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On behalf of **Edwards Lifesciences Corporation and
Edwards Lifesciences LLC**

By: Joshua J. Stowell
Craig S. Summers
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: BoxEdwards28-4@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

IPR2024-00390

Patent No. 11,497,634

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,497,634**

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<i>E.I. du Pont de Nemours & Co. v. Phillips Petroleum</i> , 849 F.2d 1430 (Fed. Cir. 1988)	29
<i>Google LLC v. Hammond Dev. Int’l, Inc.</i> , 54 F.4th 1377 (Fed. Cir. 2022)	8
<i>Koninklijke Philips N.V. v. Google LLC</i> , 948 F.3d 1330 (Fed. Cir. 2020)	28
<i>KSR Int’l Co. v. Teleflex</i> , 550 U.S. 398 (2007)	<i>passim</i>
<i>In re Nilssen</i> , 851 F.2d 1401 (Fed. Cir. 1988)	13
<i>Nintendo Co. v. Gamevice, Inc.</i> , IPR2018-01521, Paper 7 (P.T.A.B. Mar. 11, 2019)	14
<i>Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am. Inc.</i> , 924 F.3d 1243 (Fed. Cir. 2019)	8
<i>ParkerVision, Inc. v. Qualcomm Inc.</i> , 903 F.3d 1354 (Fed. Cir. 2018)	41
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	13
<i>Smith & Nephew, Inc. v. Rea</i> , 721 F.3d 1371 (Fed. Cir. 2013)	29, 60, 69
<i>TorPharm, Inc. v. Ranbaxy Pharms.</i> , 336 F.3d 1322 (Fed. Cir. 2003)	29

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<i>Unwired Planet, LLC v. Google Inc.</i> , 841 F.3d 995 (Fed. Cir. 2016).....	12
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35 U.S.C. §112	2
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Exhibit No.	Description
1001	U.S. Patent No. 11,497,634 B2 (“’634 patent”)
1002	Excerpts from the prosecution history of the ’634 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., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 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	Reserved
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	Reserved
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.
1016	Reserved

Exhibit No.	Description
1017	Cheung, Anson, et al., <i>Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human</i> , 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.
1020-1021	Reserved
1022	Smith, Craig R., et al., <i>Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients</i> , 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., <i>Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches</i> , Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Reserved
1025	Cribier, Alain, et al., <i>Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis</i> , 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al.
1027-1029	Reserved
1030	Cribier, Alain, et al., <i>Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis</i> , 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)

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Exhibit No.	Description
1031-1033	Reserved
1034	Andersen, Henning, et al., <i>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</i> , European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.
1036	Nietlispach, Fabian, et al., <i>Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems</i> , Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Pub. No. US 2009/0281619 A1 to Le et al.
1038-1044	Reserved
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al.
1046	Reserved
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	Reserved
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dkt. 1, Complaint (Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.

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Exhibit No.	Description
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 Braidó et al.
1055-1056	Reserved
1057	U.S. Patent No. 7,524,331 B2 to Birdsall (“ Birdsall ”)
1058	Reserved
1059-1071	Reserved
1072	Deposition Transcript of Stephen Brecker from August 30, 2022
1073	Deposition Transcript of Stephen Brecker from August 31, 2022
1074	U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)
1075-1105	Reserved
1106	Estridge, Trudy & Dale Feldman, <i>Quantification of Vascular Ingrowth into Dacron® Velour</i> , 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”)
1107	Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)
1108	Jonas, Richard A. et al., <i>Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments</i> , 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”)

Exhibit No.	Description
1109	Ko, Frank K., <i>Fabrics</i> , Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”)
1110	Pourdeyhimi, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyhimi”)
1111	Scott, Steward M. et al., <i>A Collogen Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)
1112	Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”)
1113-1115	Reserved
1116	U.S. Patent Pub. No. 2002/0151958 to Chuter (“ Chuter ”)
1117	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01527, Final Written Decision (“172 FWD”)
1118	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584, Final Written Decision (“011 FWD”)
1119	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00193, Final Written Decision (“538 FWD”)
1120	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00034, Final Written Decision (“846 FWD”)
1121	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00549, Institution Decision from (“735 Institution Decision”)
1122	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Dkt. 13, Second Amended Complaint (Apr. 10, 2023)

Exhibit No.	Description
1123	Aortic Innovations LLC’s Disclosure of Asserted Claims and Infringement Contentions, C.A. No. 1-23--CV-00158 (JPM) (“PO Infringement Contentions”)
1124	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 PO’s Preliminary Response (“’011 POPR”)
1125	U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment
1126	U.S. Pat. No. 4,739,762 to Palmaz
1127	U.S. Pat. No. 5,102,417 to Palmaz
1128	Deposition Transcript of Dr. Nigel Buller from November 11, 2022
1129	C. C. Chu, <i>Understanding Implantable Textiles</i> , Advanced Textiles Source (May 21, 2018) (“Chu”)
1130	“Distinct,” Merriam Webster Online Dictionary, <i>available at</i> https://www.merriam-webster.com/dictionary/distinct
1131	H.M. Russell et al., <i>Open Atrial Transcatheter Mitral Valve Replacement in Patients With Mitral Annular Calcification</i> , 72(13) J AMER. COLL. CARDIOL. 1437–48 (2018) (“Russell”)
1132	PTFE Felt, Medline, <i>available at</i> https://punchout.medline.com/product/PTFE-Felt/Surgical-Mesh/Z05-PF31252
1133	Deposition Transcript of Dr. Nigel Buller in IPR2017-00060 (June 15, 2017)
1134	U.S. Pat. No. 4,892,539 (“Koch”)
1135	U.S. Pat. No. 3,878,565 (“Sauvage”)

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Exhibit No.	Description
1136	Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”)
1137	U.S. Pat. Pub. No. 2005/0273155 (“Bahler”)
1138	U.S. Pat. Pub. No. 2012/0143324 (“Rankin”)
1139-1140	Reserved
1141	U.S. Pat. Pub. No. 2003/0023300 (“ Bailey ”)
1142	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2023-01151, PO’s Preliminary Response (“’834 POPR”)
1143	<i>Spacing</i> , Merriam Webster, available at https://www.merriam-webster.com/dictionary/spacing
1144	Reserved
1145	Declaration of Dr. Stephen J.D. Brecker Regarding Claim Construction submitted in Case No. 1-23-cv-00158 (D. Del.)
1146	Deposition Transcript of Stephen Brecker from February 8, 2023
1147	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Aortic Innovations LLC’s Identification of Preliminary Claim Constructions and Evidence (Oct. 13, 2023)
1148-1149	Reserved
1150	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Aortic Innovations LLC’s LPR4-2(c) Disclosure (Dec. 11, 2023)

U.S. Patent No. 11,497,634 Claim Listing

No.	Shorthand	Limitation
1.P	Preamble	A transcatheter aortic heart valve assembly comprising:
1.a	Graft Covering	a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto;
1.b	Frame	a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration, wherein the frame is secured to the graft covering,
1.c	Polymeric Graft Covering	wherein the graft covering is made of a polymer;
1.d	Plurality of Fibers	a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame, wherein the fibers are arcuate, spaced-apart, and outwardly extending,
1.e	Fibers Spaced Apart	wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state,
1.f	Uncovered Apices	wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers,
1.g	Fibers Compressed To Form A Seal	wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings,

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1.h	Graft Covering Engaged With Fibers	wherein the graft covering is engaged with fibers of the plurality of fibers,
1.i	Endovascularly Deployed	wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.
2	N/A	The valve assembly of claim 1, wherein the frame extends distally further than the prosthetic heart valve leaflets.
3	N/A	The valve assembly of claim 1, wherein the frame is a singular, integral component.
4	N/A	The valve assembly of claim 1, wherein the frame and the graft covering are attached by stitching at a top and bottom portion of the graft covering.
5	N/A	The valve assembly of claim 1, wherein the valve assembly is balloon expandable.
6	N/A	The valve assembly of claim 1, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.
7	N/A	The valve assembly of claim 1, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.
9	N/A	The valve assembly of claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.

Petitioners Edwards Lifesciences Corporation and Edwards Lifesciences LLC (“Petitioner”) request *inter partes* review (“IPR”) of claims 1-7 and 9 (“the Challenged Claims”) of U.S. Patent No. 11,497,634 (“the ’634 patent”) to Aortic Innovations LLC (“PO”).

I. SUMMARY OF THE ARGUMENT

The ’634 patent is a continuation of several patents challenged by Petitioner in prior IPRs.¹ Some of those IPRs resulted in Final Written Decisions (“FWDs”) in which the Board found the challenged claims unpatentable over **Spenser** and **Spenser II**. The ’634 patent issued before the FWDs, so the Examiner did not have the benefit of the Board’s decisions. The ’634 patent includes many of the claim limitations the Board found anticipated by or obvious over Spenser and Spenser II. The FWDs are now final, so the Board’s findings have preclusive effect and resolve many of the potential disputes herein. *Infra* §II (identifying estopped issues).

During prosecution of the ’634 patent, the Examiner identified two limitations as allegedly distinguishing the claims from the prior art that were not previously addressed in a FWD: (1) “wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the

¹ *Infra* §X.B (identifying prior IPRs).

most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers” (hereinafter “Uncovered Apices Limitation”) and (2) “wherein fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve is in an uncompressed state” (hereinafter “Spacings Limitation”). (Ex. 1002, 215-224, 234-236.)

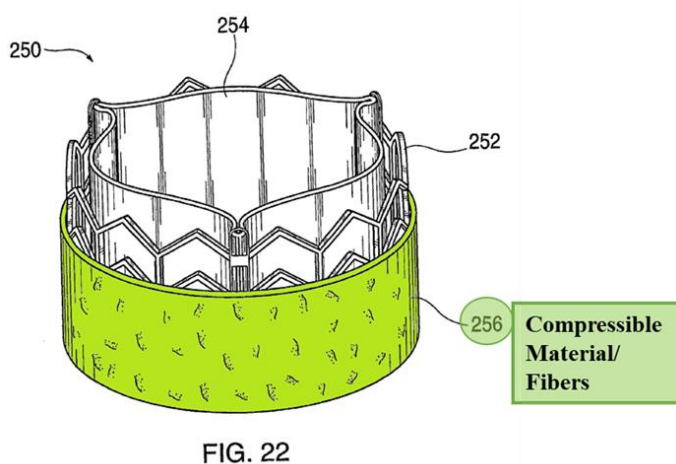
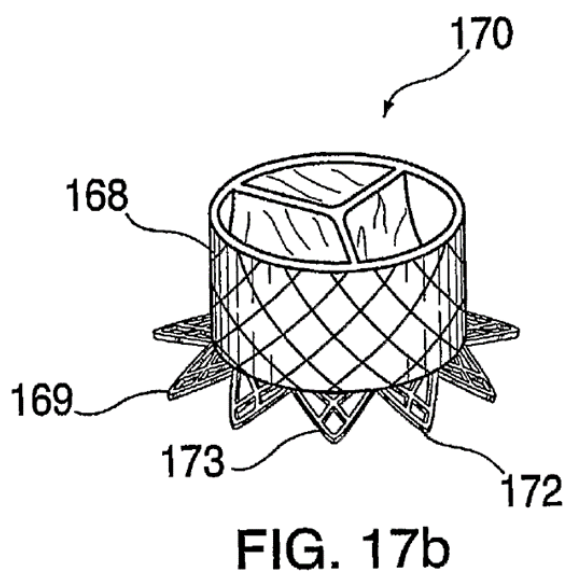
PO added both limitations to circumvent the prior art. (*Id.*) However, neither limitation is discussed in the specification. Rather, PO argued the patent figures alone disclose the limitations.² (*Id.*, 215-216.) PO also argued the limitations confer benefits to the claimed valve assembly, but the ’634 patent does not describe the benefits. The specification’s silence regarding these limitations reflects their triviality and litigation-driven purpose. As demonstrated herein, both limitations fail to distinguish the claims from the prior art.

The Board previously addressed a limitation like the Uncovered Apices Limitation in IPR2022-00549. There, Petitioner presented evidence that POSITAs would have found the limitation obvious based on Spenser and Spenser II. The

² Petitioner preserves its right to challenge whether the ’634 patent claims satisfy 35 U.S.C. §112 in future proceedings.

Board denied institution because it found that the portions of Spenser and Spenser II relied upon by Petitioner did not include any teaching or suggestion that the frame's proximal apices extend beyond the outer seal.

Here, Petitioner highlights an additional embodiment in Spenser II and introduces two additional prior-art references, which were not part of the unpatentability grounds in IPR2022-00549, disclosing transcatheter heart valves (“THVs”) with uncovered apices. Spenser II's Figures 17a-e illustrate a heart valve having a ring 172 of apices that extend further proximally than the rest of the frame. (Ex. 1011, [00136]-[00137].) When Spenser II's compressible material (Figure 22) is combined with this valve, the apices remain uncovered.



Birdsall discloses THVs having barrier materials formed from microfibers attached to the valve's exterior to prevent paravalvular leakage (“PVL”). (Ex. 1057,

6:9-25, 6:56-65, Figs. 3B-3C.) The barrier material does not cover the frame's apices at either end.

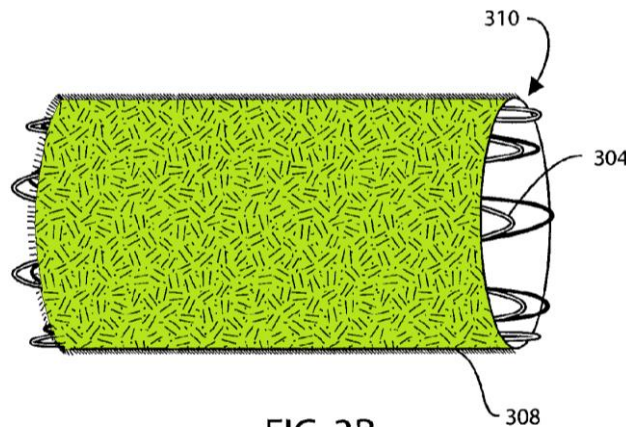
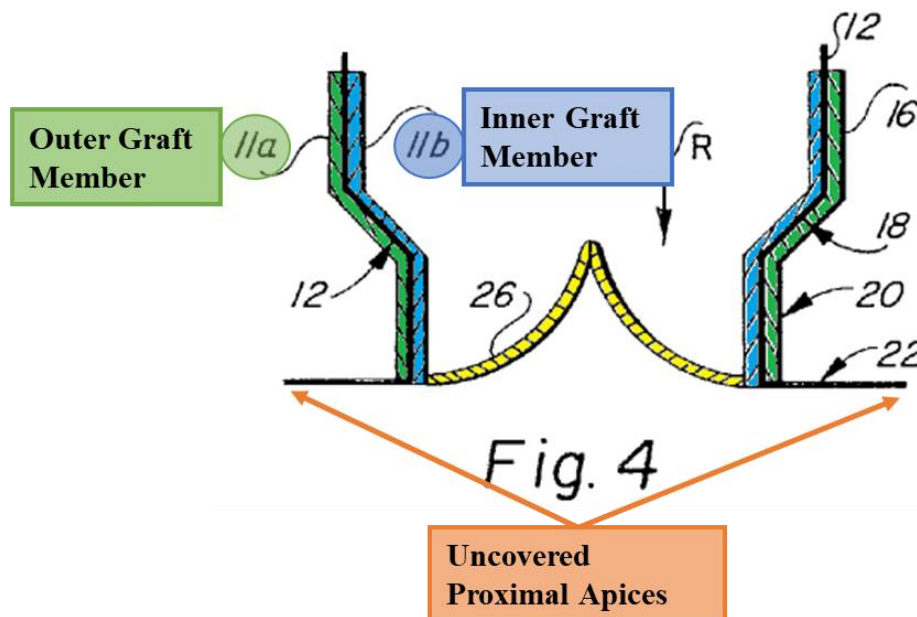


FIG. 3B

(*Id.*, Fig. 3B.) While Birdsall was listed in an IDS during prosecution, it was not applied or discussed.

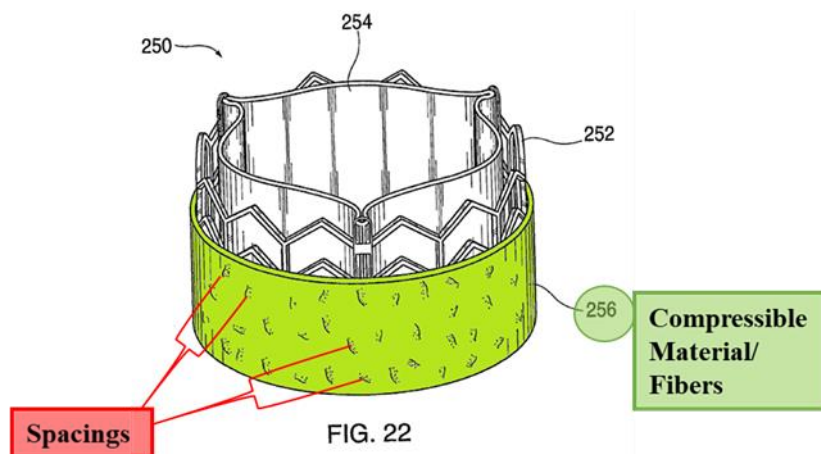
Bailey, which was not of-record during prosecution, also discloses THVs having uncovered proximal apices. (Ex. 1141, [0048]-[0049].)



(*Id.*, [0052], Fig. 4.)

Birdsall and Bailey corroborate the testimony of Petitioner’s expert that POSITAs would have found it obvious to leave the proximal apices on Spenser’s valve uncovered. Spenser II would have encouraged POSITAs to add a ring of apices to the proximal end of Spenser’s valve, and/or Birdsall and Bailey would have motivated POSITAs to slightly shorten Spenser II’s compressible material to expose the proximal apices. Further, the prior art shows POSITAs had a binary choice when arranging Spenser II’s compressible material – either the material extends as far proximally as the apices, or it does not. POSITAs would have found it obvious to try both finite, predictable solutions.

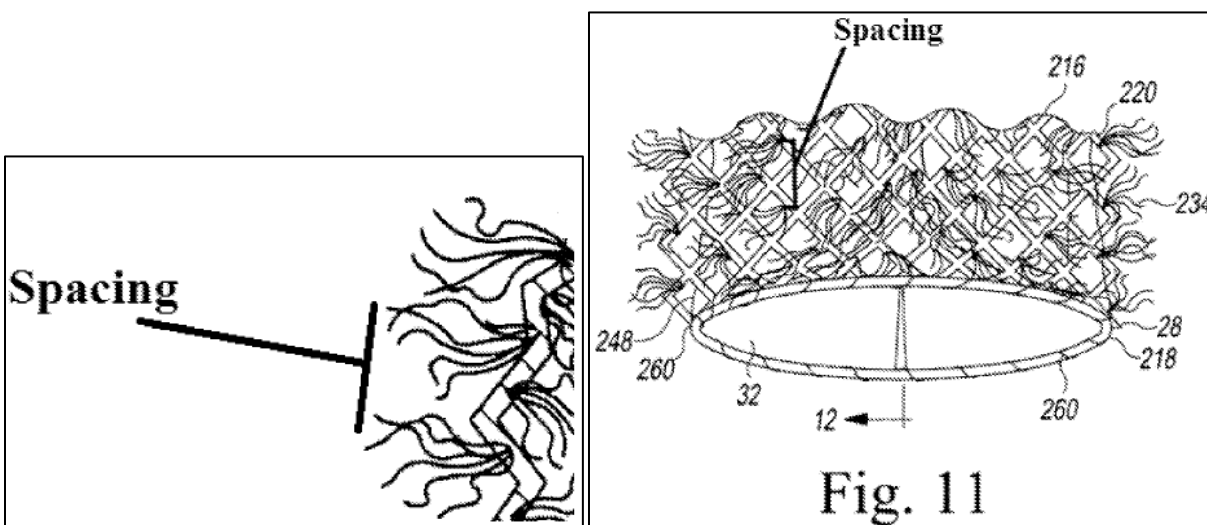
The prior art also discloses the Spacings Limitation. Spenser II illustrates spacings between the fibers of its compressible material.



PO even admitted during prosecution that “all fibers have some degree of being spaced-apart.” (Ex. 1002, 222.) PO attempted to distinguish materials like those in

Spenser II by arguing “the construction of Applicant’s claimed invention clearly requires some level more spacing.”³ (*Id.*) Yet, PO never explained what it meant by “some level more spacing.”

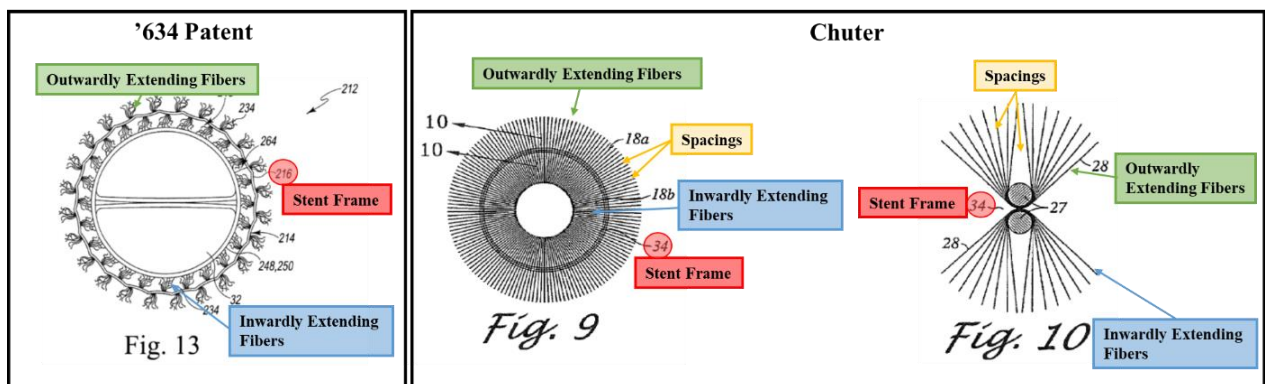
Further, PO’s argument that the ’634 patent “requires some level more spacing” is not supported by the intrinsic record and conflicts with PO’s litigation position that “spacings” should receive its plain and ordinary meaning. (*See Ex. 1150, 48-51.*) The ’634 patent does not discuss spacings between the fibers. PO relied exclusively on annotations it added to the patent figures for alleged written description support:



³ The prosecution history is unclear regarding whether the Examiner accepted PO’s argument.

(*Id.*, 378.) Yet, the patent never says the figures are drawn to scale and, therefore, the figures alone cannot limit the size of the spacings to “some level more” than the prior art. Thus, Spenser II discloses the Spacings Limitation under PO’s own admissions.

Likewise, **Chuter**, which was not of-record during prosecution, also discloses fibers that satisfy the Spacings Limitation. Chuter discloses spacings between outwardly extending fibers like those illustrated in the ’634 patent:



(Compare Ex. 1001, Fig. 13 with Ex. 1116, Figs. 9-10.) POSITAs would have found it obvious to combine Chuter’s known fibers with Spenser’s or Bailey’s known valves according to known techniques to yield predictable results.

