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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.

IPR2023-01325

Patent No. 11,491,033

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,491,033**

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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,491,033 B2 (“ ’033 patent ”)
1002	Excerpts from the prosecution history of the ’033 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“Walther”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	Reserved
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ Spenser ”)
1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
1012	Reserved
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.

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1016	Reserved
1017	Cheung, Anson, et al., <i>Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human</i> , Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020-1021	Reserved
1022	Smith, Craig R., et al., <i>Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients</i> , 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., <i>Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches</i> , Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Reserved
1025	Cribier, Alain, et al., <i>Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis</i> , 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al.
1027-1029	Reserved

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Exhibit No.	Description
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)
1031-1033	Reserved
1034	Andersen, Henning, et al., <i>Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs</i> , European Heart Journal, 13:704-08 (1992)
1035	Reserved
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.
1038-1044	Reserved
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al.
1046	Reserved
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	Reserved

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Exhibit No.	Description
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dkt. 1, Complaint (Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braidó et al.
1055-1056	Reserved
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall (“Birdsall”)
1058	Reserved
1059-1071	Reserved
1072	Deposition Transcript of Stephen Brecker from August 30, 2022
1073	Deposition Transcript of Stephen Brecker from August 31, 2022
1074	U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)
1075-1105	Reserved
1106	Estridge, Trudy & Dale Feldman, <i>Quantification of Vascular Ingrowth into Dacron® Velour</i> , 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”)

Exhibit No.	Description
1107	Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)
1108	Jonas, Richard A. et al., <i>Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments</i> , 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”)
1109	Ko, Frank K., <i>Fabrics</i> , Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”)
1110	Pourdeyhimi, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyhimi”)
1111	Scott, Steward M. et al., <i>A Collogene Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)
1112	Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”)
1113-1115	Reserved
1116	U.S. Patent Pub. No. 2002/0151958 to Chuter (“ Chuter ”)
1117	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01527, Final Written Decision (“172 FWD”)
1118	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584, Final Written Decision (“011 FWD”)
1119	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00193, Final Written Decision (“538 FWD”)

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Exhibit No.	Description
1120	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00034, Final Written Decision (“’846 FWD”)
1121	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00549, Institution Decision from (“’735 Institution Decision”)
1122	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Dkt. 13, Second Amended Complaint (Apr. 10, 2023)
1123	Aortic Innovations LLC’s Disclosure of Asserted Claims and Infringement Contentions, C.A. No. 1-23--CV-00158 (JPM) (“PO Infringement Contentions”)
1124	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 Patent Owner’s Preliminary Response (“’011 POPR”)
1125	U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment
1126	U.S. Pat. No. 4,739,762
1127	U.S. Pat. No. 5,102,417
1128	Deposition Transcript of Dr. Nigel Buller from November 11, 2012
1129	C. C. Chu, <i>Understanding Implantable Textiles</i> , Advanced Textiles Source (May 21, 2018) (“Chu”)
1130-1135	Reserved
1136	Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”)
1137-1140	Reserved

Petitioners Edwards Lifesciences Corp. and Edwards Lifesciences LLC (“Petitioner”) request *inter partes* review (“IPR”) of claims 1-2 and 4-6 (“the challenged claims”) of U.S. Patent No. 11,491,033 (“the ’033 patent”) to Aortic Innovations, LLC (“PO” or “Patent Owner”).

I. SUMMARY OF THE ARGUMENT

The ’033 patent is a continuation of several patents challenged by Petitioner in prior IPRs.¹ The unpatentability issues presented herein have largely been decided by the Board in those prior IPRs, at least some of which have preclusive effect. Many limitations of the challenged claims were at-issue in the prior IPRs, and the Board found that the same prior art asserted herein discloses or renders obvious those limitations. In response to Petitioner’s prior IPRs, PO has continued to prosecute new patents, attempting to further stretch its claims to cover Petitioner’s commercially available SAPIEN 3 Ultra valve. However, like the claims found unpatentable in Petitioner’s prior IPRs, PO’s efforts to ensnare Petitioner’s SAPIEN 3 Ultra valve have resulted in overbroad claims that cover the prior art.

¹ See *infra* §II (identifying prior IPRs).

The '033 patent claims a heart valve having: (1) a frame [red], (2) a polymer covering, (3) a leaflet assembly, and (4) a sealing assembly having fibers [green] that extend away from the frame.

