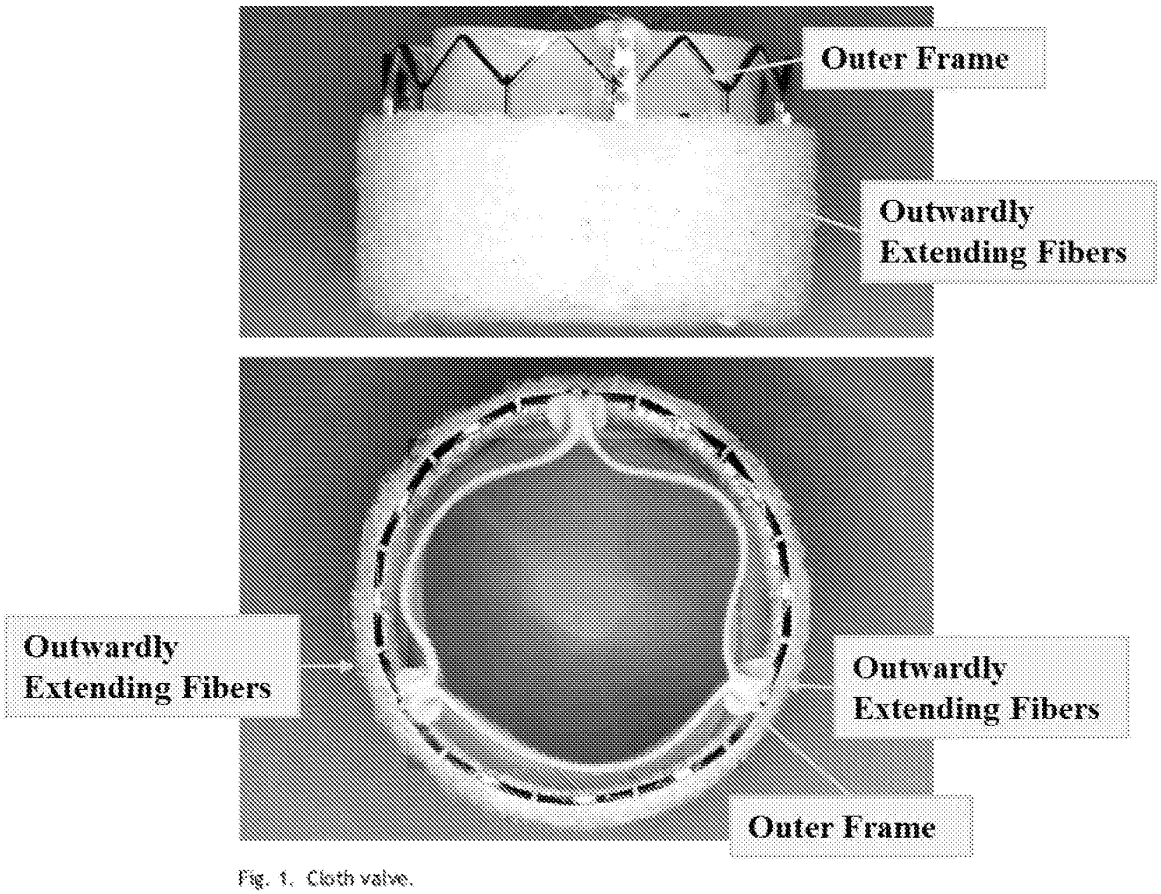
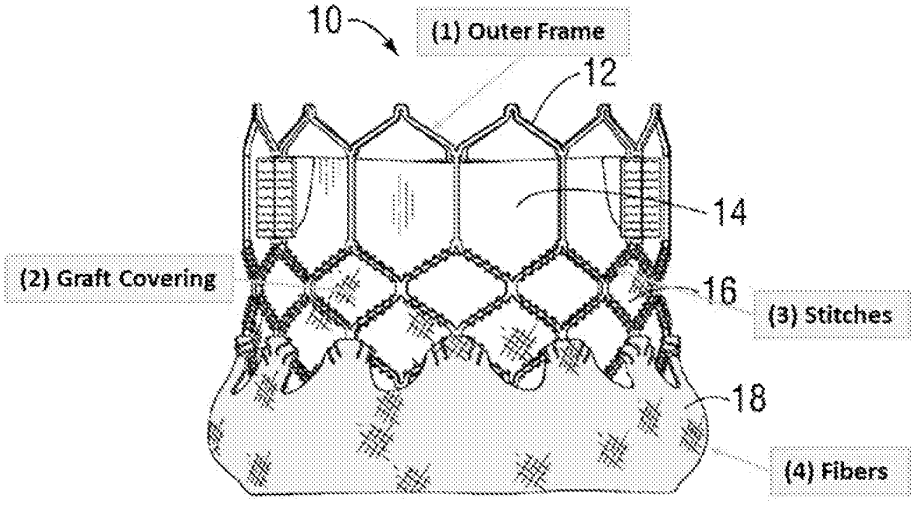


Fig. 1. Cloth valve.

(Ex. 1007, 1120-21, Fig. 1.) The "addition of an outer cloth to the SAPIEN™ valve [was] designed to reduce [PVL] by creating a seal between the two valves." (*Id.*) Thus, like THVs implanted in native valves, Walther's outer cloth created a seal by pressing against the leaflets of the previously implanted surgical valve.

Similarly, **Levi**, a patent filed by Petitioner in 2010, discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame:



(Ex. 1008, 13:49-14:14, Fig. 3.) Levi's outer skirt forms "a good fluid-tight seal between the valve and the native annulus." (*Id.*)

POSITAs also used fibrous outer seals to prevent PVL in non-aortic valve procedures as well. For example, Birdsall, a patent filed in 2006 discloses the use of a fibrous outer seal in a prosthetic valve implanted within a vascular conduit. (Ex. 1057, Abstract.) Birdsall's valve may be covered with a "barrier material 308" that "comprises directionally oriented microfibers . . . extending outward" that "contact the interior wall of the conduit and form a barrier that prevents blood from flowing

around stented valve 310, between the outer surface of the stented valve and the inner wall of the conduit":

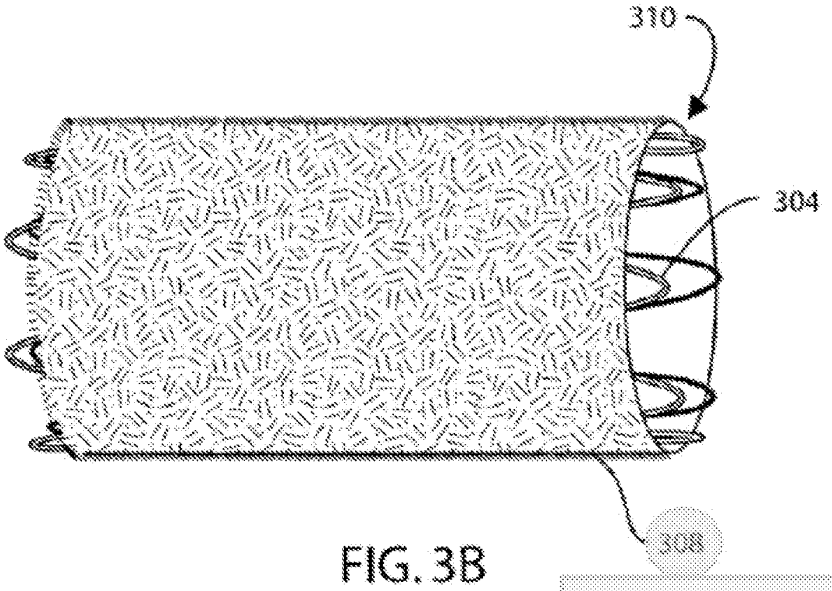


FIG. 3B

(*Id.*, 6:9-33, Fig. 3B.)

The above references show that the challenged claims merely combine known heart-valve features according to known techniques to yield predictable results. The claims do not describe any new heart-valve features or combine the known features in a nonobvious way. Therefore, the challenged claims are unpatentable.

IV. THE '236 PATENT

A. Overview

The '236 patent describes a "transcatheter aortic valve assembly" having a "dual-frame" for replacing an aortic heart valve. (Ex. 1001, 11:61-12:21.) The "dual-frame" includes a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32":

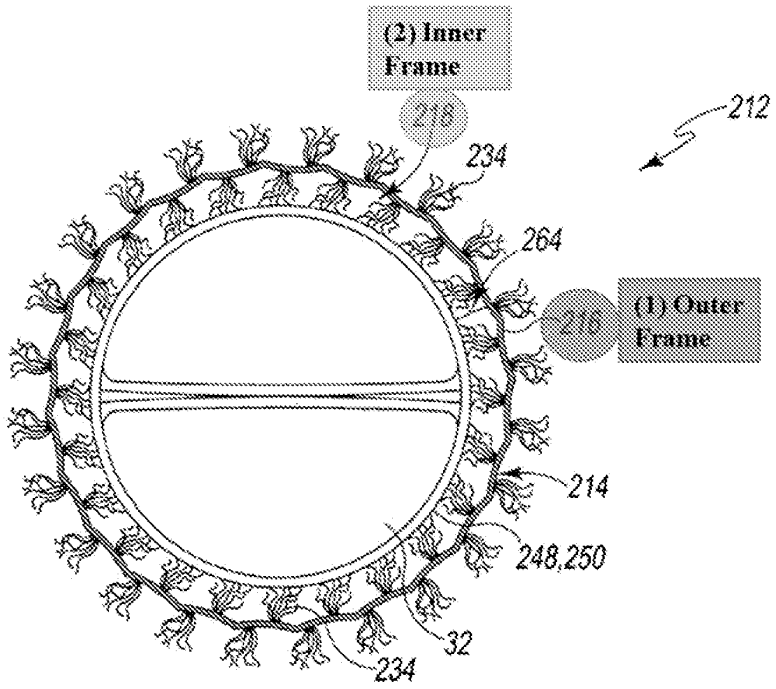


Fig. 13

(*Id.*, 12:9-12, Fig. 13.)

The metallic or polymeric outer frame [red] defines an "open-cell stent configuration." (*Id.*, 12:12-18, 13:17-20, Fig. 9.) The outer frame includes radially extending collagen fibers [green] attached to the frame to aid in preventing PVL and migration of the valve. (*Id.*, 12:43-46.) The metallic or polymeric inner frame [blue] is a "balloon-expandable tubular stent." (*Id.*, 13:41-51.) Stitches [orange] secure the inner frame to the outer frame. (*Id.*, 14:6-8.)

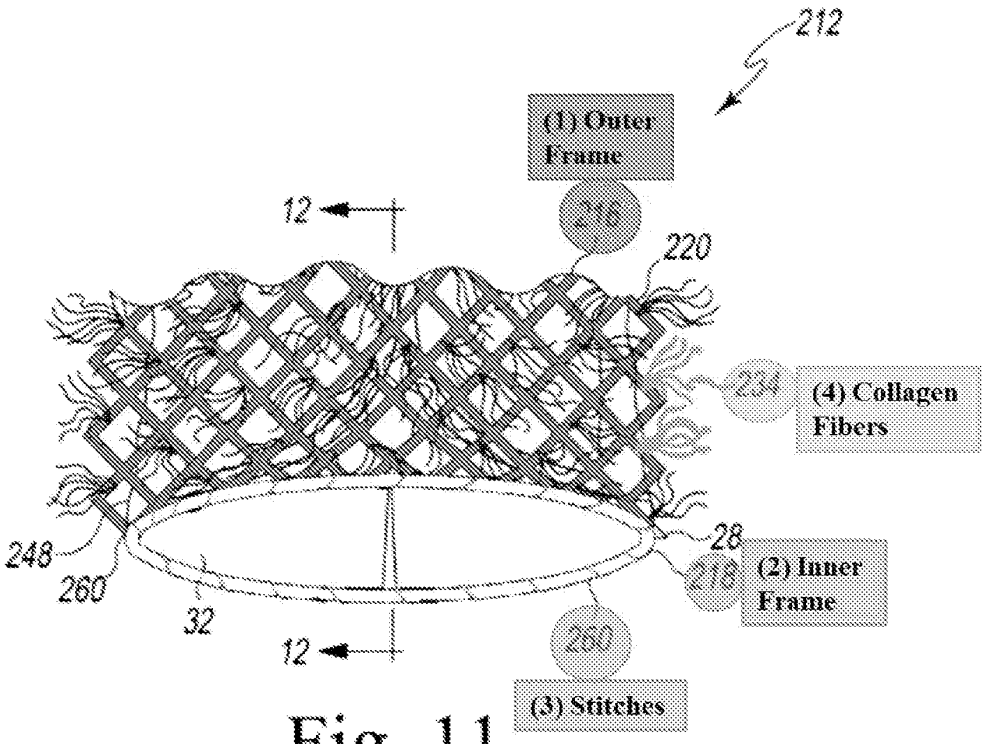


Fig. 11

B. Prosecution History

The examiner issued a single, non-final office action that included a single prior-art-based rejection. (Ex. 1002, 104-108.) None of the references asserted herein were applied in the Examiner's rejection. (*See id.*)

C. The Critical Date

The '236 patent claims priority to two provisional applications: application No. 61/567,458 ("the '458 provisional"), filed December 6, 2011; and application No. 61/723,446 ("the '446 provisional"), filed on November 7, 2012. (Ex. 1001.) During prosecution of U.S. Patent No. 10,792,172 (the "'172 patent"), which is a parent to the '236 patent, Patent Owner stated that the '172 patent's "effective filing date . . . is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012." (Ex. 1049, 274.) Additionally, in the Litigation, Patent Owner concedes that it did not file any patent applications describing outwardly extending fibers until 2012. (Ex. 1050, 9.)

Patent Owner is correct that the '236 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '236 patent's claims. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Patent Owner first added the disclosure of outwardly extending fibers in the November 2012 provisional. (Ex. 1006, [0024].).

V. STATEMENT AND RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1-4	103	Cribier + Walther
2	1-4	103	Spenser + Walther
3	1-4	103	Spenser + Spenser II
4	1-4	102(e)	Levi
5	1-4	103	Levi
6	1-4	103	Levi + Walther
7	1-4	103	Levi + Spenser II

B. The Asserted References Are Prior Art

The Critical Date of the '236 patent is November 7, 2012. (*Supra* §III.C.) The following references are prior art under pre-AIA §102(b):

(1) Cribier (Ex. 1012) published in August 2009 and was publicly available by at least August 28, 2009 (Ex. 1059, ¶¶58-65);

(2) Walther (Ex. 1007) published online on April 3, 2011 and in print on November 1, 2011 and was publicly available online on or shortly after

April 3, 2011 and in print on or shortly after November 1, 2011 (Ex. 1059, ¶¶47-57; *see also* Ex. 1065, n. 39);

(3) Spenser (Ex. 1010) issued on March 31, 2009; and

(4) Spenser II (Ex. 1011) published on January 12, 2006.

Levi (Ex. 1008) was filed on Oct. 5, 2011 and published on May 17, 2012, and is prior art under pre-AIA §102(e).

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). Each reference is from the same field as the '236 patent, e.g., minimally invasive devices for replacing heart valves. (Ex. 1003, ¶36.) The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic regurgitation or stenosis through a minimally invasive procedure. (*Id.*) As analogous art, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. LEVEL OF ORDINARY SKILL

A POSITA in November 2012 would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This

POSITA would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve. (Ex. 1003, ¶45.)

VII. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (establishing standard).

VIII. PROPOSED GROUNDS FOR UNPATENTABILITY

A. Ground 1: Claims 1-4 Obvious Over Cribier and Walther

Walther discloses modified SAPIENs having fibrous outer sealing cloths:

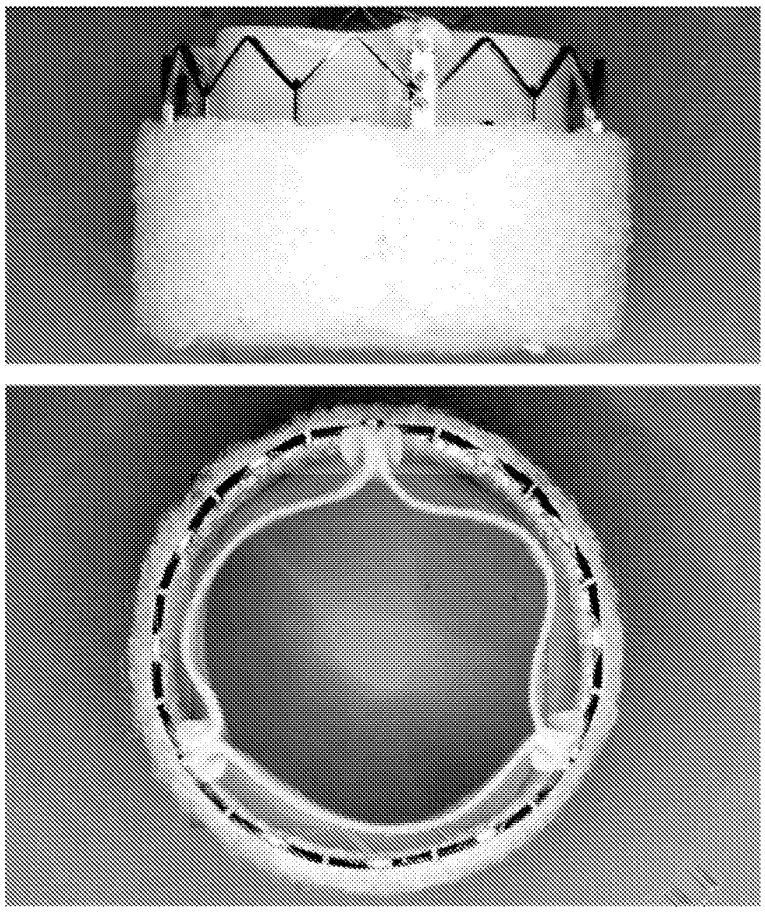


Fig. 1. Cloth valve.

(Ex. 1007, 1120-21, Figs. 1-3.) Walther's modified SAPIENs were "identical" to SAPIEN except for the outer cloth. (*Id.*, 1120.)

Cribier describes endovascularly delivering SAPIEN and includes additional details about the valve. (Ex. 1012.) Thus, Cribier combined with Walther discloses all the limitations in claims 1-4 and renders the claims obvious. (Ex. 1003, ¶97.)

1. Claim 1

Cribier and Walther render claim 1 obvious. (Ex. 1003, ¶¶98-147.)

a. Preamble

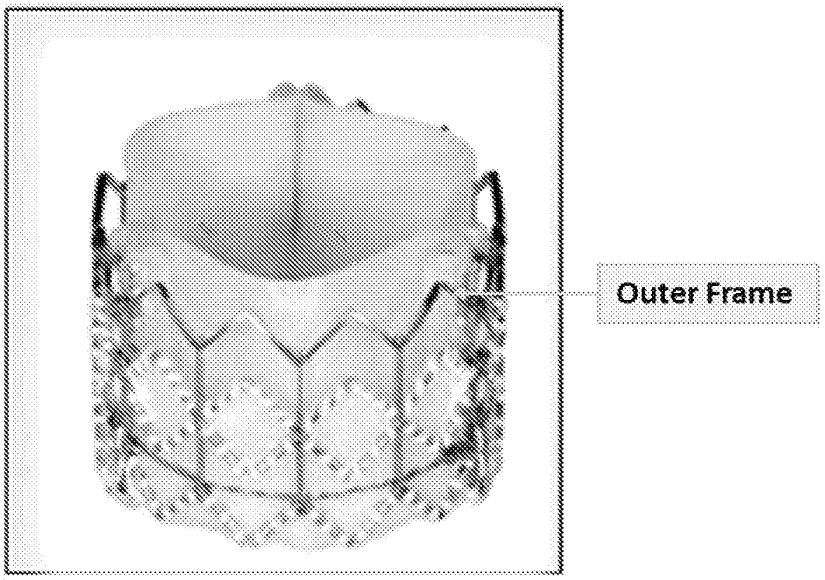
Cribier discloses a "transcatheter aortic valve assembly." (*Id.*, ¶100.) Cribier describes methods of "transcatheter aortic valve implantation with the Edwards-Sapien® heart valve using the transfemoral approach." (Ex. 1012, 347-355, Fig. 1.) SAPIEN is a "valve assembly." (*Id.*, 348.)

Similarly, Walther discloses SAPIEN with an outer cloth stitched to its perimeter. (Ex. 1007, 1120-21, Fig. 1.) Walther's cloth-covered valve is identical to SAPIEN except for the outer cloth. (*Id.*) Walther discloses delivering the modified SAPIENs through a catheter (the Ascendra system) and, thus, Walter also discloses a "transcatheter aortic valve assembly." (*Id.*, 1121; Ex. 1003, ¶102.) Notably, while the '236 patent discloses that the valve is compressible and expandable, which is necessary for transcatheter deployment, the '236 patent does not disclose any sizing for the catheter or the compressed valve. (Ex. 1003, ¶102.)

b. Outer Frame

Cribier discloses "an outer frame formed from a metallic material." (Ex. 1003, ¶¶103-104.)

Cribier discloses that SAPIEN includes "a tubular slotted stainless-steel" stent. (Ex. 1012, 348.) The stent surrounds the other valve components, making it an "outer frame":



(*Id.*, Fig. 1; Ex. 1003, ¶104.)

c. Inner Frame

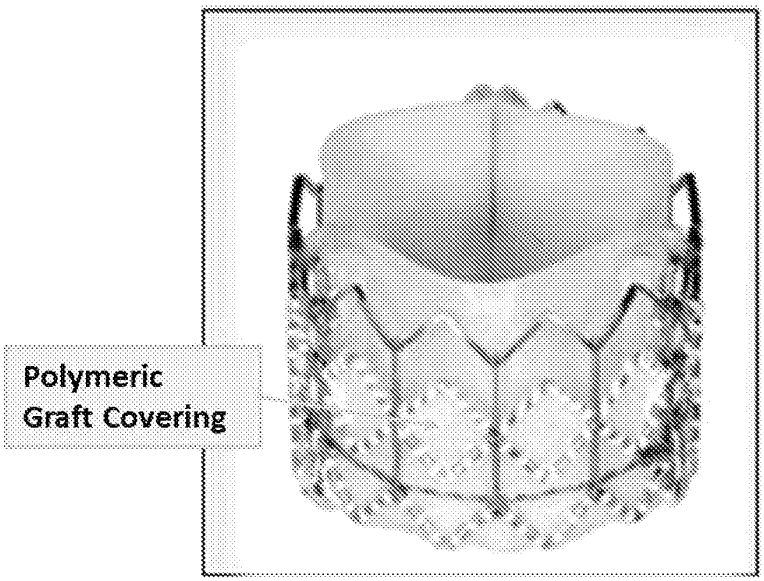
Cribier discloses "an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending

polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." (Ex. 1003, ¶¶105-110.)

During prosecution, Patent Owner argued that an inner graft covering ***alone*** satisfies the limitation "an inner frame…wherein the inner frame ***includes*** a cylindrically polymeric inner extending graft covering." For example, Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a "graft forming the inner frame." (Ex. 1002, 187). Similarly, during prosecution of a related patent having the same limitation, Patent Owner argued that Petitioner's SAPIEN 3 Ultra product is "covered by the claimed invention" because it "includes an inner frame that is a graft." (Ex. 1046, 21-22.) Patent Owner made the same allegations in the Litigation, despite SAPIEN 3 Ultra not having both outer and inner frames.[4] (Ex. 1050, 43-44.) Patent Owner also argued the claimed inventions improved upon the art "by having an inner frame that is a graft covering around the heart valve[.]" (Ex. 1046, 9.)

[4] Petitioner preserves alternative arguments that the '236 patent does not describe an inner frame that is a graft covering, and that a graft covering cannot be an inner frame.

Cribier discloses that SAPIEN includes an inner "(PET) fabric cuff," which is a polymeric graft covering:



(Ex. 1012, 348, Fig. 1.) The fabric cuff cylindrically extends at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame. (*Id.*) Based on Patent Owner's statements during the related prosecution, SAPIEN's fabric cuff meets the "inner frame" limitation. (Ex. 1003, ¶109.)

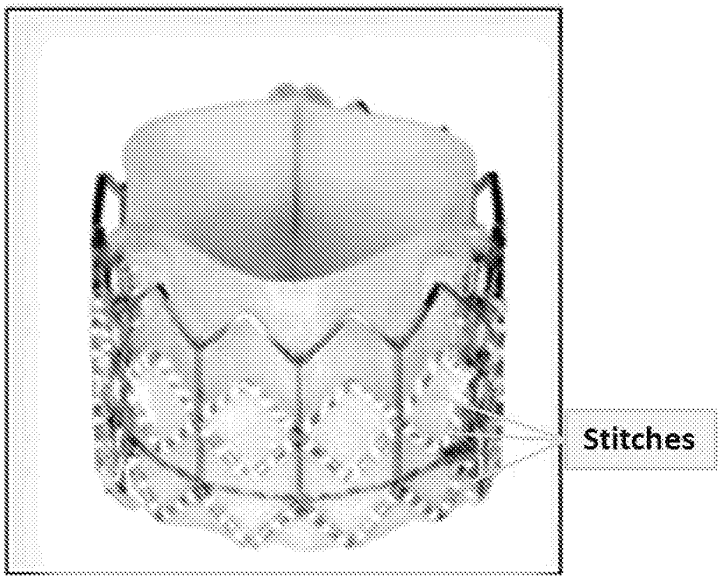
Cribier also discloses that SAPIEN includes a "tissue valve" comprised of "prosthetic leaflets." (Ex. 1012, 348.) SAPIEN's fabric cuff "engages" the leaflets along the green suture line (above). (Ex. 1012, Fig. 1; Ex. 1003, ¶109.) The fabric cuff provides sealing to the prosthetic valve. (Ex. 1003, ¶110; *see also* Ex. 1023, 154

(SAPIEN included a "higher sealing cuff…to reduce paravalvular leaks."); Ex. 1024, 1830 (same); Ex. 1027, 213 (same).) If the cuff did not provide sealing to the valve, blood could leak around the valve and undermine its efficacy. (Ex. 1003, ¶110.)

d. Stitching

Cribier discloses that "the outer frame is secured to the inner graft covering by stitching." (Ex. 1003, ¶¶111-112.)

White stitches secure SAPIEN's fabric cuff to the frame:



Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶112.)

e. First Portion of Fibers

Cribier and Walther render obvious "a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic." (Ex. 1003, ¶¶113-130.)

Walther's outer PET cloth is positioned radially outwardly of the outer frame:

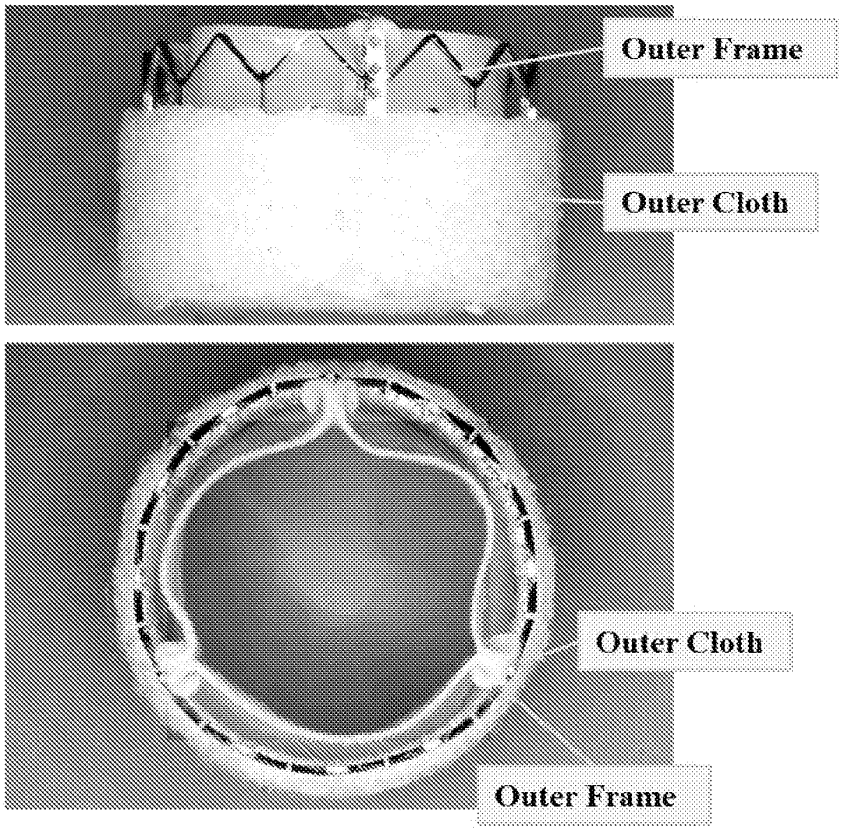
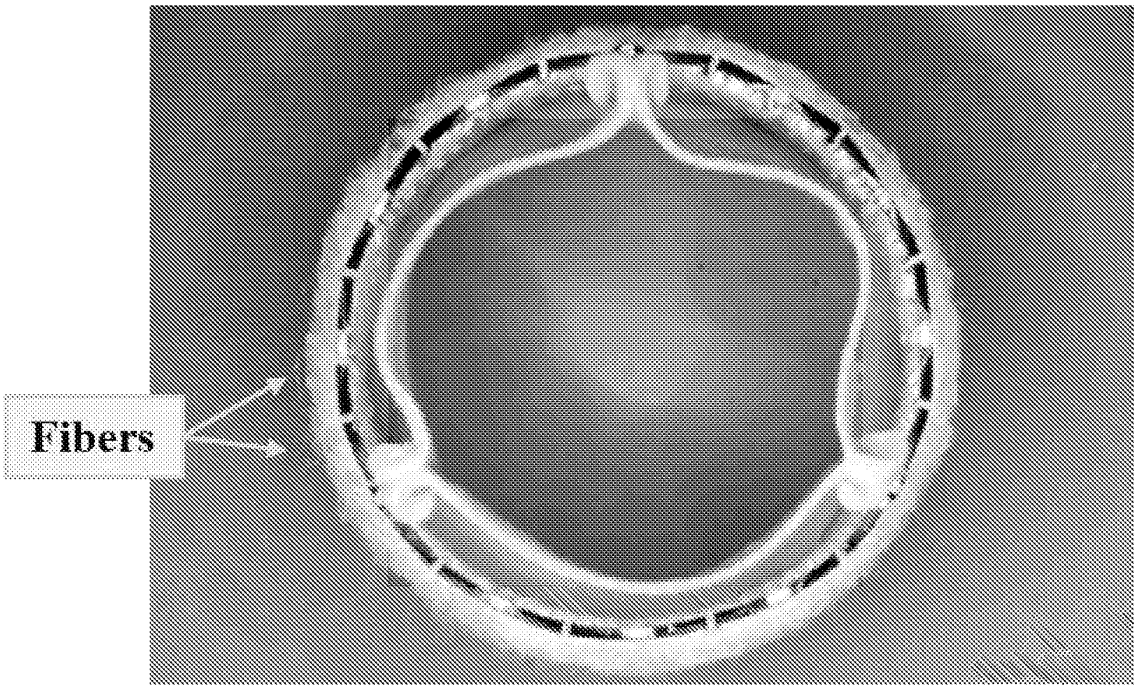


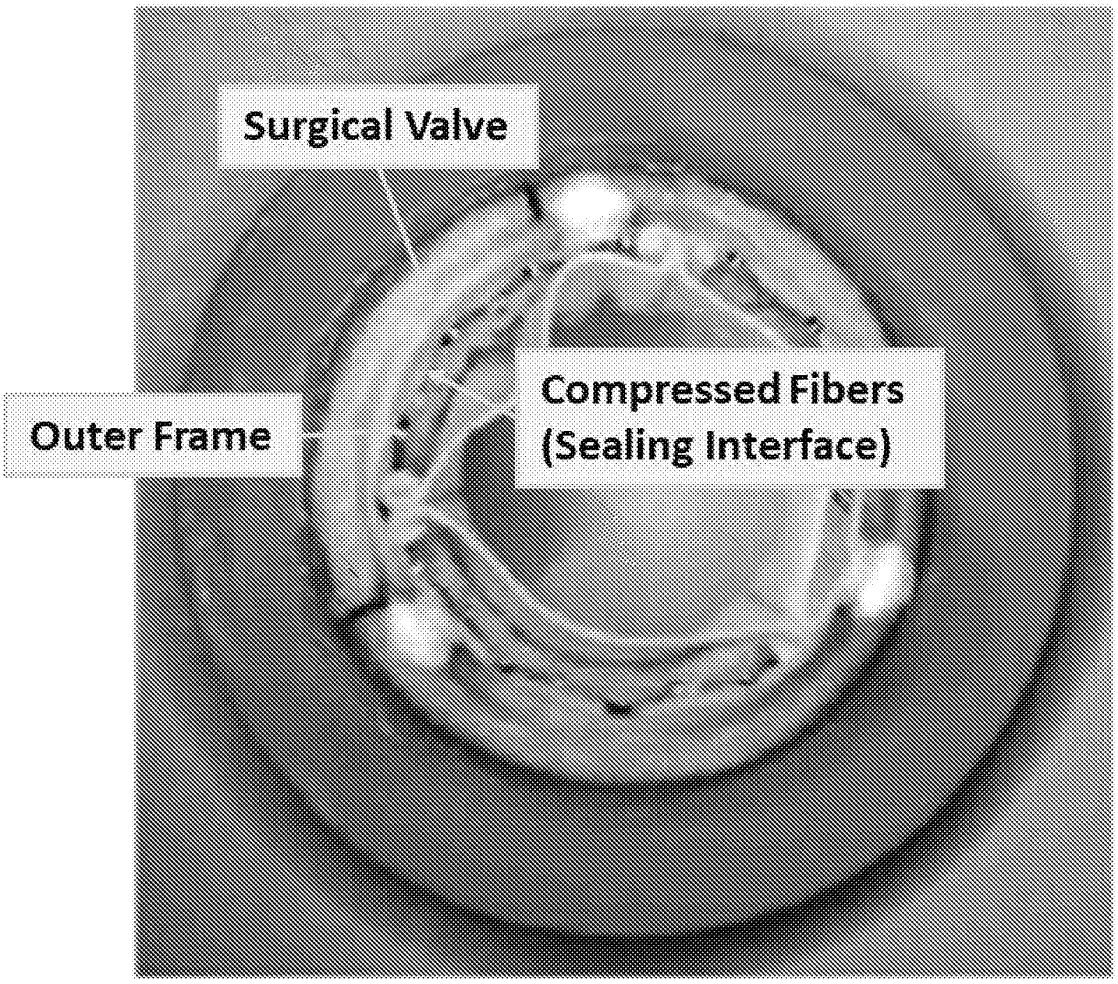
Fig. 1. Cloth valve.

(Ex. 1007, 1121, Fig. 1.) The outer cloth is formed from nonmetallic, PET fibers that extend radially outwardly of the outer frame:



(Ex. 1007, 1121, Fig. 1 (excerpt); Ex. 1003, ¶115.) The PET fibers are the "first portion of fibers" required by claim 1. (Ex. 1003, ¶¶115-117.)

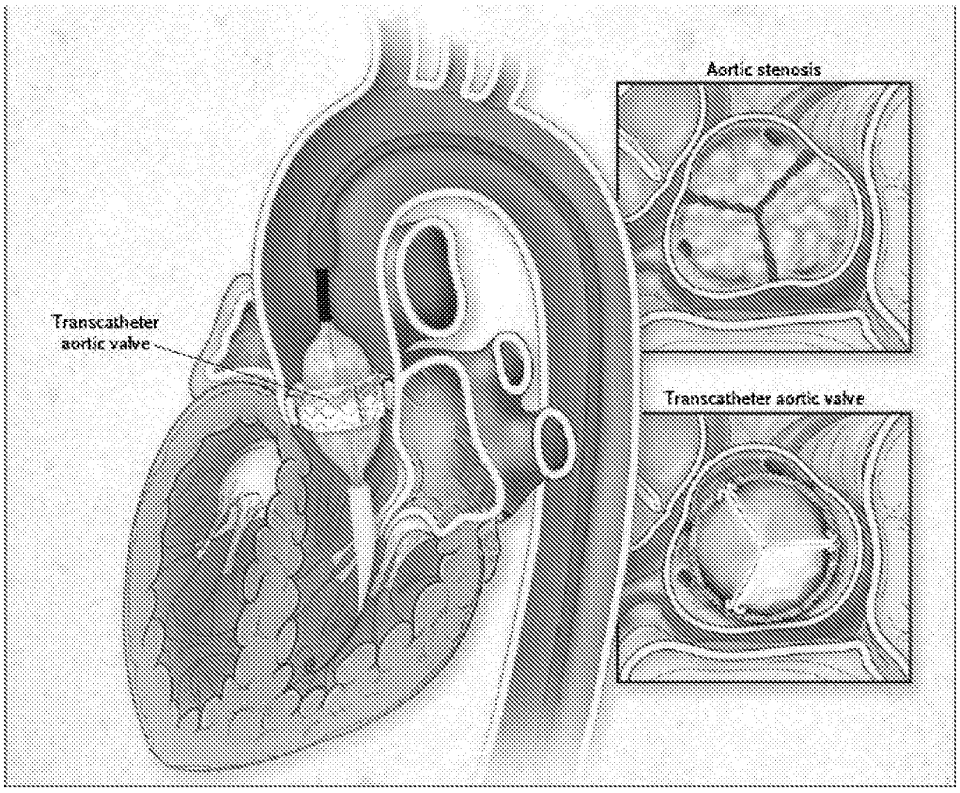
Walther's outer fibers are configured to form a sealing interface against the patient's annulus and native valve leaflets when compressed thereagainst. (*Id.*, ¶¶118-120.) Walther describes implanting the cloth-covered SAPIEN within a surgical valve. (Ex. 1007, 1120-1121.) The fibrous outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves…" by compressing the radially extending fibers against the surgical valve's annulus and leaflets:



(*Id.*, 1120-1121, Fig. 2. (excerpt))

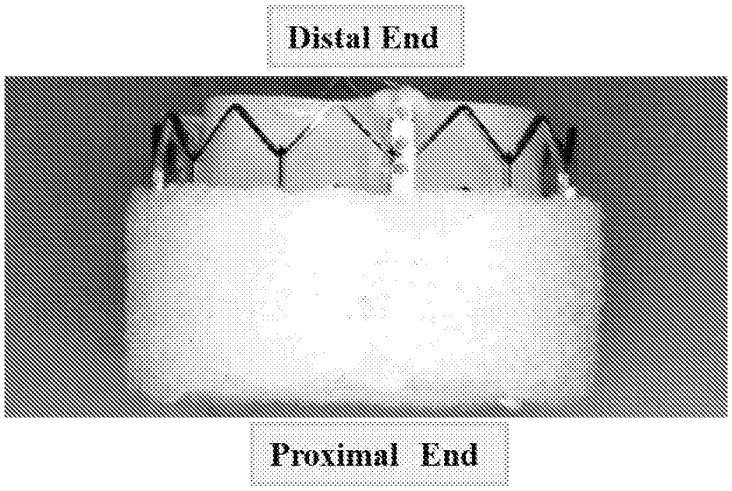
A POSITA would have understood that expanding Walther's cloth-covered SAPIEN in a patient's native aortic valve would form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst. (Ex. 1003, ¶118.) Cribier discloses that SAPIEN presses against the aortic valve's annulus and native leaflets upon implantation. Cribier

states that SAPIEN is "advanced to the native aortic valve…positioned across the aortic annulus, and delivered by balloon inflation[.]" (Ex. 1012, 347.) Cribier instructs that "before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion." (*Id.*, 353.) Consistent with the understanding in the art, the '236 patent identifies the annulus as the point where the leaflets begin. (Ex. 1001, 1:58-60, Fig. 2; Ex. 1003, ¶119; *see also* Ex. 1047, 76 ("[T]he annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the [aortic] leaflets.").) When expanded in this position, SAPIEN presses against and replaces the patient's native aortic leaflets, as illustrated below:

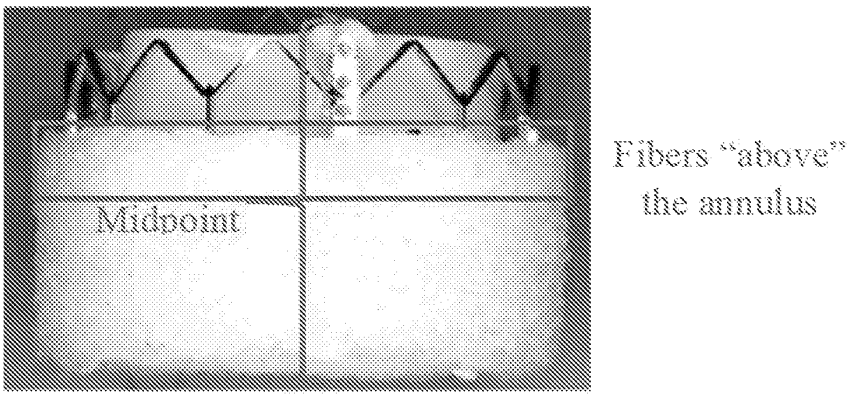


(Ex. 1022, 2189, Fig. 1; Ex. 1003, ¶119.) Some publications even describe SAPIEN as "crush[ing] the leaflets of the native valve against the wall." (Ex. 1047, 74.)

Expanding Walther's cloth-covered SAPIEN in a native aortic valve would press Walther's fibers against the patient's annulus and native leaflets to form a sealing interface. (Ex. 1003, ¶121.) Walther's outer cloth covers approximately two-thirds of SAPIEN's frame:



(Ex. 1007, Fig. 1 (excerpt).) If one-third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, the central fibers would press against the annulus and the fibers "above the annulus" would press against the leaflets:



(Ex. 1003, ¶121; Ex. 1047, 74.) In fact, Patent Owner admitted during prosecution of a related patent that an outer seal covering two frame rows would press against the leaflets. (Ex. 1046, 25.)

While Walther describes expanding the cloth-covered SAPIEN in a surgical valve, POSITAs would have found it obvious to deploy the valve within a patient's native valve so that the outer cloth forms a sealing interface with the annulus and native leaflets. (Ex. 1003, ¶122.) By November 2012, POSITAs well understood that PVL could occur with SAPIEN. (*See e.g.*, Ex. 1012, 354 (describing PVL with SAPIEN; Ex. 1022, 2194 (same); Ex. 1003, ¶124.) Thus, POSITAs would have been motivated to apply Walther's known technique for reducing PVL (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement and, as discussed below, would yield predictable results. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶124.)

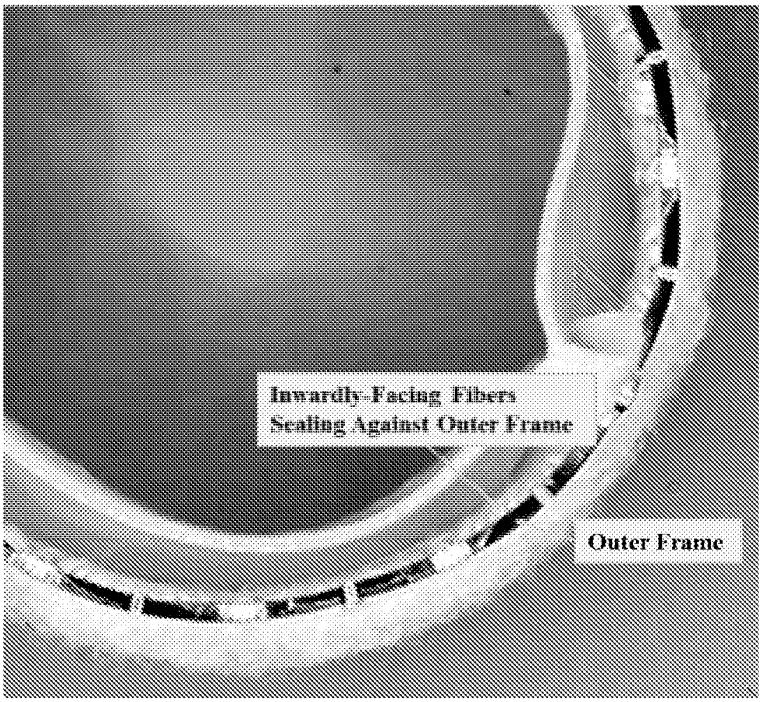
POSITAs would have reasonably expected success in deploying the cloth-covered SAPIEN in a patient's native aortic valve. (Ex. 1003, ¶125.) Walther describes the successful balloon deployment of the cloth-covered SAPIEN and concludes that the valve "demonstrated excellent hydrodynamic performance" and that an in-patient procedure "is feasible." (Ex. 1007, 1125; Ex. 1003, ¶125.) Moreover, the surgical valves described in Walther are designed to replace and simulate the native aortic valve and POSITAs would have expected Walther's cloth-covered SAPIEN to perform similarly in either environment. (Ex. 1003, ¶125.)

Consequently, POSITAs would have reasonably expected success in implanting the cloth-covered SAPIEN within a patient's native aortic valve. (*Id.*)

f. Second Portion of Fibers

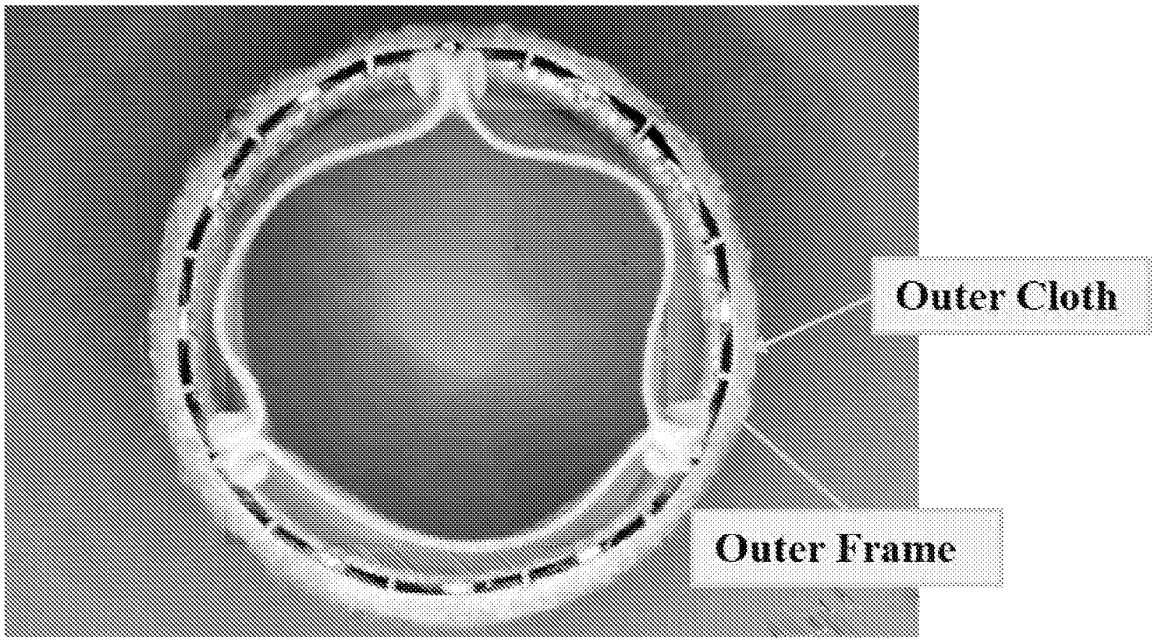
Cribier and Walther render obvious "a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second portion of fibers is non-metallic." (Ex. 1003, ¶¶131-134.)

Walther's outer cloth includes outwardly extending fibers (discussed in the prior section) that extend from the outward-facing surface of the cloth and inwardly facing fibers on the inward-facing surface of the cloth that form a sealing interface against the outer frame:



(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶132.) As shown above, some of the inwardly-facing fibers are pressed through the open cells of the outer frame and extend radially inwardly of the outer frame. (Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶132.) The inwardly-facing fibers that do not pass through the open cells of the outer frame instead press against and form a sealing interface with the outer frame. (Ex. 1003, ¶132.) The inwardly-facing, nonmetallic, PET fibers are the "second portion of fibers" required by claim 1. (*Id.*)

Walther's outer cloth is "stitched onto the perimeter of each SAPIEN valve," and carried by the outer frame:

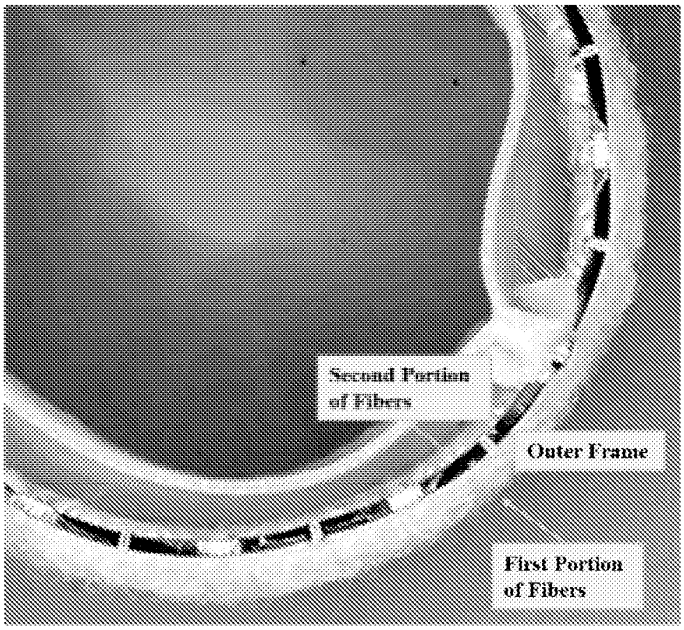


(Ex. 1007, 1121, Fig. 1 (excerpt); Ex. 1003, ¶133.) Moreover, as shown above, the inwardly-facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded. (Ex. 1003, ¶134.) The fibers must form a sealing interface with the frame in the expanded state because Walther discloses that the cloth prevents PVL, which could not happen if blood could leak between the cloth and expanded frame. (*Id.*)

g. First and Second Portions in Overlapping Radial Alignment

Cribier and Walther render obvious "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment." (Ex. 1003, ¶¶135-137.)

Walther's first and second portion of fibers are interwoven and part of a single PET cloth, as illustrated in Figure 1 below, and, therefore, are in overlapping radial alignment:



(Ex. 1007, Fig. 1; Ex. 1003, ¶¶136-137.)

h. First Sealing Interface in Overlapping Radial Alignment with Leaflets

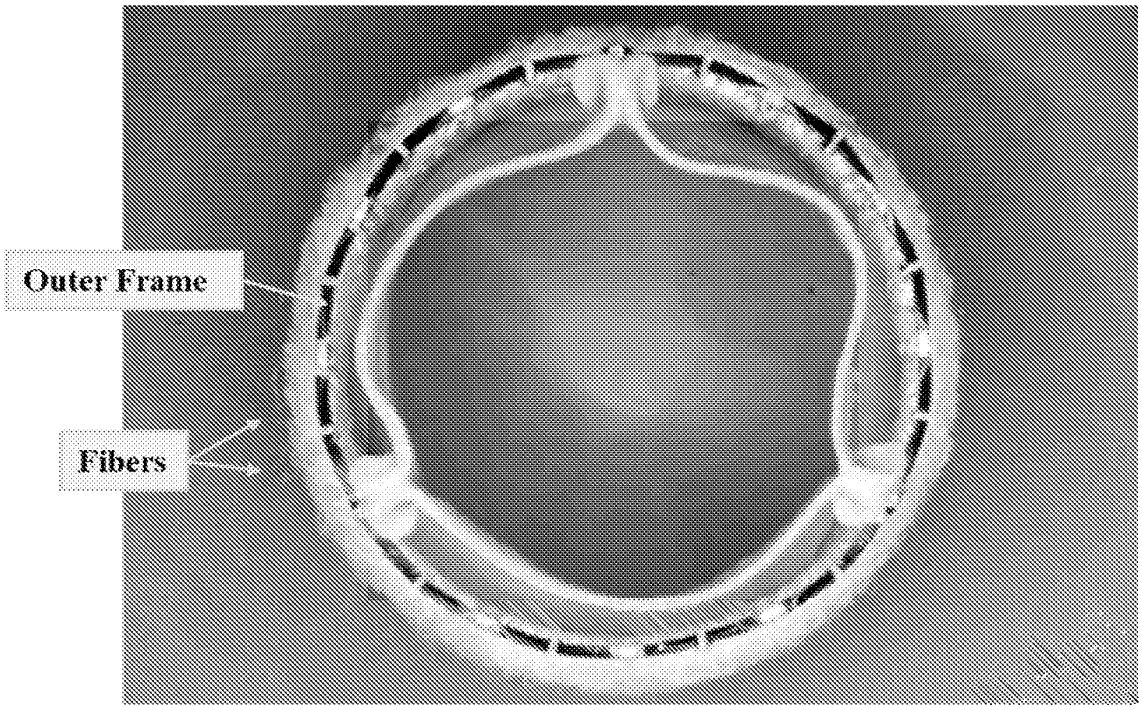
Cribier and Walther render obvious "wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst." (Ex. 1003, ¶138.)

As explained in the above section "First Portion of Fibers," Walther's cloth-covered SAPIEN is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst. (*Supra* §VIII.A.e.) POSITAs would have been motivated, and expected success, in implanting Walther's cloth-covered SAPIEN in a patient for the reasons previously provided. (*Id.*)

i. Free of an Outer Graft Covering

Cribier and Walther render obvious "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." (Ex. 1003, ¶¶139-141.)

Walther discloses that the outer cloth, which is stitched to the valve's perimeter, was the only modification made to SAPIEN. (Ex. 1007, 1120.) Walther does not state that the outer cloth includes a "graft covering" and the cloth does not include any visible graft covering:



(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶140.) SAPIEN does not include a "graft covering" on the exterior of the frame:



Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, Fig. 1; Ex. 1003, ¶140.) Thus, a POSITA would have understood that Walther's cloth-covered SAPIEN is free of an outer graft covering between the first portion of fibers and the outer frame. (Ex. 1003, ¶140.)

j. Radially Compressed and Expanded Orientation

Cribier and Walther disclose the claimed valve assembly that "has a radially compressed orientation and a radially expanded orientation." (Ex. 1003, ¶¶142-143.) Cribier discloses that SAPIEN is "***compressed*** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its

expanded size to its 'mounted' size.'" (Ex. 1012, 348 (emphasis added).) Similarly, Walther discloses that the cloth-covered SAPIENs were crimped onto a balloon and then expanded within surgical valves. (Ex. 1007, 1122, Fig. 4.)

k. Balloon Expandable

Cribier and Walther disclose "wherein the valve assembly is balloon expandable to the radially expanded orientation." (Ex. 1003, ¶¶144-145.) Cribier and Walther disclose "balloon-expandable" valve assemblies. (Ex. 1012, 348; Ex. 1007, 1122.)

l. Compress Fibers to Form a Sealing Interface

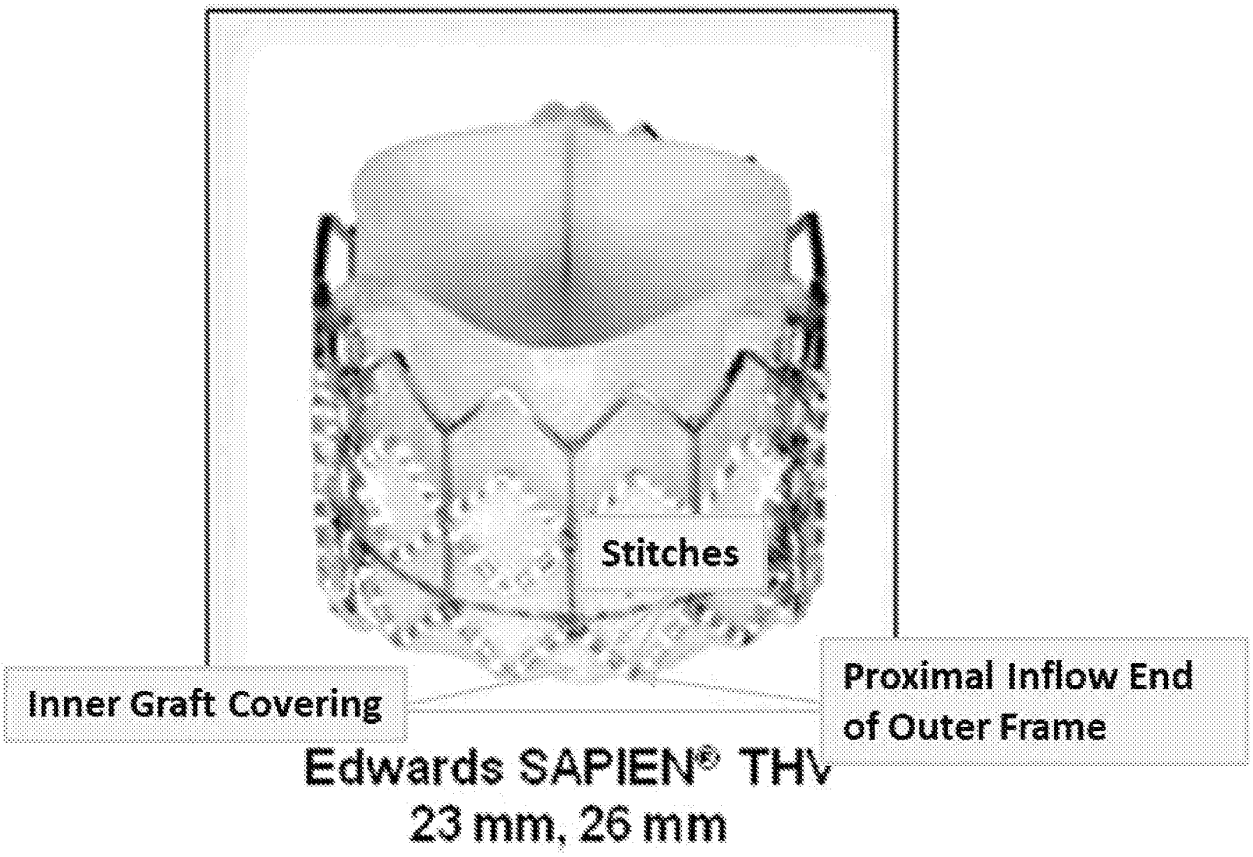
Cribier and Walther render obvious "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface." (Ex. 1003, ¶¶146-147.)

As explained above, Walther's cloth-covered SAPIEN is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. (*Supra* §§VIII.A.1.e-f.)

2. Claim 2

Cribier and Walther render obvious the "valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." (Ex. 1003, ¶¶148-149.)

Cribier shows that SAPIEN's inner PET fabric cuff (i.e., inner graft covering) extends to the proximal inflow end of SAPIEN's outer frame:

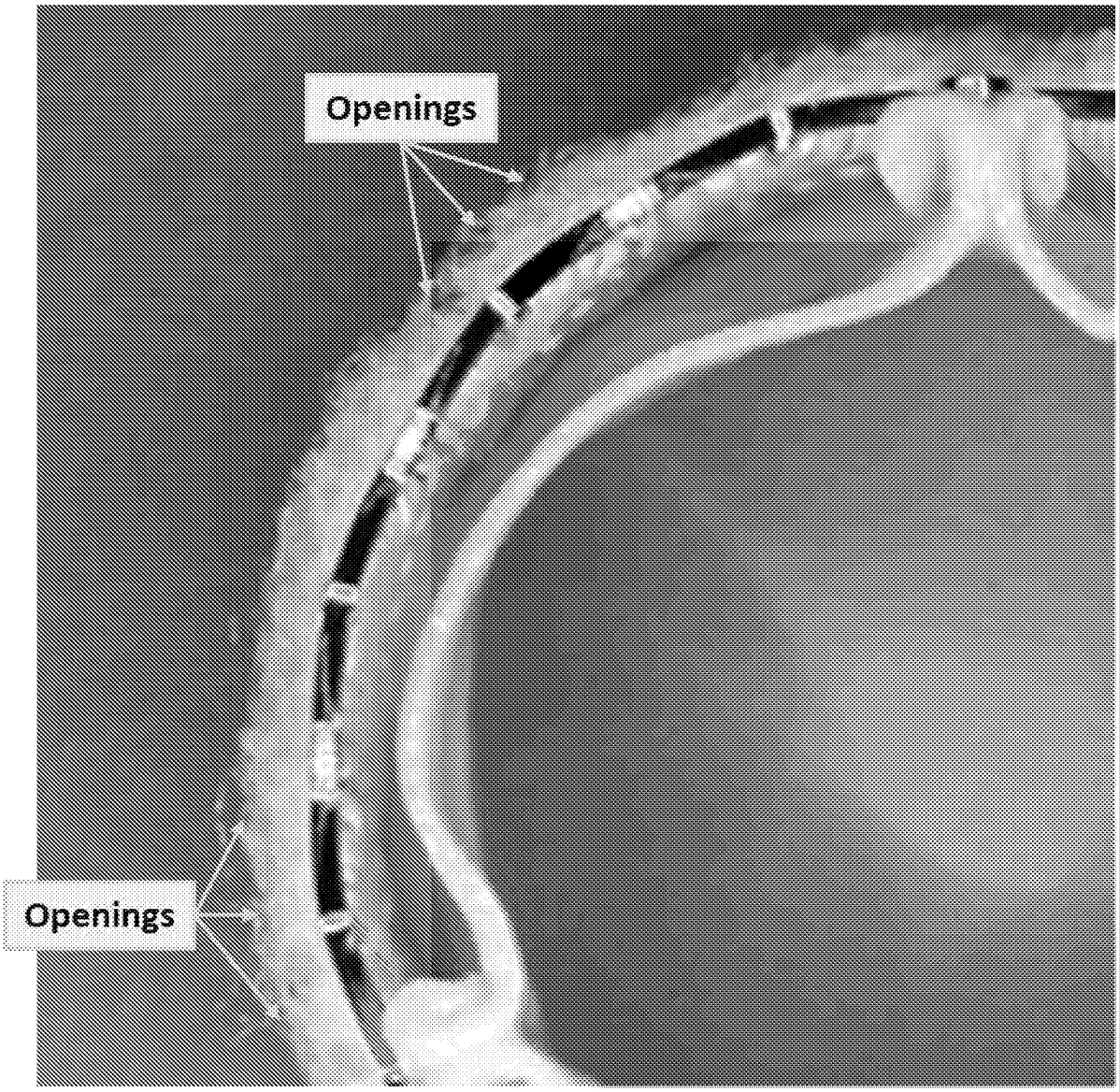


(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶149.) As shown above, white stitches extend between the fabric cuff and through the outer frame to secure the fabric cuff to the proximal inflow end of the outer frame. (*See* Ex. 1012, Fig. 1; Ex. 1003, ¶149.)

3. Claim 3

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." (Ex. 1003, ¶¶150-154.)

Walther's cloth-covered SAPIEN includes radially extending fibers (i.e., first portion of fibers). (*Supra* §VIII.A.1.e.) A POSITA would have understood that small openings inherently exist between the radially extending fibers formed by spacing between the adjacent fibers. (*See* Ex. 1007, Fig. 1; Ex. 1003, ¶152.) As shown below, the fibers are dense enough to prevent blood from flowing through the fibers, but still loose enough to create small gaps. (Ex. 1003, ¶153.) These small gaps define a plurality of "opening[s] extending through a thickness" of the radially extending fibers.



(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶152.)

If Walther does not disclose this limitation, a POSITA would have found it obvious to select different cloths having less density and larger gaps. (Ex. 1003, ¶154.) POSITAs would have had access to a range of suitable cloths having varying

thicknesses and densities and could have selected a cloth with a lower density of radially extending fibers such that even larger openings existed between the fibers. (*Id.*) A POSITA would have been motivated to select such a cloth to reduce the crimped profile of the device while still achieving the reduction in PVL provided by the fibers. (*Id.*)

Additionally, the '236 patent does not claim or disclose how to size or arrange the fibers to provide such an opening. (*Id.*, ¶151.) For example, the '236 patent never discloses the length or width of the fibers, the density of the fibers, or any particular arrangement of the fibers. (*Id.*) Consequently, Patent Owner cannot argue that the selection of materials and adaptation of the cloth-covered SAPIEN to provide such an opening would have been beyond the skill of a POSITA. *See e.g., Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013) ("[A] an unclaimed and undisclosed feature . . . cannot be the basis for finding [a] patent to be non-obvious over the prior art."); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 2013) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . . ."); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003) ("[N]onobviousness is assessed by

reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims.").

4. Claim 4

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame." (Ex. 1003, ¶¶155-158.)

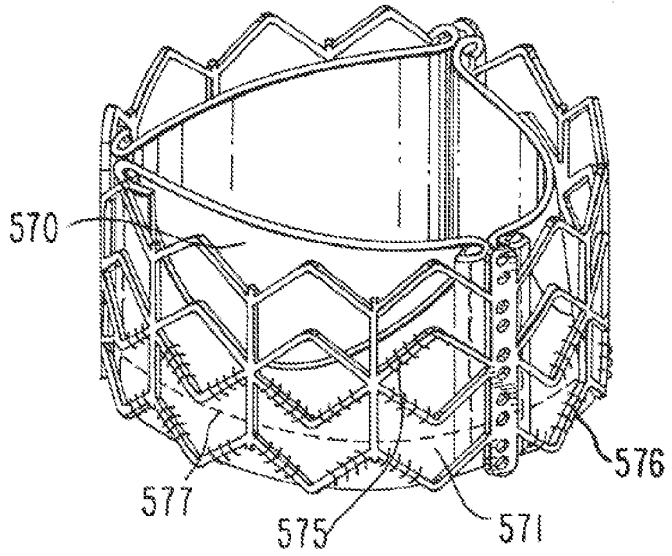
Like Walther's fibers on the outward-facing surface, the inwardly-facing fibers (i.e., second portion of fibers) inherently have small openings between the fibers formed by spacing between the adjacent fibers. (*See* Ex. 1007, Fig. 1; Ex. 1003, ¶157.) As explained in claim 3, the fibers are dense enough to prevent blood from flowing through the fibers, but still loose enough to create small gaps. (Ex. 1003, ¶157.)

If Walther does not disclose this limitation, a POSITA would have found it obvious to select different cloths having less density and larger gaps for the reasons provided in claim 3. (*Supra* §VIII.A.3; Ex. 1003, ¶158.)

B. Grounds 2-3: Claims 1-4 Obvious Over Spenser and Walther or Spenser II

Spenser describes heart valve assemblies similar to SAPIEN including the Figure 44a embodiment below:

FIG. 44a



(Ex. 1010, Fig. 44a; *see also* Ex. 1040, 6 (identifying Spenser).)

Walther discloses cloth-covered SAPIENs. (*Supra* §VIII.A.1.)

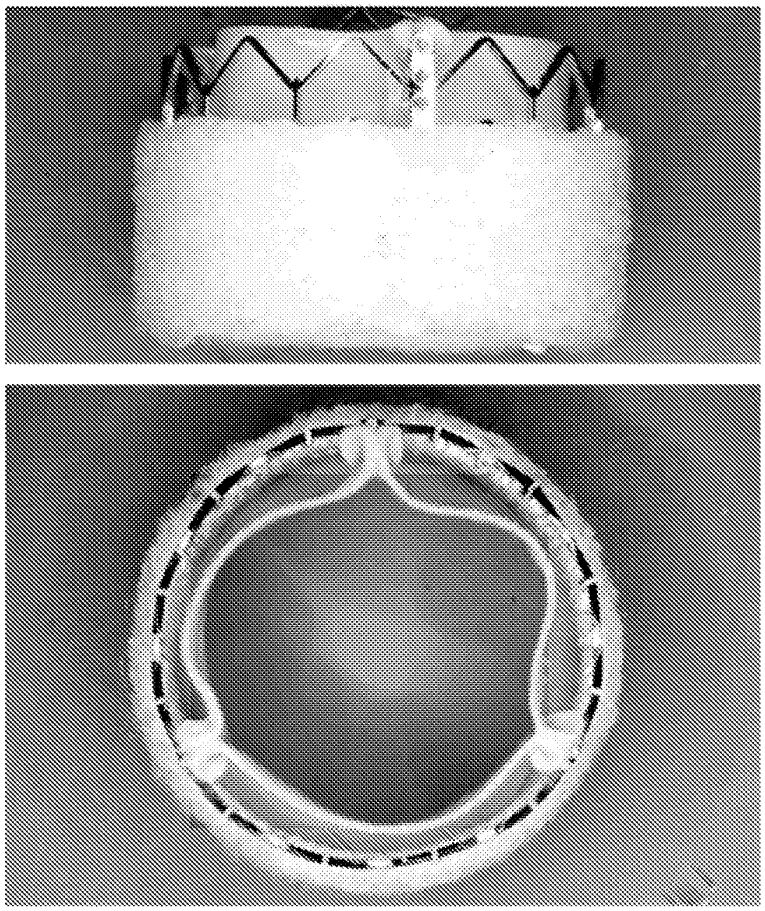


Fig. 1. Cloth valve.

Spenser II discloses heart valves having a fibrous layer of "compressible material…disposed along the outer surface of the stent structure" to reduce PVL:

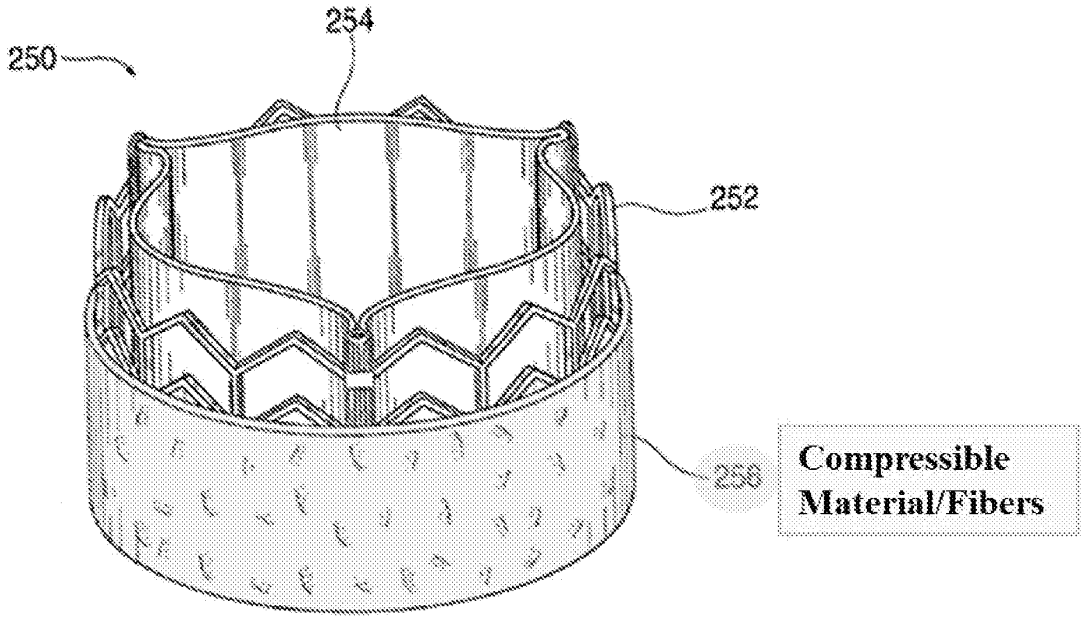


FIG. 22

(Ex. 1011, [00144]-[00145], Fig. 22.)

A POSITA would have been motivated, and found it obvious, to combine Walther's outer cloth or Spenser II's outer compressible material with Spenser's Figure 44a. (Ex. 1003, ¶163.) Thus, claims 1-4 are obvious over Spenser in combination with Walther or Spenser II. (*Id.*)

1. Claim 1

Spenser and Walther or Spenser II render claim 1 obvious. (Ex. 1003, ¶¶164-212.)

a. Preamble

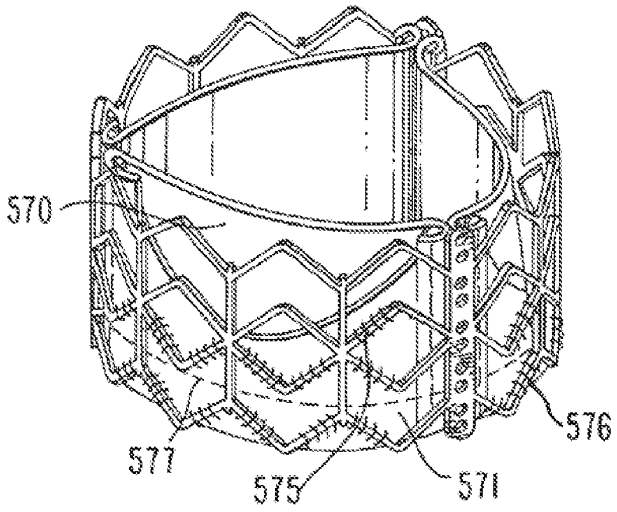
Spenser discloses a "transcatheter aortic valve assembly." (Ex. 1010, 1:13-15, 2:6-12, 5:17-25, 5:65-6:3, 17:19-18:43; Ex. 1003, ¶166.).) Spenser discloses that "[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously*** *...* ***via a large blood vessel such as the femoral artery***[.]" (Ex. 1010, 2:6-12 (emphases added).) Spenser describes delivering the valves through a catheter. (*Id.*, 5:17-6:36, 17:19-18:43.)

Walther and Spenser II also disclose "transcatheter aortic valve" assemblies. (*Supra* VIII.A.1.a; Ex. 1011, [0009], [0014], [0017], [0087], [00144]-[00145]; Ex. 1003 ¶167.)

b. Outer Frame

Spenser discloses this limitation. (Ex. 1003, ¶¶168-170.) Figure 44a illustrates "an implantable prosthetic valve" that includes "frame 575":

FIG. 44a



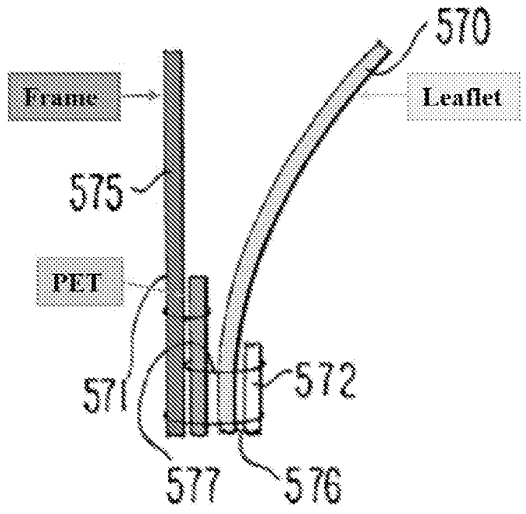
(Ex. 1010, 19:5-13, 26:30-34.) The frame may be made from metallic materials and surrounds the other valve components, making it an "outer frame." (*Id.*, 12:28-31, 28:16-19, Fig. 44a-44b; Ex. 1003, ¶170.)

c. Inner Frame

Spenser discloses this limitation. (Ex. 1003, ¶¶171-174.) Spenser's Figure 44a includes "additional pieces of PET" for "sealing and protecting the pericardium." (Ex. 1010, 26:30-34, Figs. 44a-44c.) The "pericardium" includes prosthetic leaflets 570, and the PET is a polymeric "graft covering." (*Id.*, 26:30-54; Ex. 1003, ¶172.)

PET 571 [blue] is positioned "between the leaflets [570 yellow] and frame [575 red]" and engages the leaflets[5]:

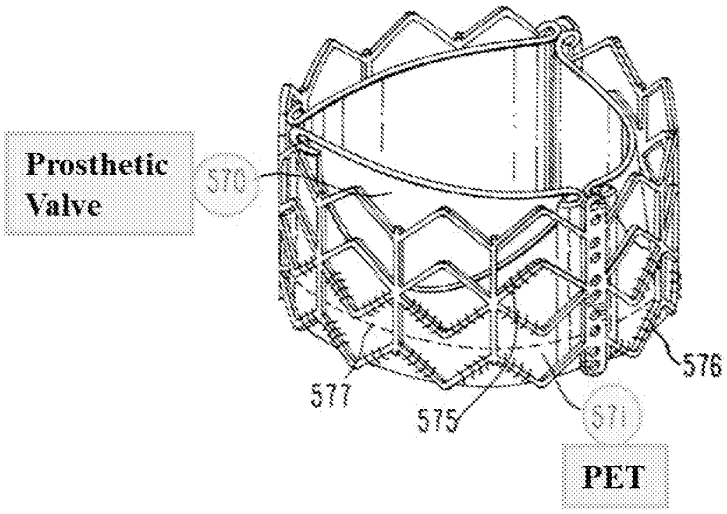
FIG. 44b



(Ex. 1010, 26:30-54, Fig. 44b.) PET 571 is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:

[5] In Fig. 44b, the lead lines for 571 and 575 point to the outer frame [red]. This is a drafter's error. The lead line for the outer PET layer 571 should point to the middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶173 n.4.)

FIG. 44a

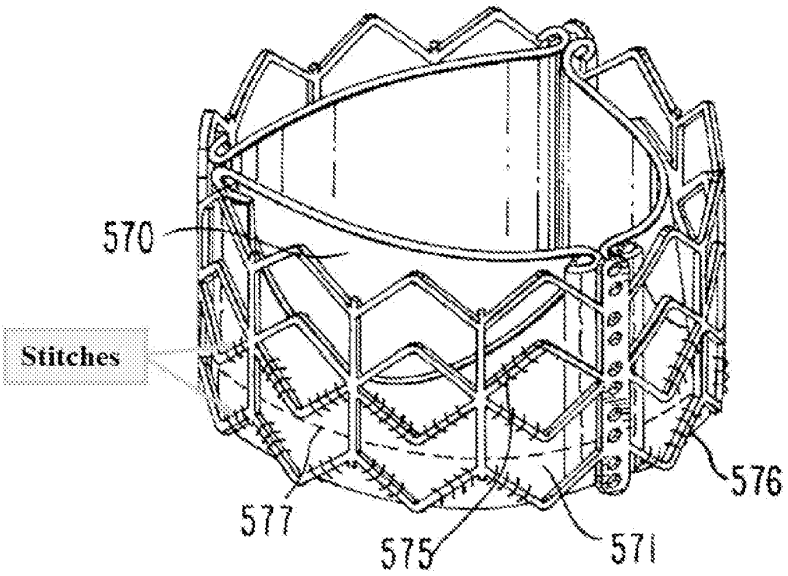


(*Id.*, 26:30-34, Fig. 44a-b.) Thus, based on Patent Owner's statements during related prosecution (*supra* §VIII.A.1.c), PET 571 satisfies the "inner frame" limitations. (Ex. 1003, ¶174.)

d. Stitching

Spenser discloses this limitation. (Ex. 1003, ¶¶175-177.) Spenser's inner graft covering is secured to the frame with stitches from sutures 576 and 578:

FIG. 44a



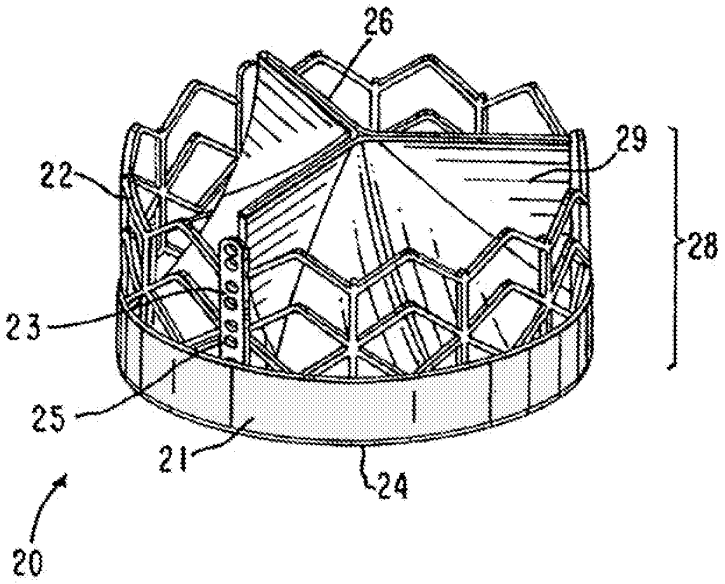
(Ex. 1010, 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30.)

e. First Portion of Fibers

i. Walther

Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.e.) A POSITA would have been motivated to combine Walther's outer cloth with Spenser's Figure 44a because Walther expressly discloses combining the outer cloth with a similar (if not identical) heart valve (SAPIEN). (Ex. 1007, 1120-1121; Ex. 1003, ¶180.) Additionally, Spenser suggests the addition of an outer cloth

to Figure 44a by disclosing a similar valve (*see* below) having an outer cuff portion 21 for sealing around the valve:

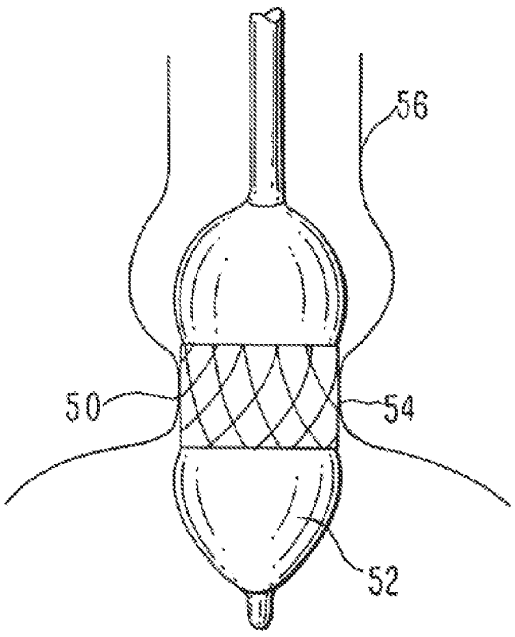


(Ex. 1010, 13:22-25, Fig. 1.) Adding Walther's outer cloth to Figure 44a would have merely entailed applying a known technique (attaching an outer cloth) to a known device (Figure 44a) ready for improvement (enhanced sealing). *KSR Int'l Co.*, 550 U.S. at 416.

A POSITA would have reasonably expected success in combining Walther's outer cloth with Figure 44a because Walther discloses how to combine the cloth with a similar heart valve, provides images of the combination, and concludes that the cloth-covered valve "demonstrated excellent hydrodynamic performance." (*See* Ex. 1007, 1125; Ex. 1003, ¶180.)

A POSITA would have understood that Walther's outer cloth is "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst" as explained in Ground 1. (*Supra* §VIII.A.1.e.) Further, like SAPIEN, Spenser's Figure 44a is configured to press against the annulus and native leaflets of the patient. (Ex. 1003, ¶181.)

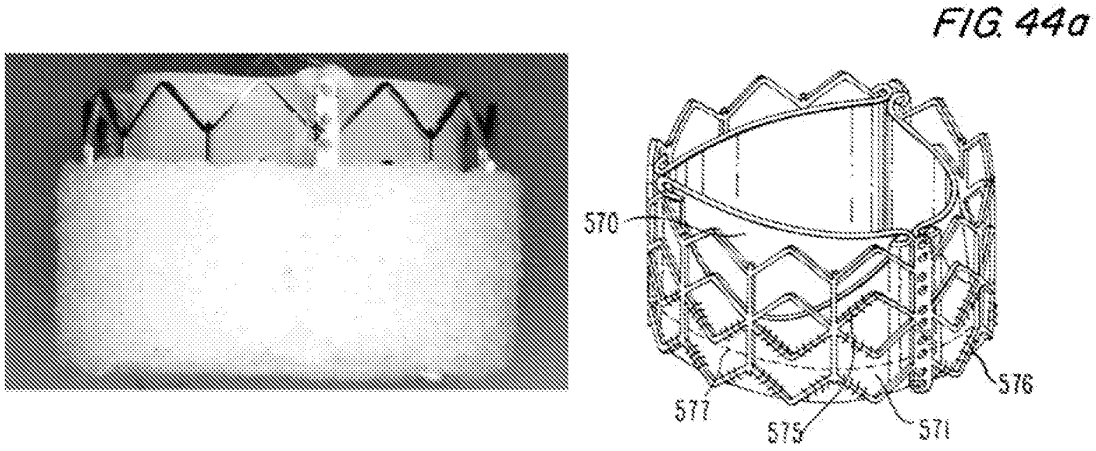
Spenser's Figure 4 (below) shows the valve deployed "in a natural aortic valve position in accordance with the present invention":



(Ex. 1010, 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b.) As shown, the valve presses against the patient's aortic annulus. (Ex. 1003, ¶181.) Although not shown in Figure 4, POSITAs would have understood that the

valve also presses against the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. (Ex. 1003, ¶180.)