For at least these reasons, the ’634 patent claims would have been obvious and should be cancelled.

II. IMPACT OF PRIOR IPRS

The Board issued FWDs in three IPRs that found almost every challenged claim unpatentable: IPR2021-01527 ('172 patent), IPR2021-01584 ('011 patent), IPR2022-00193 ('538 patent). Those FWDs were not appealed, or the appeal was dismissed. Accordingly, the Board's findings in these IPRs have preclusive effect on many issues presented herein. *See, e.g., Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am. Inc.*, 924 F.3d 1243, 1250-53 (Fed. Cir. 2019); *Google LLC v. Hammond Dev. Int'l, Inc.*, 54 F.4th 1377, 1381 (Fed. Cir. 2022). PO is precluded from challenging at least the following findings:

- POSITAs would have been motivated to add Spenser II's compressible material to Spenser's THVs and reasonably expected success in doing so (Ex. 1117, 64-66; Ex. 1118, 67-70);
- POSITAs would have reasonably expected the THV resulting from Spenser + Spenser II to be endovascularly deliverable (Ex. 1117, 57-64; Ex. 1118, 57-68);
- Petitioner's expert, Dr. Nigel Buller, is qualified as an expert and a POSITA (Ex. 1117, 51-53, Ex. 1118, 55-57);

- Spenser II and Norris disclose sealing materials comprising a plurality of outwardly extending fibers that “terminate in an end thereof outwardly of the outer frame” (Ex. 1117, 20-26, 71; Ex. 1118, 65); and
- Spenser discloses:
 - a polymeric graft covering extending around a prosthetic heart valve for providing sealing thereto;
 - a metallic frame forming a gridded configuration;
 - a polymeric graft covering stitched to the metallic frame; and
 - a polymeric graft covering extending beyond and over the proximal end of the frame to cover the end.

(Ex. 1117, 18-20, 71; Ex. 1118, 20-23, 74).

III. THE '634 PATENT

A. Overview

The '634 patent describes a “valve assembly” having a “dual-frame” for replacing an aortic heart valve. (Ex. 1001, 17:57-61.) The “dual-frame” 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”:

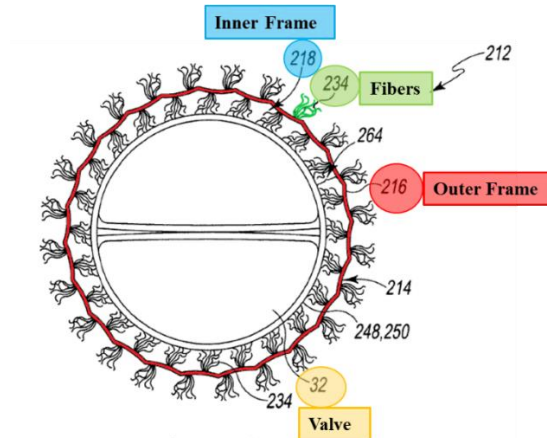


Fig. 13

(*Id.*, 18:1-12, Fig. 13.)

The outer frame includes collagen fibers that purportedly aid in preventing PVL and valve migration. (*Id.*, 18:1-37, Fig. 9.) The inner frame is a “balloon-expandable tubular stent.” (*Id.*, 13:48-54.)

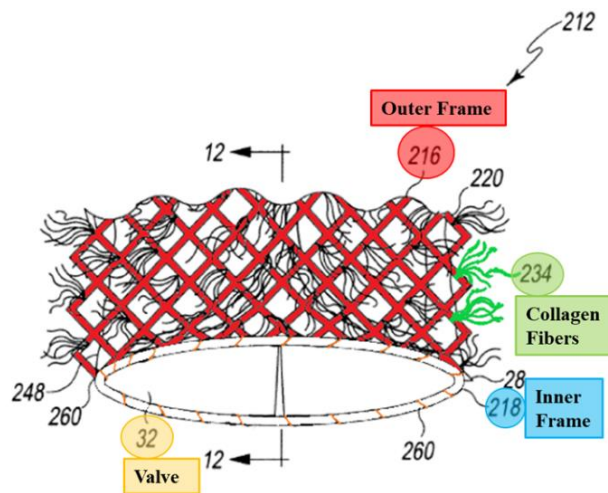


Fig. 11

B. Prosecution History

The Examiner initially rejected the pending claims as obvious over Spenser in combination with Spenser II. (Ex. 1002, 385-388.) Following an amendment requiring the valve assembly to be deployed endovascularly through the femoral artery, the Examiner issued a Final Rejection based on Levi (Ex. 1008) combined with Spenser II and Rankin (Ex. 1138). (Ex. 1002, 247-251.) After another amendment, which added the Spacings Limitation and Uncovered Apices Limitation, the Examiner issued a Notice of Allowance, stating that the prior art does not disclose or render obvious those limitations. (*Id.*, 85-91; *see infra* §IX (discussing prosecution).)

IV. OVERVIEW OF GROUNDS AND ASSERTED REFERENCES

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1-7, 9	103	Spenser + Spenser II
2	1-7, 9	103	Spenser + Spenser II + Birdsall
3	1-7, 9	103	Spenser + Spenser II + Bailey
4	1-7, 9	103	Spenser + Birdsall
5	1-7, 9	103	Spenser + Chuter + Birdsall
6	1-7, 9	103	Spenser + Chuter + Bailey
7	1-7, 9	103	Bailey + Spenser II
8	1-7, 9	103	Bailey + Birdsall
9	1-7, 9	103	Bailey + Chuter

B. The Asserted References Are Prior Art

The priority date of the '634 patent is November 2012. Each of the references forming the unpatentability grounds was published or issued by 2009 and is prior art under pre-AIA §102(b).

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). The references are from the same field as the '634 patent, e.g., cardiovascular implant devices, including endografts and THVs. (Ex. 1003, ¶40.) The references

are also pertinent to the problem the inventor was focused on, e.g., treating cardiovascular disease through minimally invasive procedures and providing effective sealing in such procedures. (*Id.*) Accordingly, POSITAs are presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

V. 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, ¶49.)

VI. 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 prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). No terms require construction to resolve the patentability issues herein. Petitioner’s grounds are based on PO’s allegations in the co-pending litigation that the ’634 patent covers Petitioner’s SAPIEN 3 Ultra valve. (Ex. 1122; Ex. 1123, 2, 262-476); *see also 10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00087, Paper 9 at 9-10, 15-19 (P.T.A.B. Apr. 27, 2020) (“[W]e see no problem with

Petitioner relying on statements by [PO] in the related district court action in which [PO] took a position on the scope of a challenged claim.”); *Nintendo Co. v. Gamevice, Inc.*, IPR2018-01521, Paper 7 at 7 n. 5 (P.T.A.B. Mar. 11, 2019). Petitioner reserves its right to propose claim constructions in district court and to contest PO’s infringement allegations.

VII. PROPOSED GROUNDS FOR UNPATENTABILITY

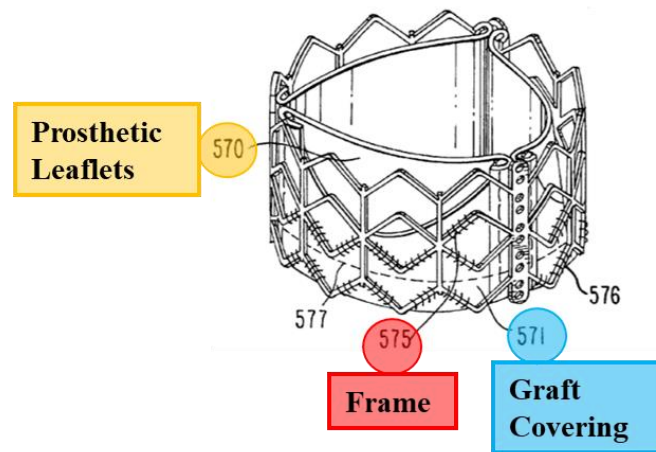
A. Grounds 1-3: Claims 1-7, 9 Obvious Over Spenser And Spenser II, And Optionally Birdsall Or Bailey

1. Claim 1

Spenser and Spenser II, and optionally Birdsall or Bailey, render claim 1 obvious. (Ex. 1003, ¶¶102-175.)

a. 1.P-Preamble

If the preamble is limiting, Spenser discloses a “transcatheter aortic heart valve assembly.” (*Id.*, ¶¶103-106.) Spenser describes aortic THVs having a frame, an inner graft covering, and prosthetic heart valve leaflets:



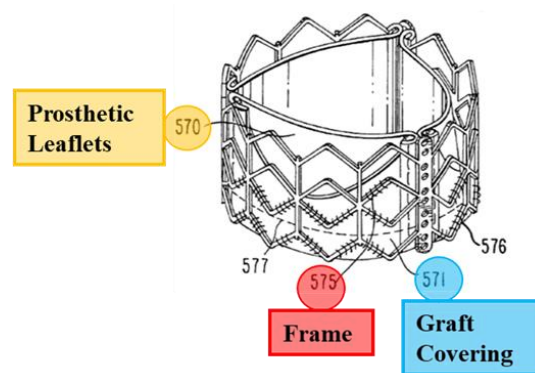
(Ex. 1010, 11:66-12:17, Fig. 44a.)

b. 1.a-Graft Covering

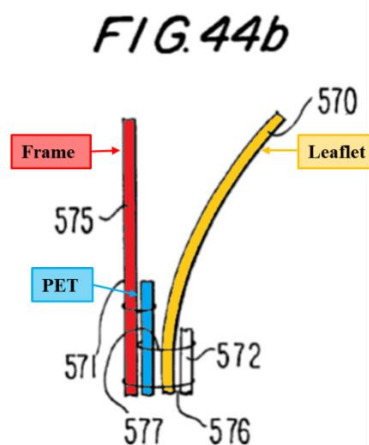
Spenser discloses this limitation.⁴ (Ex. 1003, ¶¶107-110.) In prior IPRs, PO did not contest, and the Board found, Spenser discloses a graft covering according to this limitation. (Ex. 1117, 19-20; Ex. 1118, 20-22). PO is estopped from challenging those findings here. *Supra* §II.

Spenser describes “pieces of PET” 571 for “sealing and protecting the pericardium.” (Ex. 1010, 26:30-34, Figs. 44a-44c.) The “pericardium” includes the prosthetic leaflets 570. (*Id.*, 26:30-54; Ex. 1003, ¶108.)

⁴ The Declaration of Nigel Buller, M.D. (Ex. 1003) repeats the claim language for each limitation in full.



PET 571⁵ [blue] is a “graft covering” that extends around the leaflets 570, and engages the leaflets 570:

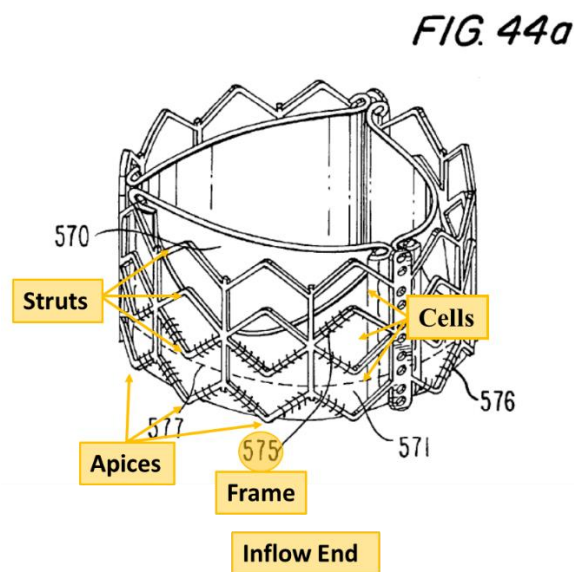


(Ex. 1010, 26:30-54, Fig. 44b; *see also id.*, Fig. 44a.)

⁵ The lead line for 571 points to the frame [red]. This is a drafter’s error. The lead line for 571 should point to the middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶107 n.5.)

c. 1.b-Frame

Spenser discloses this limitation. (Ex. 1003, ¶¶111-113.) Spenser’s “frame 575” is metallic and defines a plurality of continuously extending struts extending through a circumference of the frame that cooperatively form an open cell configuration:



(Ex. 1010, 12:28-31, 19:5-13, 26:30-34, Fig. 44a-44b.) The frame’s struts join each other at the inflow end to form apices. (*Id.*, 12:28-31, Fig. 44a-44b.) Frame 575 is secured to PET 571 via sutures. (*Id.*, 26:45-47, Figs. 44a-44c.)

d. 1.c-Polymeric Graft Covering

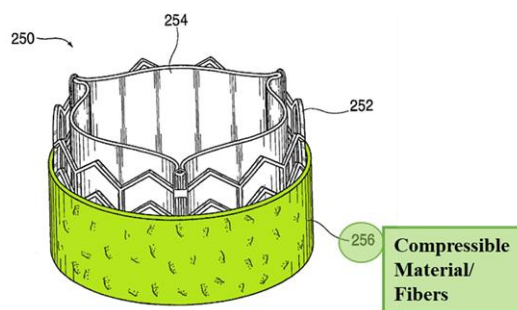
Spenser discloses this limitation. (Ex. 1003, ¶¶114-115.) Spenser’s graft covering may be made of PET, a polymer. (*Supra* §VII.A.1.b.)

e. 1.d-Plurality of Fibers

Spenser and Spenser II render obvious this limitation. (Ex. 1003, ¶¶116-131.)

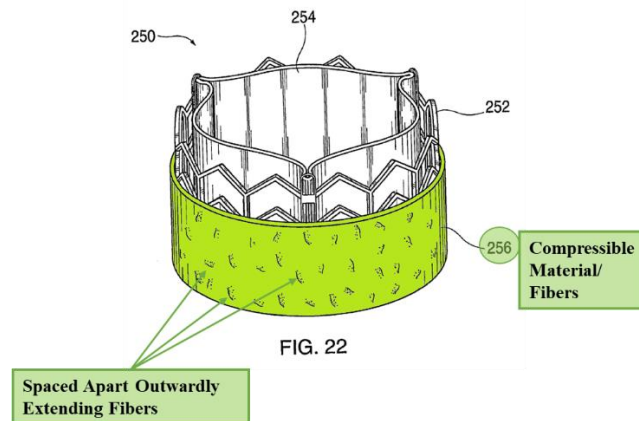
In prior IPRs, PO did not contest, and the Board found, that Spenser II discloses fibers according to this limitation. (Ex. 1118, 23-27, 55.) The Board also found that “Spenser II provides, and the prior art Norris provide ample motivation for combining a compressible cloth, as a sealing material, with the TAVR disclosed by Spenser.” (Ex. 1117, 64; *see also* Ex. 1118, 68; Ex. 1119, 80-81; Ex. 1003, ¶¶118-121.) PO is estopped from challenging those findings here. *Supra* §II.

Spenser II also discloses “arcuate, spaced-apart” fibers. Spenser II discloses, “a layer of compressible material 256 is disposed along an outer surface of the stent structure 252” that “may resemble a cloth or fabric having small fibers extending from the surface of the material”:



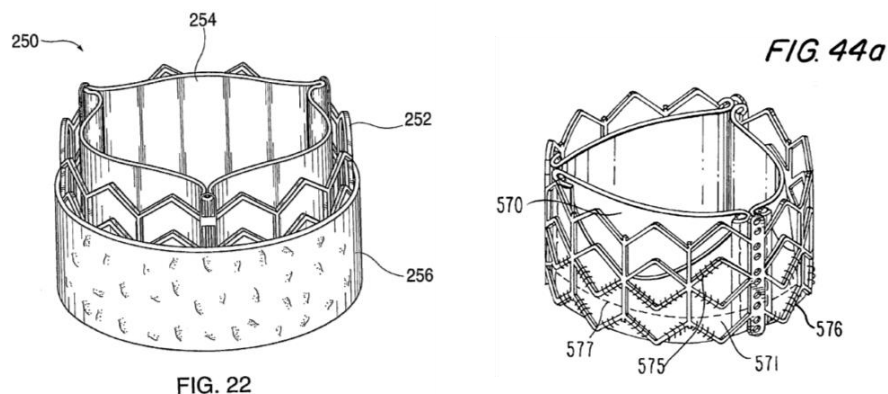
(Ex. 1011, [00145], Fig. 22.) The fibers “may be straight, curved or hook-shaped.”

(*Id.*) Additionally, the outwardly extending fibers are “spaced apart”:



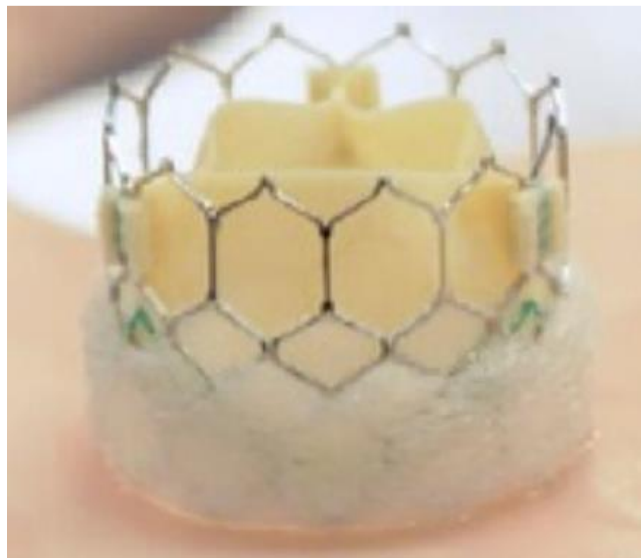
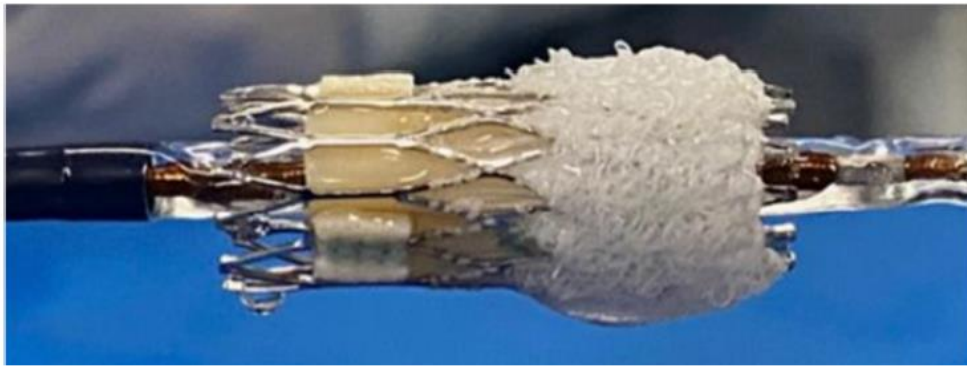
(*Id.*, Fig. 22.) PO admitted during prosecution that the fibers in all cloths are spaced apart. (Ex. 1002, 222.) Spenser II’s fibers are spaced apart so the material can compress, encourage tissue ingrowth, and promote blood coagulation. (Ex. 1003, ¶117.)

In prior IPRs, PO did not contest, and the Board found, that if Spenser II’s compressible material were added to Spenser’s Figure 44a valve, the material would cover at least two rows of open cells:



(Ex. 1118, 25-26, 74; Ex. 1011, Fig. 22; Ex. 1010, Fig. 44a; Ex. 1003, ¶122.)

Additionally, Spenser II's compressible material would be "in contact" with at least two rows of open cells at the inflow end of Spenser's frame. During prosecution, PO suggested that this limitation is met if the "sealing material is in contact with the outer frame." (See Ex. 1002, 224.) PO's infringement contentions regarding Petitioner's SAPIEN 3 Ultra valve, which are premised on the photos below, rely on a similar application of the limitation:



(See Ex. 1123, 329-330.) Spenser II discloses this limitation as applied by PO because Spenser II’s compressible material is “disposed along an outer surface of the stent structure 252”:

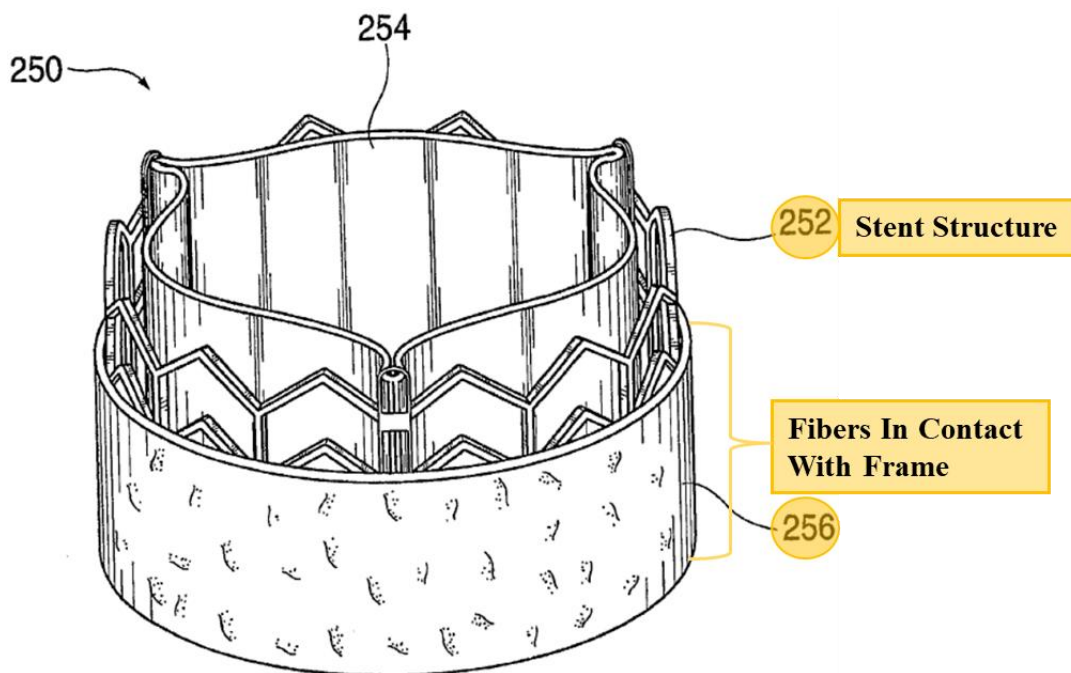


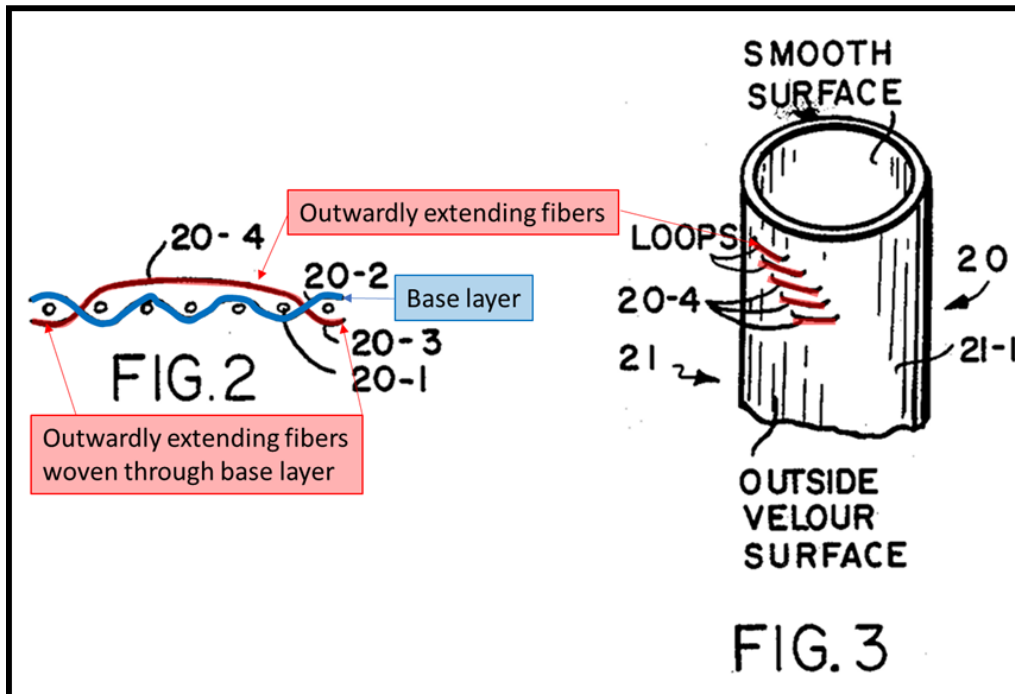
FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶123.)