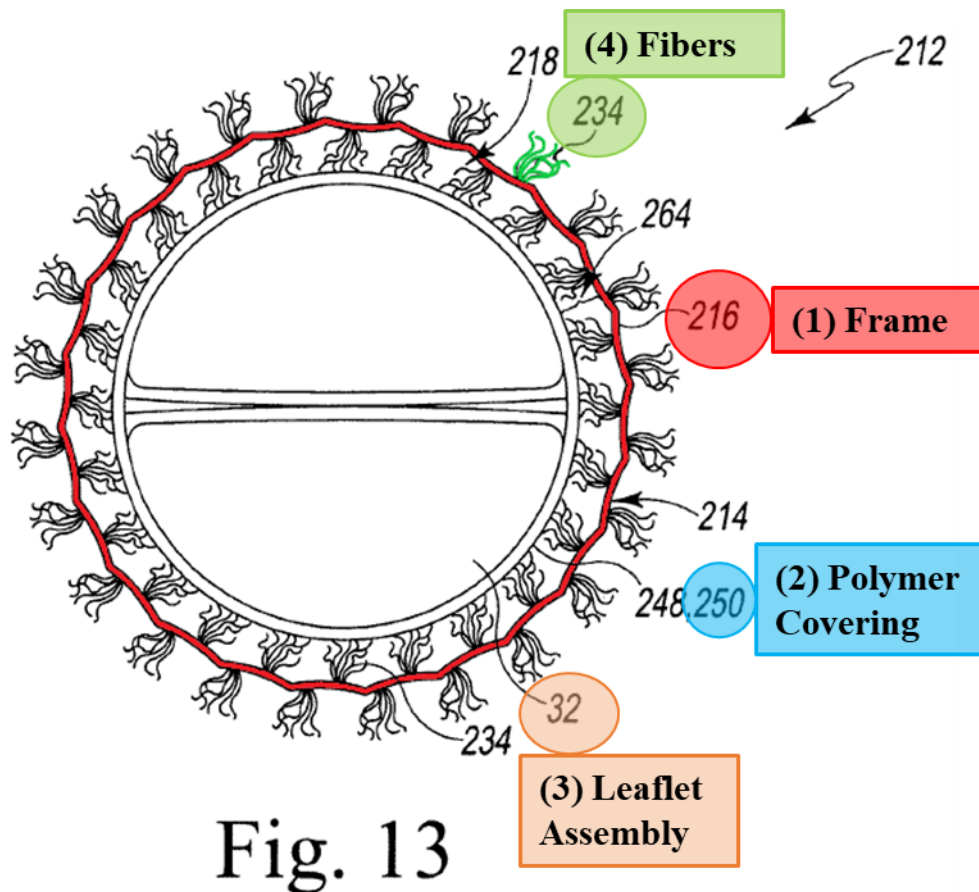


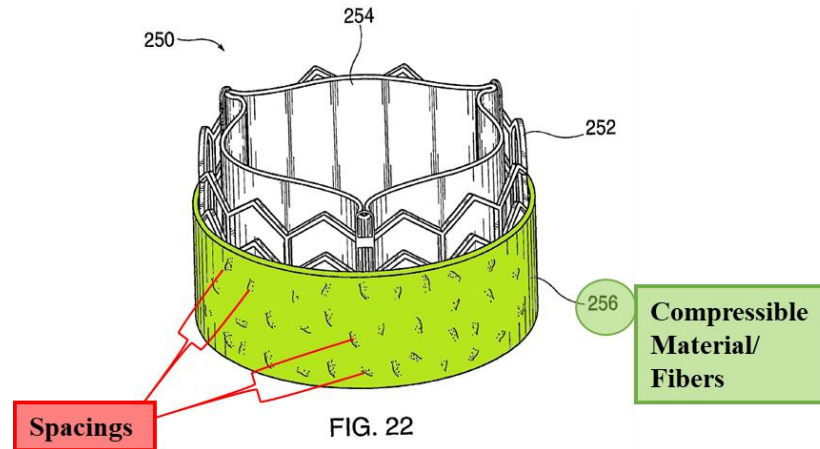
Fig. 13

In attempting to distinguish the '033 patent from the claims previously found unpatentable, PO included limitations requiring: (1) “spacings extending through a thickness of the sealing assembly” that “allow fluid to pass therethrough” when the valve is in an undeployed state, (2) the “valve assembly is sized and shaped to be endovascularly deployed through a femoral artery,” and (3) the sealing assembly

“lays against the frame” in the radially compressed and expanded configurations. Notably, the ’033 patent specification does not include many of the terms in these new claim limitations, including “spacings,” “thickness,” “sealing assembly,” and “lays against the frame.” During prosecution, PO relied exclusively on the figures to support these terms. However, because the ’033 patent does not state that the figures are drawn to scale, and PO has not argued to the contrary, the ’033 patent does not disclose or require any dimensions for the recited “spacings” and “thickness” beyond the language in the claims. These litigation-driven limitations do not distinguish the challenged claims from the prior art.²

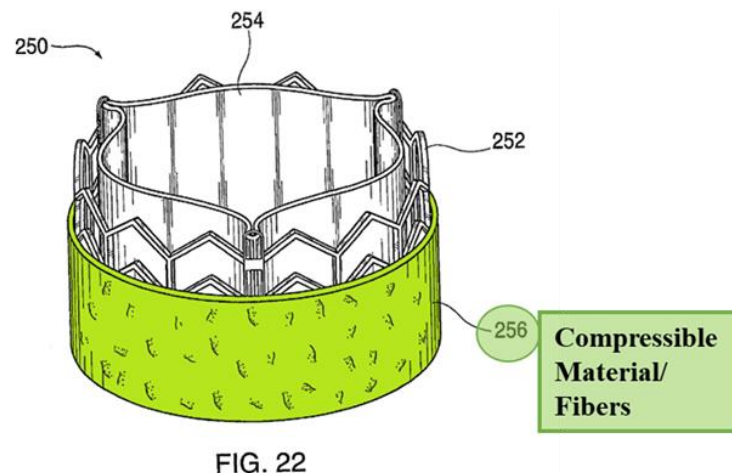
For example, **Spenser II**, which the Board relied upon for its unpatentability findings in the prior IPRs, discloses the required “spacings.” Spenser II discloses a heart valve having a “compressible material” that “may resemble a cloth or fabric having small fibers extending from the surface of the material.” Spenser II’s Figure 22 illustrates spacings between the fibers extending from the surface of the material. These “spacings” extend through “a thickness of the sealing assembly.”

² Petitioner expressly reserves its right to challenge whether the ’033 patent claims satisfy 35 U.S.C. §112 in future proceedings.



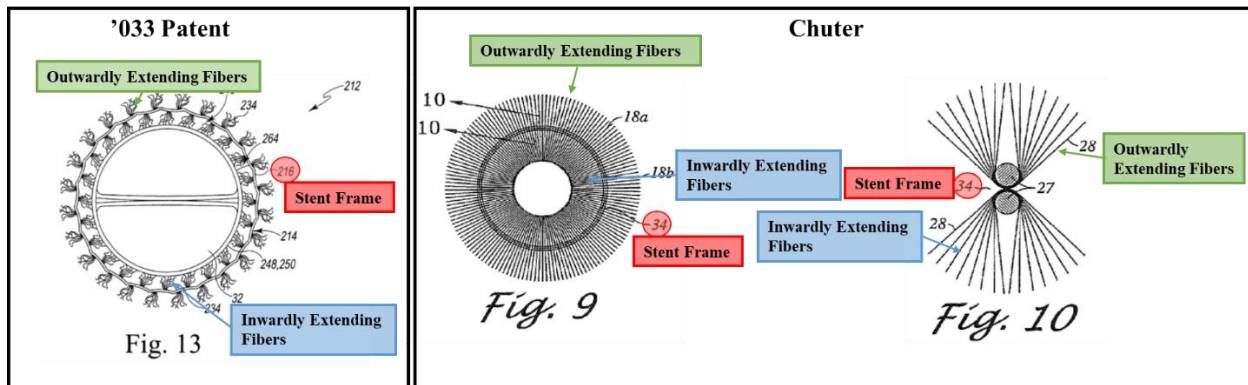
Moreover, the illustrated spacings between the fibers of the “compressible material” are large enough to allow “fluid to pass therethrough.” Porous materials, like those disclosed and illustrated in Spenser II, were well known in the prior art and used for sealing cardiovascular implants for decades before the priority date of the ’033 patent.