Walther's outer cloth would cover at least the two proximal rows of Figure 44's outer frame, as illustrated by the comparison of Walther's Figure 1 (left) and Spenser's Figure 44a (right) below:



(Ex. 1007, Fig. 1; Ex. 1010, Fig. 44a; Ex. 1003, ¶182.) As illustrated by Spenser's Figure 4 and understood by a POSITA, expanding Figure 44a would cause at least a portion of the proximal two rows to press against the patient's annulus and native aortic leaflets. (Ex. 1003, ¶182.) Thus, expansion of Figure 44a would press the outwardly extending fibers of Walther's outer cloth against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst. (*Id.*)

A POSITA would have been motivated to, and expected success in, deploying the combination of Figure 44a with Walther's outer cloth in a patient's native valve

for the same reasons a POSITA would have been motivated to, and expected success in, deploying Walther's cloth-covered SAPIEN in a patent. (*Supra* §VIII.A.1.e.)

ii. Spenser II

Spenser II also discloses this limitation. (Ex. 1003, ¶187.) Spenser II discloses, "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252":

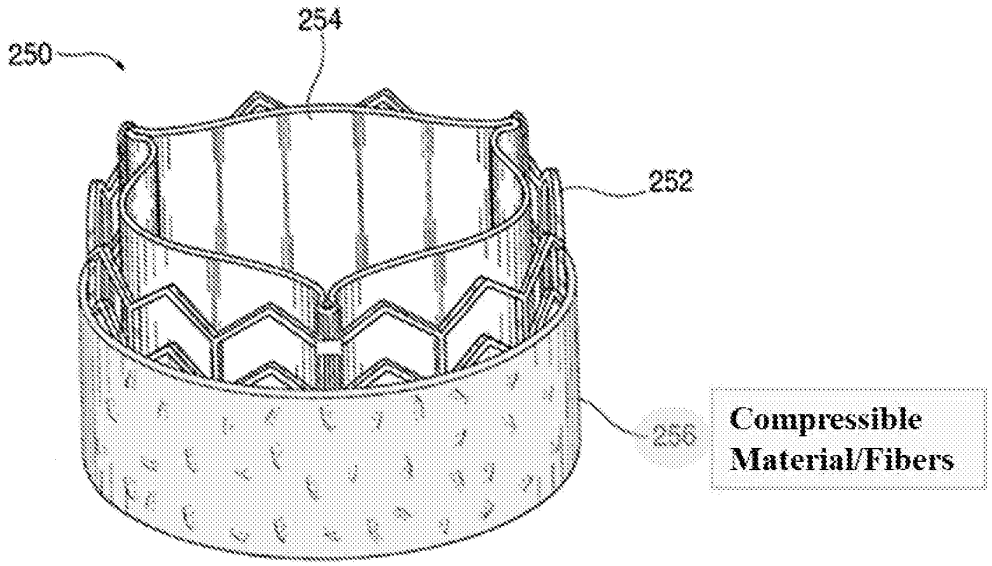
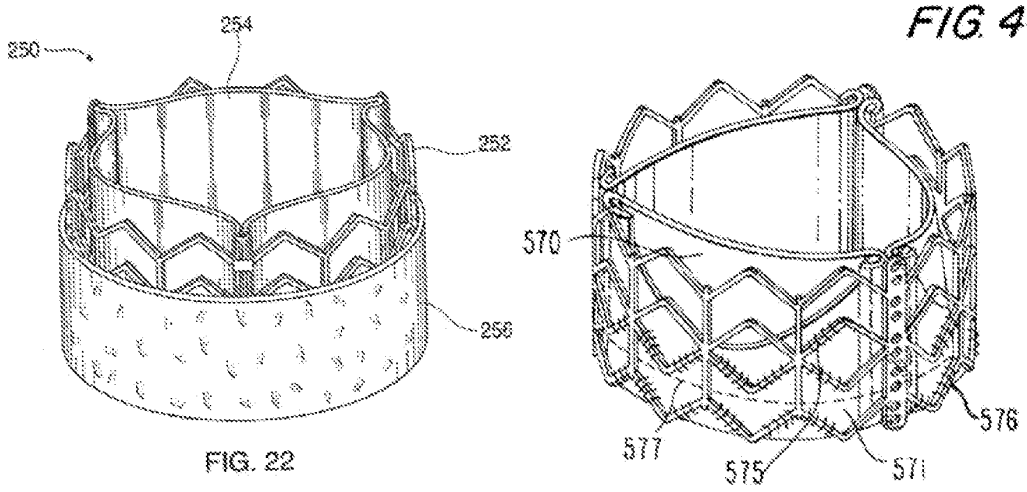


FIG. 22

(Ex. 1011, [00145], Fig. 22.) The compressible material "***may resemble a cloth or fabric having small fibers extending from the surface of the material***." (*Id.* (emphasis added).) The fibers extending outwardly from the compressible material are a "first portion of fibers" required by claim 1. (Ex. 1003, ¶187.) In a preferred

embodiment, the compressible material is formed of PET fibers, which are "non-metallic." (Ex. 1011, [00145]; Ex. 1003, ¶187.)

Spenser II's compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." (Ex. 1011, [00145].) Thus, Spenser II's compressible material (i.e., first portion) is "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst." (Ex. 1003, ¶188.) Moreover, when added to Spenser's Figure 44a, the compressible material would cover the bottom two rows of grids formed by the frame, as shown in the below comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



(Ex. 1010, Fig. 44a; Fig. 1011, Fig. 22; Ex. 1003, ¶188.) As explained in the preceding section, expanding Spenser's Figure 44a within a patient's native aortic valve would cause at least a portion of the proximal two rows of the frame to press against the native annulus and aortic leaflets. (*Supra* §VIII.B.1.e.i.) Thus, expansion of Figure 44a would press the outwardly extending fibers of Spenser II's compressible material against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst. (Ex. 1003, ¶188.)

A POSITA would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a for several reasons. Spenser and Spenser II describe similar valves, share three common inventors, and Spenser II explicitly references Spenser's parent application: U.S. Publication No. 2003/0153974 (Ex. 1015). (*See, e.g.*, Ex. 1010, Abstract, 2:5-15; Ex. 1011, [0001], [0009]-[0014]; Ex. 1003, ¶189.) Given this overlap, POSITAs would have reasonably anticipated that the teachings in Spenser II would apply to Spenser. (Ex. 1003, ¶189.)

Also, PVL was known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. (*Id.*, ¶190.) POSITAs would have been motivated to combine Spenser II's compressible material with Figure 44a to "address leaks that can occur around the implanted valve" and "to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [0010], [0145]; Ex. 1003,

¶190.) Moreover, adding the compressible material to Figure 44a would have merely entailed the combination of known elements (Figure 44a and compressible material) according to known methods (stitching or otherwise attaching) to yield the predictable result of reducing PVL. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶190.)

POSITAs would have reasonably expected success in combining Spenser II's compressible material with Figure 44a because the valve assemblies share many common features, including similar balloon-expandable stents and a three-leaflet prosthetic valve. (*See, e.g.*, Ex. 1010, 2:5-15; 12:28-36, 13:26-54, 19:5-13; Ex. 1011, [0011]-[0015], [00144]; Ex. 1003, ¶191.) Moreover, Spenser discloses valves having a sealing material positioned around its inlet, which would have given POSITAs confidence that other sealing structures, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. (Ex. 1010, 13:22-25, Fig. 1; Ex. 1003, ¶191.)

f. Second Portion of Fibers

i. Walther

Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.f.) POSITAs would have been motivated to combine Walther's outer cloth with Spenser's Figure 44a with a reasonable expectation of success as explained in the previous section. (*Supra* §VIII.B.1.e.i.)

Walther's outer cloth is stitched to and carried by SAPIEN's outer frame. (*Supra* §VIII.A.1.f.) POSITAs would have been motivated to stitch Walther's outer cloth to Figure 44a's frame because Walther describes this method of attachment and stitching is simple and would have been known to POSITAs. (Ex. 1003, ¶194.) The combination of Walther's outer cloth with Figure 44a would therefore include a second portion of fibers "carried by the outer frame." (*Id.*) The second portion of fibers of Walther's outer cloth would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" as explained in Ground 1. (*Supra* §VIII.A.1.f.)

ii. Spenser II

Spenser II also discloses this limitation. (Ex. 1003, ¶195.) Spenser II's compressible material "is disposed along an outer surface of the stent structure 252" and, thus, is "carried by the outer frame":

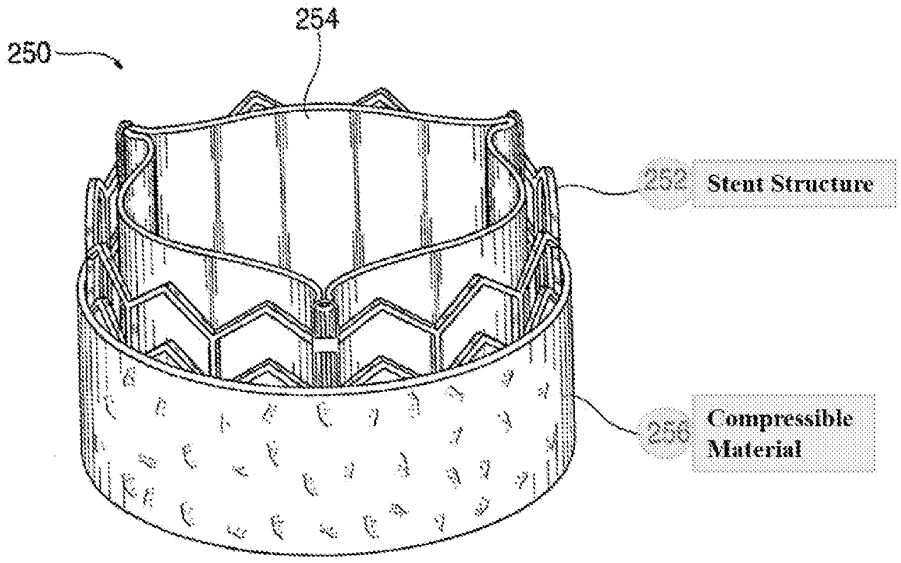


FIG. 22

(Ex. 1011, [00145], Fig.22; Ex. 1003, ¶195.) The compressible material "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." (Ex. 1011, [00145].) The material has an outward-facing surface (i.e., a first portion), discussed in the previous section, and an inward-facing surface also formed of non-metallic fibers. (*Id.*, Fig. 22; Ex. 1003, ¶195.) The inward-facing fibers are the "second portion of fibers" required by claim 1. As shown in Figure 22 above, the inwardly-facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded. (Ex. 1003, ¶195.) The fibers must form a sealing interface with the frame in the expanded state because Spenser II discloses that the cloth prevents PVL, which could not happen if blood could leak between the cloth and expanded frame. (*Id.*)

g. First and Second Portions in Overlapping Radial Alignment

i. Walther

Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.g.)

ii. Spenser II

Spenser II also discloses this limitation. (Ex. 1003, ¶198.) Spenser II discloses that its compressible material "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." (Ex. 1011, [00145].) As explained above, a POSITA would understand that such a PET cloth or fabric would include fibers on both its outward-facing surface (a first portion) and on its inward-facing surface (a second portion). (*Supra* §VIII.B.1.e-f.) Because the two portions of fibers are part of a single PET cloth disposed along the exterior of the outer frame, a POSITA would understand that the two portions of fibers, located on opposite surfaces of the compressible material, are in overlapping radial alignment. (Ex. 1003, ¶198.)

h. First Sealing Interface in Overlapping Radial Alignment with Leaflets

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶199-201.)

As explained in the "First Portion of Fibers" section, Walther's outer cloth and Spenser II's compressible material, in combination with Spenser's Figure 44a, are configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst. (*Supra* §VIII.B.1.e.) A POSITA would have been motivated, and expected success, in combining Walther's outer cloth or Spenser II's compressible material with Figure 44a for the reasons previously provided. (*Id.*)

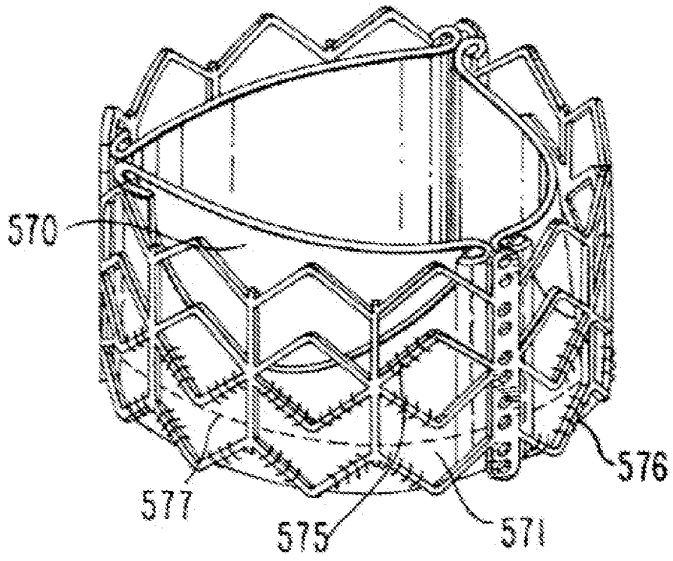
i. Free of an Outer Graft Covering

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶202-206.)

i. Walther

Walther's outer cloth is "free of an outer graft covering between the first portion of fibers and the outer frame." (*Supra* §VIII.A.1.i.) Likewise, Spenser's Figure 44a does not include any "outer graft covering" on the exterior of the outer frame 575:

FIG. 44a



(Ex. 1010, Fig. 44a; Ex. 1003, ¶203.) Therefore, the combination of Walther's outer cloth with Figure 44a would have no "outer graft covering" between the outer cloth's first portion of fibers and the outer frame. (Ex. 1003, ¶203.)

ii. Spenser II

Spenser II's compressible material is "free of an outer graft covering between the first portion of fibers and the outer frame." (*Id.*, ¶205.) Spenser II discloses that the compressible material, which "may resemble a cloth or fabric having small fibers extending from the surface of the material," is "disposed along an outer surface" of the stent. (Ex. 1011, [00145].) Spenser II does not disclose or suggest any "outer graft covering" between the outwardly extending fibers of the outward-facing

surface of the compressible material (i.e., first portion) and the stent. (Ex. 1003, ¶205.) Therefore, a POSITA would understand that there is no such "outer graft covering" between the fibers of the compressible material and the outer frame. (*Id.*) Moreover, Spenser's Figure 44a does not include any "outer graft covering" on the exterior of the outer frame 575. (*Supra* §VIII.B.1.i.i.) Therefore, the combination of Spenser II's compressible material with Figure 44a would have no "outer graft covering" between the compressible material's first portion of fibers and the outer frame. (Ex. 1003, ¶205.)

j. Radially Compressed and Expanded Orientation

Spenser, Walther, and Spenser II disclose this limitation. (Ex. 1003, ¶¶207-208.) Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.j.) Spenser teaches that its prosthetic valve "has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation]." (Ex. 1010, 27:67-28:2.) Spenser II discloses valves that comprise "an expandable stent structure" that may be "adapted for radial expansion using a balloon catheter." (Ex. 1011, [00144].)

k. Balloon Expandable

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶209-210.)

Spenser discloses that the valve assembly depicted in Figure 44a "resembles the valve shown in Fig. 43." (Ex. 1010, 26:34-35.) The valve shown in Figure 43 may be "inflated by a balloon . . . [such that] the frame is expanded to the full diameter." (*Id.*, 1010, 26:19-22; *see also id.*, 12:4-8, 14:10-14, 17:19-18:43 (balloon-expandable assemblies).) A POSITA would therefore have understood that Figure 44a is balloon expandable. (Ex. 1003, ¶210.) A POSITA would have further understood that Figure 44a would remain balloon expandable after adding either Walther's outer cloth or Spenser II's outer compressible material, as both references explicitly disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. (*See* Ex. 1007, 1122 (cloth-covered SAPIEN was balloon expandable); Ex. 1011, [00144] (valve "adapted for radial expansion using a balloon catheter").)

l. Compress Fibers to Form a Sealing Interface

i. Walther

As explained in Ground 1, Walther's cloth-covered SAPIEN is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. (*Supra* §§VIII.A.1.e-f.) Walther's outer cloth would behave in the same

way if it were added to Figure 44a because Figure 44a and SAPIEN are similar, if not identical. (Ex. 1003, ¶212.)

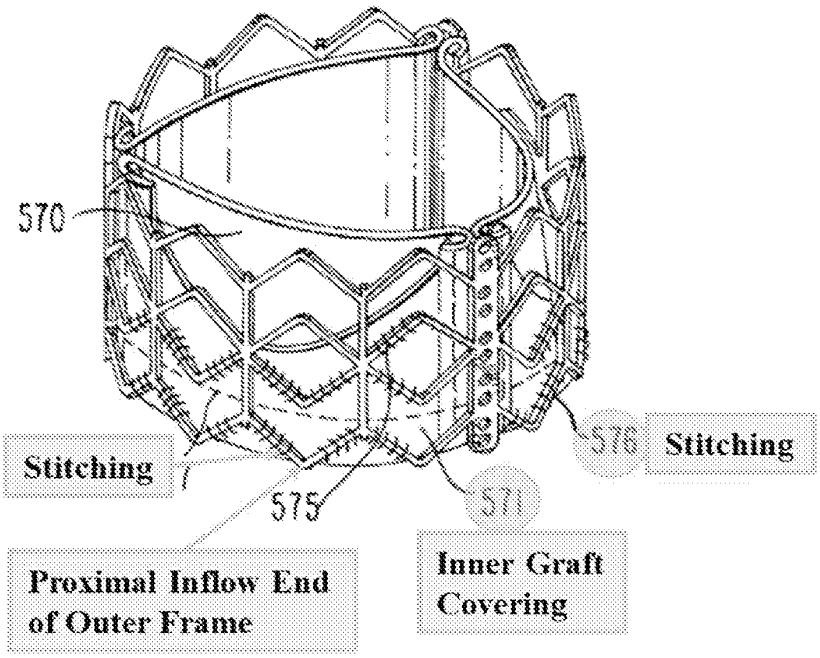
ii. Spenser II

As explained above, Spenser II's compressible material, in combination with Spenser's Figure 44a, is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. (*Supra* §§VIII.B.1.e-f.)

2. Claim 2

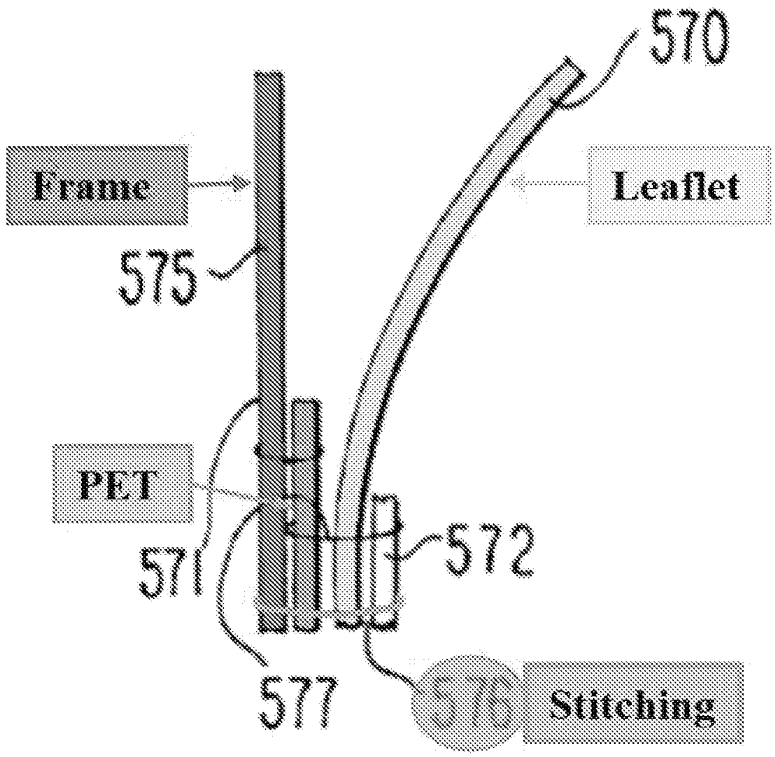
Spenser discloses this limitation. (Ex. 1003, ¶¶214-215.) Spenser discloses that a "[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a strong sealing line." (Ex. 1010, 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30.)

FIG. 44a



Figures 44a (above) and 44b (below) illustrate that PET 571 (i.e., inner graft covering) extends to the proximal inflow end of the outer frame, and that bottom sutures 576 extend between PET 571 and through the outer frame to secure PET 571 to the proximal inflow end of the outer frame:

FIG. 44b



(*Id.*, Figs. 44a, 44b; Ex. 1003, ¶215.)

3. Claim 3

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶216-219.)

a. Walther

Walther's outer cloth discloses this limitation, or renders it obvious, as explained in Ground 1. (*Supra* §VIII.A.3.)

b. Spenser II

Spenser II also discloses this limitation or renders it obvious. (Ex. 1003, ¶218.) Spenser II discloses that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material." (Ex. 1011, [00145].) A POSITA would have understood that small openings inherently exist between the radially extending fibers formed by spacing between the adjacent fibers. (*See* Ex. 1007, Fig. 1; Ex. 1003, ¶218.) These small openings define a plurality of "opening[s] extending through a thickness" of the radially extending fibers.

If Spenser II does not disclose this limitation, a POSITA would have found it obvious to select different cloths having less density and larger gaps. (Ex. 1003, ¶219.) POSITAs would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of extending fibers such that even larger openings existed between the fibers. (*Id.*) A POSITA would have been motivated to select such a cloth to reduce the crimped profile of the device while still achieving the reduction in paravalvular leakage and coagulation of blood provided by the fibers. (*Id.*) In addition, as explained in Ground 1, the '236 patent does not contain any disclosure regarding how to size or arrange the fibers to provide such an opening. (*Supra* §VIII.A.3.) Consequently, Patent

Owner cannot argue that the adaption of Walther's outer cloth to provide such an opening would have been beyond the skill of a POSITA. (*Id.*)

4. Claim 4

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶220-223.)

i. Walther

Walther discloses this limitation, or renders it obvious, as explained in Ground 1. (*Supra* §VIII.A.4.)

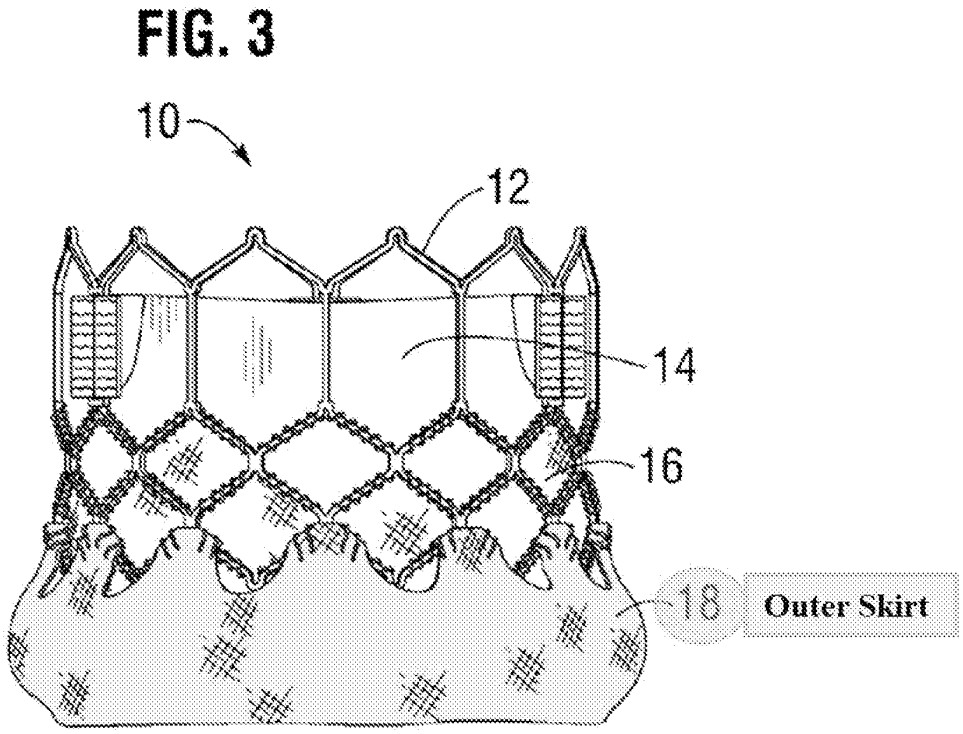
ii. Spenser II

Spenser II also discloses this limitation or renders it obvious. (Ex. 1003, ¶222.) Like Spenser II's outwardly extending fibers, the inwardly-facing fibers (i.e., second portion of fibers) inherently have small openings between the fibers formed by spacing between the adjacent fibers. (Ex. 1003, ¶222.) As explained in claim 3, the fibers are dense enough to prevent blood from flowing through the fibers, but still loose enough to create small gaps. (*Id.*)

If Spenser II does not disclose this limitation, a POSITA would have found it obvious to select different cloths having less density and larger gaps for the reasons provided in claim 3. (*Supra* §VIII.B.3; Ex. 1003, ¶223.)

C. Grounds 4-7: Claims 1-4 Anticipated or Obvious in View Levi Alone or With Walther or Spenser II

Levi discloses a valve having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame. (Ex. 1008, 13:50-66.)



(*Id.*, Fig. 3.) Levi discloses or suggests every limitation of claims 1-4 and anticipates the claims or renders them obvious. However, if Levi does not disclose or suggest first and second portions of fibers, Walther and Spenser II do. A POSITA would have found it obvious to substitute Walther's outer cloth or Spenser II's

compressible material for Levi's outer skirt. (Ex. 1003, ¶225.) Therefore, Levi combined with Walther or Spenser II renders claims 1-4 obvious. (*Id.*)

1. Claim 1

Levi anticipates claim 1 or renders it obvious alone or with Walther or Spenser II. (Ex. 1003, ¶¶226-274.)

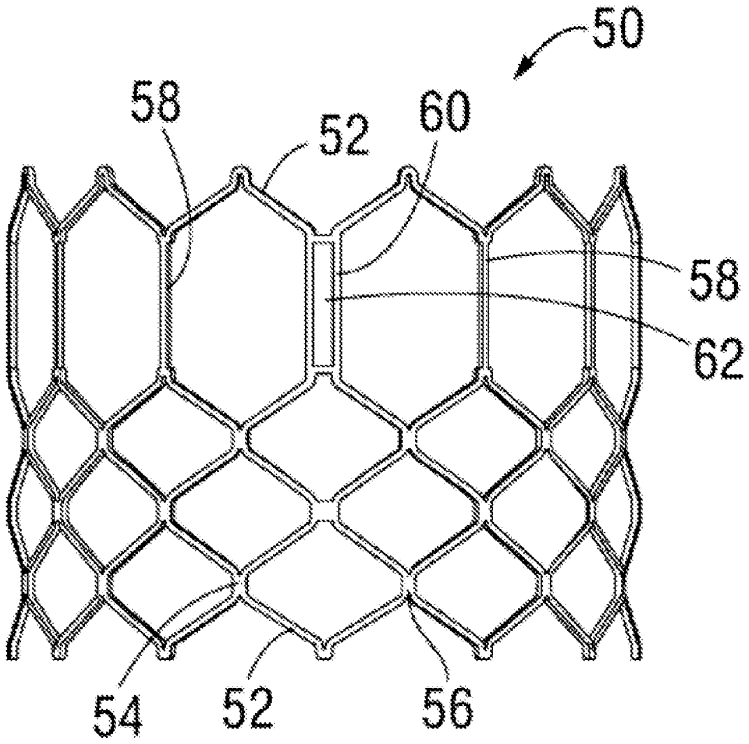
a. Preamble

Levi discloses a "transcatheter aortic valve assembly." (Ex. 1008, 1:16-18, 5:52-56; Ex. 1003, ¶228.) Levi discloses "collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent." (Ex. 1008, 1:57-2:7; *see also id.*, 5:53-56, 6:46-49, 7:10-12, 14:60-64; Ex. 1051, 5:14-67, 28:37-48, Fig. 4.)

b. Outer Frame

Levi discloses this limitation. (Ex. 1003, ¶¶229-230.) Levi discloses an expandable metal frame that surrounds the other valve components, making it an "outer frame":

FIG. 11

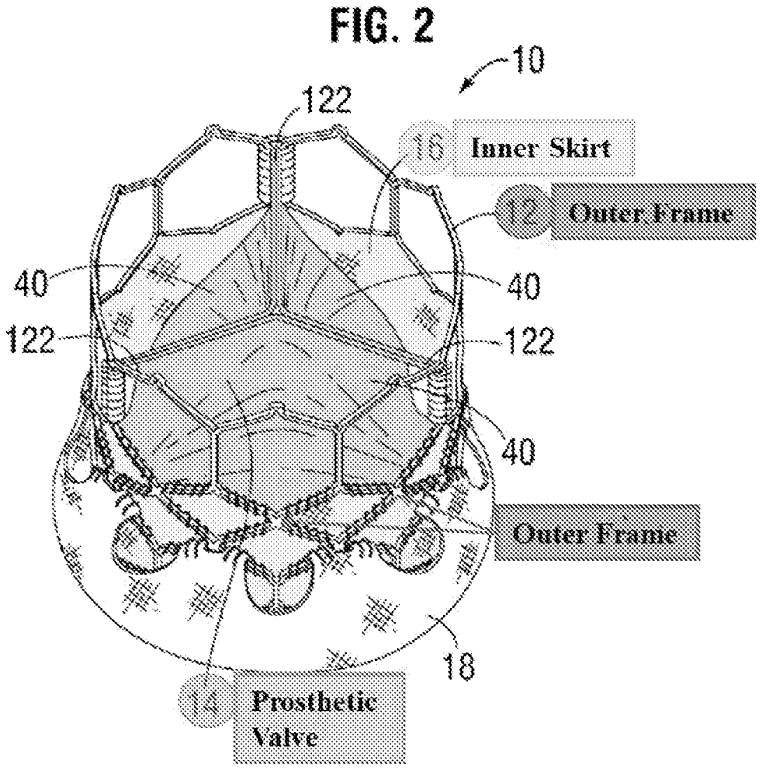


(Ex. 1008, 6:17-24, Fig. 11; Ex. 1003, ¶230.)

c. Inner Frame

Levi discloses this limitation. (Ex. 1003, ¶¶231-232.) Levi discloses an "inner skirt 16 … to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets." (Ex. 1008, 9:7-11.) The inner skirt is constructed of "a tough, tear resistant material such as polyethylene terephthalate (PET)." (*Id.*, 9:11-16.) PET

is a "polymeric graft covering." (Ex. 1003, ¶232.) The inner skirt is engaged to the valvular structure "via one or more thin PET reinforcing strips." (Ex. 1008, 9:25-29.) The "valvular structure 14 can comprise three leaflets 40, collectively forming a leaflet structure." (Ex. 1008, 5:59-62, Fig. 2.) The leaflets of the valvular structure are "prosthetic leaflets." (Ex. 1003, ¶ 232.) Levi's inner skirt 16 [yellow] cylindrically extends at least partially radially outwardly of prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red]:

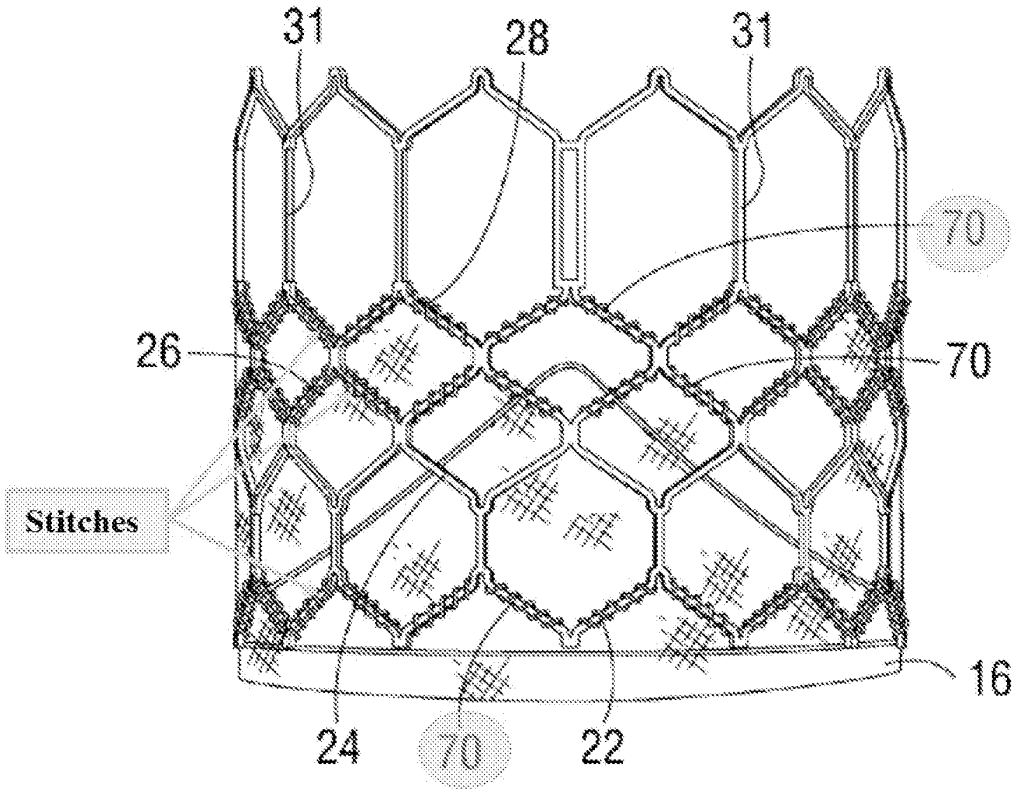


(Ex. 1008, Fig. 2; Ex. 1003, ¶232.)

d. Stitching

Levi discloses this limitation. (Ex. 1003, ¶¶233-234.) Levi's inner skirt 16 is secured to the outer frame 12 via a plurality of sutures 70:

FIG. 20

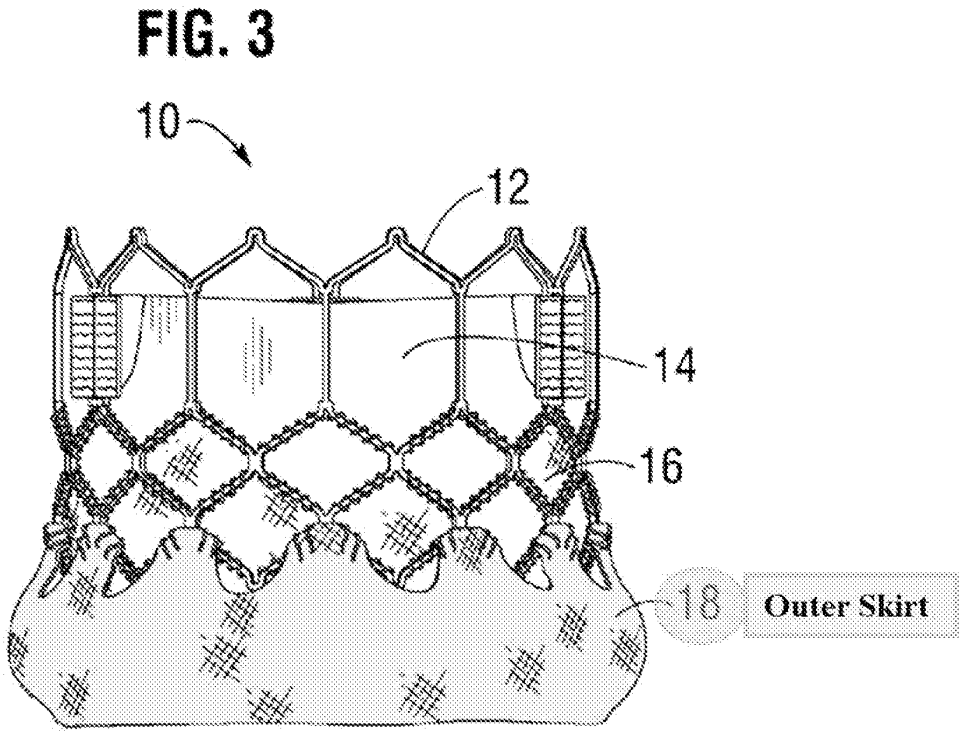


(Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39.)

e. First Portion of Fibers

i. Levi

Levi discloses this limitation in two ways. (Ex. 1003, ¶237.) Levi discloses an outer skirt of woven PET fabric [yellow] secured to the exterior surface of the frame. (Ex. 1008, 13:50-53, 13:62-66.)



(*Id.*, Fig. 3.) The non-metallic, PET fibers that comprise the portion of the outer skirt that is positioned radially outwardly of the frame is the "first portion of fibers" required by claim 1. (*See id*, 9:52-56, 13:50-53; Ex. 1003, ¶237.) These fibers "extend radially outwardly of the outer frame" because Levi teaches that the outer

skirt, and thus its fibers, "bulge outwardly" from the outer frame. (Ex. 1008, 9:52-56, 13:62-14:2; Ex. 1003, ¶237.)

Alternatively, a POSITA would have understood that the outer surface of Levi's outer skirt would not be entirely smooth, but would necessarily have fibers, or strands, that extend radially outwardly from the surface of the woven PET fabric. (Ex. 1003, ¶238.) A POSITA would have known that textile polyester yarn, such as PET yarn, exhibits a property known as "hairiness," which describes the "amount and length of fibre ends and loops protruding from the body of the yarn." (Ex. 1028, 124.) The hairiness of yarn can be influenced by a number of factors, and a POSITA would have known that polyester fabrics, such as PET, would exhibit some level of hairiness. (*See id.*; *see also* Ex. 1029, 32 (disclosing that 100% polyester yarn included between 50 and 150 hairs per meter).) Therefore, even if the bulging fabric of the outer skirt does not itself constitute a "first portion of fibers," a POSITA would have nonetheless understood that Levi's outer skirt includes a "first portion of fibers" protruding outwardly from the surface of the outer skirt that "extend radially outwardly of the outer frame." (Ex. 1003, ¶238.)

Levi's outer skirt is constructed with excess material that bulges radially outwardly as the frame expands. (Ex. 1008, 13:62-14:2.) The excess material allows the outer skirt to "fill in gaps between the frame 12 and the surrounding native

annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." (*Id.*, 14:3-7.) When the outer skirt "form[s] a good fluid-tight seal between the valve and the native annulus," the fibers of the outer skirt would also seal against the native aortic leaflets, which are attached to the native annulus and extend distally therefrom. (Ex. 1003, ¶239.) Patent Owner has previously admitted that Levi's outer skirt would "extend[] into crevices created by the native leaflets." (Ex. 1046, 21.) Therefore, both the fibers that comprise Levi's outer skirt ***and*** the small fibers projecting outwardly from the skirt are "first portion of fibers" that are "configured to form a first sealing interface against the annulus and native valve leaflets of the patient" when the outer skirt is pressed thereagainst. (Ex. 1003, ¶¶237-239.)

ii. Walther or Spenser II

Walther's outer cloth and Spenser II's compressible material satisfy this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.1.e, VIII.B.1.e.) A POSITA would have found it obvious to replace Levi's bulging outer PET skirt with Walther's outer cloth or Spenser II's compressible material. (Ex. 1003, ¶¶241, 248.) POSITAs would have known that Levi's outer skirt, Walther's outer cloth, and Spenser II's compressible material were interchangeable. (Ex. 1003, ¶¶241, 248.) While the specific materials have slightly different constructions, they were all designed for use with balloon-expandable heart valves to prevent PVL and could

sufficiently compensate for any elongating or foreshortening of the valve frame during compression and expansion. (*Id.*; Ex. 1007, 1122; Ex. 1011, [00144], Ex. 1008, 6:17-28.)

Moreover, a finite number of methods to address PVL existed in November 2012. (Ex. 1003, ¶¶242, 249.) Walther, Spenser II, and Levi disclose three such methods. (*Id.*) POSITAs would have found it obvious to select any one of these finite, predictable solutions and, as discussed below, would have reasonably expected success in doing so. (*Id.*) Further, POSITAs would have found it obvious to try each material because the different constructions provide unique potential advantages. (*Id.*) For example, Walther discloses that its fibrous outer cloth promotes tissue ingrowth. (Ex. 1007, 1120.) Spenser II's compressible material "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [00145].) Ultimately, the combination of Levi with Walther or Spenser II would have merely entailed substitution of one known element (outer cloth/compressible material) for another (Levi's outer skirt) to yield the predictable results of reducing PVL. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶¶241, 248.)

A POSITA would have reasonably expected success in substituting Walther's outer cloth or Spenser II's compressible material for Levi's outer skirt. (Ex. 1003, ¶¶243-246, 250-251.) The valve frames in Walther, Spenser II, and Levi share many

common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. (*Id.*) Further, Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that in-patient implantation of the valve "is feasible," suggesting that other cloth-covered valves would achieve similar success. (Ex. 1007, 1125; Ex. 1003, ¶¶243-246, 250-251.)

Moreover, Levi suggests adding other components, like an outer skirt or seal, to the inflow portion of the outer frame, stating "if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component." (Ex. 1008, 16:41-45.) Levi also discloses methods to reduce the frame's diameter at the inlet, or to modify the leaflets to reduce the frame size, to create room for an outer seal. (*Id.*, 16:24-17:18.) POSITAs would have understood they could utilize one or more of these methods to add Walther's outer cloth or Spenser II's compressible material to Levi's frame instead of the outer skirt. (Ex. 1003, ¶¶244-246, 251.)

When substituted for Levi's outer skirt, Walther's outer cloth or Spenser II's compressible material would be configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is

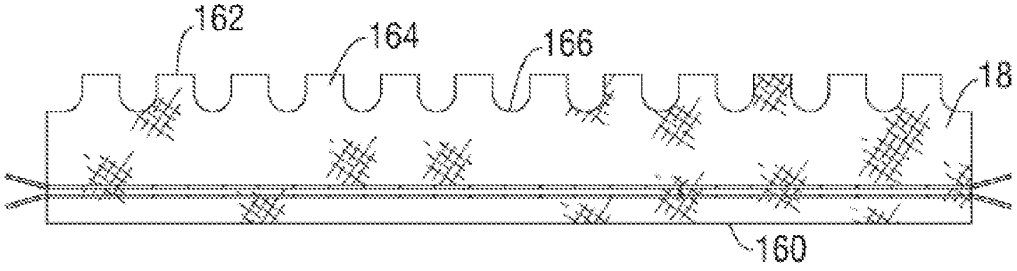
compressed thereagainst for the reasons previously discussed. (*Supra* §§VIII.A.1.e, VIII.B.1.e, VIII.C.1.e.i.)

f. Second Portion of Fibers

i. Levi

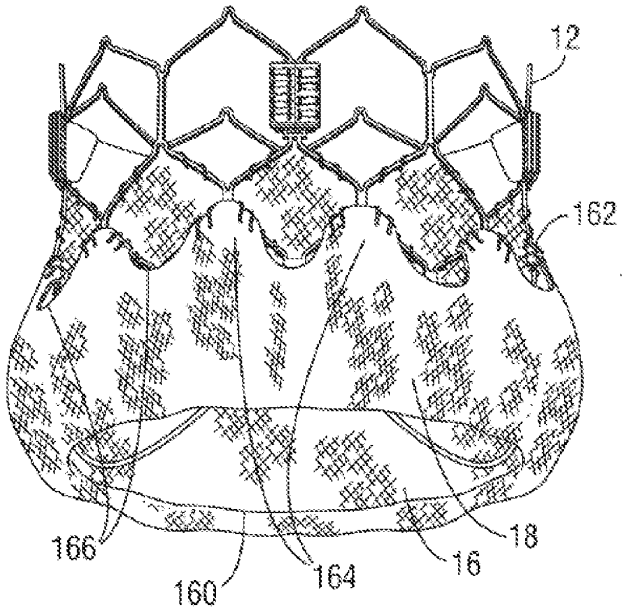
Levi discloses this limitation in two ways. (Ex. 1003, ¶253.) First, Levi's outer skirt, which is comprised of non-metallic, PET fibers, includes "an upper edge 162 defining a plurality of alternating projections 164 and notches 166." (Ex. 1008, 13:53-55.)

FIG. 41



(*Id.*, Fig. 41.) "As shown in Figure 43, each projection 164 can be sutured to the second rung II of struts 24 of the frame 12." (*Id.*, 13:58-59.) "The corners 162 of the projections 164 can be folded over [the] respective struts of rung II and secured with sutures 168." (*Id.*, 13:60-61.)

FIG. 42



(*Id.*, Fig. 42.) The non-metallic fibers that comprise the corners 162 that are wrapped around the struts and reside on the interior of the frame are the "second portion of fibers" required by claim 1. (Ex. 1003, ¶254.) As shown, the corners are sutured to and "carried by" the outer frame. (*Id.*) Likewise, the corners are configured to "form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst." (*Id.*) As the outer skirt bulges outward, the outer skirt pulls upon the corners and compresses the fibers forming the corners against the outer frame. (*Id.*) This compression creates a sealing interface between the corners of the outer skirt and frame. (*Id.*) It also helps create the sealing interface between

the outer skirt and the patient's native tissue by holding the skirt against the frame. (*Id.*)

Alternatively, the interior surface of the outer skirt has small fibers extending from its surface just like the outer surface. (*Supra* §VIII.C.1.e.) As explained previously, the outer skirt is "carried by" the frame and forms a seal between the valve and native tissue. (*Id.*) When the valve is expanded to form the outer seal, the interior surface of the outer skirt is compressed against the outer frame. (Ex. 1003, ¶255.) The small fibers extending from the interior surface of the outer skirt therefore "form a second sealing surface against the outer frame when the second portion of fibers is compressed thereagainst." (*Id.*)

ii. Walther or Spenser II

Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.1.f, VIII.B.1.f.) POSITAs would have been motivated to substitute Walther's outer cloth or Spenser II's compressible material for Levi's outer skirt with a reasonable expectation of success as explained in the previous section. (*Supra* §VIII.C.1.e.ii.)

Further, Levi's outer skirt is stitched to and carried by Levi's outer frame. (*Supra* §VIII.C.1.f.i.) A POSITA would have been motivated to stitch Walther's outer cloth or Spenser II's compressible material to Levi's frame because Levi

describes this method of attachment and stitching is simple and would have been known to POSITAs. (Ex. 1003, ¶257.) The combination of Walther's outer cloth or Spenser II's compressible material with Levi's valve would therefore include a second portion of fibers "carried by" the outer frame. (*Id.*) The second portion of fibers of Walther's outer cloth or Spenser II's compressible material would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" as explained in Grounds 1-3. (*Supra* §§VIII.A.1.f, VIII.B.1.f.)

g. First and Second Portions in Overlapping Radial Alignment

Levi discloses this limitation in two ways. (Ex. 1003, ¶259.) As described above, the fibers that comprise the corners are wrapped around the struts and oppose the fibers in the rest of the outer skirt. (*Supra* §VIII.C.1.f.i.) Thus, the fibers in the corners and the outer skirt are in overlapping radial alignment. (Ex. 1003, ¶259.)

Alternatively, the outer skirt is made of woven PET fibers. (*Supra* §VIII.C.1.e.i.) Thus, the small fibers extending from the outer and inner surfaces of the skirt are in overlapping radial alignment with each other. (Ex. 1003, ¶259.)

Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.1.g, VIII.B.1.g.)

h. First Sealing Interface in Overlapping Radial Alignment with Leaflets

Levi discloses this limitation. (Ex. 1003, ¶262.) Levi's valve "is adapted to be implanted in the native aortic annulus" and, when the frame is expanded, the outer skirt will "fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." (Ex. 1008, 5:52-54, 14:3-7.) A POSITA would understand that to "fill in gaps between the frame 12 and the surrounding native annulus," the fibers of the outer skirt (i.e., first portion) would be positioned in radially overlapping alignment with the patient's native valve leaflets, which are attached to the native annulus and extend distally therefrom. (Ex. 1003, ¶262.)

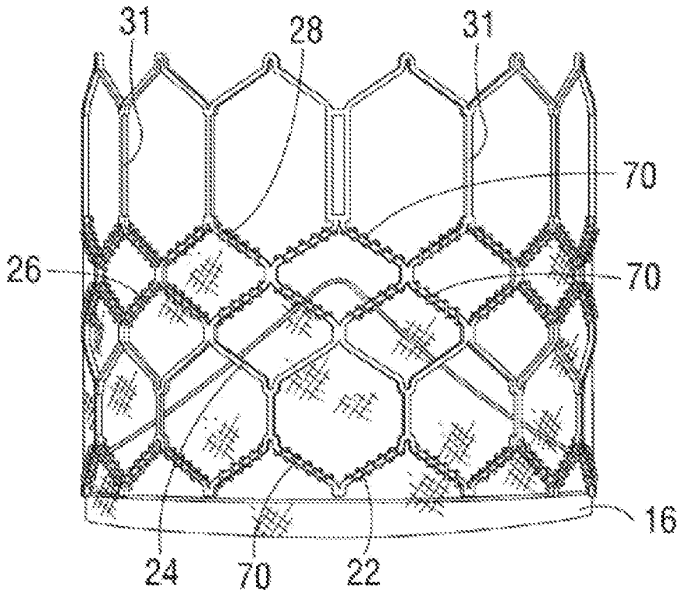
Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's compressible material, a POSITA would understand that the fibers of the outer cloth/compressible material, rather than the outer skirt, would be positioned to radially overlap with the patient's native leaflets. (*Id.*, ¶263.)

i. Free of an Outer Graft Covering

Levi discloses this limitation. (Ex. 1003, ¶264.) Levi's valve is free of an "outer graft covering" between the fibers of the outer skirt and the outer frame. (Ex. 1003, ¶265.) Levi teaches that the outer skirt is sutured to the exterior of the outer

frame. (Ex. 1008, 13:58-61.) Levi does not include any "outer graft covering" on the exterior of the outer frame:

FIG. 20



(*Id.*, Fig. 20; Ex. 1003, ¶265.) Therefore, POSITAs would have understood that when the outer skirt is stitched to the exterior of the outer frame, there would be no "outer graft covering" between the fibers of the outer skirt (i.e., first portion) and the outer frame. (Ex. 1003, ¶265.)

Alternatively, Levi and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶266.) POSITAs would have understood that when Levi's outer skirt is replaced with Walther's outer cloth or Spenser II's compressible material, there

would be no "outer graft covering" between the radially extending fibers of the outer cloth/compressible material (i.e., first portion) and the outer frame because Levi does not include any "outer graft covering" on the exterior of the outer frame. (Ex. 1003, ¶266; *supra* §§VIII.A.1.i, VIII.B.1.i.)

j. Radially Compressed Expanded Orientation

Levi, Walther, and Spenser II disclose this limitation. (Ex. 1003, ¶¶267-268.)

Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.j.) Spenser II discloses this limitation as explained in Grounds 2-3. (*Supra* §VIII.B.1.j.) Levi discloses that its valve is "radially collapsible and expandable." (Ex. 1008, Abstract.) Levi teaches that "[w]hen constructed of a plastically-expandable material, the frame 12 (and thus the valve 10) ***can be crimped to a radially compressed*** state on a delivery catheter and then ***expanded*** inside a patient by an inflatable balloon or equivalent expansion mechanism." (*Id.*, 6:20-24 (emphases added).)

k. Balloon Expandable

Levi discloses this limitation or renders it obvious in combination with Walther or Spenser II. (Ex. 1003, ¶¶269-271.)

Levi discloses that "the frame 12 (and thus the valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient

by an inflatable balloon." (Ex. 1008, 6:17-28.) Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's compressible material, a POSITA would have understood that the resulting valve would remain balloon expandable because both Walther and Spenser II disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. (*See* Ex. 1007, 1122; Ex. 1011, [00144]; Ex. 1003, ¶271.)

I. Compress Fibers to Form a Sealing Interface

Levi discloses this limitation or renders it obvious in combination with Walther or Spenser II. (Ex. 1003, ¶¶272-274.)

As explained above, Levi's outer skirt is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. (*Supra* §§VIII.C.1.e-f.)

Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.1.l, VIII.B.1.l.) Therefore, when Walther's outer cloth or Spenser II's compressible material is added to Levi's valve, expansion of the valve within a patient's native aortic valve would be configured to (1) compress the outwardly extending fibers of the outward-facing surface of the outer

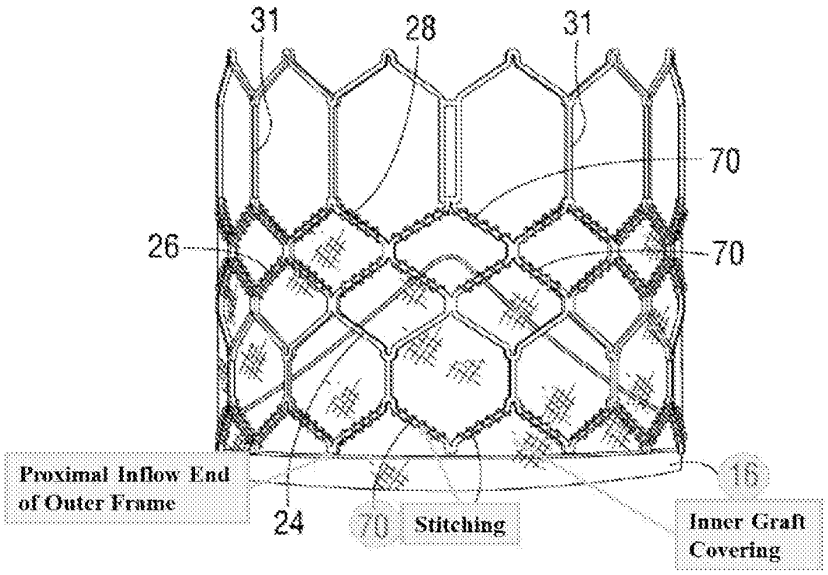
cloth/compressible material (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface, and (2) compress the PET fibers of the inward-facing surface (i.e., second portion) against the valve's outer frame to form a second sealing interface. (Ex. 1003, ¶274.)

2. Claim 2

Levi discloses this limitation. (Ex. 1003, ¶§§275-276.)

Levi's inner skirt (i.e., inner graft covering) extends to the proximal inflow end of the outer frame:

FIG. 20



(Ex. 1008, Fig. 20.) As shown above, sutures 70 extend between the inner skirt and through the outer frame to secure the inner skirt to the proximal inflow end of the outer frame. (*See id.*; Ex. 1003, ¶276.)

3. Claim 3

Levi discloses this limitation or renders it obvious. (Ex. 1003, ¶277.) Levi's outer skirt (i.e., first portion of fibers) is constructed of "woven PET" fabric. (Ex. 1008, 13:50-53.) A POSITA would understand that woven PET fabric, including Levi's outer skirt, would include small gaps or spacing between the interwoven fibers of the fabric. (*See, e.g., id.*, 10:48-57 (discussing spacing between the woven fibers of the inner PET skirt); Ex. 1003, ¶278.) A POSITA would therefore understand that gaps existed between the woven PET fibers of Levi's outer skirt which define "opening[s] extending through a thickness" of the outer skirt (i.e., first portion). (Ex. 1003, ¶278.)

Alternatively, a POSITA would have understood that small fibers would extend from the outer surface of the outer skirt. (*Supra* §VIII.C.1.e.) A POSITA would have understood that the small fibers would occur at spaced intervals, thereby defining an opening extending through the thickness created by spacing formed between the small fibers. (Ex. 1003, ¶280.)

Moreover, POSITAs would have had access to a range of suitable PET fabrics having varying thicknesses and densities and could have selected a fabric with a lower density of woven fibers such that even larger openings existed between the fibers. (*Id.*, ¶279; *see* Ex. 1008, 10:48-57.) A POSITA would have been motivated to do so to facilitate further axial elongation of the outer skirt as the valve is expanded to provide a more uniform and predictable crimping profile. (Ex. 1003, ¶279; Ex. 1008, 10:35-57.)

Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.3, VIII.B.3.)

4. Claim 4

Levi discloses this limitation. (Ex. 1003, ¶283.) Just as Levi's outer skirt (first portion of fibers) would have defined openings, the corners of the outer skirt (second portion of fibers), which are made from the same PET and carried by the frame, would define an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers. (*Id.*) Likewise, the fibers extending from the inner surface of the outer skirt would also define such an opening for the same reasons as the small fibers extending from the outer surface. (*Id.*; *supra* §VIII.C.3.) At least some of these openings would extend to the outer frame because the second

portion of fibers in the outer skirt directly abuts, and is compressed against, the outer frame when the valve is expanded. (Ex. 1003, ¶283.)

Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. (*Supra* §§VIII.A.4, VIII.B.4.)

IX. SECONDARY CONSIDERATIONS

Petitioner understands that Patent Owner does not practice the '236 patent or sell any products covered by the '236 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶286-287.) If Patent Owner identifies any evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

X. THE BOARD SHOULD NOT DENY INSTITUTION UNDER 35 U.S.C. §325(D)

Walther, which describes the cloth-covered SAPIEN, was not of record during prosecution. Likewise, Cribier and Spenser, which describe SAPIEN, were not of record. Thus, the Examiner did not consider any reference (or combination of references) that disclosed Walther's combination of a prosthetic heart valve having (1) a fibrous outer seal stitched to the exterior of a balloon-expandable stent frame and (2) an "inner graft covering" stitched to the interior of the stent frame. Because

Walther, Cribier, and Spenser were never before the Examiner, the Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d).

Spenser's parent's publication, Publication No. 2003/0153974, was listed on an Information Disclosure Statement (IDS), but the publication does not disclose Spenser's Figure 44a relied on herein. (*Compare* Exs. 1010, 1026.)

Patent Owner also characterized Levi and Spenser II in a Preliminary Amendment. Patent Owner attempted to distinguish the prior art on two primary grounds. First, Patent Owner argued adding an outer seal to a valve having an inner seal "undesirably increases the overall valve profile" such that a POSITA would not be motivated to do so. (Ex. 1002, 194.) As described above, this assertion is incorrect. (*Supra* §§VIII.A.1, VIII.B.1, VIII.C.1.) Moreover, the '236 patent does not describe methods to reduce the valve profile and, therefore, Patent Owner cannot rely on this argument to distinguish the prior art. *See e.g., Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013) ("[A]n unclaimed and undisclosed feature . . . cannot be the basis for finding [a] patent to be non-obvious over the prior art."); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . . ."); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1331 (Fed.

Cir. 2003) ("[N]onobviousness is assessed by reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims.").

Second, Patent Owner argued that "one would not look to stent graft seals to modify" a heart valve. (Ex. 1002, 197.) This argument is irrelevant because Petitioner does not rely on stent grafts for any combinations.

Regarding Levi, Patent Owner ***admitted*** that Levi "appears to teach an inner and outer seal in FIG. 42." (Ex. 1002, 186-187.) However, Patent Owner also included attorney argument that Levi's "seal . . . had a relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta." (Ex. 1002, 194-195.) Yet, as admitted by Patent Owner, Levi's outer seal presses against the patient's native leaflets. (*Supra* §VIII.C.1.h.) Moreover, no claim requires the seal to press against the leaflets "at a most narrow spot of the ascending aorta." (Ex. 1002, 195.) Patent Owner also never addressed combining Levi with Walther or Spenser II as proposed herein.

Regarding Spenser II, patent owner ***admitted*** that Spenser II "appears to teach a thick band with fibers emanating therefrom in FIG. 22," but argued that "there is no graft forming the inner frame, thus the inner seal is missing." (Ex. 1002, 187.)

However, as explained herein, POSITAs would have found it obvious to combine Spenser II with Spenser or Levi, which explicitly disclose an inner frame that includes a graft covering. (*Supra* §VIII.B.1, VIII.C.1.) Patent Owner never addressed these combinations.

Patent Owner also included attorney argument that POSITAs would not add Spenser II's outer seal to a valve that included an inner seal due to concerns about increasing the crimped profile, restricting expansion and foreshortening of the valve, and because Spenser II already provides a method for addressing PVL. (*See* Ex. 1002, 196.) However, the '236 patent does not discuss the problems of crimped profile or restriction of the expansion or foreshortening of the valve, nor does it discuss how to address or solve them. For example, the '735 patent never discloses the length, width, or density of the collagen fibers or the valve's crimped diameter. Consequently, Patent Owner cannot argue that adapting a valve with an outer seal to account for increased crimped profile, expansion, and valve foreshortening would have been beyond POSITAs' skill. *See e.g., Smith & Nephew*, 721 F.3dat 1380-81; *see also E.I. du Pont de Nemours*, 849 F.2dat 1433; *TorPharm*, 336 F.3dat 1331 . Moreover, Walther demonstrates these arguments are unfounded. In the real world, POSITAs added an outer seal, similar to Spenser II's compressible material, to SAPIEN, which included an inner graft covering. (*Supra* §VIII.A.1.)

Patent Owner also included attorney argument that "Spenser [II] appears to include an outer graft covering between the fibers and the outer frame." (Ex. 1002, 196.) Patent Owner provided no support for this statement and did not cite to any portion of Spenser II that supposedly teaches such an "outer graft covering." (*Id.*) As explained herein, Spenser II contains no such disclosure. (*Supra* §VIII.B.1.i.ii; Ex. 1011, [00145].)

Consequently, the Board should not deny institution under §325(d) based on Patent Owner's statements in the Preliminary Amendment. *See Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining to deny institution under §325(d)).

XI. MANDATORY NOTICES UNDER 37 C.F.R. §42.8(A)(1)

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Edwards Lifesciences Corp. and Edwards Lifesciences LLC are the real parties in interest.

B. Related Matters (37 C.F.R. §42.8(b)(2))

Petitioner has filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,792,172 ("'172 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01527 (Filed Sept. 10, 2021). Petitioner has also filed a Petition for *Inter*

Partes Review of U.S. Patent No. 10,857,011 ("the '011 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2021-01584 (Filed Sept. 28, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,966,846 ("'the '846 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2022-00034 (Filed Oct. 11, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,881,538 ("the '538 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2022-00193 (Filed Nov. 11, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 11,129,735 ("the '735 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2022-**** (Filed February 4, 2022). The '236 patent is part of the same patent family and shares a specification with the '172, '011,'846, '538, and '735 patents.

Patent Owner also recently filed suit against Petitioner alleging infringement of the '735 patent, '538 patent, the '846 patent, and '236 patents by Petitioner's SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1:21-CV-01377 (D. Del., filed Sept. 28, 2021). When this Petition was filed, the Complaint, associated papers, and a Motion to Dismiss filed by Petitioner were the only documents filed in the case. The court has set a hearing on the Motion to Dismiss for March 10, 2022.

Petitioner is not aware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com BoxEdwards21-5@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

D. Service Information Under 37 C.F.R. §42.8(b)(4)

Please address all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxEdwards21-5@knobbe.com.

XII. FEES

The fee for this petition has been paid. Any additional fees may be charged to Deposit Account 11-1410.

XIII. GROUNDS FOR STANDING UNDER 37 C.F.R. §42.104

Petitioner certifies that the '236 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims on the identified grounds.

XIV. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that the challenged claims are unpatentable as anticipated or obvious and, therefore, requests that the Board institute an *inter partes* review and cancel the claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 7, 2022

By: */Joshua J. Stowell/*
Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Brian C. Barnes (Reg. No. 75,805)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,987,236**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,462 words and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 7, 2022

By: */Joshua J. Stowell/*
Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Brian C. Barnes (Reg. No. 75,805)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,987,236** and **EXHIBITS 1001 – 1070** are being served on, via Federal Express overnight mail on counsel of record for U.S. Patent 10,987,236 as addressed below:

Justin Nifong
NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

Dated: February 7, 2022 By: /Joshua J. Stowell/

Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Brian C. Barnes (Reg. No. 75,805)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

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Filed: February 4, 2022

On behalf of **Edwards Lifesciences Corporation and Edwards Lifesciences LLC**
By: Craig S. Summers
Joshua J. Stowell
Brian C. Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxEdwards21-7@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC
Petitioners,

v.

AORTIC INNOVATIONS, LLC
Patent Owner.

IPR2022-00549
Patent No. 11,129,735

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,129,735

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TABLE OF EXHIBITS

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1001	U.S. Patent No. 11,129,735 B2 ("**'735 patent**")
1002	Excerpts from the prosecution history of the '735 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) ("**Walther**")
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. ("**Levi**")
1009	Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010,* 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. ("**Spenser**")
1011	WO 2006/005015 A2 to Spenser et al. ("**Spenser II**")
1012	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009) ("**Cribier**")
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.

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1024	Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) ("Zajarias")
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1027	Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
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1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)
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1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
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1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. ("Cribier '321")
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020

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1047	Piazza, Nicolo, et al., *Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve*, Cir Cardiovascular Intervention 1:74-81 (2008).
1048	WO 2011/051043 A1 to Essinger et al.
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD

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1060	Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves,* 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (November 2011), obtained from the University of California Los Angeles Library
1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
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1065	Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009), obtained from the British Library
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1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD

Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, "Petitioner") request *inter partes* review ("IPR") of claims 1-9 and 11-12 ("the challenged claims") of U.S. Patent No. 11,129,735 ("the '735 patent"), purportedly assigned to Aortic Innovations, LLC ("Patent Owner").

I. SUMMARY OF THE ARGUMENT

The '735 patent describes endograft devices for repairing aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments comprise multi-component structures extending into the patient's ascending aorta and aortic arch.[1]

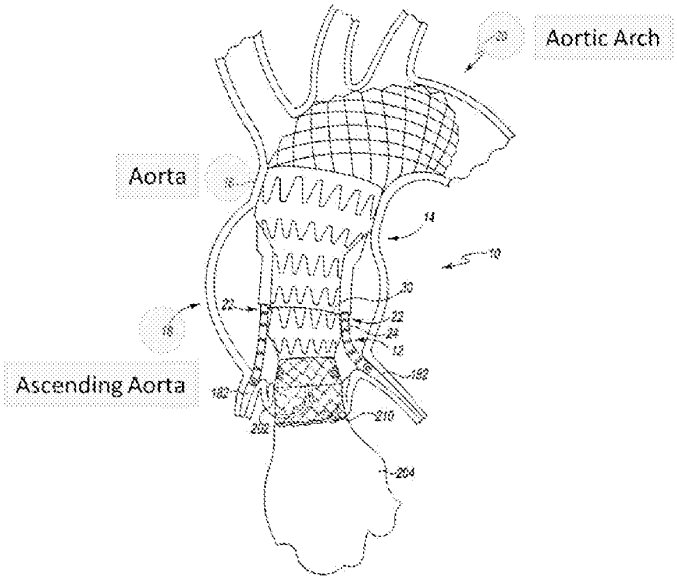


Fig. 2

[1] Color and labels added to figures unless otherwise noted.

The challenged claims, however, describe only the heart-valve component. Petitioner recently filed IPR Petitions against Patent Owner's U.S. Patent Nos. 10,792,172, 10,857,011, 10,966,846, and 10,881,538 ("IPR patents"). The '735 patent shares a common specification with the IPR patents. Like the IPR patents, the '735 patent claims a valve assembly having four principal elements: (1) a metallic outer frame [red], (2) an inner frame that includes a cylindrically extending graft covering [blue], (3) stitches securing the inner frame to the outer frame [orange], and (4) an outer seal attached to the outer frame, formed of "outwardly extending fibers positioned externally to the outer frame" [green].

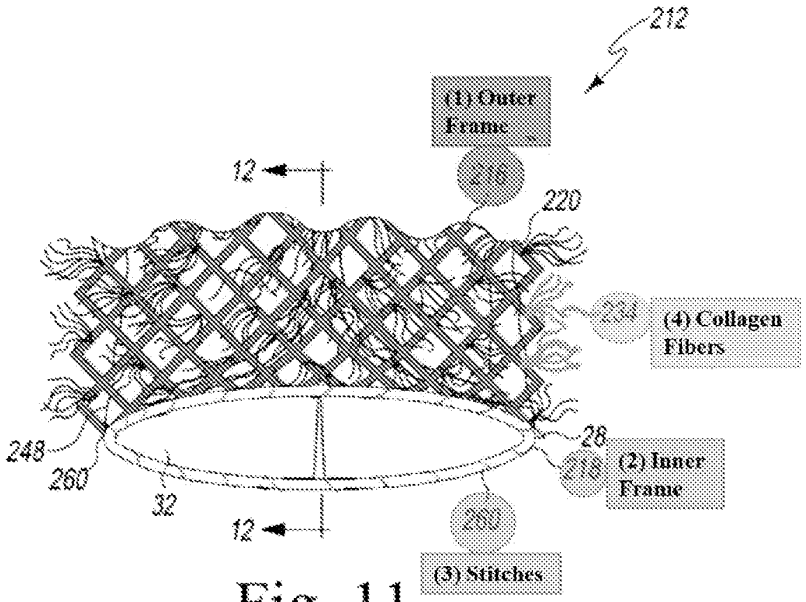


Fig. 11

The prior art discussed below discloses and renders obvious all of the claimed limitations, which were well known in the field by November 2012, the '735 patent's priority date ("Critical Date").

Patent Owner does not make or sell heart valves that practice the '735 patent. Rather, the '735 patent is part of a calculated attempt by Patent Owner to secure claims covering Petitioner's commercially successful SAPIEN 3 Ultra transcatheter heart valve. During prosecution of several related patents, Patent Owner argued that Petitioner's SAPIEN 3 Ultra was covered by the claims. Patent Owner also recently filed suit against Petitioner asserting that the SAPIEN 3 Ultra infringes the '735 patent ("the Litigation"). However, in its effort to snare SAPIEN 3 Ultra, Patent Owner broadened its patent claims so far that they cover the prior art.

The '735 patent claims a dual-frame valve that must include a metallic "outer frame" [red] and an "inner frame" [blue]:

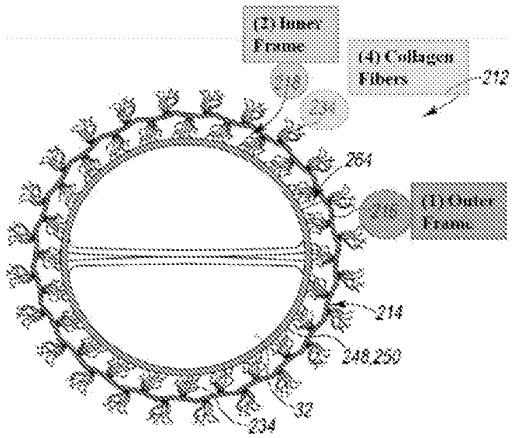
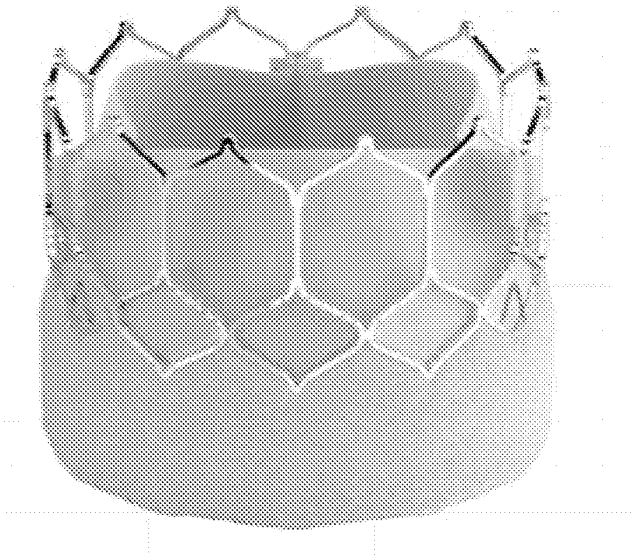


Fig. 13

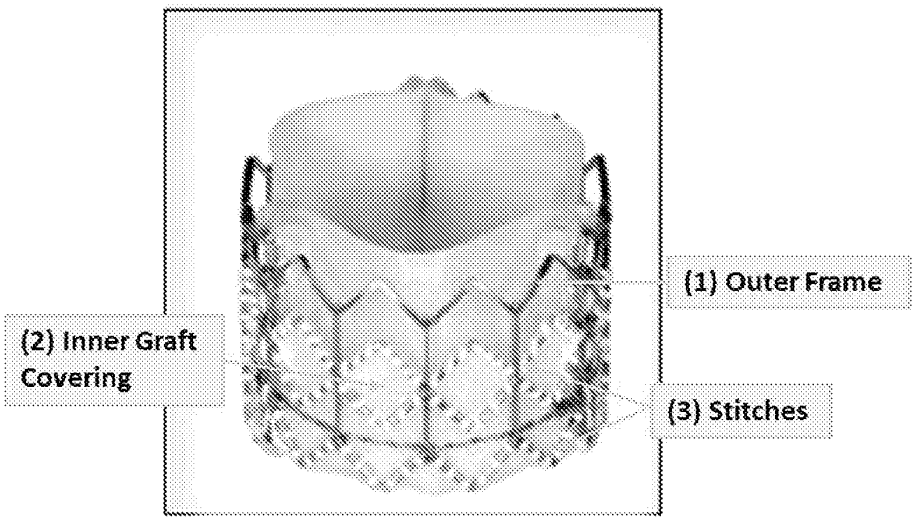
In contrast, SAPIEN 3 Ultra has only one frame, not inner and outer frames, and an outer skirt:



In an attempt to capture SAPIEN 3 Ultra, Patent Owner argued during prosecution of the '735 patent family that the limitations in claim 1 requiring "an outer frame"

and "inner frame" that includes an "inner graft covering" are satisfied by a valve that has ***only*** one frame and an "inner graft covering." Patent Owner also argued that an outer skirt satisfied the limitation requiring "outwardly extending fibers." But Petitioner's prior-art publications and patents describe earlier SAPIEN heart valves having precisely these features.

For example, Petitioner's SAPIEN THV (a predecessor to SAPIEN 3 Ultra) was one of the world's first THVs. Petitioner received regulatory approval for SAPIEN in Europe in 2007 and the United States in 2011, both before the Critical Date. **Cribier**, a publication relied on herein, discloses that SAPIEN includes: (1) a metallic "outer" frame, (2) an "inner graft covering," and (3) stitches securing the graft covering to the outer frame.



Edwards SAPIEN® THV
23 mm, 26 mm

Petitioner also modified SAPIEN to include an outer cloth comprising (4) an outer seal including outwardly extending fibers. **Walther** describes and pictures this modified SAPIEN.

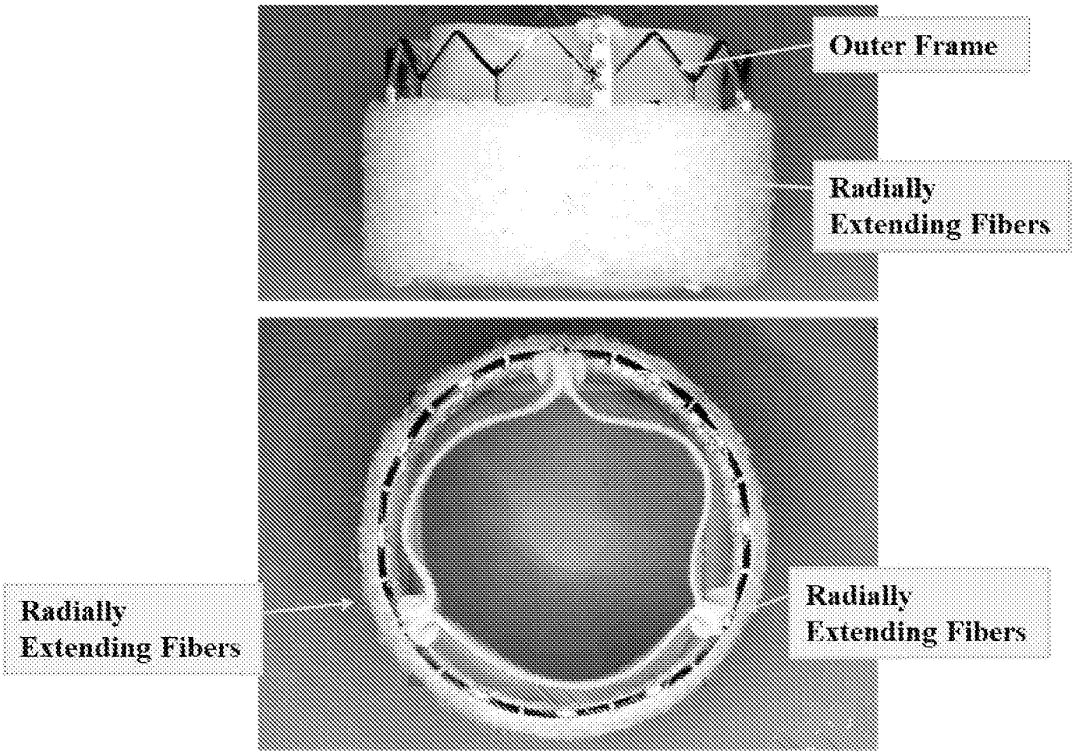


Fig. 1. Cloth valve.

Walther discloses implanting the modified SAPIEN within a surgical valve where the fibrous outer cloth reduces leaks around the SAPIEN, known as paravalvular leakage (PVL), and increases fit between SAPIEN and the surgical valve.

Petitioner also filed patent applications in the early 2000s disclosing THVs like SAPIEN having an outer seal for reducing PVL. **Spenser II** discloses a heart

valve having a "compressible material" that "may resemble a cloth or fabric having small fibers extending from the surface of the material."

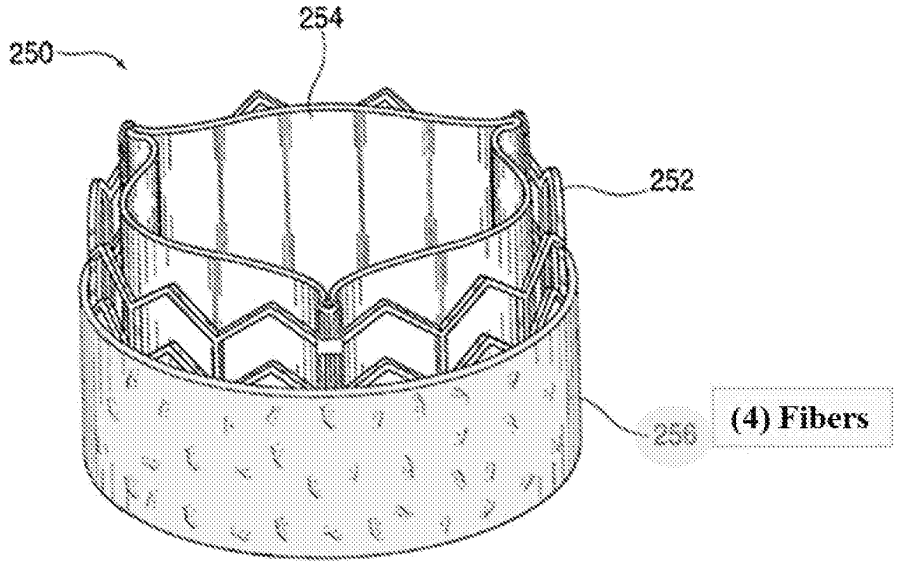
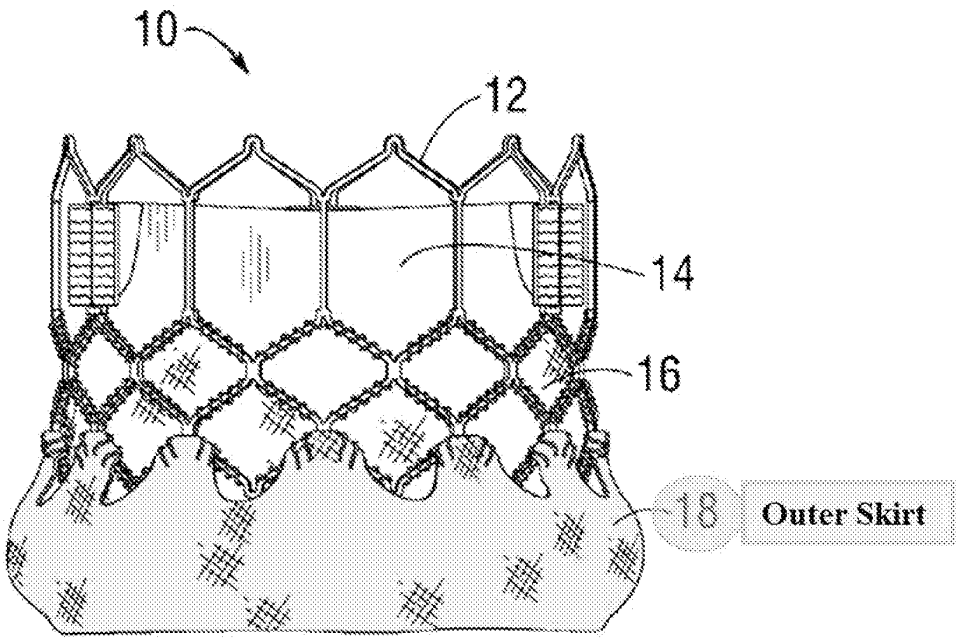


FIG. 22

Spenser II's compressible material prevents PVL by sealing against the patient's native tissue.

Likewise, **Levi** discloses a heart valve having an inner graft covering and fibrous outer skirt for sealing against the native annulus and leaflets to reduce PVL.

FIG. 3



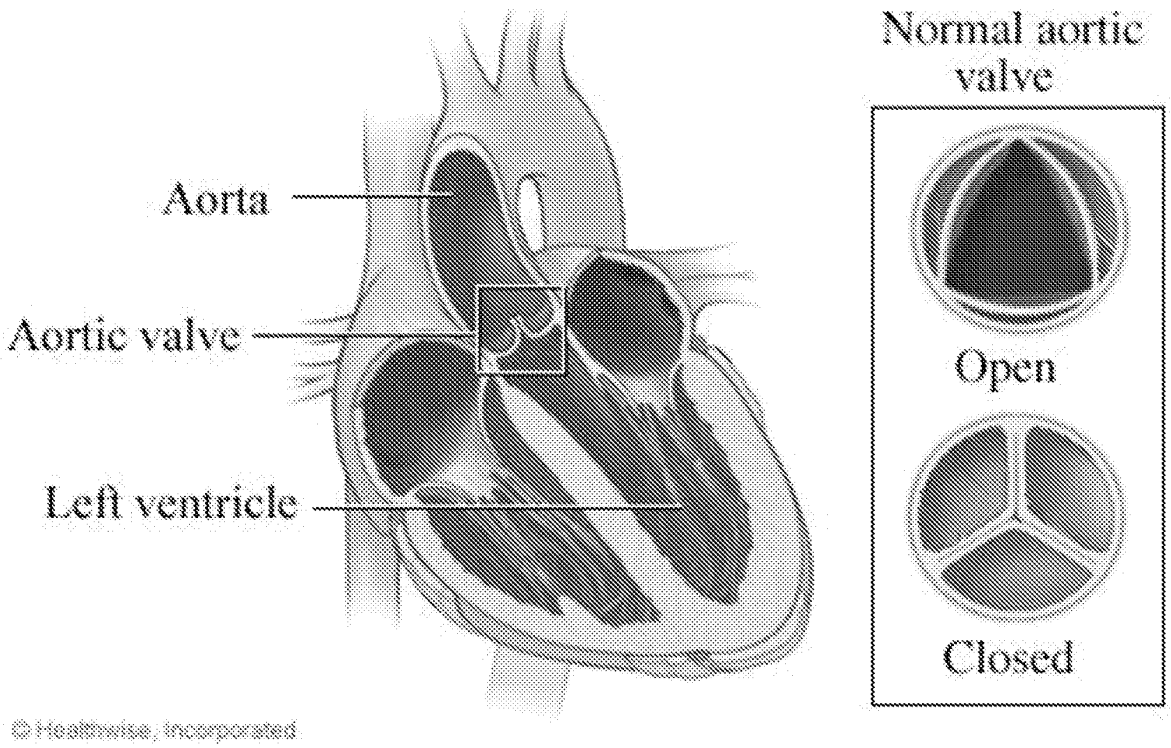
This prior art demonstrates that Petitioner and persons of ordinary skill in the art (POSITAs) disclosed the claimed heart valves before the Critical Date. Unfortunately, the Examiner of the '735 patent did not apply any of the prior art references relied on herein during prosecution, nor was she aware of all of the prior art. Cribier and Spenser were not of record during prosecution.