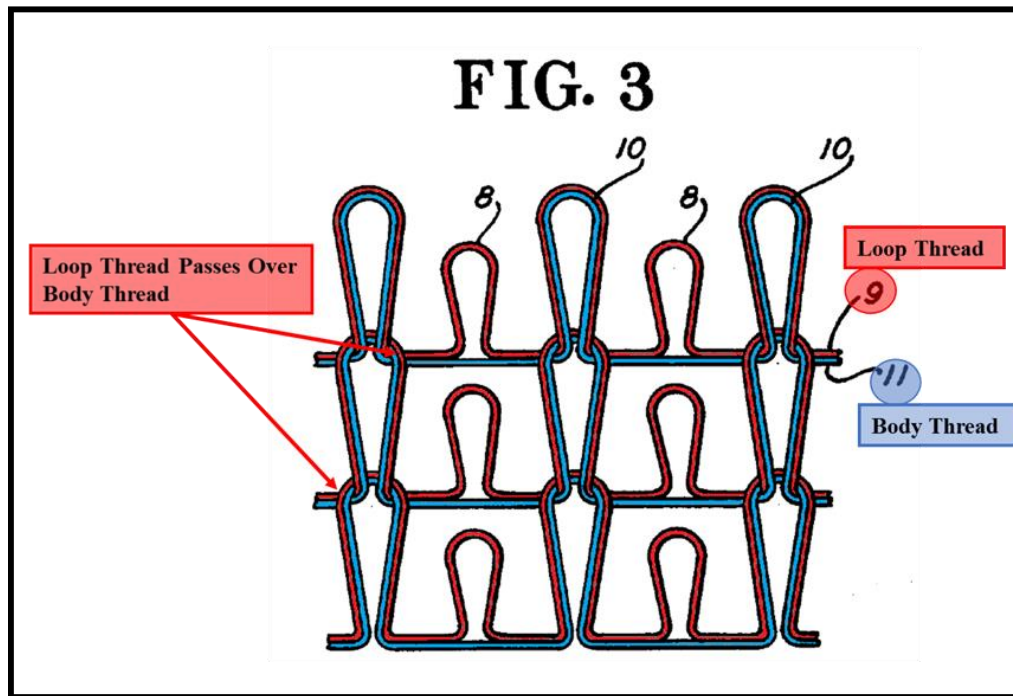
If this limitation has a different scope than PO has alleged, and requires the **outwardly extending fibers** of the sealing material to be in direct contact with the frame, then Spenser II still discloses or renders obvious this limitation in two ways. (Ex. 1003, ¶¶124-131.) First, in Spenser II’s embodiments having a cloth with fibers extending from the surface, POSITAs would have found it obvious to weave or knit the outwardly extending fibers through the base layer so that the fibers are in contact

with the frame along a height of the sealing material, as illustrated in Koch (weaving)
and Sauvage (knitting):

Koch (Woven Velour)



Sauvage (Knitted Velour)



(Ex. 1134, 2:55-3:9, Figs. 2-3; Ex. 1135, 1:44-60, Fig. 3; Ex. 1003, ¶¶125-129.) In both Koch and Sauvage, the radially extending fibers (loops 20-4 and loop thread 9) extend through the base layer and, therefore, would be in contact with the THV frame. (Ex. 1003, ¶¶125-129.) Woven and knitted velours, like Koch and Sauvage, were commonly used in cardiovascular implants before November 2012. (*Id.*; see also *id.*, ¶¶83-84.) For example, Norris, which the Board relied upon in prior IPRs, describes making a “compressible resilient fabric 10” using the methods illustrated in Koch and Sauvage. (Ex. 1074, 13:31-41; Ex. 1003, ¶¶125-129.)

Koch, Sauvage, and Norris represent the state of the relevant art prior to November 2012. POSITAs would have been motivated, and found it obvious, to

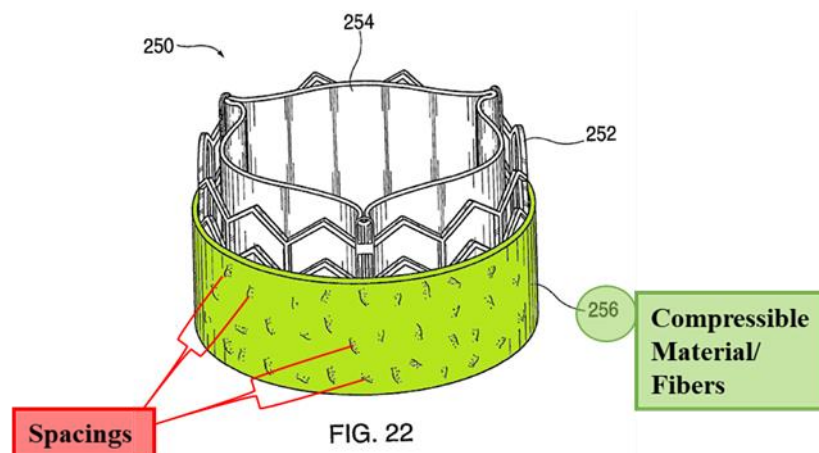
make Spenser II’s compressible material out of such velour cloths due to their known benefits. (Ex. 1003, ¶¶125-129.) Koch and Sauvage disclose that velour cloths can promote tissue ingrowth, and Sauvage discloses that velour can enhance blood coagulation. (Ex. 1134, 1:26-30; Ex. 1135, 1:56-60.) Additionally, Norris discloses that velour cloths can be highly compressible, allowing for smaller delivery profiles. (Ex. 1074, 4:54-60, 9:18-39.) POSITAs would have reasonably expected success in making Spenser II’s compressible material out of woven or knitted velour given its prior use and the predictability of the material. (Ex. 1003, ¶¶125-129.)

Second, while Spenser II discloses “cloth” embodiments, Spenser II also encompasses embodiments where the compressible fibers are not knitted or woven into cloth. (*Id.*, ¶¶130-131.) Spenser II broadly describes a “layer of compressible material” and states the cloth is only an embodiment. (Ex. 1011, [00145].) Spenser II does not limit the compressible material to cloth that surrounds the entire valve, as shown in Figure 22, stating that the material “**may** extend partially around the stent structure or **may** extend entirely around the stent structure, such as in the form of a sleeve.” (*Id.* (emphasis added).) Spenser II’s permissive language informs POSITAs that additional configurations are within the scope of the compressible material. A POSITA would have understood those additional materials to include

fibers attached directly to, and in contact with, the fame, like those disclosed in Birdsall and Chuter. (Ex. 1003, ¶¶130-131.)

f. 1.e-Spaced-Apart Fibers

Spenser and Spenser II render obvious this limitation. (Ex. 1003, ¶¶132-144.) PO and its expert have admitted that the fibers in all cloths, including those in Spenser II's compressible material, are spaced apart. (Ex. 1002, 222; Ex. 1146, 185:18-20; *see also supra* §VII.A.1.e (describing spacings in Spenser II's cloth).) PO's admission is correct. Any woven or knitted cloth has spacings between the fibers where the fibers overlap and those spacings extend through the fibrous and base layers. (Ex. 1003, ¶117).



Thus, consistent with PO's admissions, Spenser II's compressible material discloses the Spacings Limitation.

PO argued in a related IPR that PO disclaimed a "sleeve," "layer," or "cloth" such as Spenser II's compressible material from the scope of the term "spacings."

However, PO makes inconsistent arguments in district court, arguing that “spacings” should receive its plain and ordinary meaning and that PO made no disclaimer. (*Compare* Ex. 1142 at 10-12 with Ex. 1147 at 44-45.) The plain meaning of “spacings” does not require a specific size of “spacings” between the fibers, nor does the ’634 patent describe “spacings” or state that the patent figures are drawn to scale. (Ex. 1003, ¶134.) Thus, the Board should apply PO’s proposed claim construction from district court, the plain and ordinary meaning. *See, e.g., 10X Genomics, Inc.*, IPR2020-00087, Paper 9 at 9-10, 15-19.

Additionally, POSITAs would have been motivated, and found it obvious, to use a cloth with spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame for several reasons. (Ex. 1003, ¶¶136-144.) First, Spenser II discloses several embodiments for addressing PVL that include an “impermeable sealing material” that “prevents the passage of fluids through the stent.” (*See e.g.,* Ex. 1011, [0017], [0033]-[0037], Figs. 4b, 5a-d, 13a-d, 16a-b.) Yet, Spenser II does **not** describe Figure 22’s compressible material as “impermeable.” Thus, POSITAs would have understood that the compressible material is not impermeable to fluids and, therefore, has spacings that extend from the outermost aspect of the fibers to the frame. (Ex. 1003, ¶141.)

Second, POSITAs would have understood that compressible materials, like Spenser II's material, should have spacings for the fibers to compress into. (Ex. 1003, ¶¶136, 139; *see also* Ex. 1109, 1048; Ex. 1074, 8:3-7, 8:45-48.) A material without spacings is not compressible. Additionally, for knitted cloths having fibrous and base layers, like velour, POSITAs would have understood spacings should extend through both layers. (Ex. 1003, ¶139.) If the spacings did not extend through both layers, the layer without spacings would not compress, negatively impacting the material's overall compressibility, and causing the material to disadvantageously bunch during crimping. (*Id.*) Norris, for example, confirms the desirability of spacings in the base layer, disclosing "the ground layer 20 can have a porosity that can provide some space into which the loops 32 can be compressed." (Ex. 1074, 8:45-48.)

Third, Spenser II states the compressible material "expands after deployment at a treatment site" and that "[a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue." (Ex. 1011, [00145].) POSITAs would have recognized the compressible material should have spacings through all layers to create room for the expansion. (Ex. 1003, ¶137.) Again, a cloth without spacings will not expand (or compress).

Fourth, Spenser II states the fibers “encourage coagulation of blood to further fill the gaps and prevent leakage.” (Ex. 1011, [00145].) POSITAs would have understood the compressible material should have spacings between the fibers in the fibrous and base layers to create openings for the coagulation. (Ex. 1003, ¶138.) Further, spacings that are sufficiently large to allow the ingress of blood also allow fluid to pass therethrough when the material is not compressed. (*Id.*, ¶140; *see also*, *e.g.*, Ex. 1006, 158; Ex. 1108, 657; Ex. 1111, Summary; Ex. 1137, 2:42-49, 8:36-49.)

Fifth, POSITAs regularly used porous (i.e., spacings extending throughout the cloth) velour cloths to seal cardiovascular devices prior to 2012. (Ex. 1003, ¶142); *see also, e.g., Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020) (affirming Board’s obviousness finding where limitation “was not only in the prior art, but also within the general knowledge of a skilled artisan”). The prior experience with such cloths would have given POSITAs a reasonable expectation of success in using such a cloth. (Ex. 1003, ¶¶142-144.)

Finally, the ’634 patent does not claim or disclose how to size or arrange the fibers to create the spacings. (*Id.*, ¶133.) For example, the patent never discloses the length or width of the fibers, the density or number of fibers, or require a particular arrangement of fibers. Nor does the patent describe or disclose any size

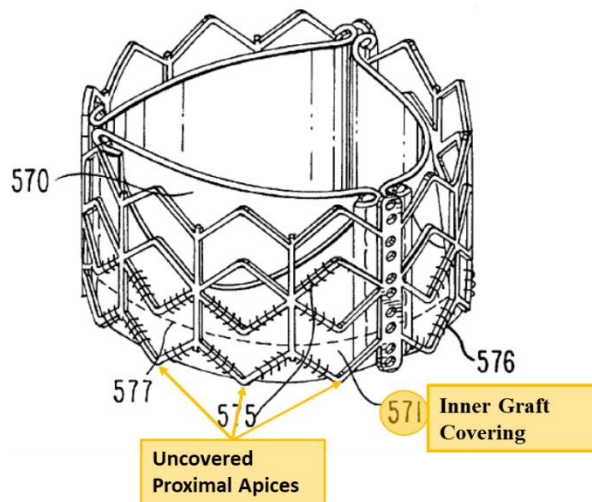
for the “spacings” or disclose that fluid can pass through any “spacings.” The patent figures depict only a random distribution of fibers around the frame that fail to define the size of the “spacings.” (*Id.*) Consequently, PO cannot argue that the selection of materials and adaptation of the compressible material to provide such spacings would have been beyond the skill of POSITAs. *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*, 849 F.2d 1430, 1433 (Fed. Cir. 1988); *TorPharm, Inc. v. Ranbaxy Pharms.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003).

g. 1.f-Uncovered Apices

Spenser and Spenser II, and optionally Birdsall *or* Bailey, render obvious this limitation. (Ex. 1003, ¶¶145-160.)

Spenser’s PET layer 571 (graft covering) does not cover the ends of the proximal apices:

FIG. 44a



(Ex. 1010, Fig. 44a; Ex. 1003, ¶146.)

In the Institution Decision for IPR2022-00549, the Board concluded that Spenser II’s Figure 22 alone does not disclose this limitation because there was no “express teaching or suggestion that the proximal apices extend beyond the proximal portion of the outer seal.” (Ex. 1121, 23-24.) The Board’s prior findings do not address Spenser II’s Figure 17, Birdsall, or Bailey, relied on herein, because Petitioner did not rely on the figures and references in its unpatentability grounds.

i. Spenser and Spenser II

Spenser II’s Figure 22 illustrates a valve having a compressible material around the valve’s exterior. (Ex. 1011, [00145].) Additionally, Figures 17a-e illustrate valves having a similar frame with an additional ring 172 of apices that extend further proximally than the rest of the frame. (*Id.*, [00136], [11037].)

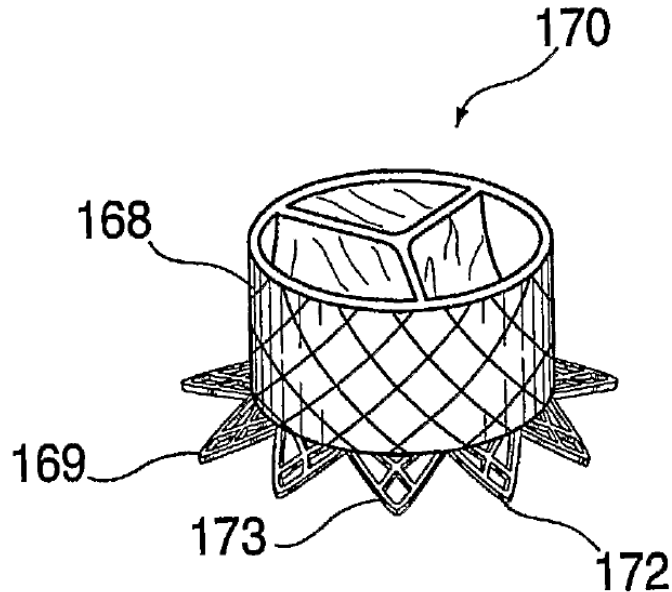


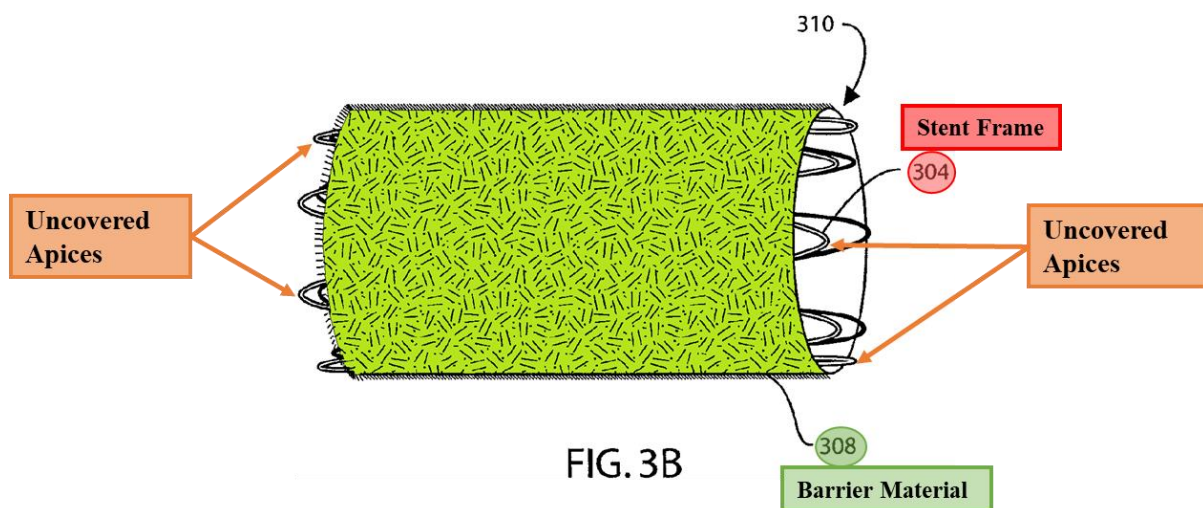
FIG. 17b

POSITAs would have found it obvious to incorporate both the ring 172 and compressible material into the Spenser's valve to enhance sealing. (Ex. 1003, ¶148.) Spenser II describes improvements to Spenser and, thus, POSITAs are taught to utilize Spenser II's features to improve Spenser's valves. (Ex. 1011, [0009]-[0010]; *see also supra* §VII.A.1.e; Ex. 1003, ¶148.) POSITAs would have understood that the ring and compressible material would be additive and provide better sealing than either feature alone. (Ex. 1003, ¶148.) In such a combination, the ring's apices would extend further proximally than, and be uncovered by, the compressible material and the inner graft covering. (*Id.*, ¶149.) POSITAs would have reasonably expected success in adding the ring to Spenser's valve because the ring may be "geometrically constrained" during delivery so as not to impact the crimp profile

and effectively seals “paravalvular cavities and associate[d] leaks.” (*Id.*, ¶150; Ex. 1011, [00136].)

ii. **Spenser, Spenser II, and Birdsall**

Birdsall’s “barrier member” may include (1) “directionally oriented microfibers attached to the surface of stented valve 310 and extending outward,” (2) microfibers “attached to a thin, pliable film or fabric,” or (3) a polyester batting comprised of a “disordered array of polyester microfibers that forms a soft, compressible mass.” (Ex. 1057, 6:10-65.) The barrier material prevents valve migration and PVL. (*Id.*) Birdsall’s barrier material does not cover the frame apices at either end:



(*Id.*, Fig. 3B.)

Birdsall would have motivated POSITAs to slightly shorten Spenser II’s compressible material so that it did not extend as far proximally as the apices of

Spenser's valves. (Ex. 1003, ¶¶152-154.) Birdsall and Spenser disclose similar THVs comprised of a metallic stent surrounding prosthetic leaflets. (*Id.*) While Birdsall describes pulmonic valve replacements, POSITAs would have been encouraged to apply Birdsall's design to Spenser II's compressible material and Spenser's THVs given the similarities between the pulmonic and aortic heart valves. (*Id.*, ¶¶152-153.) Both the pulmonic and aortic valves include three leaflets and regulate the flow of blood from a heart chamber to a major artery. (Ex. 1057, 1:22-24, 4:29-50, Fig. 1; Ex. 1003, ¶152.) Both valves can suffer from stenosis and regurgitation, and PVL can affect prosthetic valves implanted at both sites. (Ex. 1057, 1:14-21, 6:4-9; Ex. 1011, [00144]; Ex. 1003, ¶152.)