Spenser II also discloses a sealing assembly that “lays against the frame.” Figure 22 illustrates the compressible material laying against the frame in the expanded configuration:



The compressible material also “lays against the frame” in the compressed configuration because the compressible material is sutured to the frame and pressed against the frame during the crimping and delivery process. Spenser II also discloses implanting the valve through a small perforation in the groin area, which refers to endovascular delivery through the femoral artery.

Chuter also discloses the new limitations. Chuter discloses a sealing assembly formed of fibers attached to a stent frame, extending both inwardly and outwardly from the frame:



(Compare Ex. 1001, Fig. 13 with Ex. 1116, Figs. 9-10.) As shown, “spacings” exist between Chuter’s fibers that are like the spacings illustrated in the ’033 patent. Chuter’s spacings “extend through a thickness of the sealing member” and are clearly large enough to allow “fluid to pass therethrough.” Chuter’s sealing assembly also “lays against the frame” in the same way as that of the ’033 patent. Chuter also discloses implanting the device through “one of the arteries in the legs”

(e.g., femoral artery). (Ex. 1116, [0062].) Notably, Chuter was not considered in the prior IPRs resulting in a Final Written Decision.

The Board previously concluded that Spenser II, in addition to other art cited herein, discloses or renders obvious nearly every limitation of the challenged claims. Because the new limitations were also known in the art, the Board should find every challenged claim unpatentable.

II. PRIOR IPRS OF RELATED PATENTS

Petitioner has previously filed eight IPRs (“prior IPRs”) challenging patents having the same specification and drawings as the ’033 patent. The status of those IPRs is summarized below:

IPR No.	Challenged Patent	Outcome/Status
IPR2021-01527	10,792,172	All challenged claims obvious over Spenser + Spenser II (FINAL)
IPR2021-01584	10,857,011	All challenged claims obvious over Spenser + Spenser II (FINAL)
IPR2022-00193	10,881,538	Claims 1–8, 10–18, and 20 obvious over Spenser + Spenser II; Claims 9 and 19 not unpatentable under different grounds
IPR2022-00034	10,966,846	Claim 6 not unpatentable due to “free of an outer graft covering” limitation
IPR2022-00556	10,987,236	IPR instituted, oral hearing held June 16, 2023
IPR2022-00549	11,129,735	Institution denied based on “apices of the outer frame...are uncovered” limitation
IPR2023-01151	11,337,834	Filed June 29, 2023
IPR2023-01232	11,389,310	Filed July 20, 2023

As shown, the Board found every challenged claim in Petitioner’s prior IPRs that have reached a Final Written Decision unpatentable based on Spenser and Spenser II except claims that recite: (1) “fibers extending radially inwardly from the outer frame;” (2) the valve assembly is “free of an outer graft covering between the fibers and the outer frame;” or (3) “an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering” and “the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal.” (See Ex. 1119, 107; Ex. 1120, 39-52; Ex. 1121, 17-19, 22-24, 29-31.) None of the presently challenged claims include these limitations.

The Board’s unpatentability findings in IPR2021-01527 (’172 patent) and IPR2021-01584 (’011 patent) have preclusive effect on many of the issues presented herein because PO did not appeal the Board’s decisions and PO’s deadline for filing an appeal has passed. See, e.g., *Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am. Inc.*, 924 F.3d 1243, 1250-53 (Fed. Cir. 2019) (applying collateral estoppel based on final IPR decision); *Google LLC v. Hammond Dev. Int’l, Inc.*, 54 F. 4th 1377, 1381 (Fed. Cir. 2022) (“It is well established that collateral estoppel applies to IPR proceedings.”). Notably, “collateral estoppel may apply even if the patent claims use slightly different language to describe substantially the same invention, so long as the differences between the unadjudicated patent claims and adjudicated

patent claims do not materially alter the question of invalidity.” *Google*, 54 F. 4th at 1381. (internal quotation marks omitted). Accordingly, PO is precluded from challenging at least the following issues for the ’033 patent:

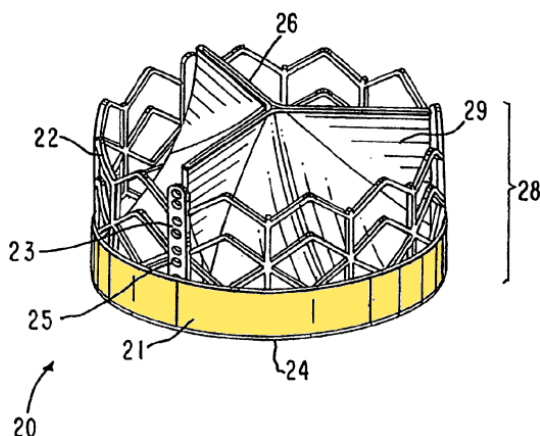
- POSITAs would have been motivated to add Spenser II’s compressible material to Spenser’s transcatheter heart valves (“THVs”) (Ex. 1117, 64-66; Ex. 1118, 67-70);
- POSITAs would have reasonably expected success in combining Spenser + Spenser II (Ex. 1117, 64-66; Ex. 1118, 67-70);
- POSITAs would have reasonably expected the THV resulting from Spenser + Spenser II would be endovascularly deliverable (Ex. 1117, 57-64; Ex. 1118, 57-68);
- Petitioner’s expert, Dr. Nigel Buller, is qualified as an expert and a POSITA (Ex. 1117, 51-52, Ex. 1118, 55-57);
- Spenser II and Norris disclose sealing materials comprising a plurality of outwardly extending fibers that “terminate in an end thereof outwardly of the outer frame” (Ex. 1117, 20-26, 71; Ex. 1118, 65); and
- Spenser discloses:
 - a polymeric graft covering extending around a prosthetic heart valve for providing sealing to the heart valve;

- a metallic frame that forms a gridded configuration;
- a polymeric graft covering stitched to the metallic frame; and
- a polymeric graft covering extending beyond and over the proximal end of the frame to cover the proximal end of the frame.