Additionally, Patent Owner inaccurately or incompletely characterized some of the prior art during prosecution. *Infra* §X. Unlike here, the Examiner did not have the benefit of expert testimony to correct some of these incomplete or inaccurate characterizations, which were based exclusively on attorney argument. As shown

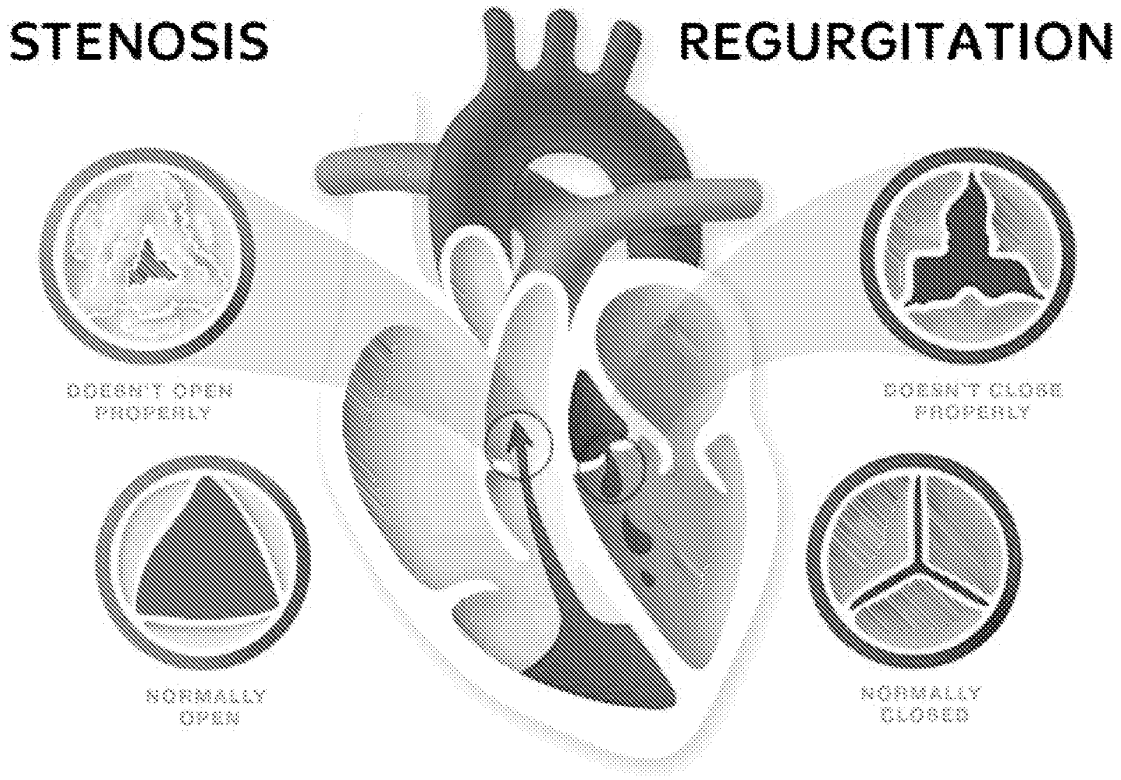
herein, the prior art discloses the limitations in the challenged claims and renders the claims obvious. Thus, the Board should institute this IPR to evaluate the patentability of the claims based on an accurate and complete record and with the benefit of expert testimony.

II. ANATOMY AND BACKGROUND

The human heart has two upper chambers (left and right atriums) and two lower chambers (left and right ventricles). (Ex. 1003, ¶46.) The aortic valve connects the left ventricle with the aorta on the left side of the heart. (*Id.*) It includes three leaflets that coapt and expand to operate as a one-way valve that regulates blood flow from the left ventricle into the aorta and prevents backflow of blood into the left ventricle. (*Id.*)



Aortic stenosis occurs when the opening of the aortic valve is narrowed, often by excessive buildup of calcium deposits on the valve. (*Id.*, ¶47) Aortic regurgitation occurs when the aortic leaflets fail to coapt properly, allowing blood to flow backward from the aorta into the left ventricle. (*Id.*)

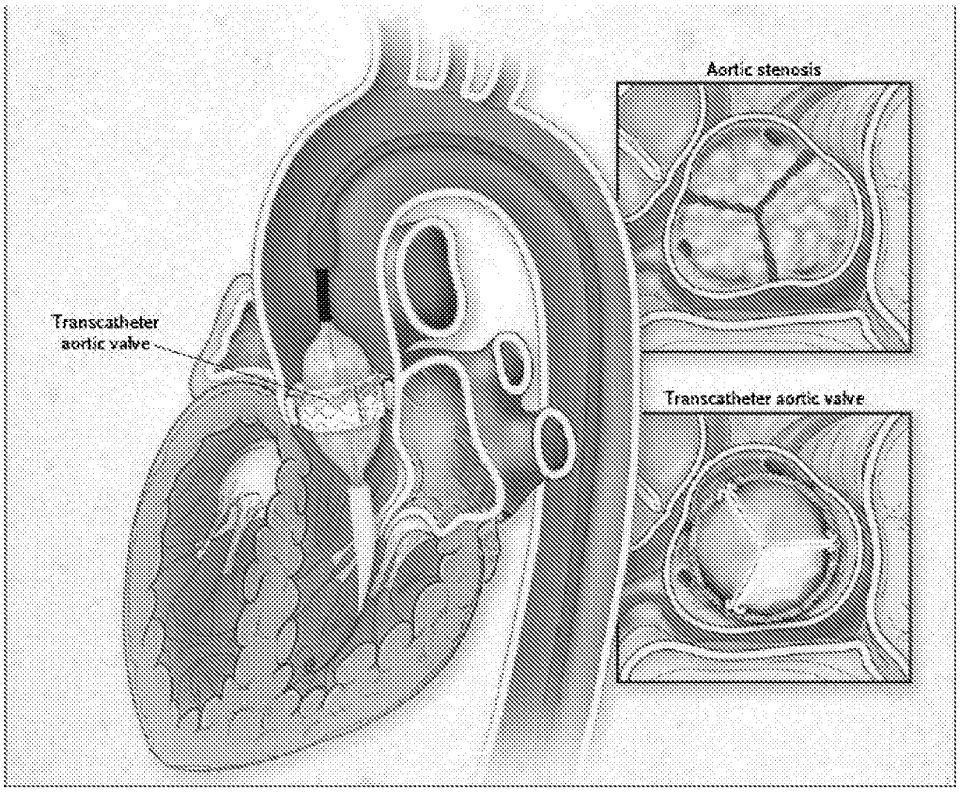


A common treatment for both aortic stenosis and aortic regurgitation is replacement of the diseased native aortic valve with a prosthetic heart valve. (*Id.*, ¶48.) A key consideration for prosthetic aortic valves is ensuring an effective seal between the valve and the patient's native aortic tissue. (*Id.*) Without such a seal,

blood can leak between the prosthetic valve and the native tissue, causing PVL.[2] (*Id.*)

To avoid the risks of open-heart surgery associated with surgical prosthetic valves, minimally invasive transcatheter heart valves ("THVs") were developed that could be implanted through the patient's vasculature via a catheter. (*Id.*, ¶49.) Rather than the sewing rings used in many surgical valves, which required open-heart surgery and suturing, THVs created a seal by pressing the exterior of the THV against the diseased native leaflets and surrounding tissue, as shown in the illustration of Petitioner's SAPIEN THV below:

[2] "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve. (Ex. 1003, ¶48, n.1.)

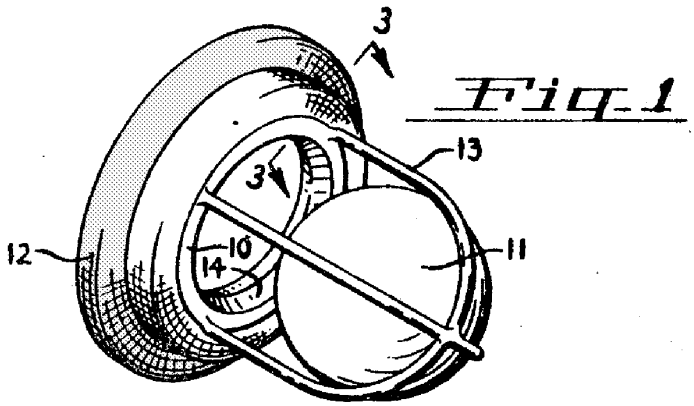


(*Id.*; Ex. 1022, 2189, Fig. 1.) THVs could be implanted in severely ill patients not eligible for open-heart surgery, and they quickly became highly successful. (Ex. 1003, ¶49.) Despite their success, however, the potential for PVL remained a concern. (*Id.*) As discussed in detail below, this concern motivated those in the art, including Petitioner, to develop methods for minimizing PVL by creating more effective outer seals.

III. STATE OF THE ART

Petitioner was founded in 1958. Petitioner's earliest work related to surgically implantable heart valves. One of Petitioner's first commercial valves, the Starr-

Edwards valve, included an outer sewing ring 12 that formed a seal between the valve and tissue to prevent PVL:



(Ex. 1013, 1:37-46 Fig. 1; Ex. 1003, ¶54.)

In 1989, Dr. Henning Andersen conceived of the first THV. The balloon-expandable valve included a wire stent and was implanted with a catheter. Dr. Andersen's work led to U.S. Patent 5,411,552, which was filed in 1994, and discloses a THV having a metallic outer frame (2, 3) and graft covering (24):

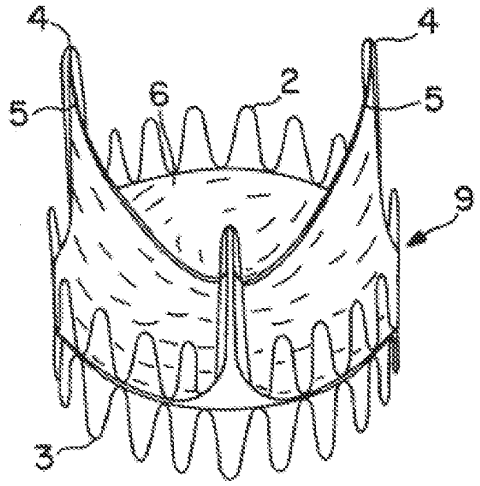


FIG. 2

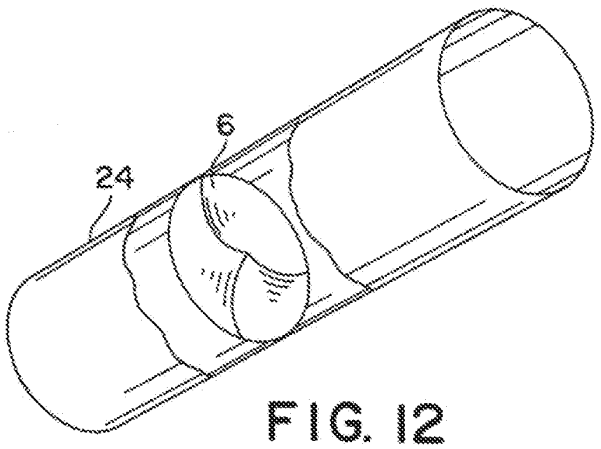


FIG. 12

(Ex. 1014, 4:3-17, 5:9-28, Figs. 2, 11-12; Ex. 1003, ¶¶57-59.)

Shortly thereafter, POSITAs began adding outer seals to THVs to reduce PVL. In 1996, Dr. Alain Cribier filed a patent application on a THV having an internal cover (19′) that is "rolled up to be applied to the external wall of the stent" to form an outer seal (19″) [yellow]:

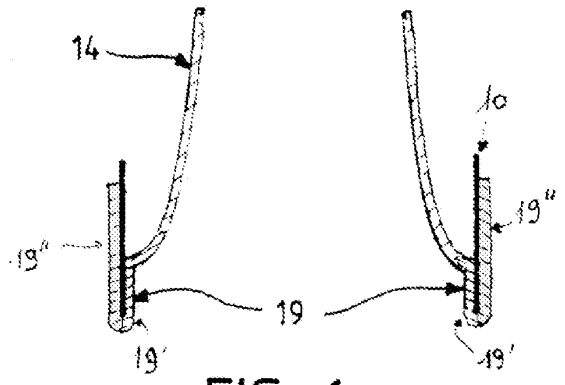
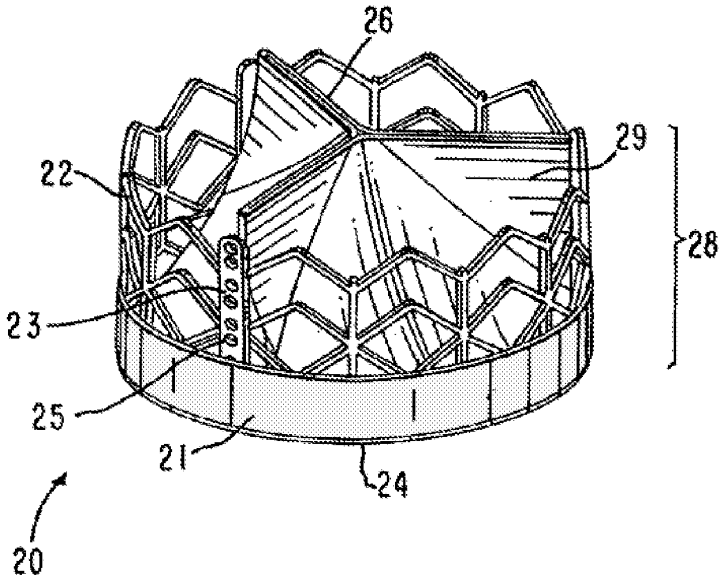


FIG_6d

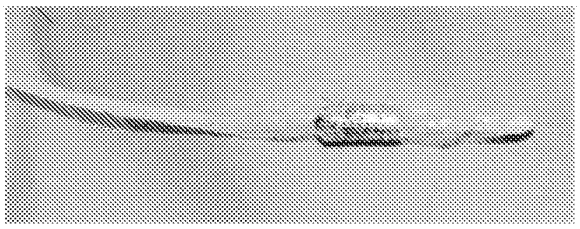
(Ex. 1018, 22:11-26, Fig. 6d.) The outer seal (19″) presses against the patient's native diseased tissue and prevents blood from leaking through or around the device. (*Id.*)

Similarly, in 2001, Percutaneous Valve Technologies ("PVT"), a company founded by Dr. Cribier, filed a patent application on a THV that disclosed an outer seal, or "cuff portion," highlighted in yellow below, and wrapped around the support stent's inlet:



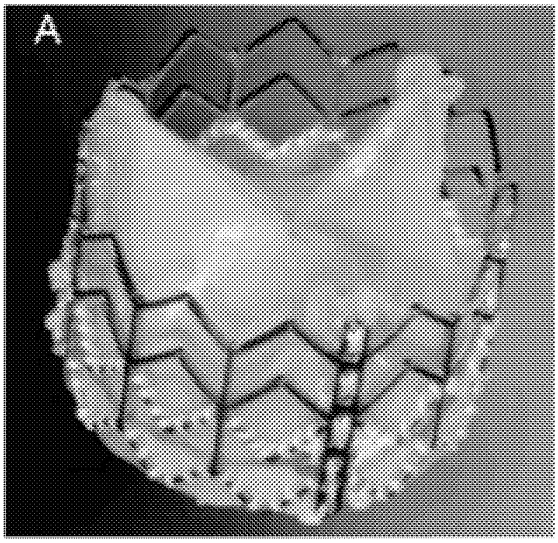
(Ex. 1019, 9:19-22, Fig. 1.) The cuff portion helped prevent leakage around the stent. (*Id.*, 8:47-50; Ex. 1003, ¶65.) **Spenser**, relied on herein, is a continuation-in-part of the 2001 patent application and includes the above embodiment. (Ex. 1010, 13:22-25, Fig. 1.)

In April 2002, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. (Ex. 1025, 3006.) The THV included a metallic balloon-expandable stent that was crimped onto a delivery balloon and endovascularly delivered through the right femoral vein:



(*Id.*, 3006-3007, Fig. 1.)

In 2004, Petitioner acquired PVT and began testing the Cribier-Edwards THV, which included (1) a metallic "outer" frame, (2) an inner graft covering, and (3) stitches securing the graft covering to the outer frame:



(Ex. 1023, 154, Fig. 3A (excerpt); Ex. 1003, ¶69.)

Petitioner also collaborated with physicians to modify the Cribier-Edwards THV to include an external fabric cuff designed "to provide a better seal…[and] minimize[e] paraprosthetic leak." (Ex. 1017, 2, Fig. 2.)

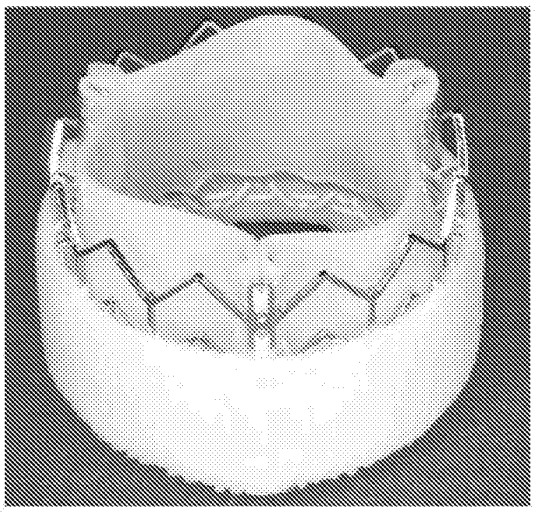


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

In 2004, Petitioner filed **Spenser II**, which discloses a THV having "a layer of compressible material 256 … disposed along an outer surface of the stent structure 252" to prevent PVL:

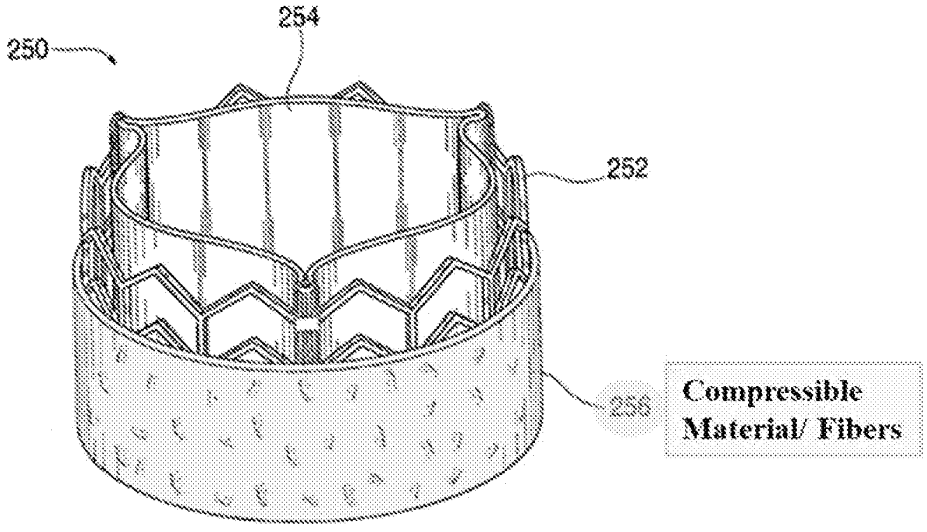


FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶¶69-70.) The compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material" and formed a mechanical seal with the native tissue to prevent PVL. (*Id.*)

By 2007, Petitioner had modified the Cribier-Edwards valve to create SAPIEN. SAPIEN was one of the world's first commercially available THVs and the subject of a large clinical trial, the results of which were published in The New England Journal of Medicine in 2010. (Ex. 1022.) SAPIEN addressed a long-felt need in the industry for an aortic valve replacement device that did not require open-heart surgery. (Ex. 1003, ¶72.) The FDA approved SAPIEN for use in patients in 2011. (Exs. 1032-1033.)

Walther, a 2011 publication referenced herein, discloses implanting SAPIENs having a fibrous outer cloth into existing surgical valves:

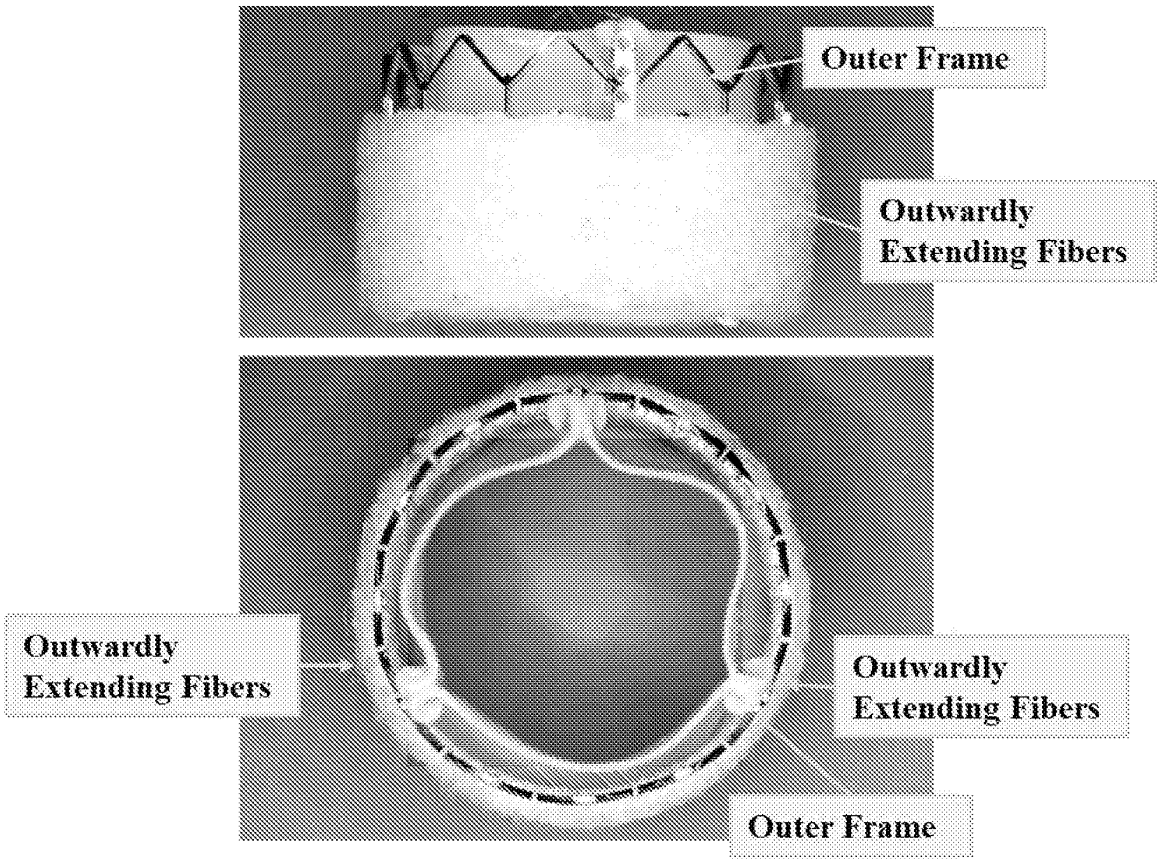
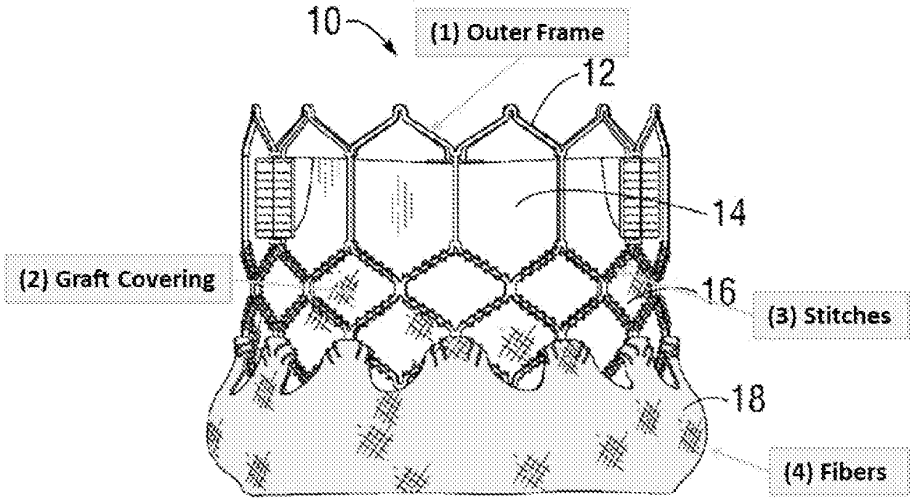


Fig. 1. Cloth valve.

(1007, 1120-21, Fig. 1.) The "addition of an outer cloth to the SAPIEN cloth valve [was] designed to reduce [PVL] by creating a seal between the two valves." (*Id.*) Thus, like THVs implanted in native valves, Walther's outer cloth created a seal by pressing against the leaflets of the previously implanted surgical valve.

Similarly, **Levi**, a patent filed by Petitioner in 2010, discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame:



(Ex. 1008, 13:50-14:7, Fig. 3.) Levi's outer skirt forms "a good fluid-tight seal between the valve and the native annulus." (*Id.*)

POSITAs also used fibrous outer seals to prevent PVL in non-aortic valve procedures. For example, Birdsall, a patent filed in 2006, discloses a valve inserted in a conduit covered with a "barrier material 308" that "comprises directionally oriented microfibers . . . extending outward" that "contact the interior wall of the conduit and form a barrier that prevents blood from flowing around stented valve 310":

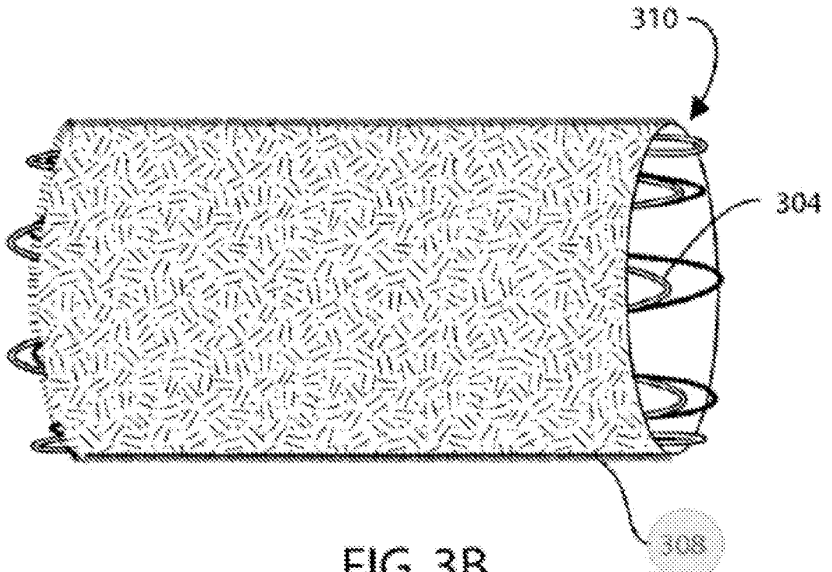


FIG. 3B

(Ex. 1057, 6:9-33, Fig. 3B.)

The above references show that the challenged claims merely combine known heart-valve features according to known techniques to yield predictable results. The claims do not describe any new heart-valve features or combine the known features in a nonobvious way. Therefore, the challenged claims are unpatentable.

IV. THE '735 PATENT

A. Overview

The '735 patent describes a "heart valve assembly" having a "dual-frame" for replacing an aortic heart valve. (Ex. 1001, 11:63-12:14.) The "dual-frame" includes a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218

[blue] that is secured to the self-expanding outer frame 216 and houses the valve 32":

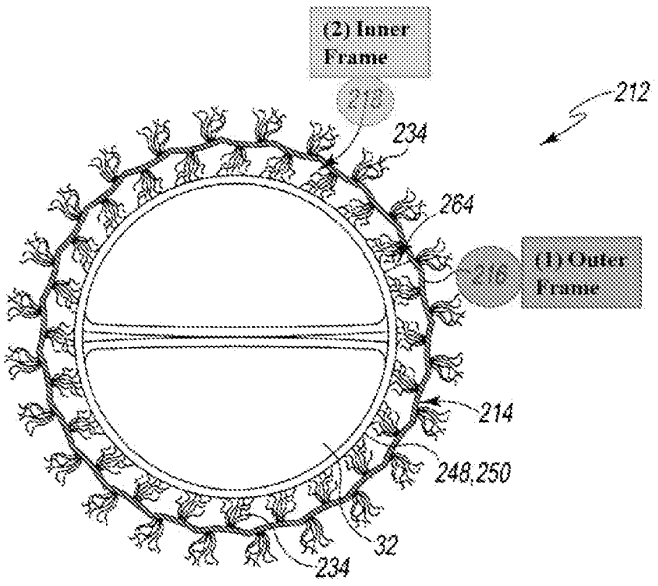


Fig. 13

(*Id.*, 11:63-12:14, Fig. 13.)

The metallic or polymeric outer frame [red] defines an "open-cell stent configuration." (*Id.*, 12:14-20, 13:19-22, Fig. 9.) The outer frame includes radially extending collagen fibers [green] attached to the frame to aid in preventing PVL and migration of the valve. (*Id.*, 12:45-48.) The metallic or polymeric inner frame [blue] is a "balloon-expandable tubular stent." (*Id.*, 13:43-46.) Stitches [orange] secure the inner frame to the outer frame. (*Id.*, 14:8-10.)

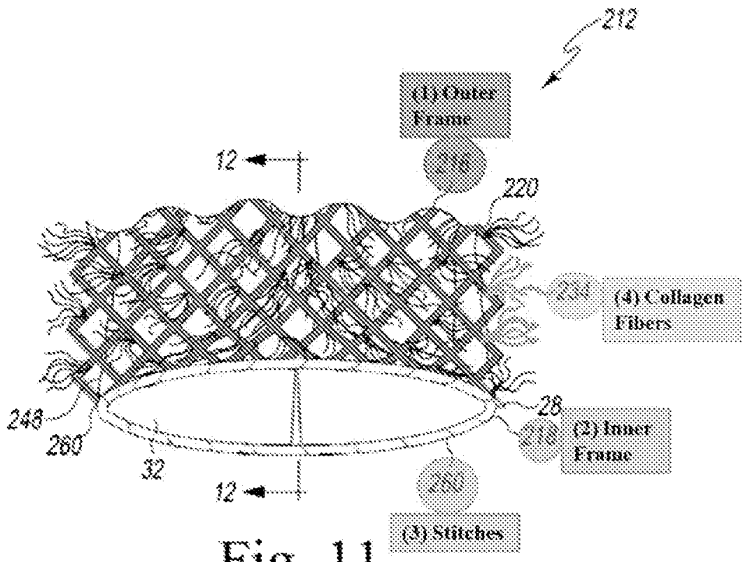


Fig. 11

B. Prosecution History

The examiner issued a single, non-final office action that included an obviousness rejection. (Ex. 1002, 292-302.) None of the references asserted herein were included in the rejection. (*See id.*)

Patent Owner added the following limitations during prosecution: "wherein an end of the most proximal apices of the outer frame are uncovered by the outer seal and the graft covering," and "wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." *(Id.*, 279-280.) Those limitations are not described in the specification of the '735 patent and are not supported by the drawings. (Ex. 1003, ¶84-85) During prosecution, Patent Owner argued that Figure 12 supported these limitations. (Ex. 1002, 272.)

Patent Owner argued, "FIG. 11 and FIG. 12…differ in construction of the inner graft covering and outer seal." (*Id.*) Patent Owner further argued, "in FIG. 11, the inner graft covering 248/inner frame 218 extends over apices of the stent frame":

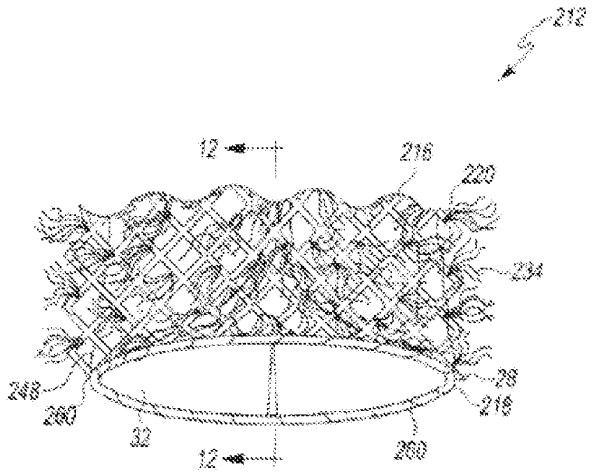


Fig. 11

(*Id.*) Patent Owner argued that "in the embodiment illustrated in FIG. 12 (annotations added), the end of the apices of the struts are shown uncovered by both the sealing member and the inner graft covering 248":

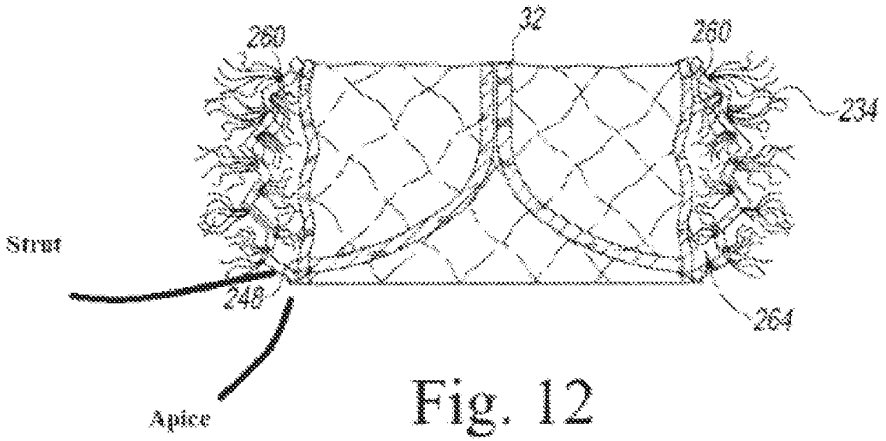


Fig. 12

(*Id.*, 272-273 (annotations by Patent Owner).)

Patent Owner's characterization of Figures 11 and 12 as representing different constructions and embodiments directly conflicts with the specification. The '735 patent states, "FIG. 11 is a perspective view [sic] a proximal end of the proximal prosthetic component of FIG. 8" and "FIG 12 is a cross-sectional elevation view of the proximal prosthetic component of FIG. 8 ***taken along the line 12-12 in FIG. 11***." (Ex. 1001, 5:53-57 (emphasis added).) Thus, Figures 11 and 12 depict the same valve embodiment and cannot provide support for a valve with the proximal apices covered ***and*** uncovered by the inner graft covering. This inconsistency is yet another example of an inaccurate statement made by Patent Owner to the Examiner to improperly broaden the patent and capture Petitioner's products.

C. The Critical Date

The '735 patent claims priority to two provisional applications: application No. 61/567,458 ("the '458 provisional"), filed December 6, 2011; and application No. 61/723,446 ("the '446 provisional"), filed November 7, 2012. (Ex. 1001.) Patent Owner relied on the '446 provisional as the basis for priority of the '735 patent during prosecution. (*See* Ex. 1002, 273). Additionally, in the Litigation, Patent Owner concedes that it did not file any patent applications describing outwardly extending fibers until 2012. (Ex. 1050, 9.)

Patent Owner is correct that the '735 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '735 patent's claims. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Patent Owner first added the disclosure of outwardly extending fibers in the November 2012 provisional. (Ex. 1006, [0024].)

V. STATEMENT AND RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1, 3-6, 8-9, 11-12	103	Cribier + Walther
2	1-9, 11-12	103	Spenser + Walther

3	1-9, 11-12	103	Spenser + Spenser II
4	1-9, 12	103	Levi + Walther
5	1-9, 12	103	Levi + Spenser II

B. The Asserted References Are Prior Art

The Critical Date of the '735 patent is November 7, 2012. (*Supra* §IV.C.) The following references are prior art under pre-AIA §102(b):

(1) Cribier (Ex. 1012) published in August 2009 and was publicly available by at least August 28, 2009 (Ex. 1059, ¶¶58-65);

(2) Walther (Ex. 1007) published online on April 3, 2011 and in print on November 1, 2011 and was publicly available online on or shortly after April 3, 2011 and in print on or shortly after November 1, 2011 (Ex. 1059, ¶¶47-57; *see also* Ex. 1065, n. 39);

(3) Spenser (Ex. 1010) issued on March 31, 2009; and

(4) Spenser II (Ex. 1011) published on January 12, 2006.

Levi (Ex. 1008) was filed on Oct. 5, 2011 and published on May 17, 2012. Thus, Levi is prior art under pre-AIA §102(e).

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir.

2016). Each reference is from the same field as the '735 patent, e.g., minimally invasive devices for replacing heart valves. (Ex. 1003, ¶36.) The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic regurgitation or stenosis through a minimally invasive procedure. (*Id.*) As analogous art, POSITAs are presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. LEVEL OF ORDINARY SKILL

A POSITA in November 2012 would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This POSITA would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve. (Ex. 1003, ¶45.)

VII. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by POSITAs at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

VIII. PROPOSED GROUNDS FOR UNPATENTABILITY

A. Ground 1: Claims 1, 3-6, 8-9, 11-12 Obvious Over Cribier and Walther

Walther discloses modified SAPIENs having fibrous outer sealing cloths:

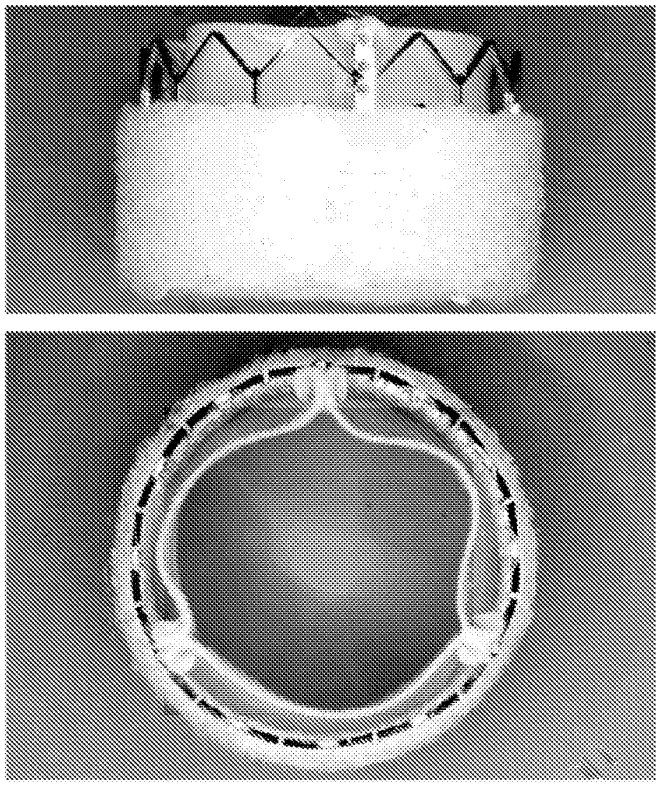


Fig. 1. Cloth valve.

(Ex. 1007, 1120-21, Figs. 1-3.) Walther's modified SAPIENs were "identical" to SAPIEN except for the outer cloth. (*Id.*, 1120.)

Cribier describes endovascularly delivering SAPIEN and includes additional details about the valve. (Ex. 1012.) Thus, Cribier combined with Walther discloses all the limitations in claims 1, 3-6, 8-9, and 11-12 and renders the claims obvious. (Ex. 1003, ¶99.)

1. Claim 1

Cribier and Walther render claim 1 obvious. (*Id.*, ¶100.)

a. Preamble

Cribier discloses an "endovascular transcatheter valve assembly." (*Id.*, ¶102.) Cribier describes methods of "transcatheter aortic valve implantation with the Edwards-Sapien® heart valve using the transfemoral approach." (Ex. 1012, 347-355, Fig. 1.) SAPIEN is a "valve assembly." (*Id.*, 348.) The "transfemoral approach" is an endovascular delivery approach through the femoral artery. (*Id.*, 347-355; Ex. 1003, ¶106.) Thus, SAPIEN, as confirmed by Cribier, is an "endovascular transcatheter valve assembly." (Ex. 1003, ¶106.)

Walther discloses SAPIEN with an outer cloth stitched to its perimeter. (Ex. 1007, 1120-21, Fig. 1.) Walther's cloth-covered valve is identical to SAPIEN except for the outer cloth. (*Id.*) As confirmed by Cribier, SAPIEN is an "endovascular transcatheter valve assembly" and, thus, Walther discloses such an assembly. (Ex. 1003, ¶107.)

If Patent Owner argues that Walther does not disclose an "endovascular" transcatheter valve assembly because Walther describes deploying the cloth-covered SAPIEN in "[b]ench-top testing" with Edwards' Ascendra transapical[3] delivery

[3] Transapical delivery is delivery method that involves inserting the valve through the heart wall. (Ex. 1003, ¶108.)

system, POSITAs would have found it obvious to endovascularly deliver Walther's cloth-covered SAPIEN in a patient. (Ex. 1007, 1121; Ex. 1003, ¶¶109-111.) The purpose of Walther's testing was to confirm that the cloth-covered valve would work in a patient. (Ex. 1007, 1120-21.) Based on the testing, Walther concluded that an in-patient procedure "is feasible." (*Id.*, 1125.) Thus, POSITAs would have been motivated, and expected success, in implanting the valve in a patient. (Ex. 1003, ¶109.)

POSITAs would have been motivated to endovascularly deliver Walther's cloth-covered SAPIEN because POSITAs generally considered endovascular delivery to be less invasive than other forms of delivery, like open-heart surgery or transapical delivery. (*Id.*, ¶¶109-110.) By November 2012, POSITAs had endovascularly delivered SAPIEN through several blood vessels, including the femoral and common iliac arteries. (Ex. 1012, 353; Ex. 1043, 273-276.) The larger-diameter common iliac artery was particularly useful in cases where the femoral artery was too small or calcified for safe delivery. (Ex. 1043, 273-276; Ex. 1003, ¶109.) POSITAs would have reasonably expected success in delivering the cloth-covered SAPIEN through the common iliac artery given the prior successful deliveries through that route and the larger diameter of the artery. (Ex. 1003, ¶112.)

POSITAs also would have been motivated, and expected success, in endovascularly delivering Walther's cloth-covered SAPIEN through the femoral artery. (*Id.*, ¶¶110-112.) Many POSITAs considered transfemoral delivery "as the technique of first choice" and safer than transapical delivery. (Ex. 1009, 515-516.) SAPIEN had been approved for transfemoral delivery by the FDA before 2012, and successfully delivered numerous times. (*See e.g.*, Ex. 1009, 517; Ex. 1012, 355; Ex. 1032; Ex. 1003, ¶112.)

POSITAs would have possessed the necessary skills and equipment to adapt the size of the cloth-covered SAPIENs for transfemoral delivery, to the extent any adaption was necessary. (Ex. 1003, ¶111.) First, POSITAs would have had access to many suitable cloths having varying thicknesses and densities and could have selected an appropriately dimensioned cloth to ensure transfemoral delivery. (*Id.*; Ex. 1011, [0055], [00145]; Ex. 1008, 13:49-53.) Second, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. (Ex. 1036, 295-297; Ex. 1037, [0005]-[0006].) These delivery systems permitted POSITAs to crimp valves to smaller diameters and thus endovascularly deliver valves having additional components, such as an outer seal. (Ex. 1003, ¶111.) Third, by 2012, Petitioner had adopted new frame metals that reduced profile and developed ways to adapt the frame and leaflets to create additional space for an outer

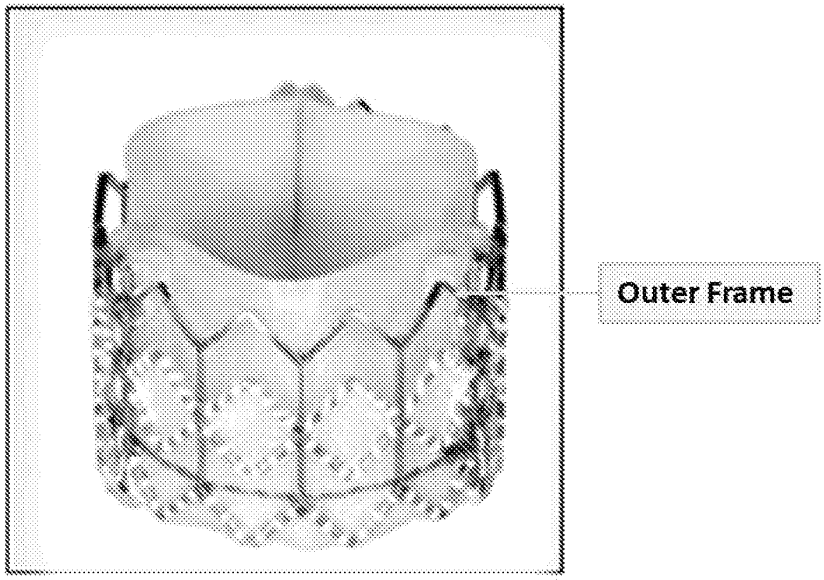
seal. (*Id.*; *see e.g.*, Ex. 1008, 6:31-49, 15:33-17:18.) POSITAs would have found it obvious to utilize one or more of these known techniques to adapt the cloth-covered SAPIEN for transfemoral delivery. (Ex. 1003, ¶111.)

Additionally, the '735 patent does not claim or disclose how to size the valve for endovascular delivery. (*Id.*, ¶104) For example, the '735 patent never discloses the length, width, or density of the collagen fibers or the valve's crimped diameter. (*Id.*) In fact, the '735 patent consistently defers to the knowledge of POSITAs for sizing. (*E.g.*, Ex. 1001, 7:34-37, 13:44-45.) Consequently, Patent Owner cannot argue that adapting the cloth-covered SAPIEN for endovascular delivery would have been beyond POSITAs' skill. *See e.g., Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013) ("[A]n unclaimed and undisclosed feature . . . cannot be the basis for finding [a] patent to be non-obvious over the prior art."); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . . ."); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003) ("[N]onobviousness is assessed by reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims.").

b. Outer Frame

Cribier discloses the claimed "outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration wherein the outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof, wherein the outer frame is formed by a plurality of struts that adjoin each other at the inflow end to form apices." (Ex. 1003, ¶¶113-116.)

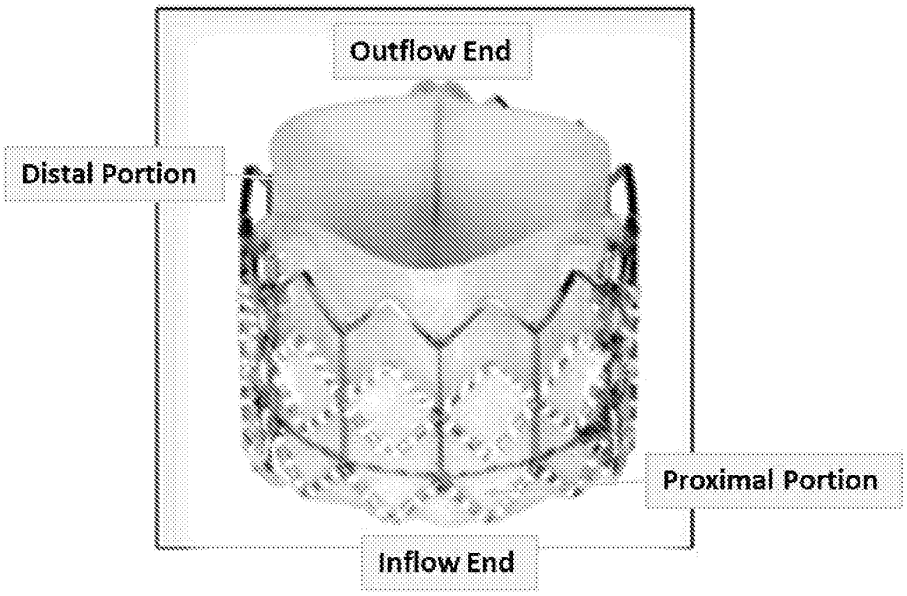
Cribier discloses that SAPIEN includes "a tubular slotted stainless-steel" stent. (Ex. 1012, 348.) The stent defines an open cell configuration and surrounds the other valve components, making it an "outer frame":



Edwards SAPIEN® THV
23 mm, 26 mm

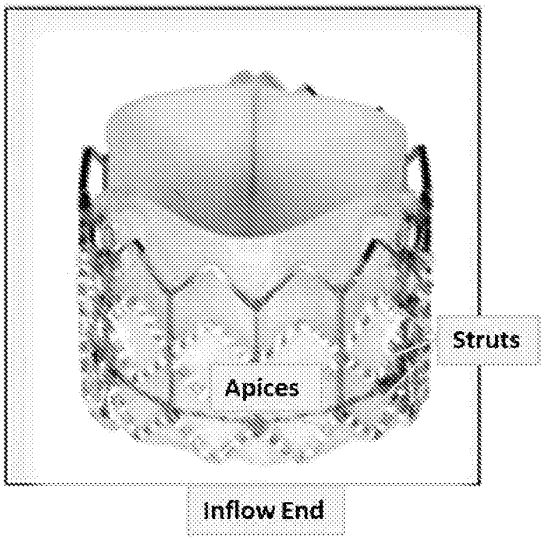
(*Id.*, Fig. 1; Ex. 1003, ¶114.)

SAPIEN's outer frame includes an inflow end at a proximal portion thereof and an outflow end at a distal portion thereof:



(Ex. 1012, Fig. 1; Ex. 1003, ¶115.)

SAPIEN's outer frame is formed by a plurality of struts that adjoin each other at the inflow end to form apices:



(Ex. 1012, Fig. 1; Ex. 1003, ¶116.)

c. Inner Frame

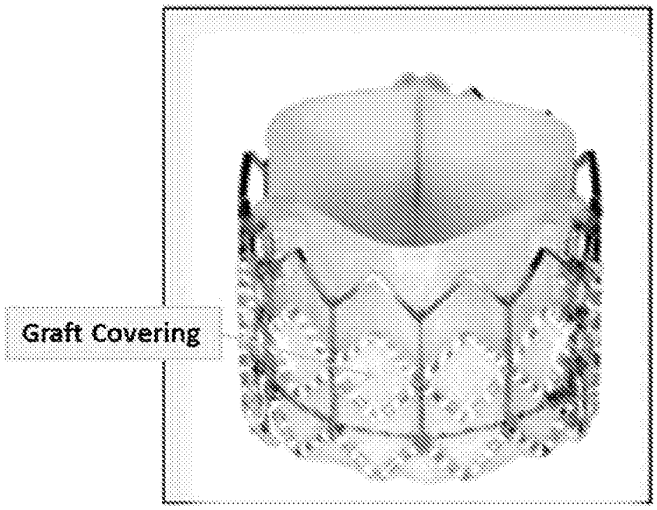
Cribier discloses the claimed "inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve." (Ex. 1003, ¶¶117-123.)

During prosecution of a related patent having a similar limitation, Patent Owner argued that an inner graft covering ***alone*** satisfies the limitation "an inner frame…wherein the inner frame ***includes*** a cylindrically extending graft covering." For example, Patent Owner argued that Petitioner's SAPIEN 3 Ultra product is "covered by the claimed invention" because it "includes an inner frame that is a

graft." (Ex. 1046, 21-22.) Patent Owner made the same allegations in the Litigation, despite SAPIEN 3 Ultra not having both outer and inner frames.[4] (Ex. 1050, 43-44) Patent Owner also argued the claimed inventions improved upon the art "by having an inner frame that is a graft covering around the heart valve[.]" (Ex. 1046, 9.) Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a "graft forming the inner frame." (*Id.*, 14.)

Cribier discloses that SAPIEN includes an inner "(PET) fabric cuff," which is a graft covering:

[4] Petitioner preserves alternative arguments that the '735 patent does not describe an inner frame that is a graft covering, and that a graft covering cannot be an inner frame.



Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, 348, Fig. 1.) The fabric cuff cylindrically extends at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame. (*Id.*) Based on Patent Owner's statements during the related prosecution, SAPIEN's fabric cuff meets the "inner frame" limitation. (Ex. 1003, ¶¶120-121.)

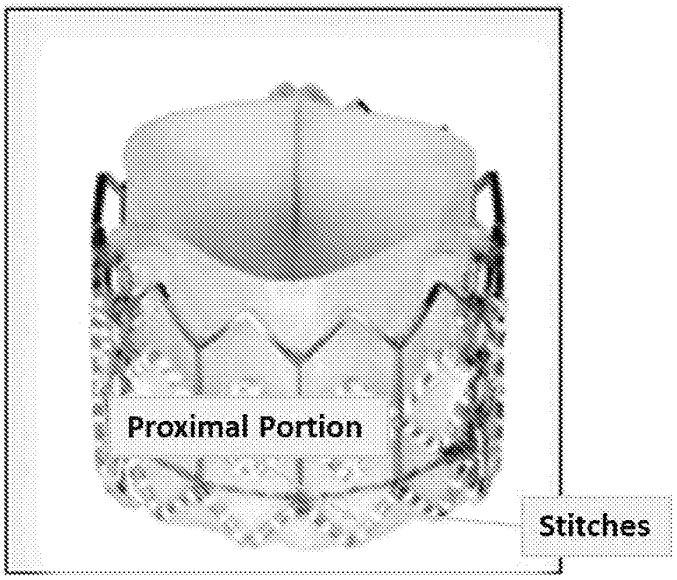
Cribier also discloses that SAPIEN includes a "tissue valve" comprised of "prosthetic leaflets." (Ex. 1012, 348.) SAPIEN's fabric cuff "engages" the leaflets along the green suture line (above). (Ex. 1012, Fig. 1; Ex. 1003, ¶122.) The fabric cuff provides sealing to the prosthetic valve. (Ex. 1003, ¶123; *see also* Ex. 1023, 154 (SAPIEN included a "higher sealing cuff…to reduce paravalvular leaks."); Ex. 1024, 1830 (same); Ex. 1027, 213 (same).) If the cuff did not provide sealing to the

valve, blood could leak around the valve and undermine its efficacy. (Ex. 1003, ¶123.)

d. Stitching

Cribier discloses that the claimed "outer frame is secured to the inner graft covering by stitching a proximal portion of the outer frame." (Ex. 1003, ¶¶124-125.)

White stitches secure SAPIEN's fabric cuff to a proximal portion of the frame:



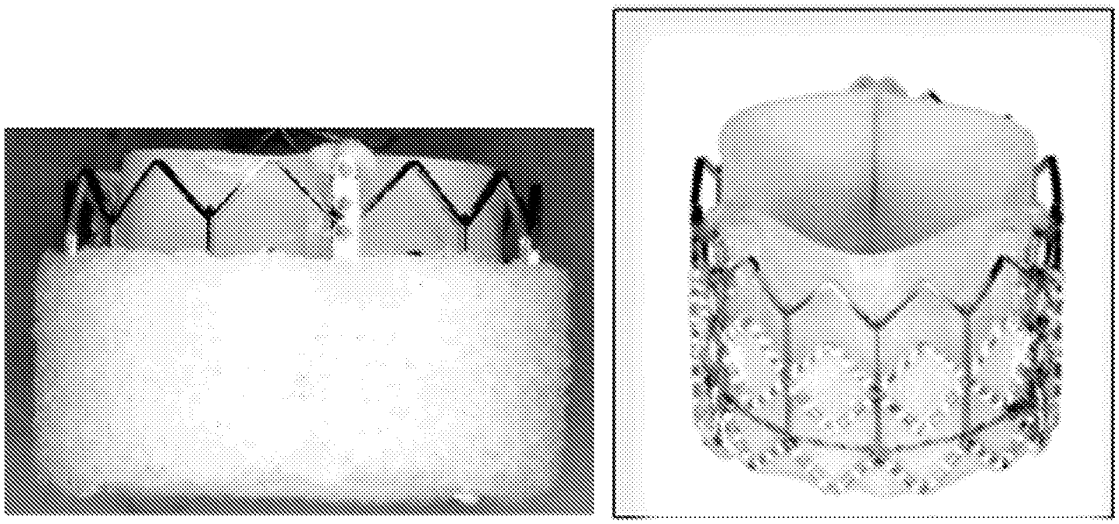
(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶125.)

e. Outer Seal

Cribier and Walther render obvious the claimed "outer seal for preventing paravalvular leaks that at least partially extends over at least two most proximal rows

of cells formed in the outer frame, wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame." (Ex. 1003, ¶¶126-134.)

Walther's outer cloth (i.e., outer seal) "is designed to reduce paravalvular leak by creating a seal[.]" (Ex. 1007, 1120; Ex. 1003, ¶127.) A comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right) illustrates that Walther's outer cloth "at least partially extends over at least [the] two most proximal rows of cells formed in" SAPIEN's frame:

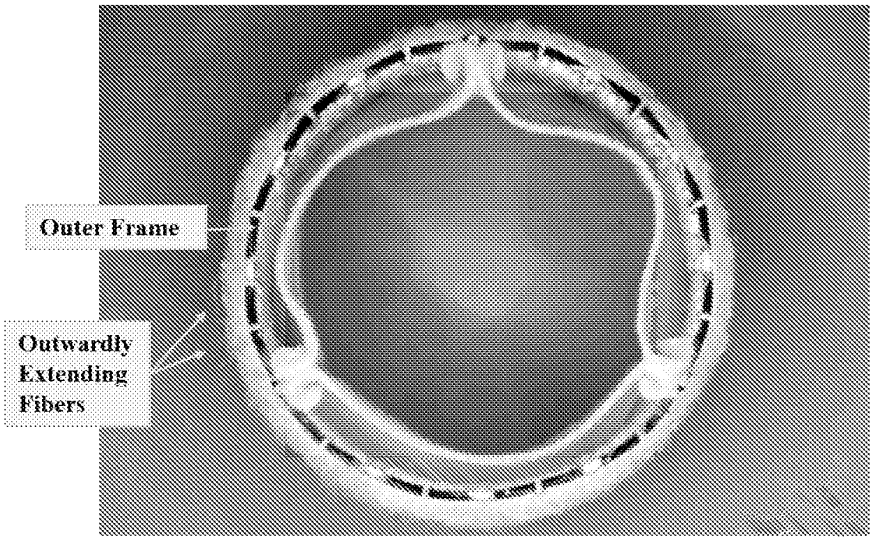


(Ex. 1007, Fig. 1; Ex. 1012, Fig. 1; Ex. 1003, ¶128.)

During prosecution of the related '846 patent, which similarly recites an outer seal "formed of outwardly extending fibers positioned externally to the outer frame," Patent Owner argued that an outer seal that ***includes*** outwardly extending fibers

satisfies this limitation. (Ex. 1046, 21-22.) Patent Owner has made the same allegations in the Litigation.[5] (Ex. 1050, 53.)

Walther's outer cloth includes outwardly extending fibers (visible below) that are positioned externally to the outer frame:



(Ex. 1007, 1121, Fig. 1 (excerpt); Ex. 1003, ¶130.) Thus, based on Patent Owner's statements during the related prosecution, Walther's outer cloth is an outer seal "formed of outwardly extending fibers." (Ex. 1003, ¶130.)

POSITAs would have been motivated to combine Walther's outer cloth with SAPIEN, as described in Cribier, because Walther expressly discloses this

[5] Petitioner preserves the alternative argument that SAPIEN 3 Ultra's outer skirt is not an "outer seal formed of outwardly extending fibers."

combination. (Ex. 1007, 1120-1121.) POSITAs would have had a reasonable expectation of success in combining Walther's outer cloth with SAPIEN because Walther describes how to make the combination, provides images of the combination, and concludes that the cloth-covered SAPIEN "demonstrated excellent hydrodynamic performance." (Ex. 1007, 1125; Ex. 1003, ¶134.)

f. Radially Compressed and Expanded Orientation

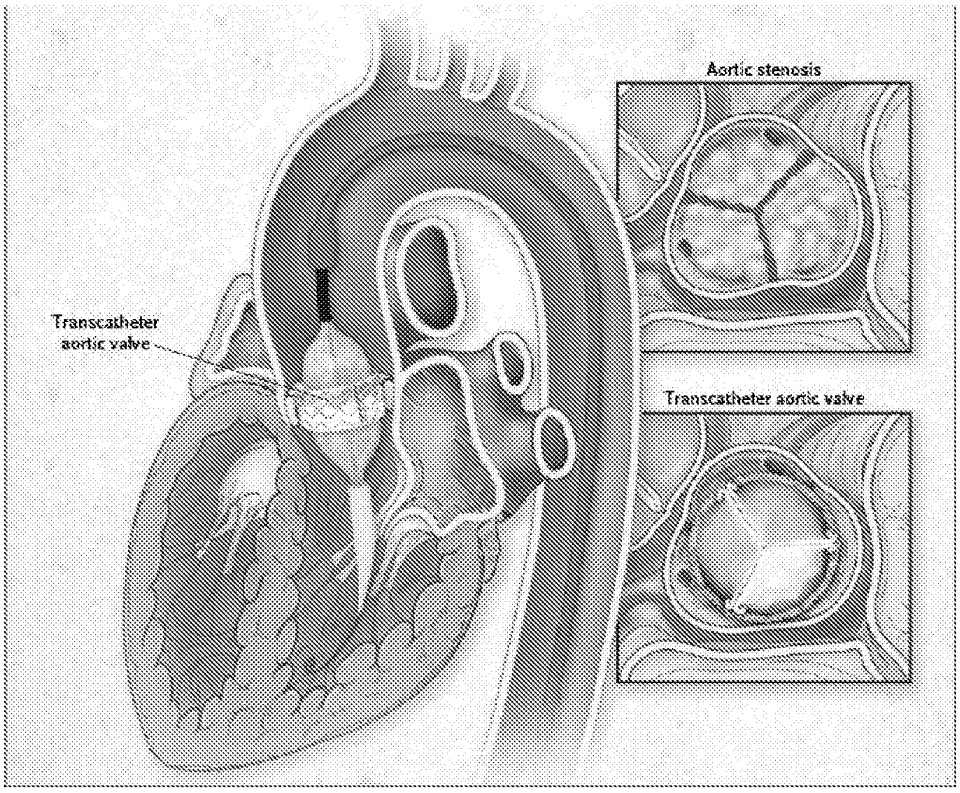
Cribier and Walther disclose the claimed valve assembly that "has a radially compressed orientation and a radially expanded orientation." (Ex. 1003, ¶¶135-136.) Cribier discloses that SAPIEN is "***compressed*** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its ***expanded size*** to its 'mounted' size.'" (Ex. 1012, 348 (emphasis added).) Similarly, Walther discloses that the cloth-covered SAPIENs were crimped onto a balloon and then expanded within surgical valves. (Ex. 1007, 1122, Fig. 4.)

g. Fibers Press Against Native Leaflets

Cribier and Walther render obvious the limitation "wherein the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient." (Ex. 1003, ¶¶137-144.)

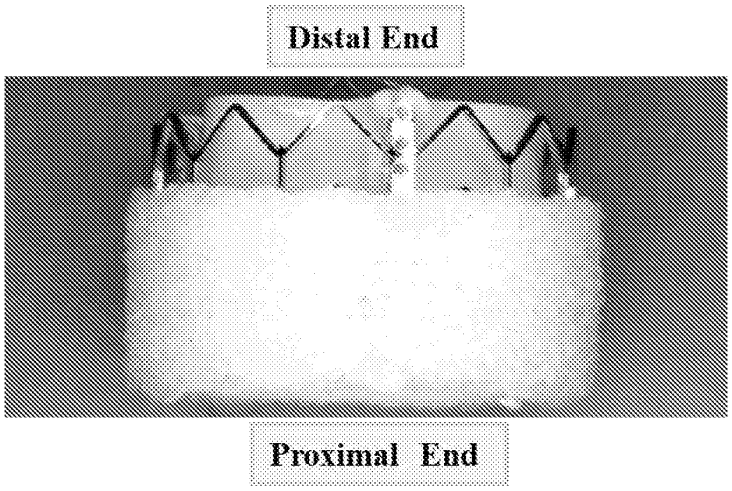
Cribier discloses that SAPIEN presses against the aortic valve's native leaflets upon implantation. Cribier states that SAPIEN is "advanced to the native aortic

valve…positioned across the aortic annulus, and delivered by balloon inflation[.]" (Ex. 1012, 347.) Cribier instructs that "before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion." (*Id.*, 353.) Consistent with the understanding in the art, the '735 patent identifies the annulus as the point where the leaflets begin. (Ex. 1001, 1:62-64, Fig. 2; Ex. 1003, ¶138; *see also* Ex. 1047, 76 ("[T]he annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the [aortic] leaflets.").) When expanded in this position, SAPIEN presses against and replaces the patient's native aortic leaflets, as illustrated below:

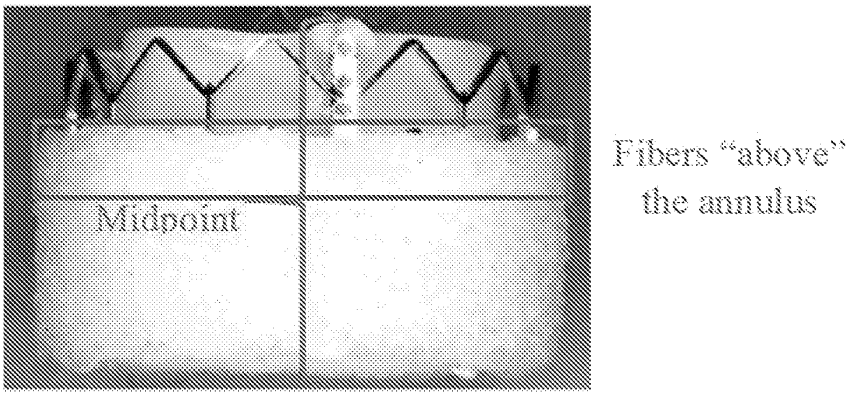


(Ex. 1022, 2189, Fig. 1; Ex. 1003, ¶139.) Some publications even describe SAPIEN as "crush[ing] the leaflets of the native valve against the wall." (Ex. 1047, 74.)

Expanding Walther's cloth-covered SAPIEN in a native aortic valve would press some of Walther's fibers against the patient's native leaflets. (Ex. 1003, ¶140.) Walther's outer cloth covers approximately two-thirds of SAPIEN's frame:



(Ex. 1007, Fig. 1 (excerpt); *supra* §VIII.A.1.e.) If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, the fibers "above the annulus" would press against the leaflets: (Ex. 1003, ¶140.)



(Ex. 1003, ¶140; Ex. 1047, 74.) In fact, Patent Owner admitted during prosecution of a related patent that an outer seal covering two frame rows would press against the leaflets. (Ex. 1046, 25.)

While Walther describes expanding the cloth-covered SAPIEN in a surgical valve, POSITAs would have found it obvious to deploy the valve within a patient's native valve so that the outer cloth presses against the native leaflets. (Ex. 1003, ¶141.) By November 2012, POSITAs well understood that PVL could occur with SAPIEN. (*See e.g.*, Ex. 1012, 354 (describing PVL with SAPIEN; Ex. 1022, 2194 (same); Ex. 1003, ¶143.) Thus, POSITAs would have been motivated to apply Walther's known technique for reducing PVL (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement and, as discussed below, would yield predictable results. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶143.)

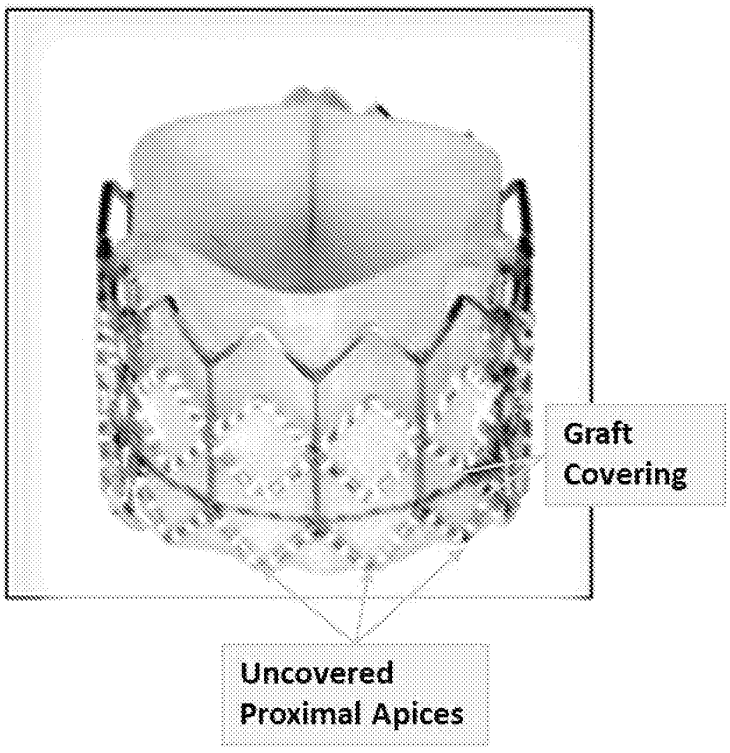
POSITAs would have reasonably expected success in deploying the cloth-covered SAPIEN in a patient's native aortic valve. (Ex. 1003, ¶144.) Walther describes the successful balloon deployment of the cloth-covered SAPIEN and concludes that the valve "demonstrated excellent hydrodynamic performance" and that an in-patient procedure "is feasible." (Ex. 1007, 1125; Ex. 1003, ¶144.) Moreover, the surgical valves described in Walther are designed to simulate the native aortic valve and POSITAs would have expected Walther's cloth-covered SAPIEN to perform similarly in either environment. (Ex. 1003, ¶144.)

Consequently, POSITAs would have reasonably expected success in implanting the cloth-covered SAPIEN within a patient's native aortic valve. (*Id.*)

h. Uncovered Proximal Apices

Cribier and Walther render obvious the claim limitation "wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering." (Ex. 1003, ¶¶145-148.)

As shown below, an end of the most proximal apices of SAPIEN's frame are uncovered by the inner fabric cuff (graft covering):



(Ex. 1012, Fig. 1; Ex. 1003, ¶146.)

Walther discloses an outer cloth stitched to the "perimeter" of the SAPIEN valves. (Ex. 1007, 1121.) Walther contains no disclosure that the outer cloth wraps around or covers the proximal apices of the frame. (Ex. 1003, ¶147.) Additionally, the outer cloth is not sutured to the inside of the valve or visible inside the valve:

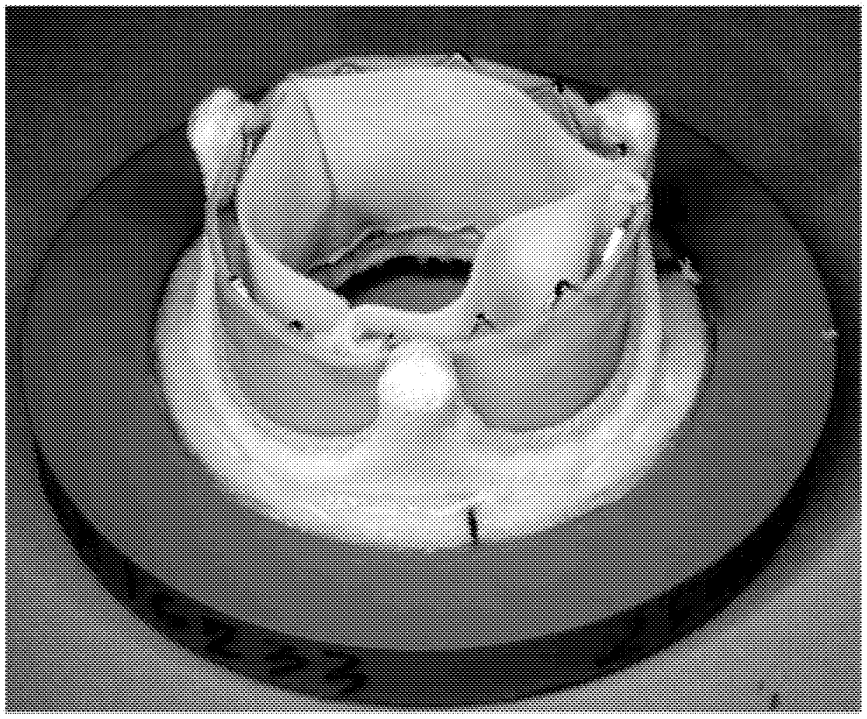


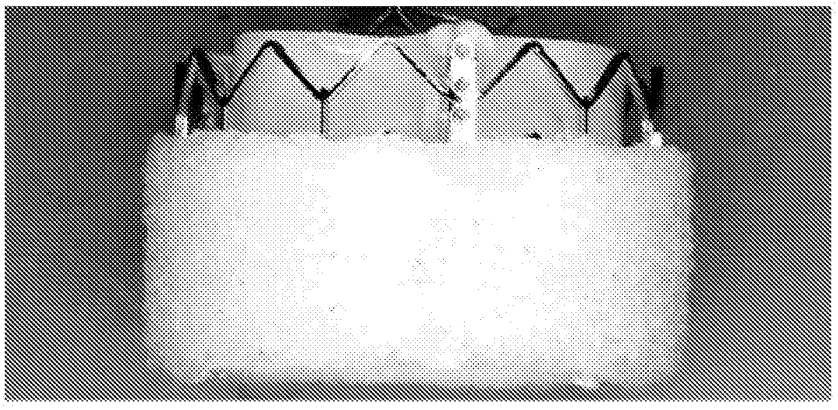
Fig. 2. Cloth THV valve deployed in surgical valve.

(Ex. 1007, Fig. 2 (excerpt).) Therefore, POSITAs would have understood that Walther's outer cloth does not cover the ends of the proximal apices. (Ex. 1003, ¶147.)

i. Proximal Apices Extend More Proximally than Outer Seal

Cribier and Walther render obvious the claim limitation "wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal." (Ex. 1003, ¶¶149-153.)

In its expanded configuration, Walther's outer seal extends roughly the same distance proximally as the most proximal apices:



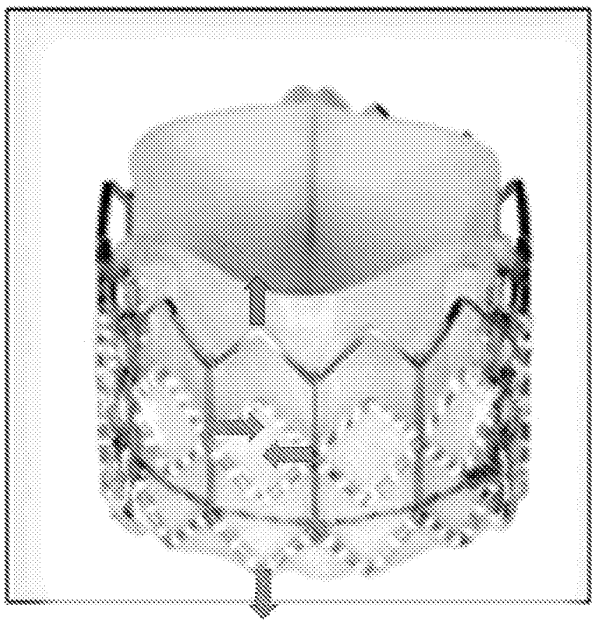
(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶150.) However, Walther's outer cloth does not need to cover the entire exterior of the SAPIEN valve, as illustrated by the uppermost row of cells that are uncovered in Figure 1. (Ex. 1007, Fig. 1) Instead, Walther's outer cloth must cover the area that will press against and seal with the existing annulus and leaflets. (*Id.*, 1120, Ex. 1003, ¶150.) Walther teaches that its cloth-covered SAPIENs were positioned within the surgical valves such that the "bottom of the frame of the cloth valve is 2 ± 2 mm below the bottom of the surgical valve." (Ex. 1007, 1122.) Accordingly, POSITAs would understand that the

proximal 2 mm of Walther's cloth-covered SAPIEN would lie below the annulus and native leaflets when implanted in a patient's native valve. (Ex. 1003, ¶150.) Because the proximal ends of the frame do not press against the annulus or native tissue, POSITAs would have understood that they do not need to be covered by the outer cloth. (*Id.*)

POSITAs would have found it obvious to adjust the size and placement of the outer cloth so that the apices extend more proximally than the outer seal. (*Id.*, ¶151.) POSITAs were motivated to routinely adjust the size and shape of outer cloths to maximize sealing while minimizing the profile of the valve. (*Id.*) The variety of outer seals disclosed in Spenser II illustrates this point. (*Id.*; *see e.g.*, Ex. 1011, Figs. 20a-22.) As explained above, POSITAs had access to many suitable cloths having varying thicknesses and densities and naturally tried different cloths having different dimensions and placements. (Ex. 1003, ¶151) Walther, Spenser II, and Levi reflect that POSITAs knew how to attach different types and shapes of outer cloths to heart valves. (*See e.g.*, Ex. 1007, Fig. 1; Ex. 1011, Fig. 22; Ex. 1008, Figs. 1, 42-43.) POSITAs would have been motivated to position Walther's outer cloth so that the apices extend more proximally because such placement would reduce the amount of cloth material on the outside of the valve, minimizing the crimped profile. (Ex. 1003,

¶151.) Additionally, such placement would help ensure that the outer cloth does not restrict expansion of the proximal apices of the frame. (*Id.*)

Walther does not picture the valve in the crimped (i.e., compressed) configuration. However, SAPIEN's frame elongates when crimped and foreshortens when expanded. (Ex. 1003, ¶152.) When the device is crimped and the vertical frame struts move towards each other (green arrows), the ends of the frame move away from each other (red arrows):



(*Id.*) Thus, POSITAs would understand that even without modification, the proximal apices of Walther's outer frame may extend proximally further than the outer cloth when the valve is crimped. (*Id.*) And where the positioning of Walther's outer cloth

is modified as proposed above, the proximal apices would continue to extend proximally further than the outer cloth when the valve is crimped.[6] (*Id.*)

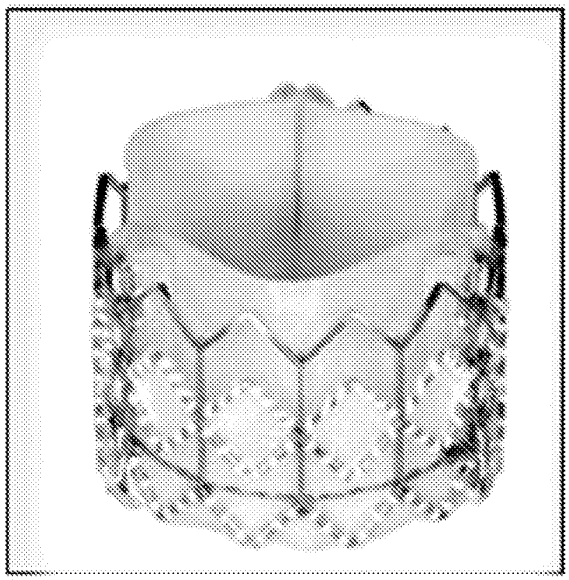
POSITAs would have had a reasonable expectation of success in slightly adjusting the position or size of Walther's outer cloth so that the proximal apices extended further proximally than the cloth. (*Id.* ¶153.) The necessary adjustments to expose the proximal apices would be minimal and the cloth would still provide ample surface area to seal against the patient's native tissue and prevent PVL. (*Id.*)

2. Claim 3

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the outer frame is a singular, integral component." (Ex. 1003, ¶¶154-155.)

Cribier discloses that SAPIEN's frame is a "tubular slotted stainless-steel" stent. (Ex. 1012, 348.) SAPIEN's stent comprises a "singular, integral component":

[6] POSITAs would understand that the plain and ordinary meaning of claim 1 requires the outer frame's proximal apices to extend proximally further than the outer seal both when the valve is in its compressed configuration, and when the valve is in its expanded configuration. (Ex. 1003, ¶152 n. 5.)



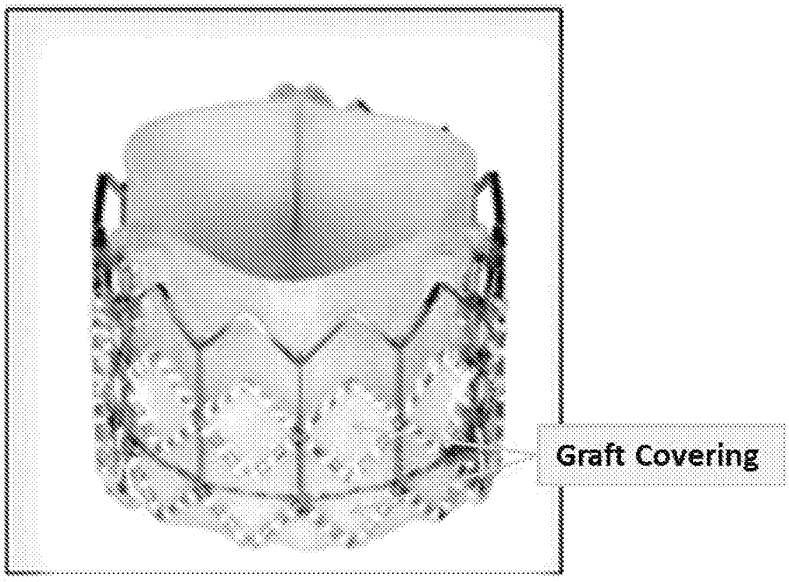
Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶155.)

3. Claim 4

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the inner graft covering and the fibers are distinct elements." (Ex. 1003, ¶¶156-158.)

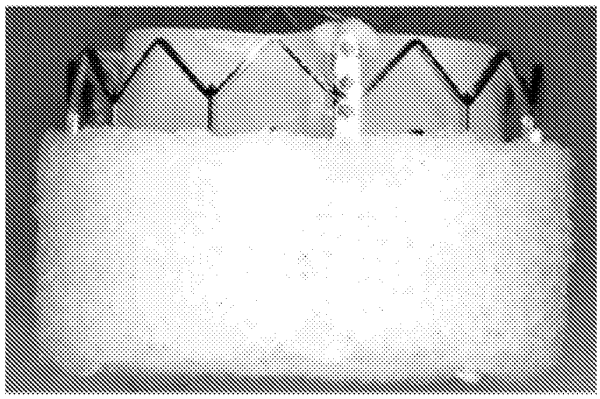
Cribier discloses that SAPIEN includes a fabric cuff (graft covering) that is stitched to the inner surface of the stent frame:



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23 mm, 26 mm

(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶157.)

Walther discloses an outer cloth (i.e., fibers) that "was stitched to the perimeter of each SAPIEN valve":



(Ex. 1007, 1121, Fig. 1 (excerpt).) Walther's outer cloth and SAPIEN's inner fabric cuff are different materials and separately attached to the valve, making them "distinct elements." (Ex. 1003, ¶158.)

4. Claim 5

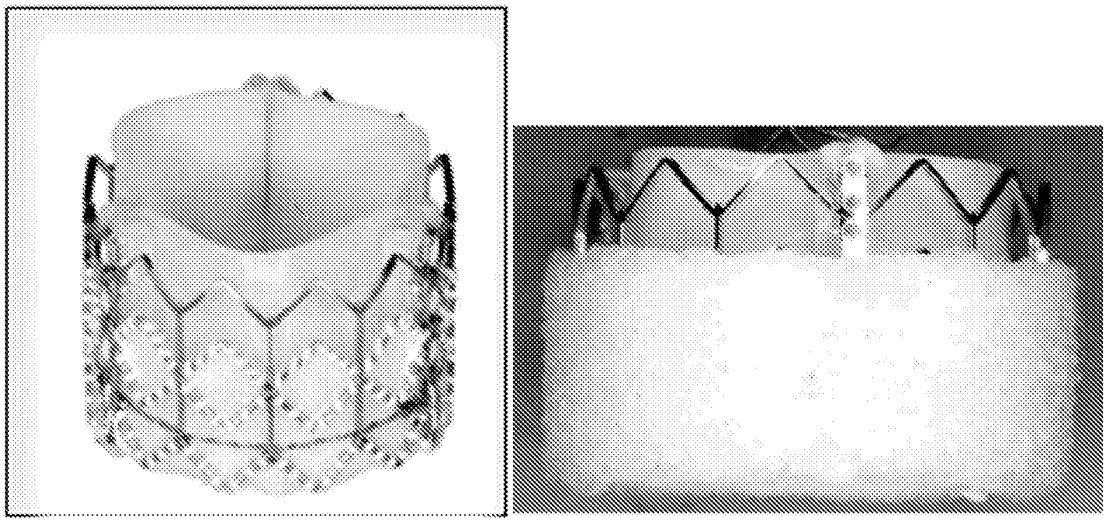
Cribier and Walther render obvious the "valve assembly of claim 1, wherein a seal is created between the inner frame and the outer frame." (Ex. 1003, ¶¶159-160.)

SAPIEN's inner fabric cuff "creates a seal between the inner frame and the outer frame" to prevent PVL. (*Id.*; Ex. 1016, 23; *supra* §VIII.A.1.c.) SAPIEN would not have worked if a seal did not exist between the fabric cuff and frame because blood could disadvantageously leak between the two. (Ex. 1003, ¶160.)

5. Claim 6

Cribier and Walther render obvious the "valve assembly of claim 1, wherein a portion of the outer frame is uncovered by the inner graft covering and the outer seal." (Ex. 1003, ¶¶161-165.)

Neither SAPIEN's inner fabric cuff nor Walther's outer cloth covers the upper row of cells of SAPIEN's frame:

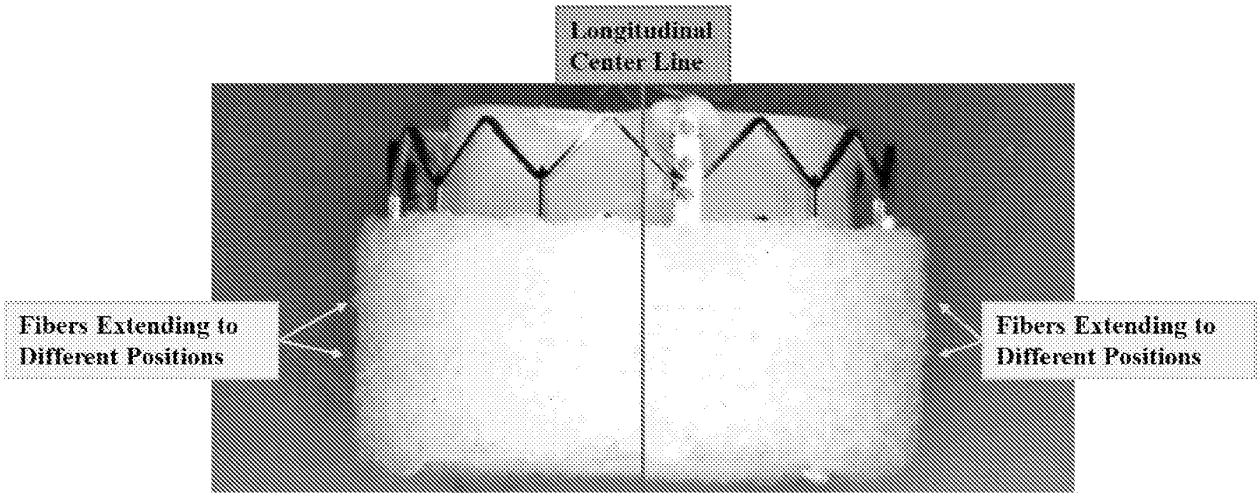


(Ex. 1007, Fig. 1 (excerpt); Ex. 1012, 348, Fig. 1.) Therefore, a portion of SAPIEN's outer frame is uncovered by the inner fabric cuff and outer cloth. (Ex. 1003, ¶¶163-165.)