Further, adapting Spenser II's compressible material so that the proximal apices extend further than the material, as taught in Birdsall, would have merely entailed applying Spenser II's known technique for reducing PVL (adding an outer compressible material) and Birdsall's known positioning and sizing of the seal (leaving the apices uncovered) to Spenser's known valves, which were ready for improvement and would yield predictable results. *KSR Int'l Co. v. Teleflex*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶154.) Additionally, placement of Spenser II's compressible material presented a binary choice – either the material extends as far proximally as the apices, or it does not. (Ex. 1003, ¶154.) POSITAs would have

found it obvious to try both finite, predictable solutions based on Spenser II and Birdsall. (*Id.*)

Further, POSITAs would have been motivated to adopt the shorter material to reduce the overall amount of material and reduce the profile. (Ex. 1003, ¶¶155-156.) Nothing in Spenser II requires a compressible material that extends to the proximal apices or touts that positioning as important. (*Id.*) While “Figure 22 of Spenser II appears to depict the proximal edge of the outer seal extending to the proximal edge of the outer frame,” (Ex. 1121, 24), Spenser II is not limited to this embodiment. Nothing in Spenser II teaches away from Birdsall’s disclosure of a sealing material that does not cover the frame’s proximal apices. In fact, Spenser II describes frames with uncovered proximal apices (i.e., ring 172):

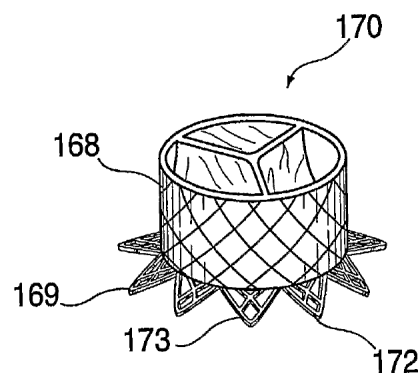


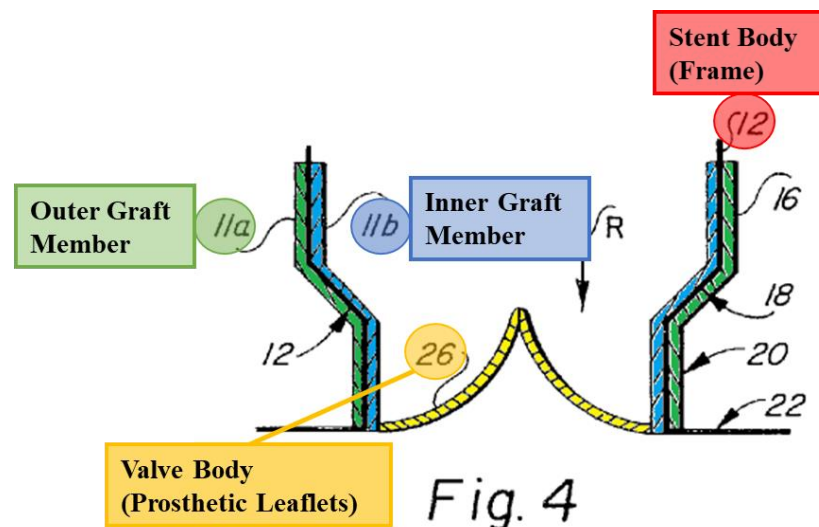
FIG. 17b

(Ex. 1011, Fig. 17b, [00136]-[00137].) Spenser II does not identify any drawbacks to the exposed apices and, therefore, would have given POSITAs additional

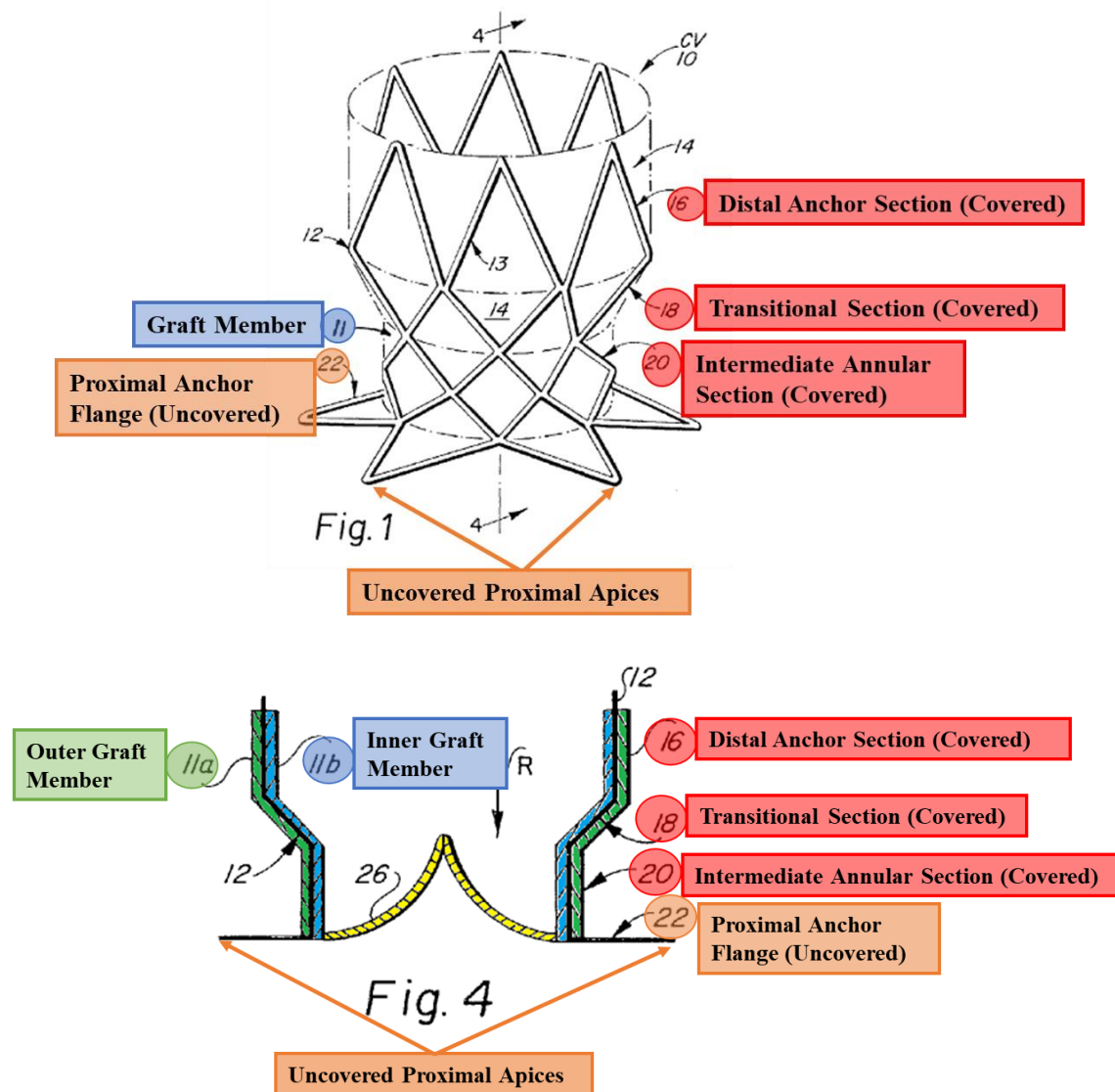
confidence that shortening Spenser II's outer cloth would not negatively impact the valve. (Ex. 1003, ¶156.)

iii. Spenser, Spenser II, and Bailey

Bailey discloses THVs having an outer graft member 11a secured to the frame's exterior surface and an inner graft member 11b secured to the frame's interior surface:



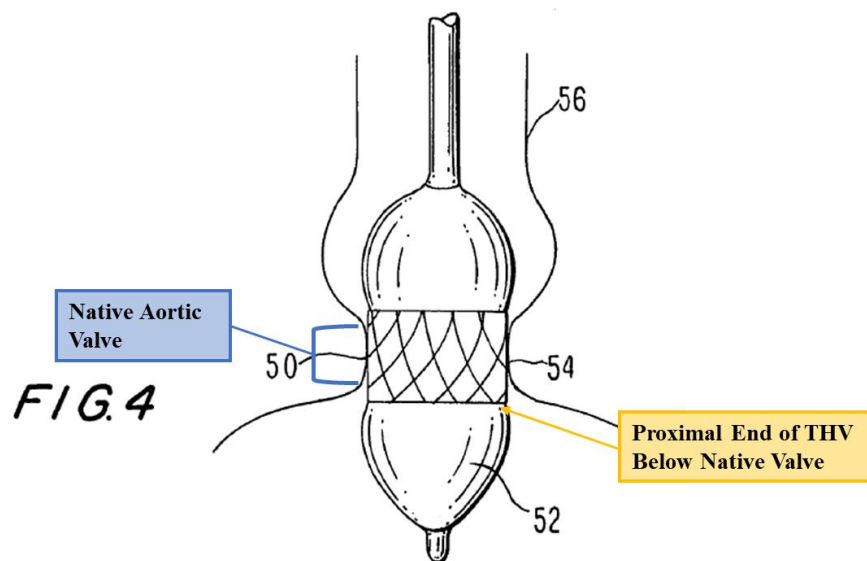
(Ex. 1141, [0048]-[0049].) Bailey discloses “the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member 12.” (*Id.*, [0052].) Bailey’s Figures 1 and 4 disclose embodiments wherein the inner and outer graft members extend over sections 16, 18, and 20 of the frame, but **not** the proximal apices:



(*Id.*, Figs. 1, 4; Ex. 1003, ¶157.)

Bailey’s instruction that “the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves” would have motivated POSITAs to position Spenser II’s compressible material over the portion of Spenser’s valve that overlaps with the native leaflets “in order to exclude the anatomic valves.” (Ex. 1141, [0052]; Ex.

1003, ¶¶158-159.) The proximal end of Spenser's frame does not overlap with the patient's native leaflets:



(Ex. 1010, 14:15-20, Fig. 4; Ex. 1003, ¶158.) Additionally, Spenser II discloses frames having projecting apices, like the frame in Bailey, and does not identify any drawbacks to that design. (*Supra* §VIII.A.1.g.i.) Accordingly, POSITAs would have recognized, based on Bailey, that Spenser II's compressible material would not need to cover the proximal ends of Spenser's frame to create an effective seal. (Ex. 1003, ¶¶157-159.) Additionally, POSITA's would have recognized that the shorter outer cloth would have reduced valve profile. (*Id.*)

The combination of Spenser's valve with Spenser II's compressible material according to Bailey would have merely entailed applying Spenser II's known technique for reducing PVL (adding an outer compressible material) and Bailey's

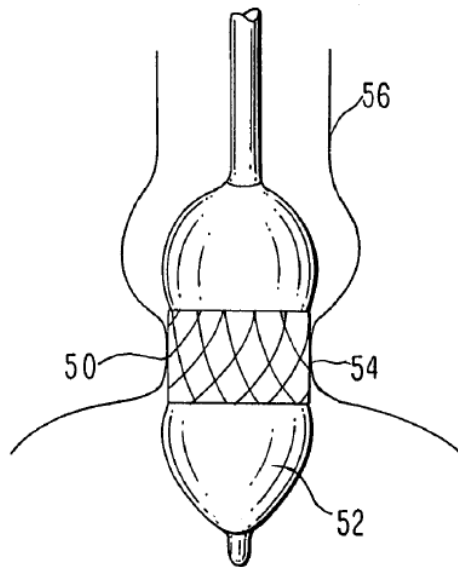
known technique for positioning the sealing material (overlapping the native leaflets and leaving the proximal apices uncovered) to Spenser’s known valves, which were ready for improvement and would yield predictable results. *KSR Int’l Co.*, 550 U.S. at 416; (Ex. 1003, ¶159.) Additionally, Bailey confirms that POSITAs found it obvious to position an outer seal to extend to, or not extend to, the frame’s proximal apices, as both arrangements were finite, predictable solutions. (*Supra* §VII.A.1.g.i; Ex. 1003, ¶159.)

h. 1.g-Fibers Compressed To Form Seal

Spenser and Spenser II render obvious this limitation. (Ex. 1003, ¶¶161-164.)

In prior IPRs, the Board found the combination of Spenser and Spenser II would press fibers against the patient’s native leaflets because POSITAs “reading Spenser II, would understand that, if the compressible material that is disposed along the outer surface of the stent extends entirely around the stent, then it would, necessarily, be in radial alignment with the native leaflets around the circumference of where the outer frame presses the native leaflets laterally.” (Ex. 1119, 83-86.) PO is estopped from challenging this finding. *Supra* §II.

The Board’s finding is correct. 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, at least two rows of the valve frame press against the patient's aortic annulus. (Ex. 1003, ¶163.) Although not shown in Figure 4, POSITAs would have understood the valve also presses against the patient's native leaflets, which are attached to the annulus and extend distally therefrom. (*Id.*) Spenser II's compressible material would extend over at least two rows of grids formed by Spenser's frame (*supra* §VII.A.1.e) and would thus press against and form a seal with the native valve leaflets when implanted. (Ex. 1003, ¶163.)

As explained above, POSITAs would have been motivated to use cloths having spacings for Spenser II's compressible material. (*Supra* §VII.A.1.f.) Spenser II teaches that "[t]he compressible material expands after deployment at a treatment site [and as] the compressible material expands, it fills the gaps between the stented

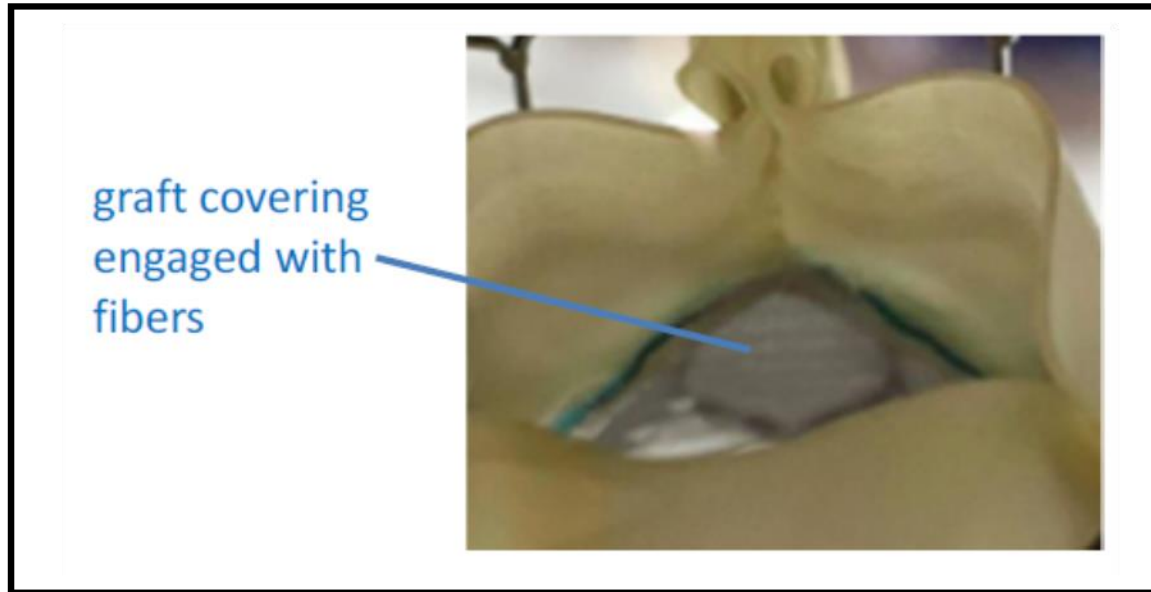
valve and the surrounding tissue” which “creates a mechanical seal that prevents paravalvular leakage.” (Ex. 1011, [00145].) POSITAs would have known the THV must fit tightly against the patient’s native valve to prevent PVL. (Ex. 1003, ¶164.) Thus, while some of the fibers of Spenser II’s compressible material would expand into the “gaps between the stented valve and the surrounding tissue,” the fibers would compress due to the tight fit between the native valve and the THV, creating the “mechanical seal that prevents paravalvular leakage.” (*Id.*; Ex. 1011, [00145].) The pressure from the surrounding tissue would cause Spenser II’s fibers to compress into the spacings between the fibers, reducing the spacings between the fibers and creating the paravalvular seal around the valve. (Ex. 1003, ¶164.)

i. 1.h-Graft Covering Engaged With Fibers

Spenser and Spenser II render obvious “wherein the graft covering is engaged with fibers of the plurality of fibers.” (Ex. 1003, ¶¶165-166.)

When Spenser II’s compressible material is added to Spenser’s valve, the fibers of the compressible material would press against and “engage” the graft covering through the open cells of the frame when the compressible material is pressed against the patient’s native tissue. (Ex. 1003, ¶166.) PO’s infringement contentions in the district court assert that such a configuration meets this limitation:

Patent Owner's Infringement Contentions



(Ex. 1123, 618-620.)

j. 1.i-Endovascularly Deployed

Claim 1 concludes with a statement of intended use that is not limiting. See *ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018). However, if the intended use is limiting, Spenser and Spenser II render this use obvious. (Ex. 1003, ¶¶167-175.)

In prior IPRs, the Board found that POSITAs would have expected the THV formed by combining Spenser's valve and Spenser II's compressible material could be delivered endovascularly. (Ex. 1117, 53-64; Ex. 1118, 57-68; Ex. 1119, 69-80.) The Board explained, "the 12F (4.0 mm) diameter of the valve taught by Spenser...is well within the maximum allowable diameter of 24F [for transfemoral delivery]

argued by [PO], such that [POSITAs] could reasonabl[y] understand that there would be sufficient additional space to accommodate the ‘compressible ... cloth or fabric,’ which Spenser II teaches can also be delivered endovascularly.” (Ex. 1117, 57.) Thus, the Board has already determined the combination of Spenser and Spenser II would be reasonably understood to have a crimped profile less than 24F, which would permit endovascular delivery through the femoral artery. (*See id.*) PO is estopped from challenging this finding. *Supra* §II.

Spenser describes “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.” (Ex. 1010, 2:6-12.) Spenser’s valve may be crimped to a small diameter of 4mm that is “suitable for percutaneous catheterization and deployment.” (*Id.*, 14:12-14, 27:67-28:2; *see also id.*, 5:17-6:36, 12:8-17, 12:28-36, 13:26-54, 17:19-18:43.) POSITAs would have understood Spenser’s disclosure of endovascular delivery through the femoral artery applies to the valve in Figure 44a because Spenser states the figure illustrates a “preferred embodiment of the present invention.” (Ex. 1010, 2:6-12, 26:30-34; Ex. 1003, ¶170.)

Similarly, Spenser II discloses “a series of new percutaneous concepts of paravalvular repairs.” (Ex. 1011, Abstract; *see also id.*, [0014].) Spenser II explains,

“[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.*, [0012].) Introduction of the valve through a small perforation in the groin area refers to, at least, endovascular delivery through the femoral artery. (Ex. 1003, ¶171.)

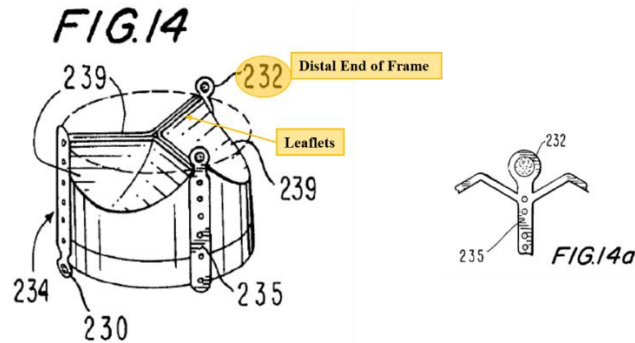
POSITAs would have reasonably expected Spenser's valve would remain suitable for endovascular delivery through the femoral artery after the addition of Spenser II's compressible material given Spenser's teaching that its valve can be crimped to 4mm and Spenser II's disclosure that the compressible material may have “a thickness ranging from about 1 to 5 mm” when the material is uncompressed. (Ex. 1003, ¶¶172-175; Ex. 1010, 27:67-28:2; Ex. 1011, [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. (Ex. 1003, ¶¶172-175; *see also* Ex. 1117, 57.) Additionally, POSITAs would have recognized Spenser II encompasses thin and highly compressible materials that will result in a low profile. (Ex. 1003, ¶¶172-175.) “This becomes particularly evident when one looks to the teachings of ... Norris.” (Ex. 1117, 58; Ex. 1118, 62.)

Norris discloses a fabric, suitable for sealing heart valves, which is compressible to enable “a small enough delivery catheter to reach a target implant site.” (Ex. 1074, 8:23-39.) Norris describes a fabric having an uncompressed thickness of 1 to 5 mm and explains, “In the compressed configuration 41, the fabric 10 can have a thickness 44 in the range of about 0.004–0.008 inches [0.102–0.203 mm]...[which] can allow the fabric 10 to be easily inserted into a delivery catheter along with an intraluminal medical device.” (*Id.*, 7:66-8:3.) Norris would have reinforced the reasonable expectation of success in endovascularly delivering Spenser’s valve with Spenser II’s compressible material through the femoral artery. (Ex. 1003, ¶¶172-175.)

2. Claim 2

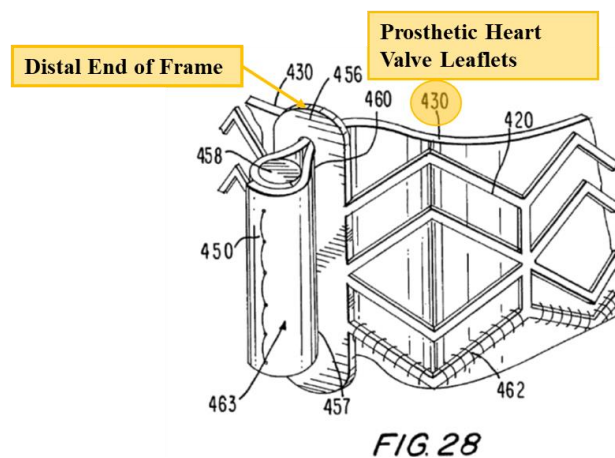
Spenser discloses this limitation. (Ex. 1003, ¶¶176-178.) In prior IPRs, PO did not challenge, and the Board found, that Spenser discloses this limitation. (Ex. 1119, 35, 89-90.) PO is estopped from challenging that finding. *Supra* §II.

Spenser illustrates valves having “heavy metal markers [232] on the stent,” which allow visualization of the device:



(Ex. 1010, 16:27-51, Figs. 14-14a.) The portion of the frame having the marker extends distally further than the leaflet assembly. (Ex. 1003, ¶177.) POSITAs would have been motivated to add markers to Figure 44a's stent to better visualize the stent during deployment and would have reasonably expected success in doing so because Spenser describes using the marker with a stent like Figure 44a and metal markers were common in the field by 2012. (*Id.*)

Spenser also illustrates a method of attaching the leaflets 430 to the frame 420 where the frame extends distally further than the leaflets:

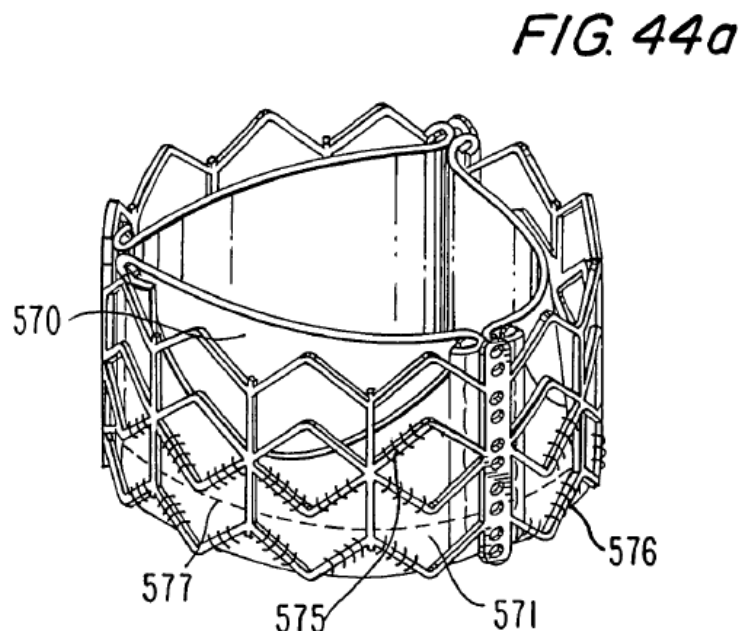


(Ex. 1010, 21:46-67, Fig. 28.) POSITAs would have been motivated to use this method with Figure 44a to reduce stress points and abrasion on the leaflets and would have reasonably expected success in doing so because Spenser discloses using the method with a valve like Figure 44a. (Ex. 1010, 21:60-67, Ex. 1003, ¶178.)

3. Claim 3

Spenser discloses this limitation. (Ex. 1003, ¶¶179-181.)