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

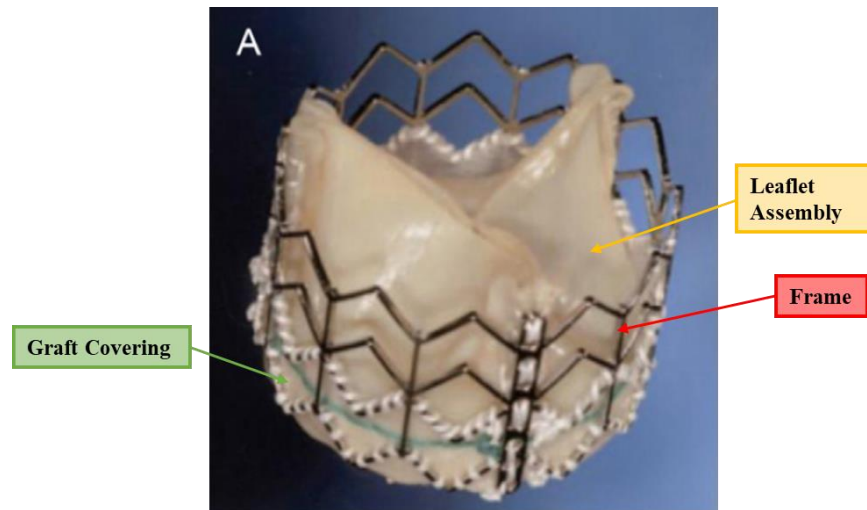
III. STATE OF THE ART

Shortly after THVs were conceived in the late 1980's, practitioners added outer seals to reduce paravalvular leak ("PVL"). For example, in 2001, Percutaneous Valve Technologies ("PVT"), a company co-founded by Dr. Alain Cribier, filed a patent application disclosing a THV having an outer seal, or "cuff portion," (see yellow below) surrounding the THV to prevent PVL:



(Ex. 1019, 8:47-50, 9:19-22, Fig. 1; Ex. 1003, ¶65.) **Spenser**, relied on herein, is a continuation-in-part of this application and includes the above embodiment. (Ex. 1010, 13:22-25, Fig. 1.)

In 2004, Petitioner acquired PVT and developed the Cribier-Edwards THV, which included (1) a frame, (2) a polymeric graft covering, and (3) a leaflet assembly:



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

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

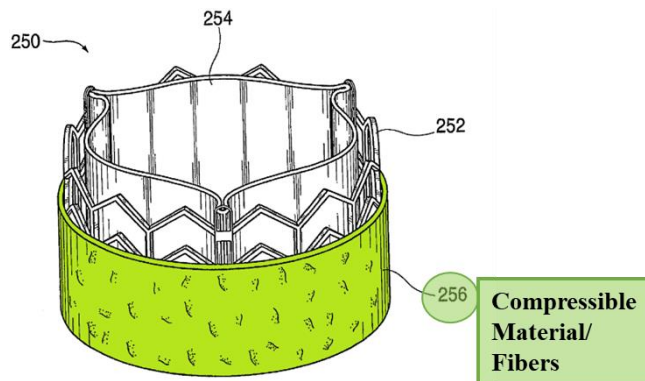
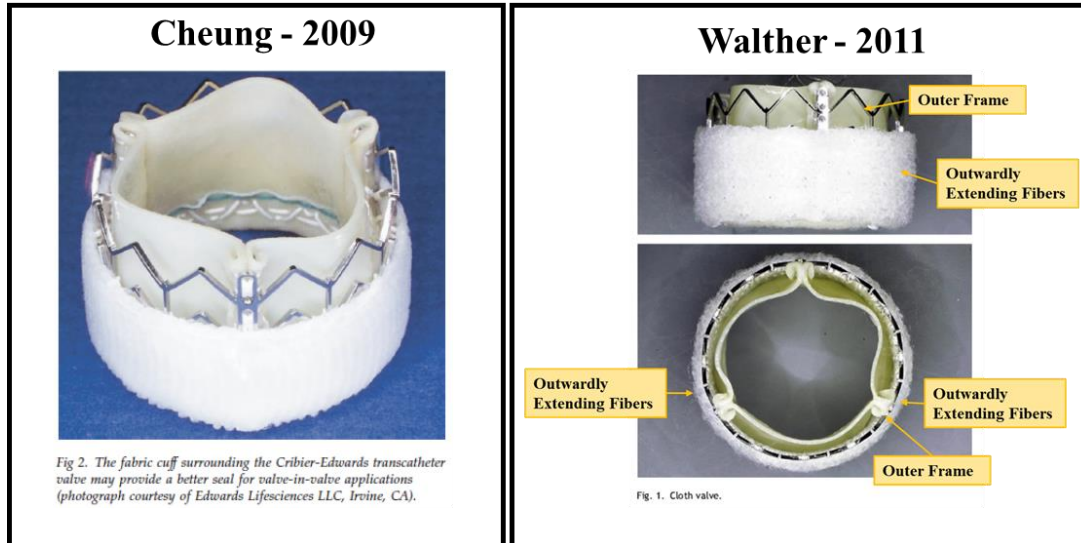


FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶69.)

In 2009 and 2011, Petitioner developed embodiments of one of Spenser II's sealing concepts by adding compressible cloths to the outside of Petitioner's Cribier-Edwards and SAPIEN valves:



(Ex. 1017, 2, Fig. 2 (left); Ex. 1007, Fig. 1 (right).) Petitioner added these compressible cloths to provide better sealing, promote tissue ingrowth, and prevent PVL. (See Ex. 1017, 2; Ex. 1007, 1120-21.)

Many other types of compressible materials with outwardly extending fibers were known in the prior art, consistent with Spenser II's teachings. For example, practitioners used porous velour-like fabrics as outer sealing materials in cardiovascular implants for decades prior to the November 2012 critical date of the '033 patent. (See Ex. 1107; Ex. 1106, 158; Ex 1110, 172; Ex. 1003, ¶81.) They adopted these velour-like fabrics for their ability to promote tissue ingrowth, which

led to better healing and sealing of the device with the patient's tissue. (*See, e.g.*, Ex. 1107, 180-181; Ex. 1106, 158; Ex. 1110, 172; Ex. 1003, ¶81.)

Norris, a patent issued in 2011, discloses “a compressible resilient fabric” for a heart valve or stent that “can include a ground layer 20 of knitted yarn, and a loop layer 30 comprising a plurality of loops 32 of yarn 31, each loop 32 having a point 33 knit into the ground layer 20.”

