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On behalf of **Edwards Lifesciences Corporation and
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC**

Petitioners,

v.

Aortic Innovations, LLC

Patent Owner.

IPR2022-00034

Patent No. 10,966,846

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,966,846**

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Exhibit No.	Description
1001	U.S. Patent No. 10,966,846 B2 (“ ’846 patent ”)
1002	Excerpts from the prosecution history of the ’846 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	Conradi, Lenard, et al., <i>Transcatheter aortic and mitral valve interventions: update 2010</i> , 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ Spenser ”)
1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
1012	Cribier, Alain, et al., <i>Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach</i> , Herz, 34:347-56 (2009) (“ Cribier ”)
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.

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1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.
1016	Alkashkari, MD, et al., <i>Percutaneous Pulmonary Valve Implantation for RVOT Defects</i> , Cardiac Interventions Today, 21-29 (September/October 2010) (“Alkashkari”)
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	Yuksel, Uygur, <i>Balloon-Expandable Transcatheter Aortic Valve Implantation</i> , Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., <i>Transapical Minimally Invasive Aortic Valve Implantation</i> , 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) (“Walther II”)
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	Zajarias, Alan and Cribier, Alain G., <i>Outcomes and Safety of Percutaneous Aortic Valve Replacement</i> , 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) (“Zajarias”)

Exhibit No.	Description
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. (“Spenser Parent”)
1027	Roselli, E.E., <i>Engineering transcatheter aortic valve devices: a surgeon’s perspective</i> , 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) (“Roselli”)
1028	Tyagi, G.K., <i>Yarn structure and properties from different spinning techniques</i> , (“Tyagi”)
1029	Kothari, V K, <i>Hairiness properties of polyester-cotton blended yarns</i> , 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) (“Kothari”)
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)
1031	Akin, Jodi and Sharma, Pooja, “Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System,” <i>Transcatheter Aortic Valve Implantation</i> , edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences’ Transcatheter Valve (October 19, 2012)

Exhibit No.	Description
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 Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., <i>In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry</i> , EuroIntervention 15:1240-1247 (2020)
1042	Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010)
1043	Kainuma, Satoshi, et al., <i>Transcatheter aortic valve implantation: first trans-iliac experience in Japan</i> , General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, <i>Iliac Arterial Conduits for Endovascular Access: Technical Considerations</i> , J. Endovasc. Ther. 14:347-351 (2007)

Edwards v. Aortic Innovations
IPR Petition – U.S. Patent 10,966,846

Exhibit No.	Description
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. (“ Cribier ’321 ”)
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020
1047	Piazza, Nicolo, et al., <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	WO 2011/051043 A1 to Essinger et al.
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from <i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , 21-cv-1377, District of Delaware (Filed Sept. 28, 2021)

Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively, “Petitioner”) request *inter partes* review (“IPR”) of claims 1-12 (“the challenged claims”) of U.S. Patent No. 10,966,846 (“the ’846 patent”), purportedly assigned to Aortic Innovations, LLC (“Patent Owner”).

I. SUMMARY OF THE ARGUMENT

The ’846 patent describes endograft devices for repairing aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments comprise multi-component structures that extend into the patient’s ascending aorta and aortic arch.¹

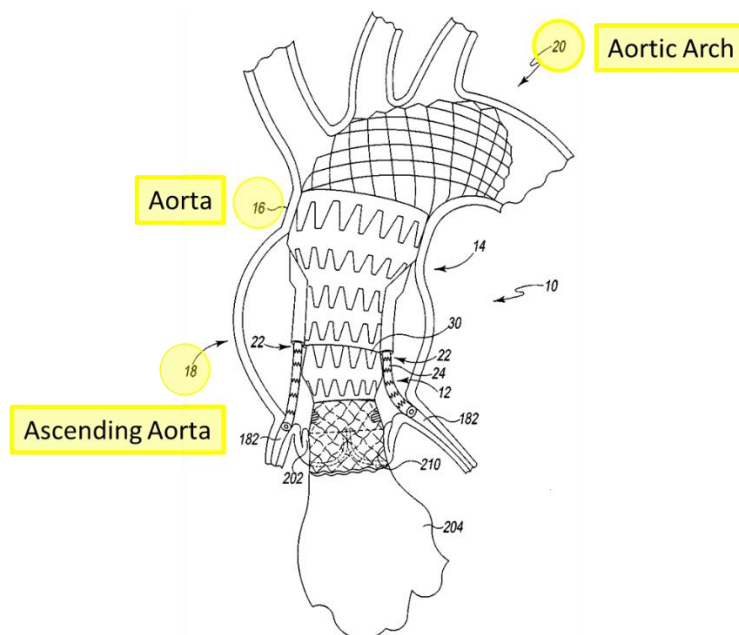
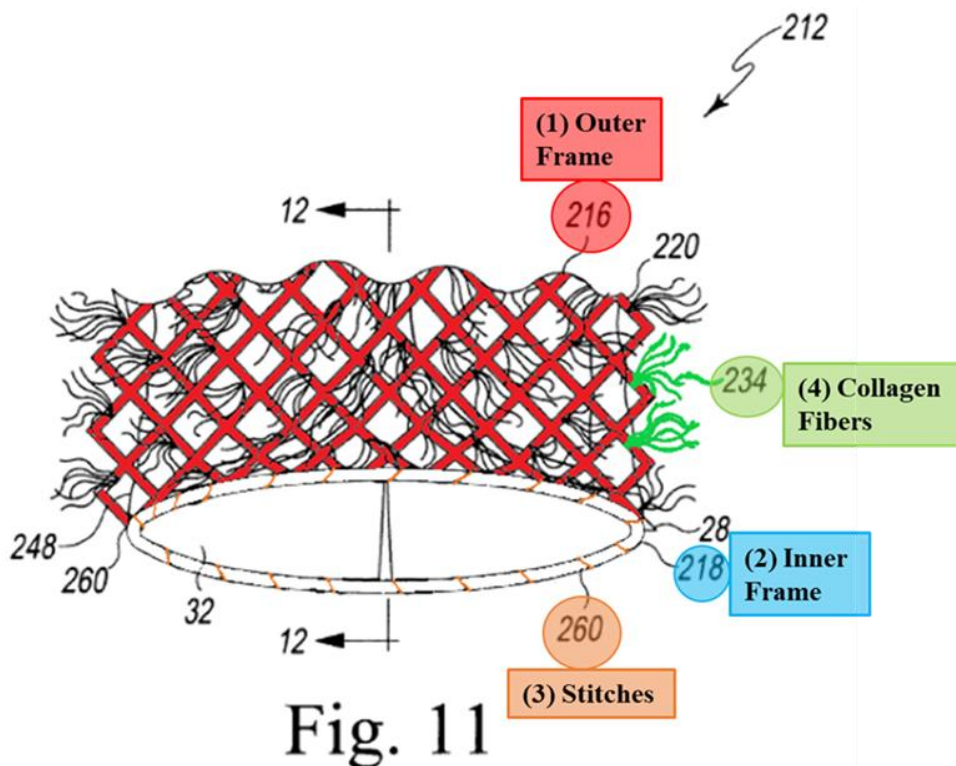


Fig. 2

¹ Color and labels added to figures unless otherwise noted.

The challenged claims, however, describe only the heart-valve component. Petitioner recently filed IPR Petitions against Patent Owner’s U.S. Patent Nos. 10,792,172 and 10,857,011 (“IPR Patents”). The ’846 patent is a continuation of the IPR Patents. Like the IPR Patents, the ’846 patent claims four principal elements: (1) a metallic outer frame [red], (2) an inner frame that includes a cylindrically extending graft covering [blue], (3) stitches securing the inner frame to the outer frame [orange], and (4) an outer seal formed of “outwardly extending fibers positioned externally to the outer frame” [green].



The ’846 patent also claims a negative limitation: “the outer seal is free of an outer graft covering between the fibers and the outer frame.” The prior art discussed below

discloses all of these claimed limitations, which were well known in the field by November 2012, the '846 patent's priority date ("Critical Date").

Patent Owner drafted the challenged claims in an effort to cover Petitioner's SAPIEN 3 Ultra transcatheter heart valve ("THV"). In a Preliminary Amendment, Patent Owner argued, "Applicant is aware that the SAPIEN 3 Ultra, a publicly available endovascular valve, appears to be covered by the claimed invention herein." Patent Owner also recently filed suit against Petitioner asserting that the SAPIEN 3 Ultra infringes the '846 patent. (referenced herein as "the Litigation"). However, in its effort to cover Petitioner's THV, Patent Owner broadened its patent claims so far that they cover the prior art.

The '846 patent discloses a "dual-frame" valve including a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218" [blue]. The valve includes collagen fibers 234 that extend outwardly from the outer frame and into the gap between the inner and outer frames.

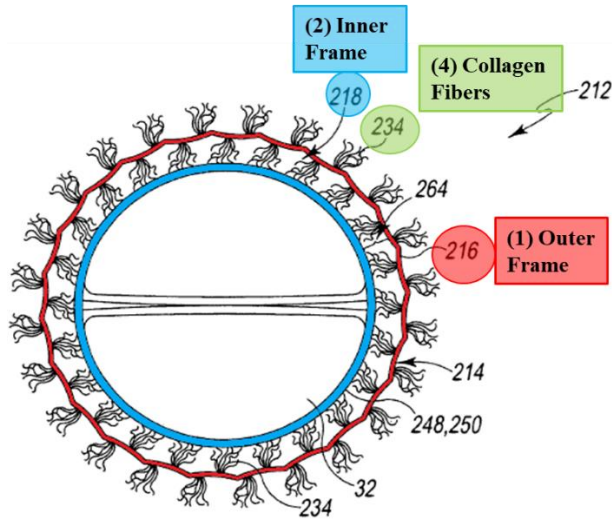


Fig. 13

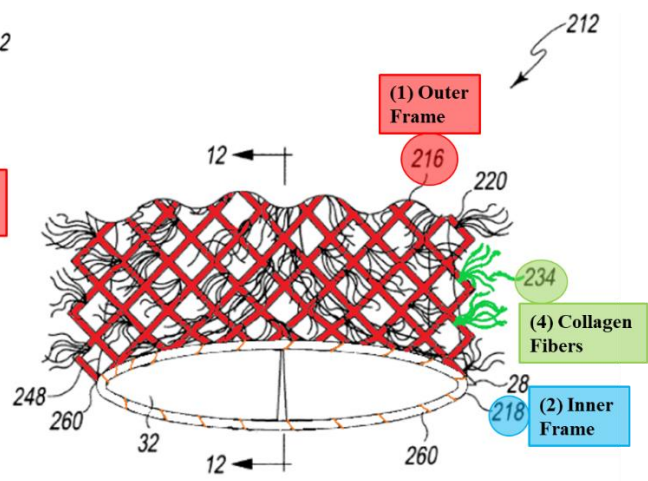


Fig. 11

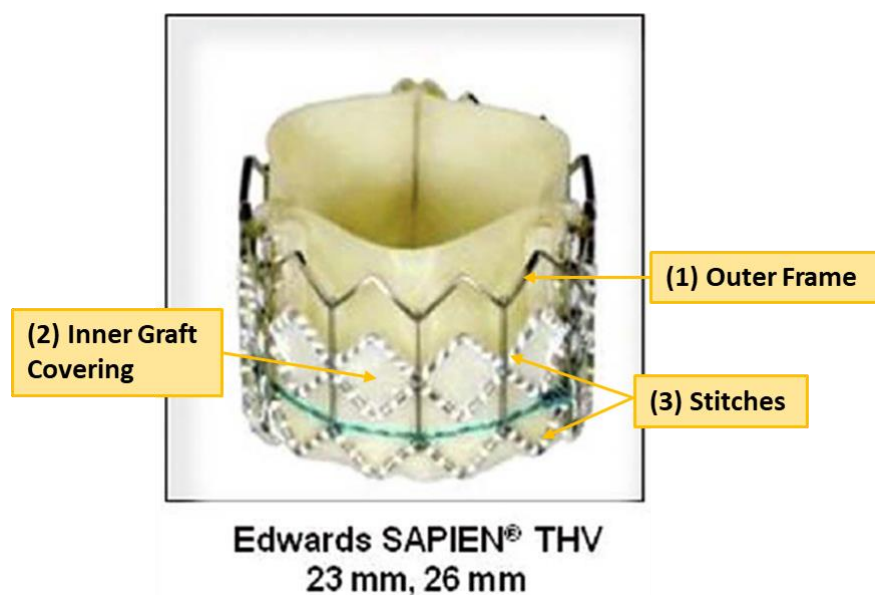
In contrast, SAPIEN 3 Ultra has only one frame, not inner and outer frames, and an outer skirt:



Thus, in its attempt to cover SAPIEN 3 Ultra, Patent Owner argued during prosecution that the limitations in claim 1 requiring “an outer frame” and “inner

frame that includes...a graft covering” are satisfied by a valve that has **only** one frame and an inner graft covering. Patent Owner also argued an outer PET skirt satisfied the limitation requiring “outwardly extending fibers.” But, Petitioner’s prior-art publications and patents describe earlier SAPIEN heart valves having one frame, an inner graft covering, and an outer skirt, rendering the challenged claims unpatentable.

For example, Petitioner’s SAPIEN THV (a predecessor to SAPIEN 3 Ultra) was one of the world’s first THVs. Petitioner received regulatory approval for SAPIEN in Europe in 2007 and the United States in 2011, both before the Critical Date. **Cribier**, a publication relied on herein, discloses that SAPIEN includes: (1) a metallic “outer” frame, (2) an inner graft covering, and (3) stitches securing the graft covering to the outer frame.



Petitioner also modified SAPIEN to include a fibrous outer cloth comprising (4) an outer seal that included fibers extending outwardly of the outer frame.

Walther describes and pictures this modified SAPIEN.

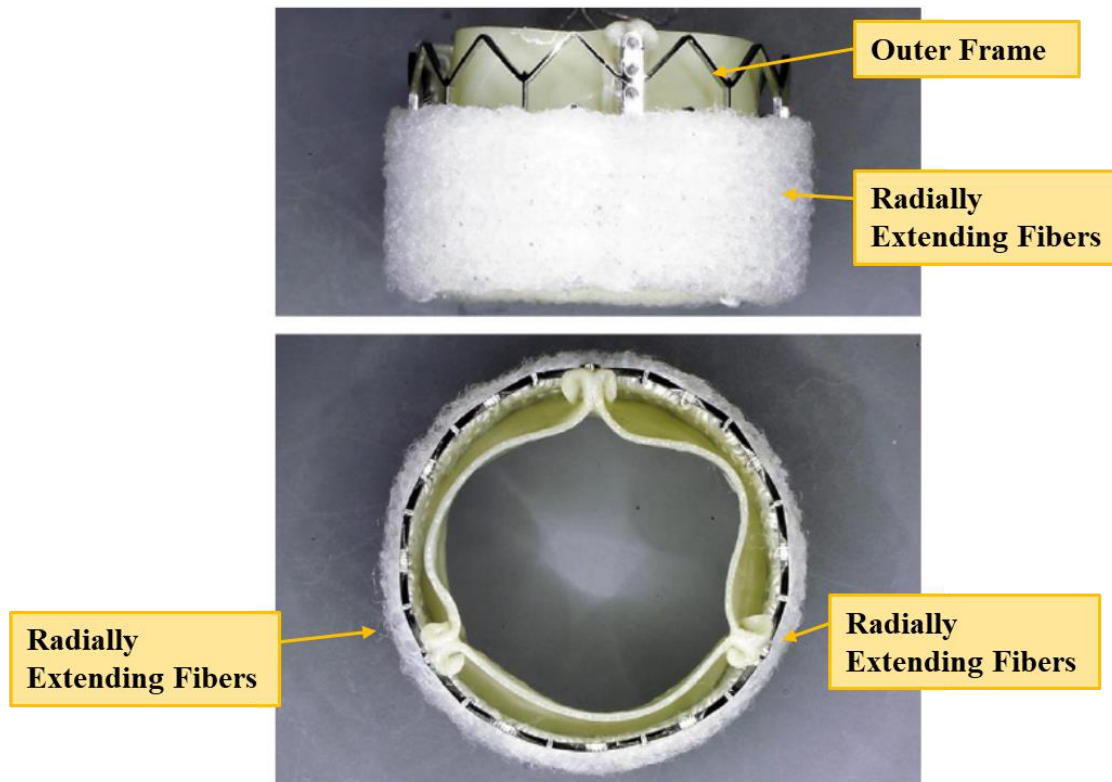
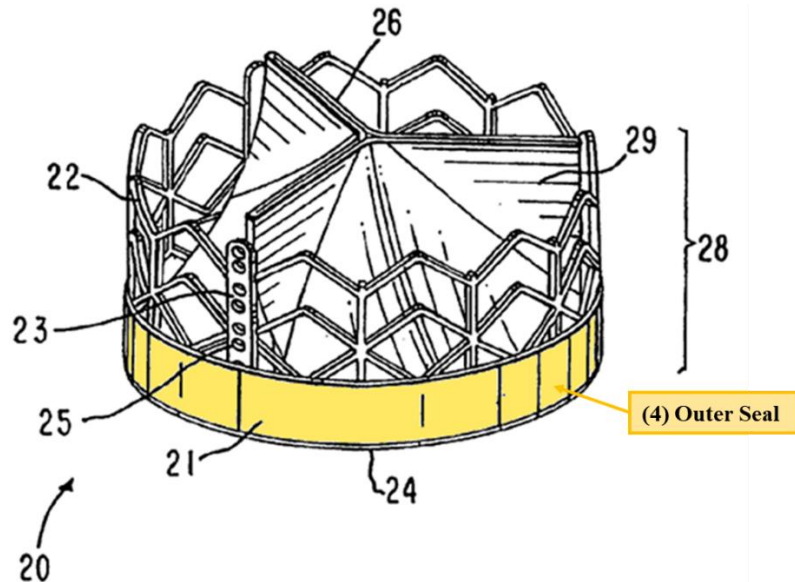


Fig. 1. Cloth valve.

Walther discloses implanting the modified SAPIEN within an existing surgical valve where the fibrous outer cloth reduces paravalvular leakage (PVL) and increases fit between SAPIEN and the surgical valve.

Petitioner also filed patents in the early 2000s disclosing THVs similar to SAPIEN having an outer seal for reducing PVL. **Spenser** discloses a heart valve that includes an outer seal positioned externally to the outer frame.



Spenser II also discloses a heart valve having a fibrous compressible material that reduces PVL.

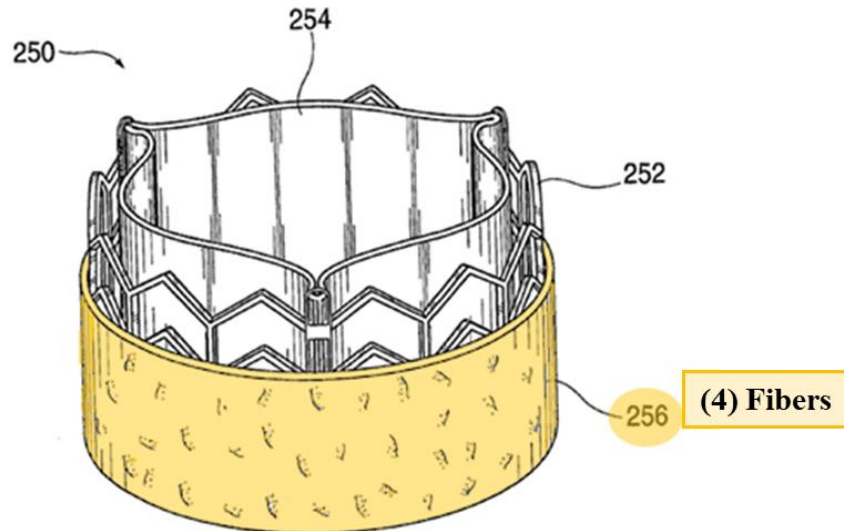
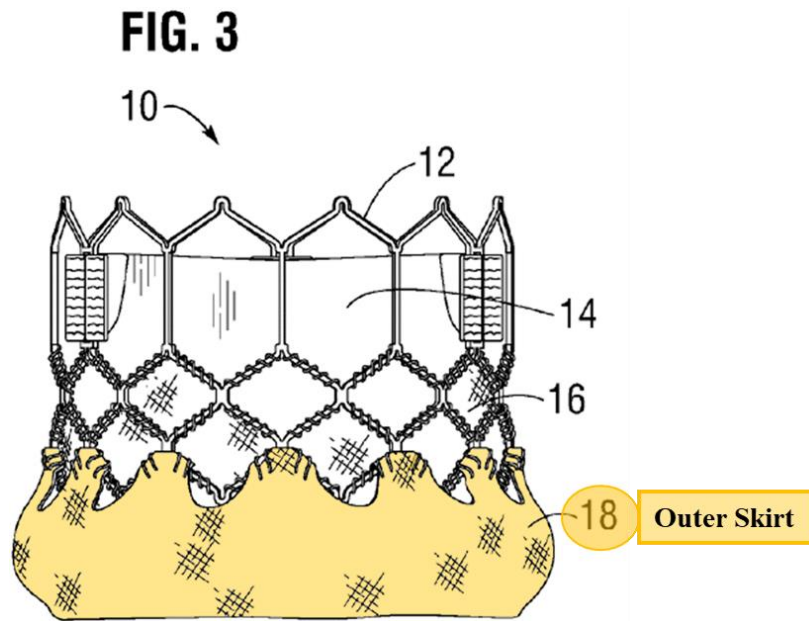


FIG. 22

During prosecution, Patent Owner admitted that Spenser II “appears to teach a thick band with fibers emanating therefrom in FIG 22[.]”

Likewise, **Levi** discloses a heart valve having an inner graft covering and fibrous outer skirt for reducing PVL.



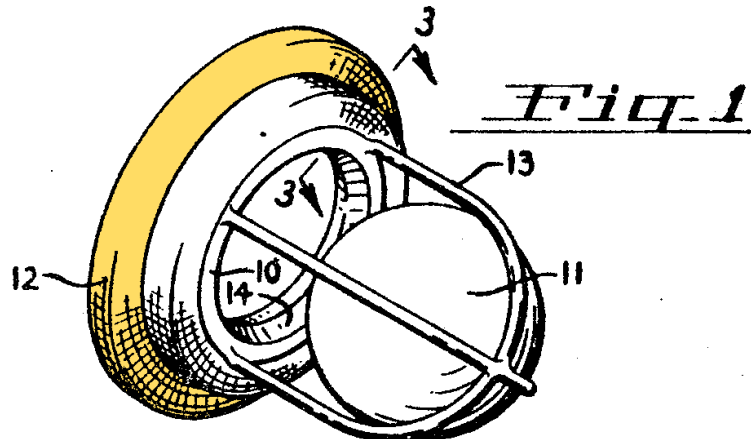
Further, the outer seals in Walther, Spenser, Spenser II, and Levi are free of an outer graft covering between the fibers and the outer frame.

This prior art demonstrates that Petitioner and persons of ordinary skill in the art (POSITAs) disclosed the claimed heart valves before the Critical Date. Unfortunately, the Examiner of the '846 patent did not make **any** prior-art-based rejections during prosecution, nor was she aware of some of the best prior art. Walther was not of record during prosecution, nor was any reference cumulative of Walther (*e.g.*, related patents). Likewise, Cribier and Spenser, which describe Petitioner's SAPIEN valve, were not of record. Patent Owner did characterize some of the prior art relied on herein in a Preliminary Amendment, but the

characterizations were attorney argument that offered an incomplete and inaccurate view of the art. Unlike here, the Examiner did not benefit from any testimony from a POSITA. Because the prior art anticipates or renders obvious the challenged claims, the Board should institute this IPR and cancel the challenged claims.

II. STATE OF THE ART

Petitioner was founded in 1958. Petitioner's earliest work related to surgically implantable heart valves. One of Petitioner's first commercial valves was the Starr-Edwards valve. Even this early valve included an outer sewing ring 12 that formed a seal between the valve and tissue to prevent PVL:



(Ex. 1013, 1:37-46 Fig. 1; Ex. 1003, ¶¶51-53.)

In 1989, Dr. Henning Andersen conceived of the first THV. The balloon-expandable valve included a wire stent and was implanted with a catheter. Dr.

Andersen's work led to U.S. Patent 5,411,552, which was filed in 1994, and discloses a THV having a metallic outer frame and graft covering:

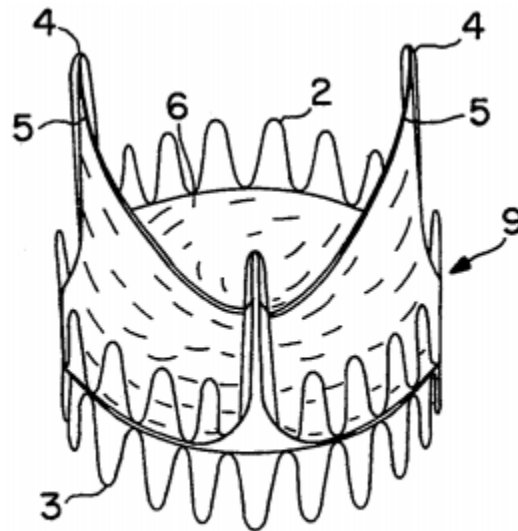
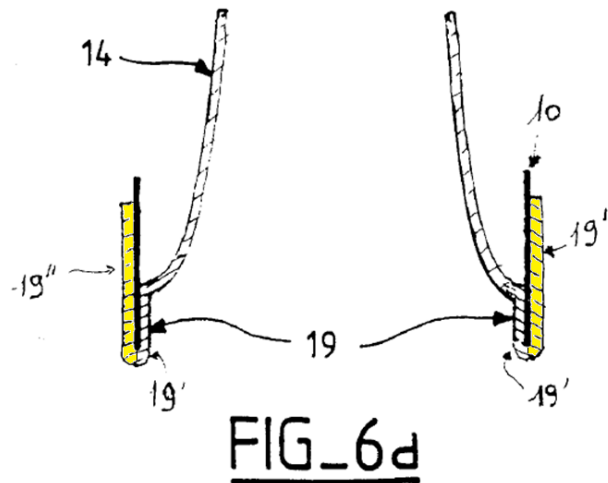


FIG. 2

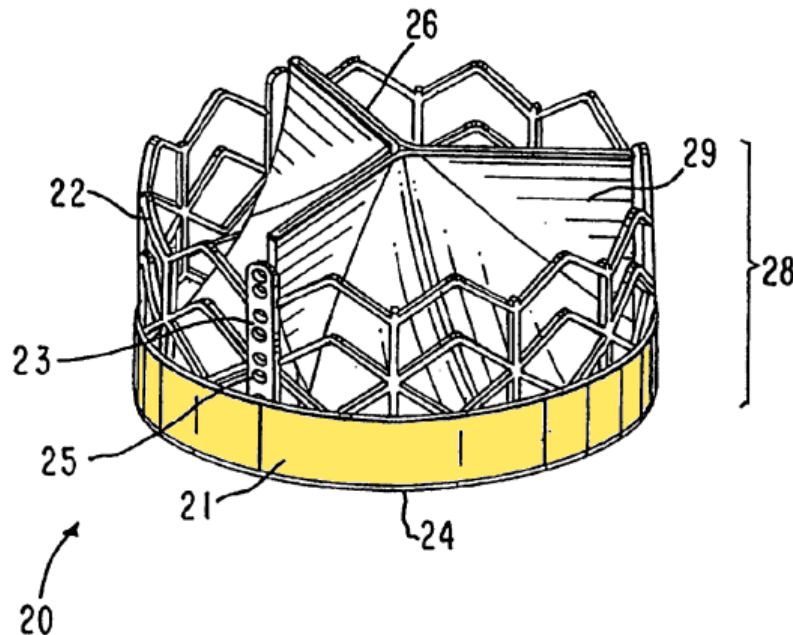
(Ex. 1014, 4:3-17, 5:9-28, Figs. 11-12; Ex. 1003, ¶¶55-57.)