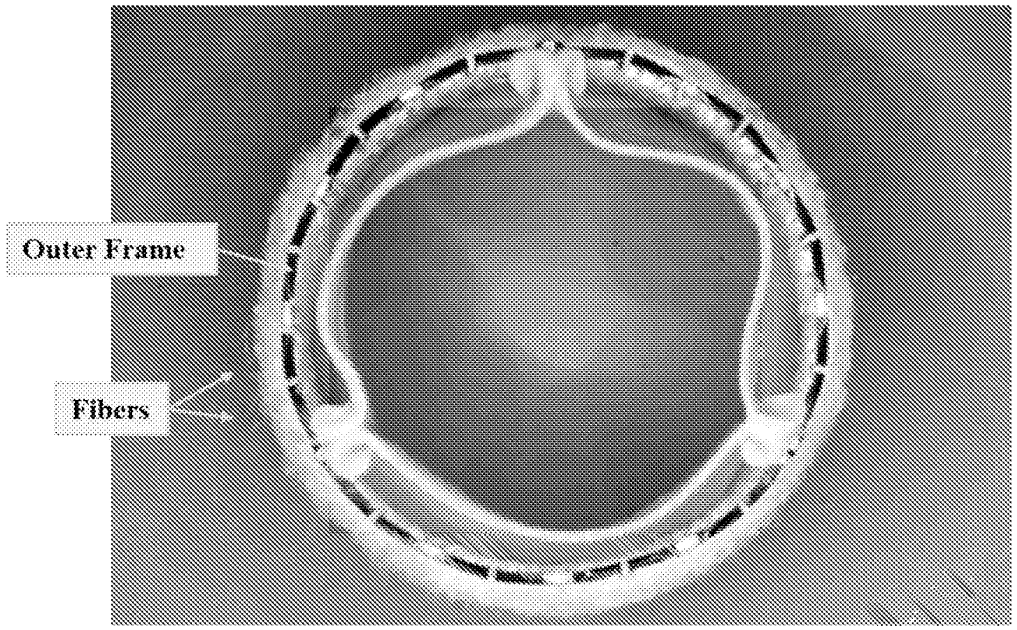
6. Claim 8

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the outwardly extending fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly." (Ex. 1003, ¶¶166-168.)

Walther's outer cloth extends to the left and right of a "centerline." Thus, Walther's outer cloth includes fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly":



(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶167.) Additionally, some fibers extend further out from the frame than others:

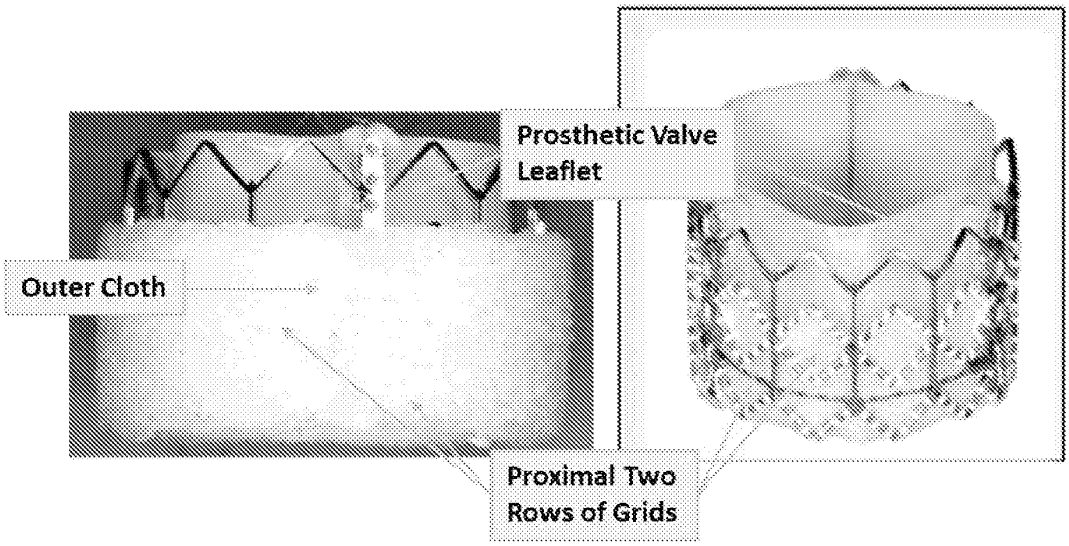


(Ex. 1007, Fig. 1 (excerpt).) Thus, even fibers on one side of the valve "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly." (Ex. 1003, ¶168.)

7. **Claim 9**

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping." (Ex. 1003, ¶¶169-171.)

Walther's outer cloth and SAPIEN's inner fabric cuff cover the proximal rows of cells:



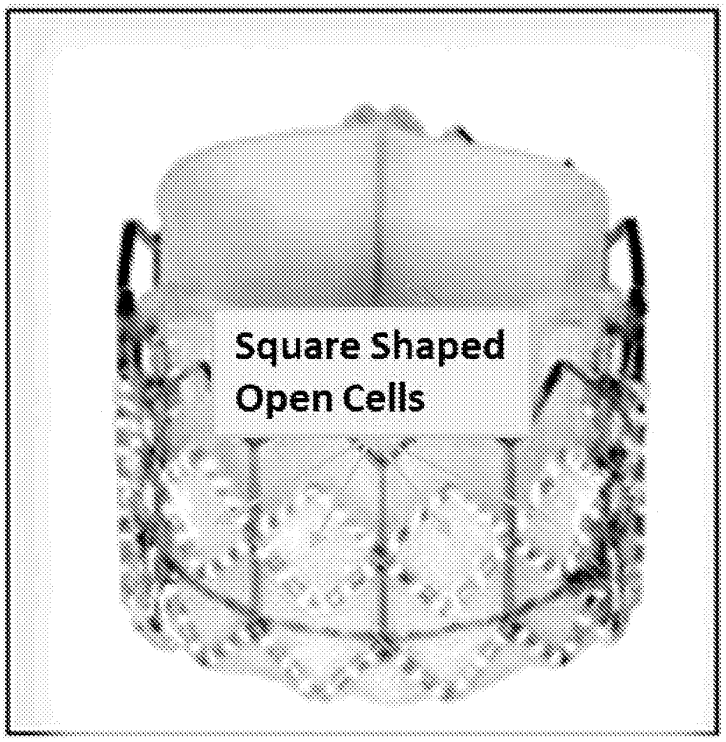
(*Supra* §VIII.A.c-e; Ex. 1007, Fig. 1 (excerpt); Ex. 1012, Fig. 1.) The leaflets are sutured to the cuff at the green line (above right), which is located within the

proximal rows of the frame. (Ex. 1003, ¶171.) Therefore, the inner cuff, outer cloth, and prosthetic leaflets radially overlap. (*Id.*)

8. Claim 11

Cribier and Walther render obvious the "valve assembly of claim 1, wherein open cells of the open cell configuration area are a square shape." (Ex. 1003, ¶¶172-173.)

SAPIEN's outer frame comprises three rows of open cells, and the middle cells are a square shape:



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23 mm, 26 mm

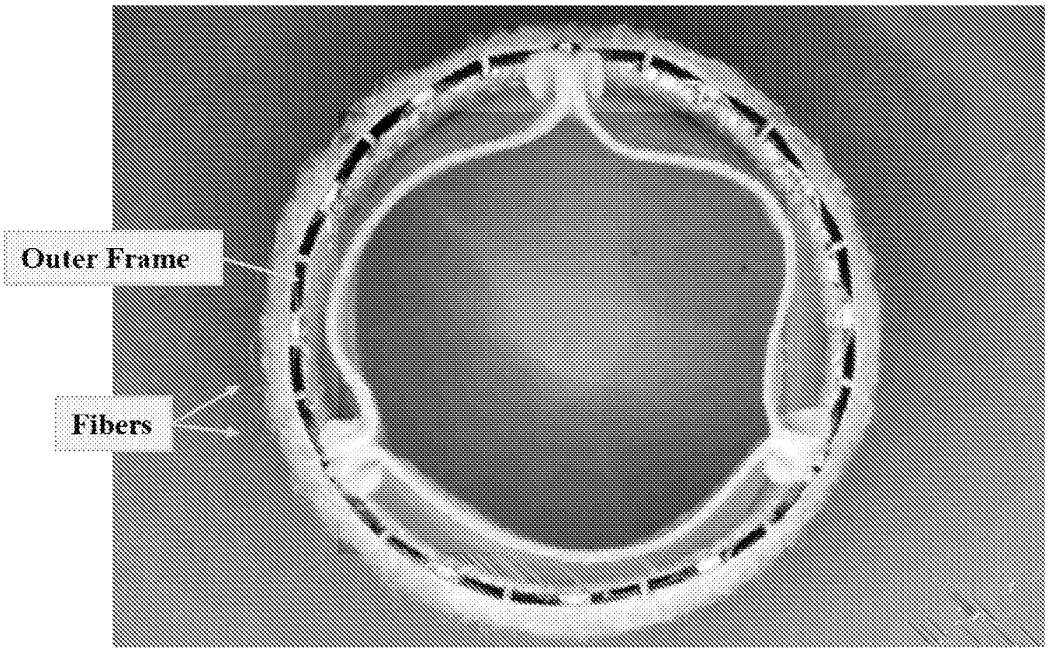
(Ex. 1012, Fig. 1; Ex. 1003, ¶173.)

9. Claim 12

Cribier and Walther render obvious the "valve assembly of claim 1, wherein the outer seal is free of a non-porous graft covering." (Ex. 1003, ¶¶174-176.)

Walther discloses that the outer cloth, which is stitched to the valve's perimeter, was the only modification made to SAPIEN. (Ex. 1007, 1120.) Walther

does not state that the outer cloth includes a "non-porous graft covering" and the cloth does not include any visible graft covering:



(*Id.*, 1121, Fig. 1 (excerpt); Ex. 1003, ¶176.) SAPIEN does not include any "non-porous graft covering" on the exterior of the frame:



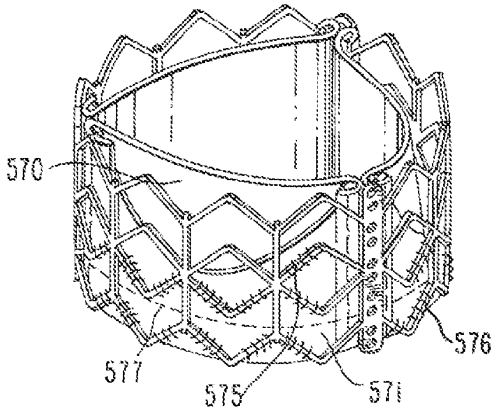
Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, Fig. 1; Ex. 1003, ¶175.) Thus, Walther's outer cloth is "free of a non-porous graft covering." (Ex. 1003, ¶176.)

B. Grounds 2-3: Claims 1-9, 11-12 Obvious Over Spenser and Walther or Spenser II

Spenser describes heart valve assemblies similar to SAPIEN including the below embodiment:

FIG. 44a



(Ex. 1010, Fig. 44a; *see also* Ex. 1040 (IFU), 8 (identifying Spenser).)

Walther discloses cloth-covered SAPIENs. (*Supra* §VIII.A.1.)

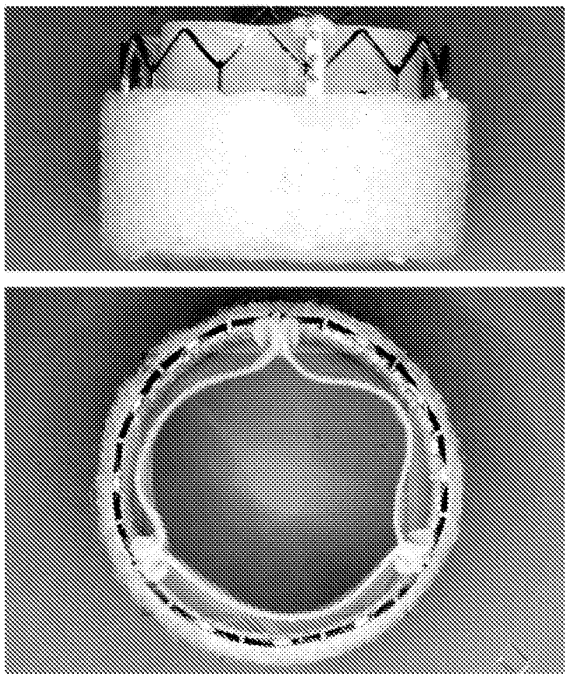


Fig. 1. Cloth valve.

Spenser II discloses heart valves having a fibrous layer of "compressible material…disposed along the outer surface of the stent structure" to reduce PVL:

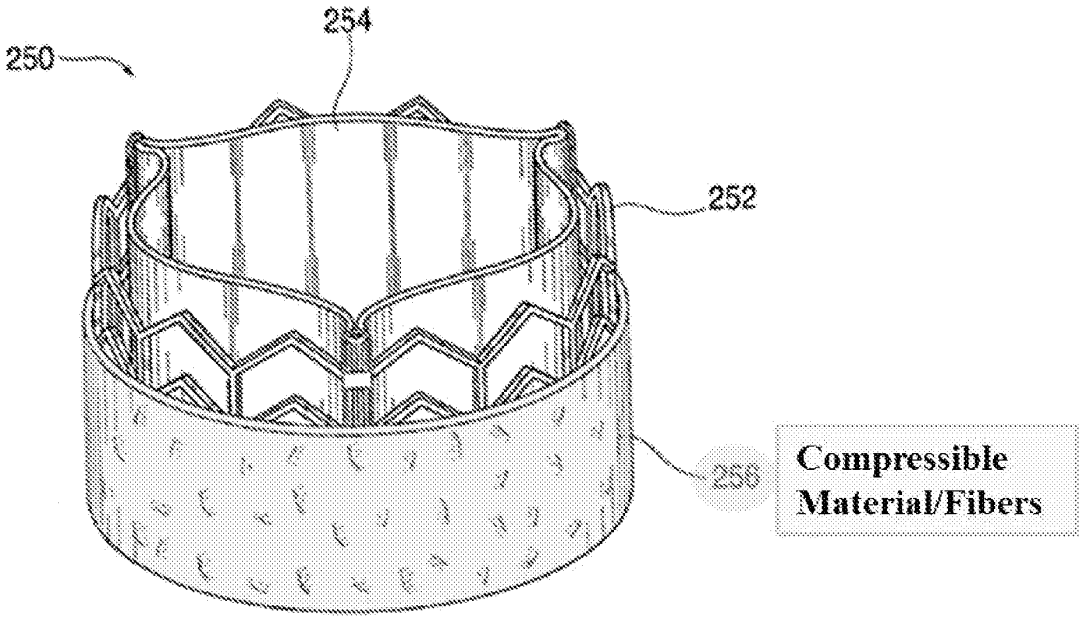


FIG. 22

(Ex. 1011, [00144]-[00145], Fig. 22.)

POSITAs would have been motivated to combine Walther's outer cloth or Spenser II's compressible material with Spenser's Figure 44a. (Ex. 1003, ¶179.) Thus, claims 1-9 and 11-12 are obvious over Spenser in combination with Walther or Spenser II. (*Id.*)

1. Claim 1

Spenser and Walther or Spenser II render claim 1 obvious. (Ex. 1003, ¶180.)

a. Preamble

Walther, Spenser, and Spenser II disclose "endovascular transcatheter valve assemblies." (*Id.* ¶¶181-188.)

Walther discloses SAPIEN, which is an "endovascular transcatheter valve assembly." (*Supra* §VIII.A.1.a.)

Spenser discloses that "[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously*** ... ***via a large blood vessel such as the femoral artery***[.]" (Ex. 1010, 2:6-12 (emphases added).) Spenser describes endovascularly delivering the valves through a catheter. (*Id.*, 5:17-6:36, 17:19-18:43.) POSITAs would have understood the disclosure of endovascular delivery to apply to Figure 44a. (*Id.*, 26:30-34, 2:6-12; Ex. 1003, ¶183.)

Spenser II also describes using catheters to endovascularly deliver heart valves "through a body duct to a target location." (Ex. 1011, [0009]; *see e.g.*, *id.*, [0014], [0017], [00144]-[00145].) POSITAs would have understood the description of endovascular delivery to apply to the cloth-covered stented valve in Figure 22. (Ex. 1003, ¶185.)

POSITAs would have been motivated to endovascularly deliver Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material. (Ex. 1003, ¶¶186-188.) POSITAs generally considered endovascular

delivery less traumatic and, by 2012, had successfully delivered SAPIEN through different blood vessels, including the femoral and common iliac arteries. (*Supra* §VIII.A.1.a.) POSITAs would have been motivated to deliver the combined valve through the common iliac artery because the artery is large and could accommodate Spenser's Figure 44a with Walther's outer cloth or Spenser II's compressible material. (Ex. 1003, ¶186; Ex. 1043.)

Moreover, if POSITAs wanted to deliver the combined valve through narrower (or more diseased) blood vessels, such as the femoral artery, POSITAs would have possessed the skills and equipment necessary to adapt the outer seal or valve for the particular vessel. (*Supra* VIII.A.1.a.) POSITAs would have reasonably expected success in combining Walther's outer cloth with Spenser's Figure 44a because Figure 44a is similar, if not identical, to SAPIEN and for the reasons provided in Ground 1. (*Id.*)

Additionally, POSITAs would have reasonably expected success in combining Spenser II's compressible material with Spenser's Figure 44a based on the dimensions disclosed in the references. Spenser discloses that the "maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter." (Ex. 1010, 27:65-67.) Spenser's prosthetic valve "has the ability to change its diameter from about 4 mm to about 25 mm." (*Id.*, 27:67-28:2.) Spenser

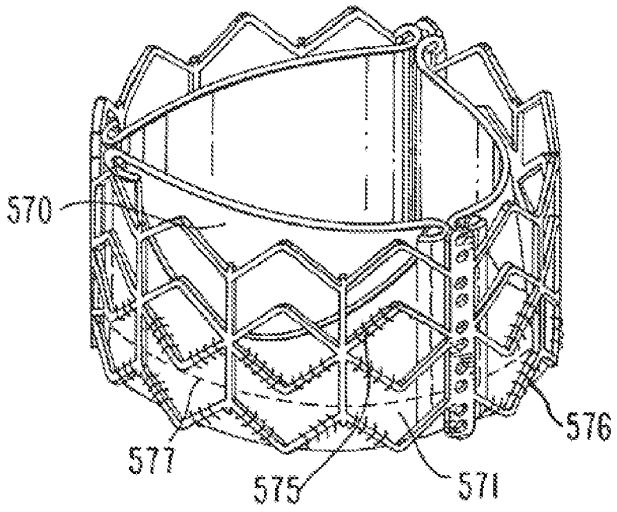
II's compressible material can have "a thickness ranging from about 1 to 5 mm." (Ex. 1011, [00145].) POSITAs would have reasonably expected that adding a compressible material 1mm thick to Spenser's 4-mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery. (Ex. 1003, ¶188.)

Finally, the '735 patent does not claim or disclose how to size the disclosed valve for endovascular delivery. (*Supra* §VIII.A.1.a) Consequently, Patent Owner cannot argue that adapting a cloth-covered valve for endovascular delivery would have been beyond POSITAs' skill. (*Id.*)

b. Outer Frame

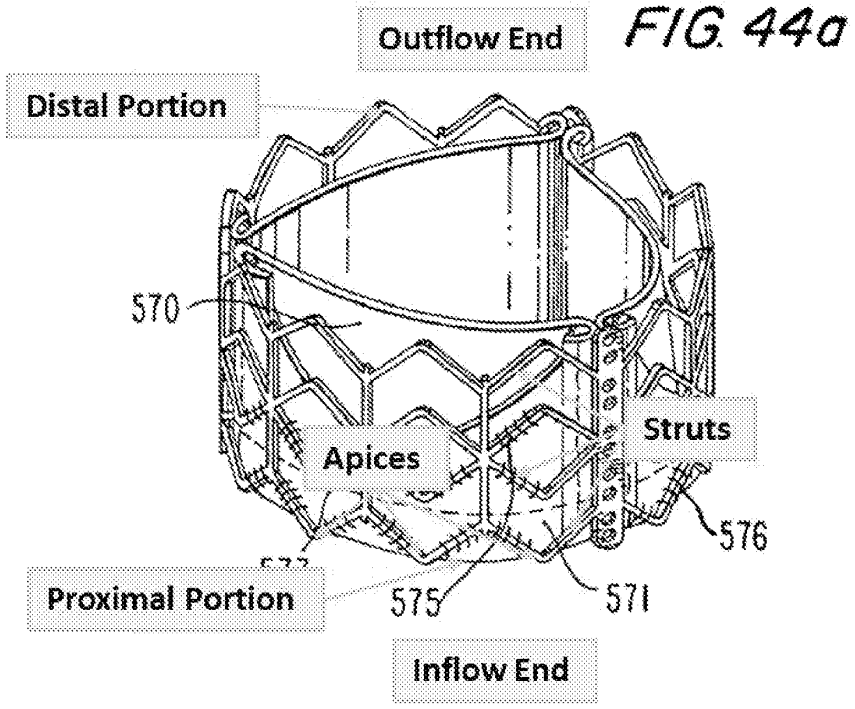
Spenser's Figure 44a illustrates "an implantable prosthetic valve" that includes "frame 575":

FIG. 44a



(Ex. 1010, 19:5-13, 26:30-34.) The frame may be made from metallic materials, defines an open cell configuration, and surrounds the other valve components, making it an "outer frame." (*Id.*, 12:28-31, 28:16-19, Fig. 44a-44b; Ex. 1003, ¶191.)

Frame 575 includes an inflow end at its proximal portion and an outflow end at its distal portion and is formed from a plurality of struts that adjoin at the inflow end of the frame to form apices:



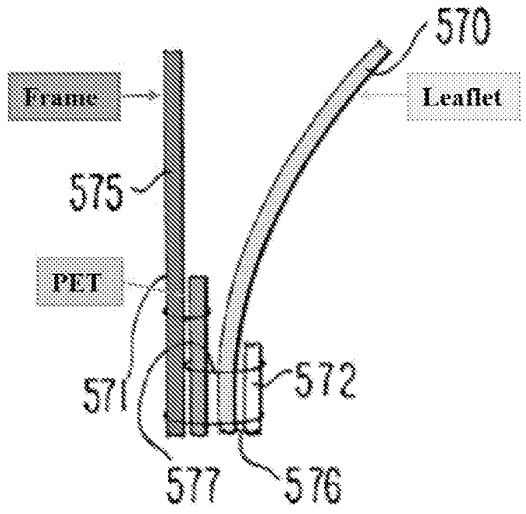
(Ex. 1010, Fig. 44a; Ex. 1003, ¶192.)

c. Inner Frame

Spenser's Figure 44a includes "additional pieces of PET" for "sealing and protecting the pericardium." (Ex. 1010, 26:30-34, Figs. 44a-44c.) The "pericardium" includes prosthetic leaflets 570, and PET is a "graft covering." (*Id.*, 26:30-54; Ex.

1003, ¶194.) PET 571 [blue] is positioned "between the leaflets [570 yellow] and frame [575 red]" and engages the leaflets[7]:

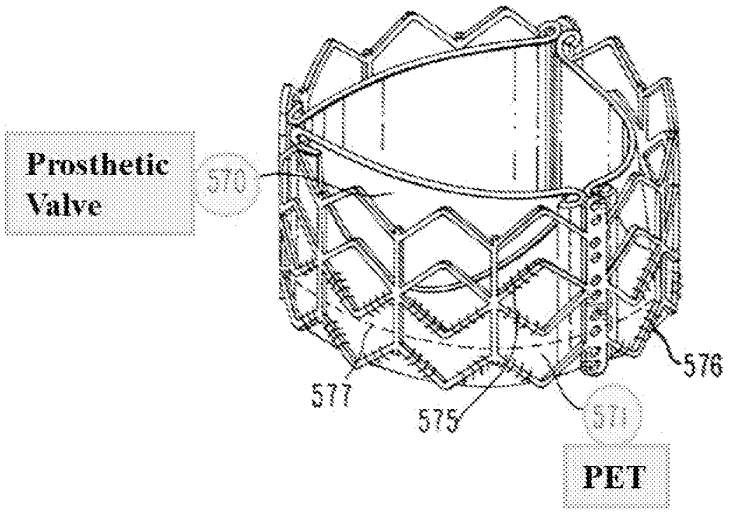
FIG. 44b



(Ex. 1010, 26:30-54, Fig. 44b.) PET 571 is "cylindrically extending" and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:

[7] In Fig. 44b, the lead lines for 571 and 575 point to the outer frame [red]. This is a drafter's error. The lead line for the outer PET layer 571 should point to the middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶195 n.7.)

FIG. 44a

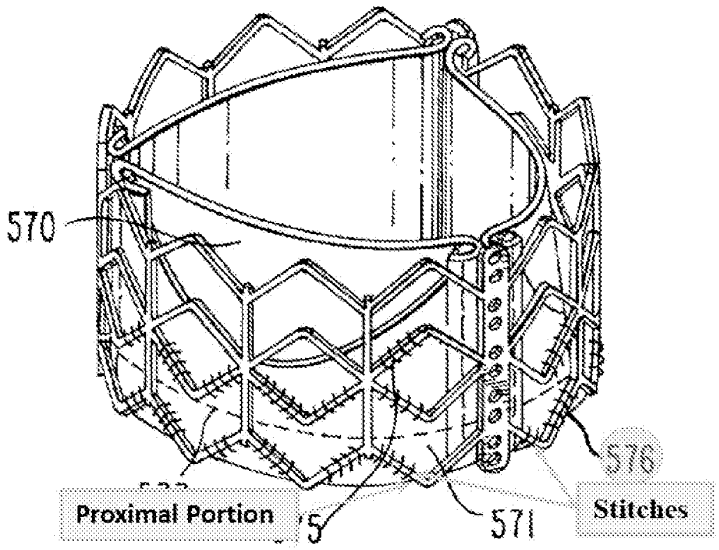


(*Id.*, 26:30-34, Fig. 44a-b.) Thus, based on Patent Owner's statements during related prosecution (*supra* §VIII.A.1.c), PET 571 satisfies the "inner frame" limitations. (Ex. 1003, ¶196.)

d. Stitching

Spenser's inner graft covering is secured to the proximal portion of the frame with stitches from suture 576:

FIG. 44a



(Ex. 1010, 26:45-47, Figs. 44a-c.)

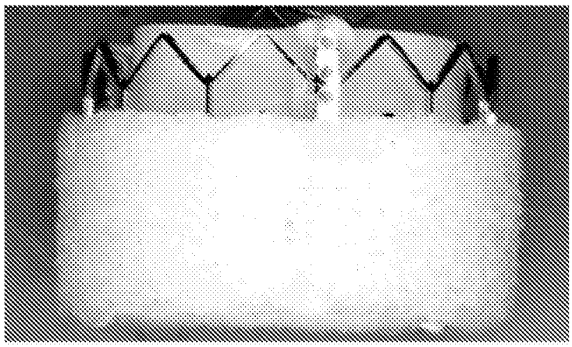
e. Outer Seal

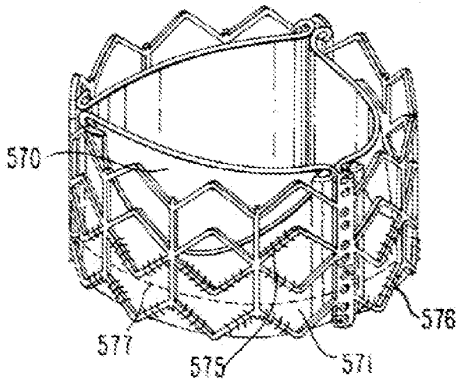
Spenser and Walther or Spenser II render the "outer seal" limitations obvious. (Ex. 1003, ¶¶200-210.)

i. Walther

Walther discloses a fibrous outer cloth for preventing PVL that extends over the two most proximal rows of cells formed in the frame. (*Supra* §VIII.A.1.e.) SAPIEN is similar (if not identical) to Spenser's Figure 44a. (Ex. 1003, ¶202.) Thus, Walther's outer cloth would also cover the two proximal rows of Figure 44a's frame:

FIG. 44a

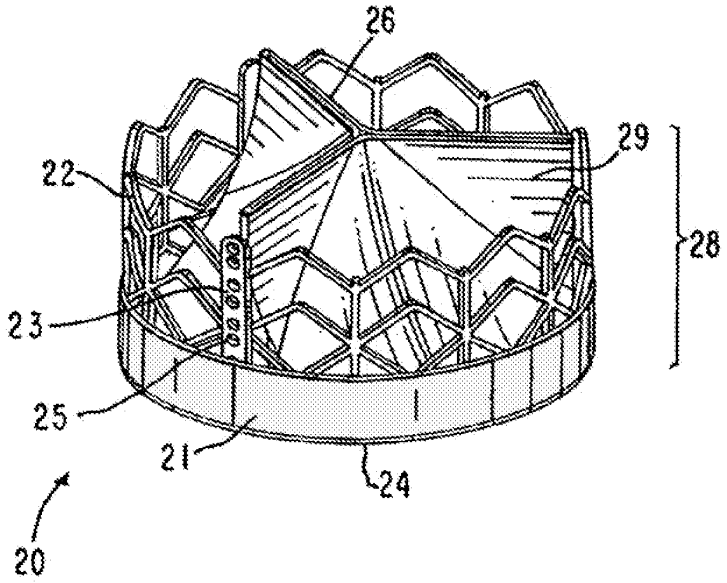




(Ex. 1007, Fig. 1 (excerpt); Ex. 1010, Fig. 44a; Ex. 1003, ¶201.)

Walther's outer cloth includes outwardly extending fibers positioned externally to the outer frame. (*Supra* §VIII.A.1.e.) If Walther's outer cloth were added to Figure 44a, the combined valve would also include outwardly extending fibers positioned externally to the outer frame. (Ex. 1003, ¶201.)

POSITAs would have been motivated to combine Walther's outer cloth with Spenser's Figure 44a because Walther expressly discloses combining the outer cloth with a similar (if not identical) heart valve (SAPIEN). (Ex. 1007, 1120-1121; Ex. 1003, ¶202.) Additionally, Spenser suggests adding an outer cloth to Figure 44a by disclosing a similar valve with an outer cuff portion 21 for sealing around the valve:



(Ex. 1010, 13:22-25, Fig. 1.) Adding Walther's outer cloth to Figure 44a would have merely entailed applying a known technique (attaching an outer cloth) to a known device (Figure 44a) ready for improvement (enhanced sealing). *KSR Int'l Co.*, 550 U.S. at 416.

POSITAs would have reasonably expected success in combining Walther's outer cloth with Figure 44a because Walther discloses how to combine the cloth with a similar heart valve, provides images of the combination, and concludes that the cloth-covered valve "demonstrated excellent hydrodynamic performance." (Ex. 1007, 1125; Ex. 1003, ¶203.)

ii. Spenser II

Spenser II also discloses the claimed outer seal. (Ex. 1003, ¶205.) Spenser II discloses, "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252":

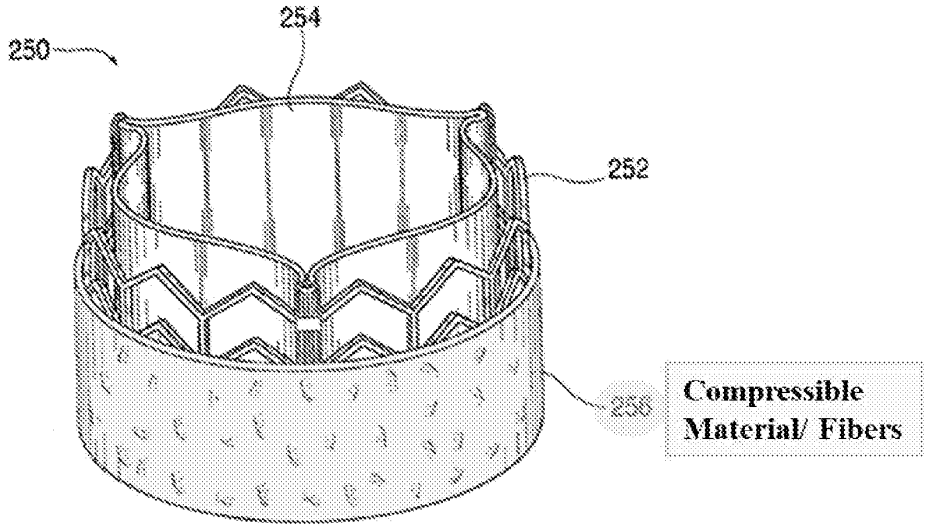


FIG. 22

(Ex. 1011, [00145], Fig. 22.) The compressible material "***may resemble a cloth or fabric having small fibers extending from the surface of the material***." (*Id.* (emphasis added).) The compressible material expands upon implantation and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." (*Id.*)

Spenser II's compressible material extends over at least the two most proximal rows of cells formed in stent structure 252:

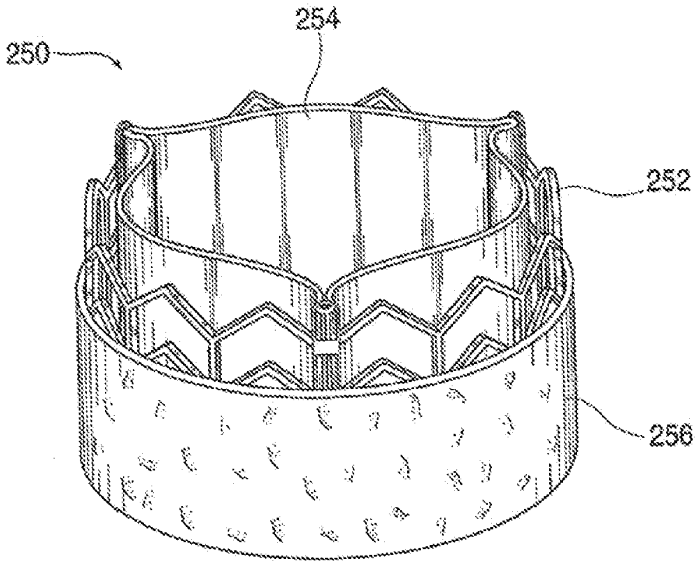
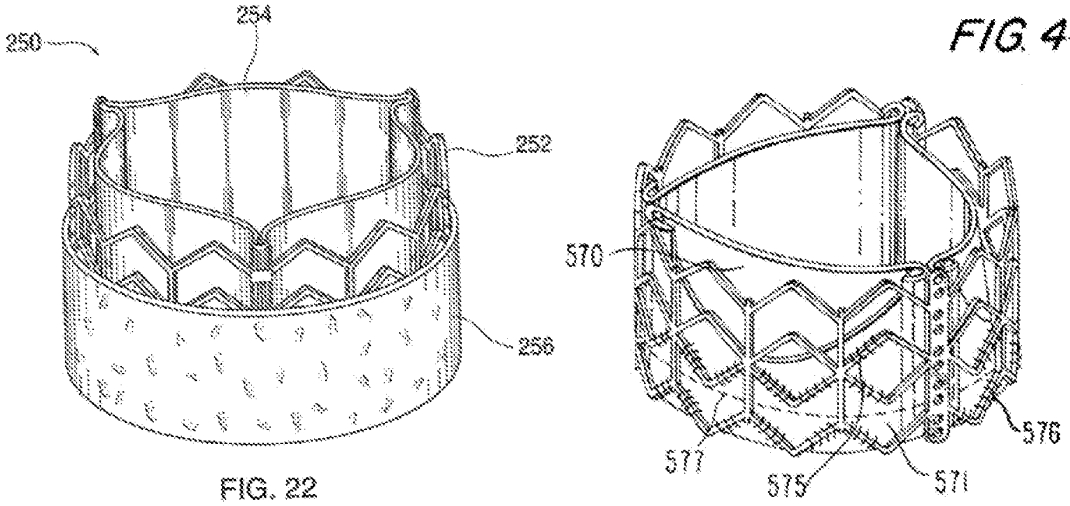


FIG. 22

(Ex. 1011, Fig. 22; Ex. 1003, ¶206; *see also* Ex. 1010, Figure 44a.)

When added to Spenser's Figure 44a, the compressible material would also extend over the proximal two rows of cells formed by the stent frame:



(Fig. 1011, Fig. 22; Ex. 1010, Fig. 44a; Ex. 1003, ¶207.) The cell shape and orientation are the same in Figures 22 and 44a. (Ex. 1003, ¶207.)

POSITAs would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a for several reasons. Spenser and Spenser II describe similar valves, share three common inventors, and Spenser II explicitly references Spenser's parent application: U.S. Publication No. 2003/0153974 (Ex. 1015). (*See, e.g.*, Ex. 1010, Abstract, 2:5-15; Ex. 1011, [0001], [0009]-[0014]; Ex. 1003, ¶208.) Given this overlap, POSITAs would have reasonably anticipated that the teachings in Spenser II would apply to Spenser. (Ex. 1003, ¶208.)

Also, PVL was known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. (*Id.*, ¶209.) POSITAs would have been motivated to combine Spenser II's compressible material with Figure 44a to "address leaks that can occur around the implanted valve" and "to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [0010], [0145]; Ex. 1003, ¶209.) Moreover, adding the compressible material to Figure 44a would have merely entailed the combination of known elements (Figure 44a and compressible material) according to known methods (stitching or otherwise attaching) to yield the predictable result of reducing PVL. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶209.)

POSITAs would have reasonably expected success in combining Spenser II's compressible material with Figure 44a because the valve assemblies share many common features, including similar balloon-expandable stents and a three-leaflet prosthetic valve. (*See, e.g.*, Ex. 1010, 2:5-15; 12:28-36, 13:26-54, 19:5-13; Ex. 1011, [0011]-[0015], [00144]; Ex. 1003, ¶210.) Moreover, Spenser discloses valves having a sealing material positioned around its inlet, which would have given POSITAs confidence that other sealing structures, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. (Ex. 1010, 13:22-25, Fig. 1; Ex. 1003, ¶210.)

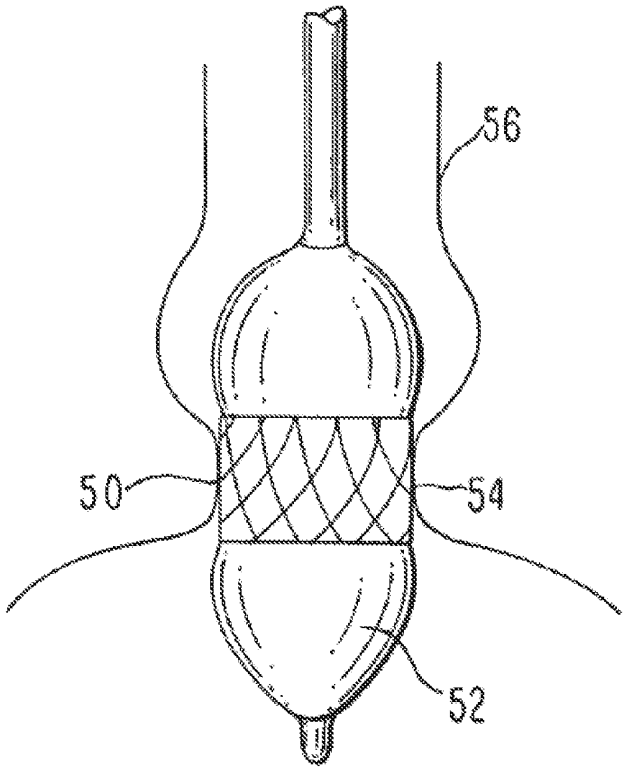
f. Radially Compressed and Expanded Orientation

Spenser, Walther, and Spenser II disclose this limitation. (Ex. 1003, ¶¶211-212.) Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.1.f.) Spenser discloses that its valve "has the ability to change its diameter from about 4mm [compressed orientation] to about 25mm [expanded orientation]." (Ex. 1010, 27:67-28:2.) Spenser II discloses valves that comprises "an expandable stent structure" that may be "adapted for radial expansion using a balloon catheter." (Ex. 1011, [00144].)

g. Fibers Press Against Native Leaflets

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶213-218.)

Spenser's Figure 4 depicts "valve deployment in a natural aortic valve position in accordance with the present invention":



(Ex. 1010, 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b.) As illustrated, the valve presses against the patient's aortic annulus. (*Id.*, Fig. 4; Ex. 1003, ¶214.) The valve also presses against the patient's native aortic leaflets

(not shown), which are attached to the annulus and extend distally therefrom. (*Supra* §VIII.A.1.g; Ex. 1003, ¶214.) Figure 4 illustrates the placement of Figure 44a because Figure 4 describes "the ***present invention***" and Figure 44a describes a "preferred embodiment of the ***present invention***." (Ex. 1010, 8:66-67, 26:30-34 (emphasis added); Ex. 1003, ¶214.)

Walther's outer cloth and Spenser II's compressible material would cover at least the two proximal rows of Figure 44's outer frame. (*Supra* §VIII.B.1.e.) Thus, expansion of the combined valve would press some of the fibers of Walther's outer cloth and Spenser II's compressible material against the patient's native aortic leaflets for the reasons explained in Ground 1. (*Supra* §VIII.A.1.g; Ex. 1003, ¶215.)

POSITAs would have found it obvious to deploy Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material within a patient's native valve. (Ex. 1003, ¶216.) Spenser discloses methods of implanting the described valves, such as Figure 44a, at the native aortic valve. (*See e.g.,* Ex. 1010, 5:17-6:36.) Additionally, by November 2012, POSITAs well understood that PVL could occur with SAPIEN (which is similar if not identical to Figure 44a). (*See e.g.*, Ex. 1012, 354 (describing PVL with SAPIEN; Ex. 1022, 2194 (same); Ex. 1003, ¶216.) Thus, POSITAs would have been motivated to apply Walther's or Spenser II's known technique for reducing PVL (adding an outer cloth) to a known device

(Figure 44a), which was ready for improvement and, as discussed below, would yield predictable results. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

POSITAs would have reasonably expected success in deploying Figure 44a with Walther's outer cloth or Spenser II's compressible material in a patient's native aortic valve. (Ex. 1003, ¶217.) Walther discloses that the valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." (*See* Ex. 1007, 1125; Ex. 1003, ¶217.) Likewise, Spenser II describes the implantation of a valve with a compressible material in a native valve and, given the similarities between the stents in Spenser's Figure 44a and Spenser II's Figure 22, POSITAs would have expected implantation in a native valve to work equally well if the compressible material were added to Spenser's Figure 44a. (Ex. 1011, [0144]-[0145]; Ex. 1003, ¶217.)

Additionally, Spenser describes implantation of its embodiments, including Figure 44a, within the aortic valve and POSITAs had successfully implanted SAPIEN, which is similar to Figure 44a, within a patient's native aortic valve many times by November 2012. (Ex. 1003, ¶218; Ex. 1010, 2:6-12, 12:8-36, 13:26-54, 14:12-14.) Thus, POSITAs would have been confident in implanting Figure 44a with

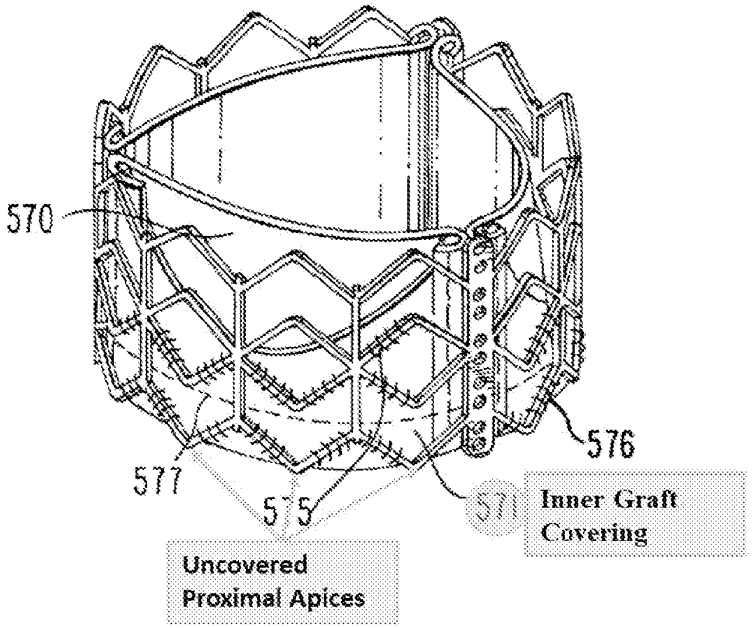
Walther's outer cloth or Spenser II's compressible material within a patient's native aortic valve. (Ex. 1003, ¶218.)

h. Uncovered Proximal Apices

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶219-222.)

PET layer 571 does not cover the ends of the most proximal apices of the frame:

FIG. 44a



(Ex. 1010, Fig. 44a; Ex. 1003, ¶220.)

i. Walther

Walther's outer cloth also does not extend over the ends of the most proximal apices of SAPIEN's outer frame. (*Supra* §VIII.A.1.h.) POSITAs would have been motivated to position Walther's outer cloth on Figure 44a in the same way with a reasonable expectation of success because Walther discloses that arrangement created a successful seal. (Ex. 1003, ¶221.) Thus, Walther's outer cloth would not extend over the ends of the most proximal apices of Figure 44a's outer frame. (*Id.*)

ii. Spenser II

Spenser II discloses a "compressible material disposed along an outer surface of stent structure 254." (*Supra* §VIII.B.1.e.ii.) Spenser II does not disclose that the compressible material extends over the proximal apices and such an interpretation would be inconsistent with the description that the material is "disposed along an outer surface":

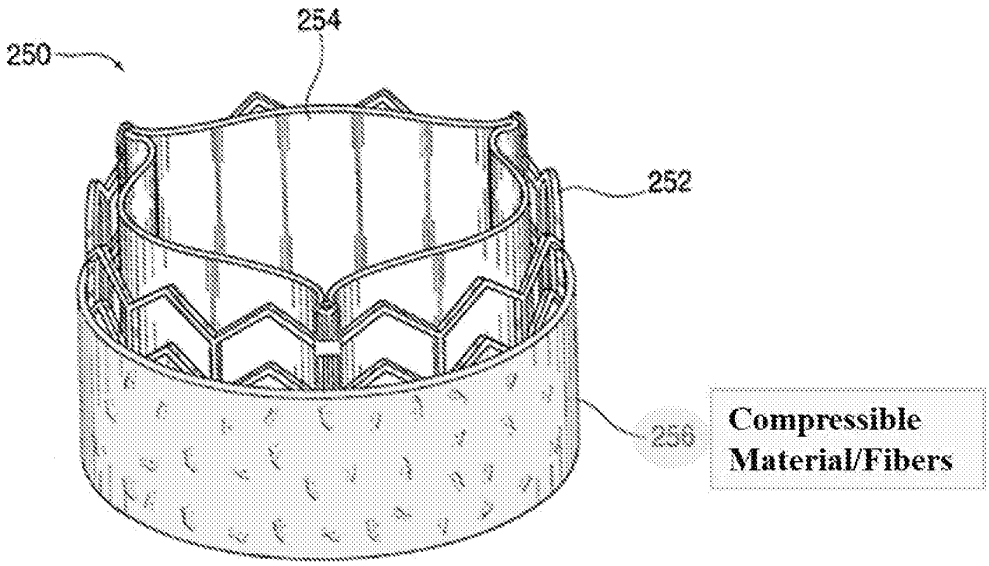


FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶222.) If Spenser II's compressible material were "disposed along an outer surface" of Figure 44a's frame, the material would not cover the ends of the most proximal apices. (Ex. 1003, ¶222.)

i. Proximal Apices Extend More Proximally than Outer Seal

Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶223-225.)

i. Walther

POSITAs would have found it obvious to adjust the size and placement of Walther's outer cloth so that the apices extend more proximally for the reasons provided in Ground 1. (*Supra* §VIII.A.1.i.)

ii. Spenser II

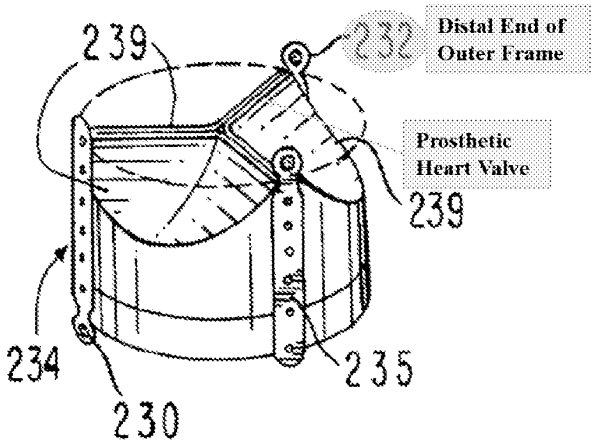
Spenser II's compressible material is "disposed along the outer surface of the stent structure 252." (Ex. 1011, [00145].) POSITAs would have found it obvious to adjust the size and placement of the compressible material such that the most proximal apices of Figure 44a's outer frame extend proximally further than the compressible for the same reasons explained in Ground 1 with respect to Walther's outer cloth. (*Supra* §VIII.A.1.i.; Ex. 1003, ¶225)

2. Claim 2

Spenser and Walther or Spenser II render obvious the "valve assembly of claim 1, wherein the outer frame extends distally further than the prosthetic heart valve." (Ex. 1003, ¶¶226-228.)

Spenser discloses this limitation in two ways. (*Id.*, ¶227.) First, Spenser illustrates valves having "heavy metal markers [232] on the stent," which allow visualization of the device during delivery:

FIG.14



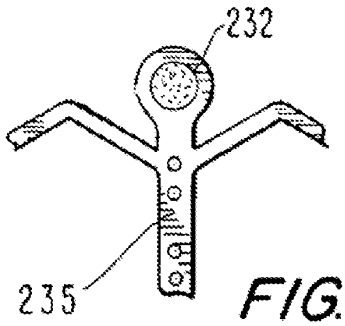


FIG.14a

(Ex. 1010, 16:27-51, Figs. 14-14a.) The portion of the frame having the marker extends distally further than the prosthetic valve. (Ex. 1003, ¶227.) POSITAs would have been motivated to add markers to Figure 44a's stent to better visualize the stent during deployment. (*Id.*) POSITAs would have reasonably expected success because Spenser describes using the markers with stents similar to Figure 44a and metal markers were common in the field by 2012. (*Id.*)

Second, Spenser illustrates a method of attaching the leaflets 430 to the frame 420:

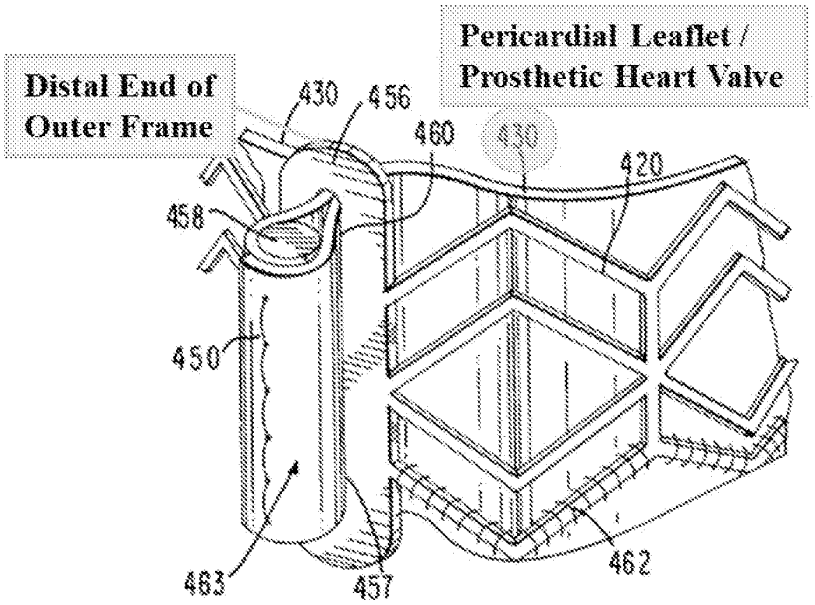


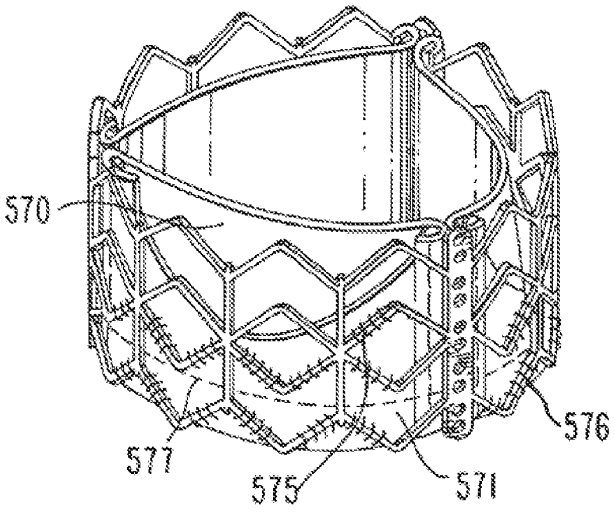
FIG 28

(Ex. 1010, 21:46-67, Fig. 28.) The outer frame portion 456 extends distally further than the prosthetic heart valve. (Ex. 1003, ¶228.) POSITAs would have been motivated to use this method of attachment in Figure 44a to reduce stress points and abrasion on the leaflets. (Ex. 1010, 21:60-67, Ex. 1003, ¶228.) POSITAs would have reasonably expected success in using this method with Figure 44a because Spenser discloses using the method with a valve like Figure 44a. (Ex. 1003, ¶228.)

3. Claim 3

Spenser's Figure 44a includes "frame 575," which is a singular, integral component:

FIG. 44a



(Ex. 1010, 26:30-34, 19:5-13, Figs. 44a-44b; Ex. 1003, ¶230.)

4. Claim 4

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶231-232.) Walther's outer cloth or Spenser II's compressible material and Spenser's inner PET layer are separate materials and, therefore "distinct elements." (*Id.*, ¶232.)

5. Claim 5

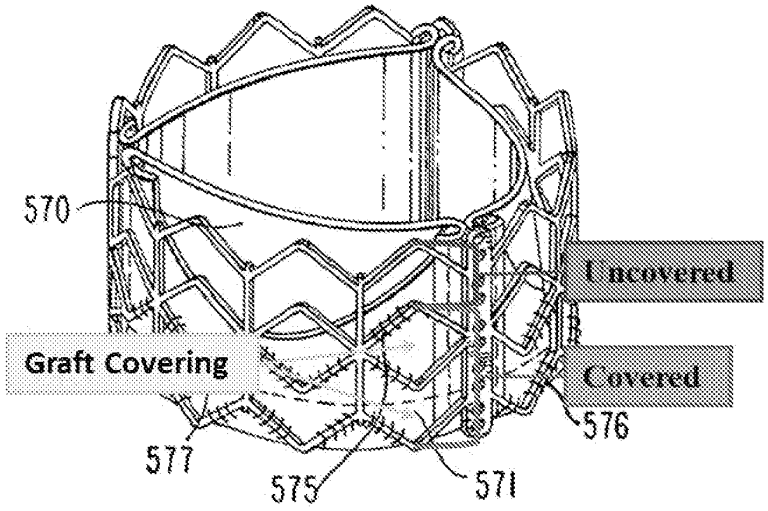
Figure 44a's inner PET layer is "***for sealing*** and protecting the pericardium." (Ex. 1010, 26:30-54 (emphasis added).) Spenser further discloses that the "[b]ottom attachment suture 576, connects . . . the leaflet and both PET layers to the frame and ***forms a strong sealing line***." (*Id.*, 26:45-47 (emphasis added).) Thus, POSITAs

would have understood that a seal is created between the inner PET layer and outer frame. (Ex. 1003, ¶234.)

6. Claim 6

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶235-241.) Figure 44a's inner PET layer ***does not*** cover the uppermost row of cells:

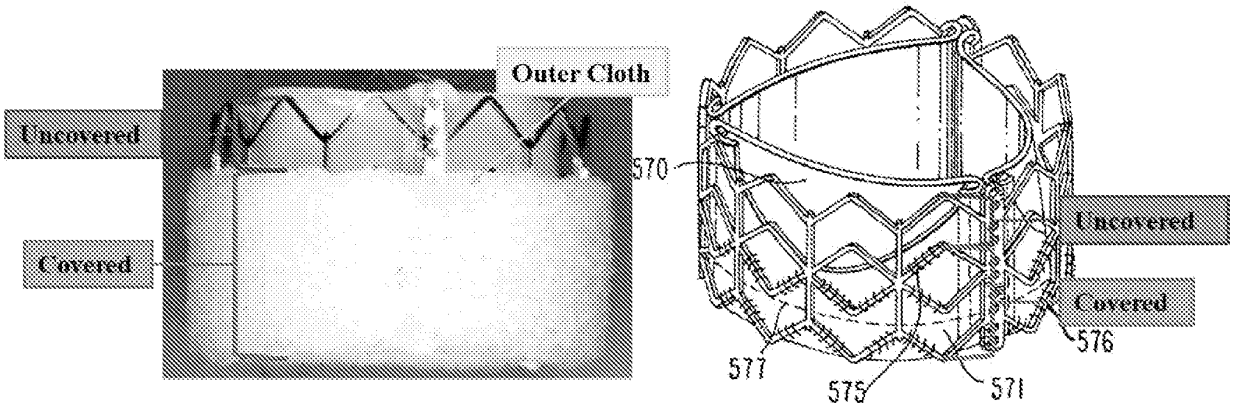
FIG. 44a



(Ex. 1010, Fig. 44a.)

Similarly, Walther's outer cloth does not cover the upper row of cells. (*Supra* §VIII.A.5.) If Walther's outer cloth were added to Spenser's Figure 44a, the cloth ***would not*** cover the uppermost row of cells:

FIG. 44a



(Ex. 1007, Fig. 1 (excerpt); Ex. 1010, Fig. 44a; Ex. 1003, ¶238.)

Spenser II's compressible material also does not cover the stent's upper row of cells. (Ex. 1011, Fig. 22.) When added to Spenser's Figure 44a, the compressible material would ***not*** cover the uppermost row of cells:

FIG. 44a

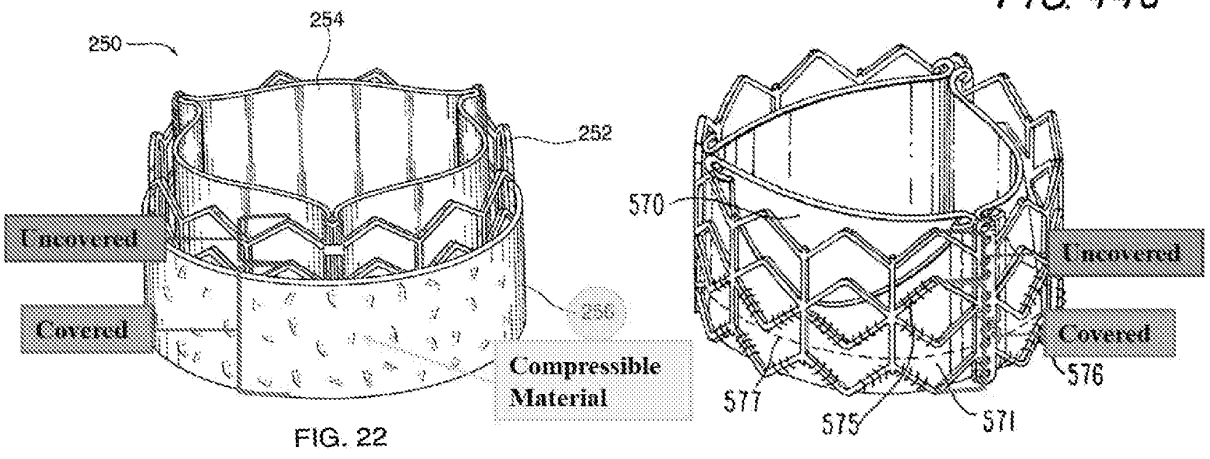


FIG. 22

(Ex. 1011, Fig. 22; Ex. 1010, Fig. 44a; Ex. 1003, ¶241.)

Therefore, Spenser combined with Walther or Spenser II yields a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (Ex. 1003, ¶¶239, 241.)

7. Claim 7

Spenser and Walther or Spenser II render obvious the "wherein a distal end of the outer frame extends distally beyond the prosthetic leaflets." (Ex. 1003, ¶¶242-244.)

This claim is substantially similar to claim 2. (*Id.*) Spenser discloses this limitation as described in claim 2. (*Supra* §VIII.B.2.)

8. Claim 8

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶245-248.) Walther discloses this limitation as explained in Ground 1. (*Supra* §VIII.A.6.)

Spenser II's compressible material includes fibers that extend to the left and right of the "centerline," which thus "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly":

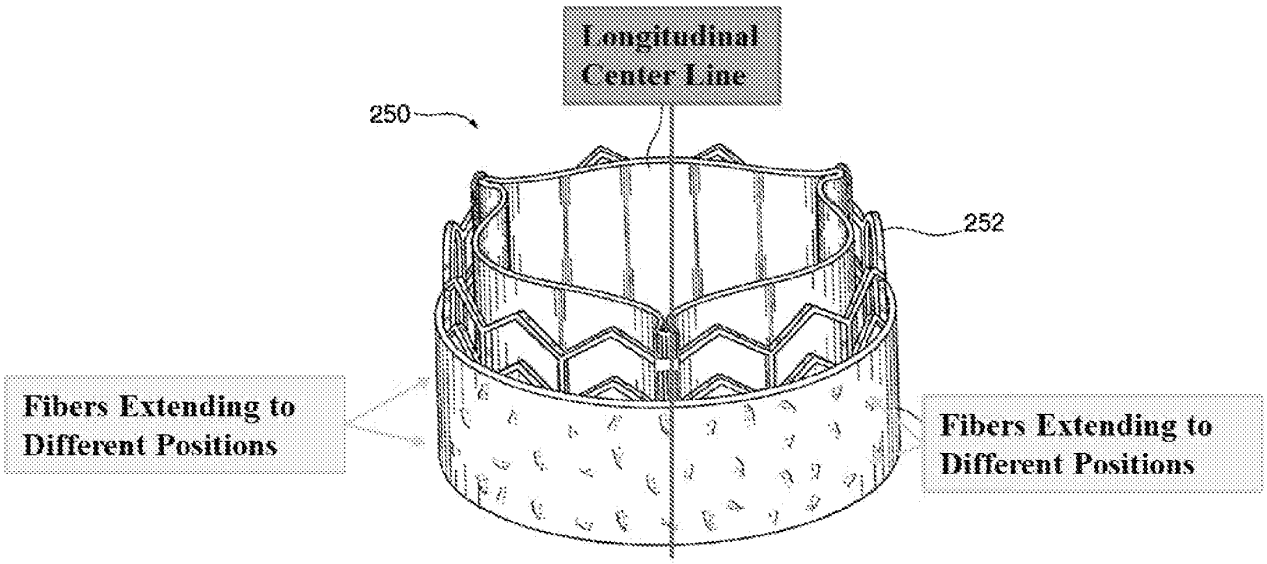


FIG. 22

(Ex. 1011, Fig. 22; Ex. 1003, ¶247.)

Additionally, the fibers of the compressible material "may be straight, curved, or hook shaped." (Ex. 1011, [00145].) As indicated by the speckled markings below, some fibers extend further out from the frame than others:

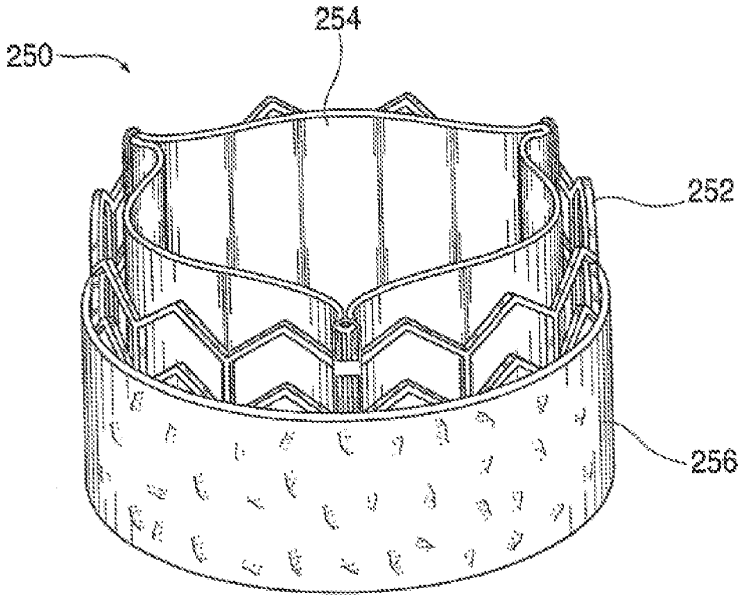


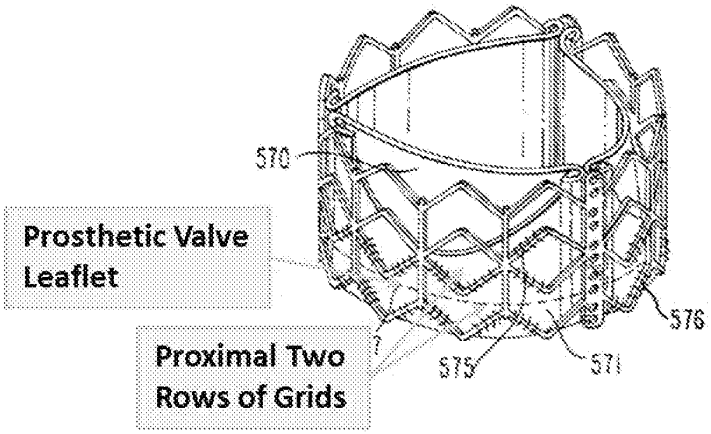
FIG. 22

(*Id.*, Fig. 22.) Thus, even fibers on one side of the valve "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly." (Ex. 1003, ¶248.)

9. Claim 9

If Walther's outer cloth or Spenser II's compressible material were added to Spenser's Figure 44a, the cloth/material would cover the proximal two rows of cells. (*Supra* §VIII.B.1.e.) The two circumferentially extending rows covered by the cloth/material would radially overlap with inner graft covering and prosthetic leaflets:

FIG. 44a

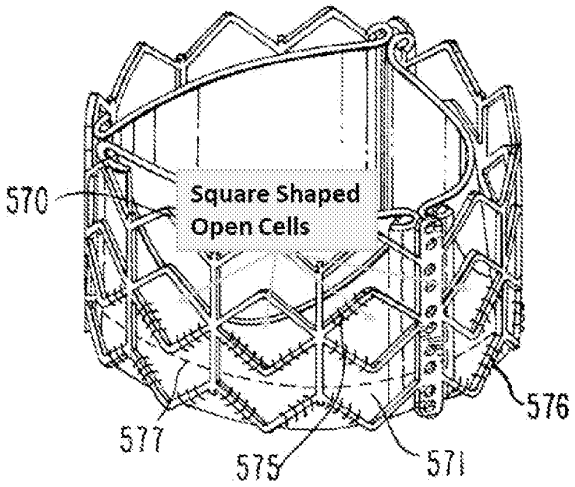


(*Supra* §VIII.B.6; Ex. 1003, ¶250.)

10. Claim 11

Figure 44a's outer frame comprises three rows of open cells, and the middle cells are a square shape:

FIG. 44a



(Ex. 1010, Fig. 44a; Ex. 1003, ¶256.)

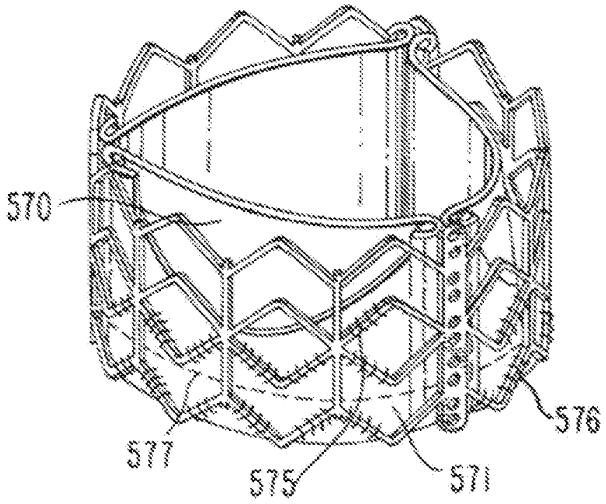
11. Claim 12

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶257-260.)

a. Walther

Walther's outer cloth is "free of a non-porous graft covering." (*Supra* §VIII.A.9.) Likewise, Spenser's Figure 44a does not have a "non-porous graft covering" on the exterior of the outer frame 575:

FIG. 44a



(Ex. 1010, Fig. 44a; Ex. 1003, ¶258.) Therefore, if Walther's outer cloth were added to Figure 44a's frame, there would be no "non-porous graft covering" between the outer cloth and the frame. (Ex. 1003, ¶258.)

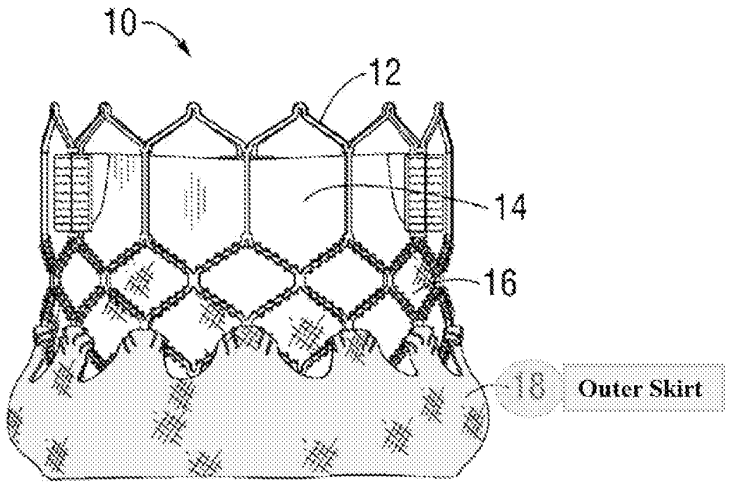
b. Spenser II

Spenser II's compressible material is also "free of a non-porous graft covering." (Ex. 1003, ¶259.) Spenser II's compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material[.]" (Ex. 1011, [00145].) Spenser II never discloses or pictures a "non-porous graft covering" as part of the compressible material. (Ex. 1003, ¶259.) Therefore, if Spenser II's compressible material were added to Figure 44a's frame there would be no "non-porous graft covering" between the fibers of the compressible material and the frame. (Ex. 1003, ¶¶259-260.)

C. Grounds 4-5: Claims 1-9, 12 Obvious in View of Levi And Walther or Spenser II

Levi discloses a valve having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame:

FIG. 3



(Ex. 1008, 13:50-66, Fig. 3.) Levi's inner and outer skirts extend beyond and over the proximal apices of the outer frame. However, as explained below, POSITAs would have found it obvious to substitute Walther's outer cloth or Spenser II's compressible material for Levi's outer skirt. Neither outer seal covers the ends of the proximal apices. Therefore, Levi in combination with Walther or Spenser II renders claims 1-9 and 12 obvious.

1. Claim 1

Levi and Walther or Spenser II renders claim 1 obvious. (Ex. 1003, ¶262.)

a. Preamble

Levi discloses this limitation. (Ex. 1003, ¶264.) Levi discloses "collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by

utilization of a self-expanding frame or stent." (Ex. 1008, 1:57-2:7; *see also id.*, 5:53-56, 6:46-49, 7:10-12, 14:60-64; Ex. 1051, 5:14-67, 28:37-48, Fig. 4.)

POSITAs would have understood that after replacing Levi's outer skirt with Walther's outer cloth or Spenser II's compressible material (*infra* §VIII.C.1.e), the resulting device would remain suitable for endovascular delivery. (Ex. 1003, ¶267.) POSITAs would have understood that even if the substitution slightly increased the valve's diameter, the valve could still be endovascularly delivered through the common iliac artery. (*Id.*; Ex. 1043; *supra* §VIII.A.1.a.)

Moreover, Levi discloses that "[w]hen crimped, the frame 12 has a reduced diameter region extending along a portion of the frame…that generally corresponds to the region of the frame covered by the outer skirt 18" so that the outer skirt "does not increase the overall crimp profile of the valve." (Ex. 1008, 8:46-54; *see also id.*, 2:22-35, 14:22-35, 16:38-45, 17:14-18.) Walther's outer cloth or Spenser II's compressible material would also cover the reduced diameter region, ensuring that the outer cloth/compressible material would not disadvantageously increase the crimp profile. (*Id.*, 8:46-54; Ex. 1003, ¶268.)

Levi also suggests adding other components to the inflow portion of the outer frame, stating "if additional components are mounted to that portion of the valve…the reduced profile of that portion of the valve can help offset or minimize

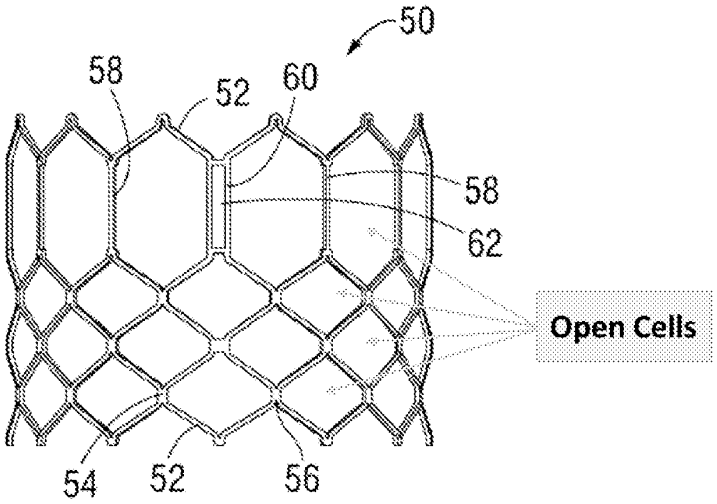
the increase in diameter caused by the additional component." (Ex. 1008, 16:41-45.) POSITAs would have understood that Walther's outer cloth or Spenser II's compressible material would be potential "additional components." (Ex. 1003, ¶271.)

Levi also discloses other features to enable endovascular delivery. (*Id.*, ¶269.) For example, Levi's frame is preferably constructed of nickel-cobalt-chromium-molybdenum alloy, which allows for a thinner frame so that "the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body." (Ex. 1008, 6:46-49; *see also id.*, 7:10-12.) Levi discloses that "[b]y minimizing the diameter of the valve when mounted on the delivery shaft," "the assembly can ***[be] contained within a smaller diameter catheter and thus can be passed through smaller vessels in the body*** and can be less invasive in general." (*Id.*, 14:60-64 (emphasis added).) For these reasons, POSITAs would have reasonably expected success in endovascularly delivering Levi's valve with Walther's outer cloth or Spenser II's compressible material. (Ex. 1003, ¶¶267-271.)

b. Outer Frame

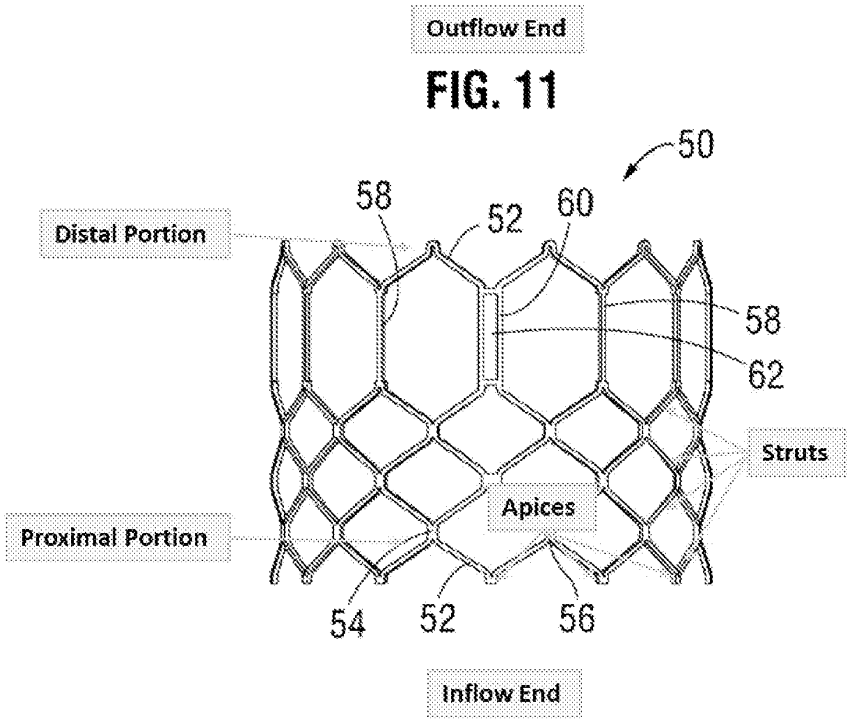
Levi discloses an expandable metal frame that defines an open cell configuration:

FIG. 11



(Ex. 1008, 6:17-24, Fig. 11.) The frame surrounds the other valve components and, therefore, is an "outer frame." (Ex. 1003, ¶273.)

Levi's frame includes an inflow end at its proximal portion and an outflow end at its distal portion. (Ex. 1008, 6:50-58, Fig. 11; Ex. 1003, ¶274.) The frame is formed from a plurality of struts that adjoin at the inflow end of the frame to form apices:



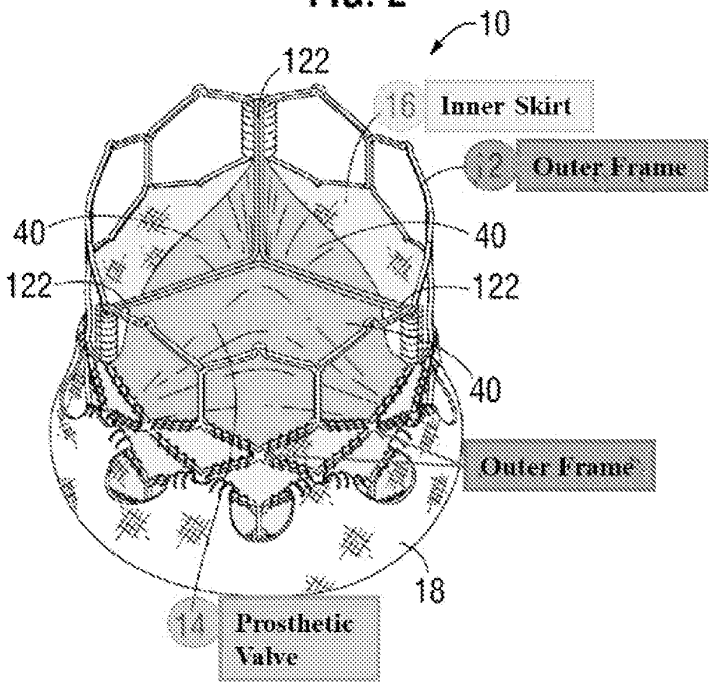
(Ex. 1008, 6:50-9:6, Fig. 11; Ex. 1003, ¶274.)

c. Inner Frame

Levi discloses an "inner skirt 16 . . . to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets." (Ex. 1008, 9:7-11.) The inner skirt is constructed of "a tough, tear resistant material such as polyethylene terephthalate (PET)[.]" (*Id.*, 9:11-16.) PET is a "graft covering." (Ex. 1003, ¶276.) The inner skirt is engaged to the valvular structure (prosthetic leaflets) "via one or more thin PET reinforcing strips[.]" (Ex. 1008, 9:25-29.) Levi's inner skirt 16 [yellow] cylindrically

extends at least partially radially outwardly of the prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red]:

FIG. 2

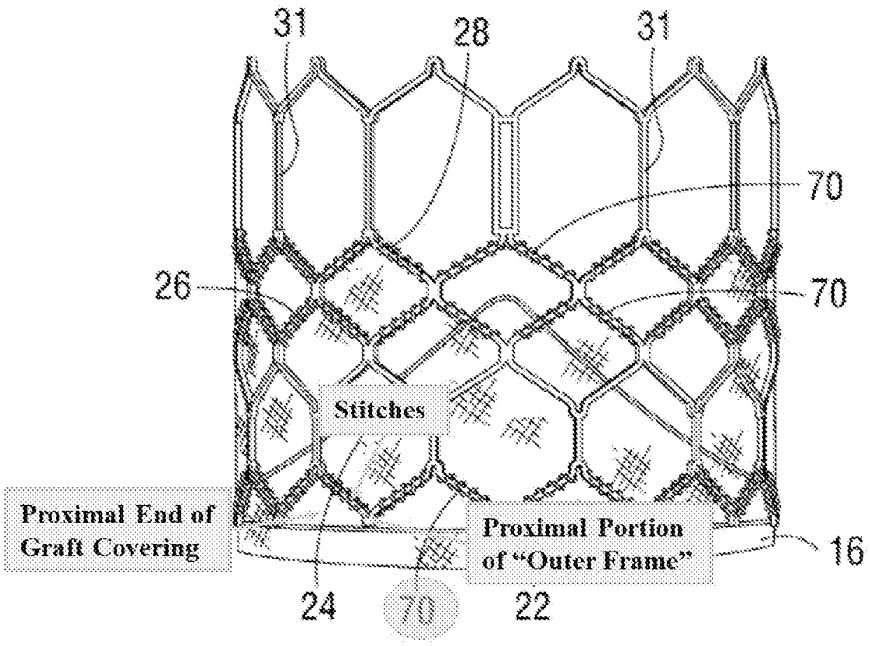


(*Id.*, Fig. 2; Ex. 1003, ¶276.)

d. Stitching

Levi's inner skirt is secured to the proximal portion of the frame with stitches from suture 70:

FIG. 20



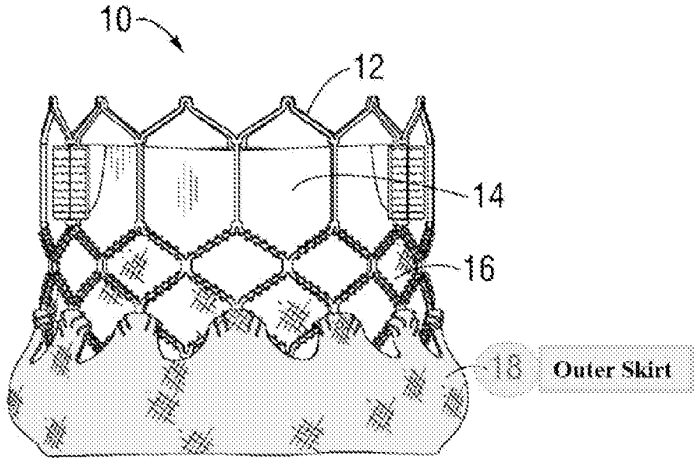
(Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39.)

e. Outer Seal

Levi and Walther or Spenser II renders this limitation obvious. (Ex. 1003, ¶¶279-291.)

Levi discloses an outer skirt of woven PET fabric [yellow] attached to the exterior of the outer frame for preventing PVL. (Ex. 1008, 13:50-53, 13:62-66, Fig. 3.)

FIG. 3



Walther's outer cloth and Spenser II's compressible material satisfy the "outer seal" limitations as explained previously. (*Supra* §§VIII.A.1.e, VIII.B.1.e.) POSITAs would have known that Levi's outer skirt, Walther's outer cloth, and Spenser II's compressible material were interchangeable. (Ex. 1003, ¶¶282, 288.) While the specific materials have slightly different constructions, they were all designed for use with balloon-expandable heart valves to prevent PVL and could sufficiently compensate for any elongating or foreshortening of the valve frame during compression and expansion. (*Id.*; Ex. 1007, 1122; Ex. 1011, [00144], Ex. 1008, 6:17-28.)

A finite number of methods to address PVL existed in November 2012. (Ex. 1003, ¶¶283, 289.) Walther, Spenser II, and Levi disclose three such methods. (*Id.*) POSITAs would have found it obvious to select any one of these finite, predictable

solutions and, as discussed below, would have reasonably expected success in doing so. (*Id.*) Further, POSITAs would have found it obvious to try each material because the different constructions provide unique potential advantages. (*Id.*) For example, Walther discloses that its fibrous outer cloth promotes tissue ingrowth. (Ex. 1007, 1120.) Spenser II's compressible material "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [00145].) Ultimately, the combination of Levi with Walther or Spenser II would have merely entailed substitution of one known element (outer cloth/compressible material) for another (Levi's outer skirt) to yield the predictable results of reducing PVL. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶¶282, 288.)