In prior IPRs, PO did not contest, and the Board found, that Spenser discloses this limitation. (Ex. 1119, 37, 89-90.) PO is estopped from challenging that finding. *Supra* §II. Spenser's Figure 44a shows that "frame 575" is a singular, integral component:

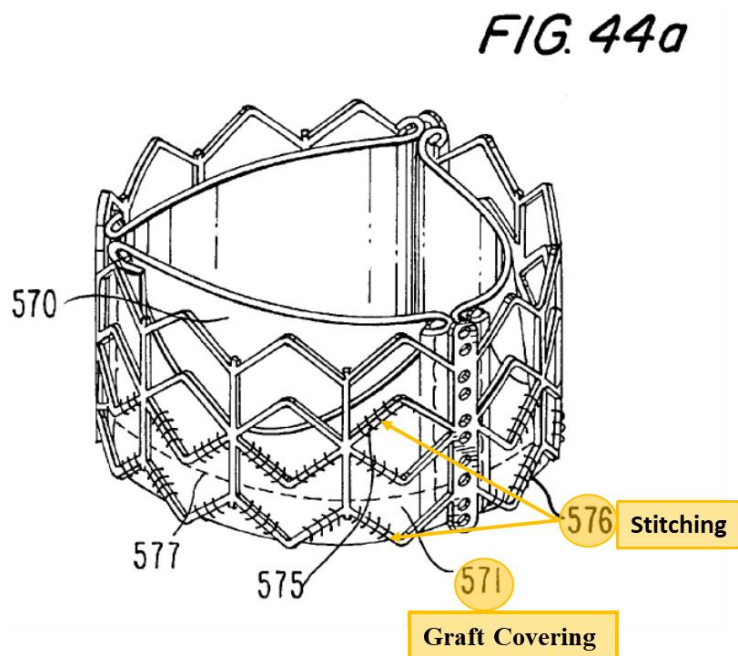


(Ex. 1010, 26:30-34, 19:5-13, Figs. 44a-44b; Ex. 1003, ¶181.)

4. Claim 4

Spenser discloses this limitation. (Ex. 1003, ¶¶182-183.) In prior IPRs, PO did not contest, and the Board found, that Spenser discloses this limitation. (Ex. 1119, 26, 37, 89-90.) PO is estopped from challenging that finding. *Supra* §II.

Spenser's PET 571 (graft covering) is attached to the frame with stitches at the top and bottom of PET 571:



(Ex. 1010, 16:45-48, Fig. 44a-b; Ex. 1003, ¶183.)

5. Claim 5

Spenser discloses this limitation. (Ex. 1003, ¶¶184-186.) In prior IPRs, PO did not contest, and the Board found, Spenser discloses this limitation. (Ex. 1119, 30, 89-90.) PO is estopped from challenging that finding. *Supra* §II.

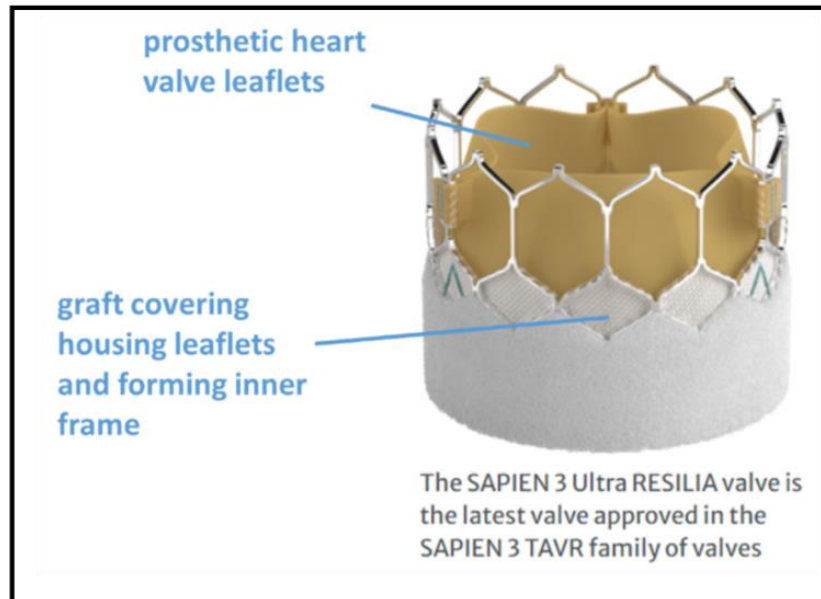
Spenser discloses that the valve depicted in Figure 44a “resembles the valve shown in Fig. 43.” (Ex. 1010, 26:34-35.) The valve in Figure 43 may be “inflated by a balloon[.]” (*Id.*, 26:19-28.) Thus, Figure 44a is also balloon expandable. (Ex. 1003, ¶185.) Spenser’s valves would remain balloon expandable after adding Spenser II’s compressible material because Spenser II discloses that the compressible material is combinable with balloon-expandable valves. (Ex. 1011, [00144]; Ex. 1003, ¶186.)

6. Claim 6

Spenser discloses this limitation. (Ex. 1003, ¶¶187-188.) In prior IPRs, the Board found Spenser discloses this limitation. (Ex. 1119, 25-26, 89-90.) PO is estopped from challenging that finding. *Supra* §II.

Spenser’s PET graft covering extends around and is attached to the prosthetic heart valve leaflets. (*Supra* §VII.A.1.b.) If a graft covering can be an inner frame, Spenser’s PET 571 forms an inner frame for housing the prosthetic heart valve leaflets. (Ex. 1003, ¶188.) PO’s infringement contentions in the district court litigation assert such a configuration meets this limitation:

Patent Owner's Infringement Contentions



(Ex. 1123, 636-639.)

7. **Claim 7**

Spenser and Spenser II, and optionally Birdsall *or* Bailey, render obvious this limitation as explained in claim 1. *Supra* §VII.A.1.j.

8. **Claim 9**

Spenser and Spenser II, and optionally Birdsall *or* Bailey, render obvious this limitation. (Ex. 1003, ¶¶190-191.)

PET 571 in Spenser's Figures 44a-b does not cover the most distal row of cells:

FIG. 44a

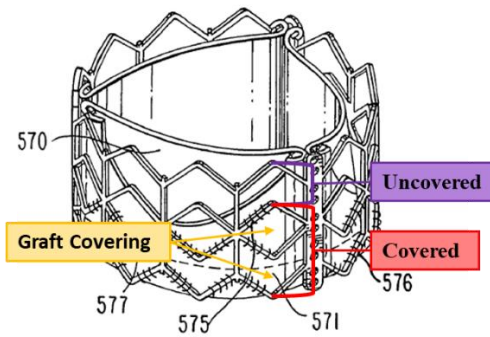
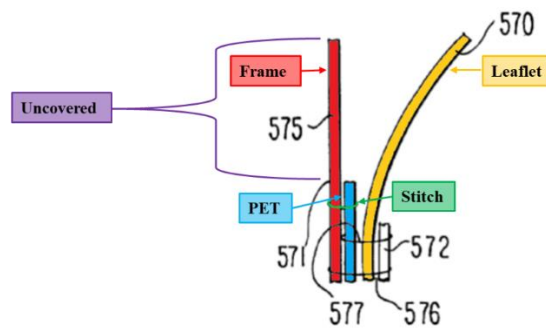
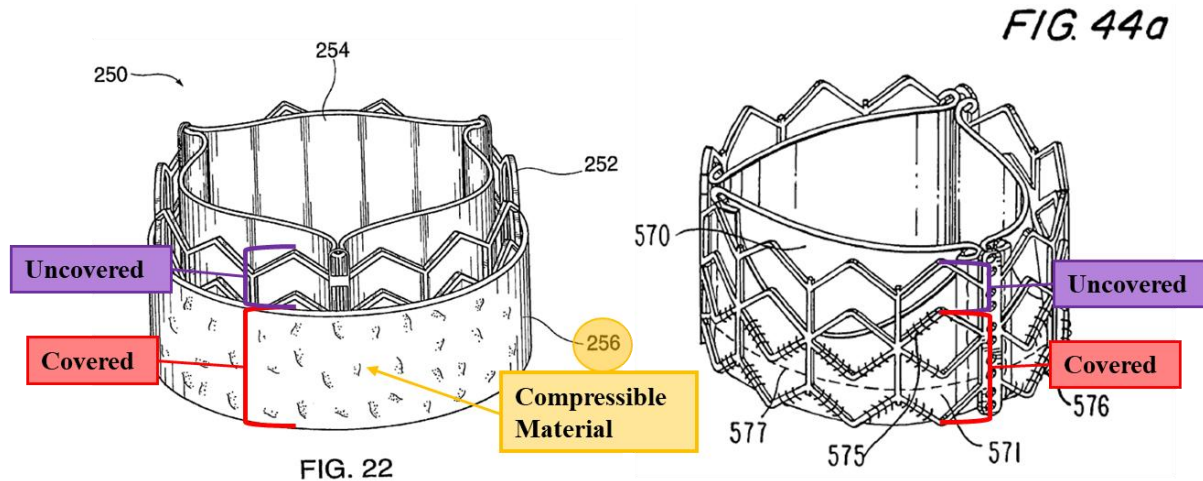


FIG. 44b



(Ex. 1010, Fig. 44a-b.) Spenser II's compressible material also does not cover the most distal row of cells and would similarly not cover the most distal row of cells when added to Spenser's valve:



(Ex. 1011, Fig. 22; Ex. 1010, Fig. 44a; Ex. 1003, ¶191.)

B. Ground 4: Claims 1-7, 9 Obvious Over Spenser and Birdsall

1. Claim 1

Spenser and Birdsall render claim 1 obvious. (Ex. 1003, ¶¶192-216.)

a. 1.P-Preamble

If the preamble is limiting, Spenser discloses this limitation. (*Supra* §VII.A.1.a.)

b. 1.a-Graft Covering

Spenser discloses this limitation. (*Supra* § VII.A.1.b.)

c. 1.b-Frame

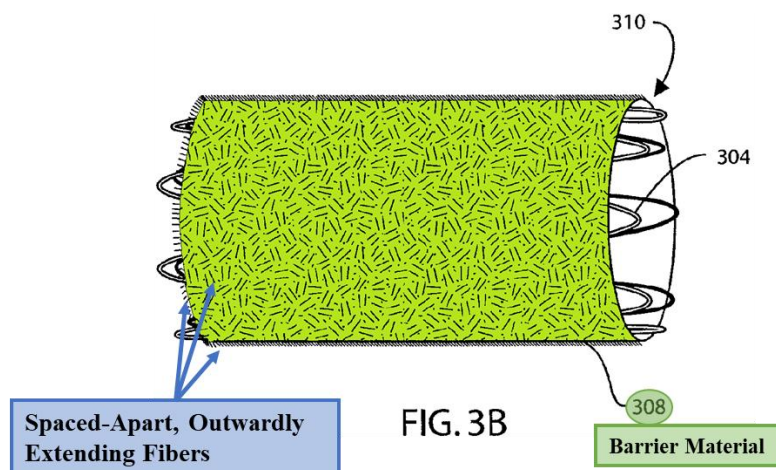
Spenser discloses this limitation. (*Supra* § VII.A.1.c.)

d. 1.c-Polymeric Graft Covering

Spenser discloses this limitation. (*Supra* § VII.A.1.d.)

e. 1.d-Plurality of Fibers

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶197-203.) Birdsall discloses THVs having a barrier material attached to the frame's exterior. (Ex. 1057, 6:4-65.) The barrier material may include (1) “directionally oriented microfibers attached to the surface of stented valve 310 and extending outward,” (2) microfibers “attached to a thin, pliable film or fabric,” or (3) a polyester batting comprised of a “disordered array of polyester microfibers that forms a soft, compressible mass.” (Ex. 1057, 6:10-65.) As shown, the barrier material's fibers are “spaced apart” and “outwardly extending”:



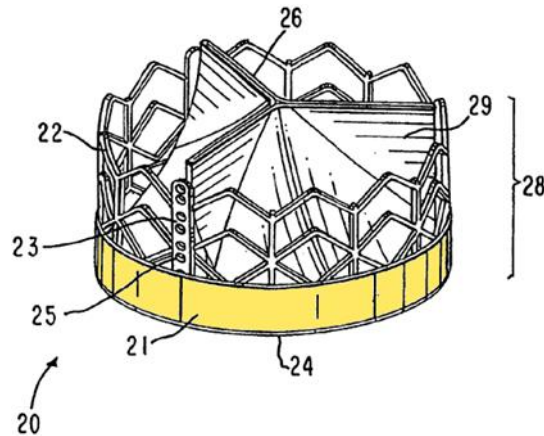
(*Id.*, Fig. 3B; Ex. 1003, ¶198.)

Birdsall discloses that the barrier material is “flexible,” and the microfibers may be made of flexible materials including polyester and nylon, or may form a “soft, compressible mass” of “batting” material formed from a “disordered array of

polyester microfibers.” (Ex. 1057, 6:15-17, 6:56-65.) Given the materials, POSITAs would have expected “arcuate” microfibers, particularly upon implantation when the microfibers are compressed against the native valve. (Ex. 1003, ¶199.)

POSITAs would have been motivated to add Birdsall’s barrier material to Spenser’s valves to prevent PVL and valve migration. (*Id.*, ¶¶200-203.) The Board previously concluded that POSITAs would have been motivated to add a sealing material to Spenser’s valves to reduce PVL, and that same motivation would have applied to Birdsall’s barrier material. (Ex. 1117, 64; *see also* Ex. 1118, 68; Ex. 1119, 80-81.) Birdsall’s barrier material helps prevent valve migration and PVL by filling gaps between the valve and the irregular, asymmetrical surface of a calcified treatment site. (Ex. 1057, 6:4-65, 7:29-44.) POSITAs would have recognized Birdsall’s material would similarly benefit Spenser’s valves. (Ex. 1003, ¶200; *Supra* §VII.A.1.e.)

Moreover, Spenser already discloses embodiments having a sealing cuff at the valve’s proximal end:



(Ex. 1010, 13:22-25, Fig. 1.) However, Spenser II disclosed that these valves could still benefit from further PVL prevention. (Ex. 1011, [0009]-[0010].) POSITAs would have been motivated to add, and reasonably expected success in adding, Birdsall's barrier material to the exterior of Spenser's valves to leverage Birdsall's benefits of reducing PVL and preventing migration. (Ex. 1003, ¶200.) Further, adding Birdsall's compressible material to Spenser's valves would have merely entailed applying Birdsall's known technique for reducing PVL (a barrier material) to Spenser's known valves, which were ready for improvement and would yield predictable results. *KSR Int'l Co.*, 550 U.S. at 416; (Ex. 1003, ¶201.)

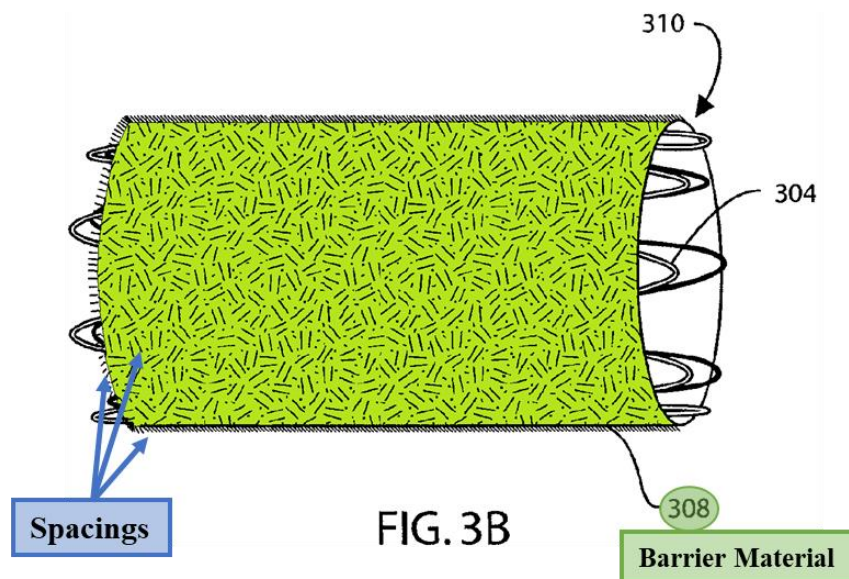
POSITAs would have been motivated to position Birdsall's barrier material over at least two rows of cells at the inflow end of Spenser's valves to ensure the barrier material filled the gaps between the valve and the calcified native leaflets and because the prior art taught that covering the proximal two rows of cells on similar

valves was effective for preventing PVL. (Ex. 1003, ¶202; Ex. 1007, Fig. 1; Ex. 1011, Fig. 22.)

The fibers of Birdsall's barrier material would be "in contact" with a plurality of rows of open cells at the inflow end of Spenser's frame. (Ex. 1003, ¶203.) Birdsall describes several types of barrier material, including materials having "directionally oriented microfibers attached to the surface of stented valve 310 and extending outward." (Ex. 1057, 6:12-14.) These fibers are attached to and, therefore, "in contact" with the frame. (Ex. 1003, ¶203.) Birdsall also discloses barrier materials formed of "directionally oriented microfibers" attached to the frame, where the microfibers may be woven into "a fabric of woven polyester fibers such as Dacron® fibers." (Ex. 1057, 6:12-27.) In such embodiments, the outwardly extending microfibers would be woven through the base layer and in direct contact with the frame as explained previously. (*Supra* §VII.A.1.e.) Birdsall also discloses barrier materials formed of "polyester batting adhered to the exterior surface" of the valve. (Ex. 1057, 6:56-65.) The fibers of the batting are in direct contact with the outer surface of the stent. (Ex. 1003, ¶203.)

f. 1.e-Fibers Spaced Apart

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶204-207.) Birdsall's figures illustrate spacings between the barrier material's fibers:



(Ex. 1057, Fig. 3B.) Figure 3B appears to show Birdsall’s embodiment where the directionally oriented microfibers are attached to a woven cloth or other material. (Ex. 1057, 6:17-27.) As discussed previously, POSITAs would have been motivated to select cloths having spacings in the fibrous and base layer that allow fluid to pass therethrough in an uncompressed state. (*Supra* §VII.A.1.e; Ex. 1003, ¶¶205-206.) Additionally, PO acknowledged during prosecution that spacings exist between the fibers in all cloths. (Ex. 1002, 222.)

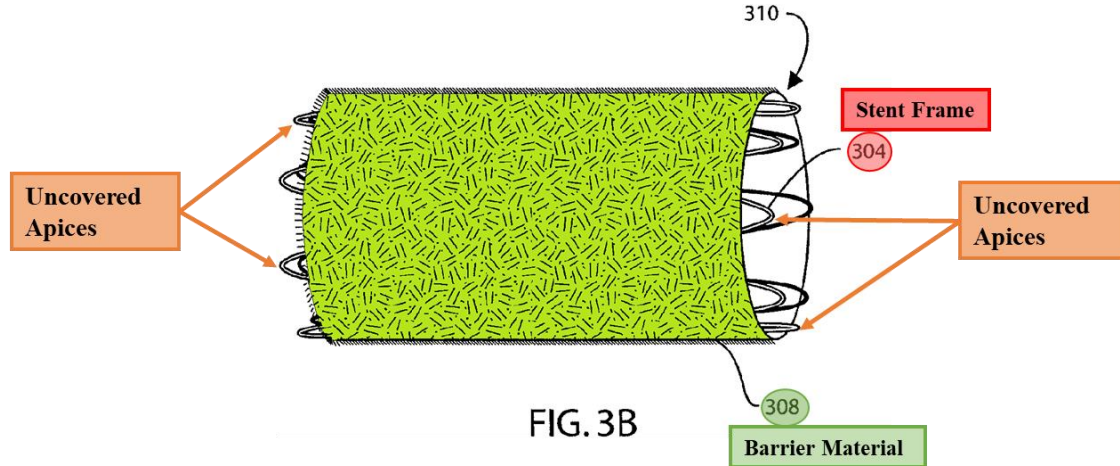
Birdsall also describes embodiments having “directionally oriented microfibers attached to the surface of stented valve 310 and extending outward.” (Ex. 1057, 6:12-14.) In such embodiments, the spacings between the “directionally oriented microfibers” extend to the outer surface of the frame because the fibers are attached directly to the frame. (Ex. 1003, ¶¶205-206.)

Birdsall also discloses barrier materials comprised of polyester batting adhered to the outer surface of the frame that “is a disordered array of polyester microfibers that forms a soft, compressible mass” that “expands and presses against the wall of the conduit” when implanted to form a seal. (Ex. 1057, 6:56-65.) POSITAs would have been motivated to select polyester batting that included spacings between the fibers so that the batting was “compressible” and could expand when implanted. (*Supra* §VII.A.1.f; Ex. 1003, ¶207.) At least some of the spacings between the fibers of the batting would extend to the outer surface of the frame because Birdsall discloses that the batting is adhered directly to the exterior surface of the frame. (Ex. 1057, 6:56-58; Ex. 1003, ¶207.)

Figure 3B suggests that the spacings between Birdsall’s fibers are large enough to be visible. Such spacings would be sufficiently large to allow fluid to pass therethrough when the barrier material is in an uncompressed state. (Ex. 1003, ¶205.) Moreover, POSITAs would have been motivated to select barrier materials with spacings large enough for fluid to pass therethrough for the reasons explained in Grounds 1-3. *Supra* §VII.A.1.e.

g. 1.f-Uncovered Apices

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶208-209.) Birdsall’s barrier material does not cover the valve’s apices at either end:



(Ex. 1057, Fig. 3B.) Birdsall would have motivated POSITAs to add Birdsall's barrier material to Spenser's valve such that the most proximal apices of Spenser's frame are uncovered by the barrier material and extend proximally further than the barrier material for the reasons explained in Grounds 1-3. (*Supra* §VII.A.1.g.ii; Ex. 1003, ¶209.)

h. 1.g-Fibers Compressed To Form Seal

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶210-211.) Birdsall discloses that the barrier material's fibers fill in the gaps between the valve and the calcified treatment site by pressing against the wall to form a seal and prevent valve migration. (Ex. 1057, 6:28-37, 6:56-65, 7:36-44.) The valve must create a tight fit with the native tissue to avoid migration, which would compress the fibers of the barrier material. (*Supra* §VII.A.1.h; Ex. 1003, ¶211.) Therefore, when the barrier material is added to Spenser's valve and the valve is implanted in a patient's

native aortic valve, the spaced-apart fibers of the barrier material would be “compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings.” (*Id.*)

i. 1.h-Graft Covering Engaged With Fibers

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶212-213.) Spenser discloses a graft covering secured to the inner surface of a frame having a plurality of open cells. (*Supra* §VII.A.1.b-c.) When Birdsall’s barrier material is added to Spenser’s valve, the fibers of the barrier material would press against and “engage” the graft covering through the open cells of the frame when the compressible material is pressed against the patient’s native tissue. (Ex. 1003, ¶213; *supra* §VII.A.1.i.)

j. 1.i-Endovascularly Deployed

Spenser and Birdsall render this limitation obvious. (Ex. 1003, ¶¶214-216.) Spenser discloses an endovascularly deployable valve. (*Supra* §VII.A.1.j.) POSITAs would have reasonably expected Spenser’s valve to remain suitable for endovascular delivery via the femoral artery after the addition of Birdsall’s barrier material. (Ex. 1003, ¶¶215-216.) Birdsall discloses that its stented valve can be percutaneously delivered “through the venous system and into a patient’s right

ventricle” via the jugular vein, the subclavian vein, the femoral vein, or the common iliac vein. (Ex. 1057, 5:37-51, 7:45-67.) Birdsall also discloses that its invention is suitable for use with valves which may be transfemorally implanted in a patient’s native aortic valve. (*Id.*, 5:65-6:3; Ex. 1035, 9:63-10:21, Fig. 3; Ex. 1003, ¶216.) Birdsall also discloses that the barrier material is “flexible” and “compressible.” (Ex. 1057, 6:9-12, 6:56-65.) Therefore, POSITAs would have reasonably expected there would be sufficient space on Spenser’s 12F compressed valve to accommodate Birdsall’s flexible, compressible material and remain suitable for endovascular delivery via the femoral artery. (*Supra* §VII.A.1.j; Ex. 1003, ¶216.) Moreover, because the ’634 patent does not disclose how to arrange the fibers to make the valve suitable for endovascular delivery, PO cannot argue that the selection of materials and adaptation of the compressible material for such delivery would have been beyond the skill of POSITAs. *See e.g., Smith & Nephew, Inc.*, 721 F.3d at 1380-81.