Shortly thereafter, POSITAs began adding outer seals to THVs to reduce PVL. In 1996, Dr. Alan Cribier filed a patent application on a THV having an internal cover (19') that is "rolled up to be applied to the external wall of the stent" to form an outer seal (19'') [yellow]:



(Ex. 1018, 22:11-26, Fig. 6d.) The outer seal (19'') prevents blood from leaking through or around the device. (*Id.*) **Cribier '321**, relied on herein, is a continuation-in-part of the 1996 application and includes the above embodiment. (Ex. 1045, 13:28-30, Fig. 6d.)

Similarly, in 2001, Percutaneous Valve Technologies (“PVT”), a company founded by Dr. Cribier, filed a patent application on a THV that disclosed an outer seal, or “cuff portion,” wrapped around the support stent’s inlet:



(Ex. 1019, 9:19-22, Fig. 1.) The cuff portion helped prevent leakage around the stent. (*Id.*, 8:47-50; Ex. 1003, ¶64.) **Spenser**, relied on herein, is a continuation-in-part of the 2001 patent application and includes the above embodiment. (Ex. 1010, 13:22-25, Fig. 1.)

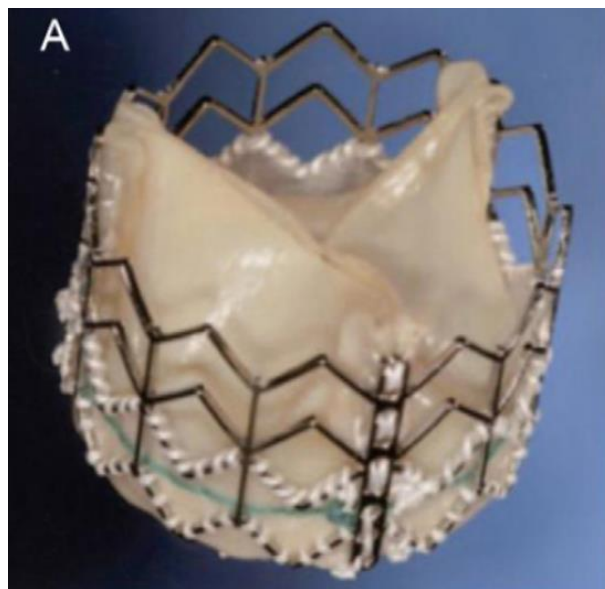
In April 2002, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. (Ex. 1025, 3006.) The THV included a metallic balloon-expandable stent that was crimped onto a delivery balloon:



(*Id.*, 3006, Fig. 1.) The THV was implanted through the patient's right femoral vein.

(*Id.*, 3007.)

In 2004, Petitioner acquired PVT and began testing the Cribier-Edwards THV, which included (1) a metallic outer frame, (2) an inner graft covering, and (3) stitches securing the graft covering to the outer frame:



(Ex. 1023, 154, Fig. 3A (excerpt); Ex. 1003, ¶68.)

Petitioner also collaborated with physicians to modify the Cribier-Edwards THV to include an external fabric cuff designed “to provide a better seal...[and] minimize[e] paraprosthetic leak.”² (Ex. 1017, 2, Fig. 2.)

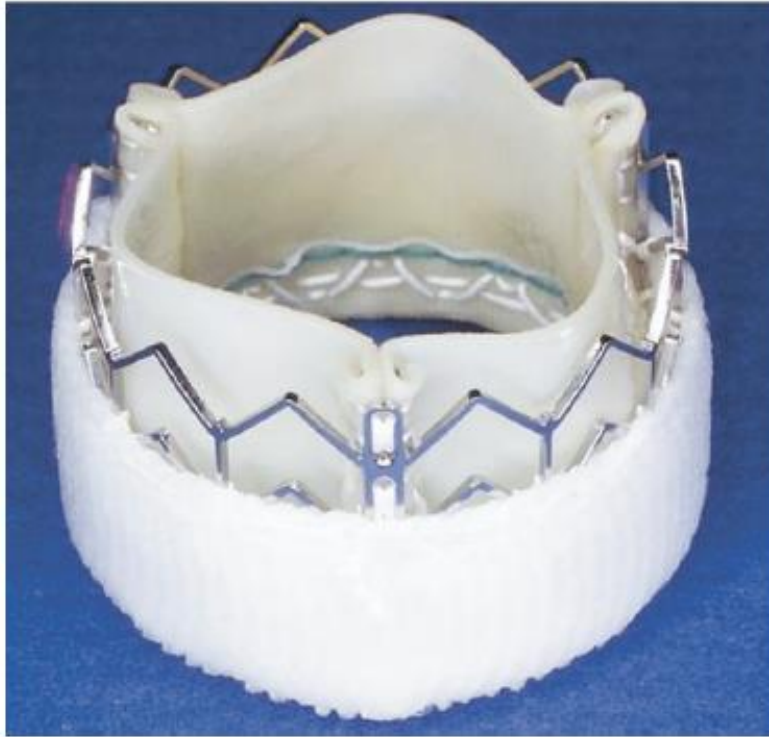
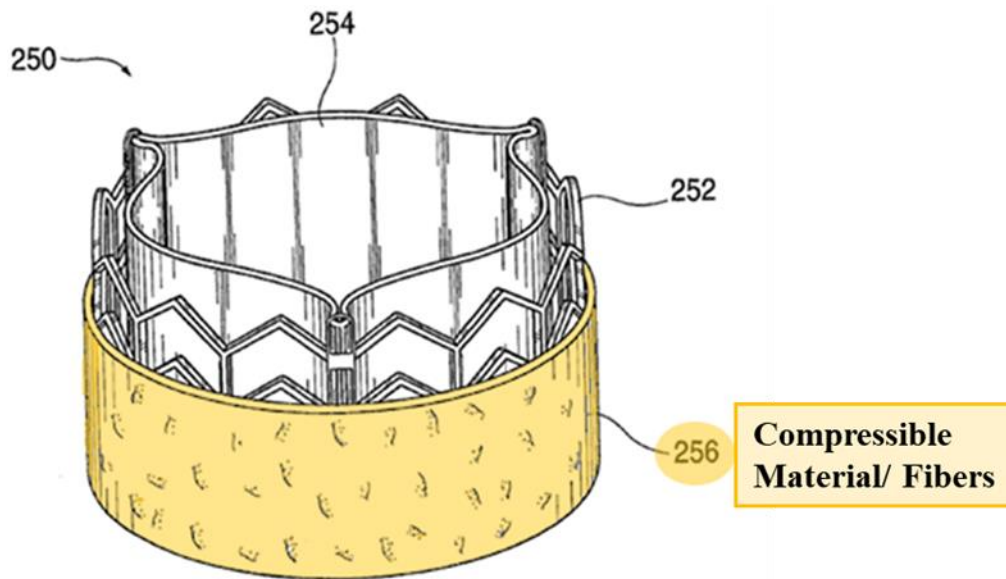


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

² “Paraprosthetic,” “perivalvular,” and “paravalvular” leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve. (Ex. 1003, ¶71, n.3.)

In 2004, Petitioner filed **Spenser II**, which discloses a THV having “a layer of compressible material 256 ... disposed along an outer surface of the stent structure 252” to prevent PVL:



(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶¶69-70.) The compressible material “may resemble a cloth or fabric having small fibers extending from the surface of the material.” (*Id.*)

By 2007, Petitioner had modified the Cribier-Edwards valve to create SAPIEN. SAPIEN was one of the world’s first commercially available THVs and the subject of a large clinical trial, the results of which were published in The New England Journal of Medicine in 2010. (Ex. 1022.) SAPIEN addressed a long-felt need in the industry for an aortic valve replacement device that did not require open-

heart surgery. (Ex. 1003, ¶72.) The FDA approved SAPIEN for use in patients in 2011. (Exs. 1032-1033.)

Walther, a 2011 publication referenced herein, discloses implanting SAPIENs having a fibrous outer cloth into existing surgical valves:

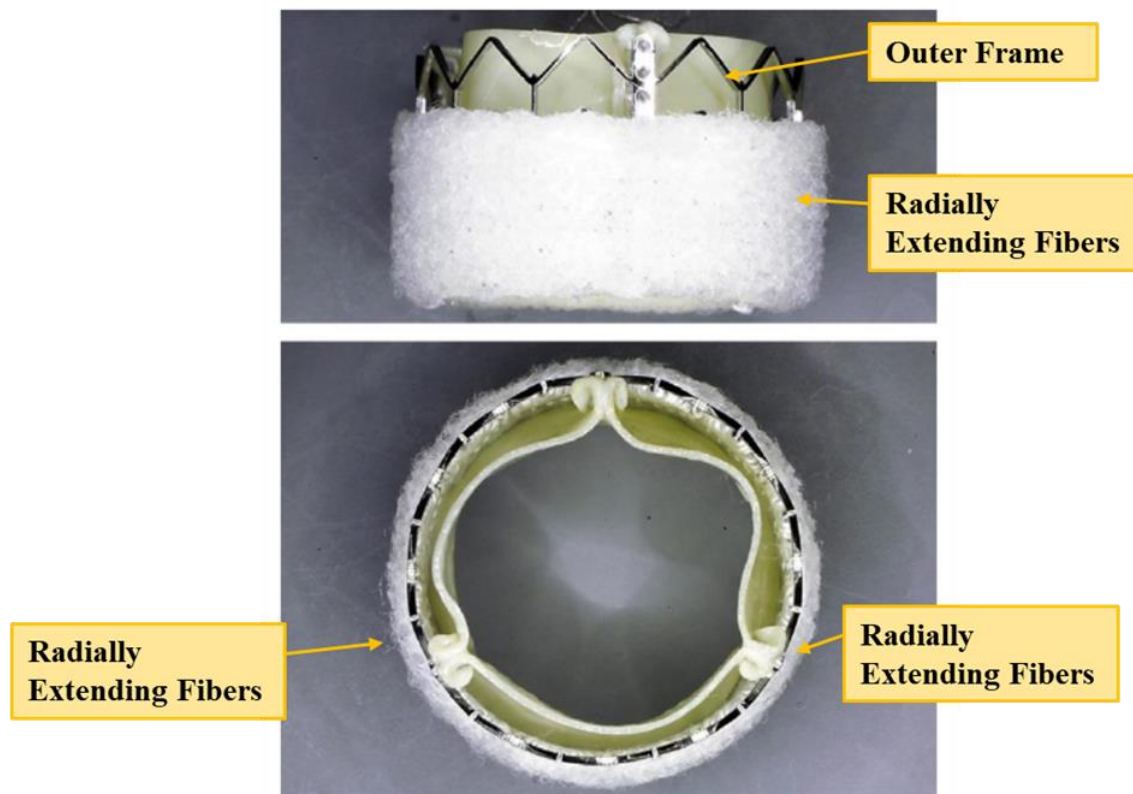
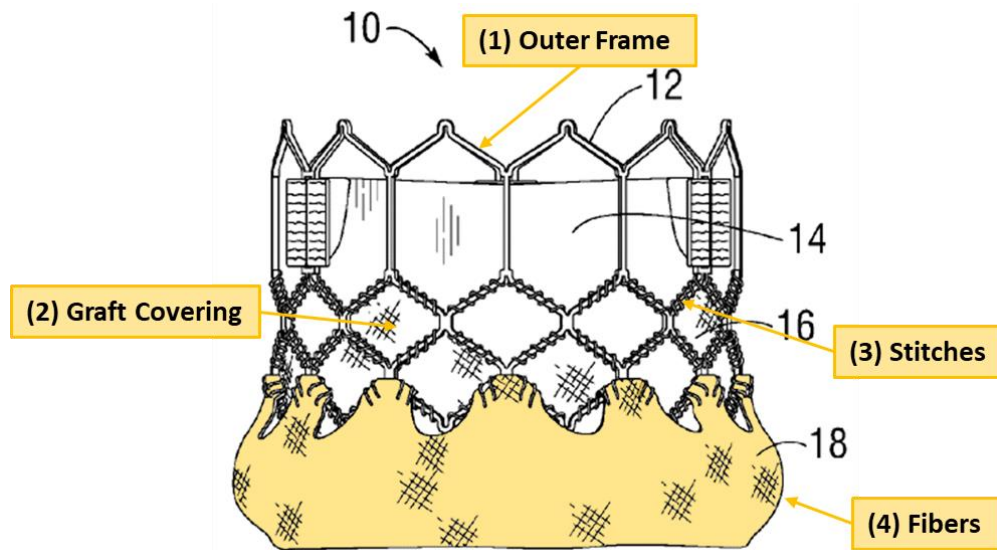


Fig. 1. Cloth valve.

(1007, 1120-21, Fig. 1.) Walther explains that the “addition of an outer cloth to the SAPIEN cloth valve is designed to reduce [PVL] by creating a seal between the two valves.” (*Id.*) Walther concludes that the cloth-covered SAPIEN “demonstrated excellent hydrodynamic performance.” (*Id.*, 1125.)

Similarly, **Levi**, a patent filed by Petitioner in 2010, discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame:



(Ex. 1008, 13:50-14:7, Fig. 3.) Levi’s outer skirt forms “a good fluid-tight seal between the valve and the native annulus.” (*Id.*)

The above references show that the challenged claims merely combine known heart-valve features according to known techniques to yield predictable results. The claims do not describe any new heart-valve features or combine the known features in a nonobvious way. Therefore, the challenged claims are unpatentable.

III. THE ’846 PATENT

A. Overview

The ’846 patent describes a “heart valve assembly” having a “dual-frame” that includes a “self-expanding outer frame 216” [red] and a “balloon-expandable inner

frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32”:

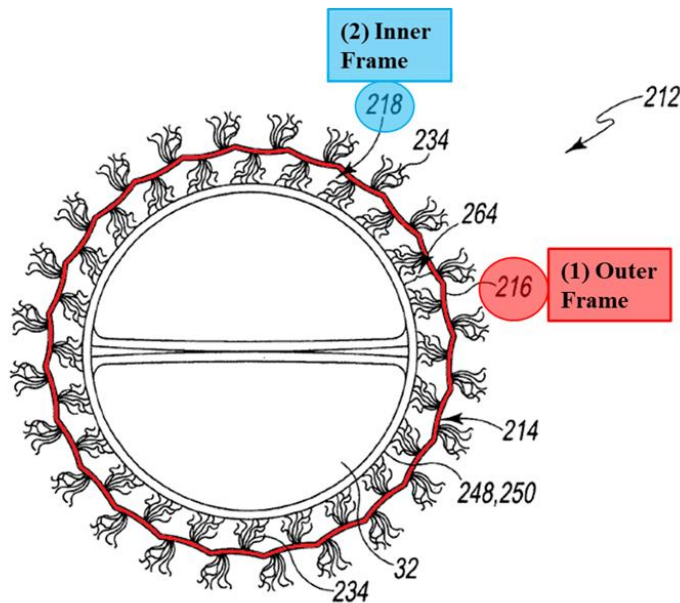
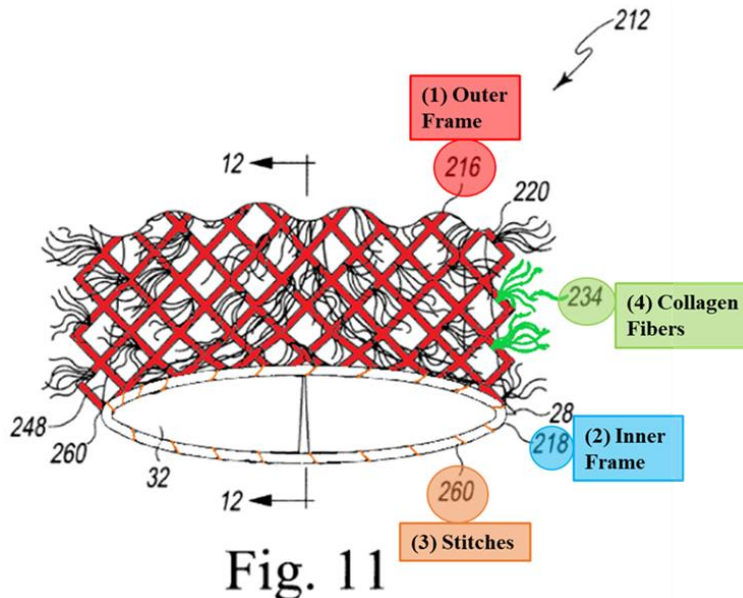


Fig. 13

(Ex. 1001, 11:61-12:21, Fig. 13.)

The metallic or polymeric outer frame [red] defines an “open-cell stent configuration.” (*Id.*, 13:17-20, Fig. 9.) The outer frame includes radially extending collagen fibers [green] attached to the frame to aid in preventing PVL and migration of the valve. (*Id.*, 12:43-46.) The metallic or polymeric inner frame [blue] is a “balloon-expandable tubular stent.” (*Id.*, 13:41-44.) Stitches [orange] secure the inner frame to the outer frame. (*Id.*, 14:6-8.)



B. Prosecution History

The '846 patent issued without any rejection asserted by the Examiner. (Ex. 1002.)

In a Preliminary Amendment, Patent Owner included attorney argument characterizing the prior art. However, as explained herein, the characterizations were incomplete or inaccurate. (*Infra* §IX.)

Patent Owner also alleged that Petitioner's SAPIEN 3 Ultra “appears to be covered by the claimed invention herein.” (Ex. 1002, 145-146.) Petitioner cited a publication highlighting SAPIEN 3 Ultra's success as allegedly supporting patentability of the challenged claims. (*Id.* (citing Ex. 1041).) However, SAPIEN 3 Ultra is based on technology innovated by Petitioner before the Critical Date.

Patent Owner also argued that the “claimed invention” improves on “the prior art of record in reducing PVL, while maintaining a sufficiently small enough profile to be implanted endovascularly without concerns associated of foreshortening and under-deployment typically expected of a device having an inner and outer seal where the outer seal has significant dimensionality.” (Ex. 1002, 146.) Yet, the ’846 patent does not disclose how to minimize valve profile for endovascular delivery or address “foreshortening” and “under-deployment.” Further, most of the challenged claims do not require endovascular implantation, and the one that does is devoid of limitations related to minimizing profile.

C. The Critical Date

The ’846 patent claims priority to two provisional applications: application No. 61/567,458 (“the ’458 provisional”), filed December 6, 2011; and application No. 61/723,446 (“the ’446 provisional”), filed on November 7, 2012. (Ex. 1001.) During prosecution of U.S. Patent No. 10, 792,172 (the “’172 patent), a parent to the ’846 patent, Patent Owner stated that the ’172 patent’s “effective filing date . . . is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012.” (Ex. 1049, 274.) This admission also applies to the challenged claims, which are similar in scope to the ’172 patent claims. Additionally, in the

Litigation, Patent Owner concedes that he did not file any patent applications describing outwardly extending fibers until 2012. (Ex. 1050, 9.)

Patent Owner is correct that the '846 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '846 patent's claims. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Patent Owner first added the disclosure of outwardly extending fibers in the November 2012 provisional. (Ex. 1006, [0024].)

IV. STATEMENT AND RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1, 3-8, 11-12	103	Cribier + Walther
2	1-12	103	Spenser + Walther
3	1-12	103	Spenser + Spenser II
4	1-12	102(e)	Levi
5	1-12	103	Levi
6	1-12	103	Levi + Walther
7	1-12	103	Levi + Spenser II
8	10	103	Levi + Cribier '321

9	10	103	Levi + Cribier '321 + Walther
10	10	103	Levi + Cribier '321 + Spenser II

B. The Asserted References Are Prior Art

The Critical Date of the '846 patent is November 7, 2012. (*Supra* §III.C.) The following references are prior art under pre-AIA §102(b):

- (1) Cribier (Ex. 1012) published in August 2009;
- (2) Walther (Ex. 1007) published on April 3, 2011;
- (3) Spenser (Ex. 1010) issued on March 31, 2009;
- (4) Spenser II (Ex. 1011) published on January 12, 2006; and
- (5) Cribier '321 (Ex. 1045) issued on September 8, 2009.

Levi (Ex. 1008) was filed on Oct. 5, 2011 and published on May 17, 2012. Thus, Levi is prior art under pre-AIA §102(e).

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). Each reference is from the same field as the '846 patent, e.g., minimally invasive devices for treating heart valves. (Ex. 1003, ¶38.) The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic

regurgitation or stenosis through a minimally invasive procedure. (*Id.*) As analogous art, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

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 as a team in combination with a medical device engineer to experiment with or manufacture a prosthetic heart valve. (Ex. 1003, ¶47.)

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 the prosecution history. 37 C.F.R. §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

VII. PROPOSED GROUNDS FOR UNPATENTABILITY

A. Ground 1: Claims 1, 3-8, 11-12 Obvious Over Cribier and Walther

Cribier describes SAPIEN and an endovascular technique for implanting SAPIEN. (Ex. 1012.) Walther discloses modified SAPIENs having outer sealing cloths:

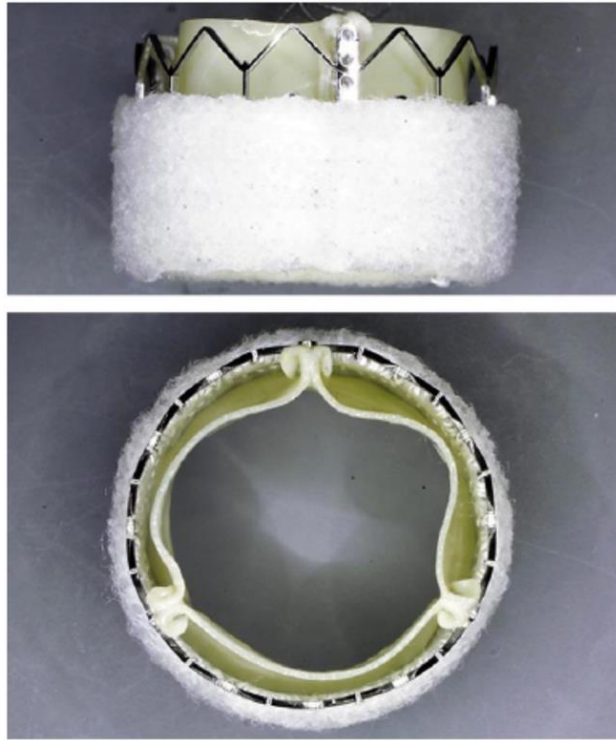


Fig. 1. Cloth valve.

(Ex. 1007, 1120-21, Figs. 1-3.) Walther explicitly discloses that the modified SAPIENs were “identical” to SAPIEN except for the outer cloth. (*Id.*, 1120.) While Walther generally describes SAPIEN, which was well known to POSITAs, it does not include some of the details in Cribier. Thus, Cribier combined with Walther discloses the limitations in claims 1, 3-8, and 11-12 and renders the claims obvious. (Ex. 1003, ¶¶96-97.)

1. Claim 1

Cribier and Walther render claim 1 obvious. (*Id.*, ¶¶98-138.)

a. Preamble

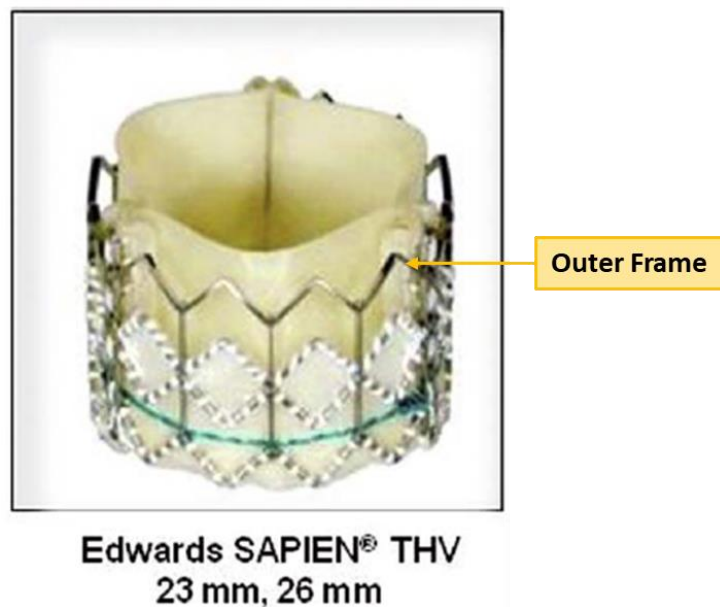
Cribier describes SAPIEN, which is a “valve assembly.” (Ex. 1012, 348, Fig.

1; Ex. 1003, ¶¶99-101.)

b. Outer Frame

Cribier discloses “an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration.” (Ex. 1003, ¶¶102-103.)

Cribier discloses that SAPIEN includes “a tubular slotted stainless-steel” stent. (Ex. 1012, 348.) The stent defines an open cell configuration and surrounds the other valve components, making it an “outer frame”:



(*Id.*, Fig. 1; Ex. 1003, ¶103.)

c. Inner Frame

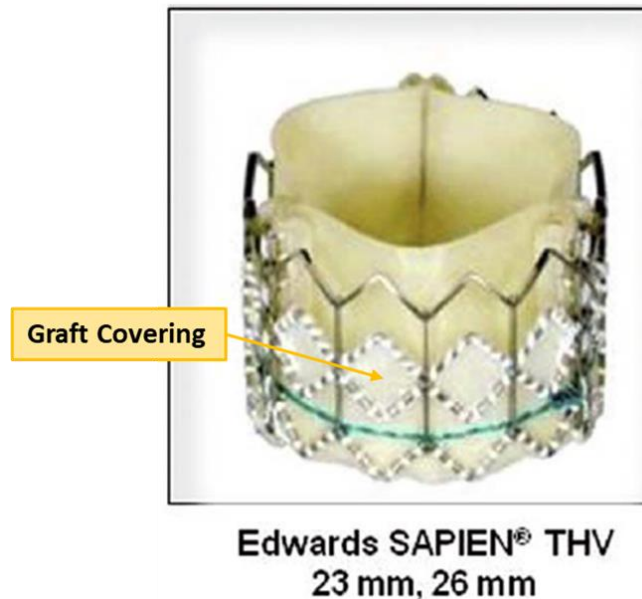
Cribier discloses “an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart

valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.” (Ex. 1003, ¶¶104-110.)