POSITAs would have reasonably expected success in substituting Walther's outer cloth or Spenser II's compressible material for Levi's outer skirt. (Ex. 1003, ¶¶284-286, 290-291.) The valve frames in Walther, Spenser II, and Levi share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. (*Id.*) Further, Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that in-patient implantation of the valve "is feasible," suggesting that other cloth-covered valves would achieve similar success. (Ex. 1007, 1125; Ex. 1003, ¶¶284, 290.)

Moreover, Levi suggests adding other components, like an outer skirt or seal, to the inlet of the outer frame. (*Supra* §VIII.C.1.a.) Levi also discloses methods to reduce the frame's diameter at the inlet, or to modify the leaflets to reduce the frame size, to create room for an outer seal. (Ex. 1008, 16:24-17:18.) POSITAs would have understood they could utilize one or more of these methods to add Walther's outer cloth or Spenser II's compressible material to Levi's frame instead of the outer skirt. (Ex. 1003, ¶¶285, 291.)

f. Radially Compressed and Expanded Orientation

Levi's valve is "radially collapsible and expandable." (Ex. 1008, Abstract, 6:20-24.)

g. Fibers Press Against Native Leaflets

Levi and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶295-297.) Levi's valve "is adapted to be implanted in the native aortic annulus" and has an outer skirt that will "fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." (Ex. 1008, 5:52-54, 14:3-7.) When the outer skirt "fills in gaps between the frame 12 and the surrounding native annulus," the outer skirt would also press against the native aortic leaflets, which are attached to the annulus. (Ex. 1003,

¶296.) Patent Owner has previously admitted that Levi's outer skirt would "extend[] into crevices created by the native leaflets." (Ex. 1046, 21.)

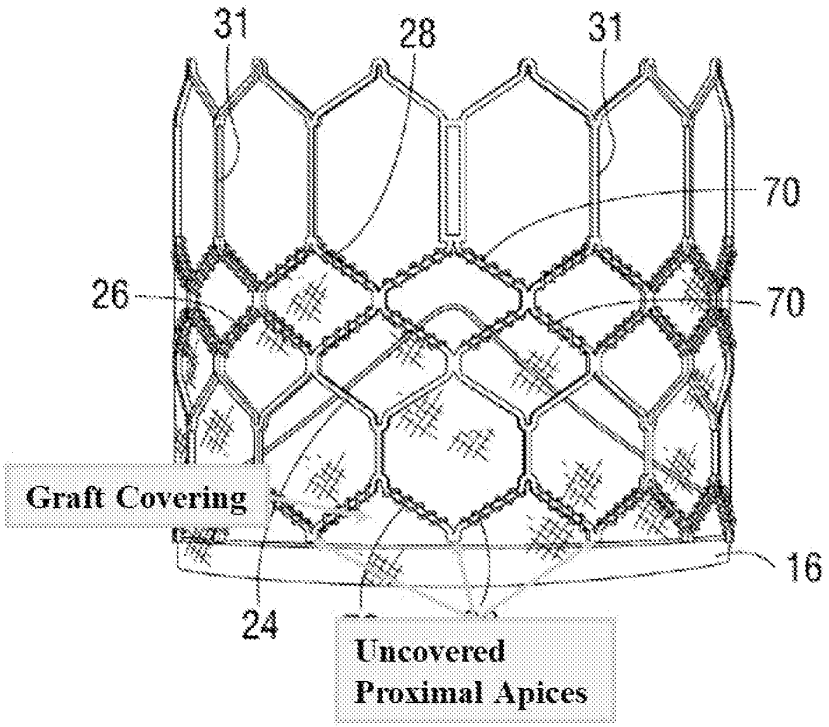
If Levi's outer skirt were replaced with Walther's outer cloth or Spenser II's outer compressible material, the fibers of the outer cloth/compressible material, rather than the outer skirt, would press against the native leaflets as explained in Grounds 1-3. (*Supra* §§VIII.A.1.g, VIII.B.1.g.)

h. Uncovered Proximal Apices

Levi and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶298-300.)

As shown below, Levi's inner skirt extends beyond, but does not expressly cover, the most proximal apices of the frame:

FIG. 20



(Ex. 1008, Fig. 20.)

Walther and Spenser II disclose an outer seal that does not cover the ends of the most proximal apices of their outer frames. (*Supra* §§VIII.A.1.h; VIII.B.1.h.) POSITAs would have been motivated to position the outer cloth/compressible material on Levi's valve in the same way because Walther and Spenser II teach that such positioning is effective for creating a seal. (Ex. 1003, ¶300.) Moreover, Levi discloses methods of reducing the diameter of the valve at the inflow end to make

space for an outer seal like the ones disclosed in Walther and Spenser II. (*Supra* §§VIII.C.1.a-e.)

i. Proximal Apices Extend More Proximally than Outer Seal

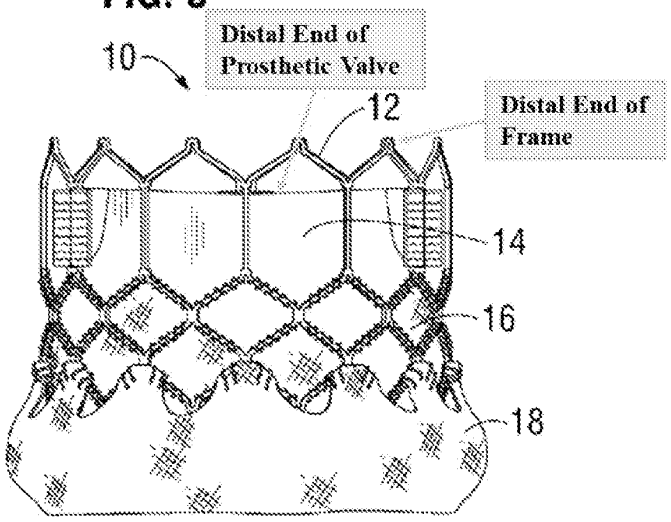
Levi and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶301-302.)

POSITAs would have found it obvious to adjust the size and placement of the Walther's outer cloth or Spenser II's compressible material such that the most proximal apices of Levi's outer frame extend proximally further than the outer cloth for the same reasons explained in the previous section and Grounds 1-3. (*Supra* §§VIII.A.1.i, VIII.B.1.i, VIII.C.1.i.)

2. Claim 2

Levi discloses that "[t]o protect against over-expansion of the leaflet structure 14," Levi teaches that the "***leaflet structure desirably is secured to the frame 12 below the upper row of struts 32***." (Ex. 1008, 8:11-13 (emphasis added).) As shown below, the frame 12 extends distally further than the prosthetic valve 14:

FIG. 3

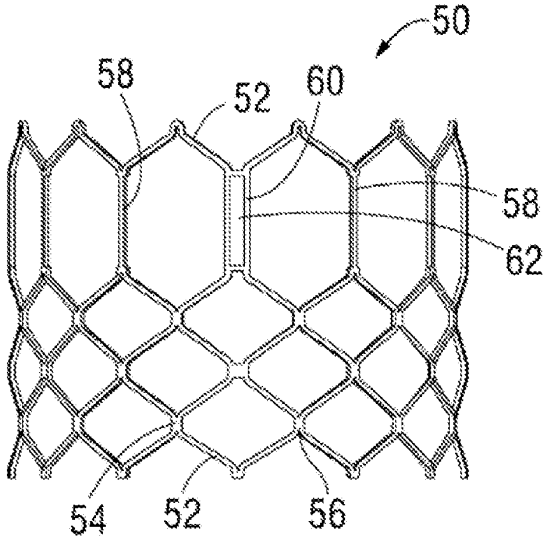


(*Id.*, Fig. 3; Ex. 1003, ¶304.)

3. **Claim 3**

Levi's outer frame is a singular, integral component:

FIG. 11



(Ex. 1003, ¶¶306-307; *see also* Ex. 1008, 6:50-7:17, 9:4-6, Figs. 4-14.)

4. Claim 4

If Levi's outer skirt were replaced with Walther's outer cloth or Spenser II's compressible material, the outer cloth/compressible material and Levi's inner skirt would be "distinct elements" at least because the elements would be positioned on opposite sides of the outer frame and separately attached thereto. (Ex. 1003, ¶310.)

5. Claim 5

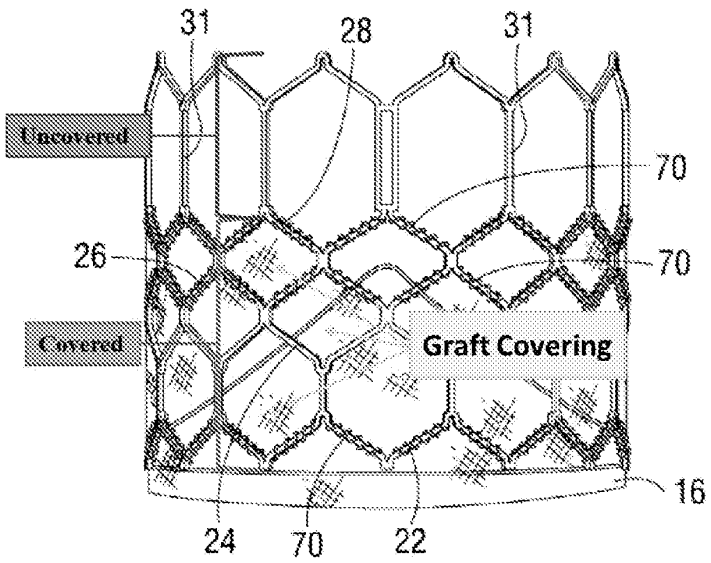
Levi's inner skirt assists "in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of the frame 12 below the lower edge of the leaflets." (Ex. 1008, 9:7-11.)

6. Claim 6

Levi and Walther or Spenser II renders this claim obvious. (Ex. 1003, ¶¶313-315.)

Levi's inner PET skirt does not cover the top row of cells of the frame:

FIG. 20

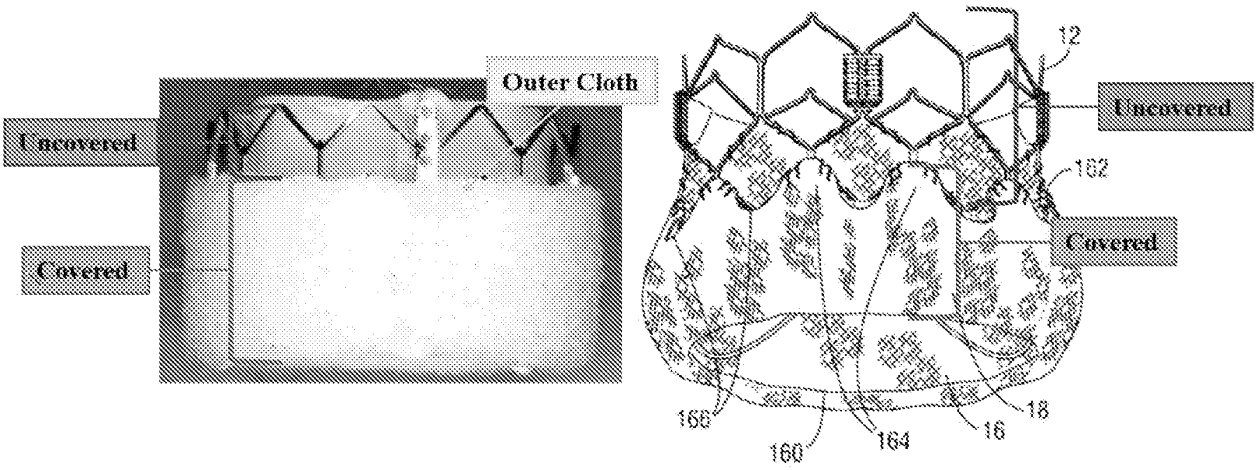


(Ex. 1008, Fig. 20; Ex. 1003, ¶315.)

a. Walther

Walther's outer cloth does not cover a portion of SAPIEN's frame. (*Supra* §VIII.A.5.) If Walther's outer cloth were substituted for Levi's outer skirt, the cloth ***would not*** cover at least the uppermost row of cells:

FIG. 42

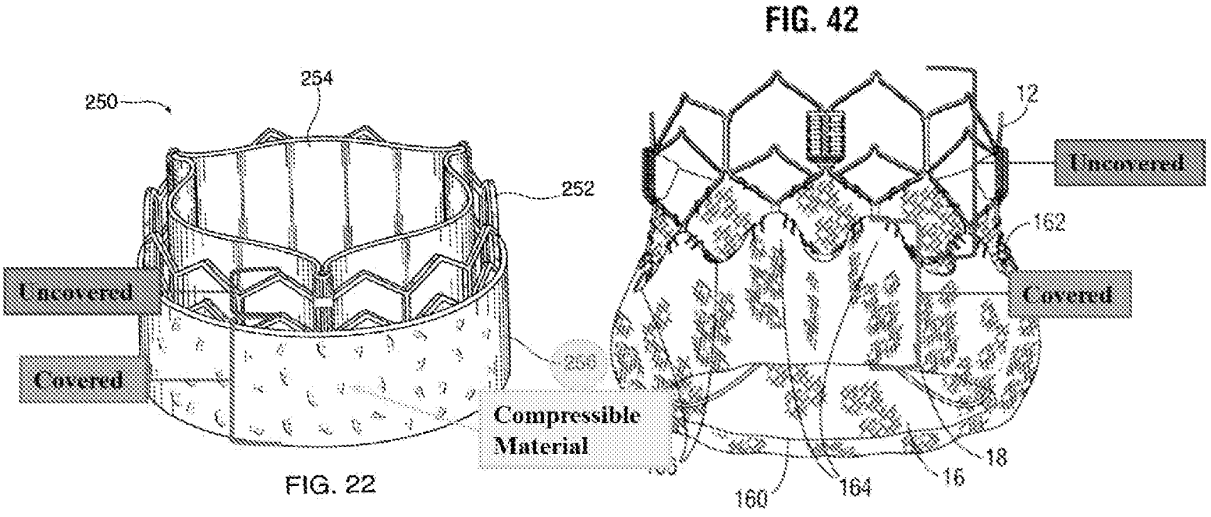


(Ex. 1007, Fig. 1; Ex. 1008, Fig. 42; Ex. 1003, ¶316.) POSITAs would have been motivated to position the outer cloth as to not cover at least the uppermost row of cells, for example, to minimize the risk of blocking the patient's coronary arteries, which are located distally from the aortic valve. (Ex. 1003, ¶316.)

Therefore, Levi combined with Walther would yield a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (*Id.* ¶317.)

b. Spenser II

Spenser II's compressible material does not cover a portion of the stent structure 252. (*Supra* §VIII.B.6.) If Spenser II's compressible material were substituted for Levi's outer skirt, the cloth ***would not*** cover at least the uppermost row of cells:



(Ex. 1011, Fig. 22; Ex. 1008, Fig. 42; Ex. 1003, ¶318.) POSITAs would have been motivated to position the compressible material this way to avoid blocking the patient's coronary arteries, as explained in the preceding section. (Ex. 1003, ¶318.)

Therefore, the combination of Levi and Spenser II would yield a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (*Id.*¶319.)

7. Claim 7

This claim is substantially similar to claim 2. (Ex. 1003, ¶320.) Levi discloses this limitation for the reasons provided in claim 2. (*Supra* §VIII.C.2.)

8. Claim 8

Levi and Walther or Spenser II renders this claim obvious. (Ex. 1003, ¶¶321-322.)

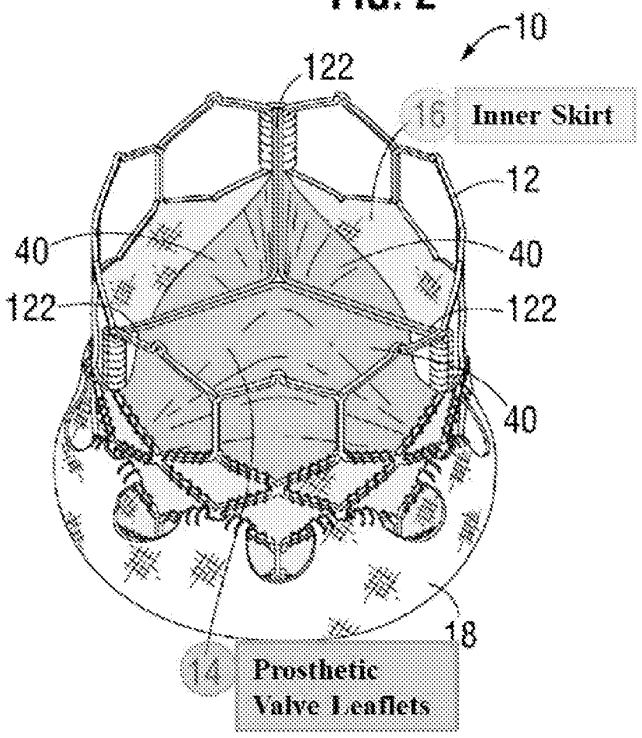
If Walther's outer cloth or Spenser II's compressible material were substituted for Levi's outer skirt, the resulting valve would include fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve" for the reasons previously stated. (*Supra* §§VIII.A.6, VIII.B.8; Ex. 1003, ¶322.)

9. Claim 9

Levi and Walther or Spenser II renders this claim obvious. (Ex. 1003, ¶323-326.)

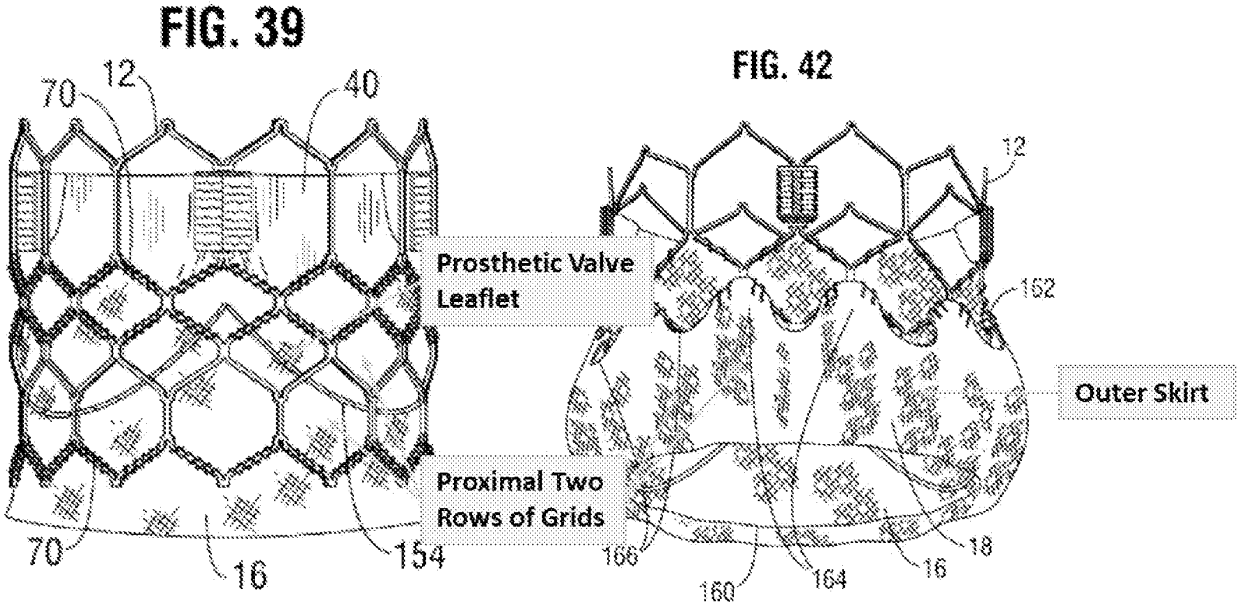
Levi's inner skirt 16 [yellow] radially overlaps with the leaflets of the prosthetic heart valve 14 [blue]:

FIG. 2



(Ex. 1008, Figs. 2, 3; Ex. 1003, ¶324.)

Similarly, Levi's outer skirt which covers the proximal two rows of cells also radially overlaps with the prosthetic leaflets:



(Ex. 1008, Figs. 39, 42; Ex. 1003, ¶325.)

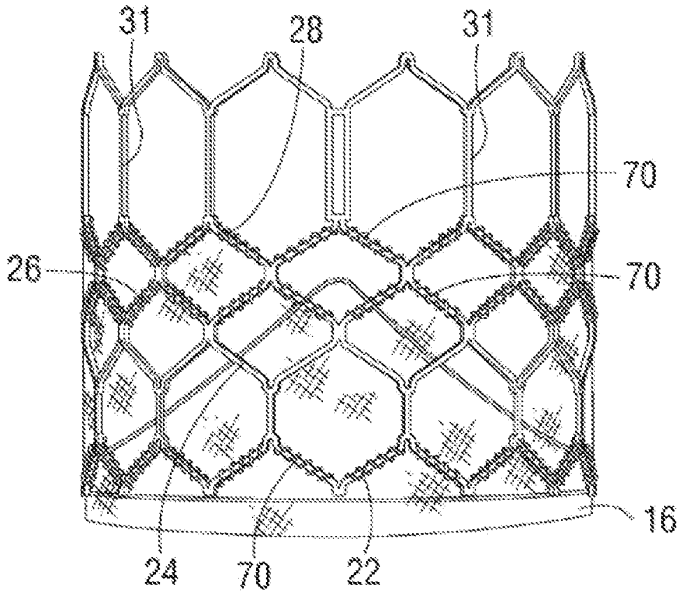
Walther and Spenser II disclose an outer seal that covers the bottom rows of the stent frame, which radially overlap with the prosthetic leaflets. (Ex. 1007, 1121, Fig. 1; Ex. 1011, [00145], Fig.22; *supra* §§VIII.A.9, VIII.B.11.) POSITAs would have been motivated to attach Walther's outer cloth or Spenser II's compressible material to Levi's outer frame in the same way, and would have expected success in doing so, because the references demonstrate that covering the bottom rows of the frame is effective at creating a seal. (Ex. 1003, ¶326.) In the combined device, the outer seal, graft covering, and prosthetic leaflets would radially overlap. (*Id.*)

10. Claim 12

Levi and Walther or Spenser II renders this claim obvious. (Ex. 1003, ¶¶327-328.)

If Levi's outer skirt were replaced with Walther's outer cloth or Spenser II's compressible material, there would be no "non-porous graft covering" between the outer cloth/compressible material and the outer frame. (Ex. 1003, ¶328.) As shown below, Levi does not include any "non-porous graft covering" on the exterior of the outer frame.

FIG. 20



(Ex. 1008, Fig. 20; Ex. 1003, ¶328.) Likewise, neither Walther's outer cloth nor Spenser II's compressible material includes such a graft covering. (Ex. 1003, ¶328; *supra* §§VIII.A.9, VIII.B.11.)

IX. SECONDARY CONSIDERATIONS

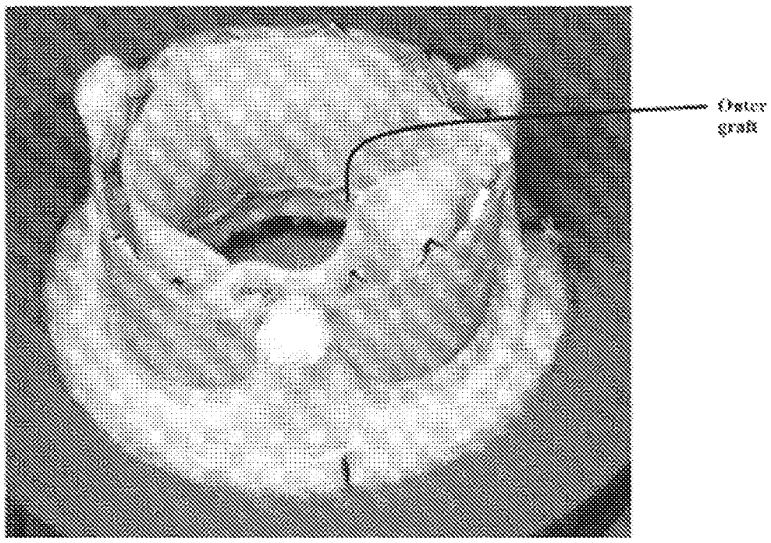
Petitioner understands that Patent Owner does not practice the '735 patent or sell any products covered by the '735 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶329-330.) If Patent Owner identifies any evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

X. THE BOARD SHOULD NOT DENY INSTITUTION UNDER §325(d)

Cribier and Spenser, which describe Petitioner's SAPIEN THV and similar valves, were not of record during prosecution. Spenser's parent's publication, Pub. No. US 2003/0153974, was listed on an IDS, but the publication does not disclose Spenser's Figure 44a relied on herein. (*Compare* Exs. 1010, 1026.) Because Cribier and Spenser were never before the Examiner, the Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d).

Patent Owner characterized Walther, Spenser II, and Levi in amendments filed during prosecution. However, the Examiner never applied the references, and Patent Owner's characterizations were incomplete and/or inaccurate. (Ex. 1003,

¶¶88-96.) For example, Patent Owner inaccurately argued that Walther's outer cloth is "wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets where the base/outer graft is then stitched to the metallic frame" to support its argument that Walther does not teach uncovered proximal apices or that the apices extend proximally further than the outer seal. (Ex. 1002, 29.) Patent Owner included the annotated version of Walther's Figure 2 below to allegedly illustrate where Walther's outer cloth is stitched to the inside of the valve:



(*Id.*, 30 (annotated version of excerpt of Ex. 1007, Fig. 2).)

Yet, Walther discloses that the outer cloth is "stitched onto the ***perimeter*** of each SAPIEN valve." (Ex. 1007, 1121 (emphasis added).) The below figures show the outer cloth's position:

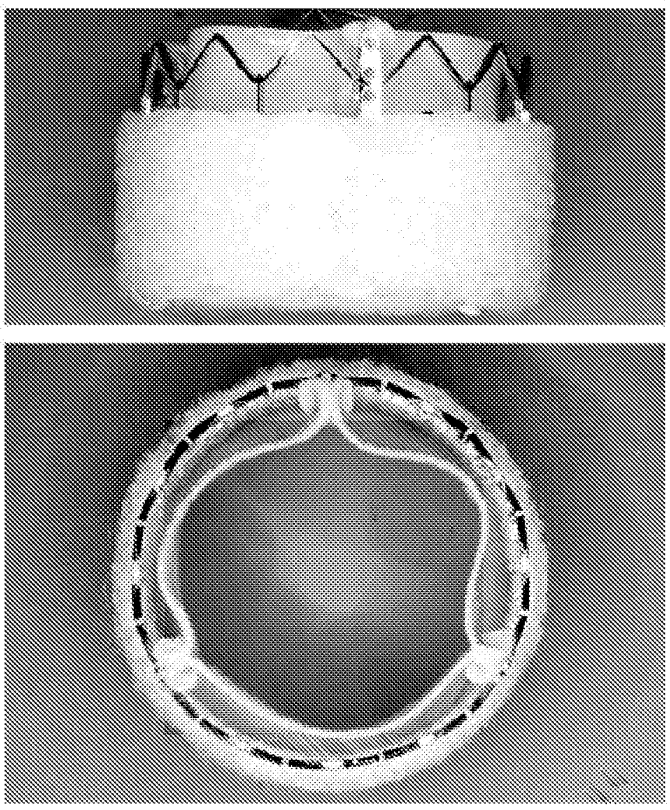


Fig. 1. Cloth valve.

(*Id.*, 1121, Fig. 1.)

The material Patent Owner labeled "Outer graft" in Walther's Figure 2 (above) does not correspond to the "outer graft," but a polytetrafluoroethylene (PTFE) suture that attaches the valve leaflets and inner fabric cuff to the frame. (Ex. 1012, Fig. 1; Ex. 1027 (Roselli) at 213; Ex. 1003, ¶94.) A higher-quality version of Walther's Figure 2 shows that the outer cloth is not flipped up into, and stitched to, the interior of the valve at the suture line identified by Patent Owner:

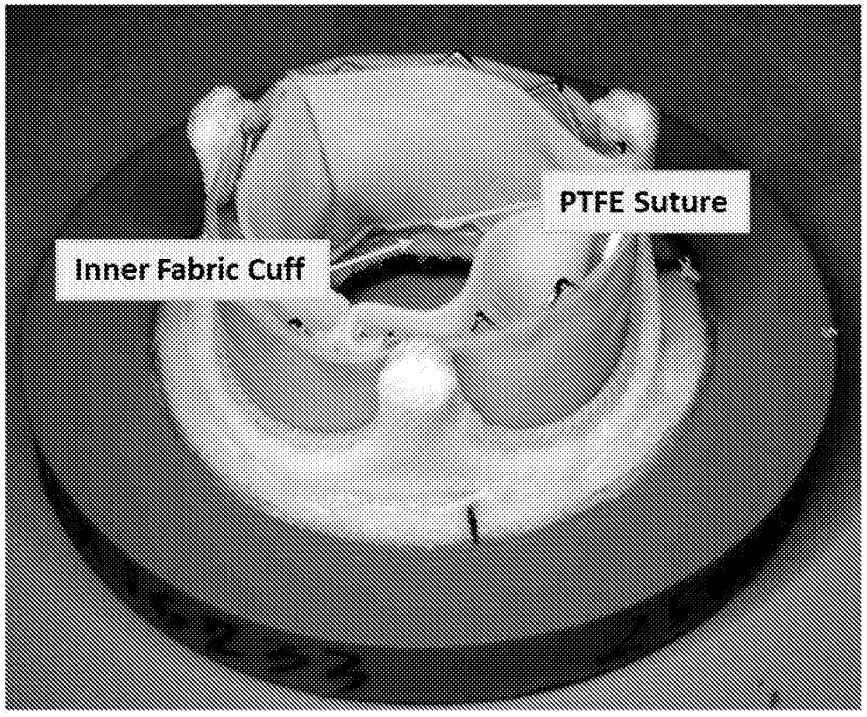
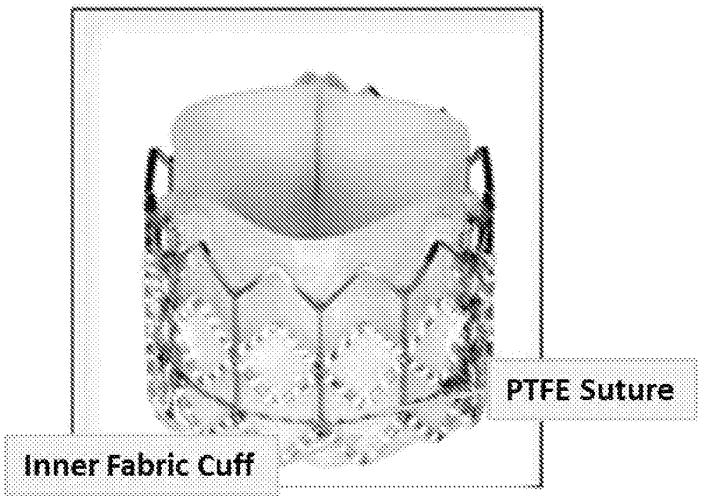


Fig. 2. Cloth THV valve deployed in surgical valve.

(Ex. 1007, Fig. 2.)

The same suture (green) identified by Patent Owner in Figure 2 is also visible on the outside of SAPIEN with no outer cloth, further demonstrating that the suture is not related to the "outer graft," as argued by Patent Owner.



(Ex. 1012, Fig. 1.)

Patent Owner also provided an incomplete description of Spenser II during prosecution.[8] Patent Owner admitted that Spenser II "teaches an outer seal where a most proximal end of the stent frame is uncovered." (Ex. 1002, 273.) However, Patent Owner also argued that Spenser II "appears to not teach that the seal extends partially over at least two most proximal rows of cells," as required by claim 1 of the '735 patent, and included the below figure:

[8] During prosecution, Patent Owner referred to the PCT Publication WO2006005015 referred to herein as "Spenser II" as "Spenser."

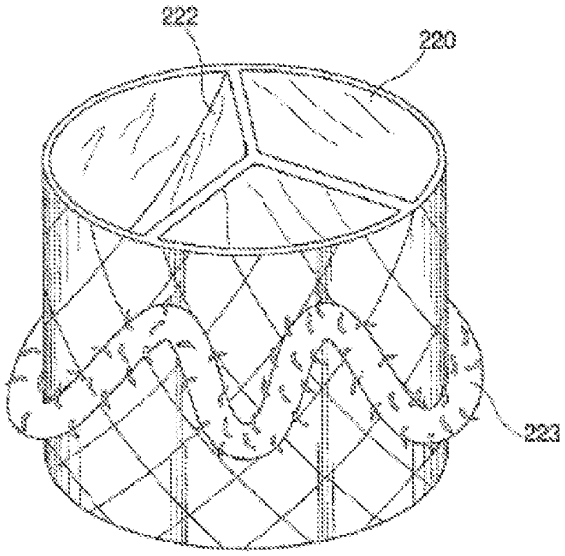


FIG. 21

(*Id.*, 273-274.) However, Patent Owner omitted the most relevant embodiment from Spenser II. Figure 22 discloses a valve having an outer seal that "extends partially over at least [the] two most proximal rows of cells" of the valve as required by the claims:

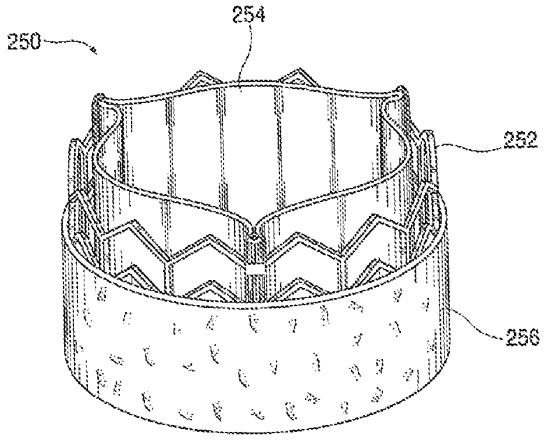


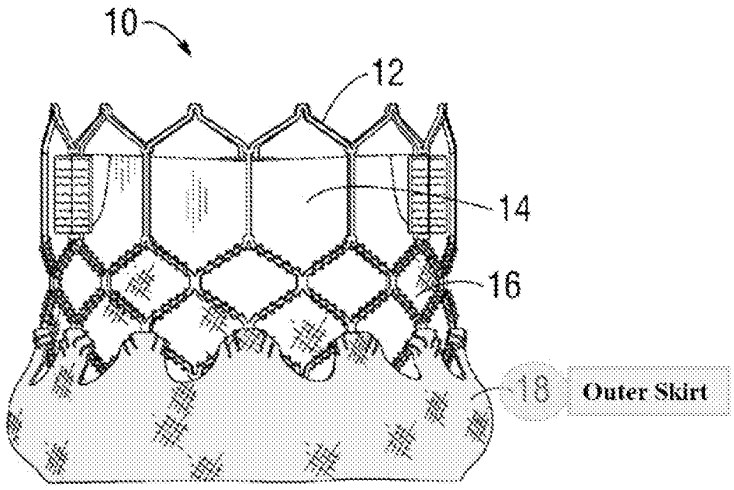
FIG. 22

(Ex. 1011, Fig. 22.) Thus, Spenser II's Figure 22 directly contradicts Patent Owner's representations.

Patent Owner also argued that Spenser II "appears to be missing an inner graft, though it is not clear." (Ex. 1002, 273.) As discussed herein, even if Spenser II does not explicitly disclose an "inner graft," POSITAs would have found it obvious to combine Spenser II's outer seal with valves having "inner grafts," such as those described in Cribier, Spenser, or Levi. (*Supra* §VIII.B-C.) Neither Patent Owner nor the Examiner ever addressed the combination of Spenser II with any other reference. *REG Synthetic Fuels, LLC v. Neste Oil, Oyj*, IPR2018-01375, Paper 36, 12-14 (PTAB Feb. 19, 2019) (declining to deny institution under §325(d) where the Examiner did not consider the combination of references asserted by the Petitioner).

Patent Owner also argued that Levi is distinguishable because Levi's outer skirt "billows outwardly and around the apices of the stent frame." (Ex. 1002, 275.)

FIG. 3



Patent Owner did not address the combination of Levi with Walther or Spenser II proposed herein, however. As previously explained, POSITAs would have found it obvious to substitute Walther or Spenser II's outer seal for Levi's outer skirt such that the proximal apices are uncovered. (*Supra*§VIII.C.1.h-i.) Neither Patent Owner nor the Examiner ever addressed any modifications to Levi or combinations of Levi with any other reference. *REG Synthetic Fuels*, IPR2018-01375, Paper 36, 12-14.

For the above reasons, the Board should not deny institution under §325(d) based on Patent Owner's characterizations of Walther, Spenser II, and Levi during prosecution. As shown, several of the characterizations were inaccurate and/or incomplete, and neither Petitioner nor the Examiner ever addressed the obviousness arguments raised herein. *Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining to deny institution under

§325(d)). Nor is there any indication in the record that the Examiner substantively considered any of the references asserted herein. *Solvay USA Inc. v. WorldSource Enterprises, LLC*, IPR2020-00768, Paper 12, 8-9 (PTAB Sept. 25, 2020) (declining to deny institution under §325(d) where the record did not reflect "any substantive consideration" of the asserted references by the Examiner); *REG Synthetic Fuels*, IPR2018-01375, Paper 36, 13 ("[T]he mere listing of a reference . . . on an information disclosure statement . . . does not amount to substantive consideration of that reference by the Examiner.").

XI. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Edwards Lifesciences Corp. and Edwards Lifesciences LLC are the real parties in interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner has filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,792,172 ("'172 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01527 (Filed Sept. 10, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,857,011 ("the '011 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28,

2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,966,846 ("'the '846 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00034 (Filed Oct. 11, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,881,538 ("the '538 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00193 (Filed Nov. 11, 2021). The '735 patent is part of the same patent family and shares a specification with the '172, '011,'846, and '538 patents.

Patent Owner also recently filed suit against Petitioner alleging infringement of the '735 patent, '538 patent, the '846 patent, and U.S. Patent No. 10,987,236 by Petitioner's SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1:21-CV-01377 (D. Del., filed Sept. 28, 2021). When this Petition was filed, the Complaint, associated papers, a Motion to Dismiss filed by Petitioner, and an Opposition to the Motion to Dismiss filed by Patent Owner were the only documents filed in the case. The court has set a hearing on the Motion to Dismiss for March 10, 2022.

Petitioner is not aware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com BoxEdwards21-7@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxEdwards21-7@knobbe.com.

XII. FEES

The fee for this petition has been paid. Any additional fees may be charged to Deposit Account 11-1410.

XIII. GROUNDS FOR STANDING UNDER 37 C.F.R. §42.104

Petitioner certifies that the '735 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims on the identified grounds.

XIV. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that the challenged claims are unpatentable as anticipated or obvious and, therefore, requests that the Board institute an *inter partes* review and cancel the challenged claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 4, 2022

By: */Joshua J. Stowell/*
Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,129,735**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,935 words and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 4, 2022

By: */Joshua J. Stowell/*
Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,129,735** and **EXHIBITS 1001 – 1070** are being served on, February 4, 2022 via Federal Express overnight mail on counsel of record for U.S. Patent 11,129,735 as addressed below:

Justin Nifong
NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

Dated: February 4, 2022 By: */Joshua J. Stowell/*

Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

Electronic Patent Application Fee Transmittal

Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
PETITION FEE-37CFR 1.17(H) (GROUP II)	2464	1	70	70
RCE- 2ND AND SUBSEQUENT REQUEST	2820	1	1000	1000
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1070**

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Decision Date : February 15, 2022

In re Application of :

Ali Shahriari

DECISION ON PETITION
UNDER CFR 1.313(c)(2)

Application No : 17327673

Filed : 22-May-2021

Attorney Docket No : 426/2/23 UTIL

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed February 15, 2022 , to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

This application file is being referred to Technology Center AU 3774 for processing of the request for continuing examination under 37 CFR 1.114 .

Office of Petitions

Electronic Acknowledgement Receipt	
EFS ID:	44995477
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	15-FEB-2022
Filing Date:	22-MAY-2021
Time Stamp:	06:12:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1070
RAM confirmation Number	E20222E712411355
Deposit Account	506191
Authorized User	Justin Nifong
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	ePetition Request Form	petition-request.pdf	39915 dbbe0f9b01d24fa5633cd212a345a834771 49389	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	qpids-rce-transmittal.pdf	1667122 49380731ff4cc42f48dc00508b464bb0963f 6310	no	3
Warnings:					
Information:					
3	Quick Path Information Disclosure Statement	sb0009.pdf	178529 60cb2e1ec1aed80eb87e599671bb505231c 5cae3	no	2
Warnings:					
Information:					
4	Quick Path Information Disclosure Statement	426-2-23UTIL-qpids-ids.pdf	1034404 ffe705364277ac415e10a4d1ca9924b4a9f4f c0f	no	1
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	1a613fbb-e774-4d09-b51d-c5fa4dfffd58.pdf	10148956 e2b6ec4750e76a8fd6d7ae2e3af095aa231d bc8e	no	188
Warnings:					
Information:					
6	Other Reference-Patent/App/Search documents	fe6e2679-e6a6-4f45-bf8d-9a41bbc793c5.pdf	14635490 8cbe55837416a41d7b32f9665cdc82a25ec 0627a	no	210
Warnings:					
Information:					

7	Other Reference-Patent/App/Search documents	14a10e5d-cdf3-4f3c-bc60-2599fbce8995-printed.pdf	11978489 98bd8f0402579a69fdbd8a1b21bb6b8587dc31ad	no	128
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	09065527-8b39-4b77-a79a-78c92bda4469-printed.pdf	17510100 2bd86c582c0375061918ef3d2f927e76e1099faa	no	148
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	40292 9663334974 38d8740a663da1770d2342d5512c89	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	57233297		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PET.AUTO Document Description: Petition automatically granted by EFS-Web	PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)**
Application Number	17327673
Filing Date	22-May-2021
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	
Attorney Docket Number	426/2/23 UTIL
Title	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:
(1) Petition fee; and
(2) One of the following reasons:
(a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

Petition Fee

◉	Small Entity
○	Micro Entity
○	Regular Undiscounted

Reason for withdrawal from issue

◯ One or more claims are unpatentable ◉ Consideration of a request for continued examination (RCE) (List of Required Documents and Fees) ◯ Applicant hereby expressly abandons the instant application (any attorney/agent signing for this reason must have power of attorney pursuant to 37 CFR 1.32(b)).	
RCE request,submission, and fee. ☐ I certify, in accordance with 37 CFR 1.4(d)(4) that : The RCE request ,submission, and fee have already been filed in the above-identified application on ☒ Are attached.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application. ◯ An attorney or agent registered to practice before the Patent and Trademark Office, acting in a representative capacity. ◯ A sole inventor ◯ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ◯ A joint inventor; all of whom are signing this e-petition	
Signature	/Justin R. Nifong/
Name	Justin R. Nifong
Registration Number	59389

Doc Code: QPIDS.REQ
Document Description: QuickPath Information Disclosure Statement

PTO/SB/09 (09-18)

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM

Non-Provisional Application Number: 17327673	Filing Date: 05/22/2021
First Named Inventor: Ali Shahriari	Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION.

1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee.
2. Check the box next to the appropriate selection:

   ☐ Each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(1).

   OR

   ☑ No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2).

   OR

   ☐ See attached certification statement in compliance with 37 CFR 1.97(e).
3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. _____.
4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a **Web-based ePetition**. **WARNING:** Do not submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE.
5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith.
6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned.
7. This certification and request is being filed as a **Web-based ePetition** and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.

Signature /Justin R. Nifong/	Date 2/15/2022
Name (Print/Typed) Justin R. Nifong	Practitioner Registration Number (If applicable) 59389

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.**

☐ *Total of _____ forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 02/09/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
02/09/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Response to Rule 312 Communication	Application No.	Applicant(s)	
	17/327,673	Shahriari, Ali	
	Examiner	Art Unit	AIA (FITF) Status
	TIFFANY P SHIPMON	3774	No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☑ The amendment filed on 26 January 2022 under 37 CFR 1.312 has been considered, and has been:
   a) ☑ entered.
   b) ☐ entered as directed to matters of form not affecting the scope of the invention.
   c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
      Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.
   d) ☐ disapproved. See explanation below.
   e) ☐ entered in part. See explanation below.

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	/THOMAS C BARRETT/ MQAS, TC 3700

OK TO ENTER: /T.P.S/ 02/02/2022

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENTS AFTER NOTICE OF ALLOWANCE UNDER 37 C.F.R. RULE 1.312

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
17327673	22-May-2021	Ali Shahriari	426/2/23 UTIL	1189

TITLE OF INVENTION :

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Small	Utility under 35 USC 111(a)	3774	001200	

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$600	$0	$600	25-Apr-2022	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
175373 Aortic Innovations, LLC 4917 Waters Edge Drive, Suite 275 Raleigh NC 27606 UNITED STATES 919-348-2194 usptomail@nkpatentlaw.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

◉ Applicant asserting small entity status. See 37 CFR 1.27.
Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

○ Applicant changing to regular undiscounted fee status.
Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee	☐ I authorize USPTO to apply my previously paid issue fee to the current fees due
☐ Publication Fee	☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____
☐ Advance Order - # of copies _____	☒ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number 50-6191 . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. NK Patent Law
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

Name	City	State	Country	Category
Aortic Innovations, LLC	Hillsboro Beach	FLORIDA	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Justin R. Nifong/	**Date**	01-26-2022
Name	Justin Robert Nifong	**Registration Number**	59389

Electronic Patent Application Fee Transmittal

Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong/Sandra Hess
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPL ISSUE FEE	2501	1	600	600
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt	
EFS ID:	44841295
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	26-JAN-2022
Filing Date:	22-MAY-2021
Time Stamp:	15:16:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E20221PF16380520
Deposit Account	506191
Authorized User	Sandra Hess
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.20 (Post Issuance fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	62738 cac006e27086a727c726e2afe9bb350e0760eb0f	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40204 8d1b9e3bf2e652d48454f105879fd809bf6b4890	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	102942		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENTS AFTER NOTICE OF ALLOWANCE UNDER 37 C.F.R. RULE 1.312

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient[[;]] ,

wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient[[,]] ;

a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers,

wherein the second plurality of fibers is in direct contact with the frame.

12. (Canceled)

13. (Previously Presented) The prosthetic heart valve of claim 11, wherein the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.

14. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

15. (Previously Presented) The prosthetic heart valve of claim 11, wherein a distance that the first plurality of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Previously Presented) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first plurality of fibers extends over each of the at least two rows of cells.

17. (Previously Presented) The prosthetic heart valve of claim 11, wherein the first plurality of fibers and the second plurality of fibers are non-metallic.

18. (Previously Presented) The prosthetic heart valve of claim 11, wherein the first plurality of fibers and the second plurality of fibers are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Previously Presented) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame.

21. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

22. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering and the first plurality of fibers and the second plurality of fibers are distinct elements.

24. (Previously Presented) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient.

25. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Previously Presented) The prosthetic heart valve of claim 11, wherein the first plurality of fibers defines a spacing that extends through a thickness thereof that is created by a distance between adjacent fibers thereof.

27. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first plurality of fibers that extend away from the frame,

wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient; and

a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers,

wherein the second plurality of fibers is in direct contact with the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient[[;]] .

wherein the prosthetic heart valve defines a spacing extending through a thickness of the first plurality of fibers that is created by a distance between adjacent fibers thereof, through a thickness of the second plurality of fibers created by a distance between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first plurality of fibers and the second plurality of fibers in response to expansion of the prosthetic heart valve compresses the first plurality of fibers relative to the spacing to create a seal thereabout.

29. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly; and

[[an]] a plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient[[;]] .

wherein the plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient[[;]] .

wherein the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacings to create a seal thereabout,

wherein the plurality of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Notice of Allowance mailed on January 25, 2022. Applicant submits typographical amendments to the claims. The issue fee is being contemporaneously paid herewith.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: January 26, 2022

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Electronic Acknowledgement Receipt	
EFS ID:	44841197
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	26-JAN-2022
Filing Date:	22-MAY-2021
Time Stamp:	15:10:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-23UTIL-20220126-312Amend.pdf	36272 55d48a6bb038d46dd52a65aaabe774c31a3dfc66	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	7
Warnings:			
Information:			
	Total Files Size (in bytes):	36272	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

175373 7590 01/25/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 01/25/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

TITLE OF INVENTION: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	04/25/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

175373 7590 01/25/2022
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

TITLE OF INVENTION: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	04/25/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
SHIPMON, TIFFANY P	3774	623-001200

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 01/25/2022

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 01/25/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	**Art Unit** 3774	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the amendments filed 11/08/2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 11 and 13-29 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: the closest prior art does not disclose or render obvious a prosthetic heart valve a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers in direct contact with the frame.

3. Also, referring to claim 29, The prior art does not disclose or render obvious the prosthetic heart valve defining a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/Jennifer Dieterle/
Supervisory Patent Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F 2/856,07,2418,82,962,24,86,89,90; 2002/061,067; 2210/00,0014,0057; 2220/008,0016,0025,0058,0075; 2230/001,0034,0067; 2250/0048,0069	07/22/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
EAST Search	07/22/2021	T.S.
EAST Search	08/25/2021	T.S.
Updated EAST Search	12/02/2021	T.S.
IPR2021-01527 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
IPR2021-01584 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
IPR2022-00034 Reviewed Petition for Inter Partes Review of US Patent No.	12/03/2021	T.S.
Consulted with Leslie Lopez	11/29/2021	T.S.

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61F	2/856	07/22/2021	T.S.
A61F	2/856	12/02/2021	T.S.

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

CPC						
Symbol					**Type**	**Version**
A61F	/	2	/	856	F	2013-01-01
A61F	/	2	/	07	I	2013-01-01
A61F	/	2	/	2418	I	2013-01-01
A61F	/	2	/	962	I	2013-01-01
A61F	/	2	/	82	I	2013-01-01
A61F	/	2002	/	061	A	2013-01-01
A61F	/	2220	/	0025	A	2013-01-01
A61F	/	2230	/	0067	A	2013-01-01
A61F	/	2002	/	067	A	2013-01-01
A61F	/	2220	/	0008	A	2013-01-01
A61F	/	2220	/	0016	A	2013-01-01
A61F	/	2230	/	001	A	2013-01-01
A61F	/	2250	/	0048	A	2013-01-01
A61F	/	2	/	89	A	2013-01-01
A61F	/	2	/	90	A	2013-01-01
A61F	/	2220	/	0058	A	2013-01-01
A61F	/	2220	/	0075	A	2013-01-01
A61F	/	2230	/	0034	A	2013-01-01
A61F	/	2	/	24	A	2013-01-01
A61F	/	2	/	86	A	2013-01-01
A61F	/	2250	/	0069	A	2013-01-01
A61F	/	2210	/	0014	A	2013-01-01
A61F	/	2210	/	0057	A	2013-01-01
A61F	/	2210	/	00	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	02 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	02 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61F	/	2	/	856

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	02 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	02 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
-	1	-	10	8	19	17	28								
-	2	1	11	9	20	18	29								
-	3	-	12	10	21										
-	4	2	13	11	22										
-	5	3	14	12	23										
-	6	4	15	13	24										
-	7	5	16	14	25										
-	8	6	17	15	26										
-	9	7	18	16	27										

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	02 December 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	02 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	12

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	SHIPMON, TIFFANY P
Attorney Docket Number	426/2/23 UTIL

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3365728	A	1968-01-30	Lowell et al.	
	2	5411552	A	1995-05-02	Andersen et al.	
	3	6893460	B2	2005-05-17	Spenser et al.	
	4	7393360	B2	2008-07-01	Spenser et al.	
	5	7510575	B2	2009-03-31	Spenser et al.	
	6	9393110	B2	2016-07-19	Levi et al.	
	7	9829057	B2	2017-11-28	Chung et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030153974	A1	2003-08-14	Spenser et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Inter Partes Review 2017-00060 of US Patent No. 8,992,608, and supporting declaration of Nigel Buller	
	2	Inter Partes Review 2021-01527 of US Patent No. 10,792,172, and supporting declaration of Nigel Buller	
	3	EPO, Office Action of corresponding European Patent Application No. 20172681.7, mailed Sep. 6, 2021, 6 pages	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	11/16/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EFS Web 2.1.18

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-09-20
Name/Print	Justin R. Nifong	Registration Number	59389

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(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany P. Shipmon
Attorney Docket Number	426/2/23 UTIL

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Receipt date: 08/26/2021	Application Number	17327673 17327673 - GAU: 3774
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
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	Examiner Name	Tiffany P. Shipmon
	Attorney Docket Number	426/2/23 UTIL

	1	JPO, Office Action from Corresponding JP Patent Application Number 2020-122656, mailed Aug. 17, 2021, 4 pages	X

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Shipmon, Tiffany
Attorney Docket Number	426/2/23 UTIL

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3365728	A	1968-01-30	Lowell et al.	
	2	5411552		1995-05-02	Andersen et al.	
	3	5957949		1999-09-28	Leonhardt et al.	
	4	6730118		2004-05-04	Spenser et al.	
	5	6893460		2005-05-17	Spenser et al.	
	6	7393360		2008-07-01	Spenser et al.	
	7	7510575		2009-03-31	Spenser et al.	
	8	7585321		2009-09-08	Cribier	

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	9	9393110		2016-07-19	Levi et al.	

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	1	20020052649	A1	2002-05-02	Greenhalgh	
	2	20030153974	A1	2003-08-14	Spenser et al.	
	3	20090281619	A1	2009-11-12	Le et al.	
	4	20110098802	A1	2011-04-28	Braido et al.	

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	1	2006005015	WO	A2	2011-04-28	Spenser		
	2	2006124649	WO	A2	2006-11-23	Nguyen et al.		

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	3	2011051043	WO	A1	2011-05-05	Essinger et al.		
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	1	Walther, Trans-catheter valve-in-valve implantation ("Walther"), April 2011	
	2	Conradi, Transcatheter aortic and mitral valve interventions, 2010	
	3	Cribier, Technique of Transcatheter Aortic Valve Implantation ("Cribier"), 2009	
	4	Alkashkari, Percutaneous Pulmonary Valve Implantation ("Alkashkari"), September 2010	
	5	Cheung, Transapical Transcatheter Mitral Valve-in-valve Implantation, 2009	
	6	Yuksel, Balloon-Expandable Transcatheter Aortic Valve Implantation, August, 2009	
	7	Walther, Transapical minimally Invasive Aortic Valve Implantation ("Walther II"), 2007	

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	8	Smith, Transcatheter versus Surgical Aortic-Valve Replacement, June 9, 2011	
	9	Webb, Transcatheter aortic valve implantation, March 16, 2012	
	10	Zajarias, Outcomes and Safety of Percutaneous Aortic Valve Replacement, 2009	
	11	Cribier, Percutaneous Transcatheter Implantation, 2002	
	12	Roselli, Engineering transcatheter aortic valve devices, 2007	
	13	Tyagi, Yarn structure and properties, 2010	
	14	Kothari, Hairiness properties of polyester-cotton blended yarns, 2003	
	15	Cribier, Early Experiences with Percutaneous Transcatheter Implantation, 2004	
	16	Akin, Chapter 8: Edwards SAPIEN	
	17	Andersen, Transluminal implantation of artificial heart valves, 1992	
	18	Nietlispach, Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems, 2010	

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	19	SAPIEN Instructions for Use	
	20	Saia, In-hospital and thirty-day outcomes, 2020	
	21	Kainuma, Transcatheter aortic valve implantation, April 2011	
	22	Craido, Iliac Arterial Conduits, 2007	
	23	Piazza, Anatomy of the Aortic Valvar Complex, 2008	
	24	Buller, Nigel declaration, IPR IPR2022-00193, associated documents	
	25	Buller, Nigel declaration, IPR IPR2022-00034, associated documents	
	26	Buller, Nigel declaration, IPR IPR2021-01584, associated documents	
	27	Buller, Nigel declaration, IPR IPR2021-01527, associated documents	
	28	Buller, Nigel declaration, IPR IPR2017-00060	

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EXAMINER SIGNATURE			
Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	12/02/2021

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/23 UTIL

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

	1	WALTHER, THOMAS, Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of the SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves, European Journal of Cario-thoracic Surgery 40, April 3, 2011

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EXAMINER SIGNATURE

Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	07/30/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-07-27
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	3	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/28 22:05
S3	21	("20120046726" | "7018404" | "7799072" | "8016877" | "20070250146" | "6334868" | "7510574" | "8002826" | "20070276464" | "6752829" | "5102417" | "7947074" | "20070095283" | "20110257731" | "7393360" | "7914569" | "8226710" | "20040210304" | "5397355" | "7780726" | "20050197687" | "20060149351" | "20090198315" | "20100042202" | "7252682" | "20030040771" | "20120089218" | "5716393" | "6254632" | "20090125098" | "6582462" | "7771467" | "8206438" | "20080132999" | "20090099644" | "8425584").PN.	USPAT	OR	OFF	2014/06/28 23:06
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S5	317	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/06/28 23:30
S7	38	a61f2/2418	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S8	59	a61f2/2412	US-PGPUB; USPAT;	OR	OFF	2014/06/28 23:31

			EPO; JPO; DERWENT			
S9	41	a61f2/2436	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S10	17	a61f2/2433	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S11	11	a61f2/2475	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S12	1	"13706896"	US-PGPUB; USPAT	OR	OFF	2014/06/29 16:46
S13	2,346	623/1.12	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:07
S14	401	S13 and fibers	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:07
S15	3	S13 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:12
S16	30	S13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:13
S17	74	623/1.13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:43
S18	2,377	stent and graft and fibers and migration	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:48
S19	317	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/06/29 18:49
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S26	3	meretei.in.	USPAT	OR	OFF	2014/07/14 09:28
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S32	2,016	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 19:59
S33	915	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 19:59
S34	0	a61f2/2418.cpc	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 20:38

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S39	2,556	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 10:24
S40	3,379	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:47
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S42	2	("13706896").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:51
S46	1	("14614628").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/03/20 19:27
S47	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/05/15 06:58
S48	2	("7799072").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:28
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S56	3,429	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:12
S57	2,489	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S58	1,308	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
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S61	1	("20070067014").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/17 16:11
S62	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/18 08:47
S63	1,461	carpentier.in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 08:54
S64	61	carpentier.in. and aorta	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/01/11 09:32

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S65	3	"20050102018"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 09:39
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S70	3,295	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S71	1,674	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
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S73	9,150	S68 S69 S70 S71 S72	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
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S81	4,461	S80 and (artery arteries)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:06
S82	1,118	S80 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:09
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S92	9	("20060155366" | "20100049313" | "6258117").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:09
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S94	6	("20070168013" | "20140172064" | "20140316513").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
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S98	4	"20140172065"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:21
S99	6	"20100049313"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:26
S100	2	"20060155366"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:29
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S102	4,593	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S103	3,601	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S104	1,864	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S105	1,380	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/07/21 10:35

			EPO; JPO; DERWENT			
S106	9,898	S101 S102 S103 S104 S105	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S107	9,898	S101 S102 S103 S104 S105 S106	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S108	1,179	S107 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 10:35
S109	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 11:44
S110	4	"14614628"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 12:36
S111	7,098	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S112	4,889	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S113	3,856	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S114	1,965	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S115	1,422	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/12/08 16:15

			EPO; JPO; DERWENT			
S116	10,508	S111 S112 S113 S114 S115	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S117	10,508	S111 S112 S113 S114 S115 S116	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S118	1,256	S117 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/12/08 16:15
S120	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S121	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S122	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S123	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S124	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S125	10,919	S120 S121 S122 S123 S124	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S126	10,919	S120 S121 S122 S123 S124 S125	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45

S127	1,305	S126 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/03/13 11:45
S128	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S129	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S130	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S131	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S132	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S133	10,919	S128 S129 S130 S131 S132	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S134	10,919	S128 S129 S130 S131 S132 S133	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S135	966	S134 and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:56
S136	5,500	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01

S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ | US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/04/13 14:46

		| US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	FPRS; EPO; JPO; DERWENT			
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44
S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

		| US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3652198-$ | US-3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-			

		5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$	US-PGPUB; USPAT;	OR	OFF	2020/06/06 16:07

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S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
S172	627	("20010039450" | "20020013571" | "20020026216" | "20020082630" | "20020107565" | "20020123802" | "20020151970" | "20020183835" | "20020183838" | "20020188348" | "20020198594" | "20030023303" | "20030050694" | "20030078652" | "20030130729" | "20030153943" | "20030163194" | "20030167071" | "20030171806" | "20030199975" | "20030229394" | "20030229395" | "20030233142" | "20030236568" | "20030236569" | "20040002719" | "20040003819" | "20040010305" | "20040015230" | "20040015232" | "20040015233" | "20040019374" | "20040019377" | "20040019378" | "20040024447" | "20040024451" | "20040024452" | "20040030321" | "20040030381" | "20040030382" | "20040030405" | "20040034380" | "20040034411" | "20040039436" | "20040039442" | "20040039443" | "20040044350" | "20040044365" | "20040044403" | "20040049207" | "20040049211" | "20040049266" | "20040059351" | "20040059411" | "20040059412" | "20040060161" | "20040073301" | "20040073302" | "20040078072" | "20040078074" | "20040082910" | "20040082923" | "20040082991" | "20040087975" | "20040088045" | "20040088046" | "20040092858" | "20040093060" | "20040093070" | "20040093080" | "20040097979" | "20040098098" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:31

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S196	50	(US-10034784-$ | US-10065824-$ | US-16736879-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
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S199	170	(rowe.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:19
S200	75	(mclean.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:22
S201	108	(vidlund.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:23
S202	1	("20080275548").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:47
S203	1	("20120283820").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:48
S204	1,050	salahieh.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48

S205	516	salahieh.in. and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48
S206	1	("20050137695").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:55
S207	7,776	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S208	5,285	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S209	4,260	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S210	2,147	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S211	1,470	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S212	11,433	S207 S208 S209 S210 S211	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S216	0	wo2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S217	0	(2006/124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:23

S218	0	(2006/0124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:24
S219	5	("2006124649").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/07/29 09:24
S220	1	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:55
S221	4	"20090125098"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:29
S222	7	"20030040771"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:30
S223	1,779	(cuff with (fiber barb))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:58
S224	270	("20020036220" | "20030023303" | "20030050694" | "20030130726" | "20040049262" | "20040093075" | "20040102837" | "20040111111" | "20040210304" | "20040260389" | "20050096726" | "20050137682" | "20050137695" | "20050137697" | "20050203605" | "20050256566" | "20060008497" | "20060020327" | "20060025857" | "20060036308" | "20060074484" | "20060122692" | "20060149360" | "20060161249" | "20060173532" | "20060178740" | "20060206202" | "20060241744" | "20060241745" | "20060259120" | "20060259136" | "20060259137" | "20060265056" | "20060276813" | "20060276874" | "20070010876" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:03

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S225	1	(spense.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17

S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20
S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53

S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:02
S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
S248	1	("4164046").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:09
S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT;	OR	OFF	2020/11/06 15:17

			USOCR; FPRS; EPO; JPO; DERWENT			
S258	0	("2006124649").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 15:17
S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S262	0	("12882605").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S263	0	("2006018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S264	1	("20060018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S265	7	"20060018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ |	US-PGPUB; USPAT;	OR	OFF	2020/11/06 19:25

		US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$ | US-3992608-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:22
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:25
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/01/16 10:26

			USOCR; FPRS; EPO; JPO; DERWENT			
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/01/16 10:27

			FPRS; EPO; JPO; DERWENT			
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:33

			JPO; DERWENT			
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:21
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:46
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48

S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51
S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
S320	5	"20060005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S321	96	"2006005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S322	5	"15876053"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:11

S323	2	("2018/0206982").URPN.	USPAT	OR	OFF	2021/02/13 09:12
S324	0	"20010049555"	USPAT	OR	OFF	2021/02/13 09:14
S325	4	"20010049555"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:14
S326	3	"20070233228"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S327	3	"20120296418"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S328	822	("20010021872" | "20020026094" | "20020032481" | "20020138135" | "20020173842" | "20030050694" | "20030100939" | "20030158597" | "20030212454" | "20040039436" | "20040186563" | "20040186565" | "20050075728" | "20050096736" | "20050188525" | "20050203614" | "20050203617" | "20050234546" | "20060004469" | "20060025857" | "20060058872" | "20060149350" | "20060183383" | "20060229719" | "20060259137" | "20070005131" | "20070010876" | "20070010877" | "20070112422" | "20070162102" | "20070203503" | "20070203575" | "20070203576" | "20070213813" | "20070260305" | "20070265700" | "20080114442" | "20080125853" | "20080154355" | "20080183271" | "20090125118" | "20090157175" | "20090276040" | "20090281619" | "20090299452" | "20090319037" | "20100049313" | "20100168844" | "20100198347" | "20100204781" | "20110015729" | "20110319991" | "20120259409" | "20130023985" | "20130190857" | "20130274873" | "20130310926" | "20130317598" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:25

		"20130331929" | "20140194981" | "20140200661" | "20140209238" | "20140277417" | "20140277419" | "20140277424" | "20140330372" | "20140343671" | "20150073545" | "20150073546" | "3409013" | "3548417" | "3587115" | "3657744" | "3671979" | "3714671" | "3755823" | "4035849" | "4056854" | "4106129" | "4222126" | "4265694" | "4297749" | "4339831" | "4343048" | "4345340" | "4373216" | "4406022" | "4441216" | "4470157" | "4535483" | "4574803" | "4592340" | "4605407" | "4612011" | "4643732" | "4655771" | "4692164" | "4733665" | "4759758" | "4762128" | "4777951" | "4787899" | "4787901" | "4796629" | "4820299" | "4829990" | "4851001" | "4856516" | "4878495" | "4878906" | "4883458" | "4922905" | "4966604" | "4979939" | "4986830" | "4994077" | "5007896" | "5026366" | "5032128" | "5037434" | "5047041" | "5059177" | "5080668" | "5085635" | "5089015" | "5152771" | "5163953" | "5167628" | "5192297" | "5266073" | "5282847" | "5295958" | "5332402" | "5360444" | "5370685" | "5397351" | "5411055" | "5411552" | "5443446" | "5480424" | "5500014" | "5545209" | "5545214" | "5549665" | "5554185" | "5558644" | "5571175" | "5584803" | "5591185" | "5591195" | "5607464" | "5609626" | "5628792" | "5639274" | "5665115" | "5716417" | "5728068" | "5749890" | "5756476" | "5769812" | "5800508" | "5840081" | "5855597" | "5855601" | "5855602" | "5925063" | "5957949" | "6027525" | "6132473" | "6168614" | "6171335" | "6174327" | "6210408" | "6217585" | "6221091" | "6231602" | "6245102" | "6299637" | "6302906" | "6350277" | "6352547" | "6425916" | "6440764" | "6454799" | "6458153" | "6461382" | "6468660" | "6482228" | "6488704" | "6527979" | "6569196" | "6582462" | "6605112" | "6652578" | "6689123" | "6716244" | "6730118" | "6733525" | "6767362" | "6769161" | "6783542" | "6830584" | "6878162" | "6893460" | "6908481" | "6936067" | "7018406" | "7018408" | "7096554" | "7225518" | "7276078" | "7276084" |			

		"7318278" | "7374571" | "7393360" | "7462191" | "7510575" | "7563280" | "7585321" | "7618446" | "7618447" | "7655034" | "7785366" | "7959672" | "7993394" | "8029556" | "8167932" | "8291570" | "8449606" | "8454685" | "8652203" | "8747463" | "9078781").PN.				
S329	4	("20130190862" | "20160317305").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:26
S330	4	("20070233228" | "20120296418").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27
S331	835	("20020173842" | "20030100939" | "20040186563" | "20050203617" | "20070162102" | "20080183271" | "20100204781" | "20130274873" | "20140200661" | "20150073546" | "4222126" | "4733665" | "4759758" | "4777951" | "5026366" | "5032128" | "5332402" | "5411055" | "5558644" | "5571175" | "5609626" | "6231602" | "6425916" | "6440764" | "6689123" | "6893460" | "6936067" | "7655034" | "7993394" | "8652203" | "20030212454" | "20050075728" | "20070112422" | "20100168844" | "20100198347" | "4829990" | "5397351" | "5545214" | "5549665" | "5584803" | "5855602" | "6027525" | "6132473" | "6168614" | "6221091" | "6302906" | "6350277" | "6454799" | "6605112" | "6908481" | "7510575" | "7563280" | "20070233228" | "20020138135" | "20050203614" | "20050234546" | "20060149350" | "20070260305" | "3714671" | "4297749" | "4441216" | "4692164" | "4762128" | "4883458" | "4994077" | "5007896" | "5163953" | "5360444" | "5411552" | "5591185" | "5639274" | "5665115" | "5716417" | "5749890" | "5756476" | "5855601" | "6171335" | "6245102" | "6299637" | "6488704" | "6569196" | "6769161" | "7393360" | "7585321" | "7959672" | "8167932" | "8747463" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27

		"9078781" | "20130190862" | "20010049555" | "20040186565" | "20060058872" | "20060229719" | "20070213813" | "20090299452" | "20120259409" | "20130023985" | "20130310926" | "20130317598" | "20130331929" | "20140209238" | "20140277417" | "20140343671" | "4265694" | "4339831" | "4373216" | "4470157" | "4592340" | "4643732" | "4796629" | "4820299" | "4856516" | "4966604" | "5047041" | "5089015" | "5266073" | "5295958" | "5591195" | "5607464" | "5957949" | "6716244" | "6767362" | "7018406" | "7096554" | "7276084" | "7374571" | "8029556" | "20020026094" | "20050096736" | "20060259137" | "20070005131" | "20090125118" | "20090157175" | "20090319037" | "20110319991" | "20140194981" | "20140277424" | "3587115" | "3657744" | "3671979" | "4343048" | "4612011" | "4787899" | "4787901" | "4878495" | "4878906" | "4979939" | "4986830" | "5059177" | "5085635" | "5152771" | "5370685" | "5500014" | "5554185" | "5728068" | "6210408" | "6352547" | "6527979" | "6783542" | "7618446" | "20030050694" | "20030158597" | "20050188525" | "20060004469" | "20070203503" | "20080114442" | "20080154355" | "20100049313" | "20110015729" | "20140277419" | "20150073545" | "3409013" | "3548417" | "4035849" | "4056854" | "4106129" | "4406022" | "4535483" | "4922905" | "5037434" | "5080668" | "5282847" | "5769812" | "5840081" | "5855597" | "6174327" | "6458153" | "6468660" | "6652578" | "6830584" | "6878162" | "7018408" | "7225518" | "7785366" | "8454685" | "20120296418" | "20010021872" | "20040039436" | "20070010877" | "20070265700" | "20080125853" | "20090281619" | "20130190857" | "20140330372" | "4345340" | "4605407" | "5545209" | "5628792" | "6217585" | "6461382" | "6730118" | "7318278" | "7462191" | "7618447" | "8449606" | "20170014229" | "20020032481" | "20060025857" | "20060183383" | "20070010876" | "20070203575" |			

		"20070203576" | "20090276040" | "3755823" | "4574803" | "4655771" | "4851001" | "5167628" | "5192297" | "5443446" | "5480424" | "5800508" | "5925063" | "6482228" | "6582462" | "6733525" | "7276078" | "8291570" | "20160317305").PN.				
S332	11	WO2006124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:13
S333	53	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:14
S334	0	"17131869"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S335	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S336	13	S328 and (outer$4 with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:49
S337	27	S328 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:00
S338	36,075	l11and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14

S339	27	S331 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S340	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:56
S341	12	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-3333075-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:57
S342	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 15:10
S343	1	("9333075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/17 05:33
S344	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/17 05:40
S345	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17007373-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 12:07

		5665117-$ | US-5824037-$ | US-20130144373-$).DID.				
S346	10	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:38
S347	34	"10555823"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:50
S348	2	"16983196"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 15:15
S349	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/21 15:20
S350	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S351	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S352	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S353	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S354	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S355	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S356	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S357	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S358	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S359	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S360	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S361	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S362	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S363	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S364	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S365	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S366	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S367	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S368	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S369	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S370	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S371	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S372	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S373	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S374	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S375	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S376	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S377	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S378	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S379	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S380	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S381	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S382	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S383	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S384	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S385	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S386	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S387	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S388	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S389	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S390	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S391	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S392	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S393	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S394	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S395	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S396	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S397	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S398	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S399	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S400	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S401	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S402	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S403	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S404	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S405	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S406	2,578	(S378 S379 S380 S381 S382 S383 S384 S385 S386 S387 S388 S389 S390 S391 S392 S393 S394 S395 S396 S397 S398 S399 S400 S401 S402 S403 S404 S405) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S407	15	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2021/03/25 16:13
S408	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S409	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S410	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

		$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	JPO; DERWENT			
S411	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S412	5,773	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S413	26,431	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S414	17,826	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S415	17,867	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S416	4,044	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S417	6,084	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S418	7,541	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S419	11,784	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S420	18,994	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S421	5,686	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S422	4,852	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S423	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S424	12,667	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S425	1,775	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S426	12,059	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S427	15,690	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S428	32,783	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S429	9,318	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S430	18,235	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S431	3,576	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S432	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S433	14,804	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S434	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S435	4,158	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S436	2,585	(S408 S409 S410 S411 S412 S413 S414 S415 S416 S417 S418 S419 S420 S421 S422 S423 S424 S425 S426 S427 S428 S429 S430 S431 S432 S433 S434 S435) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S438	0	("13706896").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:37
S439	34	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 09:37
S440	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:58
S441	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17170957-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:38
S442	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S443	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S444	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S445	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S446	5,776	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S447	26,437	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S448	17,841	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S449	17,872	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S450	4,046	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S451	6,089	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S452	7,542	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S453	11,785	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S454	18,999	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S455	5,689	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S456	4,854	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S457	555	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S458	12,674	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S459	1,777	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S460	12,063	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S461	15,695	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S462	32,786	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S463	9,323	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S464	18,239	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S465	3,579	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S466	3,175	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S467	14,810	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S468	1,657	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S469	4,160	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S470	2,587	(S442 S443 S444 S445 S446 S447 S448 S449 S450 S451 S452 S453 S454 S455 S456 S457 S458 S459 S460 S461 S462 S463 S464 S465 S466 S467 S468 S469) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S471	0	("16910189").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 16:49
S472	6	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 16:49
S473	11	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 17:22
S474	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 18:29
S475	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/04/08 18:36

			JPO; DERWENT			
S476	72	(US-10016271-$ | US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17006793-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S477	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | NO-2006005015-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110098802-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130304196-$ | NO-3829057-$ | IF-617622-$ | SO-0225223-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S478	54	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 09:42
S479	3	"20060259136"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 14:18
S480	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/09 16:30

		20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S481	28	S480 and (mitral)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 16:37
S482	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 11:44
S483	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 15:48
S484	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59

S485	5	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59
S486	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 10:57
S487	55	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:15
S488	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 10:19
S489	39	S488 and (seal with3 (inflow and outflow))	US-PGPUB; USPAT;	OR	OFF	2021/04/27 10:19

			USOCR; FPRS; EPO; JPO; DERWENT			
S490	41	S488 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:23
S491	21	("2014/0316513").URPN.	USPAT	OR	OFF	2021/04/27 10:28
S492	0	"17006793"	USPAT	OR	OFF	2021/04/27 10:32
S493	1	"16792197"	USPAT	OR	OFF	2021/04/27 10:32
S494	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 11:19
S496	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 19:42

		US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S497	41	S496 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 19:42
S498	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/24 12:23
S499	15	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/05/25 08:57
S500	54	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/05/25 08:57
S503	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/30 17:02
S504	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 13:20

S505	3	"17007373"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 16:13
S506	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/06/03 13:29
S507	15	S506 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:29
S508	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55

S509	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S510	92	S508 S509	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S511	10	S510 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S512	232	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 14:01
S513	1	("7921678").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/06/03 14:08
S514	35	(US-17170957-$ | US-20030153974-$ | US-20060025857-$ | US-20060074484-$ | US-20070282436-$ | US-20100036484-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20120022633-$ | US-20120071969-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20140018915-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/18 10:36

		US-20140155997-$ | US-20170128209-$).DID.				
S518	6	(("20130018458") or ("20110125244") or ("20110166636") or ("20110098802") or ("20060074484") or ("20120310328")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/01 09:32
S520	102	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17327673-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060025857-$ | US-20060074484-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20070282436-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100036484-$ | US-20100204781-$ | US-20110009948-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20110218619-$ | US-20110319991-$ | US-20120022633-$ | US-20120071969-$ | US-20120123529-$ | US-20120296418-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20130304196-$ | US-20140018915-$ | US-20140155997-$ | US-20150335429-$ | US-20160022444-$ | US-20170128209-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 16:59
S521	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | AI-20060025857-$ | NO-2006005015-$ | AI-20060074484-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20070282436-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100036484-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110040367-$ | AI-20110098802-$ | AI-20110125244-$ | AI-20110166636-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120022633-$ | AI-20120071969-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20120310328-$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 17:17

		| NO-2012068175-$ | AI-20130018458-$ | AI-20130073030-$ | AI-20130304196-$ | AI-20140018915-$ | AI-20140155997-$ | AI-20150335429-$ | AI-20160022444-$ | AI-20170128209-$ | NO-3829057-$ | SO-0225223-$ | VA-223131450-$).DID.				
S522	0	"17327673"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:09
S523	4	"17096253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:10
S526	17	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/07/22 15:41
S527	58	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/07/22 15:41
S528	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/07/25 16:50

		(WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S529	15	S528 and collagen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 16:50
S530	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:00
S531	23	"2005023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:16
S532	12	"20050023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:17
S533	0	("2005023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S534	1	("20050023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S535	1	("20060004442").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:19
S536	398	("2006/0004442").URPN.	USPAT	OR	OFF	2021/07/25 17:20
S537	1	("20130018458").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:28
S539	41	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/07/30 11:20

			JPO; DERWENT			
S542	22	"10299917"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/23 10:08
S545	234	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/25 14:20
S546	3	"20060276813"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/26 12:46
S547	25	"2011143263"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/26 12:47
S548	8	("20030153974" | "3365728" | "5411552" | "6893460" | "7393360" | "7510575" | "9393110" | "9829057").PN.	US-PGPUB; USPAT	OR	OFF	2021/11/16 10:19
S549	1	(("20060276813") or ("2011143263")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/16 10:26
S550	2	(("20060276813") or ("20110143263")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/16 10:26
S551	25	"2011143263"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/11/16 10:27
S552	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/11/16 13:48

S553	9	("20030153974" | "20060276813" | "3365728" | "5411552" | "6893460" | "7393360" | "7510575" | "9393110" | "9829057").PN.	US-PGPUB; USPAT	OR	OFF	2021/11/17 16:07
S554	6	"20120123529"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/11/19 19:46
S555	3	"20050273155"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/11/19 20:08
S556	1	("7511575").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 14:26
S557	1	("7510575").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 14:26
S558	1	("11129735").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:09
S559	1	("11045335").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:10
S560	1	("11026817").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:11
S561	1	("10966846").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:11
S562	1	("10888441").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:20
S563	3	(("10881538") or ("10857011") or ("10792172")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/20 16:20
S564	13	("20020052649" | "20030153974" | "20090281619" | "20110098802" | "3365728" | "5411552" | "5957949" | "6730118" | "6893460" | "7393360" | "7510575" | "7585321" | "9393110").PN.	US-PGPUB; USPAT	OR	OFF	2021/11/28 06:03

S565	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/28 10:31
S566	1	("7510575").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/11/28 10:47
S567	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/12/02 15:03
S568	13	("20020052649" | "20030153974" | "20090281619" | "20110098802" | "3365728" | "5411552" | "5957949" | "6730118" | "6893460" | "7393360" | "7510575" | "7585321" | "9393110").PN.	US-PGPUB; USPAT	OR	OFF	2021/12/02 19:07

12/3/2021 2:14:10 PM
C:\Users\tshipmon\Documents\EAST\Workspaces\13706896.wsp

Bibliographic Data

Application No: 17/327,673

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /TIFFANY P SHIPMON/ Examiner's Signature | Initials

Title: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/22/2021	623	3774	426/2/23 UTIL
RULE			

APPLICANTS

Aortic Innovations, LLC, Hillsboro Beach, FL, UNITED STATES

INVENTORS

Ali Shahriari, Hillsboro Beach, FL, UNITED STATES

CONTINUING DATA

This application is a CON of 17213251 03/26/2021

17213251 is a CON of 17096253 11/12/2020 PAT 10966846

17096253 is a CON of 17060557 10/01/2020 PAT 10888441

17060557 is a CON of 16910189 06/24/2020 PAT 10857011

16910189 is a CON of 16808137 03/03/2020 PAT 10792172

16808137 is a CON of 16736879 01/08/2020 PAT 10842655

16736879 is a CON of 16042286 07/23/2018 PAT 10555823

16042286 is a CON of 14614628 02/05/2015 PAT 10028848

14614628 is a CON of 14569306 12/12/2014 PAT 9339399

14569306 is a DIV of 13706896 12/06/2012 PAT 8940040

13706896 has PRO of 61723446 11/07/2012

13706896 has PRO of 61567458 12/06/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

05/27/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
UNITED STATES

FILING FEE RECEIVED

$3,000

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Shipmon, Tiffany
Attorney Docket Number	426/2/23 UTIL

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3365728	A	1968-01-30	Lowell et al.	
	2	5411552		1995-05-02	Andersen et al.	
	3	5957949		1999-09-28	Leonhardt et al.	
	4	6730118		2004-05-04	Spenser et al.	
	5	6893460		2005-05-17	Spenser et al.	
	6	7393360		2008-07-01	Spenser et al.	
	7	7510575		2009-03-31	Spenser et al.	
	8	7585321		2009-09-08	Cribier	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

	9	9393110		2016-07-19	Levi et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020052649	A1	2002-05-02	Greenhalgh	
	2	20030153974	A1	2003-08-14	Spenser et al.	
	3	20090281619	A1	2009-11-12	Le et al.	
	4	20110098802	A1	2011-04-28	Braido et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2006005015	WO	A2	2011-04-28	Spenser		
	2	2006124649	WO	A2	2006-11-23	Nguyen et al.		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

	3	2011051043	WO	A1	2011-05-05	Essinger et al.			
	4	9829057	WO	A1	1998-07-09	Letac			

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Walther, Trans-catheter valve-in-valve implantation ("Walther"), April 2011	
	2	Conradi, Transcatheter aortic and mitral valve interventions, 2010	
	3	Cribier, Technique of Transcatheter Aortic Valve Implantation ("Cribier"), 2009	
	4	Alkashkari, Percutaneous Pulmonary Valve Implantation ("Alkashkari"), September 2010	
	5	Cheung, Transapical Transcatheter Mitral Valve-in-valve Implantation, 2009	
	6	Yuksel, Balloon-Expandable Transcatheter Aortic Valve Implantation, August, 2009	
	7	Walther, Transapical minimally Invasive Aortic Valve Implantation ("Walther II"), 2007	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

	8	Smith, Transcatheter versus Surgical Aortic-Valve Replacement, June 9, 2011	
	9	Webb, Transcatheter aortic valve implantation, March 16, 2012	
	10	Zajarias, Outcomes and Safety of Percutaneous Aortic Valve Replacement, 2009	
	11	Cribier, Percutaneous Transcatheter Implantation, 2002	
	12	Roselli, Engineering transcatheter aortic valve devices, 2007	
	13	Tyagi, Yarn structure and properties, 2010	
	14	Kothari, Hairiness properties of polyester-cotton blended yarns, 2003	
	15	Cribier, Early Experiences with Percutaneous Transcatheter Implantation, 2004	
	16	Akin, Chapter 8: Edwards SAPIEN	
	17	Andersen, Transluminal implantation of artificial heart valves, 1992	
	18	Nietlispach, Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems, 2010	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

	19	SAPIEN Instructions for Use	
	20	Saia, In-hospital and thirty-day outcomes, 2020	
	21	Kainuma, Transcatheter aortic valve implantation, April 2011	
	22	Craido, Iliac Arterial Conduits, 2007	
	23	Piazza, Anatomy of the Aortic Valvar Complex, 2008	
	24	Buller, Nigel declaration, IPR IPR2022-00193, associated documents	
	25	Buller, Nigel declaration, IPR IPR2022-00034, associated documents	
	26	Buller, Nigel declaration, IPR IPR2021-01584, associated documents	
	27	Buller, Nigel declaration, IPR IPR2021-01527, associated documents	
	28	Buller, Nigel declaration, IPR IPR2017-00060	

If you wish to add additional non-patent literature document citation information please click the Add button Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-11-24
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	44360760
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	24-NOV-2021
Filing Date:	22-MAY-2021
Time Stamp:	08:36:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	426-2-23-ids.pdf	1035749 f91d5182ab8912071e973c8ecf70988f8dd07ff1	no	8

Warnings:

Information:					
2	Non Patent Literature	Binder1-printed.pdf	3229907 7d811d861d3f2d17c0a6edb4d923e449bebc6f8b	no	71
Warnings:					
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3	Non Patent Literature	Binder2-printed.pdf	2694947 d0a068aef183683878b2307d8b2d2f2f69a3d394	no	75
Warnings:					
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4	Non Patent Literature	Binder3-printed.pdf	4902235 cedf083c567fa46606d941229894a9d1bf5af171	no	55
Warnings:					
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5	Non Patent Literature	Binder4-printed.pdf	13482050 52503bc105281526fb12a63b0512b7c16ebc0291	no	447
Warnings:					
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7	Non Patent Literature	Binder6-printed.pdf	11484977 ae20080c56c6c576f2b613828ab8092a6c625d7d	no	328
Warnings:					
Information:					
8	Non Patent Literature	Binder7-printed.pdf	9931159 c3cd4db4d75ef1b1750fdd9db94e0f0621e403f9	no	359
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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Document Code:WFEE

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Effective Date	Sale Item Reference Number	Refund Total
08/26/2021	17327673	$130.00

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method	Account Number
I2021AIB27124935	2806	SUBMISSION-INFORMATION DISCLOSURE STMT	$130.00	Visa	**********0208



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Sale Adjustment Accounting Date:11/19/2021

Effective Date	Sale Accounting Date	Sale Item Reference Number
08/26/2021	11/19/2021	17327673

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I2021AIB27124935	2806	SUBMISSION- INFORMATION DISCLOSURE STMT	$130.00	Visa

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/08/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DAWN BREWER/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION AND RESPONSE TO OFFICE ACTION DATED 9/2/2021

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient;

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim 11, wherein the second [[array]] plurality of fibers defines ~~an opening~~ a spacing extending through a thickness thereof that is created by ~~spacing formed~~ a distance between adjacent fibers, wherein the ~~opening~~ spacing extends to the frame.

14. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

15. (Currently Amended) The prosthetic heart valve of claim 11, wherein a distance that the first [[array]] plurality of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first [[array]] plurality of fibers extends over each of the at least two rows of cells.

17. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are non-metallic.

18. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first [[array]] plurality of fibers and the frame and the second [[array]] plurality of fibers and the frame.

21. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

22. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering and the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are distinct elements.

24. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first [[array]] plurality of fibers against native leaflets of an aorta of the patient.

25. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers defines ~~an opening~~ a spacing that extends through a thickness thereof that is created by ~~spacing formed~~ a distance between adjacent fibers thereof.

27. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient;

wherein the prosthetic heart valve defines ~~openings~~ a spacing extending through a thickness of the first [[array]] plurality of fibers that is created by ~~spacing formed~~ a distance between adjacent fibers thereof, through a thickness of the second [[array]] plurality of fibers created by ~~spacing formed~~ a distance between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first [[array]] plurality of fibers and the second [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the first [[array]] plurality of fibers relative to the ~~openings~~ spacing to create a seal thereabout.

29. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

an [[array]] plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient;

wherein the [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

wherein the prosthetic heart valve defines ~~openings~~ a spacing extending through a thickness of the [[array]] plurality of fibers that is created by ~~spacing formed~~ a distance between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the [[array]] plurality of fibers relative to the ~~openings~~ spacings to create a seal thereabout,

wherein the [[array]] plurality of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Office Action dated September 2, 2021.

Applicant appreciates the resolution of several 112 rejections that were present in the August 11, 2021 Office Action. Specifically, Applicant appreciates the acknowledgement of the claim limitation of "polymer covering" being supported by the specification.

Applicant has amended "array" to respective "plurality" as requested in the Office Action to address one portion of the 35 USC 112 rejections.

The only other issue remaining in the application appears to be use of the language "openings." As it relates to that language, the Office Action states:

8. Referring to claim 13, the claim recites "wherein the second of the array of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap/spacing between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

9. The specification in the figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame. However, the specification does not adequately describe any 'openings' between adjacent fibers. Appropriate support and clarity is required.

Applicant does appreciate the concern with the use of the language "opening" since the language does not appear in the specification. Applicant has amended the claims to recite spacings, along with other limitations. Applicant submits that the figures clearly display the "spacings" limitations.

MPEP 2163 requires:

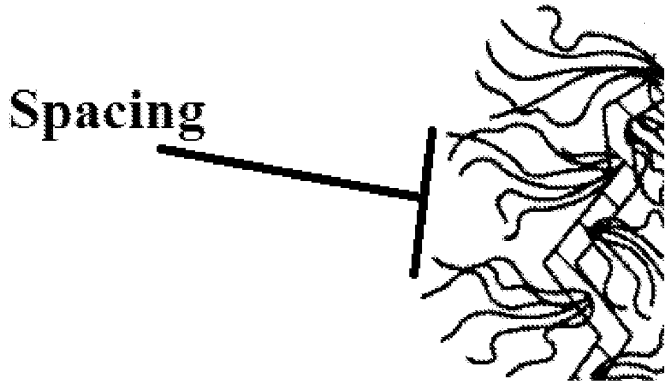
*An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118 ("**drawings alone may provide a 'written description' of an***

> ***invention as required by Sec. 112***"); *In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); Autogiro Co. of Am. v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). The description need only describe in detail that which is new or not conventional. See Hybritech v. Monoclonal Antibodies, 802 F.2d at 1384, 231 USPQ at 94. This is equally true whether the claimed invention is directed to a product or a process.*

Applicant is describing the spacing that is caused by the distance between fibers, and not the "gap/spacing between the inner and outer frames described in paragraph 91" as referenced in the Office Action. This "gap 264" is not what Applicant is claiming. What the Applicant is claiming is the spacing between segments of some fibers. (to mimic the general language of the claims, "the second plurality of fibers defines a spacing extending through a thickness thereof"). The spacing allows for inward deflection and compression of the fibers when the frame is expanded to fill any voids within the annulus and the seal formed by the fibers. This is well-illustrated in the images showing the deployed device.

Compare this to a very tightly knitted outer seal made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, or WIPO Publication 2006005015A2 to Spenser, with reference to FIG. 22, of record in the IDS dated July 11, 2021), there the lack of "spacings" between some fibers would not allow for compression of the outwardly extending fibers. Additionally, the further advantages of the spacings allowing for expansion and contraction of the stent frame compared to a tight outer seal such as a graft. Additionally, the spacing provides a lesser rigidity than a graft covering (as one example, a graft covering cannot foreshorten during crimping expansion to the same degree as a loosely defined fiber structure).

Applicant submits that FIG. 12 of the Application as filed illustrates this spacing. An annotated version is shown below:



And with further reference to annotated FIG. 11:

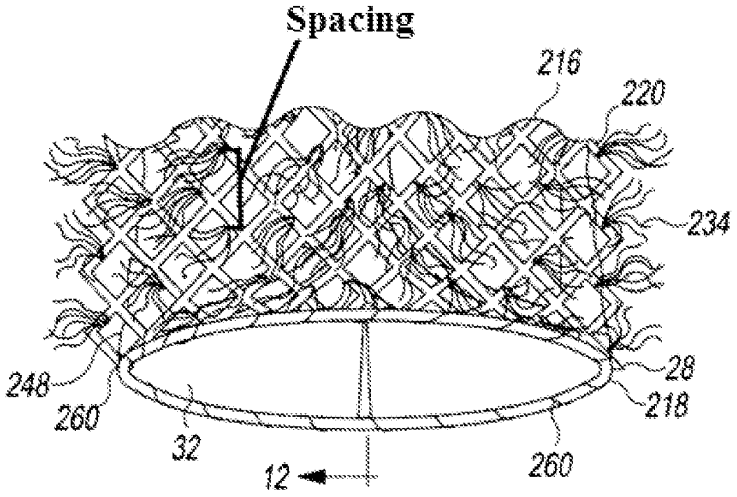


Fig. 11

As the MPEP makes clear, ***drawings alone may provide a 'written description' of an invention as required by Sec. 112***. This is the case in this instance, where the fibers are shown with spacings therebetween. This advantage is not shown in the prior art.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: November 8, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Electronic Patent Application Fee Transmittal	
Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Filed as Small Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	680	680
		Total in USD ($)		**680**

Electronic Acknowledgement Receipt	
EFS ID:	44222353
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	08-NOV-2021
Filing Date:	22-MAY-2021
Time Stamp:	04:49:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$680
RAM confirmation Number	E2021A8550063297
Deposit Account	506191
Authorized User	Justin Nifong
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-23UTIL-RCE.pdf	521524 f4621ca6dd069790b4dd8b0248e80270faeb4dc1	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Request for Continued Examination (RCE)	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	10

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38056 c9a02059606bdcdab1065e351f7cd4c68cdc83d4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	559580		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 10/21/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
10/21/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	**Art Unit** 3774	**AIA (FITF) Status** No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 September 2021 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: The claims are amended to potentially correct 112 issues. (See 37CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicants reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Additional time and consideration is required to consider the IDS.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: PTO-2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:11 and 13-29.
    Claim(s) withdrawn from consideration:_____.

/JERRAH EDWARDS/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

AFCP 2.0 Decision	Application No.	Applicant(s)	
	17/327,673	Shahriari, Ali	
	Examiner	Art Unit	AIA (FITF) Status
	TIFFANY P SHIPMON	3774	No

This is in response to the After Final Consideration Pilot request filed 28 September 2021.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☑ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

DO NOT ENTER: /T.P.S/ 10/05/2021

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION DATED 9/2/2021 WITH AFCP

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
426/2/23 UTIL	17/327,673	5/22/2021
First Named Inventor:	**Title:**	
Ali Shahriari	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
    - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
    - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
        - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
        - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
            - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
            - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Justin R. Nifong/	9/28/2021
Name (Print/Typed) Justin R. Nifong	**Practitioner Registration No.** 59389

***Note**: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION DATED 9/2/2021 WITH AFCP

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim 11, wherein the second [[array]] plurality of fibers defines ~~an opening~~ a spacing extending through a thickness thereof that is created by ~~spacing formed~~ a distance between adjacent fibers, wherein the ~~opening~~ spacing extends to the frame.

14. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

15. (Currently Amended) The prosthetic heart valve of claim 11, wherein a distance that the first [[array]] plurality of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first [[array]] plurality of fibers extends over each of the at least two rows of cells.

17. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are non-metallic.

18. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first [[array]] plurality of fibers and the frame and the second [[array]] plurality of fibers and the frame.

21. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

22. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering and the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are distinct elements.

24. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first [[array]] plurality of fibers against native leaflets of an aorta of the patient.

25. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers defines ~~an opening~~ a spacing that extends through a thickness thereof that is created by ~~spacing formed~~ a distance between adjacent fibers thereof.

27. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame,

wherein the prosthetic heart valve defines ~~openings~~ a spacing extending through a thickness of the first [[array]] plurality of fibers that is created by ~~spacing formed~~ a distance between adjacent fibers thereof, through a thickness of the second [[array]] plurality of fibers created by ~~spacing formed~~ a distance between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first [[array]] plurality of fibers and the second [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the first [[array]] plurality of fibers relative to the ~~openings~~ spacing to create a seal thereabout.

29. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

an [[array]] plurality of fibers that extend away from the frame,

wherein the [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

wherein the prosthetic heart valve defines ~~openings~~ a spacing extending through a thickness of the [[array]] plurality of fibers that is created by ~~spacing formed~~ a distance between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the [[array]] plurality of fibers relative to the ~~openings~~ spacings to create a seal thereabout,

wherein the [[array]] plurality of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Office Action dated September 2, 2021.

Applicant appreciates the resolution of several 112 rejections that were present in the August 11, 2021 Office Action. Specifically, Applicant appreciates the acknowledgement of the claim limitation of "graft covering" being supported by the specification.

Applicant has amended "array" to respective "plurality" as requested in the Office Action to address one portion of the 35 USC 112 rejections.

The only other issue remaining in the application appears to be use of the language "openings." As it relates to that language, the Office Action states:

8. Referring to claim 13, the claim recites "wherein the second of the array of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap/spacing between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

9. The specification in the Figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame. However, the specification does not adequately describe any 'openings' between adjacent fibers. Appropriate support and clarity is required.

Applicant does appreciate the concern with the use of the language "opening" since the language does not appear in the specification. Applicant has amended the claims to recite spacings, along with other limitations. Applicant submits that the figures clearly display the "spacings" limitations.

MPEP 2163 requires:

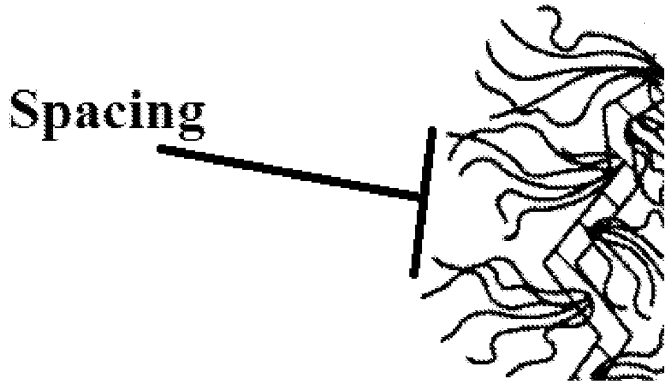
*An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118 ("**drawings alone may provide a 'written description' of an***

> ***invention as required by Sec. 112****"); In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); Autogiro Co. of Am. v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). The description need only describe in detail that which is new or not conventional. See Hybritech v. Monoclonal Antibodies, 802 F.2d at 1384, 231 USPQ at 94. This is equally true whether the claimed invention is directed to a product or a process.*

Applicant is describing the spacing that is caused by the distance between spaced-apart outwardly extending fibers, and not the "gap/spacing between the inner and outer frames described in paragraph 91" as referenced in the Office Action. This "gap 264" is not what Applicant is claiming. What the Applicant is claiming is the spacing between segments of some fibers. (to mimic the general language of the claims, "the second plurality of fibers defines a spacing extending through a thickness thereof"). The spacing allows for inward deflection and compression of the fibers when the frame is expanded to fill any voids within the annulus and the seal formed by the fibers. This is well-illustrated in the images showing the deployed device.

Compare this to a very tightly knitted outer seal made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, or WIPO Publication 2006005015A2 to Spenser, with reference to FIG. 22, of record in the IDS dated July 11, 2021), there the lack of "spacings" between some fibers would not allow for compression of the outwardly extending fibers. Additionally, the further advantages of the spacings allowing for expansion and contraction of the stent frame compared to a tight outer seal such as a graft. Additionally, the spacing provides a lesser rigidity than a graft covering (as one example, a graft covering cannot foreshorten during crimping expansion to the same degree as a loosely defined fiber structure).

Applicant submits that FIG. 12 of the Application as filed illustrates this spacing. An annotated version is shown below:



And with further reference to annotated FIG. 11:

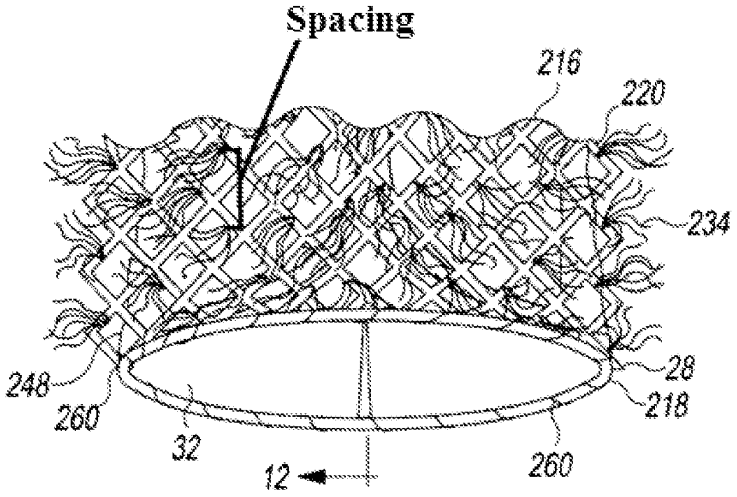


Fig. 11

As the MPEP makes clear, ***drawings alone may provide a 'written description' of an invention as required by Sec. 112***. This is the case in this instance, where the fibers are shown with spacings therebetween. This advantage is not shown in the prior art.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: September 28, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Electronic Acknowledgement Receipt

EFS ID:	43894199
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	28-SEP-2021
Filing Date:	22-MAY-2021
Time Stamp:	23:14:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	After Final Consideration Program Request	sb0434.pdf	226099 41ae210cbc675135dbb3d7ae8ca96411f8b98d22	no	2

Warnings:

Information:					
2		426-2-23UTIL-20210902-rsp-to-OA.pdf	520030 cda55f887f8b7a4b8de343e5adb4fdfa6079f894	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	10

Warnings:	
Information:	
Total Files Size (in bytes):	746129

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	09/28/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DAWN BREWER/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION DATED 9/2/2021 WITH AFCP

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 09/23/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
09/23/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Applicant-Initiated Interview Summary	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali		
	Examiner TIFFANY P SHIPMON	**Art Unit** 3774	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
TIFFANY P SHIPMON	Examiner	Telephonic
Jerrah Edwards	SPE	
Justin Nifong	Attorney	

Date of Interview: 15 September 2021

Issues Discussed:

35 U.S.C. 112

Applicants representative discussed a potential amendment to overcome the 112 rejections. The Examiner recommended to Applicant to amend the 'array' language to 'plurality' in order to be consistent with language that is supported by the specification.

Additionally, in regards to claim 13, the Examiner recommended to Applicant to present language consistent with what is supported in the specification and/or drawings in regards to spacing that occurs between the pluarlity of adjacent fibers.

☑ Attachment

/JERRAH EDWARDS/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
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RESPONSE TO OFFICE ACTION DATED 9/2/2021

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim 11, wherein the second [[array]] plurality of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

15. (Currently Amended) The prosthetic heart valve of claim 11, wherein a distance that the first [[array]] plurality of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first [[array]] plurality of fibers extends over each of the at least two rows of cells.

17. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are non-metallic.

18. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first [[array]] plurality of fibers and the frame and the second [[array]] plurality of fibers and the frame.

21. (Previously Presented) The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

22. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering and the first [[array]] plurality of fibers and the second [[array]] plurality of fibers are distinct elements.

24. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first [[array]] plurality of fibers against native leaflets of an aorta of the patient.

25. (Currently Amended) The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first [[array]] plurality of fibers defines an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

27. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first [[array]] plurality of fibers that extend away from the frame,

wherein the first [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second [[array]] plurality of fibers that is positioned radially inwardly from the first [[array]] plurality of fibers,

wherein the second [[array]] plurality of fibers is in direct contact with the frame,

wherein the prosthetic heart valve defines openings extending through a thickness of the first [[array]] plurality of fibers that is created by spacing formed between adjacent fibers thereof, through a thickness of the second [[array]] plurality of fibers created by spacing formed between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first [[array]] plurality of fibers and the second [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the first [[array]] plurality of fibers relative to the openings to create a seal thereabout.

29. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

an [[array]] plurality of fibers that extend away from the frame,

wherein the [[array]] plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

wherein the prosthetic heart valve defines openings extending through a thickness of the [[array]] plurality of fibers that is created by spacing formed between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the [[array]] plurality of fibers in response to expansion of the prosthetic heart valve compresses the [[array]] plurality of fibers relative to the openings to create a seal thereabout,

wherein the [[array]] plurality of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Office Action dated September 2, 2021.

Applicant has amended "array" to respective "plurality" as requested in the Office Action to address one portion of the 35 USC 112 rejections.

The only other issue remaining in the application appears to be use of the language "openings." As it relates to that language, the Office Action states:

> 8. Referring to claim 13, the claim recites "wherein the second of the array of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap/spacing between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.
>
> 9. The specification in the Figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame. However, the specification does not adequately describe any 'openings' between adjacent fibers. Appropriate support and clarity is required.

Applicant does appreciate the concern with the use of the language "openings" since the language does not appear in the specification, however, Applicant submits that the figures clearly display the "openings" limitations.

MPEP 2163 requires:

> *An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118 ("**drawings alone may provide a 'written description' of an invention as required by Sec. 112**"); In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); Autogiro Co. of Am. v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); Eli Lilly, 119 F.3d at 1568, 43*

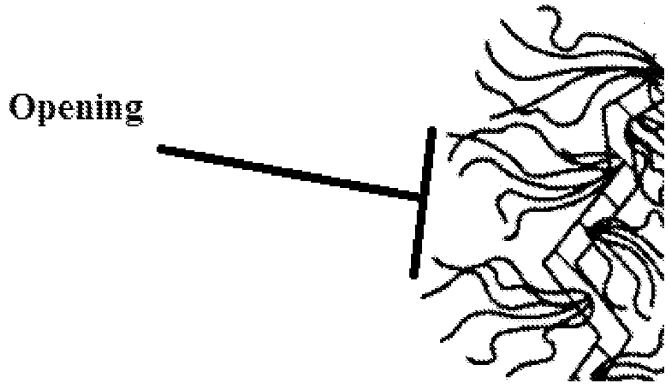
> *USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). The description need only describe in detail that which is new or not conventional. See Hybritech v. Monoclonal Antibodies, 802 F.2d at 1384, 231 USPQ at 94. This is equally true whether the claimed invention is directed to a product or a process.*

Applicant is describing the opening that is caused by spacing between outwardly extending fibers, and not the "gap/spacing between the inner and outer frames described in paragraph 91" as referenced in the Office Action. This "gap 264" is not what Applicant is claiming. What the Applicant is claiming is the opening or spacing between segments of some fibers. (to mimic the exact language of the claims, "the second plurality of fibers defines an opening extending through a thickness thereof"). The opening allows for inward deflection and compression of the fibers when the frame is expanded, to fill any voids within the annulus and the seal formed by the fibers. Paragraph [0119] of the Application contemplates this:

> *Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 416 and compresses the collagen fiber/ hydrogel coated proximal section 220 of the outer frame 416 against the aortic annulus 210.*

Compare this to a very tightly knitted outer seal made of tightly knitted fibers, there the lack of "openings" between some fibers would not allow for compression of the outwardly extending fibers. Additionally, the further advantages of the openings allowing for expansion and contraction of the stent frame compared to a tight outer seal such as a graft.

Applicant submits that FIG. 12 of the Application as filed illustrates this opening. An annotated version is shown below:



And with further reference to annotated FIG. 11:

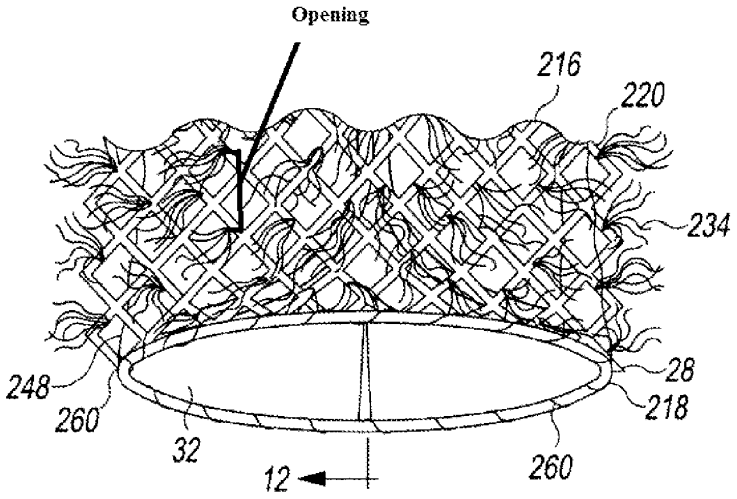


Fig. 11

As the MPEP makes clear, ***drawings alone may provide a 'written description' of an invention as required by Sec. 112***. This is the case in this instance, where the fibers are shown with openings therebetween. This advantage is not shown in the prior art.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: September 20, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

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	3	6893460	B2	2005-05-17	Spenser et al.	
	4	7393360	B2	2008-07-01	Spenser et al.	
	5	7510575	B2	2009-03-31	Spenser et al.	
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	Attorney Docket Number	426/2/23 UTIL

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	1	Inter Partes Review 2017-00060 of US Patent No. 8,992,608, and supporting declaration of Nigel Buller	
	2	Inter Partes Review 2021-01527 of US Patent No. 10,792,172, and supporting declaration of Nigel Buller	
	3	EPO, Office Action of corresponding European Patent Application No. 20172681.7, mailed Sep. 6, 2021, 6 pages	

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	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	17327673
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	Examiner Name	SHIPMON, TIFFANY P
	Attorney Docket Number	426/2/23 UTIL

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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A certification statement is not submitted herewith.

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-09-20
Name/Print	Justin R. Nifong	Registration Number	59389

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Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong/Sandra Hess
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
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Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
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		Total in USD ($)		**130**

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EFS ID:	43804869
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
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Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	20-SEP-2021
Filing Date:	22-MAY-2021
Time Stamp:	10:32:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL

CONFIRMATION NO. 1189

175373
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

PUBLICATION NOTICE

OC000000128288361

Title:TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Publication No.US-2021-0275330-A1
Publication Date:09/09/2021

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 09/02/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
09/02/2021	ELECTRONIC

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Office Action Summary	Application No. 17/327,673	Applicant(s) Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	AIA (FITF) Status No

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- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 14 August 2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 11 and 13-29 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 11 and 13-29 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Arguments

2. Applicant's arguments filed 8/14/2021 have been fully considered but they are not persuasive.

3. In regards to the 112 rejection for claim 13, Applicant points to an 'opening' in an annotated figure. However, it seems to only be a spacing rather than an opening. Applicant provides that the advantage of the limitation is that the opening reduces restrictions on expansion and contraction of the stent frame, however these features do not refer back to the specification for citations.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 11, and 13-29 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claim 11, line 10 introduces the claimed feature of "a first array'. There is no support found in the specification for this terminology. The specification only recites 'plurality' but does not support any further details or configurations of the fibers. It is unclear where such an array would be, and which fibers would comprise the array.

7. Claims 13, 15-18, 20, 23-24, 26 and 28-29, all recite language directed to 'arrays', and contain the same issue as discussed supra in claim 11.

8. Referring to claim 13, the claim recites "wherein the second of the array of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap/spacing between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

9. The specification in the Figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame. However, the specification does not adequately describe any 'openings' between adjacent fibers. Appropriate support and clarity is required.

10. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 13 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

12. Referring to claim 13, the claim recites "wherein the second of the array of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

13. The specification in the Figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame. However, the specification does not adequately describe any 'openings' between adjacent fibers. Appropriate support and clarity is required.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/JERRAH EDWARDS/
Supervisory Patent Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	Date	Examiner
A61F 2/856,07,2418,82,962,24,86,89,90; 2002/061,067; 2210/00,0014,0057; 2220/008,0016,0025,0058,0075; 2230/001,0034,0067; 2250/0048,0069	07/22/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search	07/22/2021	T.S.
EAST Search	08/25/2021	T.S.

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61F	2/856	07/22/2021	T.S.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	234	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/25 14:20
S2	3	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/28 22:05
S3	21	("20120046726" | "7018404" | "7799072" | "8016877" | "20070250146" | "6334868" | "7510574" | "8002826" | "20070276464" | "6752829" | "5102417" | "7947074" | "20070095283" | "20110257731" | "7393360" | "7914569" | "8226710" | "20040210304" | "5397355" | "7780726" | "20050197687" | "20060149351" | "20090198315" | "20100042202" | "7252682" | "20030040771" | "20120089218" | "5716393" | "6254632" | "20090125098" | "6582462" | "7771467" | "8206438" | "20080132999" | "20090099644" | "8425584").PN.	USPAT	OR	OFF	2014/06/28 23:06
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S7	38	a61f2/2418	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S8	59	a61f2/2412	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S9	41	a61f2/2436	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S10	17	a61f2/2433	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S11	11	a61f2/2475	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
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S15	3	S13 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:12
S16	30	S13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:13
S17	74	623/1.13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:43
S18	2,377	stent and graft and fibers and migration	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:48
S19	317	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/06/29 18:49
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S22	1	S21 and fibers	USPAT	OR	OFF	2014/06/29 18:52
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S25	1	("7799072").PN.	USPAT; USOCR	OR	OFF	2014/07/14 09:28
S26	3	meretei.in.	USPAT	OR	OFF	2014/07/14 09:28
S27	14	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2014/07/14 09:28
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S30	7	"7799072"	US-PGPUB; USPAT; USOCR	OR	OFF	2014/11/30 19:34
S31	369	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/11/30 19:47
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S33	915	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2014/11/30 19:59

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S35	2,002	(623/1.35-1.36).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2014/12/01 10:28
S39	2,556	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 10:24
S40	3,379	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:47
S41	2	("13706869").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:49
S42	2	("13706896").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:51
S46	1	("14614628").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/03/20 19:27
S47	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/05/15 06:58
S48	2	("7799072").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:28
S49	4	("20080132993" | "20140336749").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:29
S50	2	("7799072").PN.	US-PGPUB; USPAT;	OR	OFF	2017/05/15 08:29

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S52	18	("20050177222" | "20070067014" | "20100268318" | "6152956" | "20060276883" | "20070112411" | "20030220683" | "20040106981" | "20100094409").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:33
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S55	4,867	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:12
S56	3,429	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:12
S57	2,489	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S58	1,308	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S59	1,182	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
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S61	1	("20070067014").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/17 16:11
S62	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/18 08:47
S63	1,461	carpentier.in.	US-PGPUB; USPAT;	OR	OFF	2018/01/11 08:54

			USOCR; EPO; JPO; DERWENT			
S64	61	carpentier.in. and aorta	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 09:32
S65	3	"20050102018"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 09:39
S66	6	(US-20070168013-$ | US-20140172064-$ | US-20140316513-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:13
S67	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/02/05 09:42
S68	6,135	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S69	4,276	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S70	3,295	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S71	1,674	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S72	1,322	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S73	9,150	S68 S69 S70 S71 S72	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S74	6,389	a61f2/2418.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/04/15 09:04

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S75	4,396	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S76	3,436	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S77	1,760	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S78	1,352	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S79	9,503	S74 S75 S76 S77 S78	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S80	9,503	S74 S75 S76 S77 S78 S79	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S81	4,461	S80 and (artery arteries)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:06
S82	1,118	S80 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:09
S83	6,421	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S84	4,413	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05

S85	3,462	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S86	1,773	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S87	1,354	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S88	9,549	S83 S84 S85 S86 S87	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S89	9,549	S83 S84 S85 S86 S87 S88	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
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S91	1	("20090254172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/05/14 15:40
S92	9	("20060155366" | "20100049313" | "6258117").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:09
S93	2	("20080262592").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S94	6	("20070168013" | "20140172064" | "20140316513").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10

S95	6	("20020177890" | "5976179").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S96	3	"20140316513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:19
S97	2	"20070168013"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:20
S98	4	"20140172065"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:21
S99	6	"20100049313"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:26
S100	2	"20060155366"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:29
S101	6,666	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S102	4,593	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S103	3,601	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35

S104	1,864	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S105	1,380	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S106	9,898	S101 S102 S103 S104 S105	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S107	9,898	S101 S102 S103 S104 S105 S106	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S108	1,179	S107 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 10:35
S109	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 11:44
S110	4	"14614628"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 12:36
S111	7,098	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S112	4,889	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S113	3,856	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15

S114	1,965	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S115	1,422	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S116	10,508	S111 S112 S113 S114 S115	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S117	10,508	S111 S112 S113 S114 S115 S116	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S118	1,256	S117 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/12/08 16:15
S120	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S121	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S122	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S123	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S124	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S125	10,919	S120 S121 S122 S123 S124	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45

S126	10,919	S120 S121 S122 S123 S124 S125	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S127	1,305	S126 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/03/13 11:45
S128	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S129	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S130	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S131	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S132	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S133	10,919	S128 S129 S130 S131 S132	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S134	10,919	S128 S129 S130 S131 S132 S133	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S135	966	S134 and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:56

S136	5,500	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		| US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ |	US-PGPUB; USPAT;	OR	OFF	2020/04/13 14:46

		US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$ | US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44

S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$ | US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3652198-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

		3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/06/06 16:07

		20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	FPRS; EPO; DERWENT			
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | NO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
S172	627	("20010039450" | "20020013571" | "20020026216" | "20020082630" | "20020107565" | "20020123802" | "20020151970" | "20020183835" | "20020183838" | "20020188348" | "20020198594" | "20030023303" | "20030050694" | "20030078652" | "20030130729" | "20030153943" | "20030163194" | "20030167071" | "20030171806" | "20030199975" | "20030229394" | "20030229395" | "20030233142" | "20030236568" | "20030236569" | "20040002719" | "20040003819" | "20040010305" | "20040015230" | "20040015232" | "20040015233" | "20040019374" | "20040019377" | "20040019378" | "20040024447" | "20040024451" | "20040024452" | "20040030321" | "20040030381" | "20040030382" | "20040030405" | "20040034380" | "20040034411" | "20040039436" | "20040039442" | "20040039443" | "20040044350" | "20040044365" | "20040044403" | "20040049207" | "20040049211" | "20040049266" | "20040059351" | "20040059411" | "20040059412" | "20040060161" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:31

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S195	10	(CN-102014805-$ | NO-2005087117-$ | NO-2006127412-$ | NO-2010006627-$ | NO-2010031060-$ | NO-2010105195-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | EP-2787925-$ | JS-2012068165-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:37
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S199	170	(rowe.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:19
S200	75	(mclean.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:22
S201	108	(vidlund.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:23
S202	1	("20080275548").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:47

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S204	1,050	salahieh.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48
S205	516	salahieh.in. and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48
S206	1	("20050137695").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:55
S207	7,776	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S208	5,285	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S209	4,260	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S210	2,147	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S211	1,470	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S212	11,433	S207 S208 S209 S210 S211	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23

S216	0	wo2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S217	0	(2006/124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:23
S218	0	(2006/0124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:24
S219	5	("2006124649").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/07/29 09:24
S220	1	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:55
S221	4	"20090125098"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:29
S222	7	"20030040771"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:30
S223	1,779	(cuff with (fiber barb))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:58
S224	270	("20020036220" | "20030023303" | "20030050694" | "20030130726" | "20040049262" | "20040093075" | "20040102837" | "20040111111" | "20040210304" | "20040260389" | "20050096726" | "20050137682" | "20050137695" | "20050137697" | "20050203605" | "20050256566" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:03

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S225	1	(spense.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22

S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17
S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20
S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT;	OR	OFF	2020/08/28 15:53

			EPO; JPO; DERWENT			
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:02
S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
S248	1	("4164046").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:09

S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 15:17
S258	0	("2006124649").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 15:17
S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S262	0	("12882605").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S263	0	("2006018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S264	1	("20060018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S265	7	"20060018514"	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/11/06 16:04

			FPRS; EPO; JPO; DERWENT			
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$ | US-3992608-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:25
S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:22
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:25

		| US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	JPO; DERWENT			
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:27

			JPO; DERWENT			
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:29

			JPO; DERWENT			
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:33
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:21
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/02/11 17:46

			JPO; DERWENT			
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48
S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51
S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
S320	5	"20060005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55

S321	96	"2006005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S322	5	"15876053"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:11
S323	2	("2018/0206982").URPN.	USPAT	OR	OFF	2021/02/13 09:12
S324	0	"20010049555"	USPAT	OR	OFF	2021/02/13 09:14
S325	4	"20010049555"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:14
S326	3	"20070233228"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S327	3	"20120296418"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S328	822	("20010021872" | "20020026094" | "20020032481" | "20020138135" | "20020173842" | "20030050694" | "20030100939" | "20030158597" | "20030212454" | "20040039436" | "20040186563" | "20040186565" | "20050075728" | "20050096736" | "20050188525" | "20050203614" | "20050203617" | "20050234546" | "20060004469" | "20060025857" | "20060058872" | "20060149350" | "20060183383" | "20060229719" | "20060259137" | "20070005131" | "20070010876" | "20070010877" | "20070112422" | "20070162102" | "20070203503" | "20070203575" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:25

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"20130331929" | "20140194981" |
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"20140277417" | "20140277419" |
"20140277424" | "20140330372" |
"20140343671" | "20150073545" |
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S329	4	("20130190862" | "20160317305").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:26
S330	4	("20070233228" | "20120296418").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27
S331	835	("20020173842" | "20030100939" | "20040186563" | "20050203617" | "20070162102" | "20080183271" | "20100204781" | "20130274873" | "20140200661" | "20150073546" | "4222126" | "4733665" | "4759758" | "4777951" | "5026366" | "5032128" | "5332402" | "5411055" | "5558644" | "5571175" | "5609626" | "6231602" | "6425916" | "6440764" | "6689123" | "6893460" | "6936067" | "7655034" | "7993394" | "8652203" | "20030212454" | "20050075728" | "20070112422" | "20100168844" | "20100198347" | "4829990" | "5397351" | "5545214" | "5549665" | "5584803" | "5855602" | "6027525" | "6132473" | "6168614" | "6221091" | "6302906" | "6350277" | "6454799" | "6605112" | "6908481" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27

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S332	11	WO2006124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:13
S333	53	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:14
S334	0	"17131869"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S335	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S336	13	S328 and (outer$4 with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:49

S337	27	S328 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:00
S338	36,075	l11and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S339	27	S331 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S340	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:56
S341	12	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-3333075-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:57
S342	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 15:10
S343	1	("9333075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/17 05:33
S344	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/17 05:40
S345	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17007373-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 12:07

		| US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	JPO; DERWENT			
S346	10	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:38
S347	34	"10555823"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:50
S348	2	"16983196"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 15:15
S349	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/21 15:20
S350	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S351	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S352	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ |	US-PGPUB; USPAT;	OR	OFF	2021/03/21 18:03

		US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S353	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S354	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S355	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S356	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S357	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S358	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S359	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S360	7,540	A61F2/86.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/03/21 18:03

			USOCR; FPRS; EPO; JPO; DERWENT			
S361	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S362	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S363	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S364	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S365	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S366	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S367	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S368	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/03/21 18:03

			FPRS; EPO; JPO; DERWENT			
S369	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S370	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S371	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S372	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S373	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S374	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S375	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S376	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 18:03

			JPO; DERWENT			
S377	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S378	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S379	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S380	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S381	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S382	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S383	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S384	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S385	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S386	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S387	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S388	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S389	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S390	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S391	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S392	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S393	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S394	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S395	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S396	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S397	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S398	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S399	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S400	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/21 21:13

			JPO; DERWENT			
S401	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S402	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S403	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S404	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S405	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S406	2,578	(S378 S379 S380 S381 S382 S383 S384 S385 S386 S387 S388 S389 S390 S391 S392 S393 S394 S395 S396 S397 S398 S399 S400 S401 S402 S403 S404 S405) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S407	15	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2021/03/25 16:13
S408	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S409	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-	US-PGPUB; USPAT;	OR	OFF	2021/03/25 16:13

		20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S410	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S411	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S412	5,773	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S413	26,431	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S414	17,826	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S415	17,867	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S416	4,044	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S417	6,084	A61F2/24.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/03/25 16:13

			USOCR; FPRS; EPO; JPO; DERWENT			
S418	7,541	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S419	11,784	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S420	18,994	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S421	5,686	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S422	4,852	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S423	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S424	12,667	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S425	1,775	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/03/25 16:13

			FPRS; EPO; JPO; DERWENT			
S426	12,059	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S427	15,690	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S428	32,783	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S429	9,318	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S430	18,235	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S431	3,576	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S432	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S433	14,804	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S434	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S435	4,158	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S436	2,585	(S408 S409 S410 S411 S412 S413 S414 S415 S416 S417 S418 S419 S420 S421 S422 S423 S424 S425 S426 S427 S428 S429 S430 S431 S432 S433 S434 S435) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S438	0	("13706896").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:37
S439	34	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 09:37
S440	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:58
S441	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17170957-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:38

		5665117-$ | US-5824037-$ | US-20130144373-$).DID.				
S442	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S443	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S444	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S445	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S446	5,776	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S447	26,437	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S448	17,841	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S449	17,872	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S450	4,046	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S451	6,089	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S452	7,542	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S453	11,785	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S454	18,999	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S455	5,689	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S456	4,854	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S457	555	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S458	12,674	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S459	1,777	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S460	12,063	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S461	15,695	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S462	32,786	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S463	9,323	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S464	18,239	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S465	3,579	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S466	3,175	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S467	14,810	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S468	1,657	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S469	4,160	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S470	2,587	(S442 S443 S444 S445 S446 S447 S448 S449 S450 S451 S452 S453 S454 S455 S456 S457 S458 S459 S460 S461 S462 S463 S464 S465 S466 S467 S468 S469) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S471	0	("16910189").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 16:49
S472	6	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 16:49
S473	11	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 17:22

S474	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 18:29
S475	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 18:36
S476	72	(US-10016271-$ | US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17006793-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S477	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | NO-2006005015-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110098802-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130304196-$ | NO-3829057-$ | IF-617622-$ | SO-0225223-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S478	54	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 09:42
S479	3	"20060259136"	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/04/09 14:18

			FPRS; EPO; JPO; DERWENT			
S480	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/09 16:30
S481	28	S480 and (mitral)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 16:37
S482	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 11:44
S483	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/04/10 15:48

			JPO; DERWENT			
S484	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59
S485	5	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59
S486	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 10:57
S487	55	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:15
S488	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 10:19

		9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S489	39	S488 and (seal with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:19
S490	41	S488 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:23
S491	21	("2014/0316513").URPN.	USPAT	OR	OFF	2021/04/27 10:28
S492	0	"17006793"	USPAT	OR	OFF	2021/04/27 10:32
S493	1	"16792197"	USPAT	OR	OFF	2021/04/27 10:32
S494	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 11:19
S496	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 19:42

		US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S497	41	S496 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 19:42
S498	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/24 12:23
S499	15	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/05/25 08:57
S500	54	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/05/25 08:57
S503	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/30 17:02
S504	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 13:20

		$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.				
S505	3	"17007373"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 16:13
S506	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/06/03 13:29
S507	15	S506 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:29

S508	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S509	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S510	92	S508 S509	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S511	10	S510 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S512	232	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 14:01
S513	1	("7921678").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/06/03 14:08
S514	35	(US-17170957-$ | US-20030153974-$ | US-20060025857-$ | US-20060074484-$	US-PGPUB; USPAT;	OR	OFF	2021/06/18 10:36

		| US-20070282436-$ | US-20100036484-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20120022633-$ | US-20120071969-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20140018915-$ | US-20140155997-$ | US-20170128209-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S518	6	(("20130018458") or ("20110125244") or ("20110166636") or ("20110098802") or ("20060074484") or ("20120310328")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/01 09:32
S520	102	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17327673-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060025857-$ | US-20060074484-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20070282436-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100036484-$ | US-20100204781-$ | US-20110009948-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20110218619-$ | US-20110319991-$ | US-20120022633-$ | US-20120071969-$ | US-20120123529-$ | US-20120296418-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20130304196-$ | US-20140018915-$ | US-20140155997-$ | US-20150335429-$ | US-20160022444-$ | US-20170128209-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 16:59
S521	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | AI-20060025857-$ | NO-2006005015-$ | AI-20060074484-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20070282436-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 17:17

		| AI-20100036484-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110040367-$ | AI-20110098802-$ | AI-20110125244-$ | AI-20110166636-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120022633-$ | AI-20120071969-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20120310328-$ | NO-2012068175-$ | AI-20130018458-$ | AI-20130073030-$ | AI-20130304196-$ | AI-20140018915-$ | AI-20140155997-$ | AI-20150335429-$ | AI-20160022444-$ | AI-20170128209-$ | NO-3829057-$ | SO-0225223-$ | VA-223131450-$).DID.				
S522	0	"17327673"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:09
S523	4	"17096253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:10
S526	17	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/07/22 15:41
S527	58	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/07/22 15:41
S528	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/07/25 16:50

		20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S529	15	S528 and collagen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 16:50
S530	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:00
S531	23	"2005023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:16
S532	12	"20050023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:17
S533	0	("2005023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S534	1	("20050023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S535	1	("20060004442").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:19
S536	398	("2006/0004442").URPN.	USPAT	OR	OFF	2021/07/25 17:20

S537	1	("20130018458").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:28
S539	41	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/30 11:20
S542	22	"10299917"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/08/23 10:08

8/25/2021 4:57:07 PM
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany P. Shipmon
	Attorney Docket Number	426/2/23 UTIL

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany P. Shipmon
	Attorney Docket Number	426/2/23 UTIL

	1	JPO, Office Action from Corresponding JP Patent Application Number 2020-122656, mailed Aug. 17, 2021, 4 pages	X

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany P. Shipmon
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-08-26
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal

Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong/Jana Passe
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	130	130
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt	
EFS ID:	43607716
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Jana Passe
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	26-AUG-2021
Filing Date:	22-MAY-2021
Time Stamp:	10:41:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	E20218PA42222669
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	426-2-23UTIL-20210826-IDS.pdf	1034323 a707a251d1f6f64a6fb7d25248fcbf55dc5ce5f5	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	NPL01_426-2-4JP-20210817-OA-incl-translation.pdf	138867 6196158a52a53de514f16f7f9ec18c4261c84ff3	no	4
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	37854 df9a857901fd2e8905e3bae56eb61e53e58a8b3f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1211044		

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New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/14/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DESHONNE T. MARTINO/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION DATED 8/11/2021

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Electronic Acknowledgement Receipt

EFS ID:	43512074
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	14-AUG-2021
Filing Date:	22-MAY-2021
Time Stamp:	14:21:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-23UTIL-20210811-rsp-to-OA.pdf	2254502 ff7b1916a7e73f30a286ee233fee5fd1879ca9a7	yes	29

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	29
Warnings:			
Information:			
	Total Files Size (in bytes):	2254502	

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

~~an inner skirt~~ a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

~~an outer seal that extends radially outwardly of the frame,~~

~~wherein the outer seal comprises~~ a first array ~~plurality~~ of fibers that extend away from the frame,[[and]]

wherein the first array ~~plurality~~ of fibers [[are]] is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second array of fibers that is positioned radially inwardly from the first array of fibers,

wherein the second array of fibers is in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim [[12]] 11, wherein the second ~~plurality~~ array of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering extends proximally further than a proximal ~~scalloped~~ end of the leaflet assembly.

15. (Currently Amended) The prosthetic heart valve of claim 11, wherein a distance that the first array of fibers ~~of the outer seal~~ extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the ~~outer seal~~ first array of fibers extends over ~~covers~~ each of the at least two rows of cells.

17. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array ~~plurality~~ of fibers and the second array of fibers ~~of the outer seal~~ are non-metallic.

18. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array ~~plurality~~ of fibers and the second array of fibers ~~of the outer seal~~ are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~outer seal~~ prosthetic heart valve is free of a non-porous graft covering between the first array ~~plurality~~ of fibers ~~of the outer seal~~ and the frame and the second array of fibers and the frame.

21. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering is stitched to the frame.

22. (Currently Amended) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering and the first array of fibers and the second array of fibers ~~outer seal~~ are distinct elements.

24. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first array ~~plurality~~ of fibers ~~of the outer seal~~ against native leaflets of an aorta of the patient.

25. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array ~~plurality~~ of fibers ~~of the outer seal~~ define an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

27. (New) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first array of fibers that extend away from the frame,

wherein the first array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second array of fibers that is positioned radially inwardly from the first array of fibers,

wherein the second array of fibers is in direct contact with the frame,

wherein the prosthetic heart valve defines openings extending through a thickness of the first array of fibers that is created by spacing formed between adjacent fibers thereof, through a thickness of the second array of fibers created by spacing formed between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first array of fibers and the second array of fibers in response to expansion of the prosthetic heart valve compresses the first array of fibers relative to the openings to create a seal thereabout.

29. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

an array of fibers that extend away from the frame,

wherein the array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

wherein the prosthetic heart valve defines openings extending through a thickness of the array of fibers that is created by spacing formed between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the array of fibers in response to expansion of the prosthetic heart valve compresses the array of fibers relative to the openings to create a seal thereabout,

wherein the array of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Office Action dated August 11, 2021.

Without acquiescing to the 112 rejections in the matter, Applicant has amended the claims to address the 112 rejections.

CLAIM 11

Claim 11 has been amended to recite:

An endovascular prosthetic heart valve for use in a patient, comprising:
a frame formed of a plurality of struts that cooperate to form a plurality of cells,
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
a leaflet assembly within the frame;
~~*an inner skirt*~~ *a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame;*
~~*an outer seal that extends radially outwardly of the frame,*~~
~~*wherein the outer seal comprises*~~ *a first array* ~~*plurality*~~ *of fibers that extend away from the frame,[[and]]*
wherein the first array ~~*plurality*~~ *of fibers [[are]] is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,*
a second array of fibers that are positioned radially inwardly from first array of fibers, wherein the second array of fibers is in direct contact with the frame.

Applicant has amended "inner skirt" to recite "polymer covering." This is well supported in paragraph [0089] of the application as filed:

> *In the illustrative embodiment, the outer surface **248** of the stent **244** is covered with low-profile polyester, ePTFE, or other nonporous covering material **250** that prevents fluid from passing through the outer surface **248**. However, it should be appreciated that the stent **244 may be covered with standard polyester**, ePTFE or other nonporous materials.*

Applicant has amended "outer seal" to recite first array of fibers and second array of fibers to address the 112 rejections. While "array" is not used verbatim in the specification, array is used herein to represent a grouping of fibers that cooperate to form a structure, namely an array. Applicant submits this is well-supported by at least the drawings. Applicant may be their own lexicographer, and submits that the claim language clearly claims the invention.

CLAIM 12

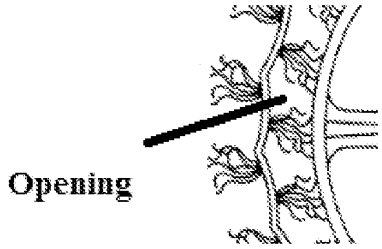
Claim 12 is canceled.

CLAIM 13

Claim 13 recites:

The prosthetic heart valve of claim 11, wherein the second array of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

This claim is well illustrated with reference to the annotated, partial view of FIG. 13:



The advantage of this limitation is that the opening reduces restrictions on expansion and contraction of the stent frame (as opposed to a solid, outer graft), and encourages thrombos of the fibers by allowing blood flow therethrough.

CLAIM 14

Claim 14 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

This is well illustrated in FIG. 12:

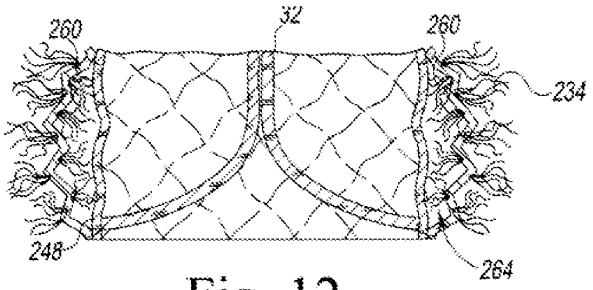


Fig. 12

CLAIM 15

Claim 15 recites:

The prosthetic heart valve of claim 11, wherein a distance that the first array of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

This is well illustrated with annotated FIG. 12:

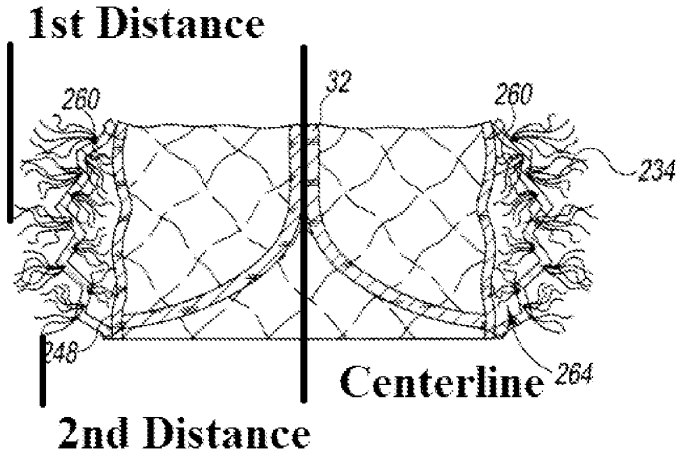


Fig. 12

The advantage of this limitation is that differing sealing profiles are applied against the native annulus, to thereby vary the sealing profile and decrease paravalvular leakage.

CLAIM 16

Claim 16 recites:

The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first array of fibers extends over each of the at least two rows of cells.

The claims have been amended to recite that the first array of fibers extends over each of the at least two rows of cells.

CLAIM 17

Claim 17 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers and the second array of fibers are non-metallic.

CLAIM 18

Claim 18 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers and the second array of fibers are collagen fibers.

CLAIM 19

Claim 19 recites:

The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

CLAIM 20

Claim 20 recites:

The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first array of fibers and the frame and the second array of fibers and the frame.

This so-called negative limitation has been discussed in related applications. MPEP 2173 is controlling on the use of support for negative limitations:

> *Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ*

> *187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under* ***35 U.S.C. 112****, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).*

Additionally, the Federal Circuit has clarified the standards for negative limitations as well. The Federal Circuit has held that a negative limitation has written description support when the specification "describes a reason to exclude the relevant limitation." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). That standard is easily satisfied with the disclosure. Such written description support need not rise to the level of disclaimer. In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material. The specification discloses multiple embodiments of a heart valve, and some of the embodiments show a design with an outer graft covering, and some of the other embodiments show a design that is free of an outer graft covering. The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

CLAIM 21

Claim 21 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

Claim 21 has been amended consistent with the base claim. The stitch is visible in FIG. 12.

CLAIM 22

Claim 22 recites:

The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

Applicant submits that this improves hemodynamic performance.

CLAIM 23

Claim 23 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering and the first array of fibers and the second array of fibers are distinct elements.

This is well-illustrated throughout the drawings.

CLAIM 24

Claim 24 recites:

The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first array of fibers against native leaflets of an aorta of the patient.

This is well-illustrated throughout the drawings.

CLAIM 25

Claim 25 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

Claim language similar to this has been presented in related applications, with reference to 218 extending over a proximal end of the frame as illustrated in FIG. 11:

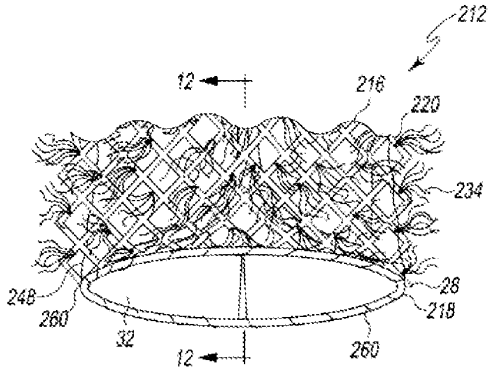


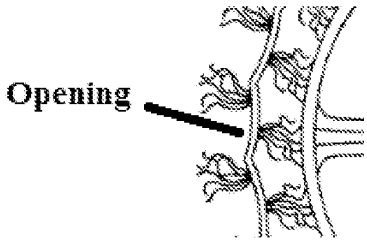
Fig. 11

CLAIM 26

Claim 26 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers defines an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

Similar to claim 13, annotated, partial view of FIG. 13 illustrates this limitation:



CLAIM 27

Claim 27 recites:

The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

These claim limitations generally recite that the length of the TAVR is radially compressible and expandable.

CLAIM 28

New claim 28 recites:

An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first array of fibers that extend away from the frame,

wherein the first array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second array of fibers that is positioned radially inwardly from first array of fibers,

wherein the second array of fibers is in direct contact with the frame,

wherein the heart valve defines openings extending through a thickness of the first array of fibers that is created by spacing formed between adjacent fibers thereof, through a thickness of the second array of fibers created by spacing formed between adjacent fibers thereof, and through the plurality of cells of the frame,

wherein, compression of the first array of fibers and the second array of fibers in response to expansion of the heart valve compresses the first array of fibers relative to the openings to create a seal thereabout.

The claim recites that the openings extend through a thickness of the first second array of fibers and into a cell of the plurality of cells. This is illustrated with reference to annotated FIG. 12, FIG. 13, and FIG. 21:

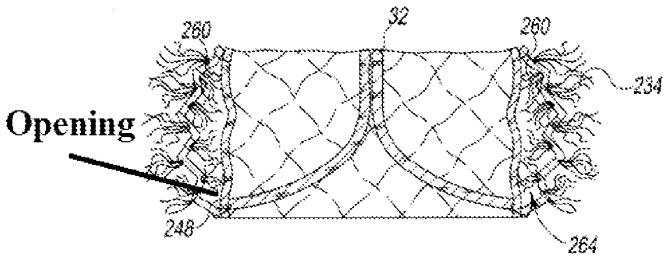


Fig. 12

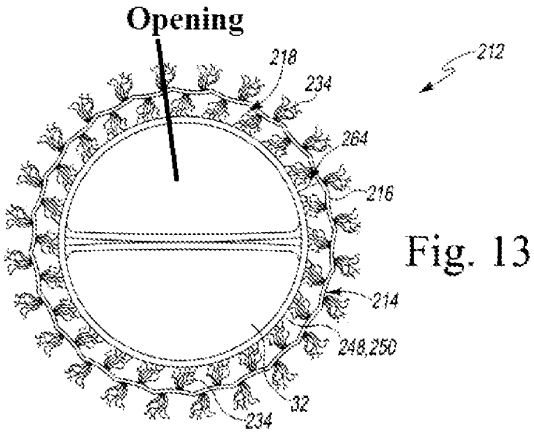


Fig. 13

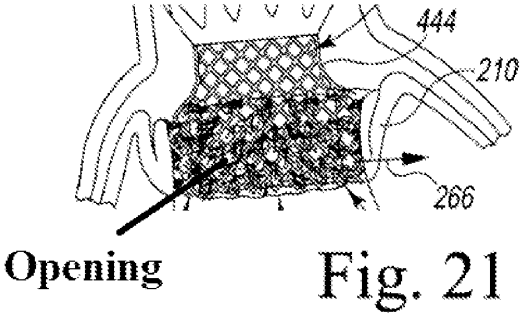


Fig. 21

The advantage of this claim limitation is the ability for thrombosis of the array of fibers about the frame to thereby seal the frame after compression of the fibers, while the lower overall fiber density of the claimed invention (as compared for example with a stent graft) allows for proper expansion of the valve without the disadvantages associated with a stent graft such as restrained valve foreshortening, under expansion, and increased valve profile size.

New claim 29 recites similar limitations, however, only recites an array of fibers, and further recites that the array of fibers extends over each of the at least two rows of cells.

PROBLEMS WITH EXISTING TAVR DEVICES

TAVR devices have competing design forces at all times. The TAVR must maximize valve leaflet size, provide sealing characteristics to reduce PVL and PVR[1], yet, must maintain a small overall crimped profile as the compressed TAVR must be delivered endovascularly

[1] https://www.acc.org/latest-in-cardiology/articles/2017/02/02/08/25/transcatheter-management-of-paravalvular-leaks

through an access artery and cross the native heart valve of the patient[2], maintain appropriate asymmetric foreshortening characteristics[3], and maintain appropriate hoop stresses and forces so that undue pressure is not required to inflate the balloon for balloon expandable valves or for self-expansion for self-expanding valves, or underexpansion of the valve assembly can occur[4].

US Patent Publication No. 20120123529 ("Levi"), which is discussed further herein, well describes this problem of crimp profile with respect to the inner skirt:

> *[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.*

While this was in reference to the inner skirt, the same concerns are presented with an outer skirt where conformability to the native annulus is even more pronounced. Thus, it should be evident that an expandable outer frame (which is thus subject to higher compressive forces) having an outer graft covering of sufficient height, along with an inner graft covering, presented significant engineering design challenges. This is partly why Levi teaches a billowing outer skirt that does not tightly fit against the frame. Designing an outer seal that would effectively seal and limit PVL for an expandable frame is thus desirable.

The issue with the outer seal is particularly relevant because paravalvular leaks and regurgitation are a persistent problem with TAVR. For example, a recent study found that the CoreValve prosthesis, one of the few available TAVR devices in the United States market, had moderate or severe PVR of 11.4% and 9.0% at 30 days. From the study involving 60 patients:

> *The primary efficacy endpoint was defined as the proportion of patients with less-than-mild prosthetic valve regurgitation at 30 days and amounted to 72.4%, with no patient showing evidence for moderate or severe regurgitation. Of the patients without a pacemaker at baseline, 11.8% required implantation of a permanent pacemaker within 30 days after TAVR. The mean transprosthetic gradient was low with 6.4 mm Hg as*

[2] https://www.sciencedirect.com/science/article/pii/S2666084919304760
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6551197/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5300953/

typical for a supra-annular valve design, though acknowledging that no patient requiring a 23-mm device was included. The pre-defined primary safety endpoints, all-cause mortality and disabling stroke at 30 days, amounted to 1.7% each in a patient population with a mean Society of Thoracic Surgeons score of 6.4%. Thirty-day rates of major vascular complications and life-threatening or disabling bleeding were 10.0% and 11.7%, respectively.

The presented data are promising and support the concept to mimic surgical-like outcomes as it relates to PVR by the addition of an external seal that compensates for incomplete stent-landing zone apposition...

http://interventions.onlinejacc.org/content/jint/11/2/169.full.pdf

From another study:

Moderate to severe regurgitation after TAVR confers a poor prognosis and is associated with an increased risk of all-cause mortality Even mild PVL has been shown to have a negative impact on survival. Kodali et al reported on the outcomes of patients who underwent TAVR from the randomized cohorts of the PARTNER trial and continued access registries. Data were analyzed from a total of 2,434 patients. PVL was reported as mild in 38% and moderate/severe in 9.1% of patients after TAVR. There was no difference in 30-day mortality. Instead, the adverse effect was expressed later with a significant increase in 1-year all-cause and cardiac mortality and repeat hospitalization in those with worsening PVL.

https://citoday.com/articles/2015-july-aug/managing-paravalvular-leaks-after-tavr

Thus, as these studies show, PVL is a long-felt problem and a method of addressing this problem has been needed. Studies show high one year mortality and rehospitalization rates of 35% and 31% may be attributed to PVL, and reducing PVL will thus reduce mortality and rehospitalization rates. According to this study, an external seal helps to address PVL and PVR. Surgical valves, as will be discussed herein, did not traditionally have significant PVL concerns because the valve leaflets were removed from the patient, and a sealing ring or similar could be stitchably engaged with the aorta in an open heart procedure. However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion,

and crossing of the aorta. Applicant submits that the claimed invention addresses these problems.

A DISCUSSION OF SOME OF THE PRIOR ART FOLLOWS:

TRANSCATHETER VALVE TECHNOLOGY

An example of a transcutaneous valve having an inner and outer seal is shown in at least WO98/29057 ("Cribier"). See for example FIG. 6D that shows a cover extending from an inner surface to an outer surface of the stent frame.

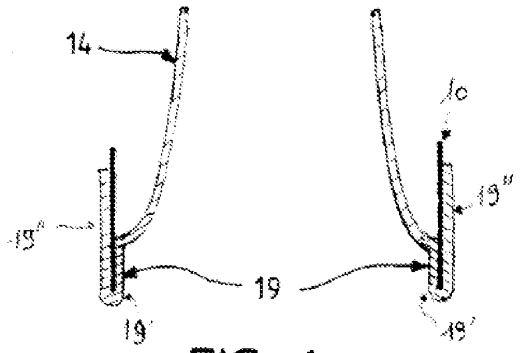
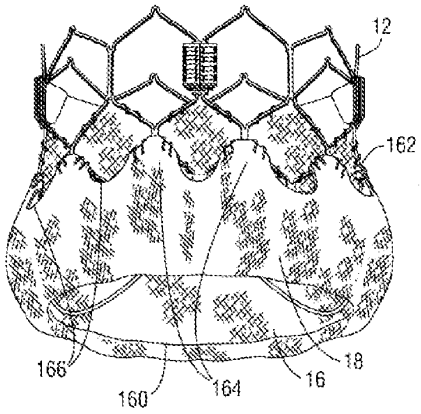


FIG_6d

Similarly, US Patent Publication No. 20120123529 ("Levi") appears to teach an inner and outer seal in FIG. 42.

FIG. 42



WO2006/005015 ("Spenser") appears to teach a thick band with fibers emanating therefrom in FIG. 22. Spenser or a valve similar to Spenser appears to be shown in the NPL Walther, submitted in the information disclosure statement dated July 27, 2021. Additionally, Spenser is unable to substantially foreshorten (see commissure supports that restrict length of stent) and thus, the issue of valve foreshortening and creating a compliant outer seal that does not restrict foreshortening would not have been apparent. The thick outer seal of Spenser adds to valve profile size and restricts foreshortening. FIG. 22 is reproduced below:

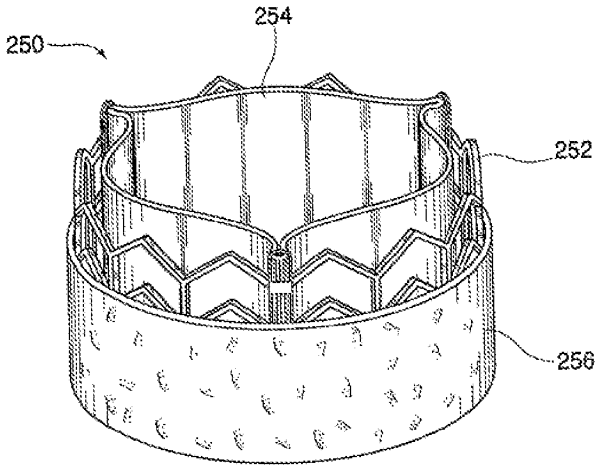
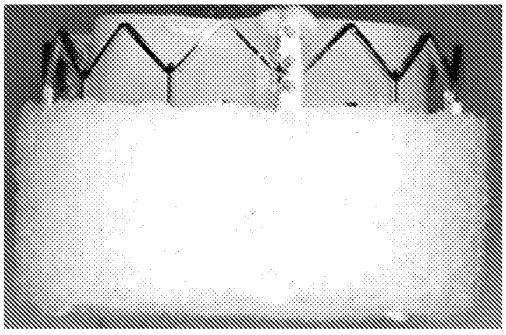


FIG. 22

And from the NPL of record that appears to be Spenser or similar to Spenser:



US Patent No. 7,381,219 ("Salaheih") teaches a repositionable TAVR with sacs filled by hydrogel or similar on an exterior of the TAVR for sealing the TAVR:

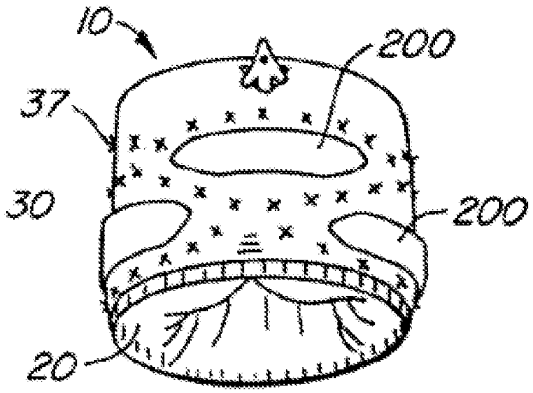


FIG. 15A

US Patent No. 9,333,075 ("Delaloye") teaches a TAVR with an outer seal at a proximal end.

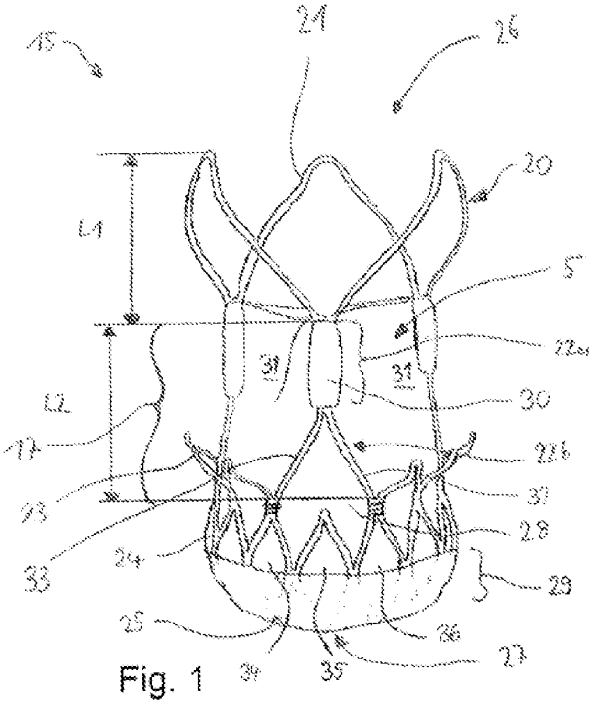


Fig. 1

US Patent No. 10,299,917 ("Morriss") teaches a ring having fibers emanating therefrom on a mitral valve design. The fiber design does not appear to teach a first array of fibers, and a second array of fibers positioned radially inwardly from the first array, among other limitations.

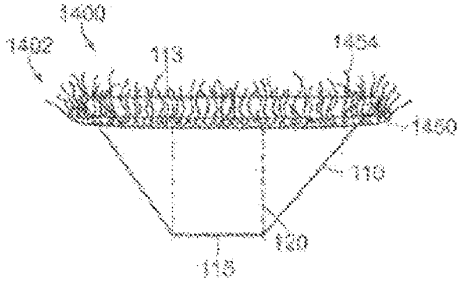


FIG. 69D

STENT GRAFT TECHNOLOGY

Various stent grafts have also been developed that include one or more seals. US Patent Publication No. 2004/0256759 ("Hartley") teaches a velour band at a distal end of the stent graft.

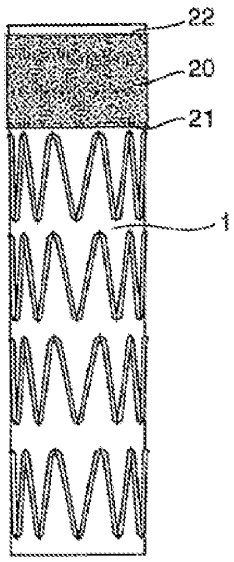


Fig 2

Similarly, US Patent No. 7,921,678 ("Norris") teaches a stent graft with loops of outwardly extending material.

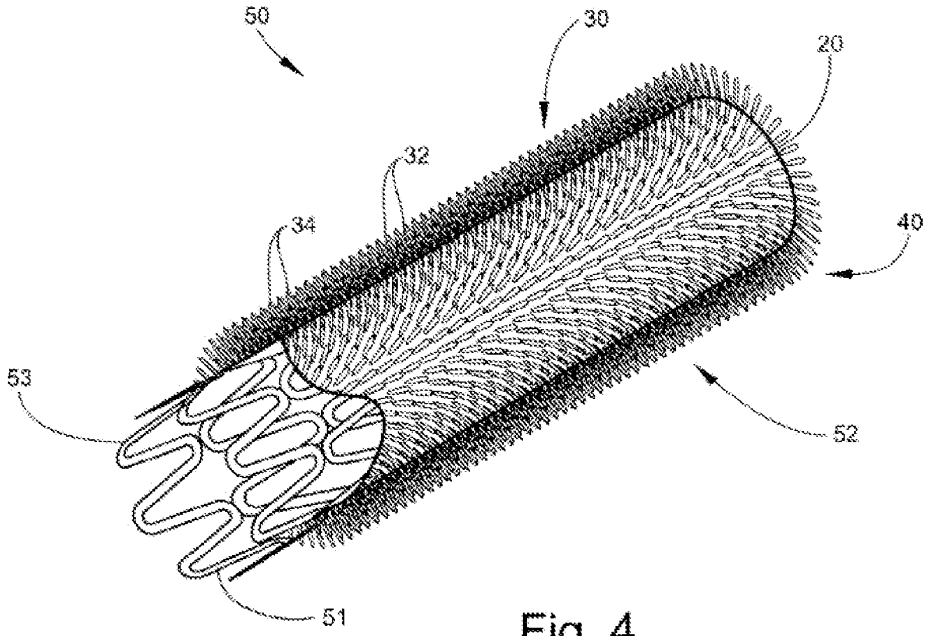


Fig. 4

US Patent Publication No. 2004/0082989 ("Cook") teaches a cuff portion with a frayed portion 22:

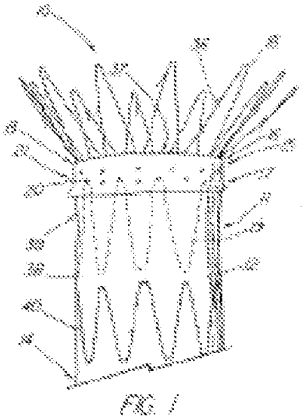


FIG. 1

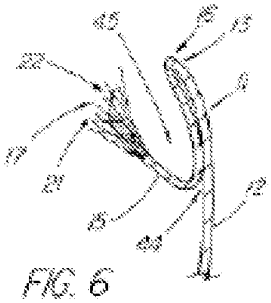


FIG. 6

US Patent Publication No. US 2002/0052649 ("Greenhalgh") teaches a stent graft with fibers emanating therefrom.

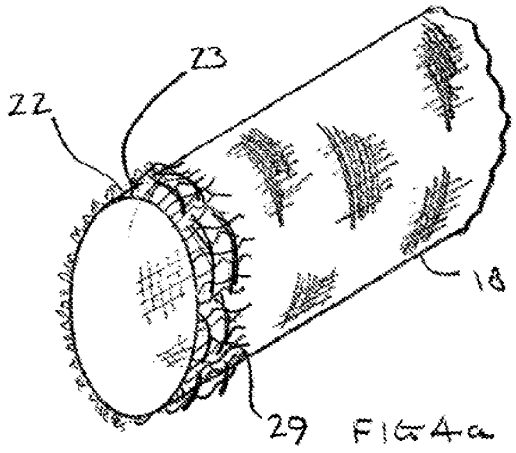


FIG 4a

Greenhalgh also further teaches pores, as an example, in FIG. 3 that may be formed by mechanically piercing the membrane, etching with chemicals or ablating with a laser. However, as indicated in Greenhalgh, these "pores" are formed in a "membrane of expanded polytetrafluoroethylene (ePTFE) is used to form the graft substrate 18" and thus, the "pores" in Greenhalgh are not formed in an array of fibers as claimed, but instead within a graft substrate.

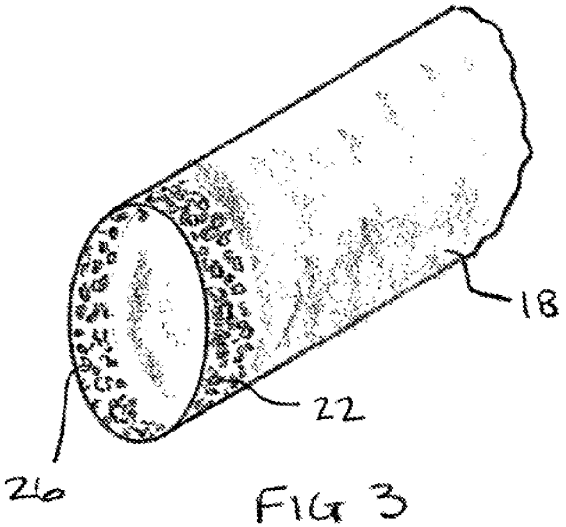
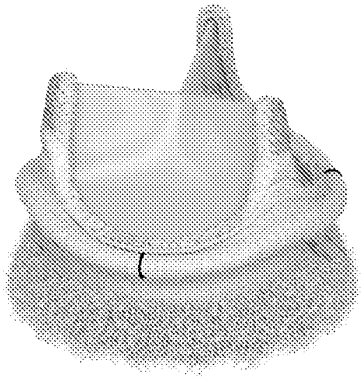


FIG 3

SURGICAL VALVES

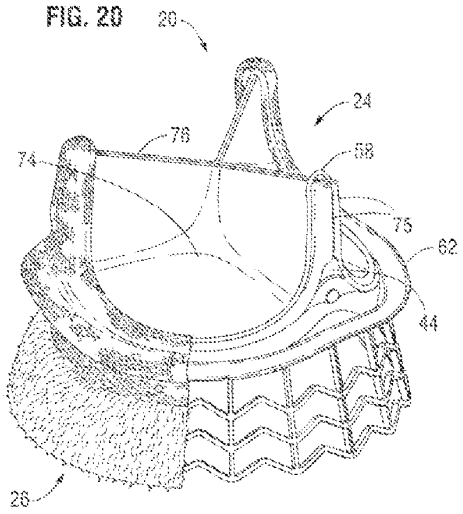
The non-patent literature of Intuity does appear to teach an external seal that includes fibers. Intuity appears to show a surgical valve from 2011 that has a plush outer seal similar to the valve shown in US Patent No. 9,370,418 ("Pintor"), which has been discussed in prosecution of Application No. 16/808,137 in front of Examiner Shipmon and that is related to this pending application.



This surgical valve would appear to teach a seal that seals below the leaflets, and not against native valve leaflets of the patient. In fact, typically the native leaflets are surgically removed during surgical heart valve replacement. Additionally, because a surgical valve does not have the access issues associated with transcatheter valves, the increased overall profile of a surgical valve such as Intuity is not as problematic. Furthermore, the Intuity valve appears to teach an outer graft covering between the outer frame and the fibers.

The portions of Pintor that generally disclose "fibers" appear to have an effective filing date after Applicant's effective filing date. However, Applicant notes that both of Pintor and Applicant's claimed invention are pre-AIA. Assuming, *arguendo*, that Pintor could have a conception and diligence date before Applicant's, Pintor does not appear to teach or render obvious the claimed invention. Pintor is a surgical valve, not an endovascularly deployed valve. Pintor teaches many embodiments and Applicant will discuss a few of each.

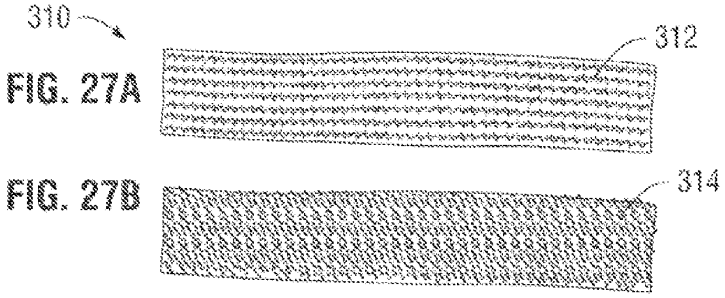
The embodiment illustrated in FIG. 20 is similar to the image shown above. As illustrated, a plurality of fibers appears to extend out of a graft covering that is stitched to the main frame. FIG. 20 is reproduced below:



Thus Applicant submits that this embodiment of Pintor does not teach a first array of fibers, and a second array of fibers, among other limitations as claimed.

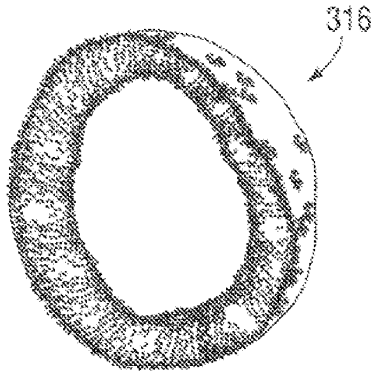
FIG. 27A and 27B of Pintor may appear to teach a seal material having a first array of fibers (312) and a second array of fibers (314). From the specification of Pintor:

> *FIGS. 27A-27B show opposite sides of a strip **310** of plush fabric used to create a sealing flange **84** on the expandable anchoring skirt **26**. The material of the strip **310** includes a relatively smooth side **312** with rows of ribs of the fabric weave, and a plush or relatively fluffy side **314** with outwardly projecting loops and loose threads of the polymer material.*



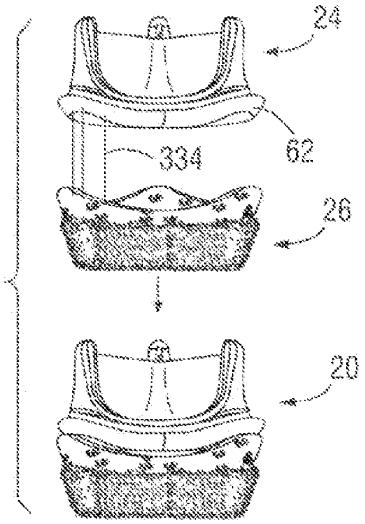
Consistent with a surgical valve where overall valve profile is not as significant of a concern as with a transcatheter valve, Pintor then teaches looping the strip 310 around to form a sewing ring of significant thickness. This is well-illustrated in FIG. 29A, reproduced below:

FIG. 29A



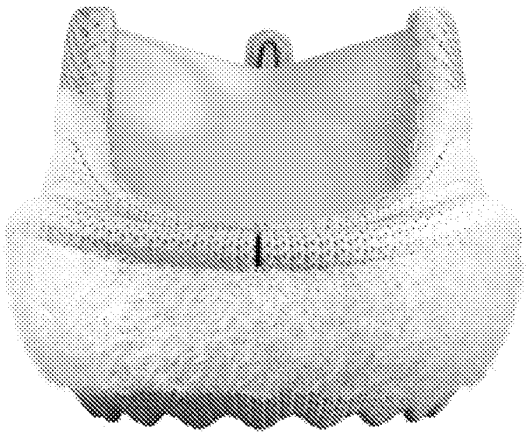
The enlarged skirt is then attached with the frame as illustrated in FIG. 32 in one embodiment:

FIG. 32



Various other embodiments are illustrated in FIGS. 36A through 41C, including various embodiments where there is no fabric cover between frame 80 and outer seal (326, 328, 330 as

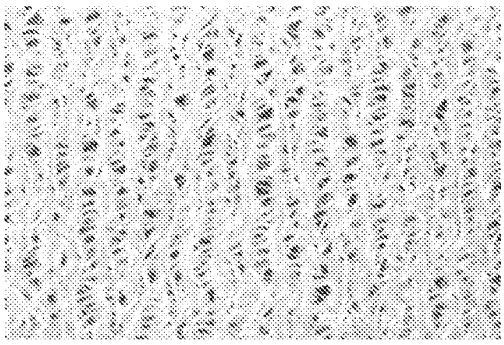
examples). To the extent that any of the embodiments are enabled, the embodiments appear to teach a thick outer seal consistent with the "folded over" disclosure with reference to FIG. 29A. Applicant submits that these embodiments may have some overlap with the Intuity embodiment shown below:



To the extent that these embodiments teach an array of fibers in contact with the frame of the stent, it is the same array of fibers that seal against the annulus of the patient, and not a different (i.e. the difference between claimed first array of fibers and second array of fibers) array of fibers as found in the claimed invention.

ADOPTION OF A SEALING SKIRT COVERED BY THE CLAIMED INVENTION HAS REDUCED PVL RATES

The Sapien 3 Ultra sealing skirt appears to be covered by the claimed invention. It is submitted that there is a first array of fibers forming a mesh, and a second array of fibers that end therefrom and into engagement with native leaflets of a patient. The fiber seal provided by the valve design is disclosed having the depicted construction where the openings within the seal provide for proper expansion of the valve with improved valve foreshortening and expansion, while maintaining overall desirable valve profile size:



Compared to the Sapien 3 product, largely embodied by Levi discussed herein, this Ultra seal assembly showed a mild PVL rate of 18.7% versus 43.0% for the Levi design in at least one study.[5] This significant reduction in mild PVL has addressed a long felt but unresolved need after years of failure by others to address the problem. Furthermore, the valve design has enjoyed significant commercial success, and quickly displaced the Levi design valve for most procedures.

APPLICANT'S CLAIMED INVENTION ADDRESSES THE PROBLEMS OF THE PRIOR ART AND IS NOT TAUGHT OR RENDERED OBVIOUS BY THE PRIOR ART

Amended claim 11 recites:

An endovascular prosthetic heart valve for use in a patient, comprising:
a frame formed of a plurality of struts that cooperate to form a plurality of cells,
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
a leaflet assembly within the frame;
~~an inner skirt~~ a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;
~~an outer seal that extends radially outwardly of the frame,~~
~~wherein the outer seal comprises~~ a first array ~~plurality~~ of fibers that extend away from the frame, [[and]]
wherein the first array ~~plurality~~ of fibers [[are]] is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.

[5] https://www.crtonline.org/news-detail/early-data-suggest-edwards-fourth-generation-sapie

a second array of fibers that is positioned radially inwardly from the first array of fibers, wherein the second array of fibers are in direct contact with the frame.

The remaining independent claims recite somewhat generally similar limitations. Applicant submits that this claim addresses the problems in the prior art, notably restricted foreshortening, underexpansion of the valve assembly, enlarged valve profile, and paravalvular leakage. The first array of fibers and the second array of fibers provide multiple seal opportunities, including against the native leaflets of the patient in an endovascular procedure, and against the main frame of the valve assembly. However, the fibrous nature of the combined seal does not cause undesired increase in rigidity of the seal, while allowing for thrombos and tissue in-growth to promote seal against paravalvular leakage.