2. Claims 2-7

Spenser discloses the limitations of claims 2-7. *Supra* §VII.A.2-7. Accordingly, Spenser and Birdsall render claims 2-7 obvious. (Ex. 1003, ¶217.)

3. Claim 9

Spenser and Birdsall render claim 9 obvious. (Ex. 1003, ¶¶218-219.) Spenser discloses embodiments wherein the most distal row of cells are uncovered by the

graft covering. *Supra* §VII.A.8. POSITAs would have been motivated to position Birdsall's barrier material on Spenser's valves such that the most distal row of cells is uncovered by the barrier material to ensure that the barrier material does not obstruct the coronary arteries when the valve is implanted, and to limit the amount of material around the valve. (Ex. 1003, ¶219.) Moreover, the prior art, including Walther and Spenser II, taught such an arrangement created an effective seal on similar THVs. (*Id.*; Ex. 1007, Fig. 1; Ex. 1011, Fig. 22.) In such a configuration, the most distal row of cells of Spenser's frame would be uncovered by the graft covering and the outwardly extending fibers. (Ex. 1003, ¶219.)

C. Grounds 5-6: Claims 1-7, 9 Obvious Over Spenser and Chuter in Combination with Birdsall *or* Bailey

1. Claim 1

Spenser and Chuter in combination with Birdsall *or* Bailey render claim 1 obvious. (Ex. 1003, ¶¶223-258.)

a. 1.P-Preamble

If the preamble is limiting, Spenser discloses this limitation. *Supra* §VII.A.1.a.

b. 1.a-Graft Covering

Spenser discloses this limitation. *Supra* §VII.A.1.b.

c. **1.b-Frame**

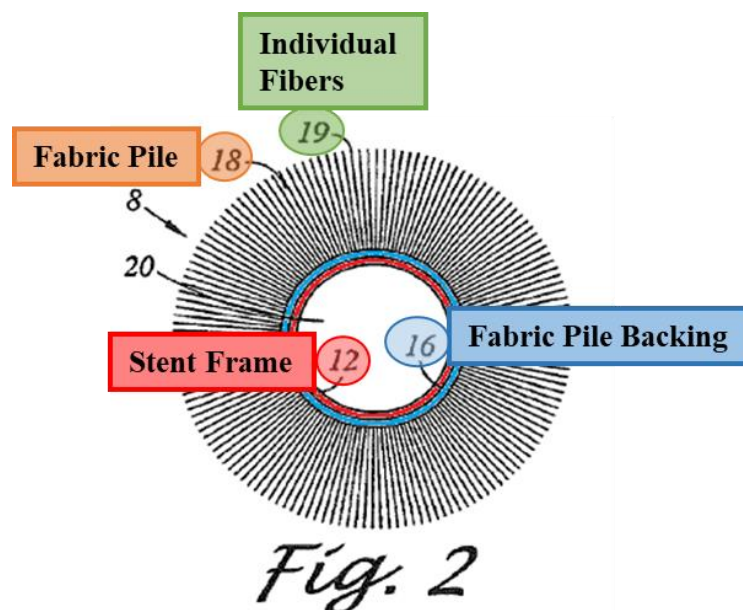
Spenser discloses this limitation. *Supra* §VII.A.1.c.

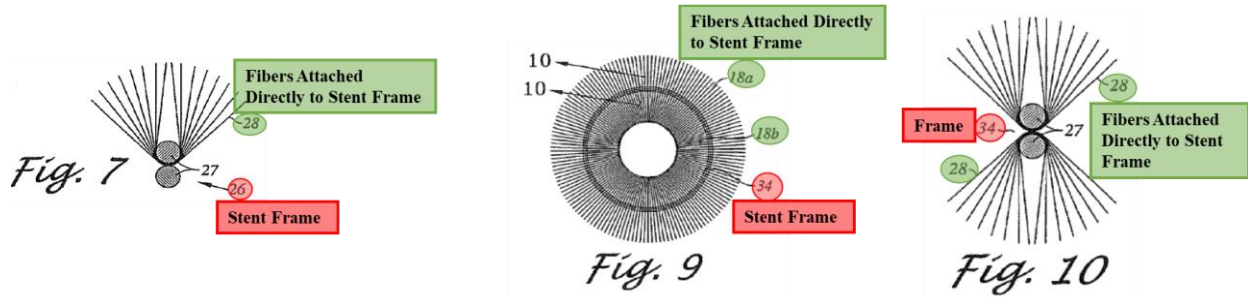
d. **1.c-Polymeric Graft Covering**

Spenser discloses this limitation. *Supra* §VII.A.1.d.

e. **1.d-Plurality of Fibers**

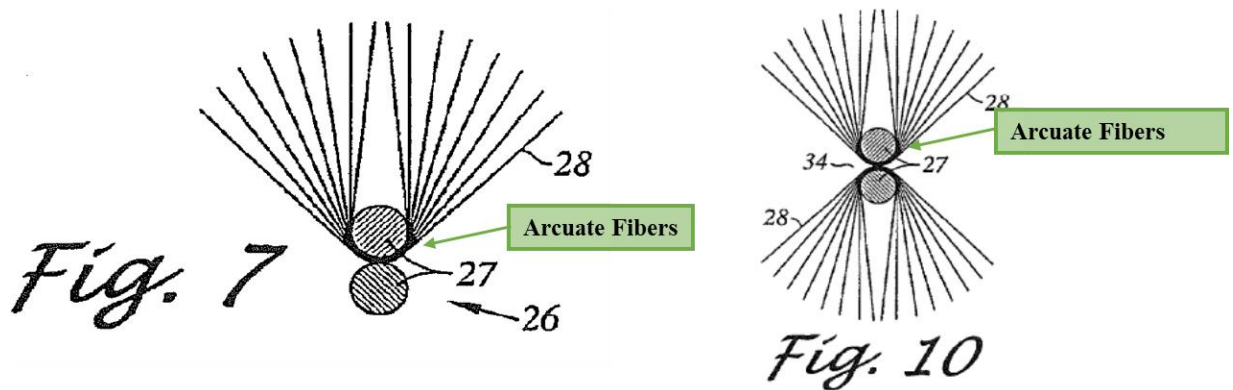
Chuter discloses embodiments of endovascularly-delivered intravascular stents having a “fiber pile” made of individual fibers that are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” (Ex. 1116, [0017]-[0022], Figs 1-10.) The individual fibers of the “fiber pile” extend outwardly from a “fabric pile backing” 16 (Fig. 2) or directly from the frame (Figs. 7, 9-10) and are spaced apart.





(*Id.*, [0054]-[0057], Figs. 1-10.)

In the embodiments without a fabric pile backing, the fibers curve around the stent frame and are arcuate:

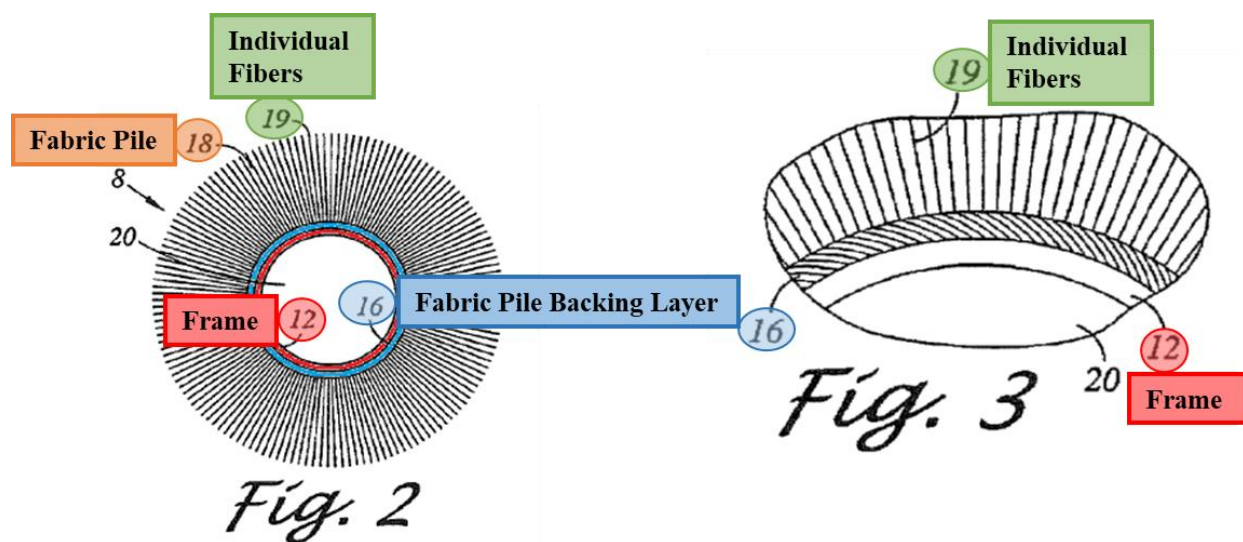


(*Id.*, Figs. 7, 10; Ex. 1003, ¶230.) In the embodiments having a backing, the outwardly extending fibers would be arcuate at least where they are secured to the backing because the fibers are woven or knitted into and around the backing. (*Id.*, ¶231; *supra* §VII.A.1.e.)

Chuter also discloses the “fibers of the fiber pile are biocompatible fibers which are known to the art” and may “include nylon fibers, polyester fibers, Mylar brand fibers and the like” and further teaches the fibers are flexible and get “push[ed] down” when the device is crimped. (Ex. 1116, [0022], [0062].) POSITAs would

therefore have understood that while Chuter's figures illustrate straight portions of fibers, not all (and likely none) of the fibers would have been perfectly straight, and at least some of the flexible fibers would be arcuate, particularly when compressed in the patient. (Ex. 1003, ¶232.)

The fibers of the fiber pile are also “in contact” with the frame. Chuter’s embodiments having a “fabric pile backing” include “a fabric pile 18 made up of individually extending fibers 19” that extend “circumferentially outwardly from the backing.”



(Ex. 1116, [0054]-[0055], Figs. 2-3.) The “fabric pile backing” is composed of fibers, as illustrated in Chuter’s Figure 3. (*Id.*, Fig. 3; Ex. 1003, ¶234.) Such a configuration was known in the art, as taught by Norris.

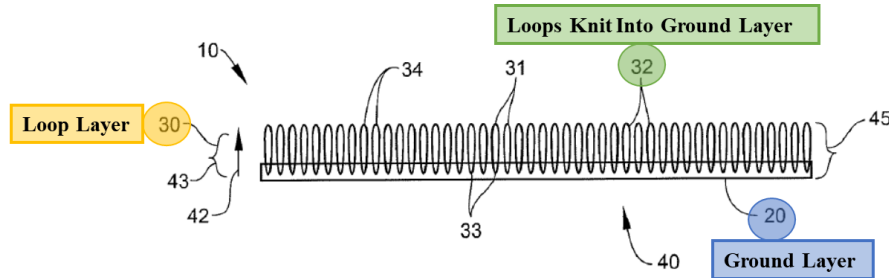
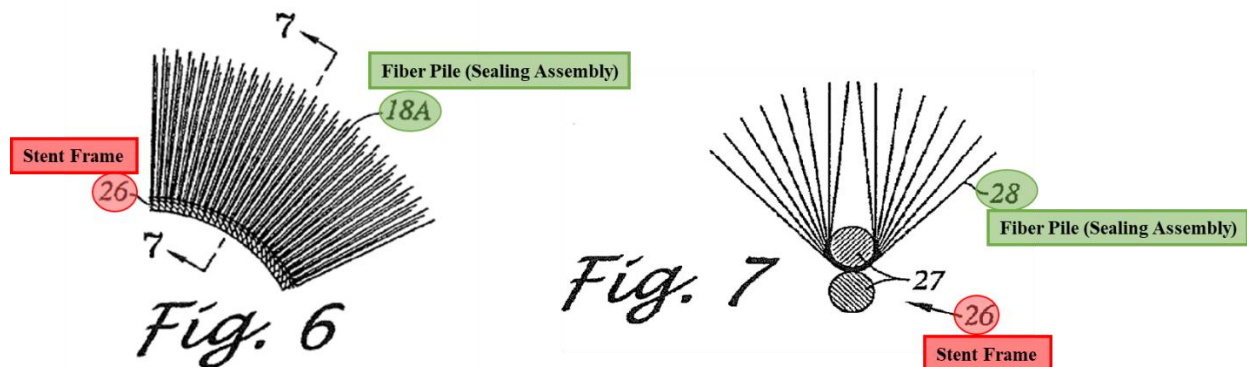


Fig. 1

(Ex. 1074, 4:22-26, Fig. 1.) The fibers of Chuter’s fabric pile backing are in contact with the frame. (Ex. 1116, Figs. 2-3; Ex. 1003, ¶234.) Moreover, as explained previously for Spenser II, POSITAs would have understood the individual fibers extending from Chuter’s fabric pile backing are woven or knitted through the backing, consistent with numerous examples in the prior art. (*Supra* §VII.A.1.e; Ex. 1003, ¶235.) Accordingly, even if this limitation requires the outwardly extending fibers to directly contact the frame, the fibers extending from Chuter’s backing meet this requirement. (*Id.*)

Chuter also discloses embodiments without the “backing,” where outwardly extending fibers are attached directly to the frame:



(Ex. 1116, [0056]-[0057], Figs. 5-10.) The fibers in these embodiments are in contact with the frame. (Ex. 1116, [0057], Figs. 6-7; Ex. 1003, ¶236.)

POSITAs would have been motivated to add Chuter's fiber pile to Spenser's valve to prevent PVL. (Ex. 1003, ¶¶237-243.) Chuter's fiber pile is "adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel" and also "fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel." (Ex. 1116, [0012]-[0013], [0017]-[0020], [0064].) These functions would have also benefited Spenser's THV, which Spenser II described as requiring additional sealing. (Ex. 1011, [0009]-[0010]; Ex. 1003, ¶237.)

Moreover, POSITAs had a finite number of predictable ways to arrange fibers on the outside of a frame to prevent PVL. Chuter describes two of the finite ways: a cloth with a backing or fibers attached directly to the frame. Birdsall identifies the third option: a batting material. (Ex. 1057, 6:56-65.) A POSITA would have found it obvious to try these finite, predictable solutions on Spenser's frame. Further, modifying Spenser's valve to include Chuter's fibers would have merely entailed applying Chuter's known technique for reducing PVL (fiber pile) to Spenser's

known valves, which were ready for improvement and would yield predictable results. *KSR Int'l Co.*, 550 U.S. at 416; (Ex. 1003, ¶237.)

In a related IPR, PO argued that POSITAs would not have been motivated to combine Chuter's fibers without a backing with Spenser because Chuter describes the embodiments in the context of an occluder. (Ex. 1142, 57-72.) PO fails to give appropriate weight to the knowledge and ordinary creativity of a POSITA. POSITAs would have recognized that Chuter's fiber pile would help prevent PVL when added to a THV and they would have possessed the necessary skills and ordinary creativity to adapt the fiber pile so that the fibers would not occlude the opening of the THV. (Ex. 1003, ¶243.) PO also ignores that Chuter's occluders seal off the vessel by having inwardly extending fibers that extend across nearly the entire diameter of the frame. (See Ex. 1116, Fig. 8.) However, Spenser's Fig. 44a includes inner PET 571 attached to the frame, which would block any inwardly extending fibers from spanning the THV. (Ex. 1003, ¶243.) Moreover, Chuter does not restrict the fiber pile embodiments to occluders and POSITAs would have recognized the broader applications of the fibers, particularly given the use of similar sealing materials to seal THVs in the prior art. (Ex. 1003, ¶243; Ex. 1011, [00145]; Ex. 1057, 6:56-65.)

In the same IPR, PO also argued that POSITAs would not reasonably expect success in adding Chuter’s fiber pile without a backing to Spenser’s valves because Spenser’s frame is not formed from helically wound double wire strands. (Ex. 1142, 63-67.) However, PO ignores that Chuter discloses using the fiber pile with a range of frames. (Ex. 1116, [0003].) POSITAs would have reasonably expected success in adding Chuter’s fiber pile to Spenser’s valve for several reasons. Chuter discloses that the fibers can be used on self-expanding or balloon expandable frames. (*Id.*) Indeed, Chuter discloses using the “present invention” with the same balloon-expandable frames described in the ’634 patent. (*See id.* (incorporating U.S. Pat. No. 4,739,762); Ex. 1001, 7:46-53 (incorporating U.S. Patent No. 5,102,417, a continuation-in-part of the ’762 patent); Ex. 1127; Ex. 1126.) Chuter also discloses “[v]irtually any expanding stent can be used” with the disclosed fiber pile embodiments. (Ex. 1116, [0012].) Thus, while some of Chuter’s embodiments illustrate frames of helically wound double wire strands, Chuter’s broad disclosure is not limited to helical frames, and Chuter teaches, and POSITAs would have reasonably expected success in, adding Chuter’s fiber pile to other types of frames such as the frame in Spenser. (Ex. 1003, ¶¶237-240, 244.)

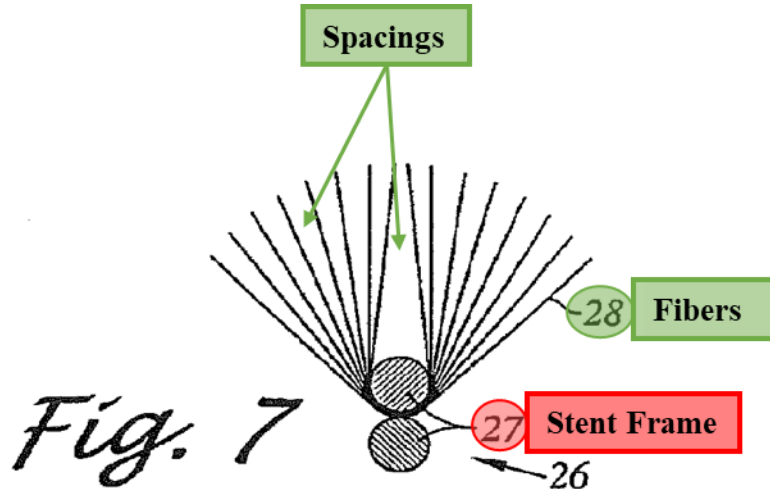
PO also ignores that the ’634 patent never discloses how its fibers are attached to the frame, and thus presumes POSITAs knew how to attach individual fibers to a

THV frame. (See Ex. 1001, 12:53-56.) Indeed, PO’s expert in prior IPR proceedings admitted the patent specification does not provide “an explicit description of how [the fibers] are attached or secured other than stating that they are attached and secured, and the assumption is that that would be by known biomedical engineering methods.” (Ex. 1073, 313:18-314:1.) Consequently, PO cannot assert it would have been beyond the skill of POSITAs to use “known biomedical engineering methods” to attach Chuter’s fiber pile to Spenser’s frame. See *e.g.*, *Smith & Nephew, Inc.*, 721 F.3d at 1380.

Spenser also discloses a frame with open cells. (*Supra* §VII.A.1.c.) POSITAs would have been motivated, and found it obvious, to position Chuter’s fiber pile over at least two rows of cells on Spenser’s valves. (Ex. 1003, ¶242.) POSITAs would have been motivated to do so to ensure the fibers press against the patient’s diseased native aortic leaflets and form a seal between the native leaflets and THV. (*Id.*) In such a configuration, Chuter’s fibers would be “in contact with a plurality of rows of open cells at the inflow end of the frame” of Spenser’s valve. (*Id.*)

f. 1.e-Fibers Spaced Apart

Chuter discloses this limitation in two ways. In the embodiments without a backing, spacings exist between the fibers that extend from the outermost aspect of the fibers to the outer surface of the frame:

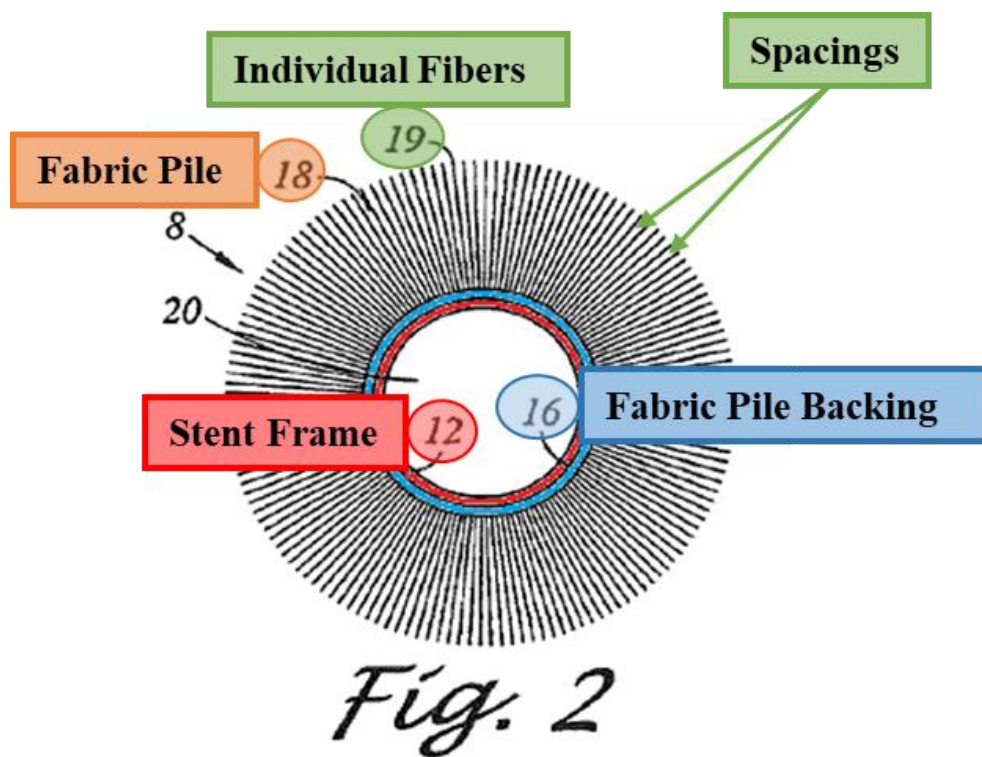


(Ex. 1116, Fig. 7; Ex. 1003, ¶247.) The visible spacings illustrated between the fibers would allow fluid to pass therethrough when the fiber pile is added to Spenser’s uncompressed THV. (Ex. 1003, ¶249.)