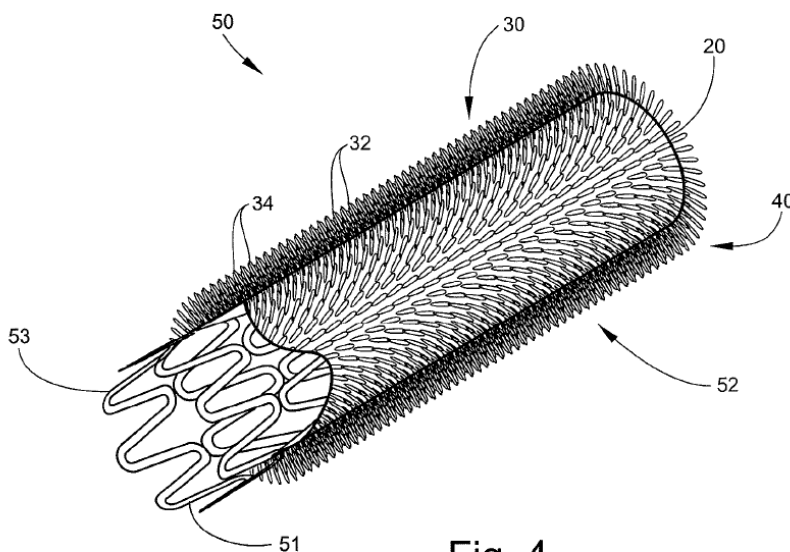
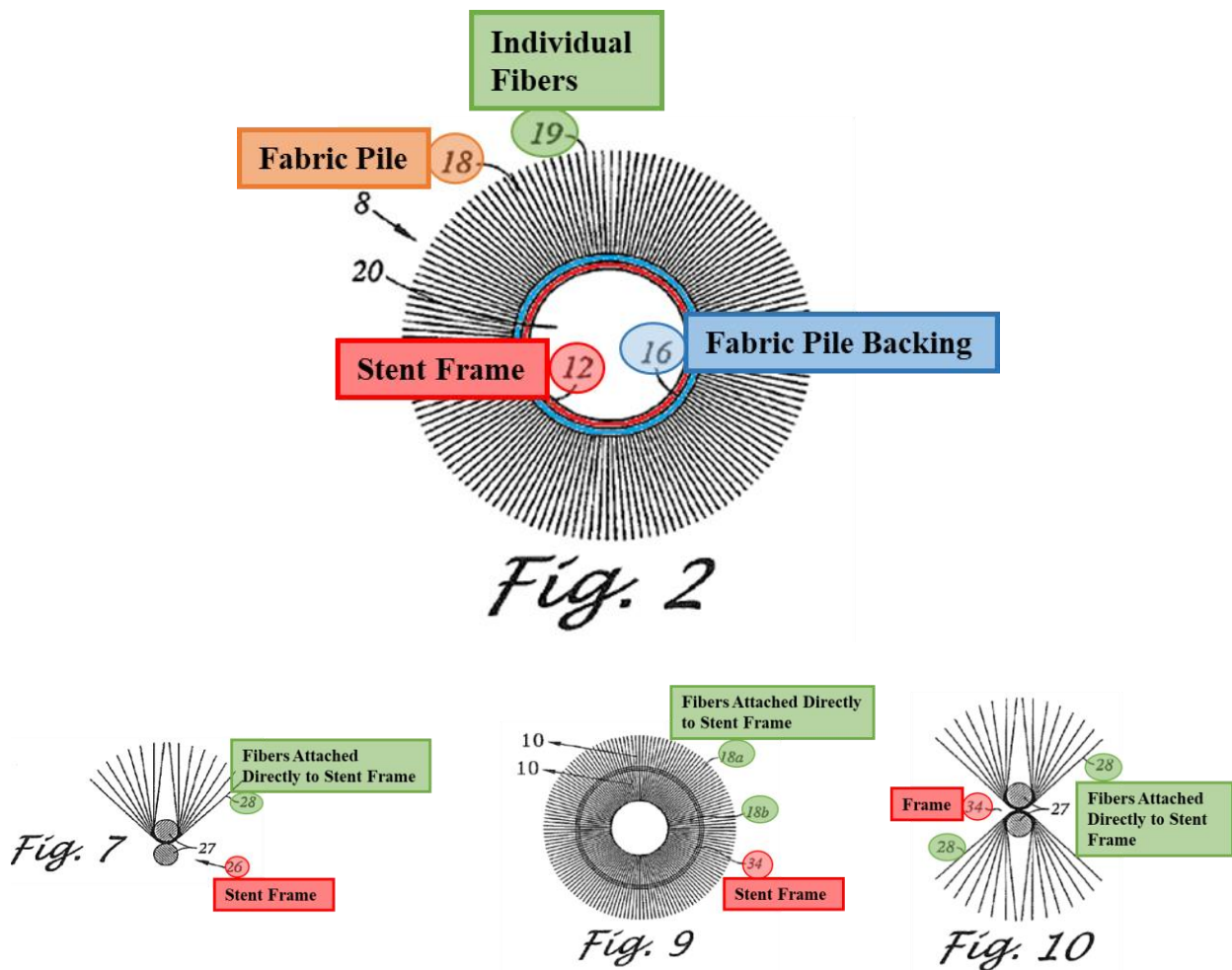


Fig. 4

(Ex. 1074, 4:22-26, 9:18-21, Fig. 4.) Norris's fabric helps prevent blood from leaking around the implanted device. (*Id.*, 9:18-26.) Norris's fabric is also highly compressible to enable endovascular delivery. (*Id.*, 8:23-39, 10:6-13.)