The prior art of record does not appear to teach these limitations. Applicant thus submits that the claimed invention is patentable over the references of record.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: August 14, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 08/11/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
08/11/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Office Action Summary	Application No. 17/327,673	Applicant(s) Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 7/21/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 11 and 13-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 11 and 13-26 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

2. The terminal disclaimer filed on 7/21/2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **US Application Numbers: 16/941117, 17007373, 17170957, 17006793; and US Patents Numbers: 10987236, 10966846, 10888441,10881538, 11026817, 10857011, 10792172** has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11, and 13-26 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The applicant recites an 'inner skirt" in claims 11, 14, 23 and 25(see below). The term 'inner skirt' is not found in the specification, or in the originally filed claim set. Applicant should use consistent terminology as described in the specification. In this case, it appears that it should be described as an 'inner frame'.

5. The applicant recites an "outer seal" in claims 1, 16, 17, 18, 20, 23, 24 and 26 (see below). The term "outer seal" is not present in the specification. Instead, the specification describes inner and outer frames that together seal the aortic annulus when expanded (see paragraphs 78 and 92). Applicant should ensure the terms in the claims are supported by and consistent with the specification.

6. Referring to claim 13, the claim recites "wherein the second of the plurality of fibers define an opening extending through a thickness thereof that is created by spacing formed of adjacent fibers, wherein the opening extends to the frame". It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

7. Referring to claim 14, applicant recites a 'scalloped end" of the leaflets. The scalloped end is not described in the specification. Applicant should ensure the terms in the claims are supported by and consistent with the specification.

8. Referring to claim 15, the claim recites "wherein a distance that the plurality of fibers of the outer seal extend from a centerline extending longitudinally through the frame varies along a length of the centerline" is not adequately described in the specification. Applicant should indicate where in the specification support for these recited features can be found. Applicant should ensure the terms in the claims are supported by and consistent with the specification.

9. Referring to claim 16, the claim recites "wherein the plurality of the cells defines at least two rows of cells at an inflow end of the frame, wherein the outer seal covers each of the at least two rows

of cells" is not adequately described in the specification. The term 'outer seal' is not found, Applicant should ensure the terms in the claims are supported by and consistent with the specification.

10. Referring to claim 20, the claim recites "wherein the outer seal is free of a non-porous graft covering between the plurality of fibers of the outer seal and the frame". The term 'outer seal' is not found in the specification, Applicant should ensure the terms in the claims are supported by and consistent with the specification.

11. Referring to claim 23, the claim recites 'an inner skirt' and 'the outer seal', these terms are not described in the specification. Applicant should ensure the terms in the claims are supported by and consistent with the specification.

12. Referring to claim 25, the claim recites "wherein the inner skirt extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame" the term 'inner skirt' is not described in the specification. Applicant should ensure the terms in the claims are supported by and consistent with the specification.

13. Referring to claim 26, the claim recites "wherein the plurality of fibers of the outer seal define openings that extend through a thickness thereof that is created by spacing formed between adjacent fibers thereof" the term 'outer seal' is not described in the specification. It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap between the inner and outer frames described in paragraph 91. If so, Applicant should ensure that this language is supported by the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

14. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13-14 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

5. Referring to claim 13, applicant recites the limitation of the second plurality of fibers defining an opening extending through a thickness that is created by spacing formed between adjacent fibers. It is unclear how the opening and spacing is being defined. It is unclear what "opening" is being referred to, but it appears that this may be an attempt to refer to the gap between the inner and outer frames described in paragraph 91. If so, Applicant should describe this limitation in a manner that is consistent with the specification, for example in terms of the unexpanded frames as described in paragraph 91 of the specification.

6. Referring to claim 14, applicant recites a 'scalloped end" of the leaflets. The scalloped end is not previously recited in the claims and therefore lacks antecedent basis.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/JERRAH EDWARDS/
Supervisory Patent Examiner, Art Unit 3774

Notice of References Cited	Application/Control No. 17/327,673	Applicant(s)/Patent Under Reexamination Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20040256759-A1	12-2004	Hartley, David Ernest	A61F2/07	264/103
*	B	US-20020052649-A1	05-2002	Greenhalgh, E. Skott	A61F2/0063	623/1.35
*	C	US-20110098802-A1	04-2011	Braido; Peter N.	A61F2/2442	623/1.26
	D					
	E					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	P					
	Q					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/327,673	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	Date	Examiner
A61F 2/856,07,2418,82,962,24,86,89,90; 2002/061,067; 2210/00,0014,0057; 2220/008,0016,0025,0058,0075; 2230/001,0034,0067; 2250/0048,0069	07/22/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search	07/22/2021	T.S.

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61F	2/856	07/22/2021	T.S.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/23 UTIL

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

	1	WALTHER, THOMAS, Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of the SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves, European Journal of Cario-thoracic Surgery 40, April 3, 2011

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EXAMINER SIGNATURE

Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	07/30/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-07-27
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	3	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/28 22:05
S3	21	("20120046726" | "7018404" | "7799072" | "8016877" | "20070250146" | "6334868" | "7510574" | "8002826" | "20070276464" | "6752829" | "5102417" | "7947074" | "20070095283" | "20110257731" | "7393360" | "7914569" | "8226710" | "20040210304" | "5397355" | "7780726" | "20050197687" | "20060149351" | "20090198315" | "20100042202" | "7252682" | "20030040771" | "20120089218" | "5716393" | "6254632" | "20090125098" | "6582462" | "7771467" | "8206438" | "20080132999" | "20090099644" | "8425584").PN.	USPAT	OR	OFF	2014/06/28 23:06
S4	36	("20120046726" | "7018404" | "7799072" | "8016877" | "20070250146" | "6334868" | "7510574" | "8002826" | "20070276464" | "6752829" | "5102417" | "7947074" | "20070095283" | "20110257731" | "7393360" | "7914569" | "8226710" | "20040210304" | "5397355" | "7780726" | "20050197687" | "20060149351" | "20090198315" | "20100042202" | "7252682" | "20030040771" | "20120089218" | "5716393" | "6254632" | "20090125098" | "6582462" | "7771467" | "8206438" | "20080132999" | "20090099644" | "8425584").PN.	US-PGPUB; USPAT	OR	OFF	2014/06/28 23:24
S5	317	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/06/28 23:30
S7	38	a61f2/2418	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S8	59	a61f2/2412	US-PGPUB; USPAT;	OR	OFF	2014/06/28 23:31

			EPO; JPO; DERWENT			
S9	41	a61f2/2436	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S10	17	a61f2/2433	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S11	11	a61f2/2475	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
S12	1	"13706896"	US-PGPUB; USPAT	OR	OFF	2014/06/29 16:46
S13	2,346	623/1.12	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:07
S14	401	S13 and fibers	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:07
S15	3	S13 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:12
S16	30	S13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:13
S17	74	623/1.13 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:43
S18	2,377	stent and graft and fibers and migration	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:48
S19	317	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/06/29 18:49
S20	19	S19 and S18	US-PGPUB; USPAT	OR	OFF	2014/06/29 18:49
S21	21	("20120046726" | "7018404" | "7799072" | "8016877" | "20070250146" | "6334868" | "7510574" | "8002826" | "20070276464" | "6752829" | "5102417" | "7947074" | "20070095283" | "20110257731" | "7393360" | "7914569" | "8226710" | "20040210304" | "5397355" | "7780726" | "20050197687" | "20060149351" | "20090198315" | "20100042202" | "7252682" | "20030040771" | "20120089218" | "5716393" | "6254632" | "20090125098"	USPAT	OR	OFF	2014/06/29 18:52

		| "6582462" | "7771467" | "8206438" | "20080132999" | "20090099644" | "8425584").PN.				
S22	1	S21 and fibers	USPAT	OR	OFF	2014/06/29 18:52
S23	3	S21 and fiber	USPAT	OR	OFF	2014/06/29 18:53
S24	3	S21 and fiber	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	OFF	2014/06/29 18:53
S25	1	("7799072").PN.	USPAT; USOCR	OR	OFF	2014/07/14 09:28
S26	3	meretei.in.	USPAT	OR	OFF	2014/07/14 09:28
S27	14	(("7799072") or ("8002826") or ("7947074")).PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2014/07/14 09:28
S28	0	"13706896"	USPAT	OR	OFF	2014/11/30 19:33
S29	1	"13706896"	US-PGPUB; USPAT; USOCR	OR	OFF	2014/11/30 19:33
S30	7	"7799072"	US-PGPUB; USPAT; USOCR	OR	OFF	2014/11/30 19:34
S31	369	(623/2.14).CCLS.	US-PGPUB; USPAT; USOCR; JPO; DERWENT	OR	OFF	2014/11/30 19:47
S32	2,016	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 19:59
S33	915	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 19:59
S34	0	a61f2/2418.cpc	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/11/30 20:38

S35	2,002	(623/1.35-1.36).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2014/12/01 10:28
S39	2,556	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 10:24
S40	3,379	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:47
S41	2	("13706869").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:49
S42	2	("13706896").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2016/02/08 11:51
S46	1	("14614628").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/03/20 19:27
S47	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/05/15 06:58
S48	2	("7799072").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:28
S49	4	("20080132993" | "20140336749").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:29
S50	2	("7799072").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:29
S51	0	("14445833").PN.	USPAT; USOCR	OR	OFF	2017/05/15 08:32
S52	18	("20050177222" | "20070067014" | "20100268318" | "6152956" | "20060276883" | "20070112411" |	US-PGPUB; USPAT; USOCR;	OR	OFF	2017/05/15 08:33

		"20030220683" | "20040106981" | "20100094409").PN.	EPO; JPO; DERWENT			
S53	651	623/2.14	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/05/15 08:35
S54	1	("20070067014").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/17 00:05
S55	4,867	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:12
S56	3,429	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:12
S57	2,489	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S58	1,308	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S59	1,182	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2017/09/17 00:13
S60	1	("14614628").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/17 16:01
S61	1	("20070067014").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/17 16:11
S62	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/18 08:47
S63	1,461	carpentier.in.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 08:54
S64	61	carpentier.in. and aorta	US-PGPUB; USPAT; USOCR;	OR	OFF	2018/01/11 09:32

			EPO; JPO; DERWENT			
S65	3	"20050102018"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2018/01/11 09:39
S66	6	(US-20070168013-$ | US-20140172064-$ | US-20140316513-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:13
S67	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/02/05 09:42
S68	6,135	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S69	4,276	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S70	3,295	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S71	1,674	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S72	1,322	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S73	9,150	S68 S69 S70 S71 S72	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S74	6,389	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S75	4,396	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04

S76	3,436	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S77	1,760	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S78	1,352	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S79	9,503	S74 S75 S76 S77 S78	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S80	9,503	S74 S75 S76 S77 S78 S79	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S81	4,461	S80 and (artery arteries)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:06
S82	1,118	S80 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:09
S83	6,421	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S84	4,413	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S85	3,462	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S86	1,773	a61f2/2433.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/04/29 11:05

			EPO; JPO; DERWENT			
S87	1,354	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S88	9,549	S83 S84 S85 S86 S87	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S89	9,549	S83 S84 S85 S86 S87 S88	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S90	1,126	S89 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/29 11:05
S91	1	("20090254172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/05/14 15:40
S92	9	("20060155366" | "20100049313" | "6258117").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:09
S93	2	("20080262592").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S94	6	("20070168013" | "20140172064" | "20140316513").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S95	6	("20020177890" | "5976179").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10

S96	3	"20140316513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:19
S97	2	"20070168013"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:20
S98	4	"20140172065"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:21
S99	6	"20100049313"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:26
S100	2	"20060155366"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:29
S101	6,666	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S102	4,593	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S103	3,601	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S104	1,864	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S105	1,380	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/07/21 10:35

			EPO; JPO; DERWENT			
S106	9,898	S101 S102 S103 S104 S105	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S107	9,898	S101 S102 S103 S104 S105 S106	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S108	1,179	S107 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 10:35
S109	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 11:44
S110	4	"14614628"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 12:36
S111	7,098	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S112	4,889	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S113	3,856	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S114	1,965	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S115	1,422	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/12/08 16:15

			EPO; JPO; DERWENT			
S116	10,508	S111 S112 S113 S114 S115	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S117	10,508	S111 S112 S113 S114 S115 S116	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S118	1,256	S117 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/12/08 16:15
S120	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S121	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S122	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S123	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S124	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S125	10,919	S120 S121 S122 S123 S124	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S126	10,919	S120 S121 S122 S123 S124 S125	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45

S127	1,305	S126 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/03/13 11:45
S128	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S129	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S130	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S131	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S132	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S133	10,919	S128 S129 S130 S131 S132	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S134	10,919	S128 S129 S130 S131 S132 S133	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S135	966	S134 and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:56
S136	5,500	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01

S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ | US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/04/13 14:46

		| US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	FPRS; EPO; JPO; DERWENT			
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44
S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

		| US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3652198-$ | US-3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-			

		5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$	US-PGPUB; USPAT;	OR	OFF	2020/06/06 16:07

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S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
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S173	171	S172 and fiber$4	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:32
S174	3,550	a61f2/2409.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 21:44
S175	3,550	a61f2/2409.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/07 10:04
S176	1,905	S175 and (seal$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/07 10:04
S180	1	("20130144373").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 09:48

S181	3,557	a61f2/2409.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:52
S182	7,673	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S183	5,229	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S184	4,210	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S185	2,127	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S186	1,467	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S187	11,297	S182 S183 S184 S185 S186	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S188	2,885	S181 and S187	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S189	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 10:48
S190	4	"16736879"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 13:27
S191	1	("20170014228").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 14:00
S192	182	(US-10028848-$ | US-10321985-$ | US-16736879-$ | US-20020177890-$ | US-20030040771-$ | US-20040210304-$ | US-20050043790-$ | US-20050197687-$	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2020/06/17 14:36

		| US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090099644-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3561102-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3715317-$ | US-3721676-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5716393-$ | US-5718159-$ | US-5752829-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$).DID.	JPO; DERWENT			
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		| AI-20080262592-$ | AI-20080275548-$ | AI-20090099644-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | AI-20100094409-$ | AI-20110257731-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130144373-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$).DID.				
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S195	10	(CN-102014805-$ | NO-2005087117-$ | NO-2006127412-$ | NO-2010006627-$ | NO-2010031060-$ | NO-2010105195-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | EP-2787925-$ | JS-2012068165-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:37
S196	50	(US-10034784-$ | US-10065824-$ | US-16736879-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
S197	8	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
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S201	108	(vidlund.in.) and stent	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 16:23
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S204	1,050	salahieh.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48

S205	516	salahieh.in. and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 16:48
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S207	7,776	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
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S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S216	0	wo2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
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S220	1	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:55
S221	4	"20090125098"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:29
S222	7	"20030040771"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:30
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S225	1	(spense.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17

S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20
S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53

S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:02
S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
S248	1	("4164046").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:09
S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT;	OR	OFF	2020/11/06 15:17

			USOCR; FPRS; EPO; JPO; DERWENT			
S258	0	("2006124649").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 15:17
S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S262	0	("12882605").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S263	0	("2006018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S264	1	("20060018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S265	7	"20060018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ |	US-PGPUB; USPAT;	OR	OFF	2020/11/06 19:25

		US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$ | US-3992608-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:22
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:25
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/01/16 10:26

			USOCR; FPRS; EPO; JPO; DERWENT			
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/01/16 10:27

			FPRS; EPO; JPO; DERWENT			
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:33

			JPO; DERWENT			
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:21
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:46
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48

S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51
S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
S320	5	"20060005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S321	96	"2006005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S322	5	"15876053"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:11

S323	2	("2018/0206982").URPN.	USPAT	OR	OFF	2021/02/13 09:12
S324	0	"20010049555"	USPAT	OR	OFF	2021/02/13 09:14
S325	4	"20010049555"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:14
S326	3	"20070233228"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S327	3	"20120296418"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S328	822	("20010021872" | "20020026094" | "20020032481" | "20020138135" | "20020173842" | "20030050694" | "20030100939" | "20030158597" | "20030212454" | "20040039436" | "20040186563" | "20040186565" | "20050075728" | "20050096736" | "20050188525" | "20050203614" | "20050203617" | "20050234546" | "20060004469" | "20060025857" | "20060058872" | "20060149350" | "20060183383" | "20060229719" | "20060259137" | "20070005131" | "20070010876" | "20070010877" | "20070112422" | "20070162102" | "20070203503" | "20070203575" | "20070203576" | "20070213813" | "20070260305" | "20070265700" | "20080114442" | "20080125853" | "20080154355" | "20080183271" | "20090125118" | "20090157175" | "20090276040" | "20090281619" | "20090299452" | "20090319037" | "20100049313" | "20100168844" | "20100198347" | "20100204781" | "20110015729" | "20110319991" | "20120259409" | "20130023985" | "20130190857" | "20130274873" | "20130310926" | "20130317598" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:25

		"20130331929" | "20140194981" | "20140200661" | "20140209238" | "20140277417" | "20140277419" | "20140277424" | "20140330372" | "20140343671" | "20150073545" | "20150073546" | "3409013" | "3548417" | "3587115" | "3657744" | "3671979" | "3714671" | "3755823" | "4035849" | "4056854" | "4106129" | "4222126" | "4265694" | "4297749" | "4339831" | "4343048" | "4345340" | "4373216" | "4406022" | "4441216" | "4470157" | "4535483" | "4574803" | "4592340" | "4605407" | "4612011" | "4643732" | "4655771" | "4692164" | "4733665" | "4759758" | "4762128" | "4777951" | "4787899" | "4787901" | "4796629" | "4820299" | "4829990" | "4851001" | "4856516" | "4878495" | "4878906" | "4883458" | "4922905" | "4966604" | "4979939" | "4986830" | "4994077" | "5007896" | "5026366" | "5032128" | "5037434" | "5047041" | "5059177" | "5080668" | "5085635" | "5089015" | "5152771" | "5163953" | "5167628" | "5192297" | "5266073" | "5282847" | "5295958" | "5332402" | "5360444" | "5370685" | "5397351" | "5411055" | "5411552" | "5443446" | "5480424" | "5500014" | "5545209" | "5545214" | "5549665" | "5554185" | "5558644" | "5571175" | "5584803" | "5591185" | "5591195" | "5607464" | "5609626" | "5628792" | "5639274" | "5665115" | "5716417" | "5728068" | "5749890" | "5756476" | "5769812" | "5800508" | "5840081" | "5855597" | "5855601" | "5855602" | "5925063" | "5957949" | "6027525" | "6132473" | "6168614" | "6171335" | "6174327" | "6210408" | "6217585" | "6221091" | "6231602" | "6245102" | "6299637" | "6302906" | "6350277" | "6352547" | "6425916" | "6440764" | "6454799" | "6458153" | "6461382" | "6468660" | "6482228" | "6488704" | "6527979" | "6569196" | "6582462" | "6605112" | "6652578" | "6689123" | "6716244" | "6730118" | "6733525" | "6767362" | "6769161" | "6783542" | "6830584" | "6878162" | "6893460" | "6908481" | "6936067" | "7018406" | "7018408" | "7096554" | "7225518" | "7276078" | "7276084" |			

		"7318278" | "7374571" | "7393360" | "7462191" | "7510575" | "7563280" | "7585321" | "7618446" | "7618447" | "7655034" | "7785366" | "7959672" | "7993394" | "8029556" | "8167932" | "8291570" | "8449606" | "8454685" | "8652203" | "8747463" | "9078781").PN.				
S329	4	("20130190862" | "20160317305").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:26
S330	4	("20070233228" | "20120296418").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27
S331	835	("20020173842" | "20030100939" | "20040186563" | "20050203617" | "20070162102" | "20080183271" | "20100204781" | "20130274873" | "20140200661" | "20150073546" | "4222126" | "4733665" | "4759758" | "4777951" | "5026366" | "5032128" | "5332402" | "5411055" | "5558644" | "5571175" | "5609626" | "6231602" | "6425916" | "6440764" | "6689123" | "6893460" | "6936067" | "7655034" | "7993394" | "8652203" | "20030212454" | "20050075728" | "20070112422" | "20100168844" | "20100198347" | "4829990" | "5397351" | "5545214" | "5549665" | "5584803" | "5855602" | "6027525" | "6132473" | "6168614" | "6221091" | "6302906" | "6350277" | "6454799" | "6605112" | "6908481" | "7510575" | "7563280" | "20070233228" | "20020138135" | "20050203614" | "20050234546" | "20060149350" | "20070260305" | "3714671" | "4297749" | "4441216" | "4692164" | "4762128" | "4883458" | "4994077" | "5007896" | "5163953" | "5360444" | "5411552" | "5591185" | "5639274" | "5665115" | "5716417" | "5749890" | "5756476" | "5855601" | "6171335" | "6245102" | "6299637" | "6488704" | "6569196" | "6769161" | "7393360" | "7585321" | "7959672" | "8167932" | "8747463" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27

		"9078781" | "20130190862" | "20010049555" | "20040186565" | "20060058872" | "20060229719" | "20070213813" | "20090299452" | "20120259409" | "20130023985" | "20130310926" | "20130317598" | "20130331929" | "20140209238" | "20140277417" | "20140343671" | "4265694" | "4339831" | "4373216" | "4470157" | "4592340" | "4643732" | "4796629" | "4820299" | "4856516" | "4966604" | "5047041" | "5089015" | "5266073" | "5295958" | "5591195" | "5607464" | "5957949" | "6716244" | "6767362" | "7018406" | "7096554" | "7276084" | "7374571" | "8029556" | "20020026094" | "20050096736" | "20060259137" | "20070005131" | "20090125118" | "20090157175" | "20090319037" | "20110319991" | "20140194981" | "20140277424" | "3587115" | "3657744" | "3671979" | "4343048" | "4612011" | "4787899" | "4787901" | "4878495" | "4878906" | "4979939" | "4986830" | "5059177" | "5085635" | "5152771" | "5370685" | "5500014" | "5554185" | "5728068" | "6210408" | "6352547" | "6527979" | "6783542" | "7618446" | "20030050694" | "20030158597" | "20050188525" | "20060004469" | "20070203503" | "20080114442" | "20080154355" | "20100049313" | "20110015729" | "20140277419" | "20150073545" | "3409013" | "3548417" | "4035849" | "4056854" | "4106129" | "4406022" | "4535483" | "4922905" | "5037434" | "5080668" | "5282847" | "5769812" | "5840081" | "5855597" | "6174327" | "6458153" | "6468660" | "6652578" | "6830584" | "6878162" | "7018408" | "7225518" | "7785366" | "8454685" | "20120296418" | "20010021872" | "20040039436" | "20070010877" | "20070265700" | "20080125853" | "20090281619" | "20130190857" | "20140330372" | "4345340" | "4605407" | "5545209" | "5628792" | "6217585" | "6461382" | "6730118" | "7318278" | "7462191" | "7618447" | "8449606" | "20170014229" | "20020032481" | "20060025857" | "20060183383" | "20070010876" | "20070203575" |			

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S332	11	WO2006124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:13
S333	53	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 10:14
S334	0	"17131869"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S335	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
S336	13	S328 and (outer$4 with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:49
S337	27	S328 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:00
S338	36,075	l11and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14

S339	27	S331 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S340	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:56
S341	12	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-3333075-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:57
S342	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 15:10
S343	1	("9333075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/17 05:33
S344	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/17 05:40
S345	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17007373-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 12:07

		5665117-$ | US-5824037-$ | US-20130144373-$).DID.				
S346	10	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:38
S347	34	"10555823"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 14:50
S348	2	"16983196"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 15:15
S349	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/21 15:20
S350	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S351	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S352	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S353	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S354	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S355	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S356	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S357	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S358	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S359	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S360	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S361	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S362	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S363	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S364	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S365	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S366	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S367	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S368	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S369	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S370	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S371	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S372	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S373	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S374	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S375	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S376	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03
S377	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 18:03

S378	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S379	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S380	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S381	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S382	5,771	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S383	26,423	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S384	17,810	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S385	17,863	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S386	4,039	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S387	6,081	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S388	7,540	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S389	11,779	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S390	18,985	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S391	5,683	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S392	4,850	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S393	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S394	12,658	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S395	1,774	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S396	12,050	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S397	15,676	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S398	32,778	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S399	9,317	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S400	18,227	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S401	3,573	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13

S402	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S403	14,799	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S404	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S405	4,153	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S406	2,578	(S378 S379 S380 S381 S382 S383 S384 S385 S386 S387 S388 S389 S390 S391 S392 S393 S394 S395 S396 S397 S398 S399 S400 S401 S402 S403 S404 S405) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/21 21:13
S407	15	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2021/03/25 16:13
S408	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S409	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S410	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

		$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	JPO; DERWENT			
S411	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S412	5,773	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S413	26,431	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S414	17,826	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S415	17,867	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S416	4,044	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S417	6,084	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S418	7,541	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S419	11,784	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S420	18,994	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S421	5,686	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S422	4,852	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S423	554	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S424	12,667	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S425	1,775	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S426	12,059	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S427	15,690	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S428	32,783	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S429	9,318	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S430	18,235	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S431	3,576	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S432	3,174	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S433	14,804	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S434	1,655	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/25 16:13

			JPO; DERWENT			
S435	4,158	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S436	2,585	(S408 S409 S410 S411 S412 S413 S414 S415 S416 S417 S418 S419 S420 S421 S422 S423 S424 S425 S426 S427 S428 S429 S430 S431 S432 S433 S434 S435) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/25 16:13
S438	0	("13706896").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:37
S439	34	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 09:37
S440	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/27 09:58
S441	70	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17170957-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:38
S442	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S443	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S444	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S445	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S446	5,776	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S447	26,437	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S448	17,841	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S449	17,872	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S450	4,046	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S451	6,089	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S452	7,542	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S453	11,785	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S454	18,999	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S455	5,689	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S456	4,854	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S457	555	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S458	12,674	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S459	1,777	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S460	12,063	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S461	15,695	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S462	32,786	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S463	9,323	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S464	18,239	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S465	3,579	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S466	3,175	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/27 10:39

			JPO; DERWENT			
S467	14,810	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S468	1,657	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S469	4,160	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S470	2,587	(S442 S443 S444 S445 S446 S447 S448 S449 S450 S451 S452 S453 S454 S455 S456 S457 S458 S459 S460 S461 S462 S463 S464 S465 S466 S467 S468 S469) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/03/27 10:39
S471	0	("16910189").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 16:49
S472	6	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 16:49
S473	11	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 17:22
S474	1	("10881538").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/04/08 18:29
S475	2	"16941117"	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/04/08 18:36

			JPO; DERWENT			
S476	72	(US-10016271-$ | US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17006793-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S477	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | NO-2006005015-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110098802-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130304196-$ | NO-3829057-$ | IF-617622-$ | SO-0225223-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/08 23:48
S478	54	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 09:42
S479	3	"20060259136"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 14:18
S480	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/09 16:30

		20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S481	28	S480 and (mitral)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/09 16:37
S482	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 11:44
S483	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/10 15:48
S484	2	"17170957"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59

S485	5	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 09:59
S486	6	"20020052649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/24 10:57
S487	55	"2006124649"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:15
S488	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 10:19
S489	39	S488 and (seal with3 (inflow and outflow))	US-PGPUB; USPAT;	OR	OFF	2021/04/27 10:19

			USOCR; FPRS; EPO; JPO; DERWENT			
S490	41	S488 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 10:23
S491	21	("2014/0316513").URPN.	USPAT	OR	OFF	2021/04/27 10:28
S492	0	"17006793"	USPAT	OR	OFF	2021/04/27 10:32
S493	1	"16792197"	USPAT	OR	OFF	2021/04/27 10:32
S494	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 11:19
S496	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/04/27 19:42

		US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S497	41	S496 and (seal$4 with3 (inflow and outflow))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/04/27 19:42
S498	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/24 12:23
S499	15	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/05/25 08:57
S500	54	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/05/25 08:57
S503	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/05/30 17:02
S504	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 13:20

S505	3	"17007373"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/02 16:13
S506	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or (WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/06/03 13:29
S507	15	S506 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:29
S508	22	(US-17170957-$ | US-20050240137-$ | US-20060013863-$ | US-20140277424-$ | US-20150148889-$ | US-20150335424-$ | US-20150335429-$ | US-20160022444-$ | US-20190192286-$ | US-20200352707-$ | US-3039757-$ | US-3421098-$ | US-3834552-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55

S509	74	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17213251-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100204781-$ | US-20110009948-$ | US-20110098802-$ | US-20110218619-$ | US-20110319991-$ | US-20120123529-$ | US-20120296418-$ | US-20130304196-$ | US-20150335429-$ | US-20160022444-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S510	92	S508 S509	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S511	10	S510 and (collagen)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 13:55
S512	232	(collagen same fibers same graft) and (heart and valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/03 14:01
S513	1	("7921678").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/06/03 14:08
S514	35	(US-17170957-$ | US-20030153974-$ | US-20060025857-$ | US-20060074484-$ | US-20070282436-$ | US-20100036484-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20120022633-$ | US-20120071969-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20140018915-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/06/18 10:36

		US-20140155997-$ | US-20170128209-$).DID.				
S518	6	(("20130018458") or ("20110125244") or ("20110166636") or ("20110098802") or ("20060074484") or ("20120310328")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/01 09:32
S520	102	(US-10258464-$ | US-10792172-$ | US-1164046-$ | US-17327673-$ | US-20020052649-$ | US-20030153974-$ | US-20040243221-$ | US-20040256759-$ | US-20060025857-$ | US-20060074484-$ | US-20060276813-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20070282436-$ | US-20080021547-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-20090105805-$ | US-20100036484-$ | US-20100204781-$ | US-20110009948-$ | US-20110040367-$ | US-20110098802-$ | US-20110125244-$ | US-20110166636-$ | US-20110218619-$ | US-20110319991-$ | US-20120022633-$ | US-20120071969-$ | US-20120123529-$ | US-20120296418-$ | US-20120310328-$ | US-20130018458-$ | US-20130073030-$ | US-20130304196-$ | US-20140018915-$ | US-20140155997-$ | US-20150335429-$ | US-20160022444-$ | US-20170128209-$ | US-3333075-$ | US-3339377-$ | US-3370418-$ | US-3408214-$ | US-3532868-$ | US-3829057-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 16:59
S521	0	(AI-20020052649-$ | AI-20030153974-$ | AI-20040243221-$ | AI-20040256759-$ | AI-20060025857-$ | NO-2006005015-$ | AI-20060074484-$ | AI-20060276813-$ | NO-2006124649-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20070282436-$ | AI-20080021547-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$ | AI-20090105805-$ | AI-20100036484-$ | AI-20100204781-$ | AI-20110009948-$ | AI-20110040367-$ | AI-20110098802-$ | AI-20110125244-$ | AI-20110166636-$ | AI-20110218619-$ | AI-20110319991-$ | AI-20120022633-$ | AI-20120071969-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20120310328-$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/21 17:17

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S522	0	"17327673"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:09
S523	4	"17096253"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/22 11:10
S526	17	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/07/22 15:41
S527	58	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/07/22 15:41
S528	52	(US-20140046426-$ or US-20060074484-$ or US-20130144373-$ or US-20140316513-$ or US-20070168013-$ or US-20060155366-$ or US-20130131787-$ or US-20200000579-$ or US-20190029848-$ or US-20150148896-$ or US-20020082684-$ or US-20130090729-$ or US-20040256759-$ or US-20020052649-$ or US-20050027348-$ or US-20170000604-$ or US-20140155997-$ or US-20140222144-$ or US-20110098802-$ or US-20100185277-$ or US-20170014228-$ or US-20050043790-$ or US-20090276040-$ or US-20110218619-$ or US-20050137695-$ or US-20140277417-$).did. or (US-20200179143-$ or US-20160354201-$ or US-20160310268-$ or US-20150190227-$ or US-20070239265-$ or US-20070233228-$ or US-20130317598-$ or US-20080319521-$).did. or (US-7252682-$ or US-7771467-$ or US-8016877-$ or US-10034784-$ or US-5824037-$ or US-6846325-$ or US-5713953-$ or US-7914569-$ or US-9867697-$ or US-9370418-$).did. or	US-PGPUB; USPAT; FPRS; DERWENT	OR	OFF	2021/07/25 16:50

		(WO-2006124649-$).did. or (US-20070067014-$ or US-20190029848-$ or US-20180325703-$ or US-20040256759-$ or US-20020052649-$ or WO-9719653-$).did.				
S529	15	S528 and collagen	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 16:50
S530	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:00
S531	23	"2005023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:16
S532	12	"20050023584"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/07/25 17:17
S533	0	("2005023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S534	1	("20050023584").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:18
S535	1	("20060004442").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:19
S536	398	("2006/0004442").URPN.	USPAT	OR	OFF	2021/07/25 17:20
S537	1	("20130018458").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/07/25 17:28

7/25/2021 7:44:18 PM
C:\Users\tshipmon\Documents\EAST\Workspaces\13706896.wsp

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/23 UTIL

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9333075		2016-05-10	Biadillah et al.	
	2	10258464		2019-04-16	Delaloye et al.	
	3	8408214		2013-04-02	Spenser	
	4	9339377		2016-05-17	Quadri et al.	
	5	9532868		2017-01-03	Braido	
	6	10792172		2020-10-06	Shahriari	
	7	7381219		2008-06-03	Salahieh et al.	
	8	7921678		2011-04-12	Norris et al.	

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	9	9333075		2016-05-10	Biadillah et al.	
	10	9370418		2016-06-21	Pintor et al.	
	11	5665117		1997-09-09	Rhodes	
	12	5824037		1998-10-20	Fogarty et al.	
	13	6663667		2003-12-16	Dehdashtian et al.	
	14	7175652		2007-02-13	Cook et al.	
	15	7470284		2008-12-30	Lambrecht et al.	
	16	7740656		2010-06-22	Mensah et al.	
	17	7972370		2011-07-05	Douk et al.	
	18	7780726		2010-08-24	SEGUIN	
	19	4164046		1979-08-14	Cooley	

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	1	20020052649	A1	2002-05-02	Greenhalgh	
	2	20060276813	A1	2006-12-07	Greenberg	
	3	20080077236	A1	2008-03-27	Letac et al.	
	4	20080188929	A1	2008-08-07	Schreck	
	5	20080319521	A1	2008-12-25	Norris et al.	
	6	20110009948	A1	2011-01-13	Huang et al.	
	7	20120123529	A1	2012-05-17	Levi	
	8	20110218619	A1	2011-09-08	Benichou et al.	
	9	20110319991	A1	2011-12-29	Hariton et al.	

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	10	20040256759	A1	2004-12-23	Hartley	
	11	20110098802	A1	2011-04-28	Braido	
	12	20030153974	A1	2003-08-14	Spenser	
	13	20130304196	A1	2013-11-14	Kelly	
	14	20040243221	A1	2004-12-02	Fawzi Natalie V. et al.	
	15	20070179591	A1	2007-08-02	Baker et al.	
	16	20070213815	A1	2007-09-13	Khairkhahan et al.	
	17	20070219620	A1	2007-09-20	Eells et al.	
	18	20080021547	A1	2008-01-24	Davidson	
	19	20090105805	A1	2009-04-23	Baker et al.	
	20	20100204781	A1	2010-08-12	Alkhatib	

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	21	20120296418	A1	2012-11-22	Bonyuet et al.	
	22	20150335429	A1	2015-11-26	Morriss	
	23	20160022444	A1	2016-01-28	Delaloye et al.	
	24	20060025857	A1	2006-02-02	Bergheim et al.	
	25	20060074484	A1	2006-04-06	Huber	
	26	20070282436	A1	2007-12-06	Pinchuk	
	27	20100036484	A1	2010-02-11	Hariton et al.	
	28	20110040367	A1	2011-02-17	Vinluan	
	29	20110125244	A1	2011-05-26	Roeder et al	
	30	20110166636	A1	2011-07-07	Rowe	
	31	20120022633	A1	2012-01-26	Olson	

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	32	20120071969	A1	2012-03-22	Li et al	
	33	20120310328	A1	2012-02-26	Olson	
	34	20130018458	A1	2013-01-07	Yohanan	
	35	20130073030	A1	2013-03-21	Tuval	
	36	20140018915	A1	2014-01-16	Biadillah et al.	
	37	20140155997	A1	2014-06-05	Braido	
	38	20170128209	A1	2017-05-11	Morriss et al.	

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	1	2006005015	WO		2012-05-17	Spenser		
	2	9829057	WO		2012-05-17	Cribier		

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	3	2006124649	WO		2006-11-23	Nguyen			
	4	2012068175	WO		2012-04-02	Aristizabal			

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MURGITROYD, Search Report dated February 2, 2021, USA	
	2	BOBO, Donald E., EDWARDS LIFESCIENCES 2011 ANNUAL REPORT, page 6, USA, published 2011.	
	3	AL-ATTAR, NAWWAR, Next generation surgical aortic biological prostheses : "sutureless valves", published December 21, 2011, available at https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-10/Next-Generation-Surgical-Aortic-Biological-Prostheses-Sutureless-Valves	
	4	KOCHER, Alfred, One-year outcomes of the Surgical Treatment of Aortic Stenosis Witha Next Generation Surgical Aortic Valve (TRITON) trial:A prospective multicenter study of rapid-deployment aortic valvereplacement with the EDWARDS INTUITY Valve System, January 2013, available at https://www.jtcvs.org/article/S0022-5223(12)01111-7/pdf	
	5	PATSPADE Search Report, dated 1/21/2021, USA	
	6	BULLER, Nigel, Declaration in IPR IPR2017-01293, 10/11/2016	
	7	INTENTUS GROUP, Invalidity Search Report, STENT SEAL (US20130144373), March 30, 2020, Pgs. 1-15	

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	Attorney Docket Number	426/2/23 UTIL

	8	SILVER, M.D., MALCOLM D., et al., The Pathology of Wear in the Beall Model 104 Heart Valve Prosthesis, http://ahajounals.org, Circulation, Vol. 56, No. 4 October, 1977 Pgs. 617-622	
	9	INVALIDITY SEARCH, DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME, June 2, 2021	

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Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	07/22/2021

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.P.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-07-11
Name/Print	Justin R. Nifong	Registration Number	59389

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	-		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTARY AMENDMENT

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

an inner skirt attached to the leaflet assembly and positioned radially inwardly of the frame;

an outer seal that extends radially outwardly of the frame,

wherein the outer seal comprises a plurality of fibers that extend away from the frame and the plurality of fibers are configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second plurality of fibers that are positioned radially inwardly from the plurality of fibers of the outer seal,

wherein the second plurality of fibers are in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim [[12]] 11, wherein the second plurality of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (Previously Presented) The prosthetic heart valve of claim 11, wherein the inner skirt extends proximally further than a scalloped end of the leaflet assembly.

15. (Previously Presented) The prosthetic heart valve of claim 11, wherein a distance that the plurality of fibers of the outer seal extend from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (Previously Presented) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the outer seal covers each of the at least two rows of cells.

17. (Previously Presented) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are non-metallic.

18. (Previously Presented) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are collagen fibers.

19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (Previously Presented) The prosthetic heart valve of claim 11, wherein the outer seal is free of a non-porous graft covering between the plurality of fibers of the outer seal and the frame.

21. (Previously Presented) The prosthetic heart valve of claim 11, wherein the inner skirt is stitched to the frame.

22. (Previously Presented) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Previously Presented) The prosthetic heart valve of claim 11, wherein the inner skirt and the outer seal are distinct elements.

24. (Previously Presented) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the plurality of fibers of the outer seal against native leaflets of an aorta of the patient.

25. (Previously Presented) The prosthetic heart valve of claim 11, wherein the inner skirt extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal define[[an]] openings that extend[[s]] through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

REMARKS

The claims have been amended to further clarify the claimed invention. The references of record do not appear to show a second plurality of fibers that are positioned radially inwardly from the plurality of fibers of the outer seal, wherein the second plurality of fibers are in direct contact with the frame. This advantageously allows a different plurality of fibers compared to the outermost plurality of fibers, which may provide different and enhanced properties compared to the first plurality of fibers.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: July 27, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

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	Attorney Docket Number	426/2/23 UTIL

	1	WALTHER, THOMAS, Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of the SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves, European Journal of Cario-thoracic Surgery 40, April 3, 2011

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-07-27
Name/Print	Justin R. Nifong	Registration Number	59389

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Electronic Acknowledgement Receipt

EFS ID:	43357552
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	27-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	21:49:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	426-reference.pdf	612780 15c27418ce6714a8fca74a279c8b914433f81405	no	7

Warnings:

Information:					
2		426-2-23UTIL-20210727-supp-amendment.pdf	191865 f8c89c5ba70b1c0b3b88d01cecd79077688211ea	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5

Warnings:					
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3	Information Disclosure Statement (IDS) Form (SB08)	426-2-23-ids.pdf	1034430 b572d8c8612eb4536ebc4e58efde0c595e085869	no	4
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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

	07/27/2021	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
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The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/327,673	05/22/2021	3774	830	426/2/23 UTIL	10	2

CONFIRMATION NO. 1189

CORRECTED FILING RECEIPT

175373
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

OC000000127123125

Date Mailed: 07/22/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Ali Shahriari, Hillsboro Beach, FL;

Applicant(s)

Aortic Innovations, LLC, Hillsboro Beach, FL;

Assignment For Published Patent Application

Aortic Innovations, LLC, Hillsboro Beach, FL

Power of Attorney: The patent practitioners associated with Customer Number 175373

Domestic Priority data as claimed by applicant

This application is a CON of 17/213,251 03/26/2021
which is a CON of 17/096,253 11/12/2020 PAT 10966846
which is a CON of 17/060,557 10/01/2020 PAT 10888441
which is a CON of 16/910,189 06/24/2020 PAT 10857011
which is a CON of 16/808,137 03/03/2020 PAT 10792172
which is a CON of 16/736,879 01/08/2020 PAT 10842655
which is a CON of 16/042,286 07/23/2018 PAT 10555823
which is a CON of 14/614,628 02/05/2015 PAT 10028848
which is a CON of 14/569,306 12/12/2014 PAT 9339399
which is a DIV of 13/706,896 12/06/2012 PAT 8940040
which claims benefit of 61/723,446 11/07/2012
and claims benefit of 61/567,458 12/06/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 05/27/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/327,673**

Projected Publication Date: 09/09/2021

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/21/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARMEN D WILLIAMS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/21/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARMEN D WILLIAMS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION AND TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17327673
Filing Date	22-May-2021
First Named Inventor	Ali Shahriari
Attorney Docket Number	426/2/23 UTIL
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Aortic Innovations LLC	100 %

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

16941117 filed on 07/28/2020

17007373 filed on 08/31/2020

17170957 filed on 02/09/2021

17006793 filed on 08/29/2020

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

10987236

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11026817

10857011

10792172

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicants claims the following fee status:

◉ Small Entity

○ Micro Entity

○ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- (●) An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

  Registration Number 59389

- ( ) A sole inventor
- ( ) A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ( ) A joint inventor; all of whom are signing this request

Signature	/Justin R. Nifong/
Name	Justin R. Nifong

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17327673
Filing Date:	22-May-2021
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17327673

Filing Date: 22-May-2021

Applicant/Patent under Reexamination: Shahriari

Electronic Terminal Disclaimer filed on July 21, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	43308523
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	21-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	14:24:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20217KE24413579
Deposit Account	506191
Authorized User	Justin Nifong
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	42436 4ee2da4d62fddd9a12dc7031635561cca53d0016	no	3
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30295 7acac02771af7a9b08601d5d4bb454931546cb2c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	72731		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	-		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

an inner skirt attached to the leaflet assembly and positioned radially inwardly of the frame;

an outer seal that extends radially outwardly of the frame,

wherein the outer seal comprises a plurality of fibers that extend away from the frame and the plurality of fibers are configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.

12. (New) The prosthetic heart valve of claim 11, further comprising a second plurality of fibers that are positioned radially inwardly from the plurality of fibers of the outer seal, wherein the second plurality of fibers seals the frame and the inner skirt.

13. (New) The prosthetic heart valve of claim 12, wherein the second plurality of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (New) The prosthetic heart valve of claim 11, wherein the inner skirt extends proximally further than a scalloped end of the leaflet assembly.

15. (New) The prosthetic heart valve of claim 11, wherein a distance that the plurality of fibers of the outer seal extend from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (New) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the outer seal covers each of the at least two rows of cells.

17. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are non-metallic.

18. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are collagen fibers.

19. (New) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (New) The prosthetic heart valve of claim 11, wherein the outer seal is free of a non-porous graft covering between the plurality of fibers of the outer seal and the frame.

21. (New) The prosthetic heart valve of claim 11, wherein the inner skirt is stitched to the frame.

22. (New) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (New) The prosthetic heart valve of claim 11, wherein the inner skirt and the outer seal are distinct elements.

24. (New) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the plurality of fibers of the outer seal against native leaflets of an aorta of the patient.

25. (New) The prosthetic heart valve of claim 11, wherein the inner skirt extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal define an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

REMARKS

Claims 1-10 have been canceled. New claims 11-26 have been added. Entry of the amendment and favorable consideration are requested. No new matter has been added.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: July 21, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Electronic Acknowledgement Receipt

EFS ID:	43308175
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	21-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	14:05:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-23UTIL-20210721-PrelimAmend-refiling.pdf	28912 081855346d05239c772c1408bc86522bbe4302dc	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	28912	

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New Applications Under 35 U.S.C. 111
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PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

	07/21/2021	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: ECOMM.AUTH/ECOMM.WTDW
Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

PTO/SB/439 (11-15)

AUTHORIZATION FOR INTERNET COMMUNICATIONS IN A PATENT APPLICATION OR REQUEST TO WITHDRAW AUTHORIZATION FOR INTERNET COMMUNICATIONS		
	Application No.	17/327,673
	Filing Date	5/22/2021
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Practitioner Docket No.	426/2/23 UTIL

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I. To authorize permission for Internet Communications.

☑ Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned and practitioners in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03)

II. To withdraw authorization for Internet Communications.

☐ The authorization given on _____, to the USPTO to communicate with the undersigned and any practitioner in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via Internet communications such as video conferencing, instant messaging, or electronic mail is hereby withdrawn. I understand that the withdrawal is effective when approved rather than when received.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 59389.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Justin R. Nifong/ — Signature

7/21/2021 — Date

Justin R. Nifong — Typed or printed name

919-348-2194 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Juristic entities must be represented by a patent practitioner (see 37 CFR 1.31, which is applicable to any paper filed on or after September 16, 2012, that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	43304277
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	21-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	10:13:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	sb0439.pdf	94468 5f9e05a481a3c78c183b5c178ad547feca9de18a	no	2

Warnings:

Information:	
Total Files Size (in bytes):	94468

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	-		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	SHIPMON, TIFFANY P		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1-10 (Canceled)

11. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

an inner skirt attached to the leaflet assembly and positioned radially inwardly of the frame;

an outer seal that extends radially outwardly of the frame,

wherein the outer seal comprises a plurality of fibers that extend away from the frame and the plurality of fibers are configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.

12. (New) The prosthetic heart valve of claim 11, further comprising a second plurality of fibers that are positioned radially inwardly from the plurality of fibers of the outer seal, wherein the second plurality of fibers seals the frame and the inner skirt.

13. (New) The prosthetic heart valve of claim 12, wherein the second plurality of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (New) The prosthetic heart valve of claim 11, wherein the inner skirt extends proximally further than a scalloped end of the leaflet assembly.

15. (New) The prosthetic heart valve of claim 11, wherein a distance that the plurality of fibers of the outer seal extend from a centerline extending longitudinally through the frame varies along a length of the centerline.

16. (New) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the outer seal covers each of the at least two rows of cells.

17. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are non-metallic.

18. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal are collagen fibers.

19. (New) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

20. (New) The prosthetic heart valve of claim 11, wherein the outer seal is free of a non-porous graft covering between the plurality of fibers of the outer seal and the frame.

21. (New) The prosthetic heart valve of claim 11, wherein the inner skirt is stitched to the frame.

22. (New) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (New) The prosthetic heart valve of claim 11, wherein the inner skirt and the outer seal are distinct elements.

24. (New) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the plurality of fibers of the outer seal against native leaflets of an aorta of the patient.

25. (New) The prosthetic heart valve of claim 11, wherein the inner skirt extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (New) The prosthetic heart valve of claim 11, wherein the plurality of fibers of the outer seal define an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

REMARKS

Claims 1-10 have been canceled. New claims 11-26 have been added. Entry of the amendment and favorable consideration are requested. No new matter has been added.

DEPOSIT ACCOUNT

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Respectfully submitted,

Date: July 19, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Electronic Acknowledgement Receipt

EFS ID:	43283466
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
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Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	19-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	13:35:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-23UTIL-20210719-PrelimAmend.pdf	28971 b7db1757cc092a534c22dd003b80def280231050	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	28971	

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/327,673	Filing Date 05/22/2021	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $240 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/19/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 16	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $240 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/327,673	05/22/2021	Ali Shahriari	426/2/23 UTIL	1189

175373 7590 07/15/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
07/15/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@nkpatentlaw.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/327,673	**Applicant(s)** Shahriari, Ali	
	Examiner KIMBERLY A INABINET	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 22 May 2021 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to KIMBERLY INABINET at (571) 272-4618. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/KIMBERLY A INABINET/ Paralegal Specialist, OPET	

U.S. Patent and Trademark Office
PTO-2298 (Rev. 02-2012)

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17327673
Filing Date	2021-05-22
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/23 UTIL

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9333075		2016-05-10	Biadillah et al.	
	2	10258464		2019-04-16	Delaloye et al.	
	3	8408214		2013-04-02	Spenser	
	4	9339377		2016-05-17	Quadri et al.	
	5	9532868		2017-01-03	Braido	
	6	10792172		2020-10-06	Shahriari	
	7	7381219		2008-06-03	Salahieh et al.	
	8	7921678		2011-04-12	Norris et al.	

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	Attorney Docket Number	426/2/23 UTIL

	9	9333075		2016-05-10	Biadillah et al.	
	10	9370418		2016-06-21	Pintor et al.	
	11	5665117		1997-09-09	Rhodes	
	12	5824037		1998-10-20	Fogarty et al.	
	13	6663667		2003-12-16	Dehdashtian et al.	
	14	7175652		2007-02-13	Cook et al.	
	15	7470284		2008-12-30	Lambrecht et al.	
	16	7740656		2010-06-22	Mensah et al.	
	17	7972370		2011-07-05	Douk et al.	
	18	7780726		2010-08-24	SEGUIN	
	19	4164046		1979-08-14	Cooley	

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	Attorney Docket Number	426/2/23 UTIL

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020052649	A1	2002-05-02	Greenhalgh	
	2	20060276813	A1	2006-12-07	Greenberg	
	3	20080077236	A1	2008-03-27	Letac et al.	
	4	20080188929	A1	2008-08-07	Schreck	
	5	20080319521	A1	2008-12-25	Norris et al.	
	6	20110009948	A1	2011-01-13	Huang et al.	
	7	20120123529	A1	2012-05-17	Levi	
	8	20110218619	A1	2011-09-08	Benichou et al.	
	9	20110319991	A1	2011-12-29	Hariton et al.	

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	Art Unit	3774
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	10	20040256759	A1	2004-12-23	Hartley	
	11	20110098802	A1	2011-04-28	Braido	
	12	20030153974	A1	2003-08-14	Spenser	
	13	20130304196	A1	2013-11-14	Kelly	
	14	20040243221	A1	2004-12-02	Fawzi Natalie V. et al.	
	15	20070179591	A1	2007-08-02	Baker et al.	
	16	20070213815	A1	2007-09-13	Khairkhahan et al.	
	17	20070219620	A1	2007-09-20	Eells et al.	
	18	20080021547	A1	2008-01-24	Davidson	
	19	20090105805	A1	2009-04-23	Baker et al.	
	20	20100204781	A1	2010-08-12	Alkhatib	

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	21	20120296418	A1	2012-11-22	Bonyuet et al.	
	22	20150335429	A1	2015-11-26	Morriss	
	23	20160022444	A1	2016-01-28	Delaloye et al.	
	24	20060025857	A1	2006-02-02	Bergheim et al.	
	25	20060074484	A1	2006-04-06	Huber	
	26	20070282436	A1	2007-12-06	Pinchuk	
	27	20100036484	A1	2010-02-11	Hariton et al.	
	28	20110040367	A1	2011-02-17	Vinluan	
	29	20110125244	A1	2011-05-26	Roeder et al	
	30	20110166636	A1	2011-07-07	Rowe	
	31	20120022633	A1	2012-01-26	Olson	

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	32	20120071969	A1	2012-03-22	Li et al	
	33	20120310328	A1	2012-02-26	Olson	
	34	20130018458	A1	2013-01-07	Yohanan	
	35	20130073030	A1	2013-03-21	Tuval	
	36	20140018915	A1	2014-01-16	Biadillah et al.	
	37	20140155997	A1	2014-06-05	Braido	
	38	20170128209	A1	2017-05-11	Morriss et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2006005015	WO		2012-05-17	Spenser		
	2	9829057	WO		2012-05-17	Cribier		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

	3	2006124649	WO		2006-11-23	Nguyen			
	4	2012068175	WO		2012-04-02	Aristizabal			

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MURGITROYD, Search Report dated February 2, 2021, USA	
	2	BOBO, Donald E., EDWARDS LIFESCIENCES 2011 ANNUAL REPORT, page 6, USA, published 2011.	
	3	AL-ATTAR, NAWWAR, Next generation surgical aortic biological prostheses : "sutureless valves", published December 21, 2011, available at https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-10/Next-Generation-Surgical-Aortic-Biological-Prostheses-Sutureless-Valves	
	4	KOCHER, Alfred, One-year outcomes of the Surgical Treatment of Aortic Stenosis Witha Next Generation Surgical Aortic Valve (TRITON) trial:A prospective multicenter study of rapid-deployment aortic valvereplacement with the EDWARDS INTUITY Valve System, January 2013, available at https://www.jtcvs.org/article/S0022-5223(12)01111-7/pdf	
	5	PATSPADE Search Report, dated 1/21/2021, USA	
	6	BULLER, Nigel, Declaration in IPR IPR2017-01293, 10/11/2016	
	7	INTENTUS GROUP, Invalidity Search Report, STENT SEAL (US20130144373), March 30, 2020, Pgs. 1-15	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17327673
	Filing Date	2021-05-22
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

	8	SILVER, M.D., MALCOLM D., et al., The Pathology of Wear in the Beall Model 104 Heart Valve Prosthesis, http://ahajounals.org, Circulation, Vol. 56, No. 4 October, 1977 Pgs. 617-622	
	9	INVALIDITY SEARCH, DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME, June 2, 2021	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/23 UTIL

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-07-11
Name/Print	Justin R. Nifong	Registration Number	59389

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	43216914
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	11-JUL-2021
Filing Date:	22-MAY-2021
Time Stamp:	11:41:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	npl1.pdf	12563134 1af854f8c6d1cd29c0cb1b23e637fdfd78be6275	no	216

Warnings:

Information:					
2	Non Patent Literature	npl2.pdf	16029942 ee4bd9e9198ec75c3cb133170d5db372bf29642c	no	259
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	426-2-23-master-IDS.pdf	1036883 5fc2a3b42c6b377fc144d7e4dc6a14a8294bc27c	no	10
Warnings:					
Information:					
		Total Files Size (in bytes):	29629959		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/327,673	Confirmation No.:	1189
Applicant	:	Ali Shahriari		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	May 22, 2021		
TC/A.U.	:	3774		
Examiner	:	-		
Docket No.	:	426/2/23 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRECTED FILING RECEIPT

Applicant hereby submits this Request for Corrected Filing Receipt. It is requested to correct the applicant to Aortic Innovations, LLC, Hillsboro Beach, FL. Please issue a corrected filing receipt in view of this request.

A replacement ADS in compliance with 37 CFR 1.76 and a Statement under 37 CFR 3.73(c) are provided herewith to reflect this request.

DEPOSIT ACCOUNT

It is not believed that any additional fees are due at this time; however, the Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: June 8, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Aortic Innovations, LLC

Application No./Patent No.: 17/327,673 Filed/Issue Date: 2021-05-22

Titled: TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Aortic Innovations, LLC, a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 056398, Frame 0241, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

   1. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

   2. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

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5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Justin R. Nifong/	2021-06-08
Signature	Date
Justin R. Nifong	59389
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

REPLACEMENT

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Ali		Shahriari	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Hillsboro Beach	State/Province	FL	Country of Residence i	US

Mailing Address of Inventor:

Address 1	977 Hillsboro Mile		
Address 2			
City	Hillsboro Beach	State/Province	FL
Postal Code	33062	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	175373		
Email Address	docket@nkpatentlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL		
Attorney Docket Number	426/2/23 UTIL	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	23	Suggested Figure for Publication (if any)	17

PTO/AIA/14 (08-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	175373		

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	Remove
Registration Number					
Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	Remove
Registration Number					

Additional Representative Information blocks may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17213251	2021-03-26

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17213251	Continuation of	17096253	2020-11-12	10966846	2021-04-06

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17096253	Continuation of	17060557	2020-10-01	10888441	2021-01-12

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17060557	Continuation of	16910189	2020-06-24	10857011	2020-12-08

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16910189	Continuation of	16808137	2020-03-03	10792172	2020-10-06

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16808137	Continuation of	16736879	2020-01-08	10842655	2020-11-24

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16736879	Continuation of	16042286	2018-07-23	10555823	2020-02-11

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16042286	Continuation of	14614628	2015-02-05	10028848	2018-07-24

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14614628	Continuation of	14569306	2014-12-12	9339399	2016-05-17

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14569306	Division of	13706896	2012-12-06	8940040	2015-01-27

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61723446	2012-11-07

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61567458	2011-12-06

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(X) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	
If the Applicant is an Organization check here.	[X] Aortic Innovations, LLC

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Applicant:

Address 1	977 Hillsboro Mile		
Address 2			
City	Hillsboro Beach	**State/Province**	FL
Country[i]	US	Postal Code	33062
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

PTO/AIA/14 (08-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	Aortic Innovations, LLC

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City	Hillsboro Beach	**State/Province**	FL
Country i	US	Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

PTO/AIA/14 (08-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	17/327,673
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Justin R. Nifong/			Date (YYYY-MM-DD)	2021-06-08
First Name	Justin	Last Name	Nifong	Registration Number	59389

Additional Signature may be generated within this form by selecting the Add button.

Electronic Acknowledgement Receipt

EFS ID:	42929355
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Sandra Hess
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	08-JUN-2021
Filing Date:	22-MAY-2021
Time Stamp:	15:00:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Corrected Filing Receipt	426-2-23UTIL-20210608-RequestForCorrFilingReceipt.pdf	19897 5aa8ac28bc94676df426f4df93e77d7da6c82e71	no	2

Warnings:

Information:					
2	Assignee showing of ownership per 37 CFR 3.73	426-2-23UTIL-20210608-373Statement.pdf	119070 9d2e71e11bd95a1ce8af930b5b213669dc4d531b	no	3
Warnings:					
Information:					
3	Application Data Sheet	426-2-23UTIL-20210608-CorrADS.pdf	272985 9f0117f2d00b9def09fd9139aa094a0a86405525	no	9
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
			Total Files Size (in bytes):	411952	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/327,673	05/22/2021		830	426/2/23 UTIL	10	2

CONFIRMATION NO. 1189

175373
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

FILING RECEIPT

OC000000125946008

Date Mailed: 06/01/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Ali Shahriari, Hillsboro Beach, FL;

Applicant(s)

Ali Shahriari, Hillsboro Beach, FL;

Assignment For Published Patent Application

Aortic Innovations, LLC, Hillsboro Beach, FL

Power of Attorney: The patent practitioners associated with Customer Number 175373

Domestic Priority data as claimed by applicant

This application is a CON of 17/213,251 03/26/2021
which is a CON of 17/096,253 11/12/2020 PAT 10966846
which is a CON of 17/060,557 10/01/2020 PAT 10888441
which is a CON of 16/910,189 06/24/2020 PAT 10857011
which is a CON of 16/808,137 03/03/2020 PAT 10792172
which is a CON of 16/736,879 01/08/2020 PAT 10842655
which is a CON of 16/042,286 07/23/2018 PAT 10555823
which is a CON of 14/614,628 02/05/2015 PAT 10028848
which is a CON of 14/569,306 12/12/2014 PAT 9339399
which is a DIV of 13/706,896 12/06/2012 PAT 8940040
which claims benefit of 61/723,446 11/07/2012
and claims benefit of 61/567,458 12/06/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 05/27/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/327,673**

Projected Publication Date: 09/09/2021

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/327,673

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	10 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	830		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ali Shahriari	Nonprovisional Application Number (if known):	
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Justin R. Nifong/	Date 2021-05-22
Name (Print/Typed) Justin R. Nifong	Practitioner Registration Number 59389

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Ali SHAHRIARI Date (Optional): 12/5/12

Signature: A. Shah

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ABSTRACT OF THE DISCLOSURE

A transcatheter valve assembly replacement device includes an improved paravalvular seal.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/23 UTIL

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2100	2100
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**3000**

Electronic Acknowledgement Receipt	
EFS ID:	42793900
Application Number:	17327673
International Application Number:	
Confirmation Number:	1189
Title of Invention:	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/23 UTIL
Receipt Date:	22-MAY-2021
Filing Date:	
Time Stamp:	05:53:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3000
RAM confirmation Number	E20215L653401525
Deposit Account	506191
Authorized User	Justin Nifong
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.21 (Miscellaneous fees and charges) 37 CFR 1.20 (Post Issuance fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	WebADS.pdf	156971 6ce907b4829ef6f7260370074ec6f91b799c678a	no	9
Warnings:					
Information:					
2	Power of Attorney	426-2-23UTIL-20210115-POA-signed.pdf	144284 de910837bce2dda58bc88dc91c9a08c087ca1e0f	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	426-2-23UTIL-Drwgs.pdf	2373975 8899036e367ce0ff2a45632f957814c6439c22f3	no	19
Warnings:					
Information:					
4	TrackOne Request	426-2-23UTIL-TrackOneRequest.pdf	113921 33c56ffb968eb5641b47b5c72bc9dc73880bd8e0	no	2
Warnings:					
Information:					
5	Oath or Declaration filed	ai-dec.pdf	71450 97556fba2fe720d724ba91bbfffcb4a20fdbd1c9	no	1
Warnings:					
Information:					
6		426-2-23-UTIL-Spec-claims-abs.pdf	291095 e8167b6a411c04b1c99afb22bf3e24711cb03909	yes	43
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	

	Abstract		43	43	
	Claims		39	42	
	Specification		1	38	
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	40154 55ccbd507041585ce8ce5707a730043d5ea30958	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3191850		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Ali		Shahriari	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Hillsboro Beach	State/Province	FL	Country of Residence i	US

Mailing Address of Inventor:

Address 1	977 Hillsboro Mile		
Address 2			
City	Hillsboro Beach	State/Province	FL
Postal Code	33062	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	175373		
Email Address	docket@nkpatentlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL		
Attorney Docket Number	426/2/23 UTIL	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	23	Suggested Figure for Publication (if any)	17

PTO/AIA/14 (08-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	175373		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17213251	2021-03-26

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17213251	Continuation of	17096253	2020-11-12	10966846	2021-04-06

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17096253	Continuation of	17060557	2020-10-01	10888441	2021-01-12

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17060557	Continuation of	16910189	2020-06-24	10857011	2020-12-08

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16910189	Continuation of	16808137	2020-03-03	10792172	2020-10-06

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16808137	Continuation of	16736879	2020-01-08	10842655	2020-11-24

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16736879	Continuation of	16042286	2018-07-23	10555823	2020-02-11

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16042286	Continuation of	14614628	2015-02-05	10028848	2018-07-24

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14614628	Continuation of	14569306	2014-12-12	9339399	2016-05-17

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14569306	Division of	13706896	2012-12-06	8940040	2015-01-27

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61723446	2012-11-07

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61567458	2011-12-06

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Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
Title of Invention	TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◯ Assignee	◯ Legal Representative under 35 U.S.C. 117	◯ Joint Inventor
◯ Person to whom the inventor is obligated to assign.	◯ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	
If the Applicant is an Organization check here. ☐	

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		**State/Province**	
Country[i]		Postal Code	
Phone Number		Fax Number	
Email Address			

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Assignee Information including Non-Applicant Assignee Information:

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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	Aortic Innovations, LLC

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City	Hillsboro Beach	**State/Province**	FL
Country i	US	Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/23 UTIL
	Application Number	
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Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Justin R. Nifong/			Date (YYYY-MM-DD)	
First Name	Justin	Last Name	Nifong	Registration Number	59389

Additional Signature may be generated within this form by selecting the Add button.

CLAIMS

1. An endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first endograft prosthetic component comprising (i) a proximal frame, and (ii) a distal frame secured to the proximal frame and extending to a distal end of the first prosthetic component,

at least one conduit secured to the first prosthetic component and positioned adjacent to the proximal frame,

a second prosthetic component secured to a proximal end of the first prosthetic component, the second prosthetic component comprising (i) a balloon-expandable frame extending distally from a proximal end of the second prosthetic component, and (ii) a self-expanding frame connected to the balloon-expandable frame and extending to a distal end of the second prosthetic component, and

a valve element secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

2. The endograft device of claim 1, wherein the self-expanding frame has an hourglass shape.

3. The endograft device of claim 2, wherein the self-expanding frame includes:

a first section that tapers inwardly between a proximal end and a distal end, and

a second section having a proximal end that is connected to the distal end of the first section, the second section tapering outwardly between the proximal end of the second section and a distal end of the second section.

4. The endograft device of claim 3, wherein the proximal end of the first section is secured to a distal end of the balloon-expandable frame.

5. The endograft device of claim 3, wherein:

the self-expanding frame includes a third section extending proximally from the proximal end of the first section, the third section having a passageway defined therein, and

the balloon-expandable frame is positioned in the passageway of the third section of the self-expanding frame.

6. The endograft device of claim 5, wherein the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

7. The endograft device of claim 6, wherein a plurality of fibers are attached to the third section of the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

8. The endograft device of claim 1, wherein the proximal frame of the first prosthetic component has a passageway defined therein, and the distal end of the second prosthetic component is positioned in the passageway of the first prosthetic component.

9. The endograft device of claim 1, wherein the at least one conduit includes a pair of conduits positioned on opposite sides of the first prosthetic component.

10. A method of implanting a heart valve in a stent component, the method comprising:

placing a heart valve in a first component;

securing the first component within a second component,

wherein the deployment occurs endovascularly.

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

[0001] This application is a continuation of U.S. Patent Application no. 17/213,251 entitled TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL, which was filed on March 26, 2021, which is a continuation of U.S. Patent Application No. 17/096,253 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on November 12, 2020, and issued as U.S. Patent No. 10,966,846 on April 6, 2021, which is a continuation of U.S. Patent Application No. 17/060,557 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on October 1, 2020 and issued as U.S. Patent No. 10,888,441 on January 12, 2021, which is a continuation of U.S. Patent Application No. 16/910,189 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on June 24, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 entitled "HEART VALVE REPLACEMENT DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on March 3, 2020 and issued as U.S. Patent No. 10,792,172 on October 6, 2020, which is a continuation of U.S. Patent Application No. 16/736,879 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on January 8, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on July 23, 2018 and issued as U.S. Patent No. 10,555,823 on February 11, 2020, which is a continuation of U.S. Patent Application No. 14/614,628 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on February 5, 2015 and issued as U.S. Patent No. 10,028,848 on July 24, 2018, which is a

continuation of U.S. Patent Application No. 14/569,306 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on December 12, 2014 and issued as U.S. Patent No. 9,339,399 on May 17, 2016, which is a divisional of U.S. Patent Application No. 13/706,896 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on December 6, 2012 and issued as U.S. Patent No. 8,940,040 on January 27, 2015, which claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Application Serial No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on December 6, 2011. Application No. 13/706,896 also claims priority under § 119 to U.S. Provisional Application Serial No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on November 7, 2012. Each of the applications referenced herein are incorporated by reference in their entirety.

TECHNICAL FIELD

[0002] The present disclosure relates to a device and method of using same for endovascular aortic repair, including repair of aortic valve disease, aortic stenosis, ascending aortic aneurysms, aortic insufficiency, aortic regurgitation, ascending aneurysm, bicuspid valve disease, and/or Type A dissections.

BACKGROUND

[0003] The normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of Valsalva, the sinutubular junction, and the tubular portion. The challenge facing practitioners of endovascular repair of ascending aortic aneurysms is that there is a very short proximal landing zone at the level of the sinutubular junction, there is variable coronary anatomy from patient to patient, and, in many cases, there is involvement of the aortic valve with either

stenosis or insufficiency. Generally speaking, and as discussed in the article SURGERY INSIGHT: THE DILATED ASCENDING AORTA — INDICATIONS FOR SURGICAL INTERVENTION, by James E. Davies and Thralf M. Sundt published in Nature Clinical Practice Cardiovascular Medicine (2007), the contents of which are incorporated herein by reference in its entirety, there are three basic types of involvement of the ascending aorta, designated as Type A, B, or C. These will be discussed in further detail below and are shown in FIGS. 1A-1C, which have been reproduced from the referenced article.

[0004] Type A aneurysms are most commonly found in younger patients and patients with connective tissue disorders such as Marfan syndrome. The anatomical characteristics of Type A aneurysms are dilatation of the sinuses of Valsalva with or without dilatation of the aortic annulus. The sinutubular junction is most often dilated. The valve could be normal, stenotic or insufficient. An example of a Type A aneurysm is shown in FIG. 1A.

[0005] The anatomical characteristics of Type B aneurysms are dilatation of the tubular portion. Initially the sinutubular junction may be normal or mildly dilated, however as the aneurysm grows, it stretches the sinutubular junction and may eventually lead to aortic insufficiency. The valve could be normal, stenotic or insufficient. The bulk of the aneurysm is at the level of the tubular aorta. An example of a Type B aneurysm is shown in FIG. lB.

[0006] The anatomical characteristics of Type C aneurysms are dilatation of the sinuses of Valsalva, sinutubular junction and the tubular portion of the aorta. The valve could be normal, stenotic or insufficient. Type B and C aneurysms are most commonly found in an older group of patients. An example of a Type C aneurysm is shown in FIG. 1C.

[0007] There are devices clinically used for endovascular repair of ascending aortic aneurysms. Although transcatheter valves are a clinical reality, none in clinical use have been

designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms. Indeed, a device is needed that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

[0008] According to one aspect of the disclosure, an endograft device for endovascular repair of ascending aortic aneurysms is disclosed. The endograft device includes a first prosthetic component that has a proximal frame and a distal frame that is secured to the proximal frame and extends to a distal end of the first prosthetic component. The endograft device also includes at least one conduit that is secured to the first prosthetic component and that is positioned adjacent to the proximal frame, and a second prosthetic component that is secured to a proximal end of the first prosthetic component. The second prosthetic component includes a balloon-expandable frame extending distally from a proximal end of the second prosthetic component and a self-expanding frame that is connected to the balloon-expandable frame and extends to a distal end of the second prosthetic component. The endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

[0009] In some embodiments, the self-expanding frame may have an hourglass shape. In some embodiments, the self-expanding frame may include a first section that tapers inwardly between a proximal end and a distal end. The endograft device may also include a second section having a proximal end that is secured to the distal end of the first section. The second section may

taper outwardly between the proximal end of the second section and a distal end of the second section. Additionally, in some embodiments, the proximal end of the first section may be connected to a distal end of the balloon-expandable frame.

[0010] In some embodiments, the self-expanding frame may include a third section that extends proximally from the proximal end of the first section. The third section may have a passageway defined therein, and the balloon-expandable frame may be positioned in the passageway of the third section of the self-expanding frame. In some embodiments, the balloon-expandable frame may be expandable between an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

[0011] In some embodiments, a plurality of fibers may be attached to the third section of the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers.

[0012] In some embodiments, the proximal frame of the first prosthetic component may have a passageway defined therein, and the distal end of the second prosthetic component may be positioned in the passageway of the first prosthetic component.

[0013] In some embodiments, the conduit may include a pair of conduits positioned on opposite sides of the first prosthetic component. Additionally, in some embodiments, the conduit may have a proximal opening that is positioned adjacent to a proximal end of the first prosthetic component.

[0014] In some embodiments, the proximal frame may include a first section secured to the distal end of the second prosthetic component, and a second section connected to the first

section. The second section may taper outward between a proximal end connected to the first section and a distal end. The conduit may have a distal opening defined in the second section of the proximal frame.

[0015] Additionally, in some embodiments, the endograft device may include a stent having a distal end positioned in the proximal opening of the at least one conduit and a proximal end configured to be positioned in a coronary artery.

[0016] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is fluid permitted to pass therethrough.

[0017] According to another aspect, a transcatheter valve is disclosed. The transcatheter valve includes a frame component having a balloon-expandable frame extending distally from a proximal end of the frame component and a self-expanding frame secured to the balloon-expandable frame. The self-expanding frame includes a first section that tapers inwardly between a proximal end and a distal end, and a second section that tapers outwardly between a proximal end secured to the distal end of the first section and a distal end. A valve element is positioned in the balloon-expandable frame at the proximal end of the frame component.

[0018] In some embodiments, the frame component may be a dual-frame component. The self-expanding frame may be an outer frame of the dual-frame component and may have a passageway defined therein. The balloon-expandable frame may be an inner frame of the dual-frame component that is positioned in the passageway defined in the self-expanding frame. Additionally, the balloon-expandable frame may be expandable between an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface

of the self-expanding frame and an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

[0019] In some embodiments, a plurality of fibers may be attached to the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers. Additionally, in some embodiments, an outer surface of the first section of the self-expanding frame may be uncovered such that fluid is permitted to pass therethrough and an outer surface of the second section of the self-expanding frame may be covered such that fluid is prevented from passing therethrough.

[0020] In some embodiments, the self-expanding frame may include an elongated section extending distally from the second section. The elongated section may have a length that is greater than a combined length of the first section and the second section. Additionally, in some embodiments, the self-expanding frame may be covered with at least one of a collagen and hydrogel. In some embodiments, the valve element may be one of a bicuspid valve and a tricuspid valve.

[0021] According to another aspect, a method of repairing a patient's aorta is disclosed. The method includes introducing a first prosthetic component into the patient's aorta such that a proximal frame of the first prosthetic component is positioned in the ascending aorta and a distal frame of the first prosthetic component is positioned in the aortic arch of the patient's aorta, advancing a covered stent through a conduit defined in the first prosthetic component into a coronary artery of the patient's aorta, securing a second prosthetic component to a proximal end of the first prosthetic component in the patient's aorta, and expanding a proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta such

that a valve secured to the proximal section is positioned in the aortic annulus proximal to the coronary arteries.

[0022] In some embodiments, expanding the proximal section of the second prosthetic component may include operating a balloon-expandable frame. Additionally, in some embodiments, expanding the proximal section of the second prosthetic component may include permitting a self-expanding frame to expand into engagement with the aortic annulus, and operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with an inner surface of the self-expanding frame after the self-expanding frame is engaged with the aortic annulus.

[0023] In some embodiments, operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with the aortic annulus.

[0024] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is permitted to pass therethrough.

[0025] In some embodiments, introducing the first prosthetic component into the patient's aorta and advancing the covered stent through the conduit defined in the first prosthetic component into the coronary artery of the patient's aorta may be performed during a first surgical procedure. In some embodiments, securing the second prosthetic component to the proximal end of the first prosthetic component and expanding the proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta may be performed during a second surgical procedure different from the first surgical procedure.

[0026] In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

[0028] FIG. 1 is an illustrative aorta;

[0029] FIG. 1A is an example of a Type A aneurysm;

[0030] FIG. 1B is an example of a Type B aneurysm;

[0031] FIG. 1C is an example of a Type C aneurysm;

[0032] FIG. 2 is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

[0033] FIG. 3 is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0034] FIG. 4 is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0035] FIG. 5 is a cross sectional view of the distal prosthetic component of FIG. 4 taken along the line 5-5 in FIG. 4;

[0036] FIG. 6 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 3 implanted therein;

[0037] FIG. 7 is a view similar to FIG. 6 showing stents extending from the distal prosthetic component;

[0038] FIG. 8 is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0039] FIG. 9 is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. 8;

[0040] FIG. 10 is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. 8;

[0041] FIG. 11 is a perspective view a proximal end of the proximal prosthetic component of FIG. 8;

[0042] FIG. 12 is a cross-sectional elevation view of the proximal prosthetic component of FIG. 8 taken along the line 12-12 in FIG. 11;

[0043] FIG. 13 is a plan view of the proximal prosthetic component of FIG. 8 showing the inner frame in an unexpanded position;

[0044] FIG. 14 is a plan view similar to FIG. 13 showing the inner frame in an expanded position;

[0045] FIG. 15 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 4 secured to the proximal prosthetic component of FIG. 8;

[0046] FIG. 16 is a view similar to FIG. 15 showing the inner frame in an expanded position;

[0047] FIG. 17 is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 3;

[0048] FIGS. 18-19 are partial cutaway views of the aorta with the transcatheter valve of FIG. 17 implanted therein;

[0049] FIG. 20 is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 8; and

[0050] FIGS. 21-22 are partial cutaway views of the aorta with the transcatheter valve of FIG. 20 implanted therein.

DETAILED DESCRIPTION OF THE DRAWINGS

[0051] While the concepts of the present disclosure are susceptible to various modifications and alternative forms, specific exemplary embodiments thereof have been illustrated by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the concepts of the present disclosure to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

[0052] Terms representing anatomical references, such as anterior, posterior, medial, lateral, superior, inferior, distal, proximal, etcetera, may be used throughout the specification in reference to the orthopaedic implants and surgical instruments described herein as well as in reference to the patient's natural anatomy. Such terms have well-understood meanings in both the study of anatomy and the field of orthopaedics. Use of such anatomical reference terms in the written description and claims is intended to be consistent with their well-understood meanings unless noted otherwise. For example, the term "proximal" refers to the direction that is generally closest to the heart, and the term "distal" refers to the direction that is generally furthest from the heart.

[0053] Referring to FIGS. 2-16, exemplary designs of an endovascular prosthetic device or endograft device 10 (hereinafter device 10) are shown. The device 10 is intended for the treatment of most ascending aortic aneurysms and is configured to treat any type of ascending aneurysm regardless of involvement of the aortic valve and the sinuses of Valsalva. As described in greater detail below, the device 10 permits future coronary and aortic valve interventions as well

as extension of a fenestrated/ branch graft into the aortic arch. Part of the device 10 may also be modified and used as a transcatheter valve, as described in greater detail below in regard to FIGS. 17-22. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

[0054] Referring now to FIGS. 2-7, the device 10 includes a proximal component 12 that is attached to a distal component 14. As shown in FIG. 2, the distal component 14 may be secured to the proximal component 12 when implanted into a patient's aorta 16. When implanted, the proximal component 12 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16. The distal component 14 includes a pair of "Endo-cabrol conduits" or conduits 22, and each conduit 22 is sized to receive a catheter or stent 24 for coronary blood flow, as described in greater detail below. The device 10 is configured to treat all ascending aneurysms with or without dilated sinutubular junctions and aortic valve disease.

[0055] As shown in FIG. 3, the proximal component 12 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 26 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 12. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 12 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 12.

[0056] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 3, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the component 12 and has a length 40 of approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter depending on, for example, the patient's anatomy. The stent 38 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester or other nonporous materials.

[0057] As shown in FIG. 3, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. Examples of balloon-expandable stents are described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz and U.S. Patent No. 6,582,462 entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis" by Henning Rud Andersen et al., which are expressly incorporated herein by reference. In the illustrative embodiment, the diameter 46 is oversized

relative to the diameter of the aortic annulus 210 (see FIG. 1) such that an interference fit is created between the stent 38 and the annulus 210 when the component 12 is implanted and the stent 38 is expanded, as described in greater detail below.

[0058] The balloon-expandable frame 34 is attached to a self-expanding frame 50. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 50 by stitching or sewing the frames 34, 50 together, thereby forming the frame 26 of the component 12. It should be appreciated that in other embodiments the frames 34, 50 may be secured together via welding or other fasteners. The frames 34, 50 may also be formed as a single, monolithic frame.

[0059] As shown in FIG. 3, the self-expanding frame 50 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 50 may be formed from a polymeric material. The frame 50 includes an inwardly tapered proximal section 60, an outwardly tapered middle section 62, and an elongated distal section 64. The section 60 includes the proximal end 54 of the frame 50 and has a distal end 66 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 60 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 60 has a length 70 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 60 may vary depending on, for example, the patient's anatomy.

[0060] The outwardly tapered middle section 62 of the self-expanding frame 50 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end

68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy. Among other things, the tapered sections 60, 62 of the proximal component 12 permit the placement of the stents 24 that extend from the distal component 14 to the coronary arteries, as described in greater detail below.

[0061] The elongated distal section 64 of the self-expanding frame 50 extends distally from the proximal end 74 to the distal end 30 of the component 12. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 25 mm and has a diameter 80 of approximately 28 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[0062] As shown in FIG. 3, the proximal section 60 of the self-expanding frame 50 is formed in an open-cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 60, 62, 64 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 60, 62, 64 may also be formed as a single monolithic component. The outer surface 82 of the self-expanding frame 50 is covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 82. In that way, the entire outer surface of the component 12 is covered to prevent fluid from passing therethrough. The covering material 84 immediately distal to the balloon-expandable frame 34 is equipped with a "trap door" 86, which may be opened to permit the passage of one or

more surgical instruments for embolization of possible paravalvular leaks. The entire outer surface of component 12 may be also covered with low-profile Dacron or other synthetic material. It should also be appreciated that all or part of the component 12 may be covered with hydrogel or other sealing material.

[0063] As described above, the device 10 also includes a distal component 14, which is secured to the distal end 30 of the proximal component 12 when the device 10 is implanted in the patient's aorta 16. Referring now to FIG. 4, the distal component 14 includes a frame 100 that extends from a proximal end 102 configured to be secured to the proximal component 12 to a distal end 104. The frame 100 has a passageway 106 defined therein, which extends through the ends 102, 104 of the component 14. The passageway 106 has a diameter 108 and is sized to receive the distal end 30 of the proximal component 12 when the device 10 is assembled.

[0064] In the illustrative embodiment, the components 12, 14 are secured together via an interference fit between the frame 100 and the distal end 30 of the proximal component 12. Specifically, the diameter 108 of the passageway 106 is less than the diameter 80 of the proximal component 12. In the illustrative embodiment, the diameter 108 is equal to approximately 26 mm. It should be appreciated that in other embodiments the components 12, 14 may be secured together via stitching or other fastening means.

[0065] As shown in FIG. 4, the component 14 includes a proximal frame 110 that is connected to an elongated distal frame 112. The proximal frame 110 and the distal frame 112 are formed from metallic materials, such as, nitinol, stainless steel, or other implant grade metallic materials. It should be appreciated that in other embodiments the frames 110, 112 may be formed from a polymeric material. The proximal frame 110 is formed in a Z-stent configuration, and the distal frame 112 is formed in an open-cell configuration. Each of the frames 110, 112 is self-

expanding. In the illustrative embodiment, the distal frame 112 is secured to the distal end 114 of the proximal frame 110 by stitching or sewing the frames 110, 112 together. It should be appreciated that in other embodiments the frames 110, 112 may be secured together via welding or other fasteners. The frames 110, 112 may also be formed as a single, monolithic frame.

[0066] The proximal frame 110 has an outer surface 120 that is covered with low profile polyester, ePTFE, or other nonporous covering material 122. As a result, fluid is prevented from passing through the surface 120. The distal frame 112 is uncovered such that fluid is permitted to pass through the openings 124 formed therein.

[0067] As shown in FIG. 4, the proximal frame 110 includes a proximal section 126, an outwardly tapered section 128 extending distally from the proximal section 126, and an elongated distal section 130. The proximal section 126 includes the proximal end 102 of the component 14 and has a distal end 132 connected to the proximal end 134 of the outwardly tapered section 128. In the illustrative embodiment, the proximal section 126 has a length 136 of approximately 25 mm. It should be appreciated that in other embodiments the dimensions of the section 126 may vary depending on, for example, the patient's anatomy.

[0068] The tapered section 128 of the frame 110 has the proximal end 134 and a distal end 140 connected to the proximal end 142 of the elongated distal section 130. The section 128 tapers outwardly from a diameter of approximately 26 mm at the end 132 to a diameter between approximately 44 mm and 48 mm at the end 140. In the illustrative embodiment, the tapered section 128 has a length 146 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 128 may vary depending on, for example, the patient's anatomy.

[0069] The elongated distal section 130 of the frame 110 extends distally from the proximal end 142 to the distal end 114 of the frame 110. In the illustrative embodiment, the section 130 has a length 150. In one particular non-limiting example, the length 150 of the elongated distal section 130 is approximately 20 mm. The section 130 also has a diameter 152 of between approximately 44 mm and 48 mm. In other embodiments, the dimensions of the section 130 may vary depending on, for example, the patient's anatomy.

[0070] As described above, the distal component 14 also includes a pair of conduits 22, which are connected to the proximal frame 110. Each conduit 22 has a distal end 160 secured to the tapered section 128 of the frame 110 and a proximal end 162 positioned adjacent to the proximal end 102 of the component 12. As shown in FIG. 4, the conduit 22 does not extend beyond the proximal end 102 of the component 12. Each conduit 22 has a passageway 164 that extends through the ends 160, 162 and is sized to receive a stent 24.