In the embodiments having a fabric pile backing, POSITAs would have found it obvious to include sufficiently large spacings between the fibers to allow fluid to pass through to maximize compressibility and tissue ingrowth. (Ex. 1003, ¶248.) Porous cloths were well known in the prior art. (*Id.*) For example, Norris discloses a compressible, resilient cloth for sealing medical devices, including prosthetic heart valves, that includes a “ground layer 20 of knitted yarn, and a loop layer 30 comprising a plurality of loops 32 of yarn 31, each loop 32 having a point 33 knit into the ground layer 20.” (Ex. 1074, 4:22-26.) Norris teaches the “the ground layer 20 can have a porosity that can provide some space into which the loops 32 can be compressed.” (*Id.*, 12:45-48.) Norris thus expressly teaches a ground layer having

spacings between adjacent fibers. (Ex. 1003, ¶248.) POSITAs would have been motivated to incorporate similar spacings into Chuter's backing to enhance compressibility. (*Id.*)

As illustrated below, Chuter's fiber pile includes spacings between the individually extending fibers extending from the outermost aspect of the fibers to the fabric pile backing:



(Ex. 1116, Fig. 2; Ex. 1003, ¶¶247-248.) Because Chuter's fabric pile backing is attached directly to the frame, at least some of the spacings between the fibers would further extend through the porous backing to the frame's outer surface. (Ex. 1003, ¶¶247-248.)

g. 1.f-Uncovered Apices

Spenser and Chuter in combination with Birdsall or Bailey render this limitation obvious. (Ex. 1003, ¶250.) POSITAs would have been motivated by Birdsall and Bailey to place Chuter's fiber pile on Spenser's valve such that the proximal apices are uncovered by the fiber pile and extend proximally further than the fiber pile for the same reasons explained in Grounds 1-3. *Supra* §VII.A.1.g.

h. 1.g-Fibers Compressed To Form Seal

Chuter discloses fibers that “press against the inner luminal wall of the arterial system to form a seal” when the stent is implanted. (Ex. 1116, [0059].) When Chuter's fiber pile is added to Spenser's THV, the fiber pile would press against the patient's native aortic leaflets when the THV is implanted, compressing the fibers into the spacings between the adjacent fibers and forming a paravalvular seal around the valve for the same reasons explained in Grounds 1-3. (*Supra* §VII.A.1.h; Ex. 1003, ¶¶251-252.)

i. 1.h-Graft Covering Engaged With Fibers

When Chuter's fiber pile is added to Spenser's valves, the fibers of the fiber pile would engage the inner graft covering through the open cells of the frame for the same reasons explained in Grounds 1-3. (*Supra* §VII.A.1.i; Ex. 1003, ¶¶253-254.)

j. 1.i-Endovascularly Deployed

Spenser discloses this limitation. (*Supra* §VII.A.1.j.) POSITAs would have reasonably expected Spenser’s THVs would remain suitable for endovascular delivery through the femoral artery after adding Chuter’s fiber pile. (Ex. 1003, ¶255-258.)

Chuter’s fiber pile is employed on endovascularly delivered vascular stents which are “delivered through catheters” inserted into the patient through “a distal branch of the arterial system” that “will normally be one of the arteries in the legs or in the arms.” (Ex. 1116, [0062].) POSITAs would have understood the femoral artery is one of the referenced arteries in the leg. (Ex. 1003, ¶257.) Chuter further discloses that the stents are compressed in a catheter and the “compression compresses the stent and pushes down the fabric pile” to allow for endovascular delivery. (Ex. 1116, [0062].) POSITAs would have reasonably expected Chuter’s compressible fabric pile would be compressed down when added to Spenser’s THV and placed in a catheter, allowing for endovascular delivery of the valve through the femoral artery. (Ex. 1003, ¶¶257-258.)

2. Claims 2-7

Spenser discloses the limitations of claims 2-7. *Supra* §VII.A.2-7. Accordingly, Spenser and Chuter in combination with Birdsall *or* Bailey renders claims 2-7 obvious. (Ex. 1003, ¶259.)

3. Claim 9

Spenser discloses valves where the most distal row of cells is uncovered by the graft covering. *Supra* §VII.A.8. POSITAs would have been motivated to position Chuter's fiber pile on Spenser's valves such that the most distal row of cells is uncovered by the fiber pile for the same reasons explained in Ground 4. *Supra* §VII.B.3. In such a configuration, the most distal row of cells of Spenser's frame would be uncovered by both the graft covering and the outwardly extending fibers. (Ex. 1003, ¶¶260-261.)

D. Grounds 7-9: Claims 1-7, 9 Obvious Over Bailey and Spenser II, Birdsall, *or* Chuter

1. Claim 1

Bailey and Spenser II, Birdsall, *or* Chuter render claim 1 obvious. (Ex. 1003, ¶¶262-298.)

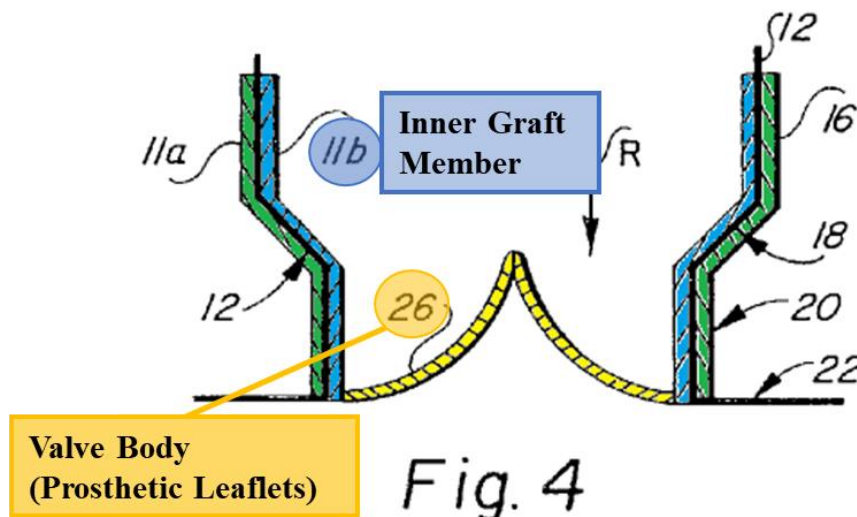
a. 1.P-Preamble

If the preamble is limiting, Bailey and Spenser II disclose this limitation.

Supra §VII.A.1.a.

b. 1.a-Graft Covering

Bailey discloses a THV having an inner graft member 11b that “is coupled, on the luminal surface of the intermediate annular section 20 of the stent body member 12.” (Ex. 1141, [0049].) Bailey’s inner graft member is a “graft covering” that extends about and engages the prosthetic leaflets to provide sealing thereto:

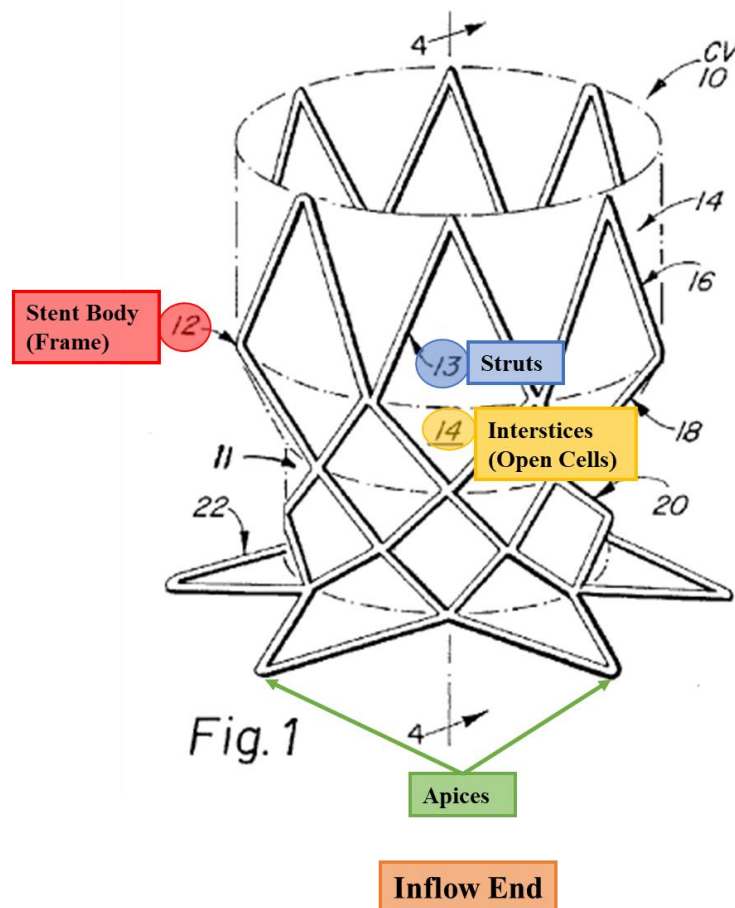


(*Id.*, [0049], Fig. 4; Ex. 1003, ¶265.)

c. 1.b-Frame

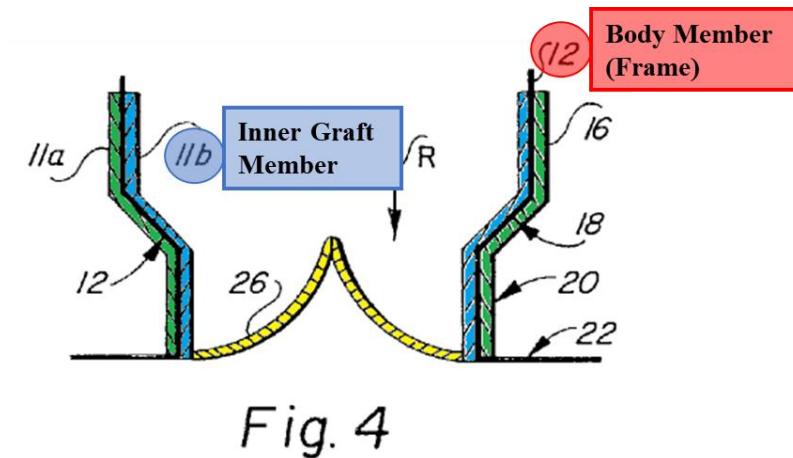
Bailey’s THV includes a metallic “expandable stent body member 12” formed by “laser cutting a hypotube or weaving wires into a tubular structure.” (Ex. 1141, [0021], [0048].) The frame includes “proximal and distal anchors, a intermediate

annular stent section, and at least one valve arm or blood flow regulator struts.” (*Id.*, [0022].) “The proximal anchor flange 22, the intermediate annular section 20 and the distal anchor section 16 are each formed during the formation of the stent body member and are formed from the same material as the stent body member and comprise stent struts 13 and intervening interstices 14 between adjacent pairs of stent struts 13.” (*Id.*, [0048].) The frame includes a plurality of apices at the inflow end of the frame:



(*Id.*, [0048], Fig. 1; Ex. 1003, ¶268.)

Bailey’s inner graft member 11*b* (graft covering) is secured to the frame along the “luminal surface of the intermediate annular section 20 of the stent body member 12.”



(Ex. 1141, [0049], [0021], Fig. 4; Ex. 1003, ¶¶268-269.)

d. 1.c-Polymeric Graft Covering

Bailey’s inner graft member (graft covering) may be made of polymers “such as DACRON or expanded polytetrafluoroethylene.” (Ex. 1141, [0048].)

e. 1.d-Plurality of Fibers

Bailey discloses an “outer or abluminal graft member 11*a*” secured to the frame:

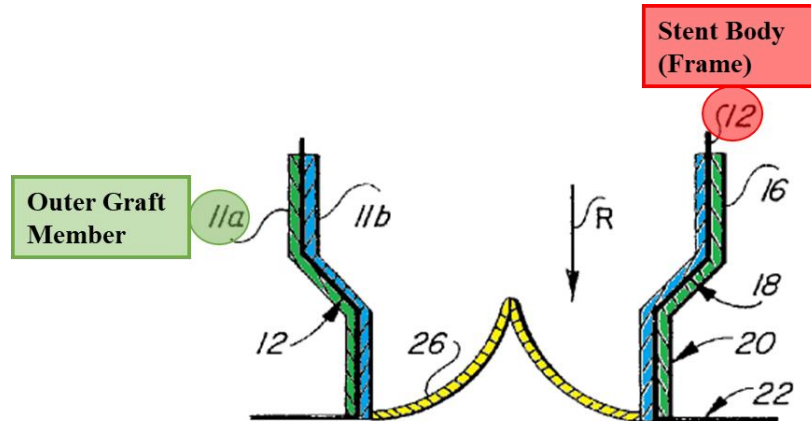


Fig. 4

(Ex. 1141, [0049], Fig. 4.) Bailey’s outer graft member “forms a sealing graft which contacts and excludes the immobilized anatomical valve leaflets.” (*Id.*, [0023].)

i. Bailey and Spenser II

POSITAs would have been motivated to substitute Spenser II’s compressible material for Bailey’s outer sealing graft 11a to further prevent PVL. (Ex. 1003, ¶¶275-276.) POSITAs would have been motivated to make the substitution based on Spenser II’s explanation that the compressible material “expands after deployment” and “fills the gaps between the stented valve and the surrounding tissue.” (Ex. 1011, [00145].) Additionally, Spenser II explains the fibers “may be adapted to encourage coagulation of blood to further fill gaps and prevent leakage” and that “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.*) POSITAs would have understood the fibers in the compressible material are

particularly effective at encouraging blood coagulation and tissue ingrowth. (*See, e.g.* Ex. 1074, 5:60-64, 6:4-14, 10:14-30; Ex. 1003, ¶275.)

The substitution of Spenser II's compressible material for Bailey's outer graft member would have merely entailed substitution of one known element (Spenser II's compressible material) for another (Bailey's outer graft member) to yield the predictable results of reducing PVL. *See KSR Int'l Co.*, 550 U.S. at 416; (Ex. 1003, ¶276.) Additionally, POSITAs would have recognized Spenser II's compressible material as one of a finite number of predictable solutions for an outer seal and would have found it obvious to try the compressible material on Bailey's THV. *See KSR Int'l Co.*, 550 U.S. at 402; (*supra* §VII.A.1.g.i; Ex. 1003, ¶276.)

POSITAs would have reasonably expected success in substituting Spenser II's compressible material for Bailey's outer graft member. (Ex. 1003, ¶277.) The frames in Spenser II and Bailey share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. (*See* Ex. 1011, [00144], Fig. 22; Ex. 1141, [0048]; Ex. 1003, ¶277.) In fact, Spenser II discloses a valve having exposed apices like the valve disclosed in Bailey:

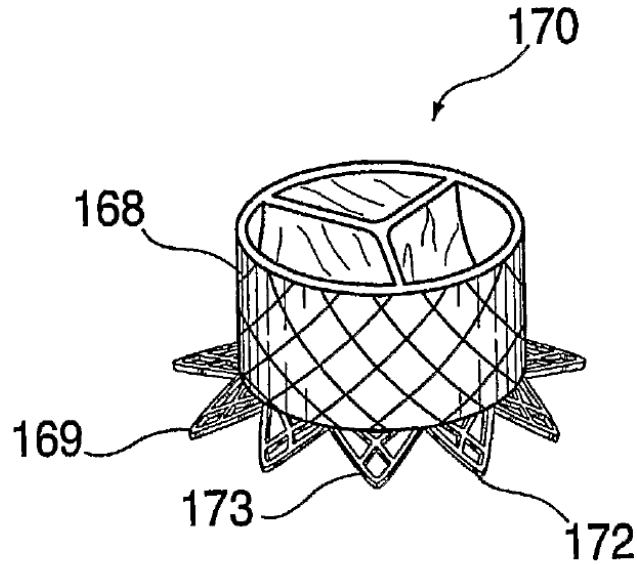
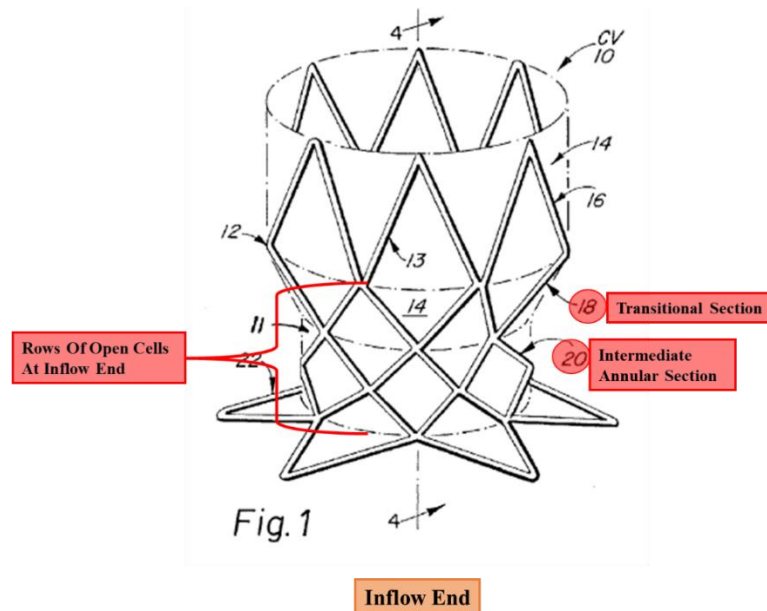


FIG. 17b

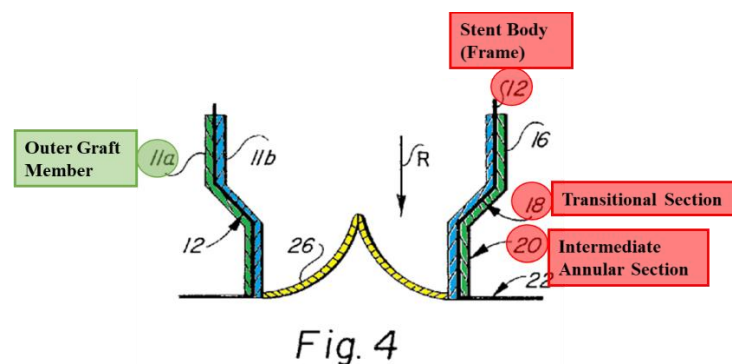
(Ex. 1011, Fig. 17b, [00136]-[00137].) Spenser II does not identify any drawbacks to the exposed apices and, therefore, would have given POSITAs additional confidence in combining Spenser II's outer cloth with Bailey. (Ex. 1003, ¶277.) Further, both references disclose THVs suitable for percutaneous (i.e., endovascular) delivery. (Ex. 1011, [0011]-[0013], [0090]; Ex. 1141, [0002], [0019], [0073]; Ex. 1003, ¶277.)

Additionally, POSITAs would have been motivated to place Spenser II's compressible material over sections 18 and 20 of Bailey's frame so that the compressible material would form a seal with the patient's native leaflets when the valve is implanted. (Ex. 1011, [00145]; Ex. 1003, ¶278.) Bailey's frame includes

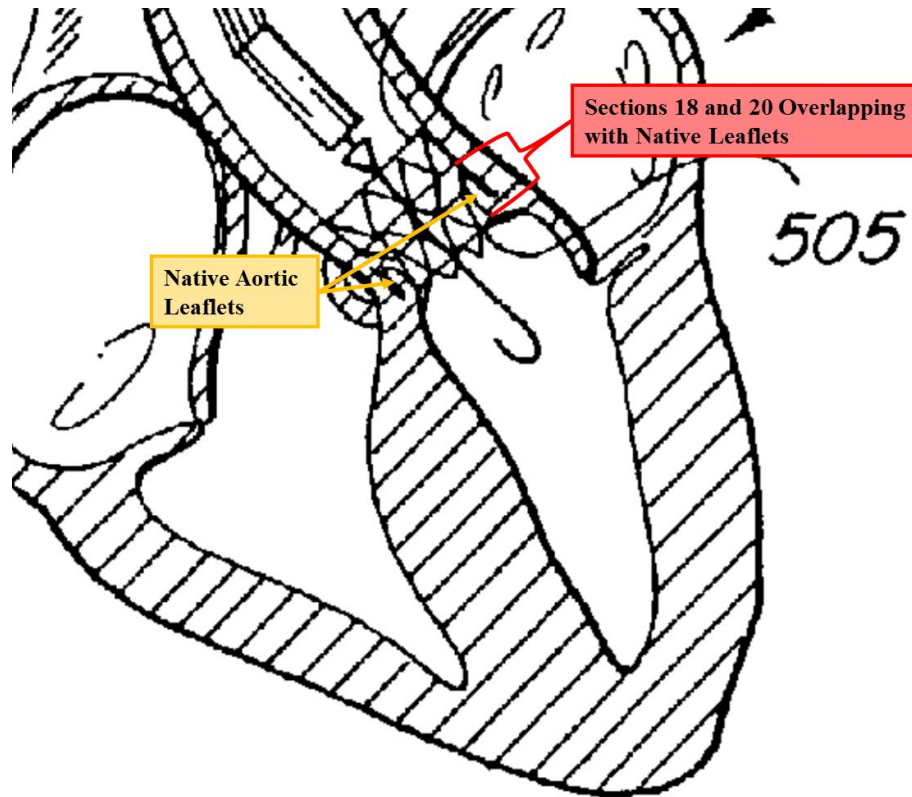
an intermediate annular section 20 and a transitional section 18 that form a plurality of rows of open cells at the inflow end of the frame:



(Ex. 1141, [0048], Fig. 1; Ex. 1003, ¶278.) Bailey's outer graft member 11a extends over the intermediate annular 20 and transitional 18 sections and is therefore in contact with the rows of open cells formed by those sections:



(Ex. 1141, [0049], Fig. 4; Ex. 1003, ¶278.) Bailey's Figure 20G confirms that frame sections 18 and 20 overlap with the native leaflets when the valve is implanted:



(Ex. 1141,[0073], Fig. 20G (excerpt); Ex. 1003, ¶278.) Thus, where Spenser II’s compressible material replaces Bailey’s outer graft member, the material would be “in contact with a plurality of rows of open cells at the inflow end of the frame.” (Ex. 1003, ¶278; *supra* §VII.A.1.e.)

ii. Bailey and Birdsall

POSITAs would have been motivated to substitute Birdsall’s barrier material for Bailey’s outer graft member 11a to further prevent PVL. (Ex. 1003, ¶¶280-281.) Birdsall’s barrier material includes microfibers that fill gaps between the valve and the calcified treatment site to prevent PVL and prevent migration of the valve within the treatment site. (Ex. 1057, 6:4-65, 7:29-44.) POSITAs would have recognized

the microfibers confer an advantage over Bailey's outer graft member. (Ex. 1003, ¶280.)

Moreover, replacing Bailey's outer graft member with Birdsall's barrier material would have merely entailed substitution of one known element (Birdsall's barrier material) for another (Bailey's outer graft member) to yield the predictable results of reducing PVL. *See KSR Int'l Co.*, 550 U.S. at 416; (Ex. 1003, ¶281.) Additionally, POSITAs would have recognized Birdsall's barrier material as one of a finite number of predicable solutions for an outer sealing material and would have found it obvious to try the barrier material to seal Bailey's THV. *See KSR Int'l Co.*, 550 U.S. at 402; (Ex. 1003, ¶281.)