During prosecution, Patent Owner argued that an inner graft covering *alone* satisfies the limitation “an inner frame...wherein the inner frame *includes* a cylindrically extending inner graft covering.” For example, Patent Owner argued the claimed inventions improved upon the art “by having an inner frame that is a graft covering around the heart valve[.]” (Ex. 1002, 133.) Patent Owner also attempted to distinguish prior art on the ground that it allegedly did not include a “graft forming the inner frame.” (*Id.*, 138.) Patent Owner also argued that Petitioner’s SAPIEN 3 Ultra product is “covered by the claimed invention” because it “includes an inner frame that is a graft.” (*Id.*, 145-146.) Patent Owner has made the same allegations in the Litigation, despite Sapien 3 Ultra not having outer and inner frames.³ (Ex. 1050, 43-44)

Cribier discloses that SAPIEN includes an inner “(PET) fabric cuff,” which is a graft covering:

³ Petitioner preserves arguments that the ’846 patent does not describe an inner frame that is a graft covering and that a graft covering cannot be an inner frame.



(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶¶107-108.) The fabric cuff cylindrically extends radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame. (*Id.*) Based on Patent Owner’s statements during prosecution, SAPIEN’s fabric cuff meets the inner frame limitation. (Ex. 1003, ¶¶107-108.)

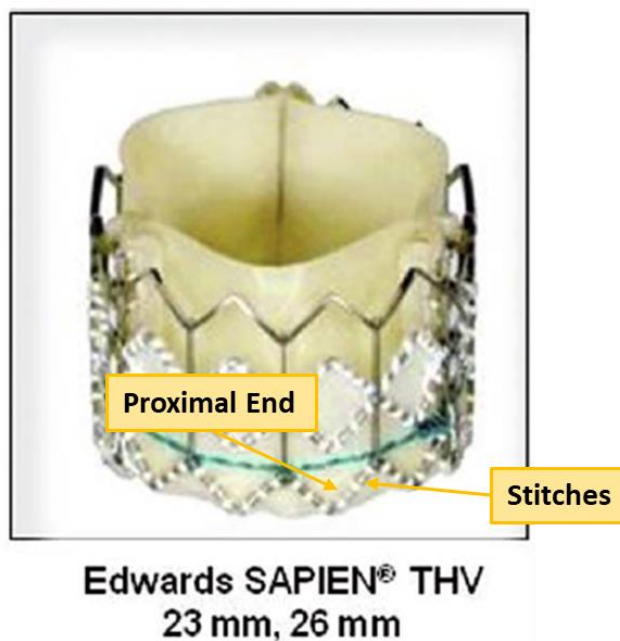
Cribier also discloses that SAPIEN includes a “tissue valve” comprised of “prosthetic leaflets.” (Ex. 1012, 348.) SAPIEN’s fabric cuff “engages” the leaflets along the blue suture line (above). (Ex. 1012, Fig. 1; Ex. 1003, ¶109.)

SAPIEN’s fabric cuff provides sealing to the prosthetic valve. (Ex. 1003, ¶110; *see also* Ex. 1023, 154 (SAPIEN included a “higher sealing cuff to reduce [PVL].”); Ex. 1024, 1830 (same); Ex. 1027, 213 (same).) If the cuff did not provide sealing to the valve, blood could leak through the valve and undermine the valve’s efficacy. (Ex. 1003, ¶110.)

d. Stitching

Cribier discloses that SAPIEN’s “outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame.” (Ex. 1003, ¶¶111-112.)

As shown below, white stitches secure SAPIEN’s fabric cuff to the proximal end of the frame:



(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶112.)

e. Outer Seal

Claim 1 recites an “outer seal for preventing paravalvular leaks” that: (1) “begins at a proximal portion of the outer frame and extends over at least two rows of cells formed in the outer frame”; (2) “is attached to the outer frame”; (3) “is formed of outwardly extending fibers positioned externally to the outer frame”; and

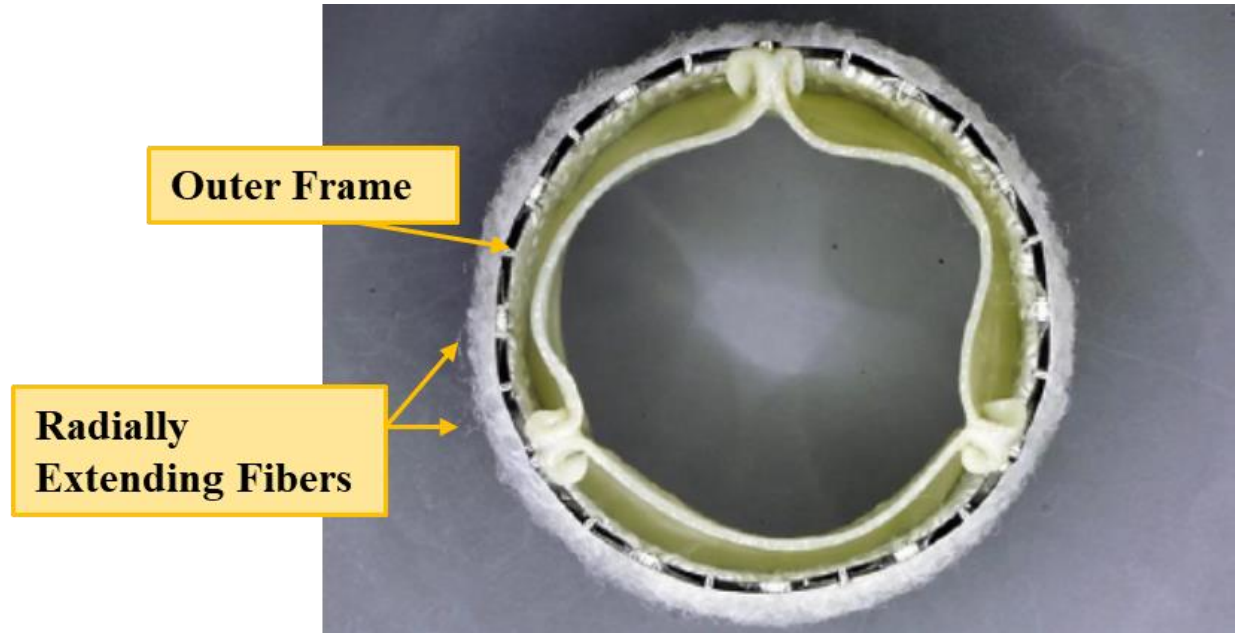
(4) “is free of an outer graft covering between the fibers and the outer frame.” Cribier and Walther render these limitations obvious. (Ex. 1003, ¶¶113-126.)

Walther’s outer cloth (i.e., outer seal) is “designed to reduce paravalvular leak by creating a seal[.]” (Ex. 1007, 1120; Ex. 1003, ¶114.) The outer cloth begins at the proximal end of SAPIEN’s outer frame and covers the bottom two rows of cells formed in the frame. (Ex. 1003, ¶115.) A comparison of Walther’s Figure 1 (left) and Cribier’s Figure 1 (right) illustrates that Walther’s outer cloth extends over at least two rows of cells:



(Ex. 1007, Fig. 1 (excerpt); Ex. 1012, Fig. 1; Ex. 1003, ¶115.) Walther’s outer cloth is “stitched” (i.e., attached) to SAPIEN’s outer frame. (Ex. 1007, 1121, Fig. 1.)

Walther’s outer cloth is formed of outwardly extending fibers positioned externally to SAPIEN’s outer frame:



(Ex. 1007, 1121, Fig. 1 (excerpt); Ex. 1003, ¶¶117-119.) As shown above, the ends of many fibers are beyond the outer frame. (Ex. 1003, ¶117.)

Walther’s outer cloth is also “free of an outer graft covering between the fibers and the outer frame.” (Ex. 1003, ¶120.) Walther’s fibers directly contact the frame without any visible intervening graft covering and Walther never mentions an “outer graft covering.” (Ex. 1007, Fig. 1; Ex. 1003, ¶120.) Walther also discloses that the outer cloth was the only modification made to the SAPIENs. (Ex. 1007, 1120.) As shown below, SAPIEN does not include any “outer graft covering” on the exterior of the frame:



**Edwards SAPIEN® THV
23 mm, 26 mm**

(Ex. 1012, Fig. 1; Ex. 1003, ¶120.)

POSITAs would have been motivated to combine Walther’s outer cloth with SAPIEN, as described in Cribier, because Walther expressly discloses this combination. (Ex. 1007, 1120-1121; Ex. 1003, ¶126.) POSITAs would have reasonably expected success in combining Walther’s outer cloth with SAPIEN because Walther describes how to make the combination, provides images of the combination, and concludes that the cloth-covered SAPIEN “demonstrated excellent hydrodynamic performance.” (Ex. 1007, 1125; Ex. 1003, ¶126.)

f. Radially Compressed and Expanded Orientation

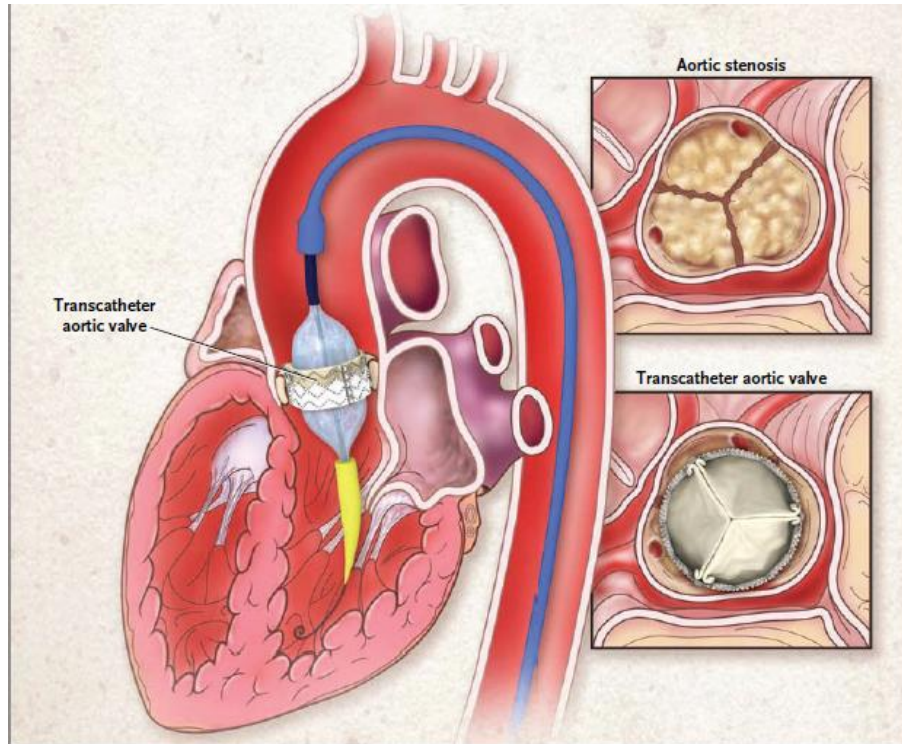
Cribier and Walther disclose “wherein the valve assembly has a radially compressed orientation and a radially expanded orientation.” (Ex. 1003, ¶¶127-128.)

Cribier discloses that SAPIEN is “**compressed** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its **expanded size** to its ‘mounted’ size.” (Ex. 1012, 348 (emphasis added).) Similarly, Walther discloses that the cloth-covered SAPIENs were crimped onto a balloon and then expanded within surgical valves. (Ex. 1007, 1122, Fig. 4.)

g. Balloon Expandable

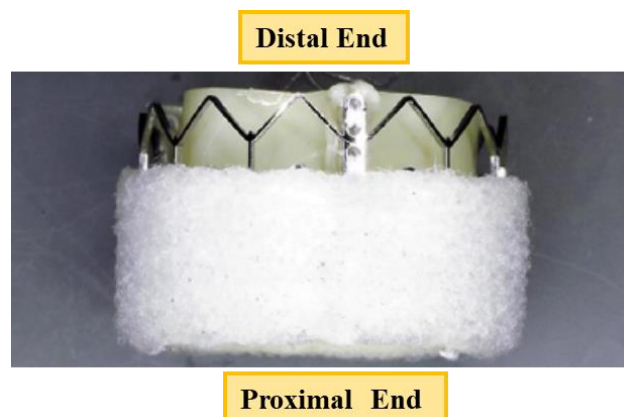
Cribier and Walther render obvious “wherein the valve assembly is balloon expandable and expansion of the valve assembly is configured to press some of the fibers against native leaflets of the aorta of the patient.” (Ex. 1003, ¶¶129-138.)

SAPIEN is balloon expandable. (Ex. 1012, 348; Ex. 1007, 1122.) SAPIEN also presses against the aortic valve’s native leaflets upon implantation. Cribier states that SAPIEN is “advanced to the native aortic valve...positioned across the aortic annulus, and delivered by balloon inflation[.]” (See Ex. 1012, 347.) Cribier instructs that “before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion.” (*Id.*, 353.) When expanded in this position, SAPIEN presses against and replaces the patient’s native aortic leaflets, as illustrated below:



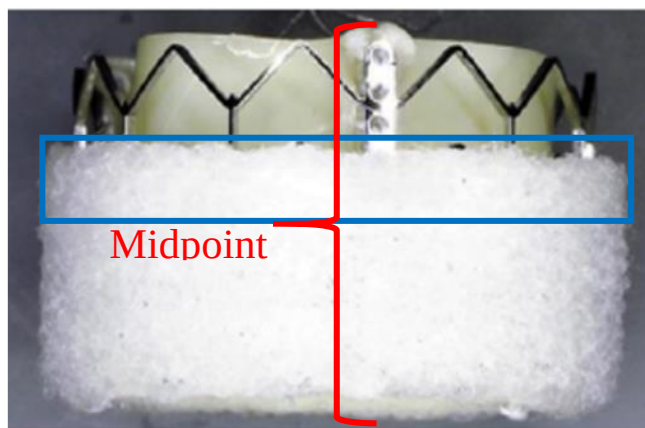
(Ex. 1022, 2189, Fig. 1; Ex. 1003, ¶132.) Some publications describe SAPIEN as “crush[ing] the leaflets of the native valve against the wall.” (Ex. 1047, 74.)

Expanding Walther’s cloth-covered SAPIEN in a native aortic valve would press some of the outer cloth’s fibers against the native leaflets. (Ex. 1003, ¶133.) Walther’s outer cloth covers approximately two-thirds of SAPIEN’s frame:



(Ex. 1007, Fig. 1 (excerpt); *supra* §VII.A.1.e.) If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, the fibers “above the annulus” would press against the leaflets. (Ex. 1003, ¶¶48-50, 133.) In fact, Patent Owner admitted during prosecution that an outer seal covering two frame rows would press against the leaflets. (Ex. 1002, 149.)

The '846 patent identifies the annulus as the point where the leaflets begin. (Ex. 1003, ¶¶48-50; Ex. 1001, 1:58-60, Fig. 2; *see also* Ex. 1047, 75-76.) Thus, any fibers “above” the annulus necessarily press against the leaflets. (Ex. 1003, ¶133; Ex. 1047, 74.)



Fibers “above”
the annulus

While Walther describes expanding the cloth-covered SAPIEN in a preexisting surgical valve, POSITAs would have found it obvious to deploy the valve within a patient’s native valve so that the device would press against the native leaflets. (Ex. 1003, ¶¶134-136.) By November 2012, POSITAs understood that PVL could occur with SAPIEN. (*See e.g.*, Ex. 1012, 354 (describing PVL with SAPIEN);

Ex. 1022, 2194 (same); Ex. 1003, ¶136.) Thus, POSITAs would have been motivated to apply Walther’s known technique for reducing PVL (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement and, as discussed below, would yield predictable results. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶136.)

POSITAs would have reasonably expected success in deploying the cloth-covered SAPIEN in a native aortic valve. (Ex. 1003, ¶¶137-138.) Walther describes the successful balloon deployment of the cloth-covered SAPIEN and concludes that the valve “demonstrated excellent hydrodynamic performance” and that an *in vivo* procedure “is feasible.” (Ex. 1007, 1125; Ex. 1003, ¶137.) Moreover, by 2012, POSITAs had successfully and repeatedly implanted SAPIENs within native aortic valves using multiple delivery techniques, including the transapical approach described in Walther, and deemed the procedures safe. (Ex. 1003, ¶137; *see e.g.*, Ex. 1012, 347, 355; Ex. 1043.) Consequently, POSITAs would have reasonably expected success in implanting the cloth-covered SAPIEN within a patient’s native aortic valve. (Ex. 1003, ¶137.)

2. Claim 3

Cribier and Walther render obvious “wherein the outer frame is a singular, integral component.” (Ex. 1003, ¶¶139-140.)

Cribier discloses that SAPIEN's frame is a "tubular slotted stainless-steel" stent. (Ex. 1012, 348.) As shown below, SAPIEN's stent comprises a "singular, integral component":



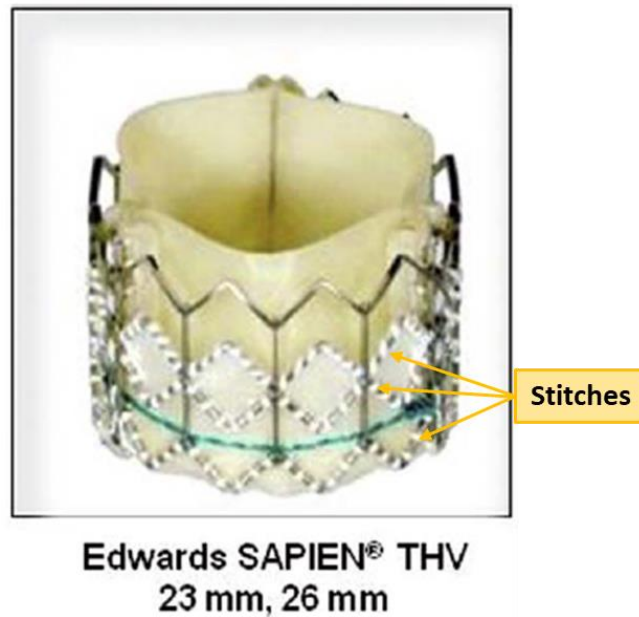
Edwards SAPIEN® THV
23 mm, 26 mm

(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶140.)

3. Claim 4

Cribier and Walther render obvious "wherein the outer frame and the inner graft covering are attached by stitches at a distal and proximal portion of the inner graft covering." (Ex. 1003, ¶¶141-142.)

As shown below, white stitches attach the inner graft covering to the frame at the distal and proximal portions of the graft covering:

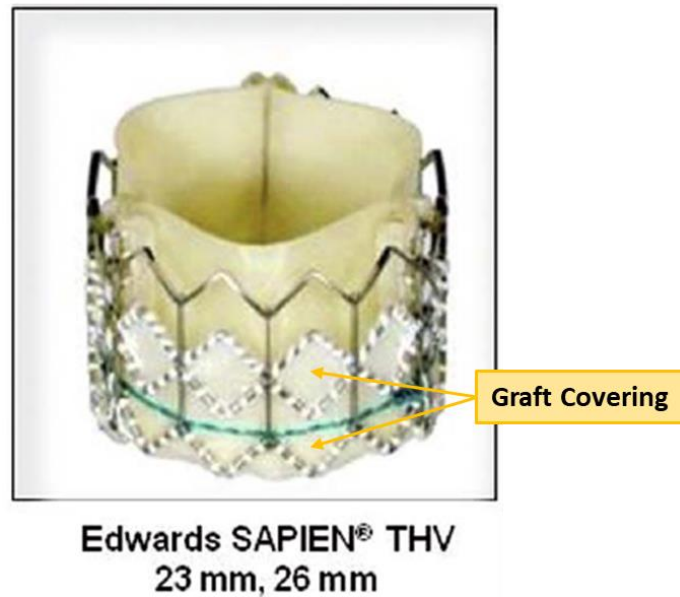


(Ex. 1012, Fig. 1; Ex. 1003, ¶142.)

4. Claim 5

Cribier and Walther render obvious “wherein the inner graft covering and the fibers are distinct elements.” (Ex. 1003, ¶¶143-145.)

Cribier discloses that SAPIEN includes a fabric cuff (graft covering) that is stitched to the inner surface of the stent frame:



(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶144.)

Walther discloses an outer cloth (i.e., fibers) that is “stitched to the perimeter of each SAPIEN valve”:



(Ex. 1007, 1121, Fig. 1 (excerpt).) Walther’s outer cloth and SAPIEN’s fabric cuff are different materials and, therefore “distinct elements.” (Ex. 1003, ¶145.)

5. Claim 6

Cribier and Walther render obvious “wherein the valve assembly is delivered endovascularly.” (Ex. 1003, ¶¶146-154.)

By November 2012, POSITAs would have known that SAPIEN could be endovascularly delivered through different blood vessels. (*Id.*, ¶148.) For example, POSITAs had successfully delivered SAPIEN through the common iliac artery, which is a larger artery that can accommodate bigger devices. (*Id.*; Ex. 1043.) Additionally, POSITAs had successfully delivered SAPIEN through the femoral artery and vein. (Ex. 1012, 347-356; *see also* Ex. 1030, 699; Ex. 1003, ¶149.)

Walther discloses implanting cloth-covered SAPIENs using Edwards’ Ascendra transapical delivery system. (Ex. 1007, 1121.) Transapical delivery is another implantation method that involves inserting the valve through the heart wall. (Ex. 1003, ¶150.)

However, in 2012, POSITAs would have been motivated to endovascularly deliver Walther’s cloth-covered SAPIEN because endovascular delivery was generally considered less invasive than transapical delivery. (*Id.*, ¶¶151-153.) POSITAs could have delivered Walther’s valve through at least the common iliac artery because the artery is large and would not have required modifications to the valve. (*Id.*; Ex. 1043.)

POSITAs also would have been motivated to endovascularly deliver Walther's cloth-covered SAPIEN through the femoral artery. (Ex. 1003, ¶¶152-153.) Many POSITAs considered transfemoral delivery "as the technique of first choice" and safer than transapical delivery. (Ex. 1009, 515-516.) POSITAs would have possessed the necessary skills and equipment to adapt the cloth-covered SAPIENs for transfemoral delivery. (Ex. 1003, ¶153.) First, POSITAs would have had access to many suitable cloths having varying thicknesses and densities and could have selected an appropriately dimensioned cloth for transfemoral delivery. (*Id.*, ¶¶75-78, 153; Ex. 1011, [0055], [00145]; Ex. 1008, 13:49-53.) Second, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. (Ex. 1036, 295-297; Ex. 1037, [0005]-[0006].) These delivery systems permitted POSITAs to endovascularly deliver valves having a greater diameter than SAPIEN alone. (Ex. 1003, ¶¶75-78, 153.) Third, by 2012, Petitioner had adopted new frame metals that reduced profile and developed ways to adapt the frame and leaflets to create additional space for an outer seal. (*Id.*; *see e.g.*, Ex. 1008, 6:31-49, 15:33-17:18.) POSITAs would have found it obvious to utilize one or more of these known techniques to adapt the cloth-covered SAPIEN for transfemoral delivery. (Ex. 1003, ¶¶75-78, 153.)

Additionally, the '846 patent does not claim or disclose how to size the valve for endovascular delivery. (*Id.*, ¶147) For example, the '846 patent never discloses the length, width, or density of the collagen fibers or the valve's crimped diameter. (*Id.*) In fact, the '846 patent consistently defers to the knowledge of POSITAs for sizing. (*E.g.*, Ex. 1001, 7:34-37, 13:44-45.) Consequently, Patent Owner cannot argue that the adaptation of the cloth-covered SAPIEN for endovascular delivery would have been beyond POSITAs' skill. *See e.g., Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013) ("[A]n unclaimed and undisclosed feature . . . cannot be the basis for finding [a] patent to be non-obvious over the prior art."); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) ("[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty . . ."); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003) ("[N]onobviousness is assessed by reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims.").

POSITAs would have reasonably expected success in endovascularly delivering the cloth-covered SAPIEN. (Ex. 1003, ¶154.) Walther concludes that in-human implantation of the cloth-covered valve "is feasible." (Ex. 1007, 1125.)

Further, SAPIEN had been approved for endovascular delivery by the FDA before 2012, and successfully delivered countless times. (*See e.g.*, Ex. 1009, 517; Ex. 1012, 355; Ex. 1032; Ex. 1003, ¶154.) POSITAs had also demonstrated that endovascular approaches using larger arteries, like the common iliac artery, were effective. (Ex. 1043; Ex. 1003, ¶154.)

6. Claim 7

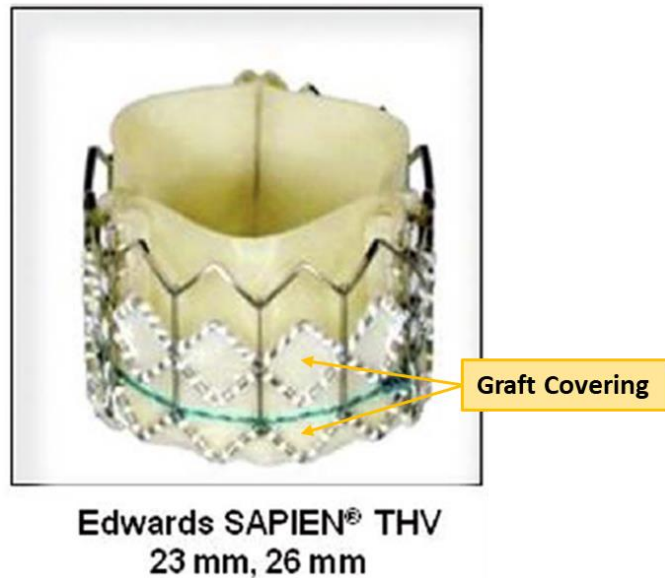
Cribier and Walther render obvious “wherein a seal is created between the inner frame and the outer frame.” (Ex. 1003, ¶¶155-156.)

SAPIEN’s inner fabric cuff “creates a seal between the inner frame and the outer frame” to prevent PVL. (*Id.*; Ex. 1016, 23; *supra* §VII.A.1.c.) SAPIEN would not have worked if a seal did not exist between the fabric cuff and frame because blood could disadvantageously leak between the two. (Ex. 1003, ¶156.)

7. Claim 8

Cribier and Walther render obvious “wherein a portion of the outer frame is uncovered by the graft covering and the outer seal.” (Ex. 1003, ¶¶157-160.)

Cribier illustrates that SAPIEN’s inner fabric cuff does not cover the upper row of cells on the frame:



(Ex. 1012, 348, Fig. 1; Ex. 1003, ¶158.)