[0071] The passageway 164 has a proximal opening 166 defined in the end 162. The opening 166 has a diameter 168 that in the exemplary embodiment is equal to approximately 5 mm. As shown in FIG. 5, the passageway 164 has a distal opening 170 that is defined in the end 160 and the tapered section 128 of the frame 110. The distal opening 170 has a diameter 172 that is greater than the diameter 168. In the illustrative embodiment, the diameter 172 is equal to approximately 8 mm. The passageway 164 measures approximately 8 mm in diameter over a distance 174 of approximately 5 mm and tapers smoothly into the approximately 5 mm diameter 168 at a junction 176. The passageway 164 maintains the diameter 168 between the junction 176 and the proximal opening 166. In the illustrative embodiment, the passageway 164 has a length 180 of approximately 2 cm between the junction 176 and the proximal opening 166.

[0072] Each conduit 22 is wire reinforced and allows for passage of catheters or stents 24 and easier cannulation of the coronary ostia, regardless of deployment orientation. This configuration allows stenting of the coronary arteries 182 (see FIG. 1) prior to the deployment of component 12, as described in greater detail below. In the illustrative embodiment, the tapered section 128 permits the uncompromised passage of stents 24 into the coronary arteries 182 in such a way that the stents are not compressed between the sinutubular junction and the device 10 itself.

[0073] As shown in FIG. 4, the elongated distal frame 112 of the component 14 extends distally from the distal end 114 of the frame 110 to the distal end 104 of the component 14. In the illustrative embodiment, the frame 112 has a length 190. In one particular non-limiting example, the length 190 of the elongated frame 112 is approximately 10 cm, which is sufficient to cover the arch 20 of the aorta 18 when implanted therein. In other embodiments, the dimensions of the frame 112 may vary depending on, for example, the patient's anatomy. The distal frame 112 permits the accurate deployment of component 14 without compromising the circulation to supra-aortic branches. It also allows for cannulation of the supra-aortic branches, if placement of a fenestrated/ branch arch device is necessary.

[0074] To implant the device 10 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The iliac arteries or an iliac conduit may also be used. After obtaining access and placing a stiff wire in the ascending aorta 18, the device 10 and the delivery system are prepared. In the illustrative embodiment, the delivery system is composed of a 100-105 cm hydrophilic sheath. As shown in FIG. 6, the distal component 14 is delivered first. After performing a lateral oblique thoracic aortogram, the component 14 is deployed such that the distal end 114 of the proximal frame 110 is positioned proximal to the

innominate artery 200, thereby ensuring that the distal openings 170 of the conduits 22 are at 12 and 6 o'clock positions in relationship to the innominate artery 200.

[0075] Using the contralateral common femoral artery wires, standard coronary guide catheters are introduced through the distal frame 112 of the component 14 into each conduit 22. The conduits 22 may then be cannulated with the catheters prior to insertion of the stents 24. Alternatively, the conduits 22 may be pre-cannulated. Using the catheters, access is obtained to the right and left coronary arteries 182. The stents 24 are advanced into the passageways 164 through the distal openings 170 and out of the conduits 22 to bridge the arteries 182 and the conduits 22, as shown in FIG. 7. In that way, each artery 182 is connected to its respective conduit 22. Each stent 24 is covered and may be embodied as a balloon-expandable stent or a self-expanding stent. It should be appreciated that coronary artery bypasses may be performed to the right and left coronary systems prior to the placement of the component 14.

[0076] The proximal component 12 may be deployed after the implantation of the distal component 14. The components 12, 14 may be deployed in a single surgical procedure taking place on a single day or the component 14 may be deployed in one procedure, and the component 12 may be deployed in another, separate procedure at a later date. As shown in FIG. 1, the proximal component 12 is deployed into the position across the native aortic valve 202.

[0077] To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 12 is passed through the valve 202. An example of a delivery system is described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz, which is incorporated herein by reference. When the delivery system is in position, the proximal component 12 is released by unsheathing the system, thereby permitting

expansion of the self-expanding frame 50. As described above, the self-expanding frame 50 engages the proximal end 102 of the distal component 14 to secure the components 12, 14 together and seal the distal end 30 of the component 12 within the distal component 14. As shown in FIG. 2, the proximal end 28 of the proximal component 12 is positioned in the aortic annulus, and the hour-glass shape of the component 12 provides a space for the native aortic valve leaflets such that the leaflets are not pressed against or over the openings of coronary arteries 182.

[0078] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only through the valve 32. As shown FIG. 1, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 12 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve 32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 12.

[0079] Referring now to FIGS. 8-16, another embodiment of a proximal component 212 of the device 10 is shown. Some features of the embodiment illustrated in FIGS. 8-16 are substantially similar to those described above in reference to the embodiment of FIGS. 1-7. Such features are designated in FIGS. 8-16 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the proximal component 212 may be secured to the distal component 14 when implanted into a patient's aorta 16. When implanted, the proximal component 212 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16.

[0080] As shown in FIG. 8, the proximal component 212 includes a dual-frame 214 that extends from a proximal end 28 to a distal end 30. The frame 214 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 212. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 212 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 212.

[0081] The dual-frame 214 of the proximal component 212 includes a self-expanding outer frame 216 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 216 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 216 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 216 may be formed from a polymeric material. The outer frame 216 includes an elongated proximal section 220, an inwardly tapered section 222, an outwardly tapered middle section 62, and an elongated distal section 64.

[0082] The elongated proximal section 220 of the outer frame 216 includes the proximal end 28 of the component 212 and has a distal end 224 connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[0083] In the illustrative embodiment, the proximal section 220 has a length 228 that is equal to approximately 15 mm. The proximal section 220 also has a diameter 230 of approximately 32 mm. It should be appreciated that in other embodiments the dimensions of the frame 216 may vary according to the anatomy of the patient. In the illustrative embodiment, the diameter 230 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the component 212 is implanted, as described in greater detail below. As shown in FIG. 9, the proximal section 220 defines a passageway 232 in the outer frame 216.

[0084] In the illustrative embodiment, collagen fibers 234 are attached to the proximal section 220 to aid in preventing paravalvular leaks and migration of the proximal component 212 within the aortic walls. The fibers 234 extend outwardly from the proximal section 220 and inwardly into the passageway 232. It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section 220. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[0085] The inwardly tapered section 222 of the outer frame 216 includes the proximal end 226 and has a distal end 236 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 222 tapers inwardly between the ends 226, 236 from approximately 32 mm at the end 226 to approximately 22 mm at the end 236. In the illustrative embodiment, the inwardly tapered section 222 has a length 238 of approximately 10 mm.

[0086] The outwardly tapered middle section 62 of the self-expanding frame 216 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal

section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[0087] The elongated distal section 64 of the self-expanding frame 216 extends distally from the proximal end 74 to the distal end 30 of the component 212. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[0088] As shown in FIG. 9, the proximal section 220 and the inwardly tapered section 222 of the self-expanding frame 216 are formed in an open-cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 62, 64, 220, 222 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 62, 64, 220, 222 may also be formed as a single monolithic component. The outer surface 240 of the sections 62, 64, 222 are covered with low profile polyester, ePTFE, or other nonporous covering material 242 such that fluid is prevented from passing through the surface 240. The covering material 242 immediately distal to the proximal section 220 is equipped with a "trap door" 86, which may be opened to permit the passage of one or more surgical instruments for embolization of possible paravalvular leaks. The outer surface 240 of the sections 62, 64, 222 may be also covered with low-profile Dacron or other

synthetic material. It should also be appreciated that all or part of the frame 216 may be covered with hydrogel or other sealing material.

[0089] As described above, the outer frame 216 of the dual-frame 214 is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232. As shown in FIG. 10, the frame 218 houses the valve 32. The balloon-expandable frame 218 is embodied as a balloon-expandable tubular stent 244 that has a length 246 of approximately 15 mm. In other embodiments, the stent 244 may be longer or shorter depending on, for example, the patient's anatomy. The stent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 244 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 248 of the stent 244 is covered with low-profile polyester, ePTFE, or other nonporous covering material 250 that prevents fluid from passing through the outer surface 248. However, it should be appreciated that the stent 244 may be covered with standard polyester, ePTFE or other nonporous materials.

[0090] As shown in FIG. 10, the stent 244 of the inner frame 218 has a diameter 252. As described in greater detail below, the balloon-expandable frame 218 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 252. In the illustrative embodiment, the expanded diameter 252 is equal to approximately 26 mm when the inner frame 218 is expanded. In other embodiments, the expanded diameter may be equal to, or greater than, the diameter 230 of the proximal section 220 of the outer frame 216. In the illustrative embodiment, the expanded diameter 252 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210

when the component 212 is implanted, and the inner frame 218 is expanded, as described in greater detail below.

[0091] Referring now to FIG. 11, the inner frame 218 of the dual-frame component 214 is secured to the outer frame 216 via a plurality of stitches 260. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame 218 to the outer frame 216. As shown in FIGS. 11-14, the inner frame 218 and the valve component 32 are positioned in the passageway 232 defined in the self-expanding frame 216. When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216. In the illustrative embodiment, a gap 264 is defined therebetween, and the gap 264 has a magnitude of about 2 mm to about 3 mm.

[0092] As shown in FIG. 14, the balloon-expandable inner frame 218 may be expanded in the direction indicated by arrows 266. As described above, the diameter 230 of the proximal section 220 of the outer frame 216 is oversized relative to the diameter of the aortic annulus 210. As such, when the component 212 is implanted, the proximal section 220 is reduced to the diameter of the annulus 210. Because the expanded diameter 252 of the stent 244 is greater than the diameter of the annulus, the outer surface 248 of the stent 244 engages the fibers 234 (and hence the inner surface of the proximal section 220 of the outer frame 216) through the covering material 250. In that way, the gap 264 is closed, and the fibers 234 and the covering material 250 create a seal between the inner frame 218 and the outer frame 216.

[0093] To implant an endograft device 10 that includes proximal component 212 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The surgeon may then implant the distal component 14 in the manner described above in regard to FIGS. 1-7 and advance the stents 24 into position in the arteries 182. The

proximal component 212 may be deployed after the implantation of the distal component 14. To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 212 is then passed through the valve 202.

[0094] When the delivery system is in position, the proximal component 212 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 216. The self-expanding frame 216 engages the proximal end 102 of the distal component 14 to secure the components 212, 14 together and seal the distal end 30 of the component 212 within the distal component 14.

[0095] When the frame 216 is unsheathed, the proximal section 220 expands into engagement with the aortic annulus 210, thereby creating an interference fit between the frame 216 and the annulus 210 and stabilizing the device 10 in place. As shown in FIG. 15, the inner frame 218 is initially unexpanded within the outer frame 216. The inner frame 218 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 216 and compresses the collagen fiber/hydrogel coated proximal section 220 of the outer frame 216 against the aortic annulus 210. As shown in FIG. 16, the combined engagement of the frames 216, 218 seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 212. As shown FIGS. 15-16, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 212 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve 32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 212.

[0096] In each of the embodiments described above, the self-expanding frame portion of proximal components 12, 212 significantly improves the accuracy and control of the deployment of the device 10. The bicuspid configuration of the valve 32 serves three distinct purposes, including (1) by reducing the number of valve commissures to two, the profile will be reduced, (2) the valve 32 may conform better to the aortic annulus, and (3) when the annulus is asymmetrical, the incidence of aortic insufficiency may be reduced.

[0097] Referring now to FIGS. 17-22, the proximal component 12 or the proximal component 212 may be used as a transcatheter valve with slight modification. Such a valve may be deployed via a transfemoral or trans-axillary route, as will be described in further detail below.

[0098] Referring now to FIGS. 17-19, one embodiment of a transcatheter valve component 312 is shown. Some features of the embodiment illustrated in FIGS. 17-19 are substantially similar to those described above in reference to the proximal component 12 of FIGS. 1-7. Such features are designated in FIGS. 17-19 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the transcatheter valve component 312 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 326 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the valve component 312. When the valve component 312 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 312.

[0099] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 17, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the transcatheter valve component 312 and has a length 40 of approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter

depending on, for example, the patient's anatomy. The stent 38 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester, ePTFE or other nonporous materials.

[00100] As shown in FIG. 17, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. In the illustrative embodiment, the diameter 46 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the stent 38 and the annulus 210 when the transcatheter valve component 312 is implanted.

[00101] The balloon-expandable frame 34 is attached to a self-expanding frame 350. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 350 by stitching or sewing the frames 34, 350 together, thereby forming the frame 26 of the transcatheter valve component 312. It should be appreciated that in other embodiments the frames 34, 350 may be secured together via welding or other fasteners. The frames 34, 350 may also be formed as a single, monolithic frame.

[00102] As shown in FIG. 17, the self-expanding frame 350 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 350 may be formed from a polymeric material. The frame 350 includes an inwardly tapered proximal section 360, an outwardly tapered middle section 62, and an elongated distal section 64. The section 360 includes the proximal end 54 of the frame 350 and has a distal end 66 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 360 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 360 has a length 70 of approximately 15 mm.

[00103] The outwardly tapered middle section 62 of the self-expanding frame 350 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[00104] The elongated distal section 64 of the self-expanding frame 350 extends distally from the proximal end 74 to the distal end 30 of the valve component 312. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[00105] As shown in FIG. 3, the proximal section 360 of the self-expanding frame 350 is formed in an open-cell stent configuration, and each of the sections 62, 64 is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 360, 62, 64 may be formed in a single configuration, including the open-cell stent configuration, mesh-like stent configuration, or Z-stent configuration. The sections 60, 62, 64 may also be formed as a single monolithic component.

[00106] As shown in FIG. 17, the outer surface 314 of the proximal section 360 of the frame 350 is uncovered such that fluid is permitted to pass through the openings 318. The outer surface 316 of the sections 62, 64 are covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 320. The outer surface 320 of the valve component 312 may also be covered with low-profile Dacron or other synthetic material. The uncovered, open cell stent section 360 is configured to allow for coronary artery perfusion. The covered sections 62, 64 serve to stabilize the valve component 312 against the aorta 18 and provide a docking station to ascending aortic extensions or fenestrated/ branch arch grafts. The covered sections 62, 64 would also permit endograft extension of the valve component 312 for suitable type B aneurysms without dilation of the sinutubular junction.

[00107] The delivery of the transcatheter valve component 312 may begin by gaining access to the left ventricle across the native aortic valve. An ascending aortogram may be performed to locate the right and left coronary arteries. An over the wire introducer system, including a guidewire, is used to introduce the valve component 312 into the aorta 18. After the guidewire has been placed into the left ventricle 204 via the iliofemoral, subclavian, or carotid vessels, the valve component 312 may be delivered through the common femoral artery and passed across the native aortic valve 202. After performing an angiogram to delineate the location of the coronary arteries

182, the valve component 312 is released by unsheathing the delivery system, thereby permitting expansion of the self-expanding frame 350, as shown in FIGS. 18-19.

[00108] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only through the valve 32 and the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182, as shown in FIGS. 18-19. The openings 318 of the uncovered section 360 of the valve component 312 permit blood flow to the coronary arteries 182 for promote circulation. It should be appreciated that the deployment of the valve component 312 may be performed during rapid ventricular pacing (RVP).

[00109] Referring now to FIGS. 20-22, another embodiment of a transcatheter valve component (hereinafter valve component 412) is shown. Some features of the embodiment illustrated in FIGS. 20-22 are substantially similar to those described above in reference to the proximal component 212 of FIGS. 8-16. Such features are designated in FIGS. 20-22 with the same reference numbers as those used in FIGS. 8-16. Similar to the proximal component 212 of FIGS. 8-16, the valve component 412 includes a dual-frame 414 that extends from a proximal end 28 to a distal end 30. The frame 414 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 412. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. When the valve component 412 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 412.

[00110] The dual-frame 414 includes a self-expanding outer frame 416 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 416 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 416 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 416 may be formed from a polymeric material. The outer frame 416 includes an elongated proximal section 220, an inwardly tapered section 422, an outwardly tapered middle section 62, and an elongated distal section 64.

[00111] The elongated proximal section 220 of the outer frame 416 includes the proximal end 28 of the component 412 and has a distal end 224 connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[00112] In the illustrative embodiment, the proximal section 220 has a length 228 that is equal to approximately 15 mm. The proximal section 220 also has a diameter 230 of approximately 32 mm. It should be appreciated that in other embodiments the dimensions of the frame 416 may vary according to the anatomy of the patient. In the illustrative embodiment, the diameter 230 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the valve component 412 is implanted, as described in greater detail below. As shown in FIG. 9, the proximal section 220 defines a passageway 232 in the outer frame 416.

[00113] In the illustrative embodiment, collagen fibers 234 are attached to the proximal section 220 to aid in preventing paravalvular leaks and migration of the valve component 412

within the aortic walls. The fibers 234 extend outwardly from the proximal section 220 and inwardly into the passageway 232. It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section 220. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[00114] The inwardly tapered section 422 of the outer frame 416 includes the proximal end 226 and a distal end 236 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 422 tapers inwardly between the ends 226, 236 from approximately 32 mm at the end 226 to approximately 22 mm at the end 236. In the illustrative embodiment, the inwardly tapered section 422 has a length 238 of approximately 10 mm.

[00115] The outwardly tapered middle section 62 of the self-expanding frame 416 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[00116] The elongated distal section 64 of the self-expanding frame 416 extends distally from the proximal end 74 to the distal end 30 of the component 412. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one

exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[00117] As shown in FIG. 20, each of the proximal section 220 and the inwardly tapered section 422 of the self-expanding frame 416 is formed in an open-cell stent configuration, and each of the sections 62, 64 is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 62, 64, 220, 422 may be formed in a single configuration, including the open-cell stent configuration, mesh-like stent configuration, or Z-stent configuration. The sections 62, 64, 220, 422 may also be formed as a single monolithic component. The outer surfaces 440 of the sections 62, 64 are covered with low profile polyester, ePTFE, or other nonporous covering material 442 such that fluid is prevented from passing through the surface 440. The outer surface 444 of the section 422 is uncovered such that fluid is permitted to pass through openings 446 defined in the surface 444. The uncovered, open cell section 422 is configured to allow for coronary artery perfusion. The covered sections 62, 64 serve to stabilize the valve component 412 against the aorta 18 and provide a docking station to ascending aortic extensions or fenestrated/ branch arch grafts.

[00118] As described above, the outer frame 416 of the dual-frame 414 is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232 and houses the valve 32. As described above, the balloon-expandable frame 218 is expandable during implantation from an unexpanded diameter 450 to the expanded diameter (not shown).

[00119] To deploy the valve component 412, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the valve component 412 is then passed through the valve 202. When the delivery system is in position, the valve component 412 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 416.

The proximal section 220 of the frame 416 expands into engagement with the aortic annulus 210, thereby creating an interference fit between the frame 416 and the annulus 210 and stabilizing the valve component 412 in place. As shown in FIG. 21, the inner frame 218 is initially unexpanded within the outer frame 416. The inner frame 218 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 416 and compresses the collagen fiber/hydrogel coated proximal section 220 of the outer frame 416 against the aortic annulus 210.

[00120] As shown in FIG. 22, the combined engagement of the frames 218, 416 seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 412. The openings 446 of the uncovered section 422 of the valve component 412 permit blood flow to the coronary arteries 182 for promote circulation.

[00121] It should be appreciated that the design of components 12, 14, 212 and the transcatheter valves 312, 412 has intentionally taken into account the potential failure modes and allows for correction of any such failure modes. For example, with respect to components 12, 14, 212, paravalvular leaks may be corrected. More specifically, with respect to a paravalvular leak (type Ia endoleak), leakage around the valve 32 would act as a type la endoleak. The trapdoors 86 in components 12, 312 would allow for coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries 182 are protected by the conduits 22 in the distal component 14, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

[00122] Aortic insufficiency (Al) after implantation may also be corrected. Significant Al has been documented in up to 17% of patients after transcatheter valve implantation. Except heavy annular calcification, the tricuspid morphology of the current valves and the ovoid shape of the aortic annulus can cause malcoaptation of the valve leaflets causing Al. The bicuspid valve nature of the designs discussed herein potentially eliminates the problem with malcoaptation and AI secondary to that.

[00123] Structural valve degeneration may also be corrected. More specifically, the bicuspid valve design allows for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00124] Coronary insufficiency may also be corrected. The Cabrol endo-conduits 22 in conjunction with the tapered section 128 of component 14 ensure uninterrupted coronary blood flow. By first deploying the component 14, the surgeon will be able to work through the Cabrol conduits 22 and using standard catheters and guidewires to cannulate the right and left coronary arteries. Stents 24 are deployed from the coronary arteries into the Cabrol conduits 22. Deployment the component 12 or component 212 may be delayed until coronary blood flow is secured. The tapered design will mitigate the risk of compression of the coronary stents between the device 10 and the aortic wall.

[00125] For the transcatheter valves 312, 412, paravalvular leaks may also be corrected in that the open cell midsections 360, 422 of the valve allow the cannulation and stenting of the coronary arteries with potential coil embolization of the leak after the protection of the coronary artery if necessary.

[00126] Structural valve degeneration in the transcatheter valves 312, 412 may be corrected in that the bicuspid valve design permit for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00127] The dual frame component may also take the form of other transcatheter valvular replacement devices such as, for example, prosthetic mitral and tricuspid valves. The dual frame component may also be used to enhance sealing zones of endovascular devices to treat abdominal and thoracic aneurysms, and in applications to treat peripheral vascular disease.

[00128] It will be appreciated that the devices and methods described herein have broad applications. The foregoing embodiments were chosen and described in order to illustrate principles of the methods and apparatuses as well as some practical applications. The preceding description enables others skilled in the art to utilize methods and apparatuses in various embodiments and with various modifications as are suited to the particular use contemplated. In accordance with the provisions of the patent statutes, the principles and modes of operation of this disclosure have been explained and illustrated in exemplary embodiments.

[00129] It is intended that the scope of the present methods and apparatuses be defined by the following claims. However, it must be understood that this disclosure may be practiced otherwise than is specifically explained and illustrated without departing from its spirit or scope. It should be understood by those skilled in the art that various alternatives to the embodiments described herein may be employed in practicing the claims without departing from the spirit and scope as defined in the following claims.

[00130] The scope of the disclosure should be determined, not with reference to the above description, but should instead be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. It is anticipated and intended that

future developments will occur in the arts discussed herein, and that the disclosed systems and methods will be incorporated into such future examples. Furthermore, all terms used in the claims are intended to be given their broadest reasonable constructions and their ordinary meanings as understood by those skilled in the art unless an explicit indication to the contrary is made herein. In particular, use of the singular articles such as "a," "the," "said," etc. should be read to recite one or more of the indicated elements unless a claim recites an explicit limitation to the contrary. It is intended that the following claims define the scope of the disclosure and that the method and apparatus within the scope of these claims and their equivalents be covered thereby. In sum, it should be understood that the disclosure is capable of modification and variation and is limited only by the following claims.

POWER OF ATTORNEY FOR PATENT APPLICATIONS

Under 37 CFR § 3.73(b) and/or (c), Aortic Innovations, LLC, hereby certifies that it is the Assignee of the entire right, title, and interest in and to the patent applications listed below. Each of the patent applications listed below is assigned to Aortic Innovations, LLC. As required by 37 CFR § 3.73(b)(1)(i) and/or (c)(1)(i), the documentary evidence of the chain of title from the original owner to the Assignee was submitted for recordation pursuant to 37 § CFR 3.11 as shown in the Reel/Frame numbers listed below.

Title	Serial No.	Filing Date	Assignment	Date
Transcathetor Arotic Valve for Endovascular Aortic Repair	61/723,446	11/7/2012	029574/0731	1/7/2013
Transcathetor Aortic Valve for Endovascular Aortic Repair	61/567,458	12/6/2011	029005/0233	9/19/2012
Branched Aortic Graft and Method of Using the Same	61/777,918	3/12/2013	030346/0253	5/3/2013
Device for Endovascular Aortic Repair and Method of Using the Same	13/706,896	12/6/2012	032145/0000	2/5/2014
Device for Endovascular Aortic Repair and Method of Using the Same	US2012/068165	12/6/2012	029574/0887	1/7/2013
Transcatheral Mitral Valve and Delivery System	61/780,242	3/13/2013	030346/0233	5/3/2013
Device for Transcatheter Mitral Valve Repair and Replacement	61/817,118	4/29/2013	032145/0000	2/5/2014

The undersigned, acting as the Assignee, hereby revokes all prior powers of attorney, if applicable, and appoints the practitioners associated with the customer number 175373 as my/our attorney(s) or agent(s) to prosecute the patent(s) and/or patent application(s) and transact all business in the United States Patent and Trademark Office connected therewith.

By: Ali Shahriari Date: 1/15/2021

Ali Shahriari, Owner

Aortic Innovations, LLC

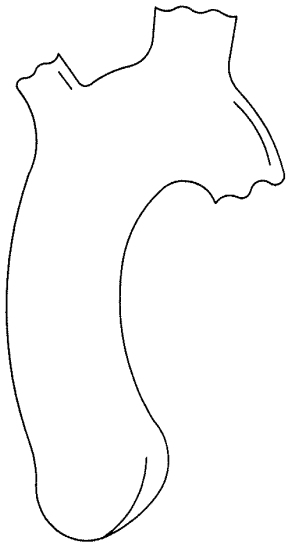


Fig. 1

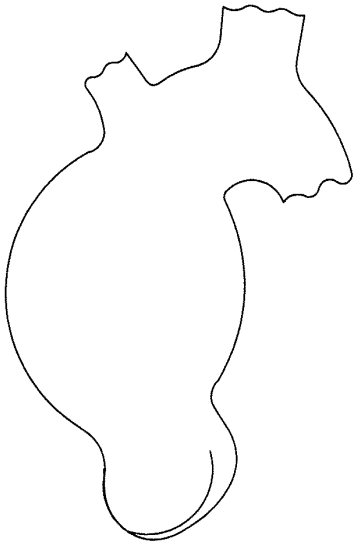


Fig. 1B

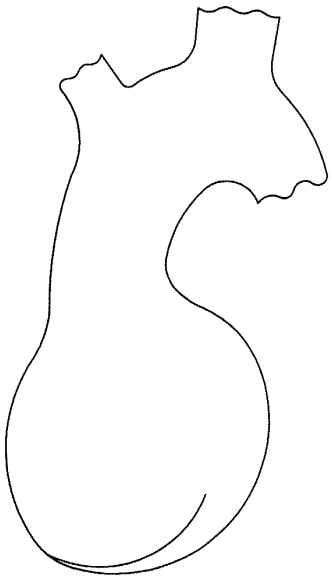


Fig. 1A



Fig. 1C

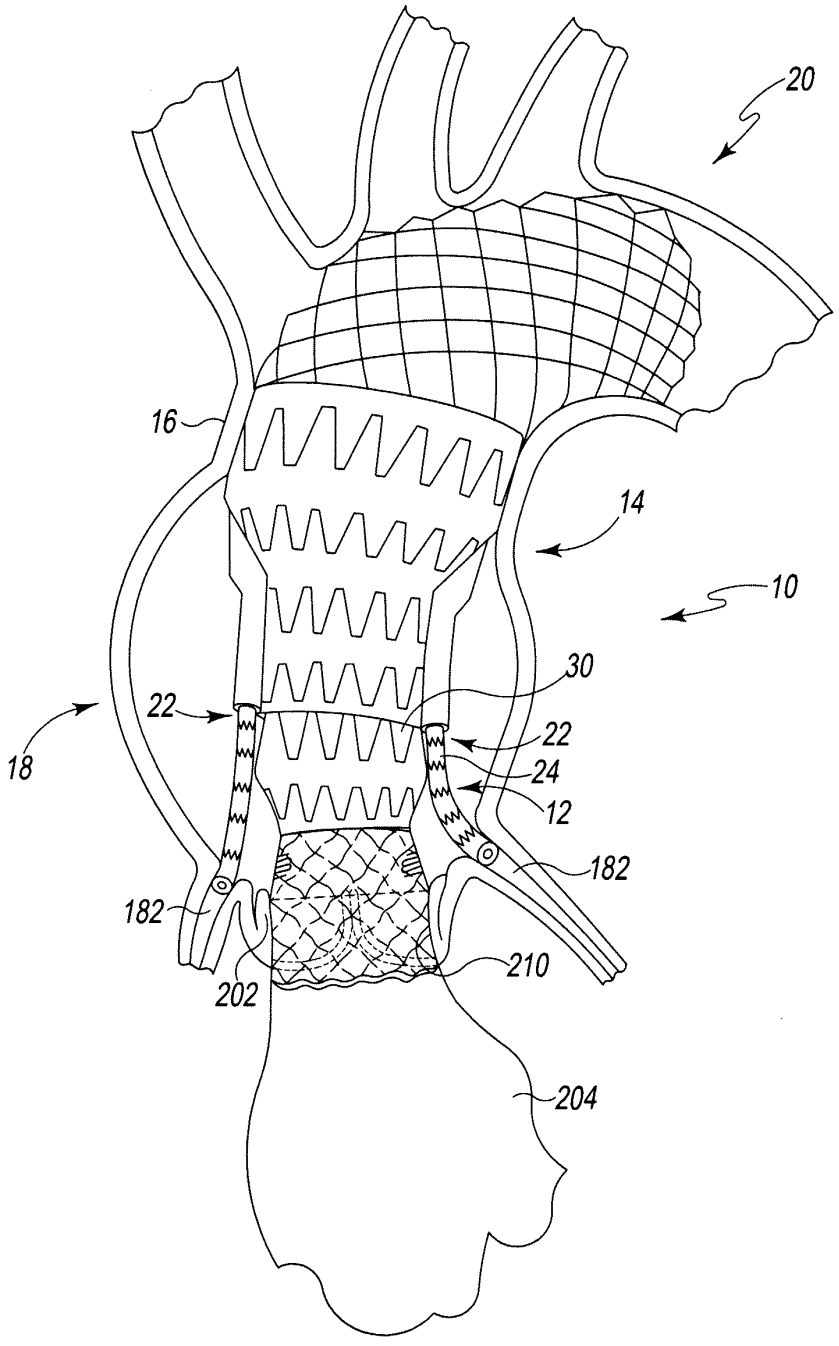


Fig. 2

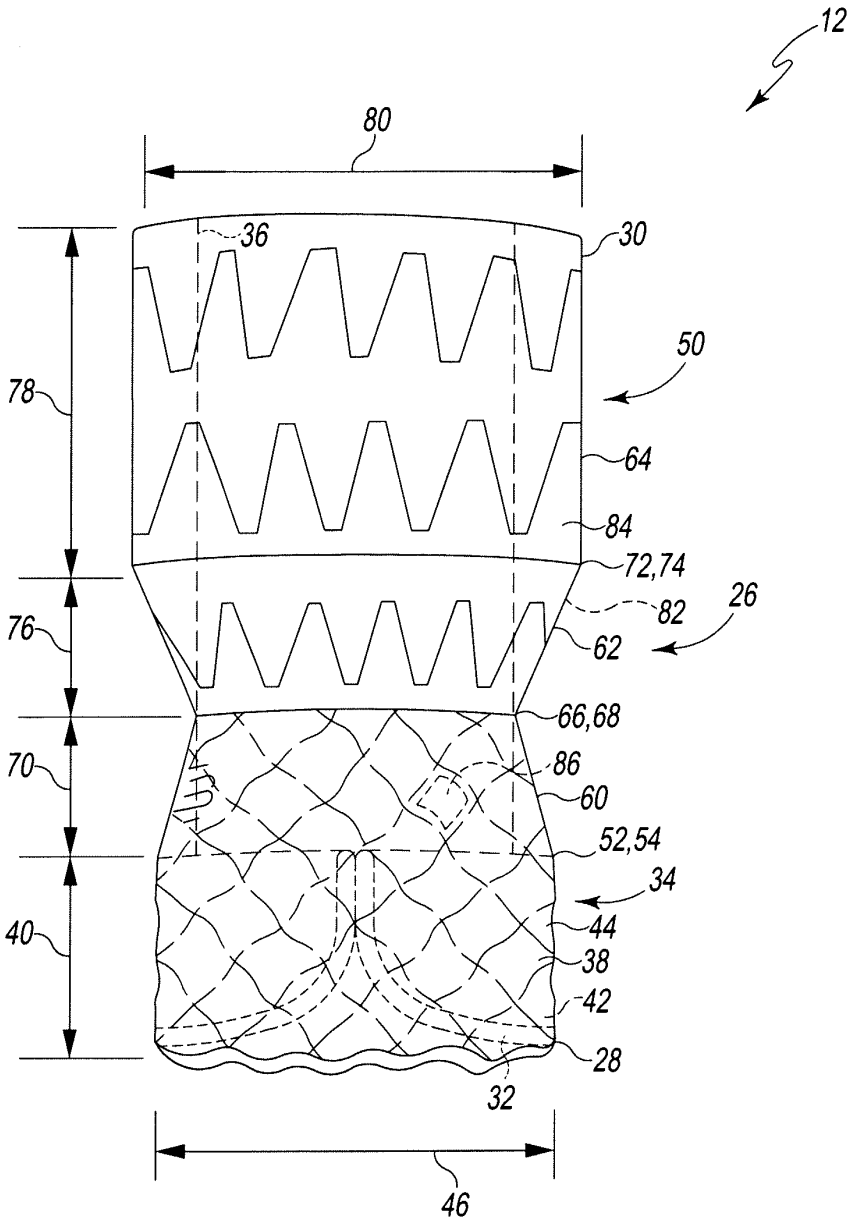

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Fig. 3

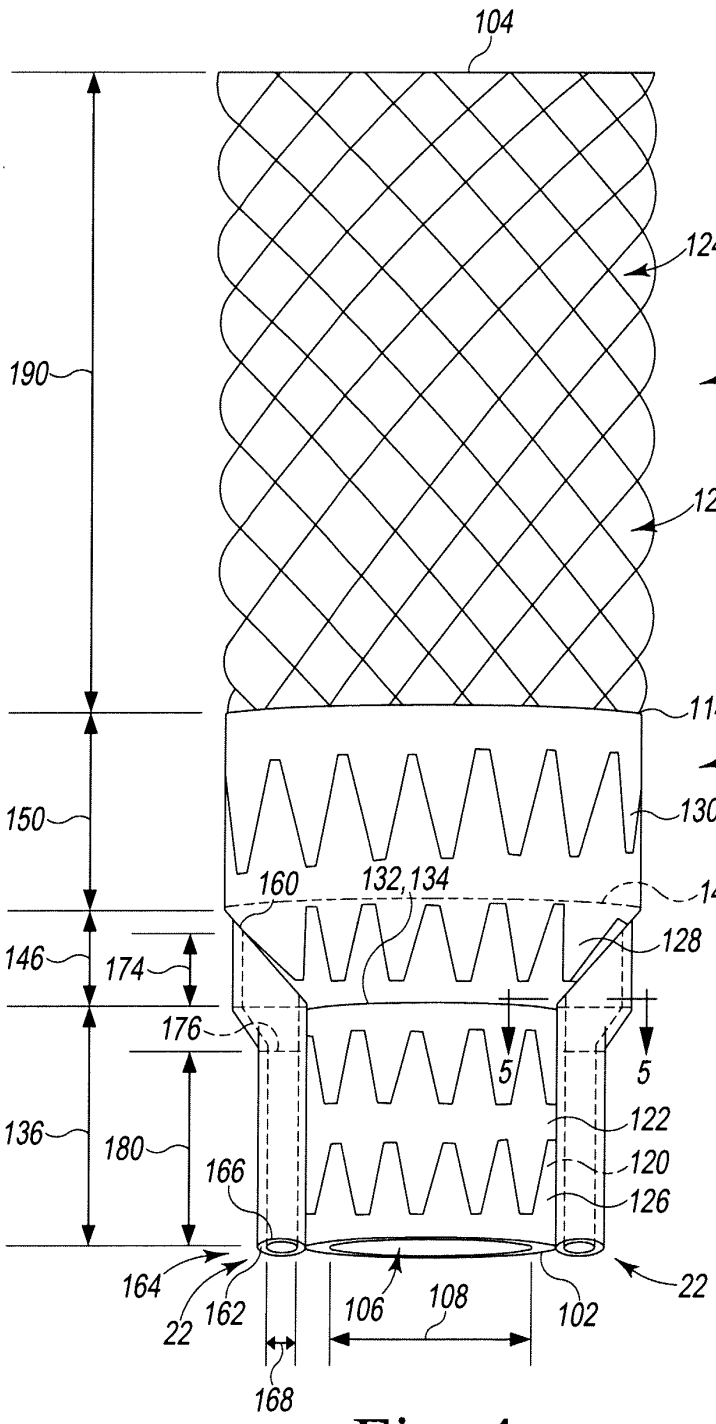

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Fig. 4

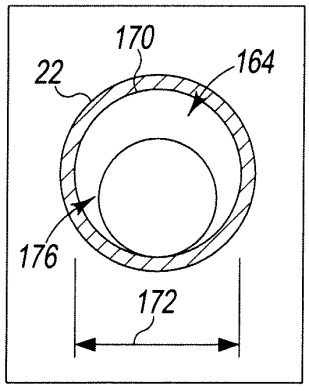

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Fig. 5

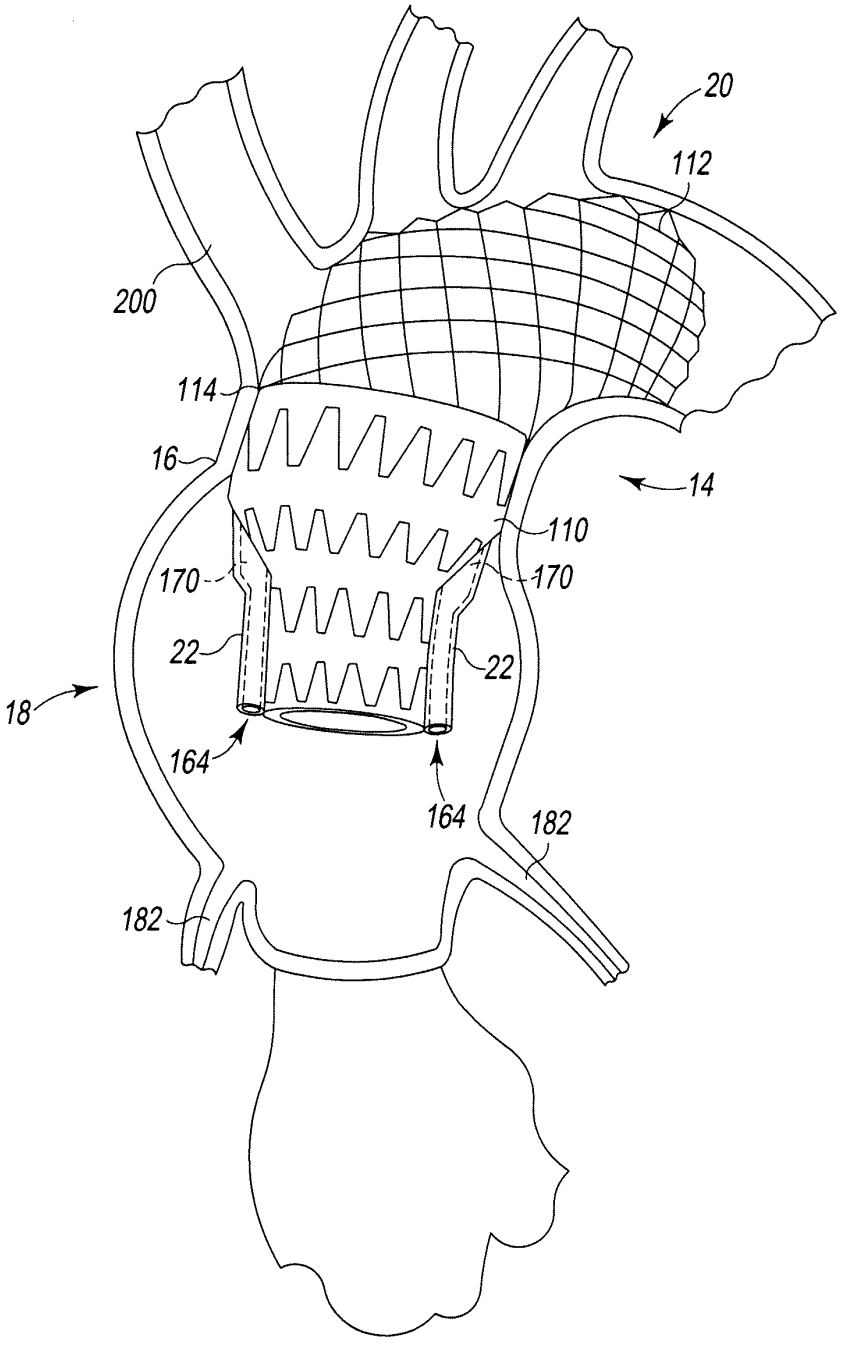


Fig. 6

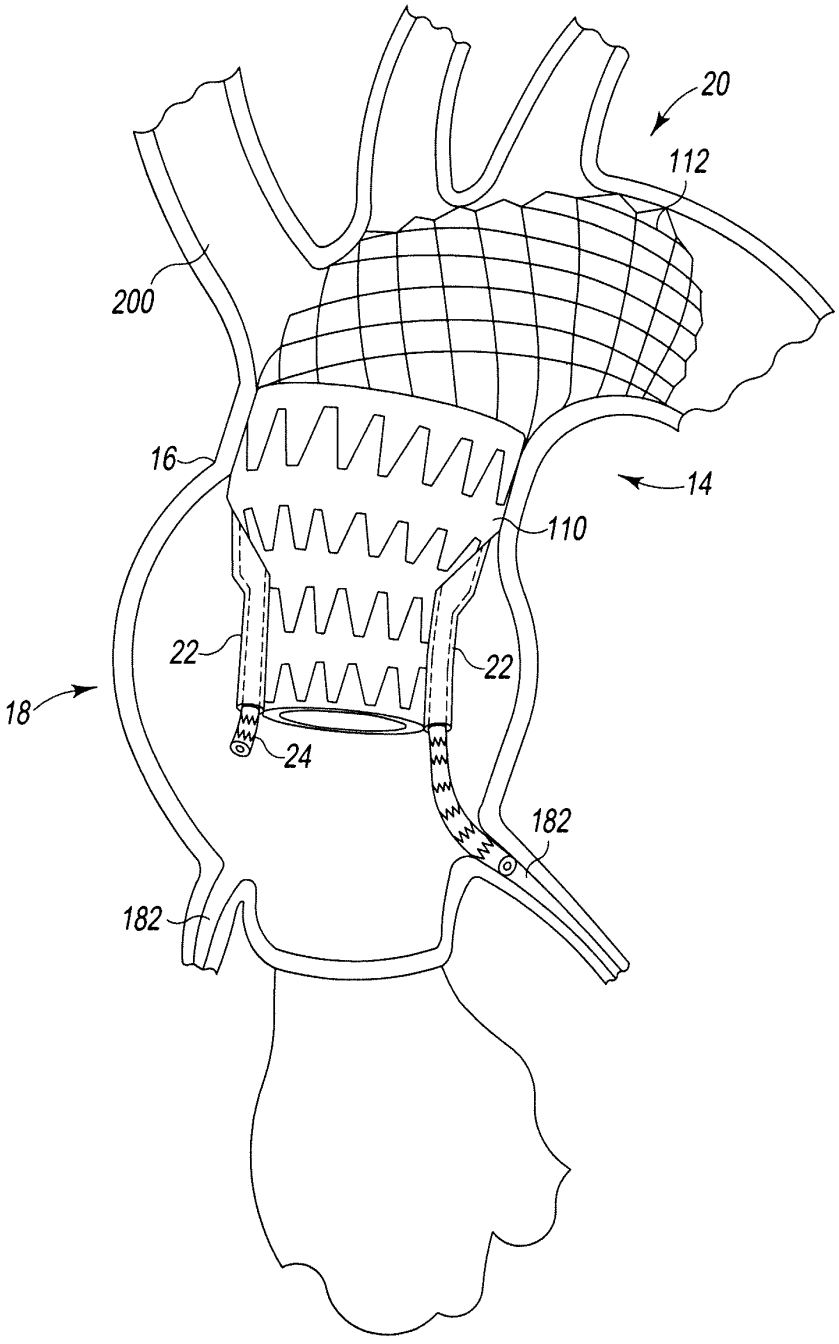


Fig. 7

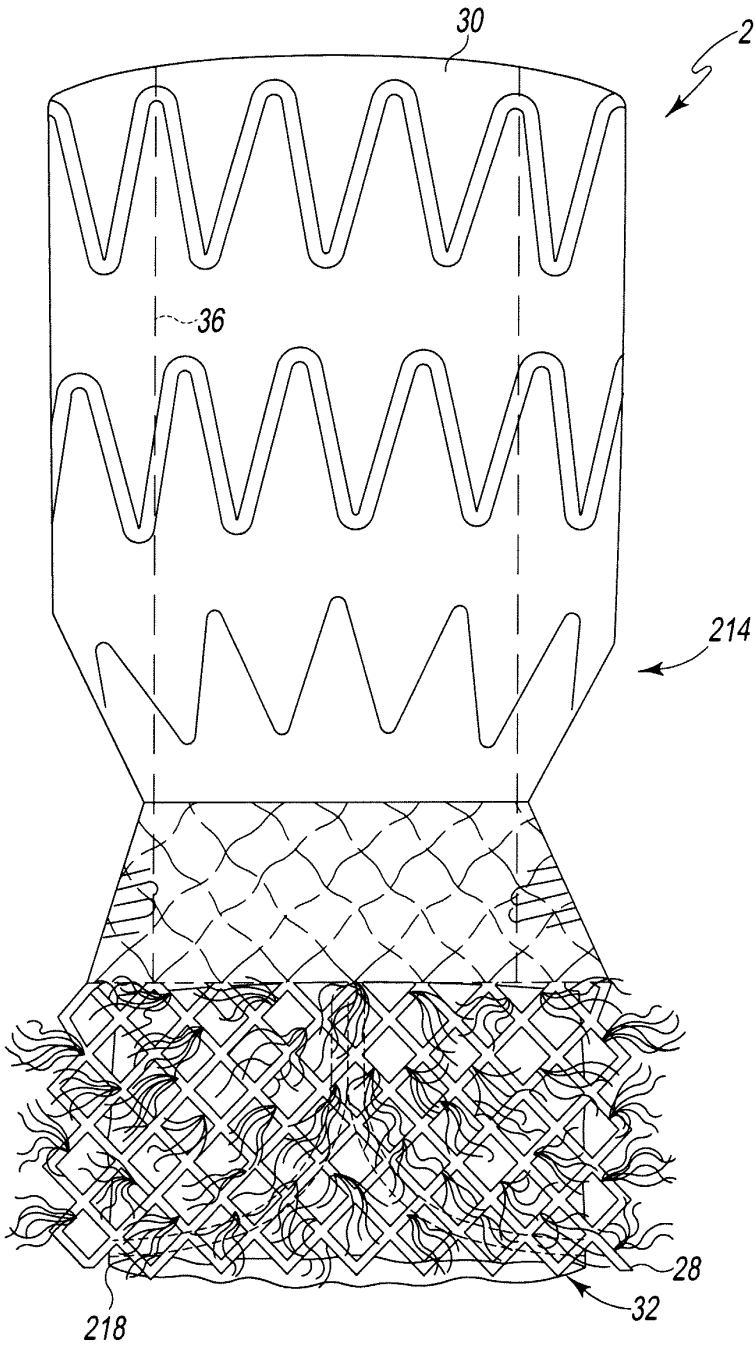


Fig. 8

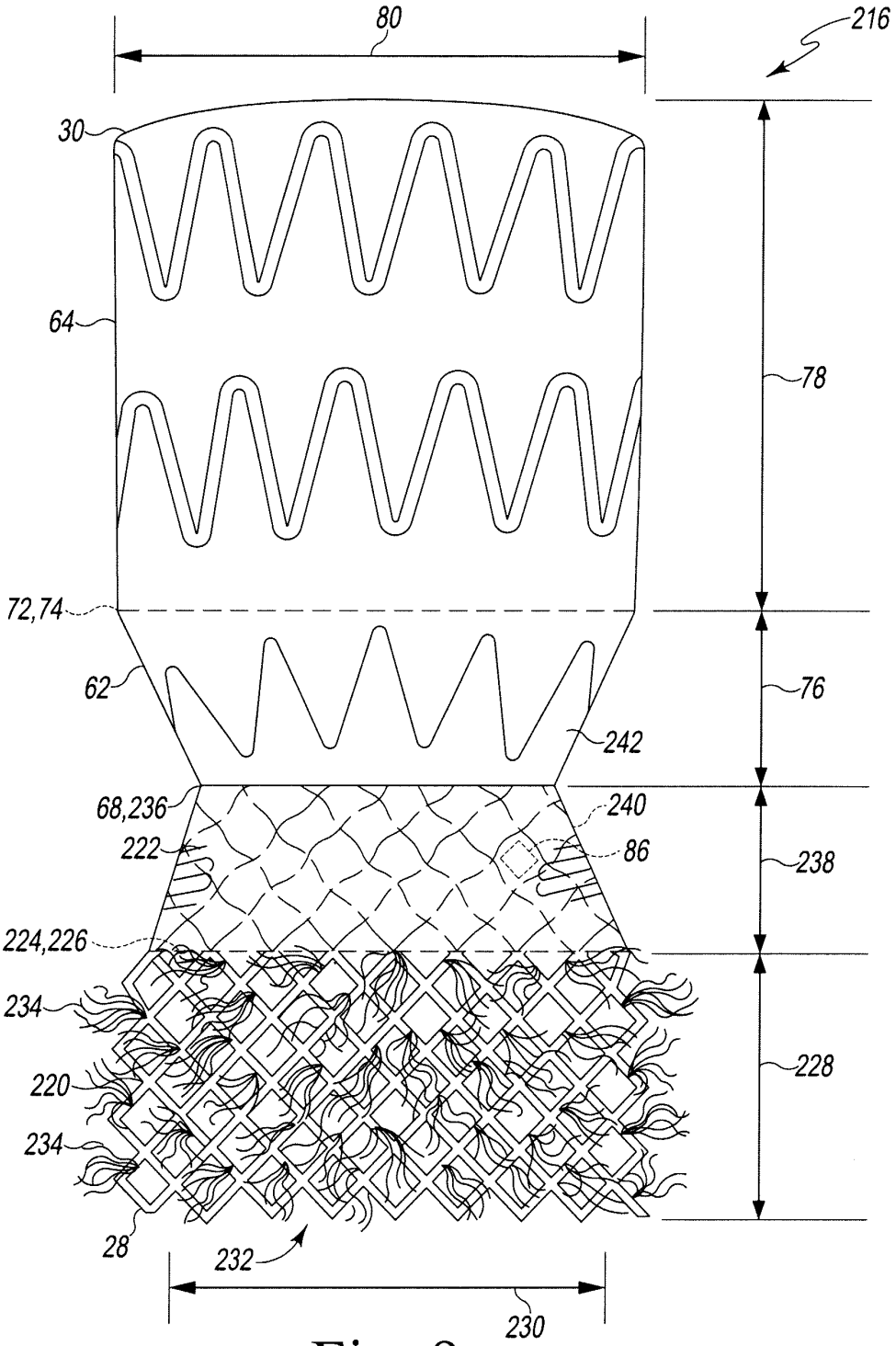

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Fig. 9

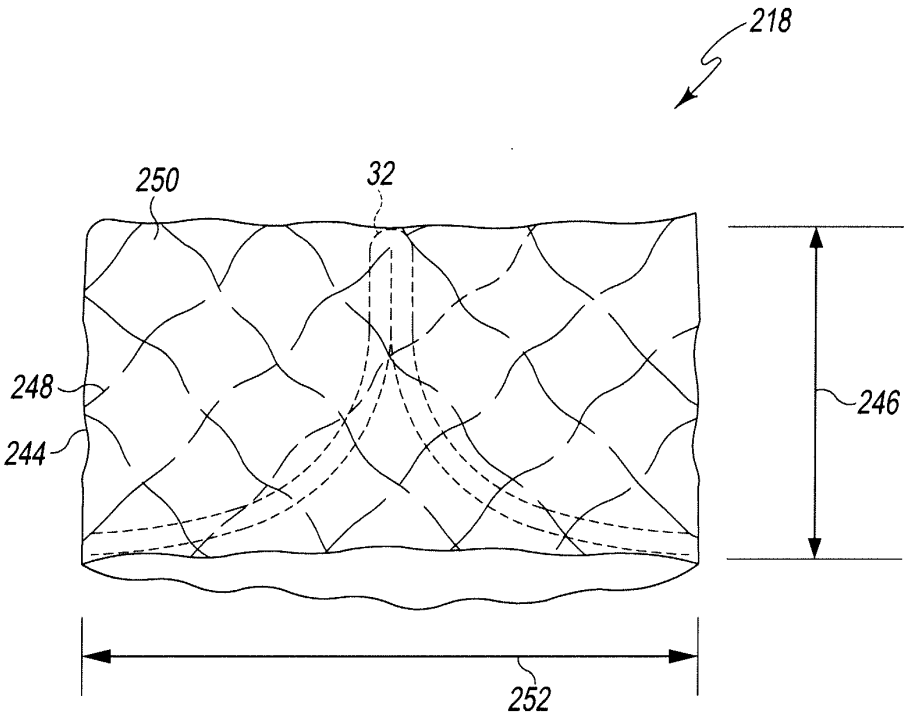


Fig. 10

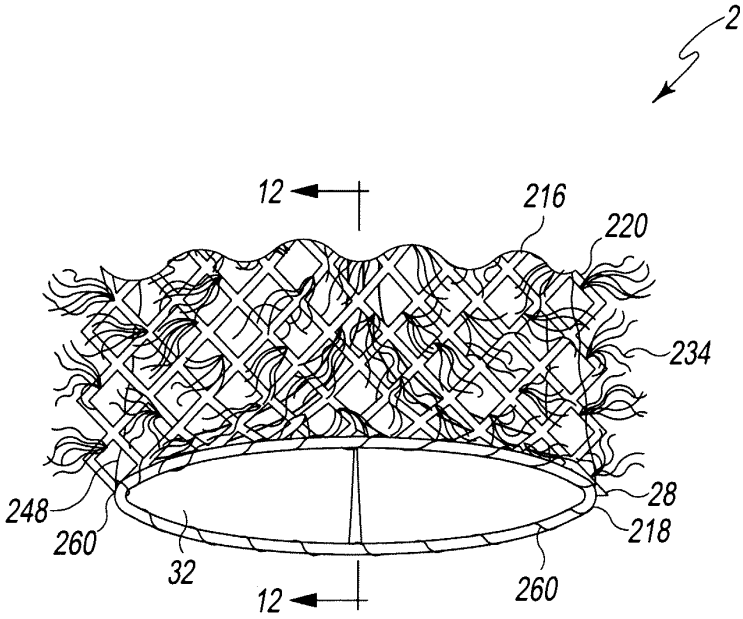


Fig. 11

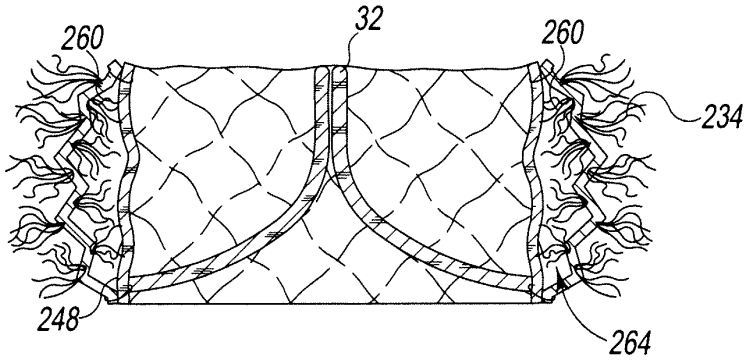


Fig. 12

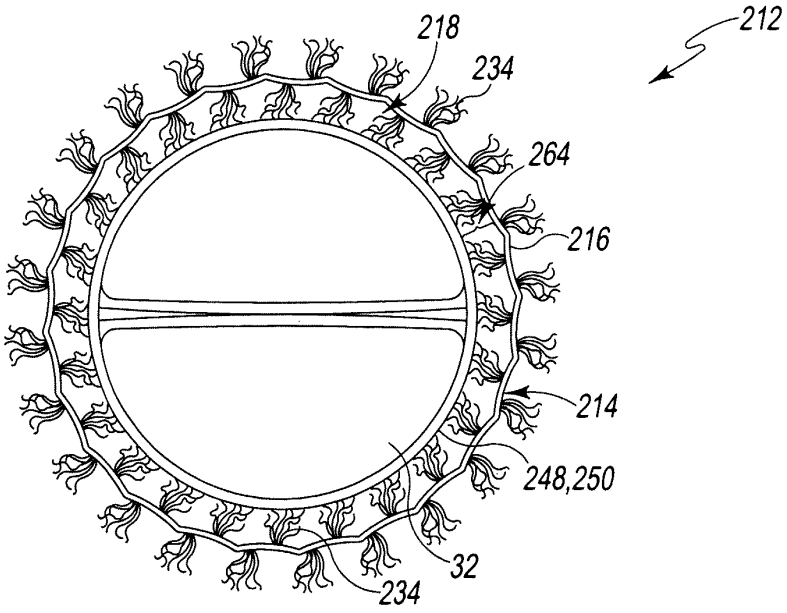

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234

Fig. 13

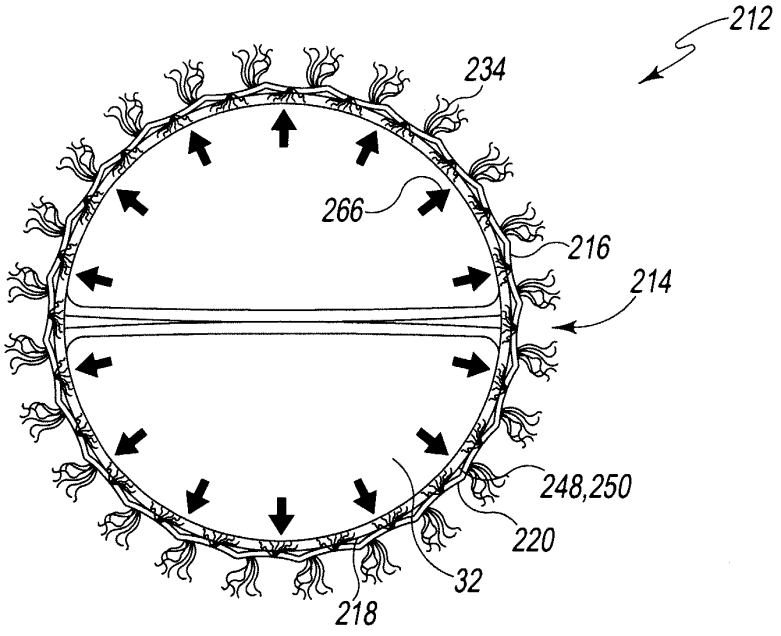

212
234
266
216
214
248,250
220
32
218

Fig. 14

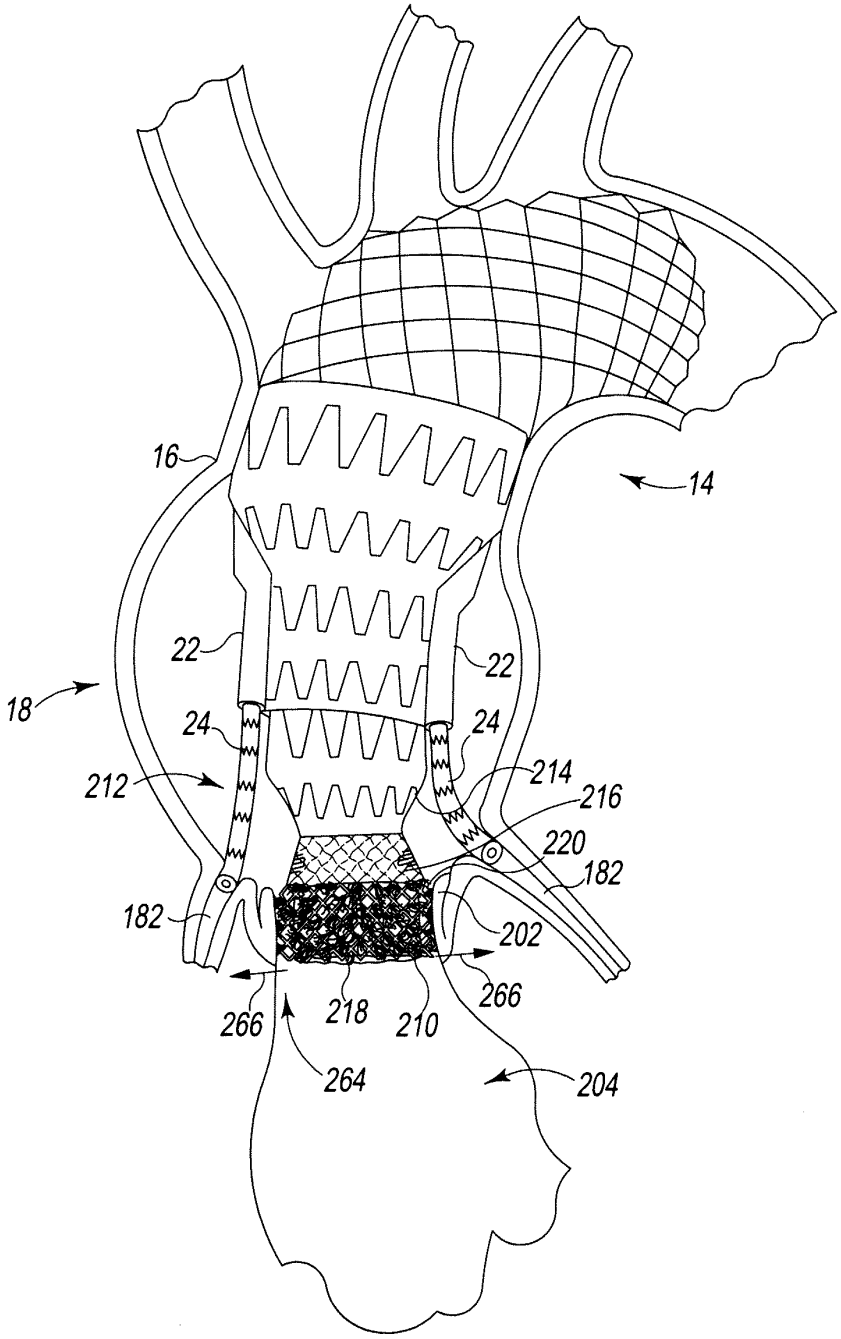

16
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212
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216
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182
182
202
266
218
210
266
264
204

Fig. 15

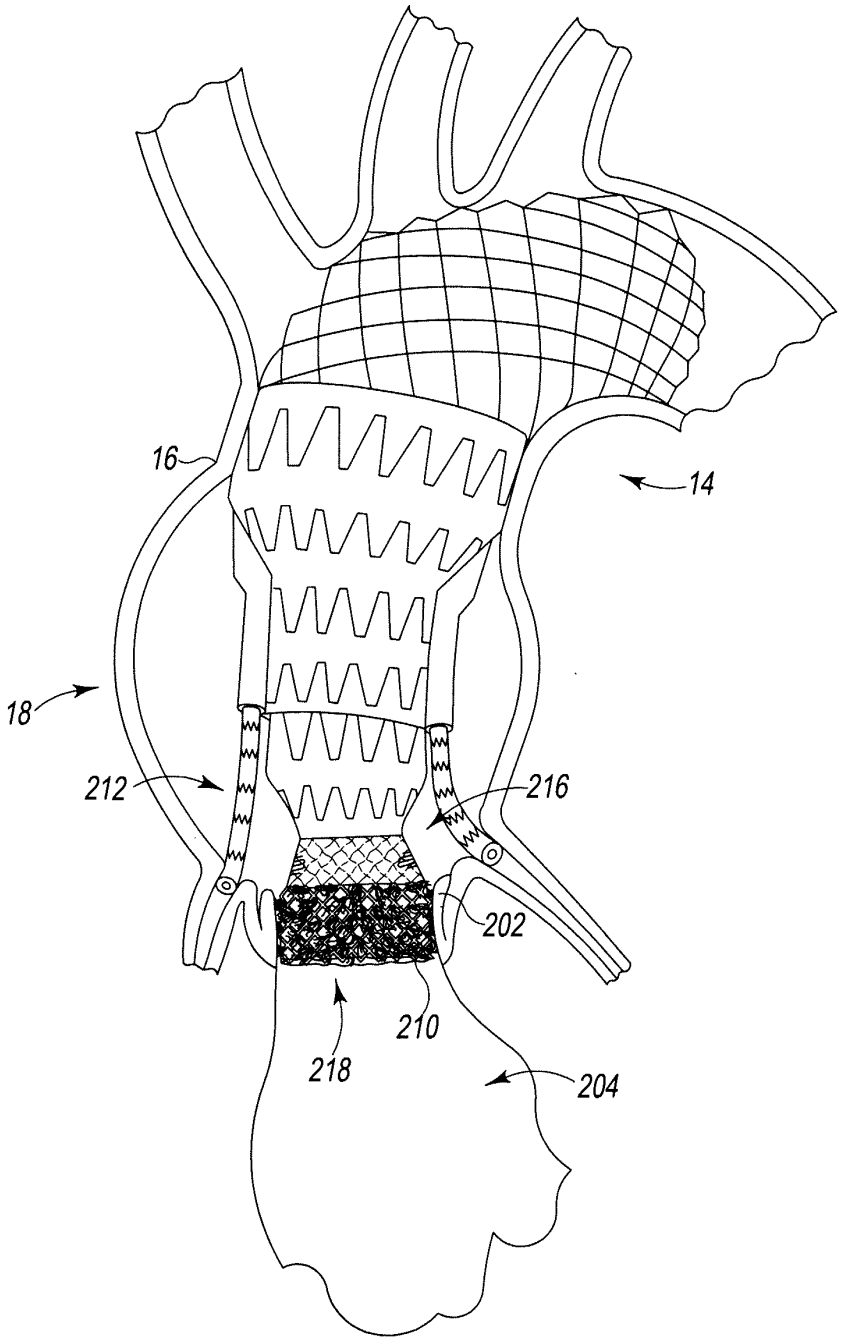


Fig. 16

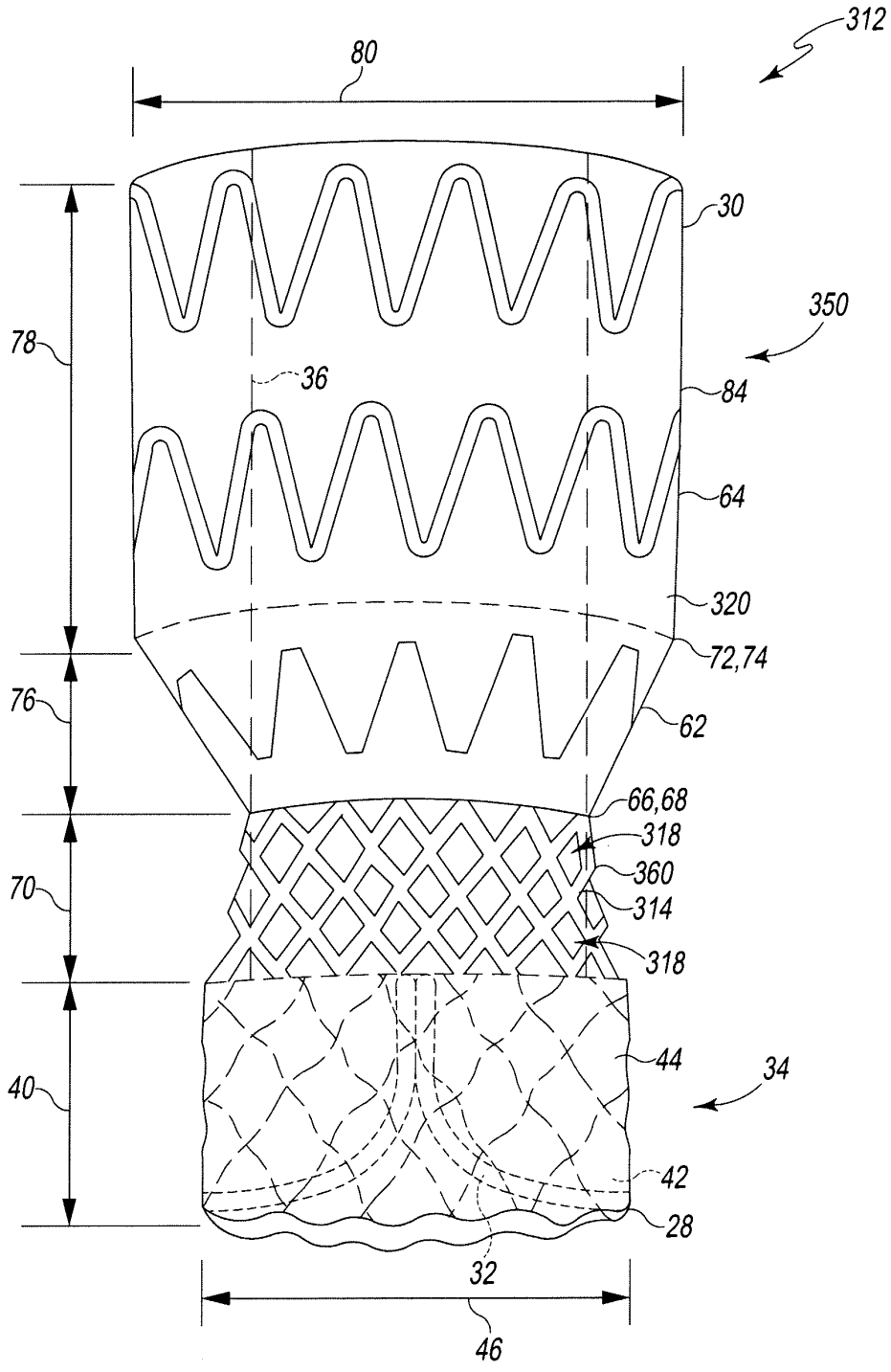

312
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66,68
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360
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42
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32
46

Fig. 17

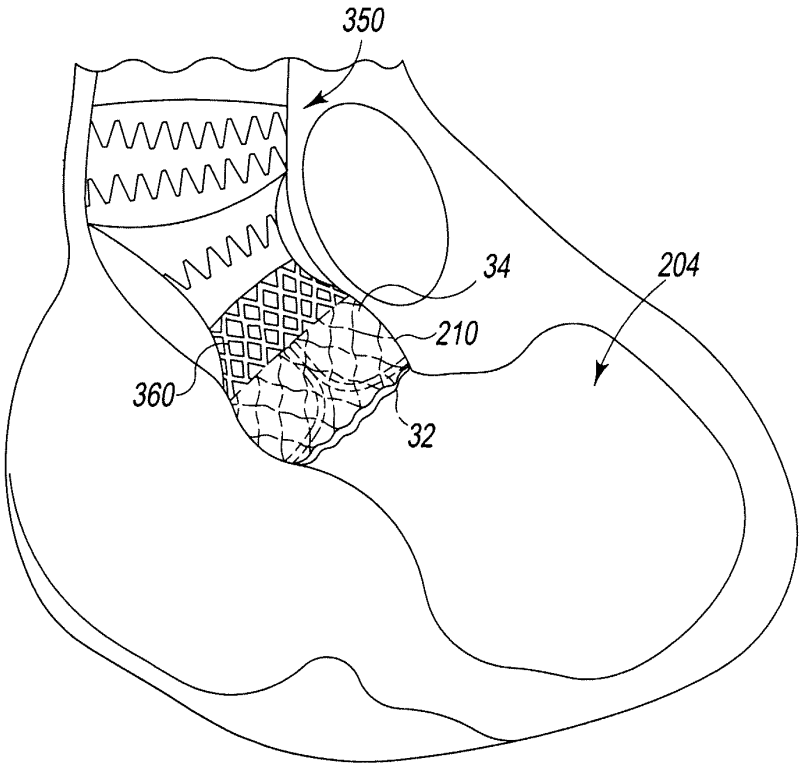


Fig. 18

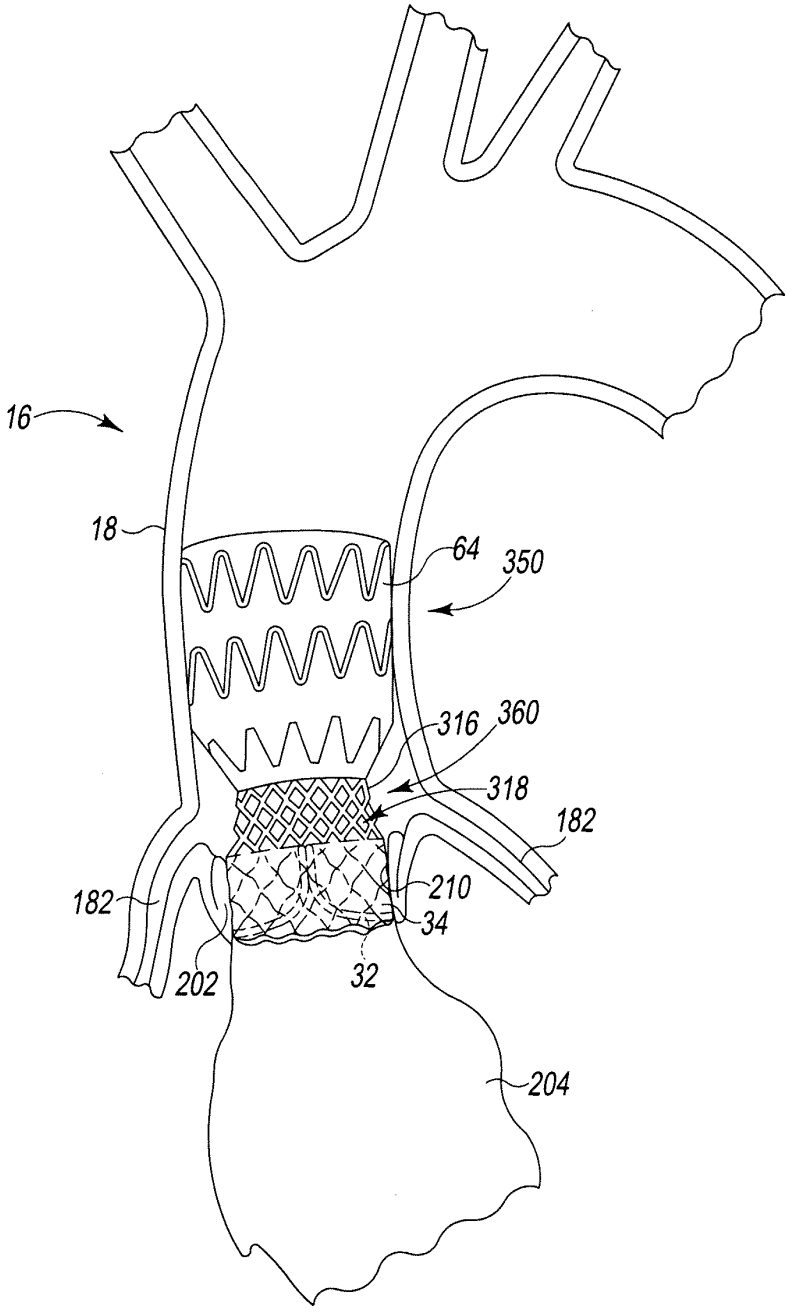


Fig. 19

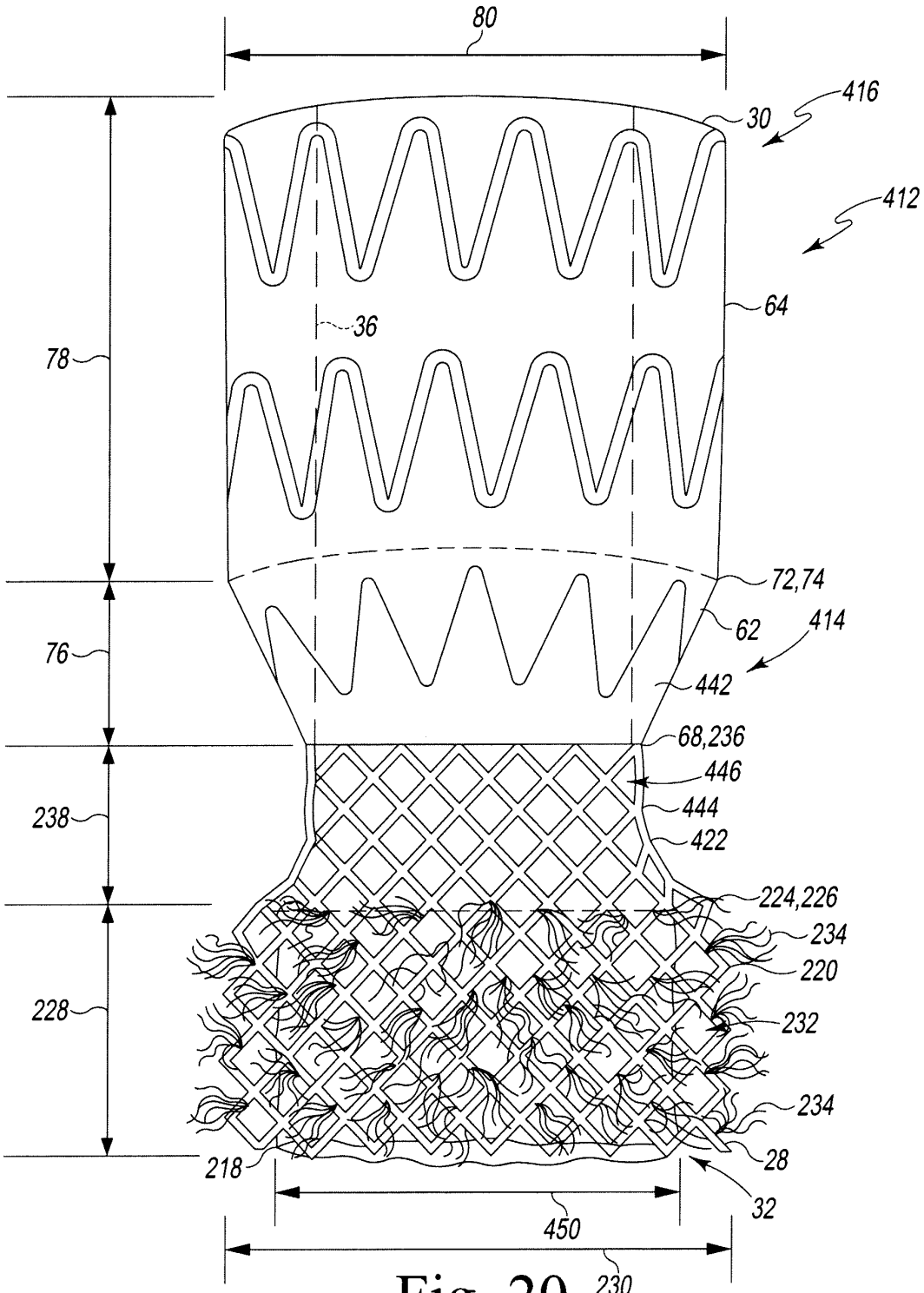

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72,74
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414
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450
230

Fig. 20

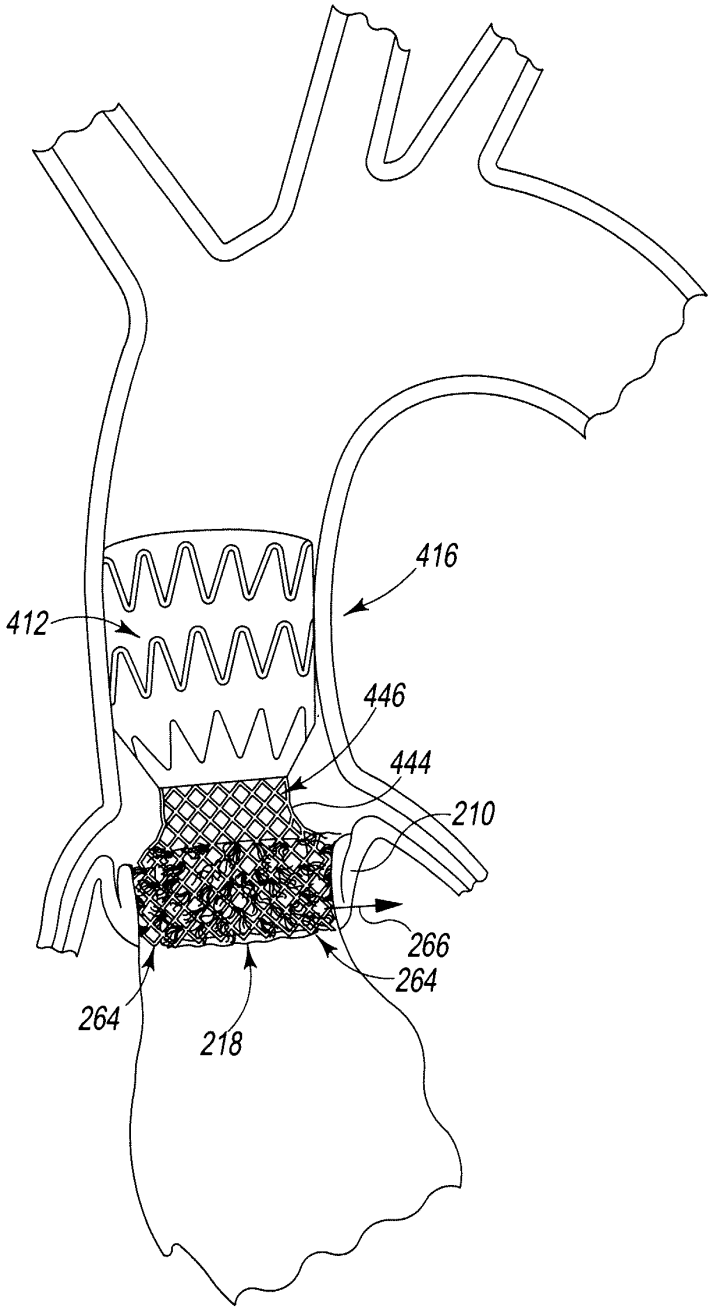


Fig. 21

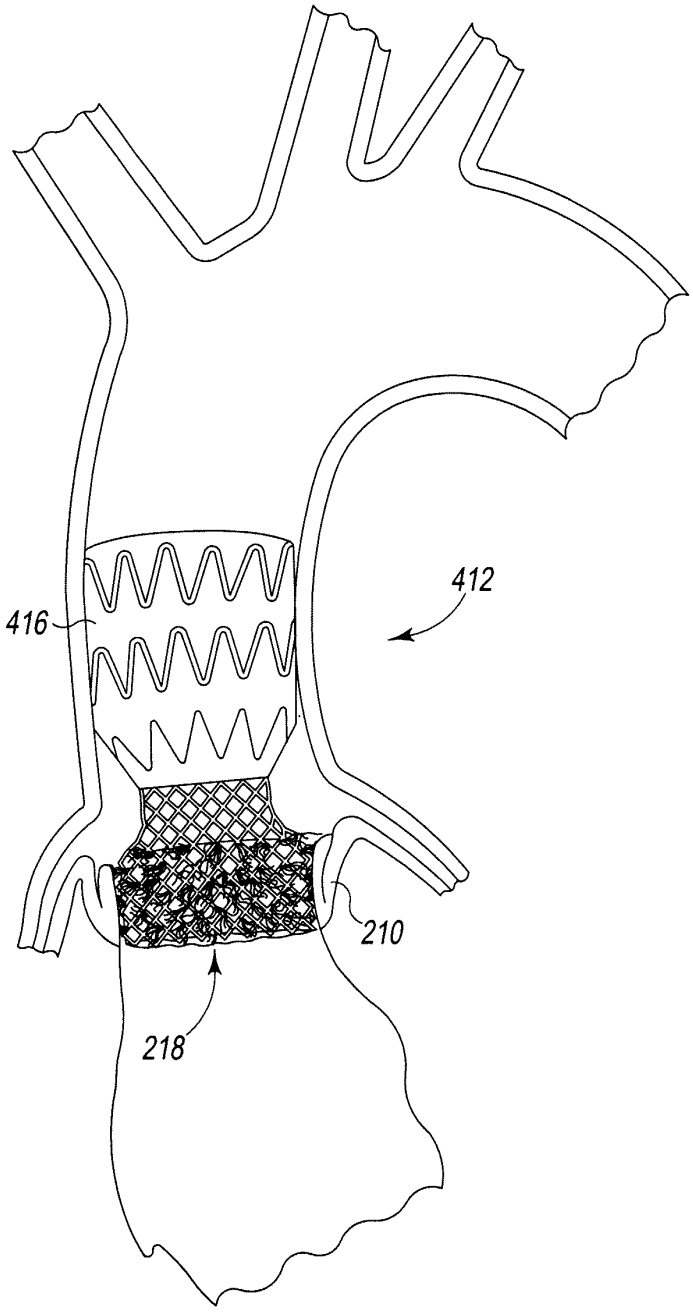


Fig. 22