POSITAs would have reasonably expected success in substituting Birdsall's barrier material for Bailey's outer graft member. (Ex. 1003, ¶282.) The valve frames in Birdsall and Bailey share many common features, including being balloon-expandable and forming rows of open cells that are interconnected by metal struts. (See Ex. 1057, 2:33-39, Fig. 3A; Ex. 1141, [0048]; Ex. 1003, ¶282.) Both references also disclose THVs suitable for percutaneous (i.e., endovascular) delivery. (Ex. 1057, 5:37-51, 7:45-67; Ex. 1141, [0002], [0019], [0073]; Ex. 1003, ¶282.)

POSITAs would have understood that the fibers of Birdsall's barrier material would be "in contact with a plurality of rows of open cells at the inflow end of the

frame” when added to Bailey’s THV for the same reasons discussed above for Bailey and Spenser II. (Ex. 1003, ¶283; *supra* §VII.D.1.e.i.)

iii. Bailey and Chuter

POSITAs would have been motivated to substitute Chuter’s fiber pile for Bailey’s outer graft member 11a to further prevent PVL and promote tissue ingrowth. (Ex. 1003, ¶¶285-286.) Chuter discloses that the fiber pile is “adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel” and “fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel.” (Ex. 1116, [0012]-[0013], [0017]-[0020], [0064].) POSITAs would have been motivated to exchange Chuter’s fiber pile with Bailey’s outer graft member to incorporate these benefits. (Ex. 1003, ¶285.)

Further, replacing Bailey’s outer graft member with Chuter’s fiber pile would have merely entailed substitution of one known element (Chuter’s fiber pile) for another (Bailey’s outer graft member) to yield the predictable results of reducing PVL. *See KSR Int’l Co.*, 550 U.S. at 416; (Ex. 1003, ¶¶286.) Additionally, POSITAs would have recognized Chuter’s fiber pile as one of a finite number of predicable solutions for an outer sealing material and would have found it obvious to try the

fiber pile to seal Bailey’s THV. *See KSR Int’l Co.*, 550 U.S. at 402; (Ex. 1003, ¶286.)

POSITAs would have reasonably expected success in adding Chuter’s fiber pile to Bailey’s valve for the same reasons explained in Grounds 5-6. (*Supra* §VII.C.1.e.) POSITAs would have understood that the fibers of Chuter’s fiber pile would be “in contact with a plurality of rows of open cells at the inflow end of the frame” when added to Bailey’s THV for the same reasons discussed above for Bailey and Spenser II. (Ex. 1003, ¶287; *supra* §VII.D.1.e.i.)

f. 1.e-Spaced-Apart Fibers

Spenser II, Birdsall, and Chuter each disclose this limitation. *Supra* §§VII.A.1.f, VII.B.1.f, VII.C.1.f.

g. 1.f-Uncovered Apices

Bailey discloses this limitation. *Supra* §VII.A.1.g.iii. When Bailey’s outer graft member is replaced with Spenser II’s compressible material, Birdsall’s barrier material, or Chuter’s fiber pile, the proximal apices would be uncovered by the graft covering and the outwardly extending fibers, and the uncovered proximal apices of the proximal anchor flange would extend proximally further than the compressible material’s fibers. (Ex. 1003, ¶291.)

h. 1.g-Fibers Compressed To Form Seal

Spenser II, Birdsall, and Chuter each disclose this limitation. *Supra* §§ VII.A.1.h, VII.B.1.h, VII.C.1.h.

i. 1.h-Graft Covering Engaged With Fibers

Bailey discloses an inner graft member (graft covering) secured to the inner surface of the frame and an outer graft member secured to the outer surface of the frame. *Supra* §VII.D.1.b. Bailey also discloses that the outer and inner graft members are “coupled” (i.e., engaged) “through the interstices 14 of the stent body member.” (Ex. 1141, [0049].) When Bailey’s outer graft member is replaced with Spenser II’s compressible material, Birdsall’s barrier material, or Chuter’s fiber pile, the fibers of the compressible material/barrier material/fiber pile would be similarly “coupled” (i.e., engaged) with the graft covering through the interstices of the frame. (Ex. 1003, ¶295.)

j. 1.i-Endovascularly Deployed

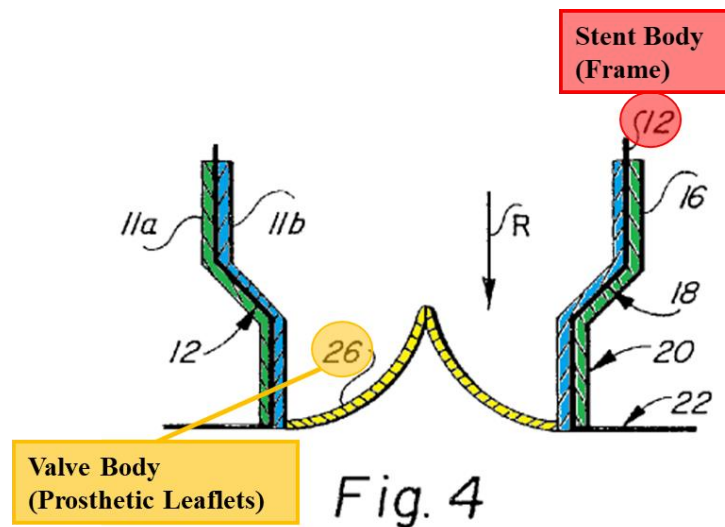
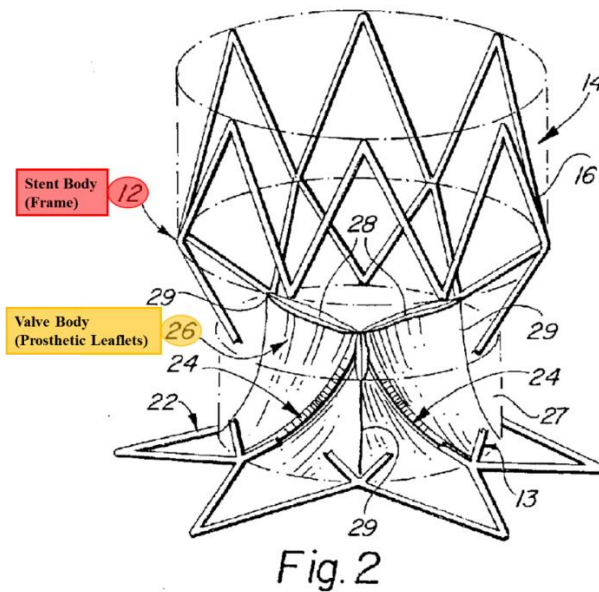
Bailey discloses a THV suitable for endovascular delivery through the femoral artery and provides “a delivery profile which does not exceed the 12 French size suitable for peripheral vascular endoluminal delivery.” (Ex. 1141, [0002]. [0019], [0073].) Spenser II, Birdsall, and Chuter similarly disclose that their sealing

materials are suitable for use with endovascularly delivered devices. *Supra* §§ VII.A.1.j, VII.B.1.j, VII.C.1.j.

POSITAs would have reasonably expected that Bailey’s THV would remain suitable for endovascular delivery through the femoral artery after replacing the outer graft member with Spenser II’s compressible material, Birdsall’s barrier material, or Chuter’s fiber pile. (Ex. 1003, ¶¶298.) The Board previously found that a 12F (4.0 mm) diameter valve, like Bailey’s valve, “is well within the maximum allowable diameter of 24F [for transfemoral delivery] argued by [PO], such that [POSITAs] could reasonabl[y] understand that there would be sufficient additional space to accommodate the ‘compressible ... cloth or fabric,’ which Spenser II teaches can also be delivered endovascularly.” (Ex. 1117, 57.) The same rationale applies to the addition of Birdsall’s barrier material or Chuter’s fiber pile. (Ex. 1003, ¶298.)

2. Claim 2

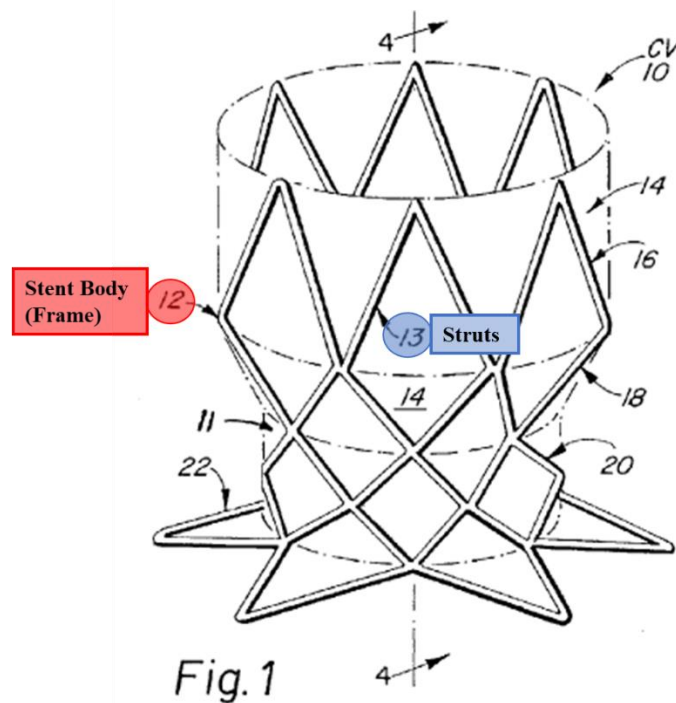
Bailey’s frame extends distally further than the prosthetic heart valve leaflets:



(Ex. 1141, Figs. 2, 4; Ex. 1003, ¶¶299-300.)

3. Claim 3

Bailey’s frame is “formed of a plurality of stent struts” that are interconnected to form a singular, integral component:



(Ex. 1141, [0048]; Ex. 1003, ¶¶301-302.)

4. Claim 4

Bailey’s inner graft member “is attached to the stent body member...by suturing to or encapsulating stent struts.” (Ex. 1141, [0021].) POSITAs would have been motivated to suture the inner graft member to the frame at both the top and bottom portion of the graft member to form a secure attachment, and reasonably expected success in doing so. (Ex. 1003, ¶¶303-304.)

5. Claim 5

Bailey’s stent body member “may be made of balloon expandable stainless steel or other plastically deformable stent materials as are known in the art.” (Ex.

1141, [0021], [0048].) Thus, Bailey's THV may be balloon expandable. (Ex. 1003, ¶306.) POSITAs would have understood Bailey's THV would remain balloon expandable after adding Spenser II's compressible material, Chuter's fiber pile, or Birdsall's barrier material because each reference discloses its sealing material can be used with balloon-expandable devices. (Ex. 1011, [00144]; Ex. 1116, [0003], [0021]; Ex. 1057, 2:33-36; Ex. 1003, ¶306.)

6. Claim 6

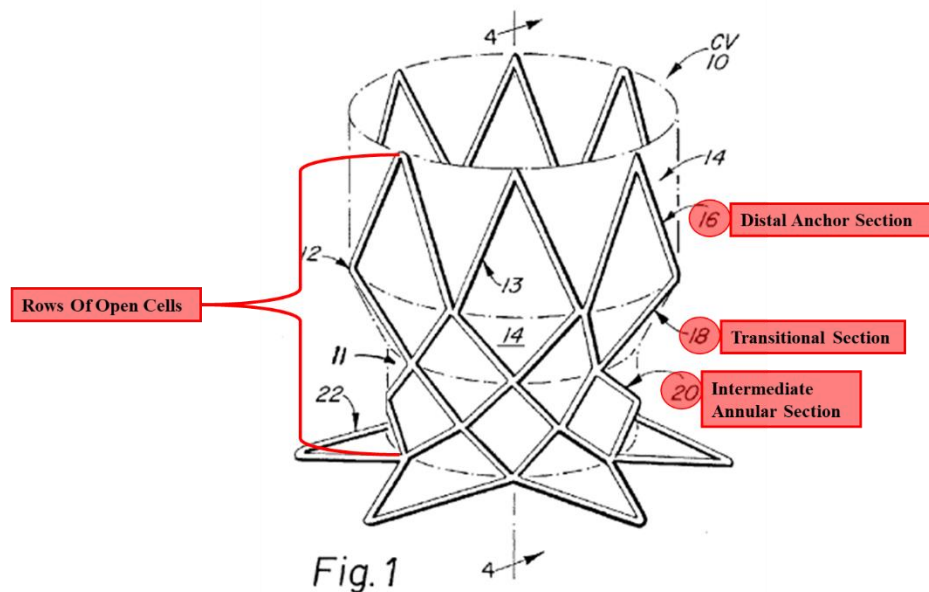
Bailey discloses an inner graft member (graft covering) that extends around and is attached to the prosthetic heart valve leaflets. *Supra* §VII.D.1.b. Therefore, if a graft covering can be an inner frame, Bailey's inner graft member forms an inner frame for supporting the prosthetic heart valve leaflets. (Ex. 1003, ¶308.)

7. Claim 7

Bailey and Spenser II, Birdsall, or Chuter render claim 7 obvious for the reasons explained for claim 1. *Supra* §VII.D.1.

8. Claim 9

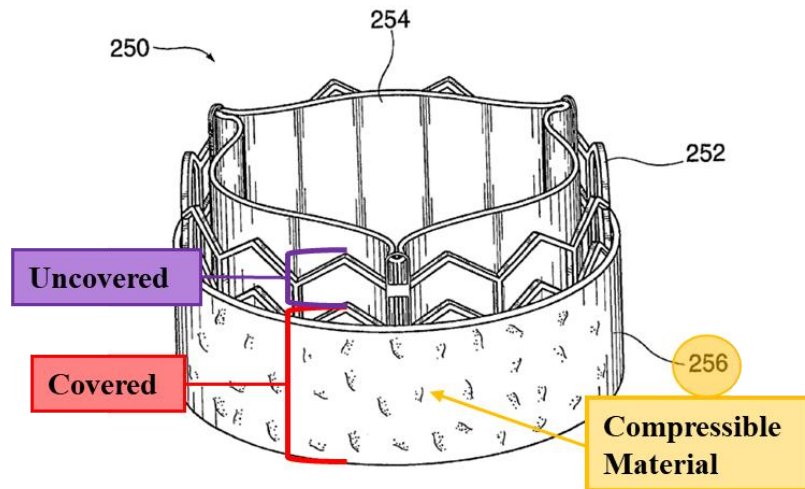
Bailey's frame is formed of interconnecting struts that form multiple rows of interstices 14 (open cells):



(Ex. 1141, [0048], Fig. 1.) Bailey teaches that “the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member 12.” (Ex. 1141, [0052].) POSITAs would therefore have understood that Bailey encompasses embodiments wherein the most distal row of open cells formed by distal anchor section 16 are uncovered by the inner and outer graft members. (Ex. 1003, ¶311.)

POSITAs would have been motivated to leave the distal row of open cells formed by the distal anchor section 16 uncovered to ensure blood flow to the coronary arteries. (See Ex. 1141, [0054], [0073], Ex. 1003, ¶312.) POSITAs would have been further motivated to select such a placement for the sealing material on

Bailey's THV by Fig. 22 of Spenser II, which illustrates an embodiment wherein the distal most row of open cells is uncovered:



(Ex. 1011, Fig. 22; Ex. 1003, ¶312.)

VIII. SECONDARY CONSIDERATIONS

Petitioner understands PO does not practice the '634 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶313-314.) If PO asserts the '634 patent solved any long-felt but unmet need, the Board has repeatedly rejected the argument in the prior IPRs. (Ex. 1117, 66-70; Ex. 1118, 71-74; Ex. 1119, 86-89.) If PO identifies any evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

IX. THE BOARD SHOULD NOT DENY INSTITUTION

UNDER §325(d)

Bailey and Chuter were not considered during prosecution of the '634 patent, so the Board should not exercise its discretion to deny institution under §325(d). These references are not cumulative of the prior art considered by the Examiner. Bailey discloses a THV with coverings that do not extend over the proximal apices of the frame, and Chuter discloses fibers secured directly to the valve frame in the same arrangement as depicted in the figures of the '634 patent. *Supra* §§VII.A.1.g.iii, VII.C.1.e.

The Board should also not exercise its discretion to deny institution under §325(d) because the Examiner erred in a manner material to the patentability of the Challenged Claims. For example, in the Notice of Allowance, the Examiner stated that “the prior art does not disclose or render obvious” the Spacings Limitation and Uncovered Apices Limitation. (Ex. 1002, 90.) That finding is materially erroneous. As detailed above, Bailey, Spenser II, and Chuter disclose and render obvious those limitations. Thus, the Examiner failed to fully consider the teachings of the prior art.

Additionally, the Examiner initially rejected the pending claims of the '634 patent as obvious over Spenser and Spenser II. (*Id.*, 385-388.) In response, PO

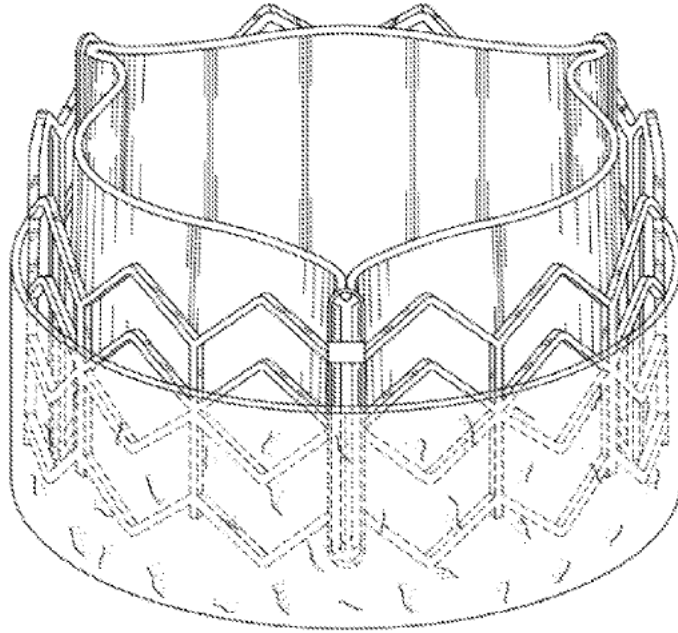
argued Spenser and Spenser II would not be capable of endovascular delivery through the femoral artery based on calculations presented in the prior IPRs. (*See id.*, 367-370.) The Examiner subsequently withdrew the rejection. (*Id.*, 245-251.) However, that withdrawal was materially erroneous. The Board rejected the same calculations in the IPRs, and PO is precluded from challenging the Board’s findings. (*See supra* §II.) Thus, the Examiner materially erred in accepting PO’s prosecution arguments regarding endovascular delivery.

PO also mischaracterized the prior art during prosecution. For example, PO mischaracterized Spenser II’s compressible material as a “high density seal” and as “a very tightly knitted outer band made of tightly knitted fibers ... where the lack of ‘spacings’ between some fibers would not allow for compression of the outwardly extending fibers.” (Ex. 1002, 373, 377.) PO provided no support for this attorney argument, and no support appears in Spenser II, which never characterizes the compressible material as “high density” or “tightly knitted.” (*See* Ex. 1011, [00145].) Rather, the compressible material is “compressible,” which undermines PO’s argument that the material lacks spacings between the fibers necessary for compression. (Ex. 1003, ¶93.)

PO also argued that Spenser II’s compressible material “is the direct opposite of Applicant’s claimed inventions where the fibers are compressed upon

deployment” because Spenser II’s compressible material “expands after deployment at a treatment site.” (Ex. 1002, 221.) Once again, PO’s attorney argument ignores Spenser II’s express disclosure that the compressible material is ***compressible*** and would thus be compressed when pressed against the native tissue upon deployment. (Ex. 1003, ¶94.) PO further argued Spenser II “teaches a surface from which fibers can extend, however, ... such surface would be a flat, smooth type surface” generally associated with a graft covering, “and not one formed from fibers with spacings therebetween. To the extent that the seal is PET, it is likely tightly woven PET as used in cardiovascular applications and not spaced-apart fibers.” (Ex. 1002, 222.) PO again provided no support for this attorney argument, nor is any found in Spenser II, which never describes the compressible material as “tightly woven,” “flat,” or “smooth.” (See Ex. 1011, [00145].) To the contrary, POSITAs would have understood Spenser II to disclose a porous compressible material with spacings between the fibers. *Supra* §VII.A.1.f.

PO also created the following image to argue Spenser II’s compressible material covers the bottom-most surface of Spenser’s frame:



(Ex. 1002, 235.) This image is **not** in Spenser or Spenser II and does not accurately represent a POSITA's understanding of Spenser II. (Ex. 1003, ¶96.) Notably, PO did not inform the Examiner that it created this image. (*See id.*)

Thus, PO's erroneous arguments during prosecution should not form the basis to deny institution under §325(d).

X. 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 nine related IPRs (“prior IPRs”) challenging patents having the same specification and drawings as the ’634 patent. The status of those IPRs is summarized below. The caption for each IPR is *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*.

IPR No.	Challenged Patent	Outcome/Status
IPR2021-01527	10,792,172	All challenged claims obvious over Spenser + Spenser II (FINAL)
IPR2021-01584	10,857,011	All challenged claims obvious over Spenser + Spenser II (FINAL)
IPR2022-00193	10,881,538	Claims 1–8, 10–18, and 20 obvious over Spenser + Spenser II; Claims 9 and 19 not unpatentable under different grounds (FINAL)
IPR2022-00034	10,966,846	Claim 6 not unpatentable due to “free of an outer graft covering” limitation (FINAL)
IPR2022-00556	10,987,236	Claims 1-4 not unpatentable due to “free of an outer graft covering” limitation (FINAL)
IPR2022-00549	11,129,735	Institution denied based on “apices of the outer frame...are uncovered” limitation
IPR2023-01151	11,337,834	Filed June 29, 2023
IPR2023-01232	11,389,310	Filed July 20, 2023
IPR2023-01325	11,491,033	Filed August 14, 2023

PO also filed suit against Petitioner alleging infringement of the ’634 patent, as well as U.S. Patent Nos. 11,523,918; 11,491,033; 11,389,310; and 11,337,834 by Petitioner’s SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1:23-00158-JPM (D. Del., filed Feb. 13, 2023). The court has not

set a trial date in the litigation. The court has scheduled a claim construction hearing for March 21, 2024.

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
Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com BoxEdwards28-4@knobbe.com <u>Postal and Hand-Delivery Address:</u> Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com <u>Postal and Hand-Delivery Address:</u> 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 BoxEdwards28-4@knobbe.com.

XI. FEES

The fee for this petition has been paid. Any additional fees may be charged to Deposit Account 11-1410.

XII. GROUNDS FOR STANDING UNDER 37 C.F.R. §42.104

Petitioner certifies that the '634 patent is available for IPR and Petitioner is not estopped from requesting IPR challenging the patent claims on the identified grounds.

XIII. CONCLUSION

Petitioner has established a reasonable likelihood of prevailing in showing that the Challenged Claims are unpatentable as obvious and, therefore, requests that the Board institute an IPR and cancel the claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 5, 2024

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. 11,497,634,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,960
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: January 5, 2024

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. 11,497,634** and **EXHIBITS
1001 – 1150** are being served on, via Federal Express overnight mail on counsel of
record for U.S. Patent 11,497,634 as addressed below:

Justin Nifong
NK Patent Law
4101 Lake Boone Trail, Suite 218
Raleigh, NC 27607

Dated: January 5, 2024

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