Walther's outer cloth also does not cover the upper row of cells, as shown by Walther's Figure 1 (left) and Cribier's Figure 1 (right):

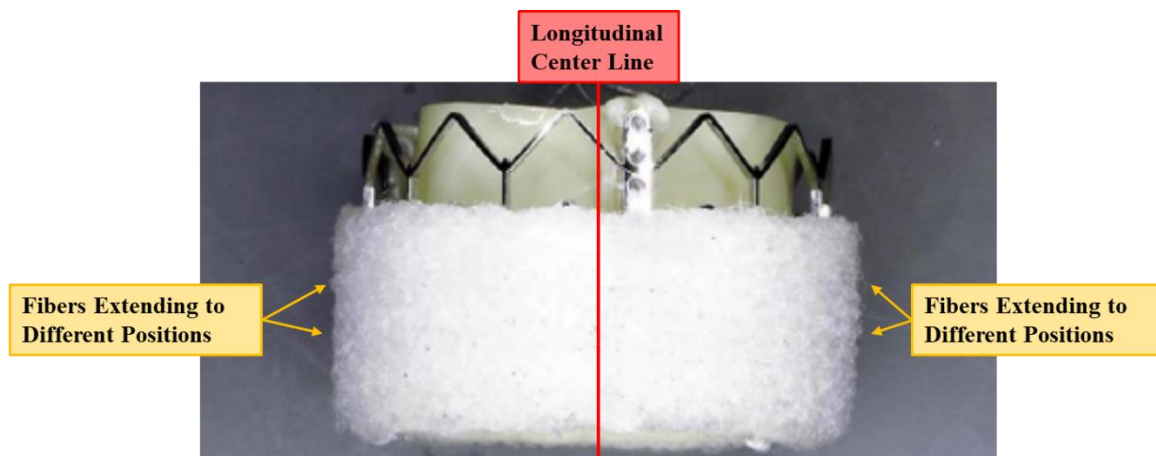


(Ex. 1007, Fig. 1; Ex. 1012, Fig. 1.) Therefore, a portion of SAPIEN's outer frame is uncovered by the fabric cuff and Walther's outer cloth. (Ex. 1003, ¶¶157-160.)

8. Claim 11

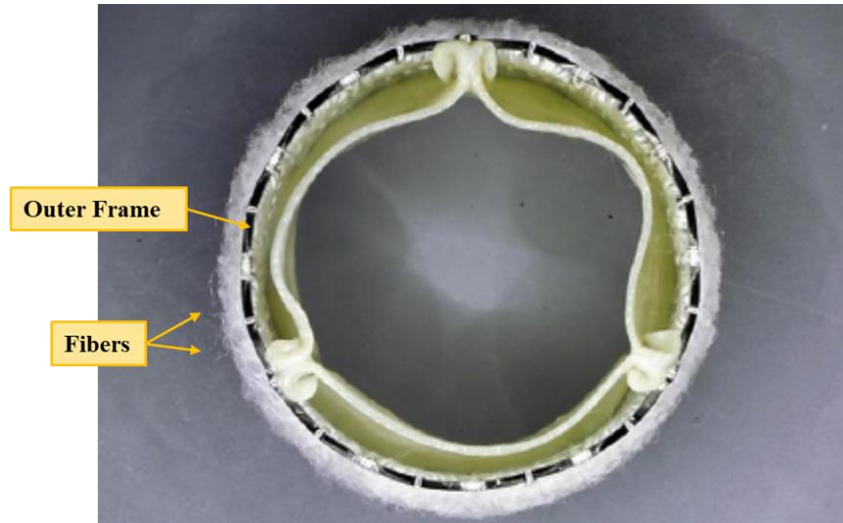
Cribier and Walther render obvious “wherein the outwardly extending fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly.” (Ex. 1003, ¶¶161-163.)

Walther’s outer cloth extends to the left and right of the “centerline.” Thus, Walther’s outer cloth includes fibers that “extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly”:



(Ex. 1007, Fig. 1 (excerpt); Ex. 1003, ¶162.)

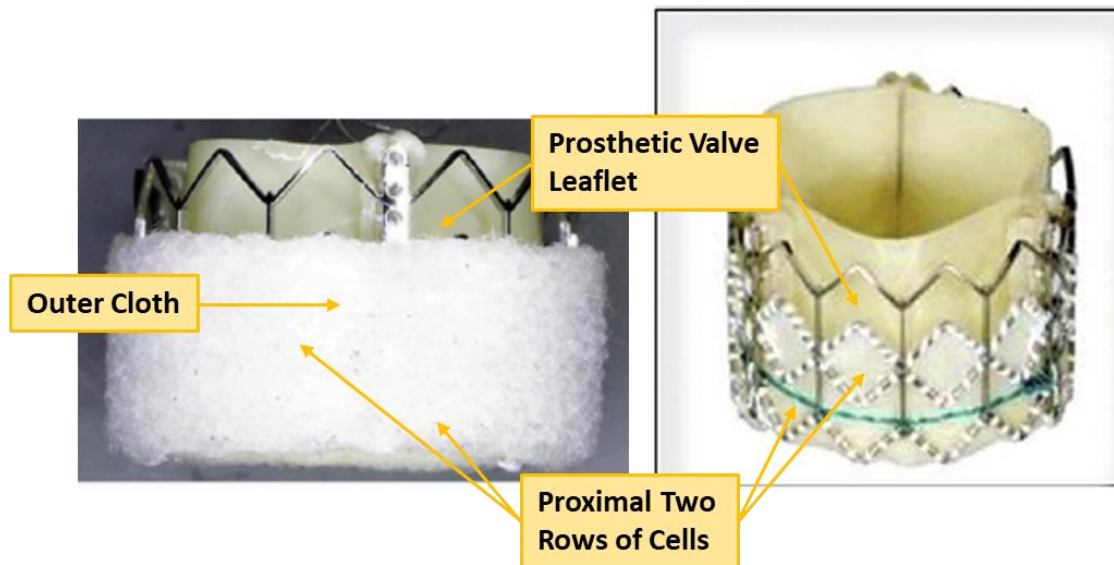
Additionally, Walther’s outer cloth is not uniform. As shown below, some fibers extend further out from the frame than others:



(Ex. 1007, Fig. 1 (excerpt).) Thus, even the fibers on one side of the valve “extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly.” (Ex. 1003, ¶163.)

9. Claim 12

Cribier and Walther render obvious “wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping.” (Ex. 1003, ¶¶164-165.) Walther’s outer cloth and SAPIEN’s fabric cuff cover the proximal two rows of cells:

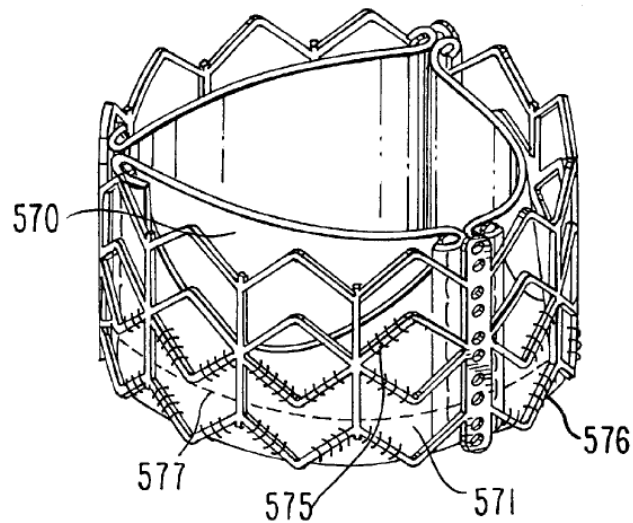


(*Supra* §VII.A.7; Ex. 1007, Fig. 1; Ex. 1012, Fig. 1.) The leaflets are sutured to the cuff at the green line (above right), which is located within the proximal rows of cells. (*Id.*) Therefore, the inner cuff, outer cloth, and prosthetic leaflets radially overlap. (Ex. 1003, ¶165.)

B. Grounds 2-3: Claims 1-12 Obvious Over Spenser and Walther or Spenser II

Spenser describes heart valves similar to SAPIEN including the below embodiment:

FIG. 44a



(Ex. 1010, Fig. 44a; *see also* Ex. 1040 (IFU), 8 (identifying Spenser).)

Walther discloses cloth-covered SAPIENs. (*Supra* §VII.A.1.)

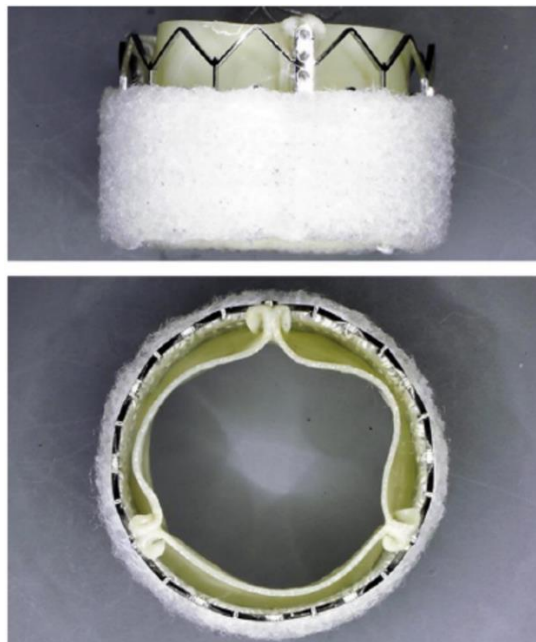


Fig. 1. Cloth valve.

Similarly, Spenser II discloses heart valves having a layer of “compressible

material...disposed along the outer surface of the stent structure” to reduce PVL:

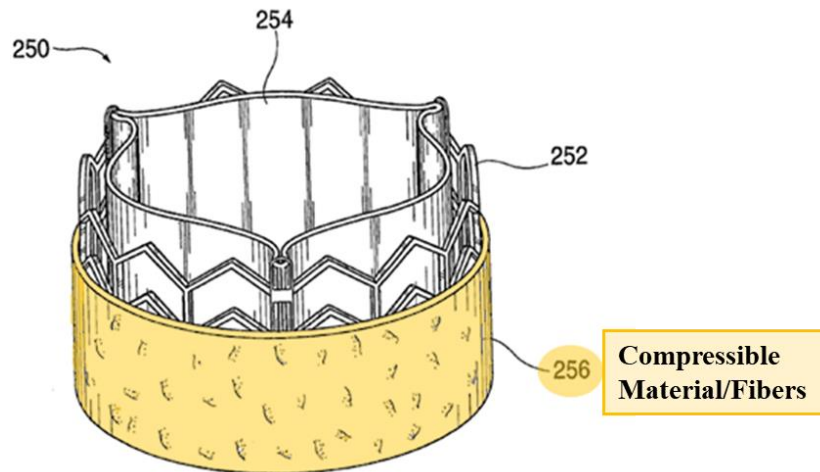


FIG. 22

(Ex. 1011, [00144]-[00145], Fig. 22.)

POSITAs would have been motivated to combine Walther’s outer cloth or Spenser II’s compressible material with Spenser’s Figure 44a as described below. (Ex. 1003, ¶¶167-168.) Thus, claims 1-12 are obvious over Spenser in combination with Walther or Spenser II. (*Id.*)

1. Claim 1

Spenser and Walther or Spenser II render claim 1 obvious. (Ex. 1003, ¶¶169-207.)

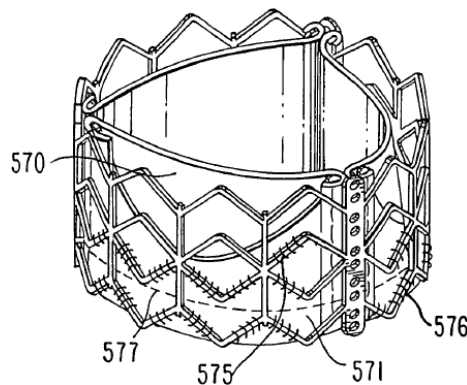
a. Preamble

Spenser discloses “valve assemblies.” (Ex. 1010, 2:29-50; Ex. 1003, ¶¶170-171.)

b. Outer Frame

Spenser discloses this limitation. (Ex. 1003, ¶¶172-174.) Spenser’s Figure 44a illustrates “an implantable prosthetic valve” that includes “frame 575”:

FIG. 44a

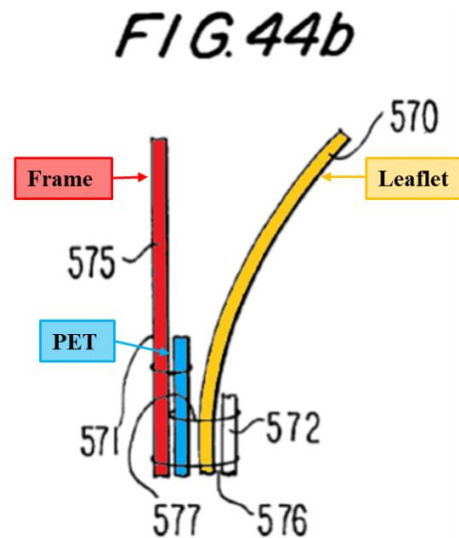


(Ex. 1010, 19:5-13, 26:30-34.) Frame 575 is an outer frame and defines an open cell configuration. (*Id.*, Fig. 44a-44b; Ex. 1003, ¶174.) The frame may be made from metallic materials such as “nickel titanium.” (Ex. 1010, 12:28-31.)

c. Inner Frame

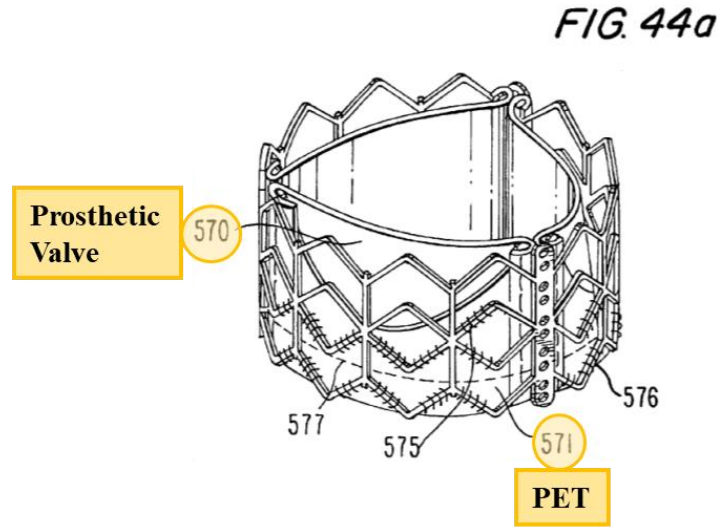
Spenser discloses this limitation. (Ex. 1003, ¶¶175-178.) Spenser’s Figure 44a includes “additional pieces of PET” for “sealing and protecting the pericardium.” (Ex. 1010, 26:30-34, Figs. 44a-44c.) The “pericardium” includes the prosthetic leaflets 570. (*Id.*, 26:30-54; Ex. 1003, ¶176.) PET is a “graft covering.” (Ex. 1003, ¶176.) PET 571 [blue] is positioned “between the leaflets [570 yellow] and frame

[575 red]” and engages the leaflets⁴:



(Ex. 1010, 26:30-54, Fig. 44a-b.) PET 571 is “cylindrically extending” and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:

⁴ In Figure 44b, the lead lines for 571 and 575 point to the outer frame [red]. This is a drafter’s error. The lead line for the outer PET layer 571 should point to the middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶177, n.5.)

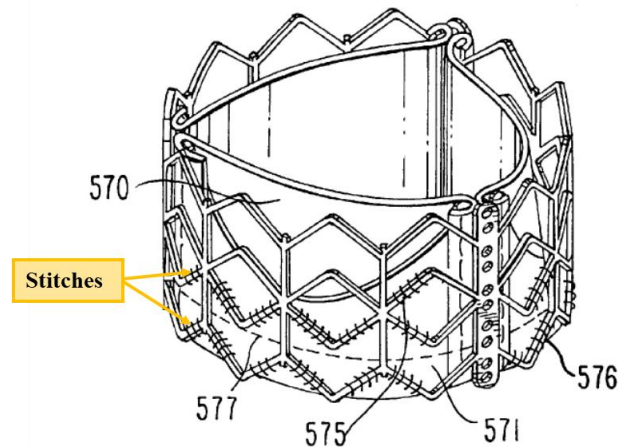


(*Id.*) Thus, based on Patent Owner’s prosecution statements, PET 571 satisfies the “inner frame” limitations. (Ex. 1003, ¶¶176-178.)

d. Stitching

Spenser discloses this limitation. (Ex. 1003, ¶¶179-181.) Spenser discloses that a “[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a strong sealing line.” (Ex. 1010, 26:45-47, Figs. 44a-44c.) As shown, the inner graft covering is secured to the proximal end of the frame with stitches:

FIG. 44a



(*Id.*, Fig. 44a-b; Ex. 1003, ¶181.)

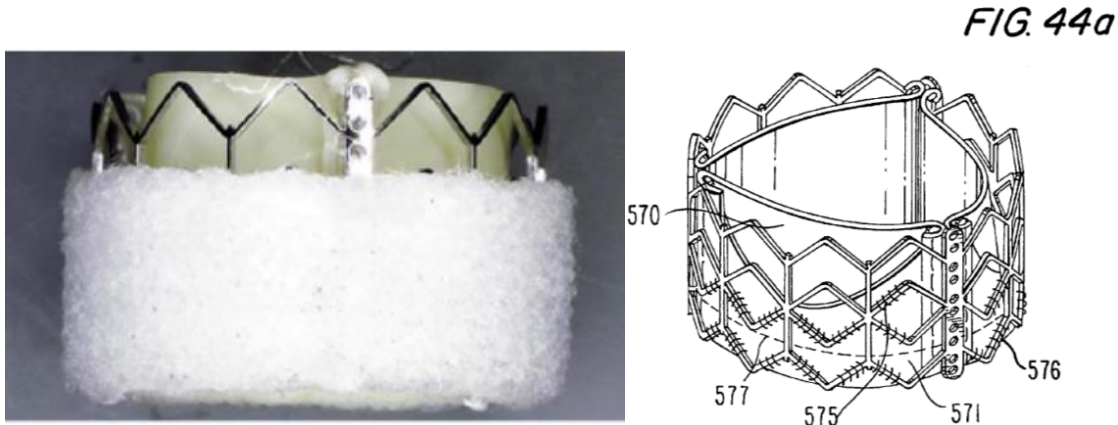
e. Outer Seal

Spenser and Walther or Spenser II render the outer seal limitations obvious.

(Ex. 1003, ¶¶182-197.)

i. Walther

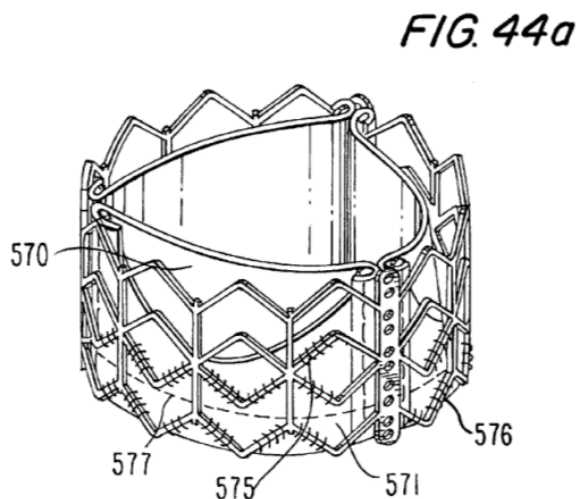
Walther discloses a fibrous outer cloth for preventing PVL that begins at the proximal portion of SAPIEN's frame and covers two rows of cells formed from the frame. (*Supra* §VII.A.1.e.) SAPIEN is similar (if not identical) to Spenser's Figure 44a. (Ex. 1003, ¶183.) Thus, Walther's outer cloth would also begin at the proximal portion of Figure 44a's frame and cover two rows. (*Id.*) A comparison of Walther's Figure 1 (left) and Spenser's Figure 44a (right) illustrates that Walther's outer cloth would begin at the proximal portion and cover the bottom two rows:



(Ex. 1007, Fig. 1; Ex. 1010, Fig. 44a; Ex. 1003, ¶183.)

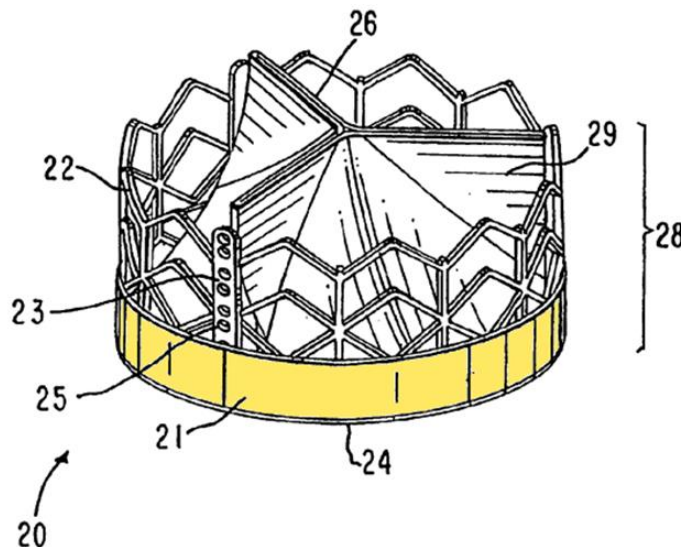
Walther's outer cloth is stitched to SAPIEN's outer frame. (*Supra* §VII.A.1.e.) POSITAs would have been motivated to attach Walther's outer cloth to Figure 44a's frame in the same way because stitching is simple, was successful in Walther, and would have been known to POSITAs. (Ex. 1003, ¶184.)

Walther's outer cloth is "free of an outer graft covering between the fibers and the outer frame." (*Supra* §VII.A.1.e.) Likewise, Spenser's Figure 44a does not have an "outer graft covering" on the exterior of the outer frame 575:



(Ex. 1010, Fig. 44a; Ex. 1003, ¶185.) Therefore, if Walther’s outer cloth were added to Figure 44a’s frame, there would be no “outer graft covering” between the outer cloth’s fibers and frame. (Ex. 1003, ¶185.)

POSITAs would have been motivated to combine Walther’s outer cloth with Spenser’s Figure 44a because Walther expressly discloses combining an outer cloth with a similar (if not identical) heart valve (SAPIEN). (Ex. 1007, 1020-1021; Ex. 1003, ¶186.) Additionally, Spenser suggests adding an outer cloth to Figure 44a by disclosing a similar valve with an outer cuff portion 21 for sealing around the valve:



(Ex. 1010, 13:22-25, Fig. 1.) Adding Walther’s outer cloth to Figure 44a would have merely entailed applying a known technique (attaching an outer cloth) to a known device (Figure 44a) ready for improvement (enhanced sealing). *KSR Int’l*, 550 U.S. at 416.

POSITAs would have reasonably expected success in combining Walther's outer cloth with Figure 44a because Walther discloses how to combine the cloth with a similar heart valve, provides images of the combination, and concludes that the cloth-covered valve "demonstrated excellent hydrodynamic performance." (Ex. 1007, 1125; Ex. 1003, ¶187.)

ii. Spenser II

Spenser II also discloses the claimed outer seal. (Ex. 1003, ¶¶189-197.) Spenser II discloses that "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252":

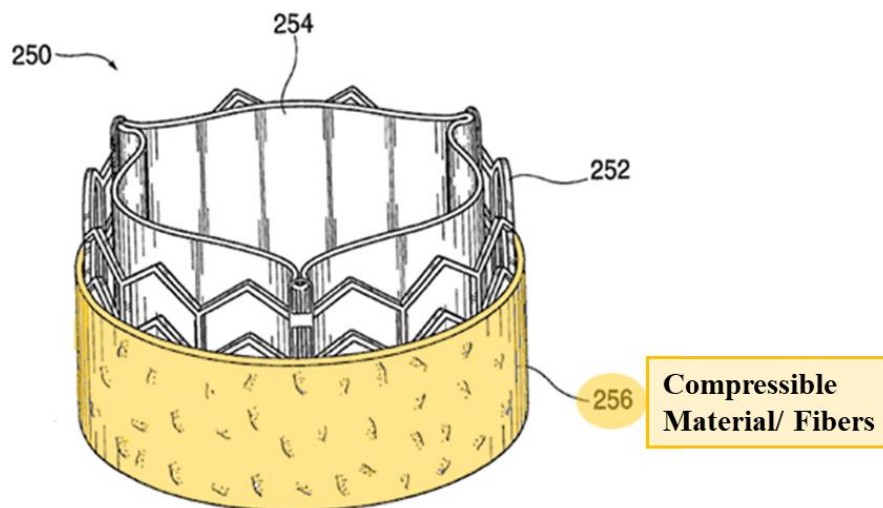


FIG. 22

(Ex. 1011, [00145], Fig. 22.) The compressible material "***may resemble a cloth or fabric having small fibers extending from the surface of the material.***" (*Id.*

(emphasis added).) Spenser II further discloses that the compressible material expands upon implantation and “fills the gaps between the stented valve and the surrounding tissue,” which “creates a mechanical seal that prevents paravalvular leakage.” (*Id.*) Thus, the compressible material is an “outer seal for preventing paravalvular leaks.” (Ex. 1003, ¶189.)

Spenser II’s compressible material begins at the proximal portion of the valve and covers the bottom two rows of cells formed by stent structure 252:

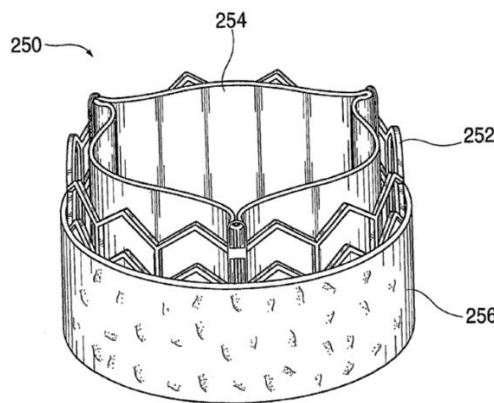


FIG. 22

(Ex. 1011, Fig. 22; Ex. 1003, ¶190.)