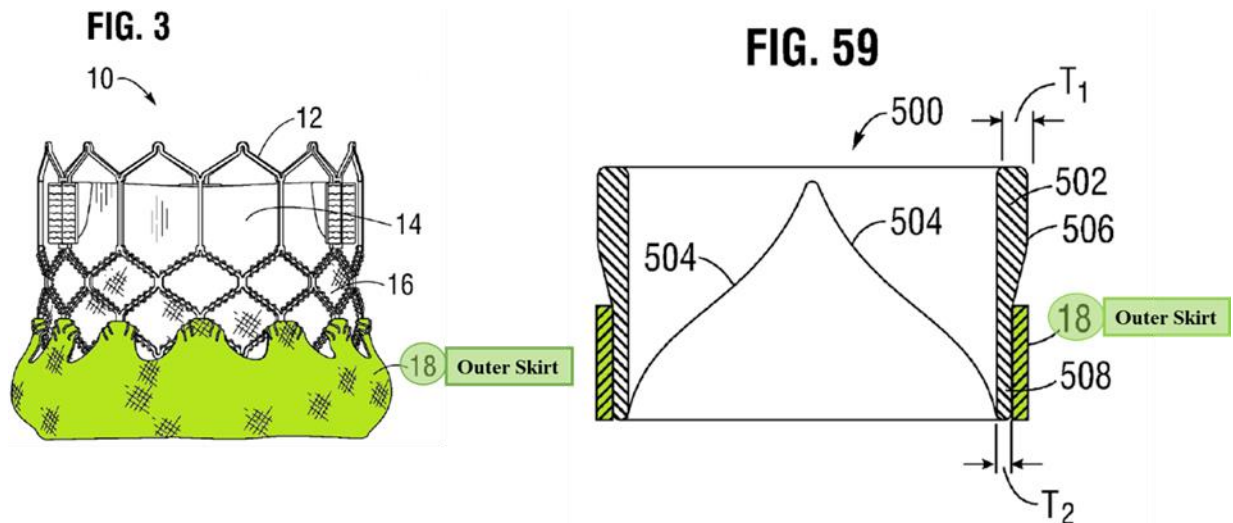
Chuter, a 2002 patent publication, provides another example of compressible materials for sealing cardiovascular implants. Chuter discloses embodiments of endovascularly-delivered intervascular stents having a “fiber pile” made of

individual fibers that are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” (Ex. 1116, [0017]-[0022], Figs 1-10.) The individual fibers of the “fiber pile” can extend from a “fabric pile backing” 16 (Fig. 2) or directly from the frame (Figs. 7, 9-10).



(*Id.*, [0054]-[0057], Figs. 1-10.) Chuter also discloses embodiments having individual fibers that extend outwardly and inwardly from the frame (Figs. 9-10). (*Id.*, [0057], Figs. 8-10.)

Levi, a patent filed by Petitioner in 2010, describes an outer fabric skirt 18 secured to a THV frame, which forms “a good fluid-tight seal between the valve and the native annulus”:



(Ex. 1008, 13:49-14:14, 16:51-54, Figs. 3, 59.) Levi also discloses several ways to minimize the impact of any outer seal on the valve’s crimped profile so the valve can be delivered through the femoral artery. (See *id.*, 6:46-49, 7:10-12, 14:60-64, 16:24-17:18.)

The above references demonstrate 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 features or combine the known features in a nonobvious way. Therefore, the challenged claims are unpatentable.

IV. THE '033 PATENT

A. Overview

The '033 patent describes a “valve assembly” having a “dual-frame” for replacing a heart valve. (Ex. 1001, 12:4-18.) The “dual-frame” includes a “self-expanding outer frame 216” and a “balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 216 and houses the valve 32”:

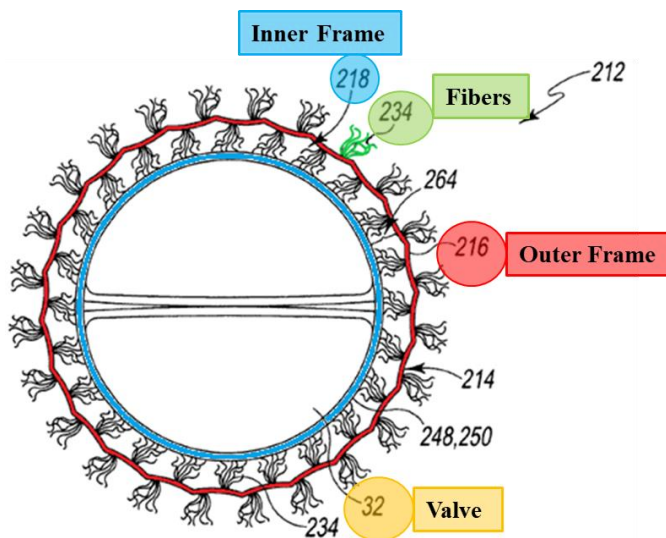


Fig. 13

(*Id.*, 12:19-22, Fig. 13.)

The outer frame includes an “open-cell stent configuration” and radially extending collagen fibers attached to the frame to aid in preventing PVL and migration of the valve. (*Id.*, 12:22-31, 12:53-56, 13:29-32, Fig. 9.) The inner frame is a “balloon-expandable tubular stent.” (*Id.*, 13:50-56.) The outer surface of the inner frame may be covered with a non-porous covering material. (*Id.*, 13:63-67.)

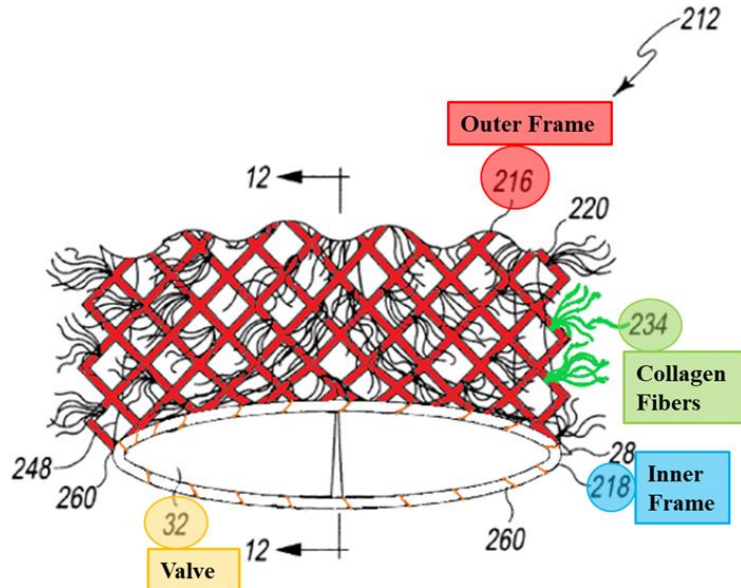


Fig. 11

B. Prosecution History

The Examiner initially rejected the claims as obvious over the combination of Nguyen et al. (WO 2006/124649) and Greenhalgh (US 2002/0052649). (Ex. 1002, 186-191; Ex. 1052; Ex. 1053.)