When added to Spenser’s Figure 44a, the compressible material would also begin at the proximal portion and cover the bottom two rows of cells formed by the frame. (Ex. 1003, ¶191.) A comparison of Spenser II’s Figure 22 (left) and Spenser’s Figure 44a (right) confirms the compressible material would cover two rows of Figure 44a:

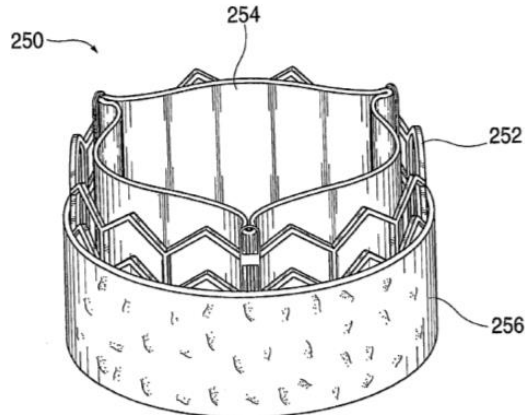
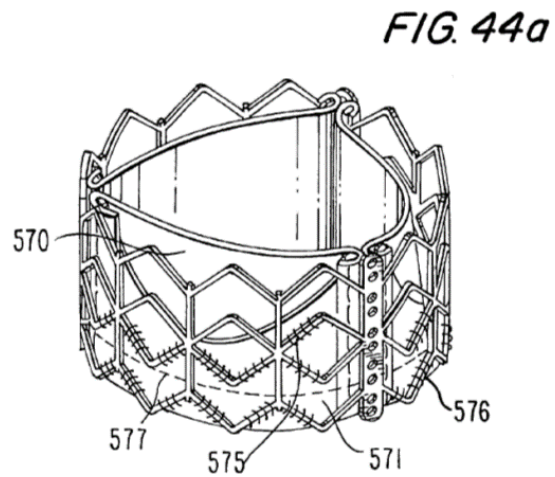


FIG. 22



(Ex. 1003, ¶191.) If claim 1 requires the outer seal to entirely cover two rows of cells, POSITAs would have found it obvious to slightly increase the height of Spenser II’s compressible material. (Ex. 1003, ¶191.)

Spenser II discloses that the compressible material 256 “is disposed along an outer surface of the stent structure 252” and, therefore, is attached to the frame:

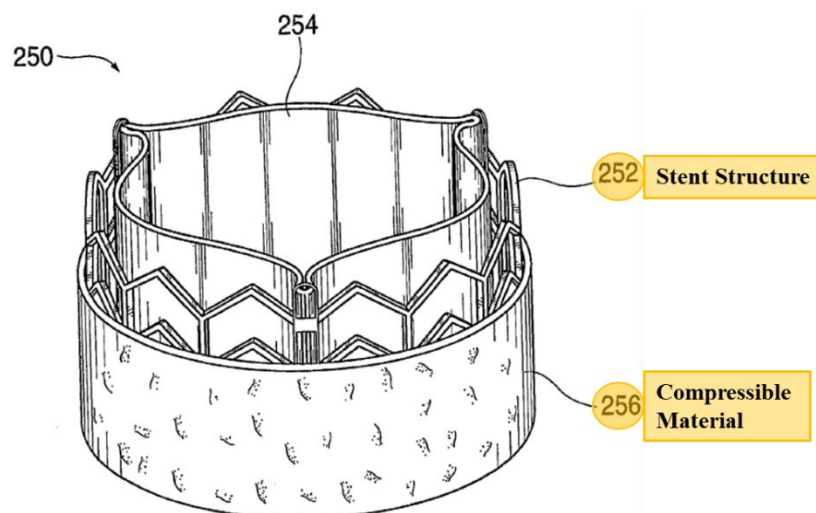


FIG. 22

(Ex. 1011, [00145], Fig.22; Ex. 1003, ¶192.)

Spenser II's compressible material is also "free of an outer graft covering between the fibers and the outer frame." (Ex. 1003, ¶193.) Spenser II never pictures or mentions an "outer graft covering" between the compressible material and frame. (*Id.*) Likewise, Spenser's Figure 44a does not show an "outer graft covering" on the exterior of frame 575. (Ex. 1010, Fig. 44a.) Therefore, if Spenser II's compressible material were added to Figure 44a's frame, there would be no "outer graft covering" between the compressible material's fibers and the frame. (Ex. 1003, ¶194.)

POSITAs would have been motivated to combine Spenser II's compressible material with Spenser's Figure 44a for several reasons. Spenser and Spenser II describe similar valves, share three common inventors, and Spenser II explicitly references Spenser's parent application: U.S. Publication 2003/0153974 (Ex. 1015). (*See, e.g.*, Ex. 1010, Abstract, 2:5-15; Ex. 1011, [0001], [0009]-[0014]; Ex. 1003, ¶195.) Thus, POSITAs would have reasonably anticipated that the teachings in Spenser II would apply to Spenser. (Ex. 1003, ¶195.)

Also, PVL was known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. (Ex. 1003, ¶196.) POSITAs would have been motivated to combine Spenser II's compressible material with Figure 44a to "address leaks that can occur around the implanted valve" and "to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [0010], [0145]; Ex. 1003,

¶196.) Moreover, adding the compressible material to Figure 44a would have merely entailed the combination of known elements (Figure 44a and compressible material) according to known methods (stitching or otherwise attaching) to yield the predictable result of reducing PVL. *KSR Int'l*, 550 U.S. at 416; (Ex. 1003, ¶196.)

POSITAs would have reasonably expected success in combining Spenser II's compressible material with Figure 44a because the valve assemblies share many common features, including a compressible, balloon-expandable metallic stent an inner graft covering, and support beams to hold the prosthetic leaflets. (*See, e.g.*, Ex. 1010, 2:5-15; 12:28-36, 13:26-54, 19:5-13; Ex. 1011, [0011]-[0015], [00144]; Ex. 1003, ¶197.) Moreover, Spenser discloses valves having a sealing material positioned around its inlet, which would have encouraged POSITAs to add other sealing structures to Spenser's valves. (Ex. 1010, 13:22-25, Fig. 1; Ex. 1003, ¶197.) Finally, Claim 1 is not limited to endovascular delivery, so small increases in valve diameter would not have discouraged POSITAs from adding the compressible material. (Ex. 1003, ¶197.)

f. Radially Compressed and Expanded Orientation

Spenser, Walther, and Spenser II disclose this limitation. (Ex. 1003, ¶¶198-199.) Walther discloses this limitation as explained in Ground 1. (*Supra* §VII.A.1.f.) Spenser discloses that its prosthetic valve “has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation].” (Ex. 1010, 27:67-28:2.) Likewise, Spenser II discloses valves that comprises “an expandable stent structure” that may be “adapted for radial expansion using a balloon catheter.” (Ex. 1011, [00144].)

g. Balloon Expandable

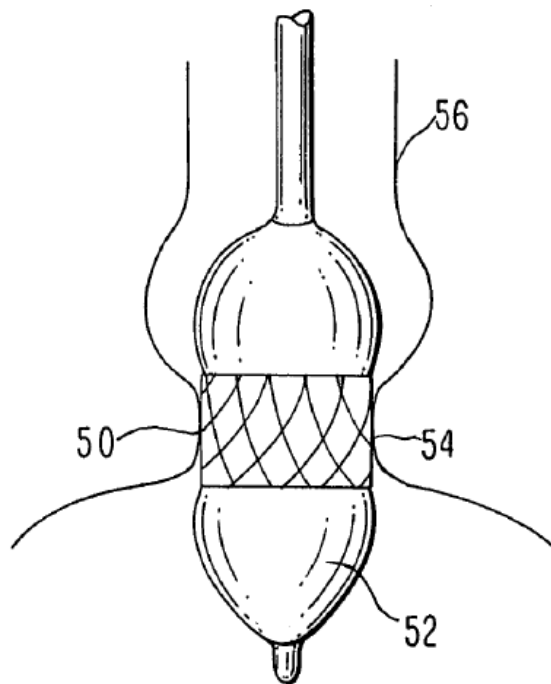
Spenser and Walther or Spenser II render this limitation obvious. (Ex. 1003, ¶¶200-207.)

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.*, 1010, 26:19-28.) Thus, Figure 44a is also balloon expandable. (Ex. 1003, ¶201.)

POSITAs would have understood that Figure 44a would remain balloon expandable after adding Walther’s outer cloth or Spenser II’s compressible material because both references disclose that the outer cloth/compressible material is combinable with balloon-expandable valves. (Ex. 1007, 1122; Ex. 1011, [00144];

Ex. 1003, ¶201.)

Spenser’s Figure 4 depicts “valve deployment in a natural aortic valve position in accordance with the present invention”:



(Ex. 1010, 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b.) As illustrated, the valve presses against the patient’s aortic annulus. (*Id.*, Fig. 4; Ex. 1003, ¶202.) The valve also presses against the patient’s native aortic leaflets (not shown), which are attached to the annulus and extend distally therefrom. (*Supra* §VII.A.1.g; Ex. 1003, ¶202.) Figure 4 illustrates the placement of Figure 44a because Figure 4 describes “the **present invention**” and Figure 44a describes a “preferred embodiment of the **present invention**.” (Ex. 1010, 8:66-67, 26:30-34 (emphasis added); Ex. 1003, ¶202.)

Walther's outer cloth and Spenser II's compressible material would cover at least the two proximal rows of Figure 44's outer frame. (*Supra* §VII.B.1.e.) Thus, expansion of the combined valve would press some of the fibers of Walther's outer cloth and Spenser II's compressible material against the patient's native aortic leaflets for the reasons explained in Ground 1. (*Supra* §VII.A.1.g; Ex. 1003, ¶203.)

POSITAs would have found it obvious to deploy Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material within a patient's native valve. (Ex. 1003, ¶¶204.) Spenser discloses methods of implanting the described valves, including Figure 44a, at the native aortic valve. (*See e.g.*, Ex. 1010, 5:17-6:36.) POSITAs would have been motivated to apply Walther's and Spenser II's known techniques for reducing PVL (adding an outer cloth) to Spenser's Figure 44a for the reasons described in Ground 1. (*Supra* §VII.A.1.g.)

POSITAs would have reasonably expected success in deploying Figure 44a with Walther's outer cloth or Spenser II's compressible material in a patient's native aortic valve. (Ex. 1003, ¶205.) Walther discloses that the valve "demonstrated excellent hydrodynamic performance" and concluded that an in-patient implantation procedure "is feasible." (*See* Ex. 1007, 1125; Ex. 1003, ¶205.) Likewise, Spenser II describes the implantation of the valve with a compressible material in a native valve and, given the similarities between the stents in Spenser's Figure 44a and Spenser

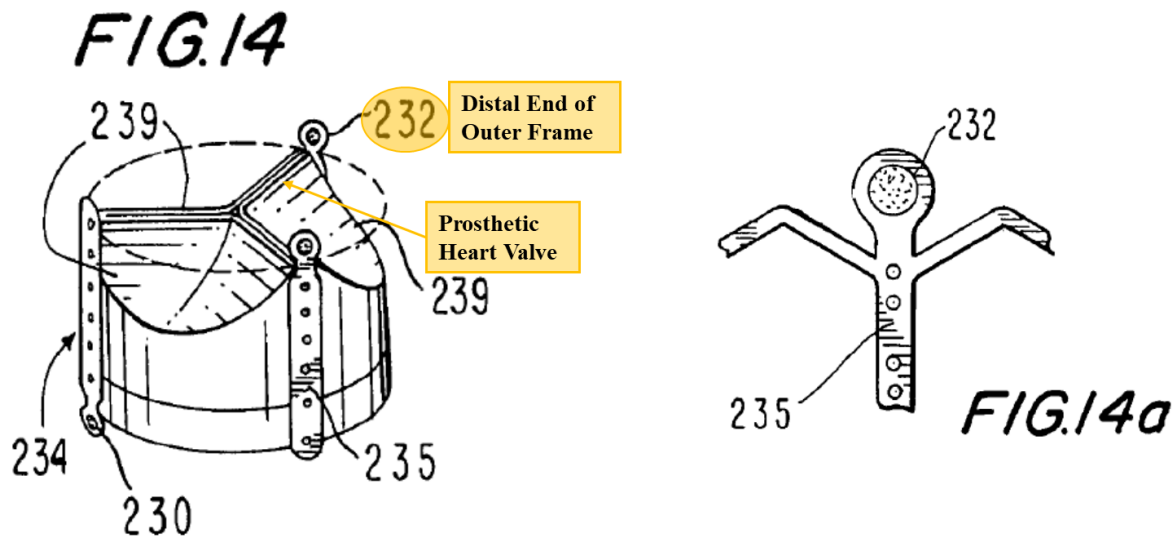
II's Figure 22, POSITAs would have expected implantation in a native valve to work equally well if the compressible material were added to Spenser's Figure 44a. (Ex. 1011, [0144]-[0145]; Ex. 1003, ¶205.)

Additionally, Spenser describes implantation of its embodiments, including Figure 44a, within the aortic valve and POSITAs had successfully implanted SAPIEN, which is similar to Figure 44a, within a patient's native aortic valve countless times by November 2012. (Ex. 1003, ¶206; Ex. 1010, 2:6-12, 12:8-36, 13:26-54, 14:12-14.) Thus, POSITAs would have been confident in implanting Figure 44a with Walther's outer cloth or Spenser II's compressible material within a patient's native aortic valve. (Ex. 1003, ¶¶205-207.)

2. Claim 2

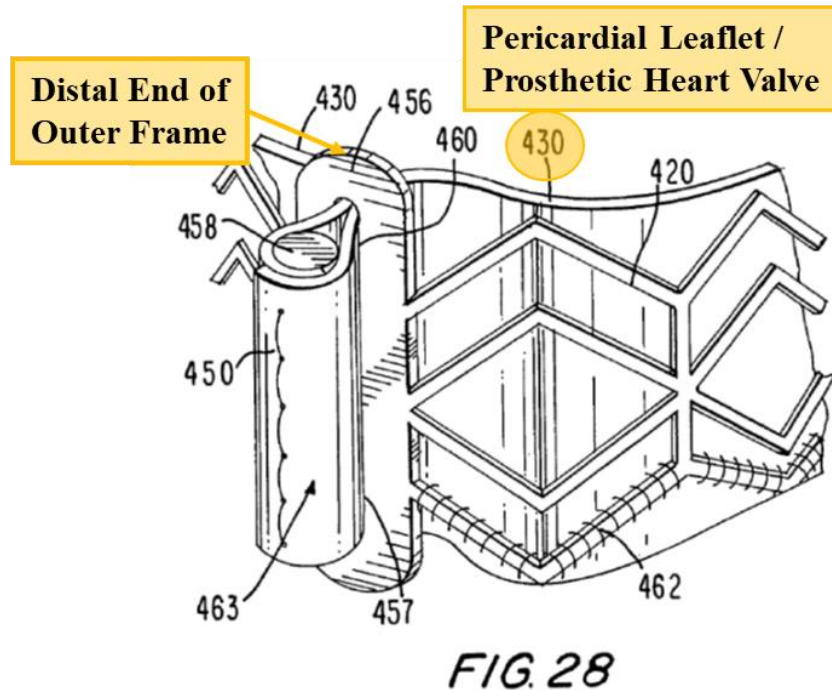
Spenser and Walther or Spenser II render obvious "wherein the outer frame extends distally further than the prosthetic heart valve." (Ex. 1003, ¶¶208-210.)

Spenser discloses this limitation in two ways. (*Id.*, ¶209.) First, Spenser discloses valves having "heavy metal markers [232] on the stent," which allow visualization of the device during delivery:



(Ex. 1010, 16:27-51, Figs. 14-14a.) The portion of the frame having the marker extends distally further than the heart valve. (Ex. 1003, ¶209.) POSITAs would have been motivated to add markers to Figure 44a's stent to better visualize the stent during deployment. (*Id.*) POSITAs would have reasonably expected success in adding the markers because Spenser describes using the markers with stents similar to Figure 44a and markers were common in the field by 2012. (*Id.*)

Second, Spenser illustrates a method of attaching the leaflets 430 to the frame 420:

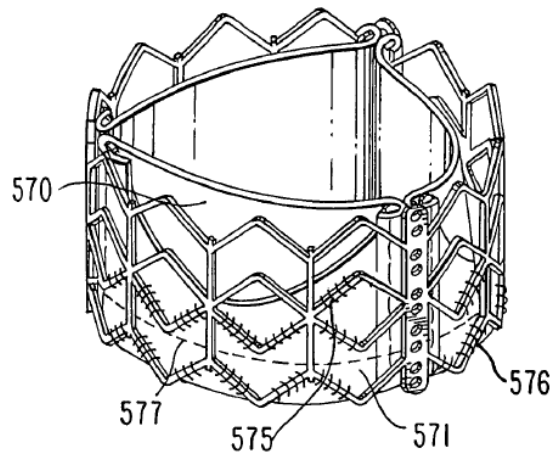


(Ex. 1010, 21:46-67, Fig. 28.) The outer frame portion 456 extends distally further than the heart valve. (Ex. 1003, ¶210.) POSITAs would have been motivated to use this method of attachment in Figure 44a to reduce stress points and abrasion on the leaflets. (Ex. 1010, 21:60-67, Ex. 1003, ¶210.) POSITAs would have reasonably expected success in applying this method to Figure 44a because Spenser discloses using the method with a valve like Figure 44a. (Ex. 1003, ¶210.)

3. Claim 3

Spenser discloses this limitation. (Ex. 1003, ¶¶211-212.) Figure 44a includes “frame 575,” which is a singular, integral component:

FIG. 44a

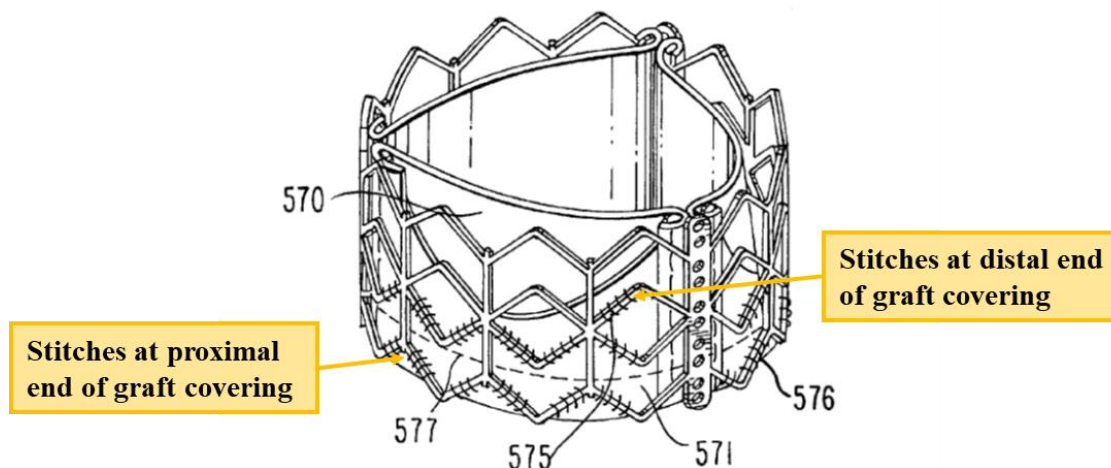


(Ex. 1010, 26:30-34, 19:5-13, Figs. 44a-44b; Ex. 1003, ¶212.)

4. Claim 4

Spenser discloses this limitation. (Ex. 1003, ¶¶213-214.) Spenser's PET layer 571 is attached to the frame 575 with bottom suture 576 and upper suture 578. (Ex. 1010, 26:42-48, Figs. 44a-44c.) The sutures attach the PET layer 571 to the outer frame with stitches at a proximal and distal portion of the graft covering:

FIG. 44a



(*Id.*, Fig. 44a; Ex. 1003, ¶214.)

5. Claim 5

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶215-216.) Walther’s outer cloth or Spenser II’s compressible material and Spenser’s inner PET layer are separate materials and, therefore “distinct elements.” (*Id.*)

6. Claim 6

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶217-223.) Spenser discloses endovascular delivery. For example, Spenser discloses that “[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously... via a large blood vessel such as the femoral artery***[.]” (Ex. 1010, 2:6-12 (emphases added).) Spenser also discloses endovascularly delivering the prosthetic valve through the patient’s vasculature to the native valve. (*Id.*, 5:17-6:36, 17:19-18:43.) POSITAs would have understood the disclosure of endovascular delivery to apply to Figure 44a. (Ex. 1010, 26:30-34, 2:6-12; Ex. 1003, ¶219.)

In 2012, POSITAs would have also been aware that SAPIEN had been successfully delivered through at least the common iliac and femoral arteries. (Ex. 1043, 2; Ex. 1022, 2188-2196.) The common iliac artery provided an alternative to

the femoral artery in cases where the femoral artery was too small or calcified for safe delivery. (*Id.*, 275; Ex. 1003, ¶221.) POSITAs would have reasonably expected that Spenser’s Figure 44a combined with Walther’s outer cloth or Spenser II’s compressible material would be suitable for endovascular delivery through at least the common iliac artery. (Ex. 1003, ¶221; Ex. 1043, 2-5; Ex. 1044.)

Moreover, if POSITAs wanted to deliver the combined valve through smaller blood vessels, POSITAs would have possessed the skills and equipment necessary to adapt the outer seal or valve for the particular vessel, including the femoral artery. (*Supra* VII.A.6.) POSITAs would have found it obvious to utilize one or more of the known techniques discussed in Ground 1 to combine Walther’s outer cloth or Spenser II’s compressible material with Spenser’s Figure 44a for endovascular delivery. (*Id.*; Ex. 1003, ¶222.)

Moreover, Spenser discloses that the “maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter.” (Ex. 1010, 27:65-67.) Spenser’s prosthetic valve “has the ability to change its diameter from about 4 mm to about 25 mm.” (*Id.*, 27:67-28:2.) Spenser II’s compressible material can have “a thickness ranging from about 1 to 5 mm.” (Ex. 1011, [00145].) POSITAs would have reasonably expected that adding a compressible material 1 mm thick to Spenser’s 4-mm valve would have resulted in a device suitable for endovascular

delivery through the femoral artery because the device’s crimped diameter would have been no more than 8 mm. (Ex. 1003, ¶223.)

Finally, the ’846 patent does not claim or disclose how to size the disclosed valve for endovascular delivery. (*Supra* §VII.A.6) Consequently, Patent Owner cannot argue that adapting a cloth-covered valve for endovascular delivery would have been beyond POSITAs’ skill. (*Id.*)

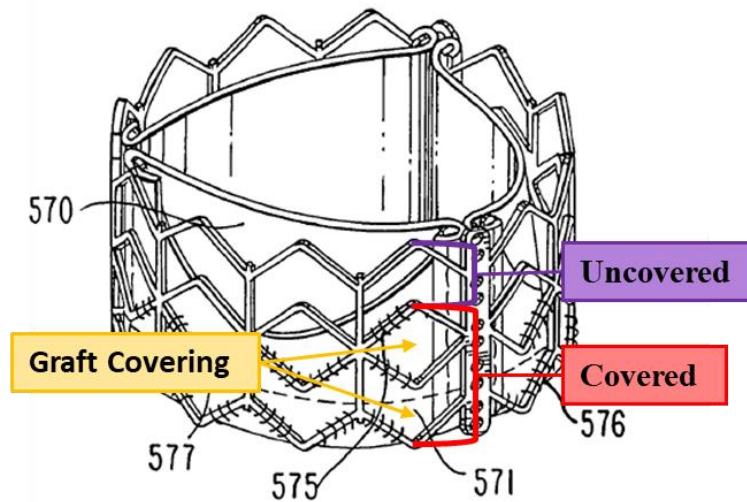
7. Claim 7

Spenser discloses this limitation. (Ex. 1003, ¶¶224-225.) Figure 44a’s PET layer 571 is “**for sealing** and protecting the pericardium.” (Ex. 1010, 26:30-54 (emphasis added).) Spenser further discloses that the “[b]ottom attachment suture 576, connects . . . the leaflet and both PET layers to the frame and **forms a strong sealing line.**” (*Id.*, 26:45-47 (emphasis added).) Thus, POSITAs would have understood that a seal is created between the inner PET layer and outer frame. (Ex. 1003, ¶225.)

8. Claim 8

Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶226-231.) Figure 44a’s inner PET layer **does not** cover the uppermost row of cells:

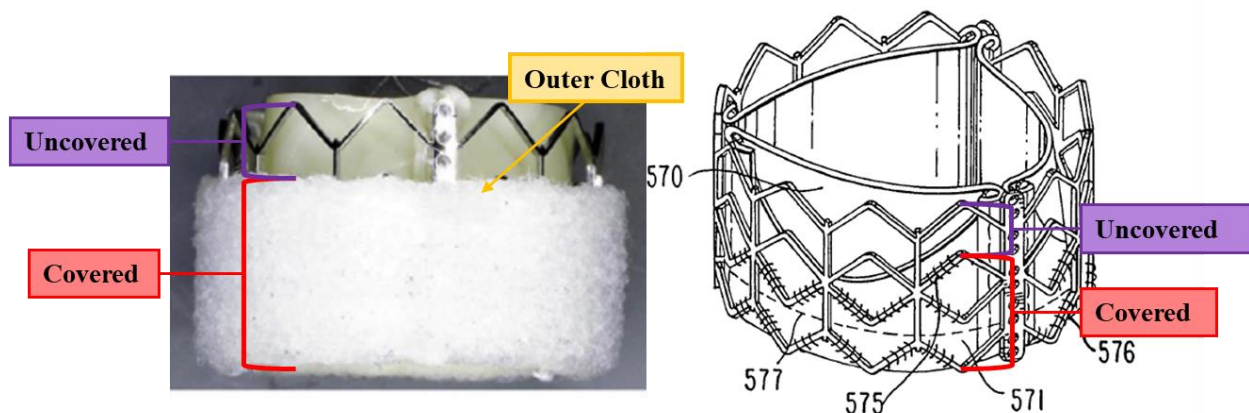
FIG. 44a



(Ex. 1010, Fig. 44a.)

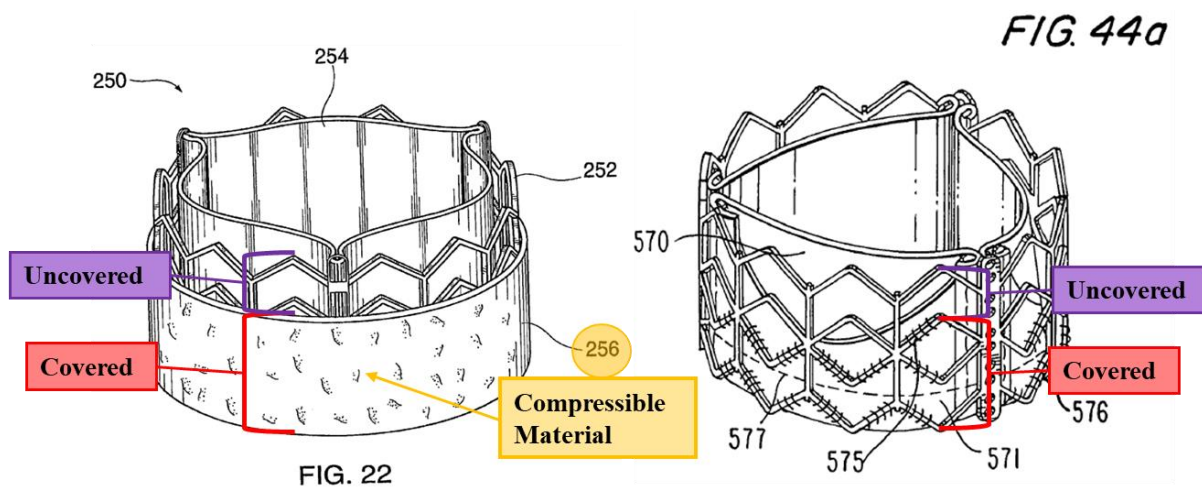
Similarly, Walther's outer cloth does not cover the upper row of cells. (*Supra* §VII.A.1.e.) If Walther's outer cloth were added to Spenser's Figure 44a, the cloth **would not** cover the uppermost row of cells, as illustrated by Walther's Figure 1 (left) and Spenser's Figure 44a (right):

FIG. 44a



(Ex. 1003, ¶¶228-229.)

Spenser II's compressible material also does not cover the upper row of cells of stent structure 252. (*Supra* §VII.B.1.e.ii.) When added to the exterior of the stent in Spenser's Figure 44a, the compressible material would **not** cover the uppermost row of cells, as illustrated by Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



(Ex. 1003, ¶¶230-231.)

Therefore, Spenser combined with Walther or Spenser II yields a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (Ex. 1003, ¶¶228-231.)

9. Claim 9

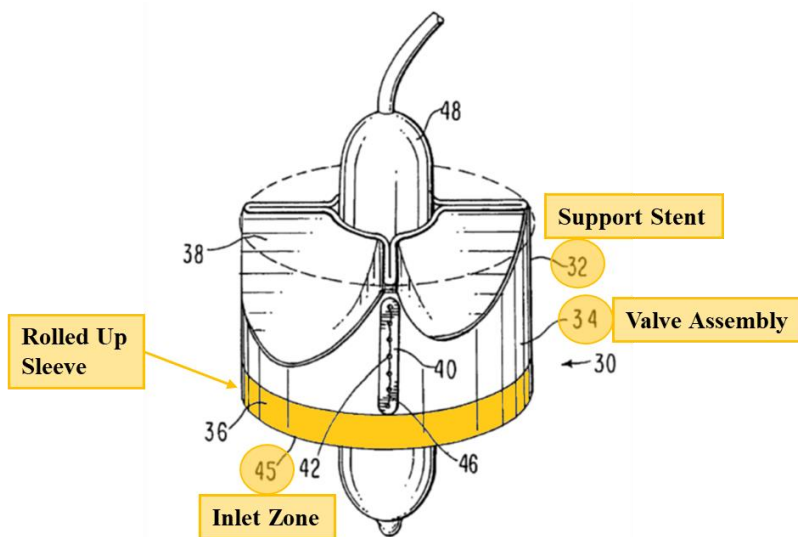
Spenser and Walther or Spenser II render obvious “wherein a distal end of the outer frame extends distally beyond the prosthetic leaflets.” (Ex. 1003, ¶¶232-234.)

This claim is substantially similar to claim 2. (*Id.*) Spenser discloses this

limitation as described in claim 2. (*Supra* §VII.B.2.)

10. **Claim 10**

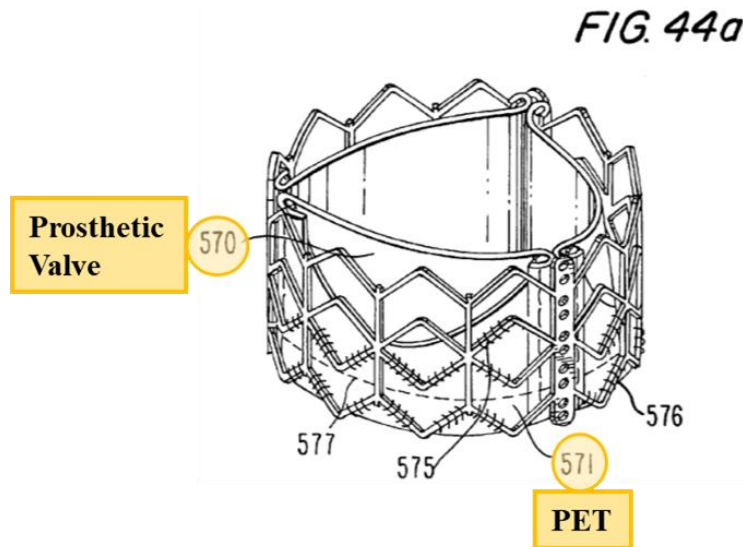
Spenser and Walther or Spenser II render obvious “wherein the graft covering extends beyond a proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” (Ex. 1003, ¶¶235-241.) Spenser discloses that a “portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve [yellow], which enhances the sealing of the device at the valve inlet”⁵:



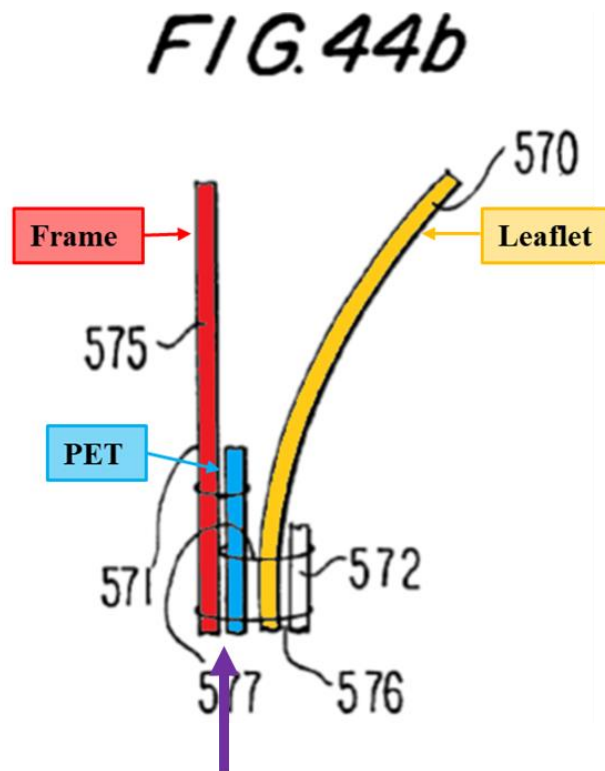
(Ex. 1010, 14:6-9, Fig. 2; *see also* 12:51-53.)

⁵ In Figure 2, the dashed lines indicate the support stent, which is not shown in full. (*Id.*, 13:63-66.)

POSITAs would have found it obvious to apply this feature to Figure 44a and extend the inner PET 571 to cover the proximal end of the frame 575. (Ex. 1003, ¶238.)



(Ex. 1010, Fig. 44a.) POSITAs would have been motivated to extend PET 571 to further “enhance[] the sealing of the device at the valve inlet.” (Ex. 1010, 14:6-9, 12:51-53; Ex. 1003, ¶238.) POSITAs would have understood that extending the inner PET fabric over the proximal end of the frame 575 would prevent blood from leaking between the inner PET 571 and the frame (see purple arrow). (Ex. 1003, ¶238.)



Additionally, POSITAs would have been motivated to extend the cuff over the proximal end to reduce the risk that the edges of the frame would damage the surrounding tissue. Ex. 1048, [0098]. This modification would have merely entailed applying a known technique (extending the cuff) to a known device (SAPIEN) ready for improvement (enhanced sealing and reduce frame exposure). (Ex. 1003, ¶239.)

POSITAs would have reasonably expected success in extending Figure 44a's inner PET because Figures 2 and 44a describe similar heart valves having an inner PET layer that is stitched to a gridded, metallic, balloon-expandable support stent that has three parallel support beams for attaching leaflets. (See Ex. 1010, 13:62-44, 26:30-54; Figs. 2, 9a-f, 44a-c; Ex. 1003, ¶240.) POSITAs would have reasonably

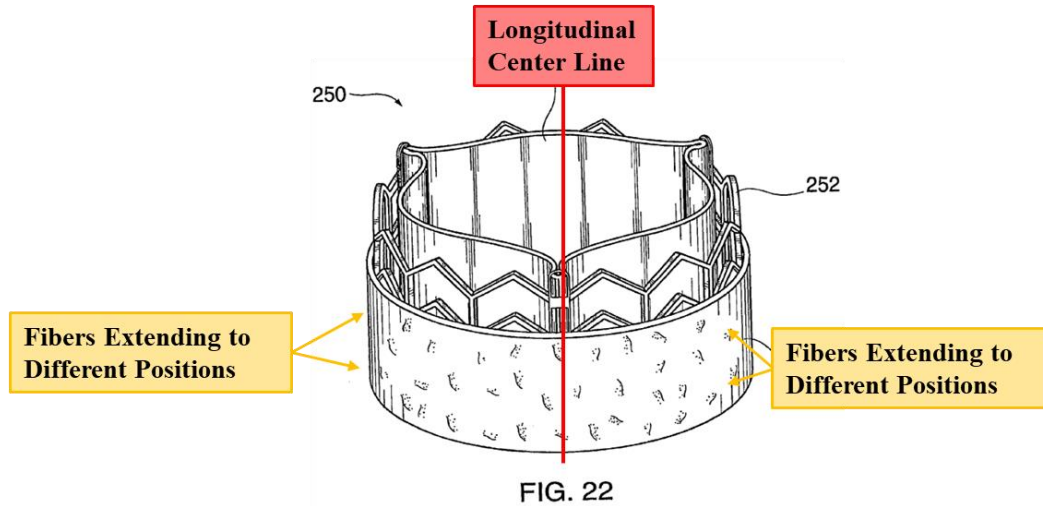
expected that the teachings of Figure 2 would apply to Figure 44a due to these similarities. (Ex. 1003, ¶240.)

POSITAs would have been motivated to add Walther's outer cloth or Spenser II's compressible material to Spenser's Figure 44a even if the inner PET 571 covered the proximal end of the frame because the outer cloth/compressible material serves a different purpose than the extended PET. (Ex. 1003, ¶241.) The extended PET prevents blood from leaking between the inner and outer frames. (*Id.*) In contrast, the outer cloth/compressible material prevents blood from leaking between the valve and surrounding tissue. (*Id.*; Ex. 1007, 1120.)

11. Claim 11

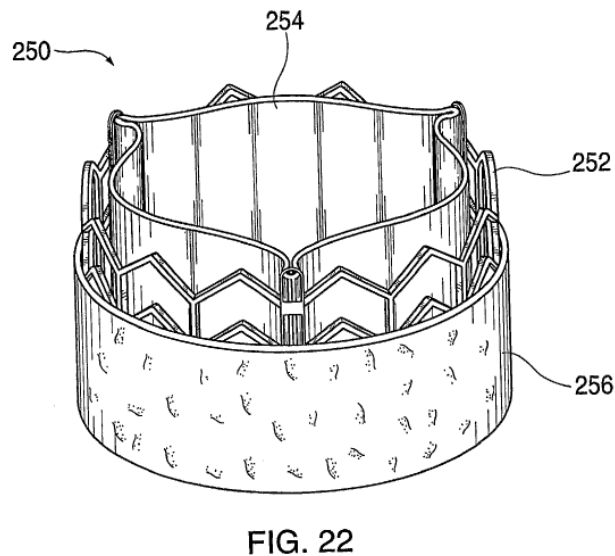
Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶242-245.) Walther discloses this limitation as explained in Ground 1. (*Supra* §VII.A.8.)

Spenser II's compressible material extends around the outer frame so fibers extend to the left and right of the "centerline." Thus, the compressible material includes fibers that "extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly":



(Ex. 1011, Fig. 22; Ex. 1003, ¶244.)

Additionally, Spenser II's compressible material does not have a uniform surface. The fibers of the compressible material “may be straight, curved, or hook-shaped.” (Ex. 1011, [00145].) As indicated by the speckled markings below, some fibers extend further out from the frame than others:

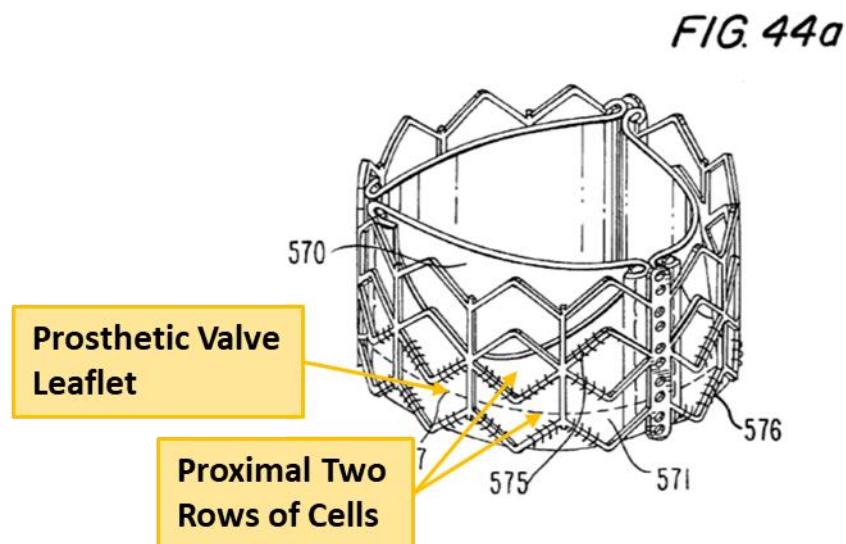


(*Id.*, Fig. 22.) Thus, even the fibers on one side of the valve “extend outwardly to

different positions relative to a centerline run through a longitudinal of the valve assembly.” (Ex. 1003, ¶245.)

12. Claim 12

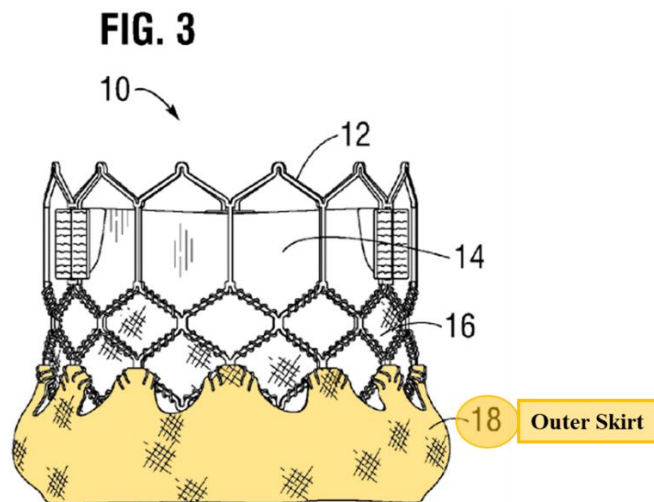
Spenser and Walther or Spenser II render this claim obvious. (Ex. 1003, ¶¶246-251.) If Walther’s outer cloth or Spenser II’s compressible material were added to Spenser’s Figure 44a, the cloth/material would cover the proximal two rows of cells. (*Supra* §VII.B.1.e.) Additionally, the two circumferentially extending rows of cells covered by the cloth/material would radially overlap with the inner graft covering and prosthetic leaflets:



(*Supra* §VII.B.8; Ex. 1003, ¶¶246-251.)

C. Grounds 4-7: Claims 1-12 Anticipated By Levi or Obvious Over Levi Alone or With Walther or Spenser II

Levi discloses a valve having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame. (Ex. 1008, 13:50-66.)



(*Id.*, Fig. 3.) Levi discloses or suggests every limitation of claims 1-12 and either anticipates or renders the claims obvious. (Ex. 1003, ¶252.)

If Levi does not disclose or suggest the claimed outer seal, Walther and Spenser II do. (*Id.*, ¶253) Therefore, Levi in combination with Walther **or** Spenser II also discloses every limitation of claims 1-12 and renders the claims obvious. (*Id.*)

1. Claim 1

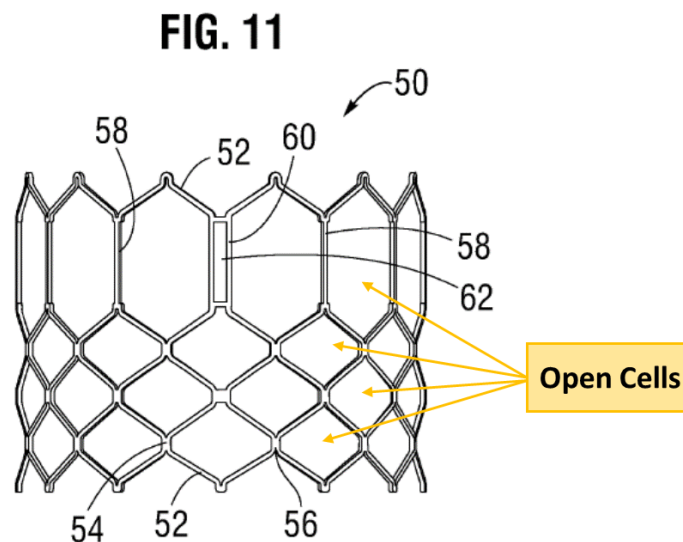
Levi anticipates claim 1 or renders it obvious alone or with Walther or Spenser II. (Ex. 1003, ¶¶254-293.)

a. Preamble

Levi discloses valve assemblies. (Ex. 1008, 1:16-17; Ex. 1003, ¶¶255-256.)

b. Outer Frame

Levi discloses this limitation. (Ex. 1003, ¶¶257-258.) Levi discloses a metal frame that defines an open cell configuration:

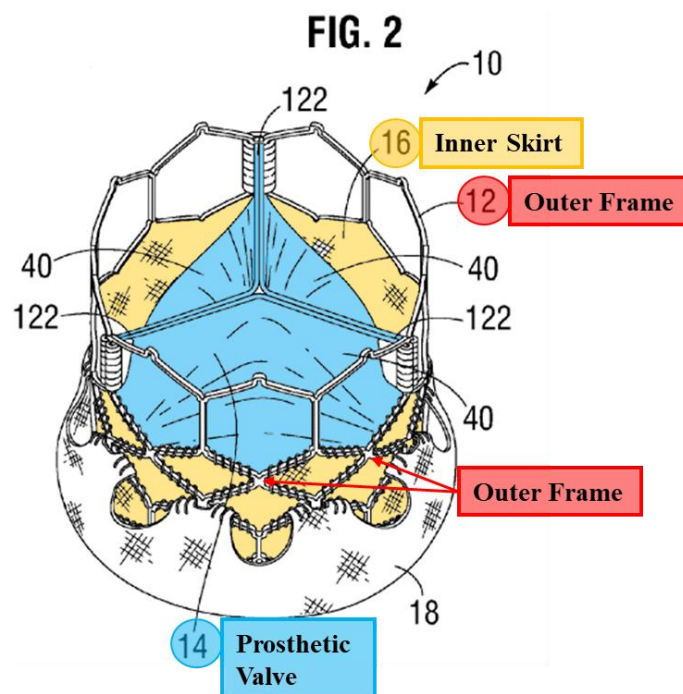


(Ex. 1008, 6:17-24, Fig. 11.) The frame surrounds the other valve components and, therefore, is an “outer frame.” (Ex. 1003, ¶258.)

c. Inner Frame

Levi discloses this limitation. (Ex. 1003, ¶¶259-260.) Levi discloses an “inner skirt 16 . . . to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of the frame 12 below the lower edge of the leaflets.” (Ex. 1008, 9:7-11.) The inner skirt is constructed of “a tough, tear resistant material such as polyethylene terephthalate (PET)[.]” (*Id.*, 9:11-16.)

PET is a “graft covering.” (Ex. 1003, ¶260.) The inner skirt is engaged to the valvular structure (i.e., prosthetic leaflets) “via one or more thin PET reinforcing strips[.]” (Ex. 1008, 9:25-29.) Levi’s inner skirt 16 [yellow] cylindrically extends at least partially radially outwardly of the prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red]:

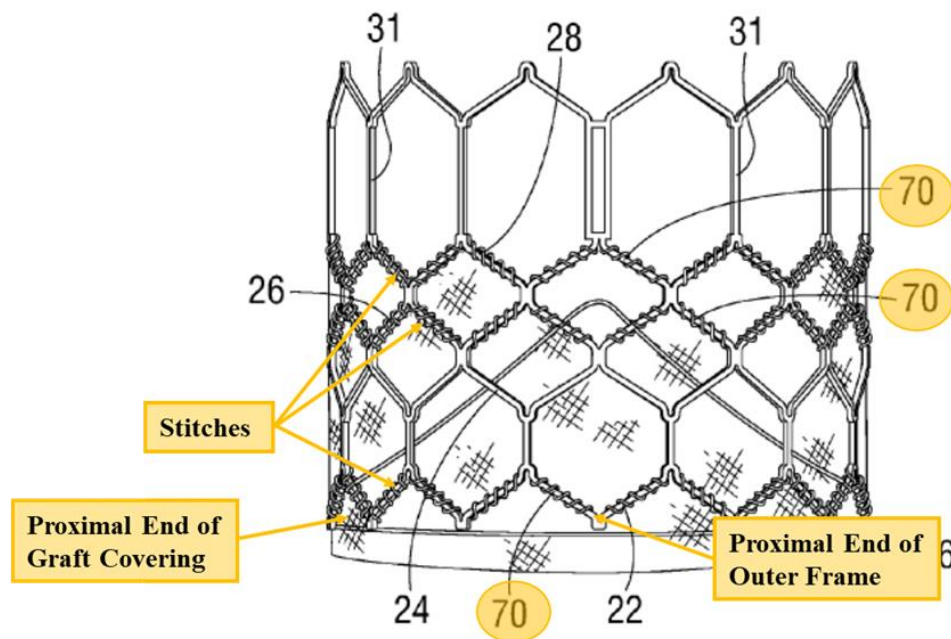


(*Id.*, Fig. 2; Ex. 1003, ¶260.)

d. Stitching

Levi discloses this limitation. (Ex. 1003, ¶¶261-262.) Levi’s inner skirt is secured to the frame by stitching (suture 70) at the proximal end of the outer frame:

FIG. 20



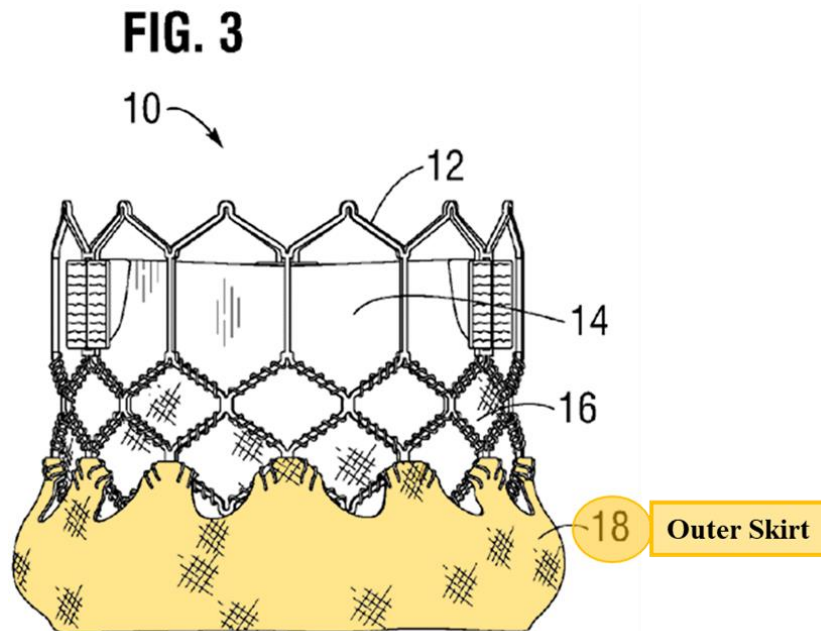
(Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39.)

e. Outer Seal

i. Levi

Levi discloses the outer seal limitations or renders them obvious. (Ex. 1003, ¶¶263-271.)

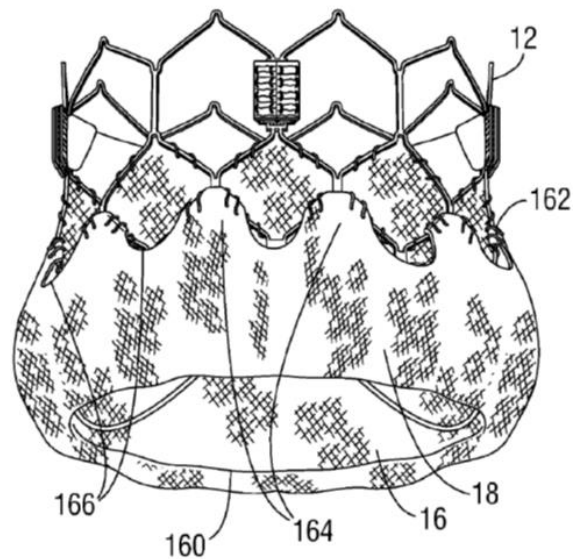
Levi discloses an outer skirt of woven PET fabric [yellow] attached to the exterior surface of the frame:



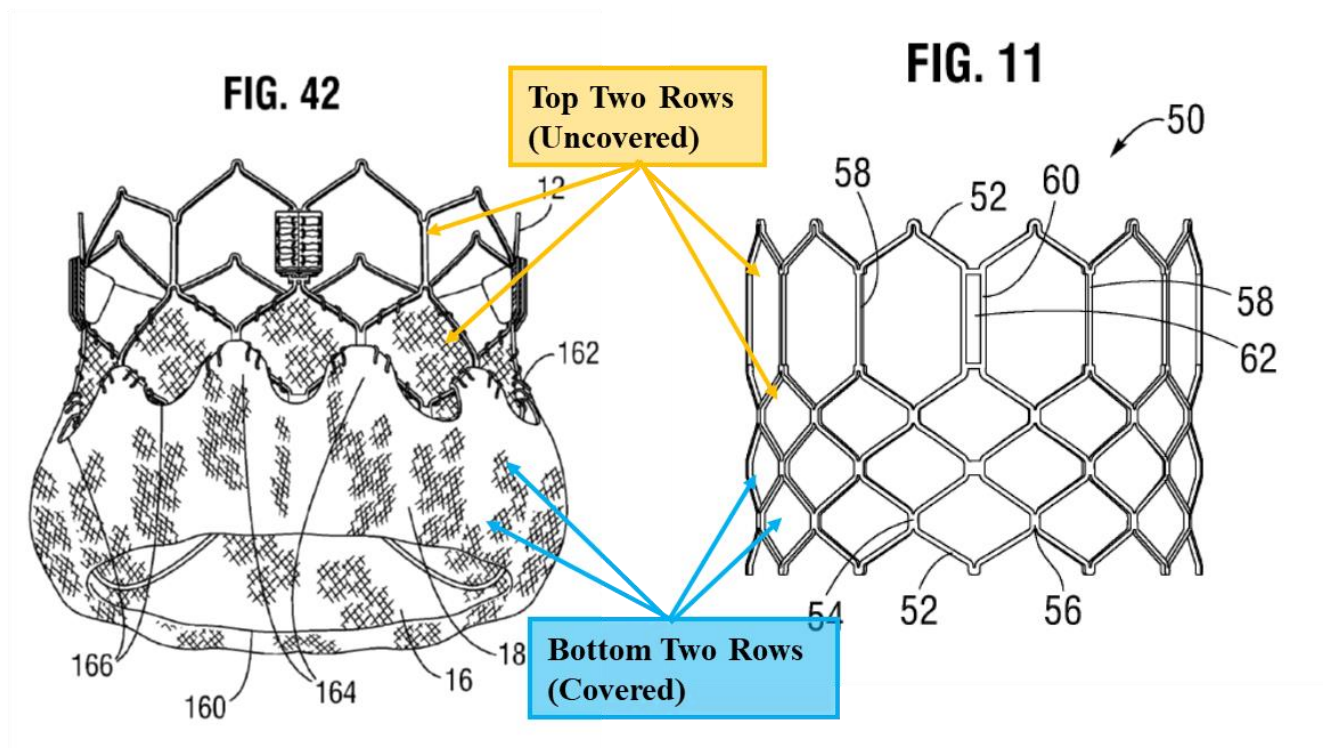
(Ex. 1008, 13:50-66, Fig. 3.) The outer skirt includes excess material that bulges radially outwardly as the frame expands. (*Id.*, 13:62-14:7.) The excess material allows the skirt to “fill gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” (*Id.*) Thus, the outer skirt is an outer seal “for preventing paravalvular leaks.” (Ex. 1003, ¶265.)