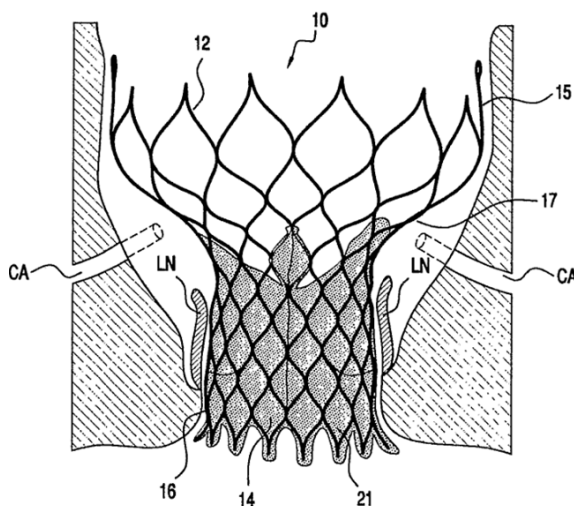


FIG. 6

Nguyen

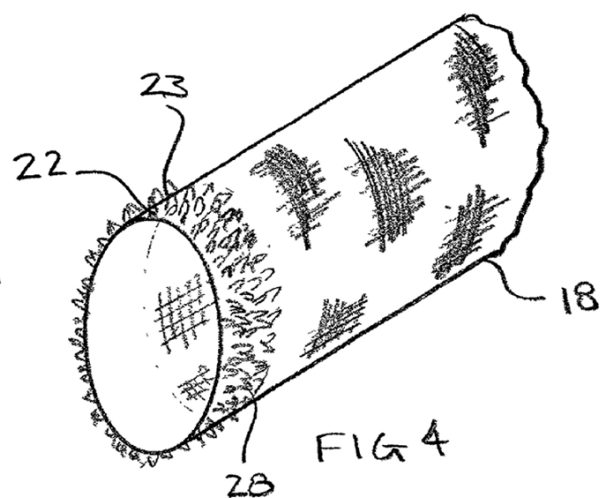


FIG. 4

Greenhalgh

In response, PO cancelled the original claims and proposed new claims, which PO alleged were supported by Provisional Patent Application 61/723,446. (Ex. 1002, 164-173.) PO argued that the combination of Greenhalgh's outwardly extending fibers with Nguyen's endovascularly-deliverable heart valve would not be suitable for delivery through the femoral artery. (*Id.*, 173-180.) The Examiner subsequently allowed most of the pending claims but rejected claim 9 under 35 U.S.C. §112 because the limitation "the polymer covering forms an inner frame for supporting the leaflet assembly" was not supported by the original disclosure. (*Id.*, 93-98.) PO subsequently cancelled pending claim 9 and the Examiner issued a Notice of Allowance. (*Id.*, 42-44, 84-88.)

None of the prior art references discussed herein were discussed or asserted by the Examiner during prosecution. Moreover, the Board has since found that the combination of Spenser II's compressible material with Spenser's heart valve would be suitable for delivery through the femoral artery and PO is estopped from challenging that finding.

C. The Critical Date

The '033 patent claims priority to two provisional applications: application No. 61/567,458 ("the '458 provisional"), filed on December 6, 2011; and application No. 61/723,446 ("the '446 provisional"), filed on November 7, 2012. (Ex. 1001.)

During prosecution of the '172 patent, which is a parent to the '033 patent, PO stated that the '172 patent's "effective filing date...is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012." (Ex. 1049, 274.) Additionally, in litigation, PO conceded that it did not file any patent applications describing outwardly extending fibers until 2012. (Ex. 1050, 9; Ex. 1122, 10.)

V. STATEMENT AND RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

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

B. The Asserted References Are Prior Art

The Critical Date of the '033 patent is November 7, 2012. (*Supra* §III.C.)

The following references are prior art under pre-AIA §102(b):

(1) Spenser (Ex. 1010) issued on March 31, 2009;

(2) Spenser II (Ex. 1011) published on January 12, 2006;

(3) Chuter (Ex. 1116) published on October 17, 2002.

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

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). The references are from the same field as the '033 patent, e.g., cardiovascular implant devices, including endografts and transcatheter heart valves. (Ex. 1003, ¶40.) The references are also pertinent to the problem the inventor was focused on, e.g., treating cardiovascular disease through minimally invasive procedures and providing effective sealing on devices used in such procedures. (*Id.*) Accordingly, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. LEVEL OF ORDINARY SKILL

A POSITA in November 2012 would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This POSITA would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve. (Ex. 1003, ¶49.)

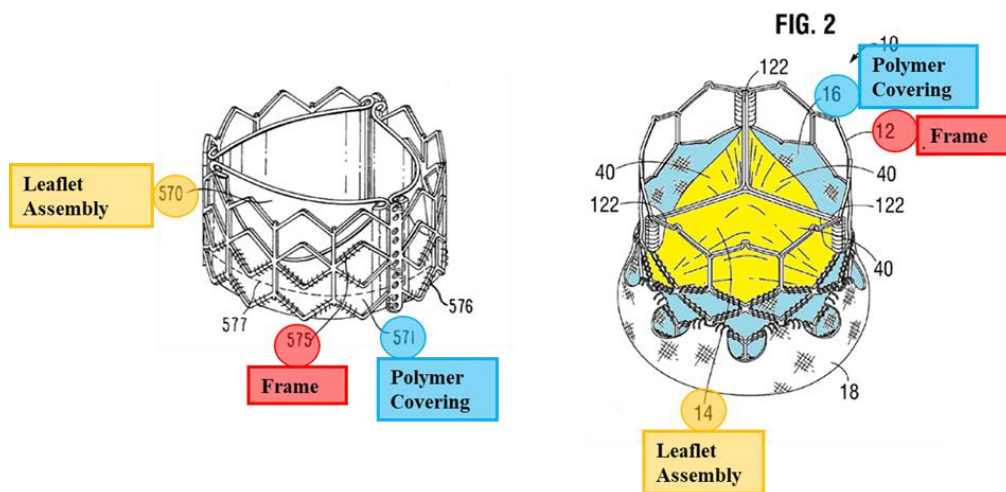
VII. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). No terms of the '033 patent require construction to resolve the patentability issues herein. Petitioner's grounds are based on PO's allegations that the '033 patent covers Petitioner's SAPIEN 3 Ultra valve and the scope of the claims as asserted by PO in litigation. (Ex. 1122; Ex. 1123, 2, 477-564; *see also 10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00087, Paper 9, at 9-10, 15-19 (P.T.A.B. Apr. 27, 2020) (“[W]e see no problem with Petitioner relying on statements by [PO] in the related district court action in which [PO] took a position on the scope of a challenged claim.”); *Nintendo Co. v. Gamevice, Inc.*, IPR2018-01521, Paper 7, at 7 n.5 (P.T.A.B. Mar. 11, 2019). Petitioner reserves its right to propose claim constructions for the '033 patent in district court and to contest PO's infringement allegations.