The outer skirt begins at a proximal portion of the outer frame and extends over at least the bottom two rows of open cells formed by the frame:

FIG. 42

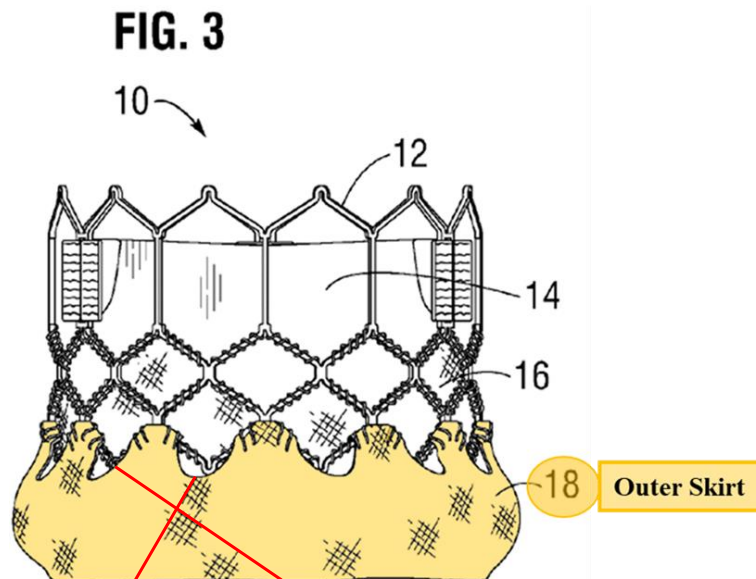


(Ex. 1008, Fig. 42; Ex. 1003, ¶266.) A comparison of Levi's Figures 11 and 42 confirms that the outer skirt covers the bottom two rows of cells:



(Ex. 1008, Figs. 11, 42; Ex. 1003, ¶266.)

Levi's outer skirt includes checkered markings to illustrate that the outer skirt is made of woven PET threads or fibers (see red lines illustrating two fibers):



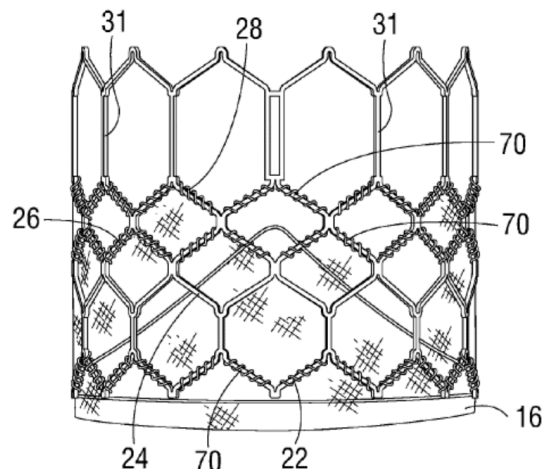
(See *id.*, 9:52-56, 13:62-14:2; Ex. 1003, ¶267.) POSITAs would have understood that each fiber is an “outwardly extending fiber” because the outer skirt “bulge[s] outwardly” from the frame. (Ex. 1003, ¶268.) Levi therefore discloses an outer seal “formed of outwardly extending fibers positioned externally to the outer frame.” (*Id.*)

Additionally, POSITAs would have understood that the outer surface of the woven skirt would not be entirely smooth, but would necessarily have fibers, or strands, that extend radially outwardly from the surface of the skirt. (Ex. 1003, ¶269.) Polyester yarn, such as PET yarn, exhibits a property known as “hairiness,” which

describes the “amount and length of fibre ends and loops protruding from the body of the yarn.” (Ex. 1028, 1024.) The hairiness of yarn is influenced by a number of factors, and POSITAs would have known that polyester fabrics, such as PET, would exhibit some level of hairiness. (*See id.*; *see also* Ex. 1029, 32, Figs. 1, 3 (disclosing that 100% polyester yarn included between 50 and 150 hairs per meter).) Therefore, even if the woven PET fabric does not itself constitute “outwardly extending fibers,” POSITAs would have nonetheless understood that the hairiness of Levi’s outer skirt includes “outwardly extending fibers” positioned externally to the outer frame. (Ex. 1003, ¶269.)

Levi’s valve is also free of an “outer graft covering” between the fibers of the outer skirt and the outer frame. (Ex. 1003, ¶¶270-271.) Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt. (Ex. 1008, 13:55-61.) Levi does not include any “outer graft covering” on the exterior of the outer frame:

FIG. 20



(*Id.*, Fig. 20; Ex. 1003, ¶¶270-271.)

ii. **Levi and Walther or Spenser II**

POSITAs would have also found it obvious to replace Levi's bulging outer skirt with Walther's outer cloth or Spenser II's compressible material. (Ex. 1003, ¶¶272-285.) POSITAs would have been motivated to use Walther's outer cloth because the cloth prevents PVL and promotes tissue ingrowth. (See Ex. 1007, 1120; Ex. 1003, ¶274.) Likewise, POSITAs would have been motivated to use Spenser II's compressible material because its radially extending fibers prevent PVL and "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." (Ex. 1011, [00145]; Ex. 1003, ¶282.) POSITAs would have been motivated to attach Walther's outer cloth or Sepnsen II's compressible material to Levi's outer frame so that the cloth/material begins at the proximal portion of the outer frame and extend over at least two rows of cells of the frame. (Ex. 1003, ¶282.) The combination of Levi with Walther or Spenser II would have merely entailed substitution of one known element (outer cloth/compressible material) for another (Levi's outer skirt) to yield the predictable results of reducing PVL. *See KSR Int'l*, 550 U.S. at 416.

Moreover, a finite number of methods to address PVL existed in November 2012. (Ex. 1003, ¶¶275, 283.) Walther, Spenser II, and Levi disclose three such

methods. (*Id.*) POSITAs would have found it obvious to select any one of these finite, predictable options and, as discussed below, would have reasonably expected success in doing so. (*Id.*)

POSITAs would have reasonably expected success in substituting Walther's outer cloth or Spenser II's compressible material for Levi's outer skirt. (Ex. 1003, ¶¶276-279, 284-285.) The valve frames in Walther, Spenser II, and Levi share many common features, including being balloon-expandable and formed of interconnected metal struts. (*Id.*) Further, Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that in-patient implantation of the valve "is feasible," suggesting that other cloth-covered valves would attain similar success. (Ex. 1007, 1125; Ex. 1003, ¶276.)

Moreover, Levi suggests adding other components, like an outer seal, to the inflow (proximal) portion of the outer frame. (Ex. 1008, 16:41-45.) Levi discloses methods to reduce the frame's diameter at the inlet, or to modify the leaflets to reduce the frame size, to create room for an outer seal. (*Id.*, 16:24-17:18.) POSITAs would have understood they could utilize one of Levi's strategies to add Walther's outer cloth or Spenser II's compressible material to Levi's frame. (Ex. 1003, ¶¶277-278, 284-285.) Notably, however, claim 1 is not limited to endovascular delivery, thus small increases in diameter due to an outer seal would not have discouraged

POSITAs from using the valve. (*Id.*, ¶279) For these reasons, POSITAs would have reasonably expected success in substituting Walther’s outer cloth or Spenser II’s compressible material for Levi’s bulging outer skirt. (*Id.*, ¶¶272-285.)

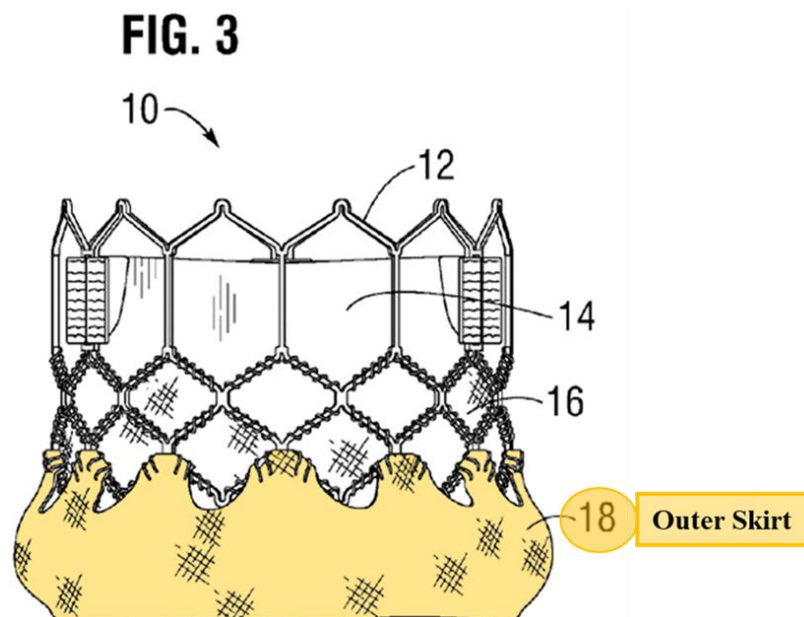
f. Radially Compressed or Expanded Orientation

Levi discloses this limitation. (Ex. 1003, ¶¶286-288.) Levi’s valve is “radially collapsible and expandable.” (Ex. 1008, Abstract, 6:20-24.)

g. Balloon Expandable

Levi discloses this limitation or renders it obvious alone or in combination with Walther or Spenser II. (Ex. 1003, ¶¶289-293.)

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

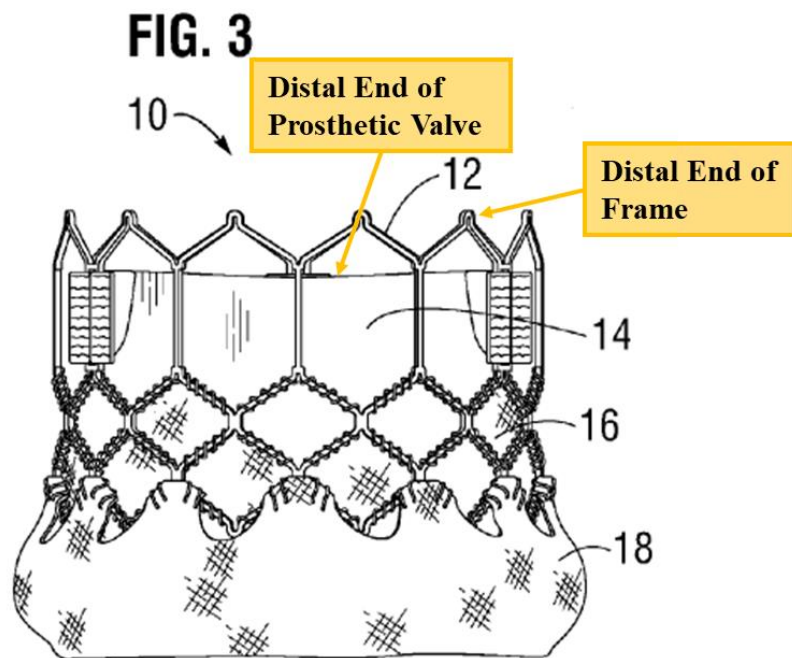


Levi discloses that the disclosed valve “is adapted to be implanted in the native aortic annulus” and that the skirt will “fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” (Ex. 1008, 5:52-54, 14:3-7.) When the outer skirt “fills gaps between the frame 12 and the surrounding native annulus,” some of the outer skirt’s fibers would also press against the native aortic leaflets, which are attached to the annulus. (Ex. 1003, ¶¶48-50, 292; *supra* §VII.A.1.g.) During prosecution, Patent Owner admitted that the outer skirt would press against the leaflets. (Ex. 1002, 145.)

Alternatively, Levi in combination with Walther or Spenser II renders this claim obvious. (Ex. 1003, ¶293.) If Levi’s outer skirt were replaced with Walther’s outer cloth or Spenser II’s outer compressible material, the resulting valve would remain balloon expandable because both Walther and Spenser II disclose that the outer cloth/compressible material is applicable to balloon-expandable valves. (See Ex. 1007, 1122; Ex. 1011, [00144].) Additionally, POSITAs would have understood that the fibers of the outer cloth/compressible material would press against the native leaflets as explained in Grounds 1-3. (*Supra* §§VII.A.1.g, VII.B.1.g.)

2. Claim 2

Levi discloses this limitation. (Ex. 1003, ¶¶294-295.) “To protect against over-expansion of the leaflet structure 14,” Levi teaches that the “**leaflet structure desirably is secured to the frame 12 below the upper row of struts 32[.]**” (Ex. 1008, 8:11-13 (emphasis added).) As shown below, the frame 12 extends distally further than the prosthetic valve 14:

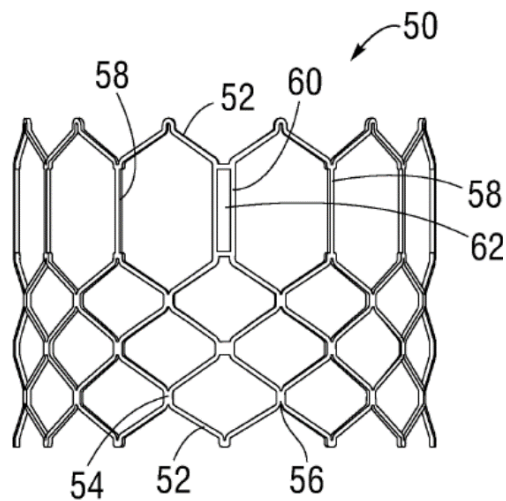


(*Id.*, Fig. 3; Ex. 1003, ¶295.)

3. Claim 3

Levi discloses this limitation. (Ex. 1003, ¶¶296-298.) Levi’s outer frame is a singular, integral component:

FIG. 11

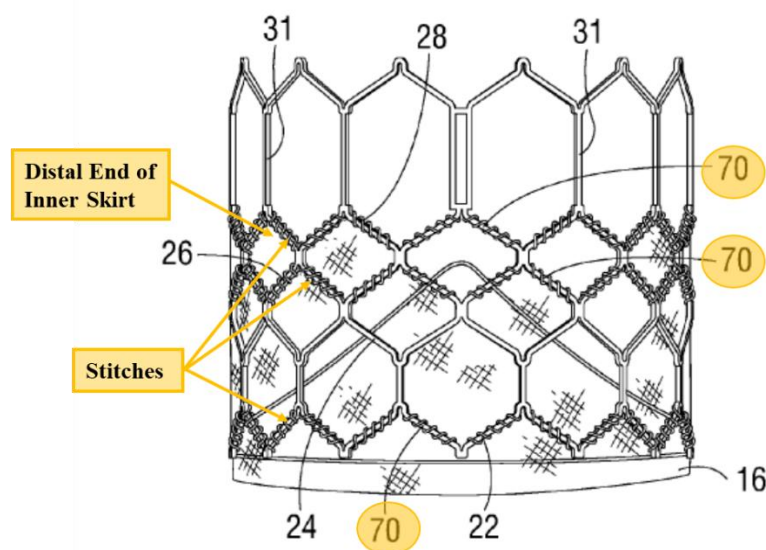


(Ex. 1008, 6:50-7:17, 9:4-6, Figs. 4-14; Ex. 1003, ¶¶297-298.)

4. Claim 4

Levi discloses this limitation. (Ex. 1003, ¶¶299-300.) Sutures 70 secure the inner skirt to the frame 12 using stitches at the proximal and distal ends of the skirt:

FIG. 20



(Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39; Ex. 1003, ¶300.)

5. Claim 5

Levi discloses this limitation. (Ex. 1003, ¶¶301-303.) Levi discloses “the lower edge 160 of the skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.” (Ex. 1008, 13:55-58, Fig. 42.) POSITAs would have understood that Levi’s outer skirt is “distinct” from the inner skirt at least because there would be no reason to suture the skirts together if they were not “distinct elements.” (Ex. 1003, ¶¶302.)

Alternatively, Levi in combination with Walther or Spenser II renders this claim obvious. (*Id.*, ¶¶303.) If Levi’s outer skirt were replaced with Walther’s outer cloth or Spenser II’s compressible material, the outer cloth/compressible material and Levi’s inner skirt would be “distinct elements” at least because the elements would be positioned on opposite sides of the outer frame and separately attached thereto. (*Id.*)

6. Claim 6

a. Levi

Levi discloses this limitation. (Ex. 1003, ¶¶304-307.) Levi discloses “collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent.” (Ex. 1008, 1:57-67.)

Levi discloses several features to enable such endovascular delivery. (*Id.*, 6:46-49; Ex. 1003, ¶¶305-306.)

For example, Levi discloses that its frame is preferably constructed of nickel-cobalt-chromium-molybdenum alloy, which allows for less material to be used so that “the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery[.]” (Ex. 1008, 6:46-49, 7:10-12.) Levi discloses that “[b]y minimizing the diameter of the valve when mounted on the delivery shaft, the assembly can [be] contained within a smaller diameter catheter and thus can be passed through smaller vessels in the body and can be less invasive in general.” (*Id.*, 14:60-64.)

Additionally, Levi discloses a number of features to accommodate additional sealing materials, like the outer skirt, at the proximal end of the device. (*Supra* §VII.C.1.e.) For example, Levi discloses methods to reduce the valve frame diameter at the inlet, or to modify the leaflets to reduce the frame size, to create room for additional components. (Ex. 1008, 16:24-17:18.) Based on these innovations, POSITAs would have expected success in delivering Levi’s valve endovascularly. (Ex. 1003, ¶307.)

b. Levi and Walther or Spenser II

Alternatively, Levi in combination with Walther or Spenser II renders this claim obvious. (*Id.*, ¶¶308-312.) POSITAs would have understood that after replacing Levi’s outer skirt with Walther’s outer cloth or Spenser II’s compressible material, the resulting device would remain suitable for endovascular delivery. (*Id.*) For example, POSITAs would have understood that even if the substitution slightly increased the valve’s diameter, the valve could still be delivered through the common iliac artery. (*Id.*; Ex. 1043; *supra* §VII.A.6.)

Moreover, Levi discloses that “[w]hen crimped, the frame 12 has a reduced diameter region extending along a portion of the frame...that generally corresponds to the region of the frame covered by the outer skirt 18” so that the outer skirt “does not increase the overall crimp profile of the valve.” (Ex. 1008, 8:46-54; *see also id.*, 2:22-35, 14:22-35, 16:38-45, 17:14-18.) Walther’s outer cloth or Spenser II’s compressible material would also cover the reduced diameter region, which would ensure that the outer cloth/compressible material would not disadvantageously increase the crimp profile. (*Id.*, 8:46-54; Ex. 1003, ¶¶309-312.)

Additionally, Levi expressly suggests adding other components to the inflow portion of the outer frame, stating “if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of

the valve can help offset or minimize the increase in diameter caused by the additional component.” (Ex. 1008, 16:41-45.) POSITAs would have understood that Walther’s outer cloth or Spenser II’s compressible material would be a potential “additional component” for replacing Levi’s outer skirt. (Ex. 1003, ¶312.) For these reasons, POSITAs would have reasonably expected success in using Walther’s outer cloth or Spenser II’s compressible material with Levi’s valve and endovascularly delivering the combined valve. (*Id.*)

7. Claim 7

Levi discloses this limitation. (Ex. 1003, ¶¶313-314.) Levi’s inner skirt assists “in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets.” (Ex. 1008, 9:7-11.)

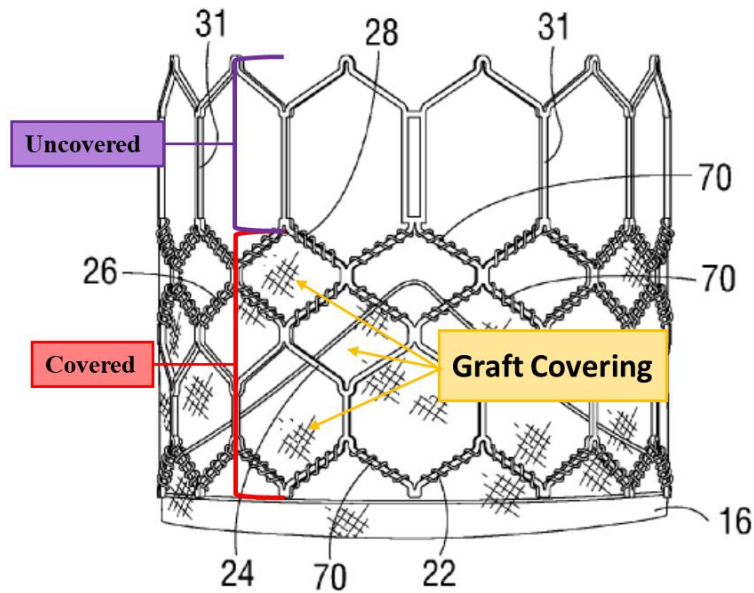
8. Claim 8

Levi discloses this limitation or renders it obvious alone or in combination with Walther or Spenser II. (Ex. 1003, ¶¶315-320.)

a. Levi

Levi’s inner PET skirt does not cover the top row of cells of the frame:

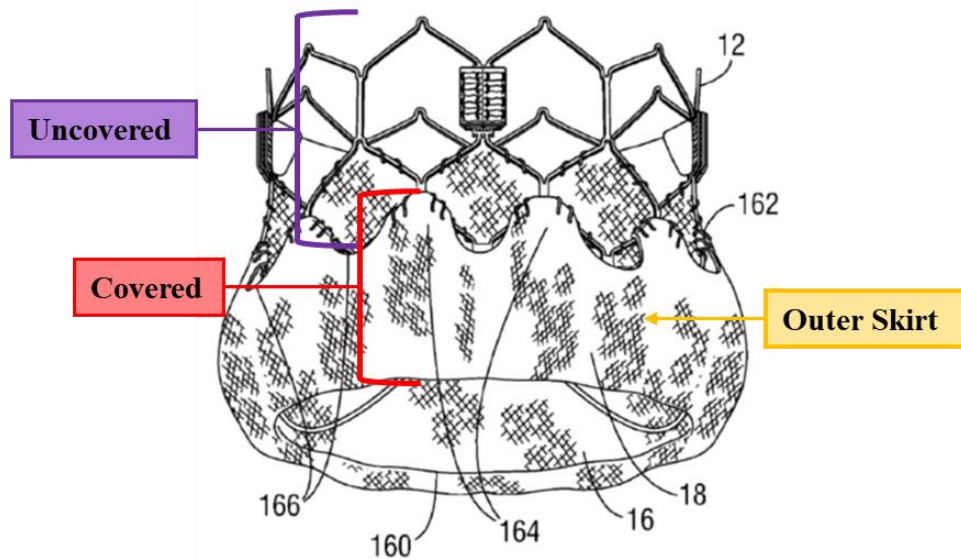
FIG. 20



(Ex. 1008, Fig. 20; Ex. 1003, ¶316.)

Similarly, Levi's outer skirt does not cover the upper rows of cells:

FIG. 42

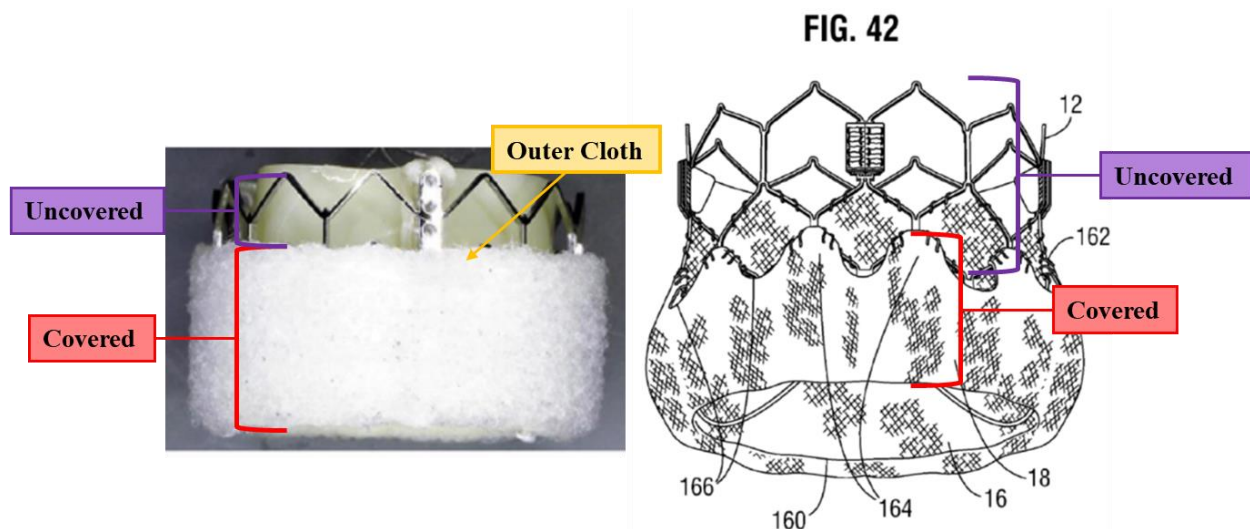


(Ex. 1008, Fig. 42.) Therefore, Levi discloses a valve wherein a portion of the outer

frame is uncovered by both the inner graft covering and outer seal. (Ex. 1003, ¶317.)

b. Walther

Walther's outer cloth does not cover a portion of SAPIEN's frame. (*Supra* §VII.A.7.) If Walther's outer cloth were substituted for Levi's outer skirt, the cloth **would not** cover at least the uppermost row of cells, as illustrated in the comparison of Walther's Figure 1 (left) and Levi's Figure 42 (right):



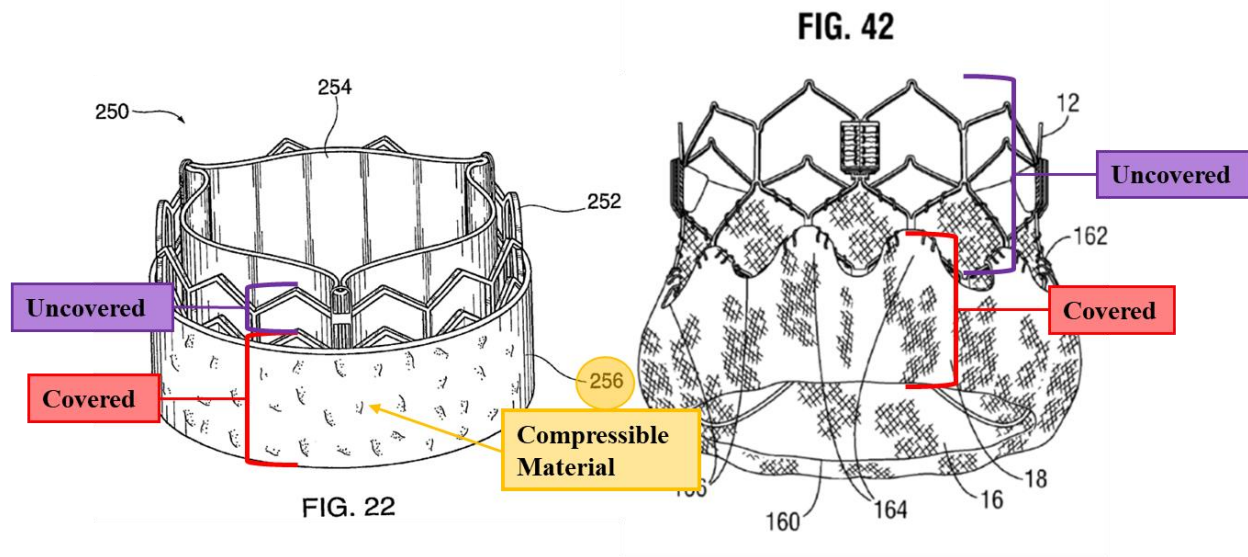
(Ex. 1007, Fig. 1; Ex. 1008, Fig. 42; Ex. 1003, ¶318.)

Therefore, Levi combined with Walther would yield a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (Ex. 1003, ¶318.)

c. Spenser II

Spenser II's compressible material does not cover a portion of the stent structure 252. (*Supra* §VII.B.8.) If Spenser II's compressible material were

substituted for Levi's outer skirt, the cloth **would not** cover at least the uppermost row of cells, as illustrated in the comparison of Spenser II's Figure 22 (left) and Levi's Figure 42 (right):



(Ex. 1011, Fig. 22; Ex. 1008, Fig. 42; Ex. 1003, ¶319.)

Therefore, the combination of Levi and Spenser II would yield a valve wherein a portion of the outer frame is uncovered by the graft covering and outer seal. (Ex. 1003, ¶320.)

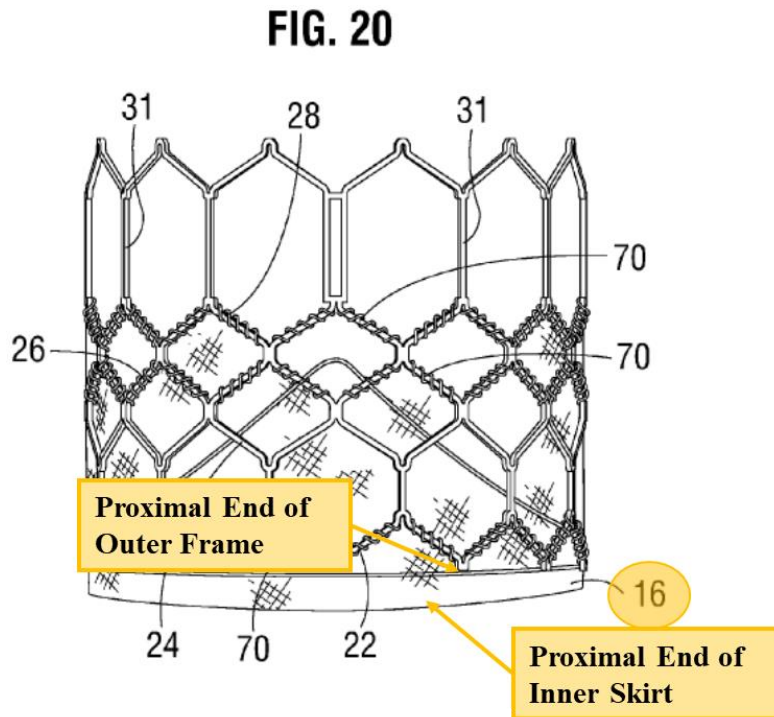
9. Claim 9

This claim is substantially similar to claim 2. (Ex. 1003, ¶321.) Levi discloses this limitation for the reasons provided in claim 2. (*Supra* §VII.C.2.)

10. Claim 10

Levi discloses this limitation or renders it obvious. (Ex. 1003, ¶¶322-325.)

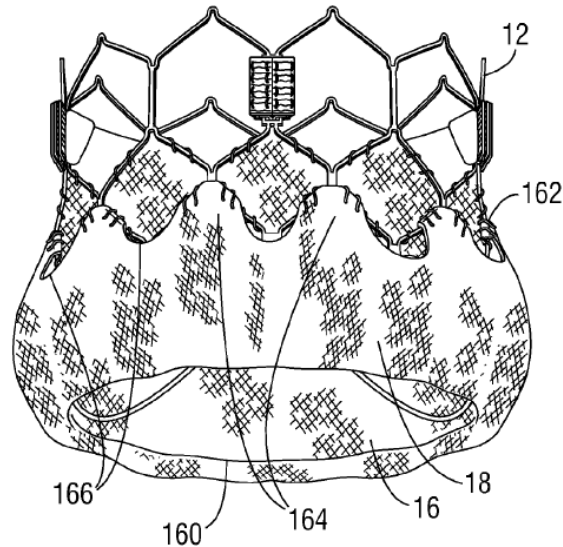
The proximal edge of Levi's inner skirt 16 extends beyond the proximal end of the frame:



(Ex. 1008, Fig. 20.)

Levi further discloses that “the lower edge 160 of the skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.” (*Id.*, 13:55-58.)

FIG. 42



Because the inner skirt extends beyond the proximal end of the outer frame, the attachment of the outer skirt necessarily causes the lower edge of the inner skirt 16 to extend over and cover the proximal end of the outer frame. (Ex. 1003, ¶324.) This is particularly true when the outer skirt bulges outwardly and pulls the proximal portion of the inner skirt out and over the distal end of the frame. (*Id.*)

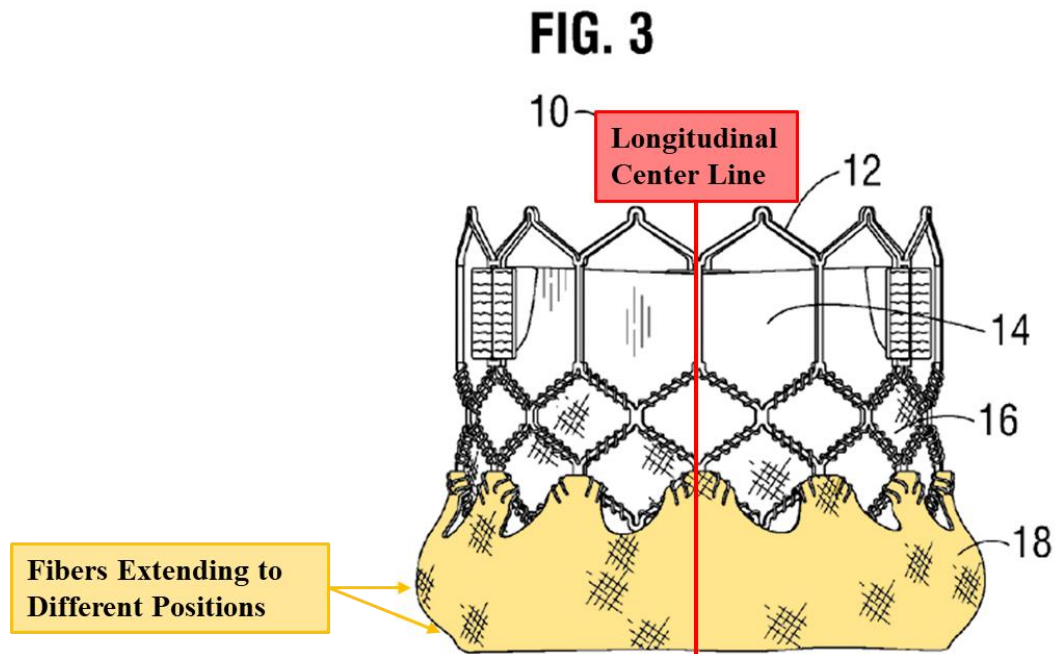
Alternatively, POSITAs would have found it obvious to extend Levi's inner skirt over the proximal end of the frame to cover the proximal end. (*Id.*, ¶325.) Levi discloses that the "upper edge portion [distal] of the [inner] skirt is wrapped around the upper surfaces of struts 28 and secured in place with sutures 70." (Ex. 1008, 10:12-26, Fig. 20.) The wrapping "provides for a stronger and more durable attachment of the skirt to the frame." (*Id.*, 10:26-28.) POSITAs would have been

motivated to apply this same technique to the lower (proximal) edge of the inner skirt to create a stronger attachment between the inner skirt and frame. (Ex. 1003, ¶325.) Because the inner skirt extends beyond the proximal end of the frame, POSITAs would have found it obvious to wrap Levi's inner skirt over the proximal end and secure the inner skirt to the outside of the frame using this wrapping technique. (*Id.*) POSITA's would have expected success in attaching the inner skirt in this way because Levi discloses that it was successful for the skirt's distal end. (*Id.*) In this configuration, the outer skirt could still be stitched to the inner skirt or frame and operate the same way. (*Id.*)

11. Claim 11

Levi anticipates claim 11 or renders it obvious alone or in combination with Walther or Spenser II. (Ex. 1003, ¶¶326-328.)

Levi discloses an outer skirt of woven PET fabric formed of outwardly extending fibers. (*Supra* §VII.C.1.e.) The outwardly extending fibers of the outer skirt “extend outwardly to different positions relative to a centerline run through a longitudinal of the valve” as a result of the bulging:



(Ex. 1008, Fig. 3; Ex. 1003, ¶327.)

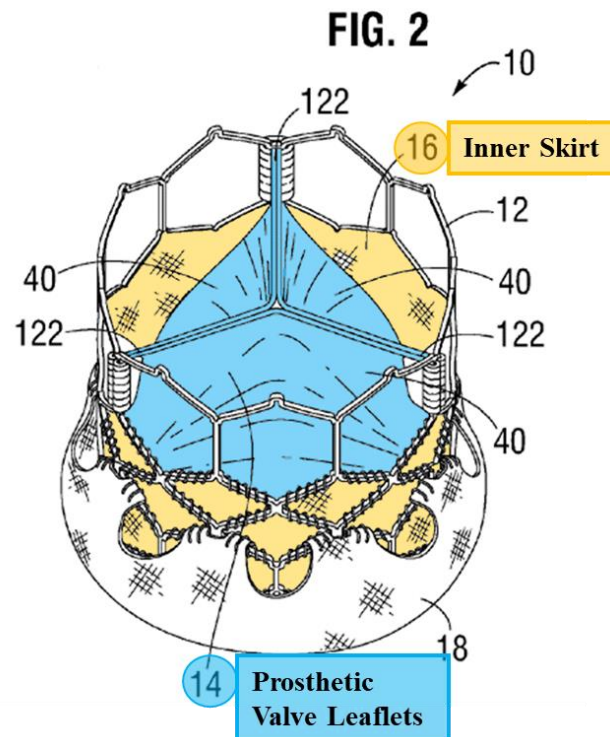
Alternatively, if Walther’s outer cloth or Spenser II’s compressible material were substituted for Levi’s outer skirt, the resulting valve would include fibers that “extend outwardly to different positions relative to a centerline run through a longitudinal of the valve” for the reasons previously stated. (*Supra* §§VII.A.8, VII.B.11; Ex. 1003, ¶328.)

12. Claim 12

Levi discloses this limitation or renders the limitation obvious alone or in combination with Walther or Spenser II. (Ex. 1003, ¶329-332.)

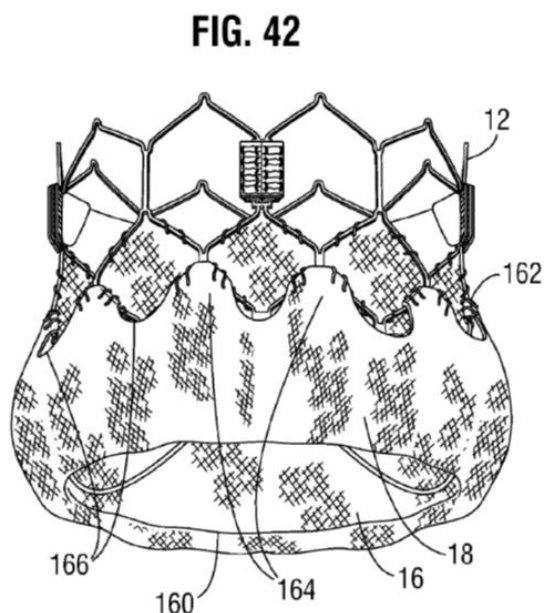
Levi discloses an inner skirt that extends around the prosthetic valve leaflets. (*Supra* §VII.C.1.c.) Levi’s inner skirt 16 [yellow] radially overlaps with the leaflets

of the prosthetic heart valve 14 [blue]:

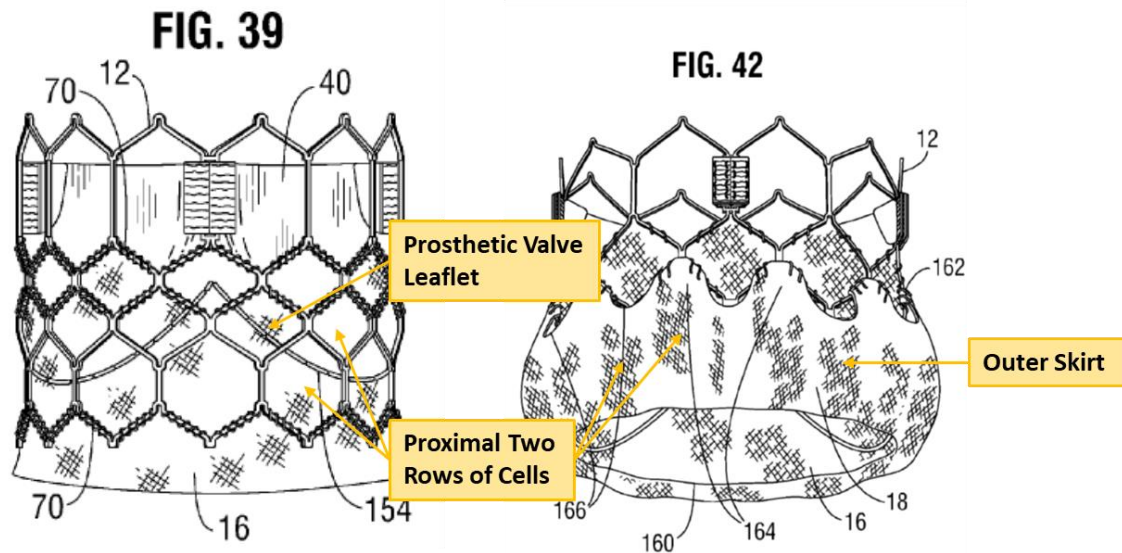


(Ex. 1008, Figs. 2, 3; Ex. 1003, ¶¶330-331.)

Similarly, Levi's outer skirt covers the bottom rows of cells of the outer frame:



(See Ex. 1008, Fig. 42; Ex. 1003, ¶331.) A comparison of Levi's Figures 39 and 42 confirms that the outer skirt radially overlaps with the prosthetic valve leaflets:



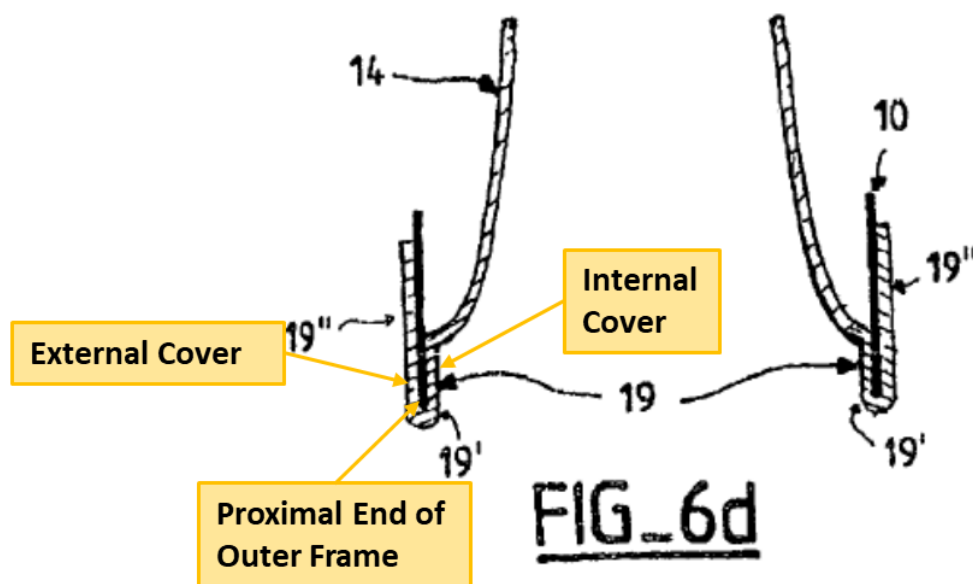
(Ex. 1008, Figs. 39, 42; Ex. 1003, ¶331.) Therefore, Levi discloses a valve wherein the graft covering, outer seal, and prosthetic leaflets radially overlap.

Alternatively, Levi in combination with Walther and Spenser II renders this claim obvious. (Ex. 1003, ¶332.) Walther and Spenser II disclose an outer seal that covers the bottom rows of cells of the stent frame, which radially overlap with the prosthetic leaflets. (Ex. 1007, 1121, Fig. 1; Ex. 1011, [00145], Fig.22; *supra* §§VII.A.9, VII.B.12.) POSITAs would have been motivated to attach Walther's outer cloth or Spenser II's compressible material to Levi's outer frame in the same way, and would have expected success in doing so, because the references demonstrate that covering the bottom rows of cells is effective at creating a seal. (Ex.

1003, ¶332.) In the combined device, the outer seal, graft covering, and prosthetic leaflets would radially overlap. (*Id.*)

D. Grounds 8-10: Claim 10 Obvious Over Levi and Cribier '321 and Optionally Walther or Spenser II

If Levi does not disclose this limitation, Cribier '321 does. Cribier '321 discloses a valve having an internal cover 19 that “is extended at its lower [proximal] end 19' to an external cover 19'' which is rolled up to be applied on the external wall of the stent 10.” (Ex. 1045, 13:28-30.) As shown below, the internal cover 19 (i.e., graft covering) extends beyond and over the proximal end of the frame 10 to cover the proximal end:



(*Id.*, Fig. 6d.) The internal cover is preferably “made of synthetic biocompatible material such as TEFLON[®] or DACRON[®], polyethylene, polyamide” and, therefore, is a graft covering. (*Id.*, 5:15-18, 13:15-16; Ex. 1003, ¶334.)

POSITAs would have found it obvious to apply Cribier ’321’s teaching to Levi’s inner skirt. (Ex. 1003, ¶335.) POSITAs would have been motivated to use Levi’s inner skirt to cover the proximal end of the frame to further “enhance[] the sealing of [Levi’s] device at the valve inlet.” (Ex. 1010, 14:6-9; Ex. 1003, ¶335.) POSITAs would have understood that extending Levi’s inner skirt over the proximal end of the outer frame would prevent leaks between the inner skirt and frame. (*Supra* §VII.A.1.e; Ex. 1003, ¶335.)

Additionally, POSITAs would have been motivated to extend the skirt over the proximal end to reduce the risk that the edges of the frame would damage the surrounding tissue. (Ex. 1003, ¶336; *see also* Ex. 1048, [0098].) This modification would have merely entailed applying a known technique (extending the skirt) to a known device (Levi’s frame) ready for improvement (enhanced sealing). *KSR Int’l Co.*, 550 U.S. at 416.

POSITAs would not have expected the outer skirt’s performance to be impacted by extending Levi’s inner skirt beyond and over the proximal end of the outer frame. (Ex. 1003, ¶339.) Levi teaches that the “lower edge of the [outer] skirt

18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.” (Ex. 1008, 13:55-58.) As explained above, in this configuration, Levi’s inner skirt extends beyond and over the proximal end of the valve. (*Supra* §VII.C.10.) Further, if the inner skirt were extended over the proximal end of the frame and secured to the exterior of the frame, the outer skirt could still be sutured to the inner skirt, or another part of the valve, so that it continued to operate in the same way. (*Id.*)

Likewise, POSITAs would not have been discouraged from extending Levi’s inner skirt if Walther’s outer cloth or Spenser II’s compressible material were substituted for Levi’s outer skirt for the reasons explained previously. (*Supra* §VII.B.10; Ex. 1003, ¶340.)

VIII. SECONDARY CONSIDERATIONS

Petitioner understands that Patent Owner does not practice the ’846 patent or sell any products covered by the ’846 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶341-342.) If Patent Owner identifies any evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

IX. THE BOARD SHOULD NOT DENY INSTITUTION UNDER §325(d)

Walther, which describes the cloth-covered SAPIEN, was not of record during prosecution. Likewise, Cribier and Spenser, which describe SAPIEN, were not of record. Thus, the Examiner did not consider any reference (or combination of references) that disclosed Walther’s combination of a prosthetic heart valve having (1) a fibrous outer seal stitched to the exterior of a balloon-expandable stent frame and (2) an inner graft covering stitched to the interior of the stent frame. Because Walther, Cribier, and Spenser were never before the Examiner, the Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d).

Spenser’s parent’s publication, Pub. No. US 2003/0153974, was listed on an Information Disclosure Statement (IDS). However, the publication does not disclose Spenser’s Figure 44a, which is similar (if not identical) to SAPIEN, relied on herein. (*Compare* Exs. 1010, 1026.)

Patent Owner also characterized several prior art references, including Cribier ’321’s parent publication, WO 98/29057 (“the ’057 publication”), Levi’s publication, US 2012/0123529 (“the ’529 publication”), and Spenser II, in a Preliminary Amendment. (Ex. 1002, 136-149.) Patent Owner attempted to distinguish the prior art on two primary grounds. First, Patent Owner argued that the “valve profile would be unsatisfactorily increased” if an outer seal were combined

with a valve having an inner seal. (*Id.*, 147.) As described above, this assertion is incorrect. (*Supra* §§VII.A.1, VII.A.5, VII.B.1, VII.B.6; Ex. 1003, ¶¶88-94.) Moreover, the '846 patent does not describe methods to reduce the valve profile and, therefore, Patent Owner cannot rely on this argument to distinguish the prior art. (*Id.*, §VII.A.5.)

Second, Patent Owner argued that “one would not look to stent graft seals to modify” a heart valve. (Ex. 1002, 148.) This argument is irrelevant because Petitioner does not rely on stent grafts for any combinations.

Regarding Cribier '321 specifically, Patent Owner **admitted** that the '057 publication “shows a cover extending from an inner surface to an outer surface of the stent frame.” (Ex. 1002, 136-137.) Patent Owner never addressed combining Cribier '321 with the references as proposed herein, nor did the Examiner.

Regarding Levi, Patent Owner **admitted** that Levi “appears to teach an inner and outer seal in Fig. 42.” (*Id.*, 137.) However, Patent Owner also included attorney argument that Levi’s “seal . . . had a relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta[.]” (*Id.*, 145.) Yet, as admitted by Patent Owner, Levi’s outer seal presses against the patient’s native leaflets. (*Supra* §VII.C.1.g.) Moreover, no claim

requires the seal to press against the leaflets “at a most narrow spot of the ascending aorta.” (Ex. 1002, 145.) Patent Owner also never addressed combining Levi with Walther or Spenser II as proposed herein.

Regarding Spenser II, Patent Owner ***admitted*** that Spenser II discloses “a thick band with fibers,” but argued “there is no graft forming the inner frame, thus the inner seal is missing.” (Ex. 1002, 138.) However, as explained herein, POSITAs would have found it obvious to combine Spenser II with Spenser or Levi, which disclose an inner graft covering. (*Supra* §§VII.B.1.e, VII.C.1.e.) Patent Owner never addressed these combinations.

Patent Owner also included attorney argument that POSITAs would not add Spenser II’s outer seal to a valve that included an inner seal due to concerns about increasing the crimped profile, restricting expansion and foreshortening of the valve, and because Spenser II already provides a method for addressing PVL. (Ex. 1002, 145.) However, Walther demonstrates these arguments are unfounded. In the real world, POSITAs added an outer seal, similar to Spenser II’s compressible material, to SAPIEN, which included an inner graft covering. (*Supra* §VII.A.1.e.)

Patent Owner also included attorney argument that “Spenser [II] appears to include an outer graft covering between the fibers and the outer frame[.]” (Ex. 1002,

147.) As explained herein, Spenser II contains no such disclosure. (*Supra* §VII.B.1.e; Ex. 1011, [00145].)

Consequently, the Board should not deny institution under §325(d) based on Patent Owner's statements in the Preliminary Amendment. *See also*, Ex. 1003, ¶¶88-94; *Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining 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 a Petition for *Inter Partes* Review of U.S. Patent No. 10,792,172 (“’172 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01527 (Filed Sept. 10, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,857,011 (“the ’011 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021). The ’846 patent is a continuation of the ’172 and ’011 patents.

Patent Owner also recently filed suit against Petitioner alleging infringement of the '846 patent by Petitioner's SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1-21-CV-01377 (D. De., filed Sept. 28, 2021). When this Petition was filed, the Complaint and associated papers were the only documents filed in the case.

Petitioner is not aware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com BoxEdwards20-1@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	Joshua J. Stowell (Reg. No. 64,096) 2jys@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 BoxEdwards20-4@knobbe.com.

XI. FEES

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

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

Petitioner certifies that the '846 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims on the identified grounds.

XIII. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that the challenged claims are unpatentable as anticipated or obvious and, therefore, requests that the Board institute an *inter partes* review and cancel the claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 11, 2021

By: /Joshua J. Stowell/

Craig S. Summers (Reg. No. 31,430)

Joshua J. Stowell (Reg. No. 64,096)

Brian C. Barnes (Reg. No. 75,805)

Customer No. 20,995

Attorneys for Petitioners

EDWARDS LIFESCIENCES CORP. AND

EDWARDS LIFESCIENCES LLC

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,966,846,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,996
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: October 11, 2021

By: /Joshua J. Stowell/

Craig S. Summers (Reg. No. 31,430)

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Brian C. Barnes (Reg. No. 75,805)

Customer No. 20,995

Attorneys for Petitioners

EDWARDS LIFESCIENCES CORP. AND

EDWARDS LIFESCIENCES LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 10,966,846** and **EXHIBITS
1001 – 1050** are being served on, via Federal Express overnight mail on counsel of
record for U.S. Patent 10,966,846 as addressed below:

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

Dated: October 11, 2021

By: /Joshua J. Stowell/

Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
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