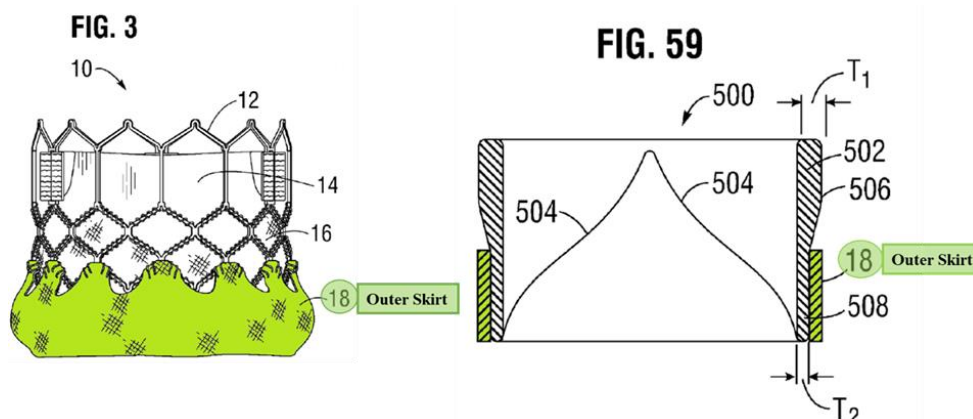
VIII. PROPOSED GROUNDS FOR UNPATENTABILITY

A. Grounds 1-2: Claims 1-2 and 4-6 Obvious Over Spenser *or* Levi and Spenser II

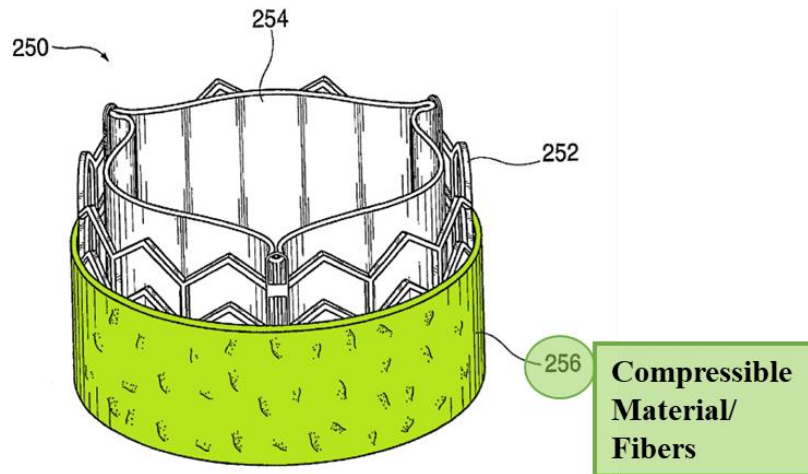
Spenser (left) and Levi (right) describe heart valves having a frame, a polymer covering, and a leaflet assembly:



(Ex. 1010, 11:66-12:17, Fig. 44a; Ex. 1008, Fig. 2.) Levi also discloses an outer fabric skirt 18 secured to the frame's exterior surface for preventing PVL. (Ex. 1008, 13:49-14:14, 16:51-54, 17:12-18, Figs. 3, 59.)



Spenser II discloses similar heart valves having fibrous compressible materials secured to the exterior surface of the frame:



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

The Board has previously concluded that POSITAs would have found it obvious to combine Spenser II's compressible materials with Spenser's valves. (See Ex. 1117; Ex. 1118; Ex. 1119.) For similar reasons, POSITAs would have found it obvious to substitute Spenser II's compressible materials for Levi's outer skirt. (Ex. 1003, ¶¶126-130; *infra* §VIII.A.1.e.ii.) Thus, Spenser *or* Levi combined with Spenser II renders the challenged claims obvious. (Ex. 1003, ¶¶97-183.)

1. Claim 1

Spenser *or* Levi combined with Spenser II renders claim 1 obvious. (Ex. 1003, ¶¶100-171.)

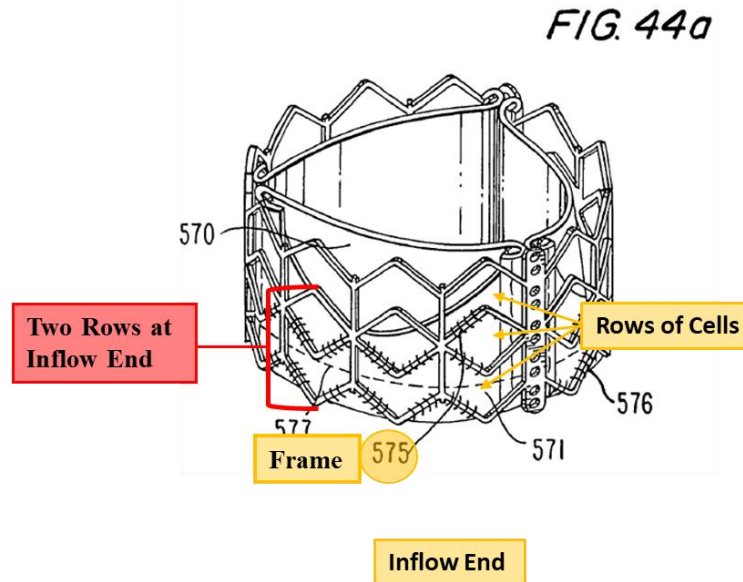
a. Preamble

If the preamble is limiting, Spenser II and Levi disclose “[a]n endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient.” (Ex. 1010, 1:13-15, 2:6-12, 5:17-25, 5:65-6:3, 17:19-18:43; Ex. 1003, ¶¶103-105.) As discussed above, Levi and Spenser II describe heart valves having improved sealing for addressing PVL. Moreover, Spenser, Levi, and Spenser II all describe “endovascular prosthetic heart valve assembl[ies].” The Board previously found that “Spenser and Spenser II both expressly teach that their TAVRs are meant to be capable of being delivered endovascularly.” (Ex. 1117, 57; *see also infra* §VIII.A.1.g (demonstrating how references disclose limitation).) PO did not appeal this decision and is collaterally estopped from contesting it here. (*Supra* §II.)

b. Frame

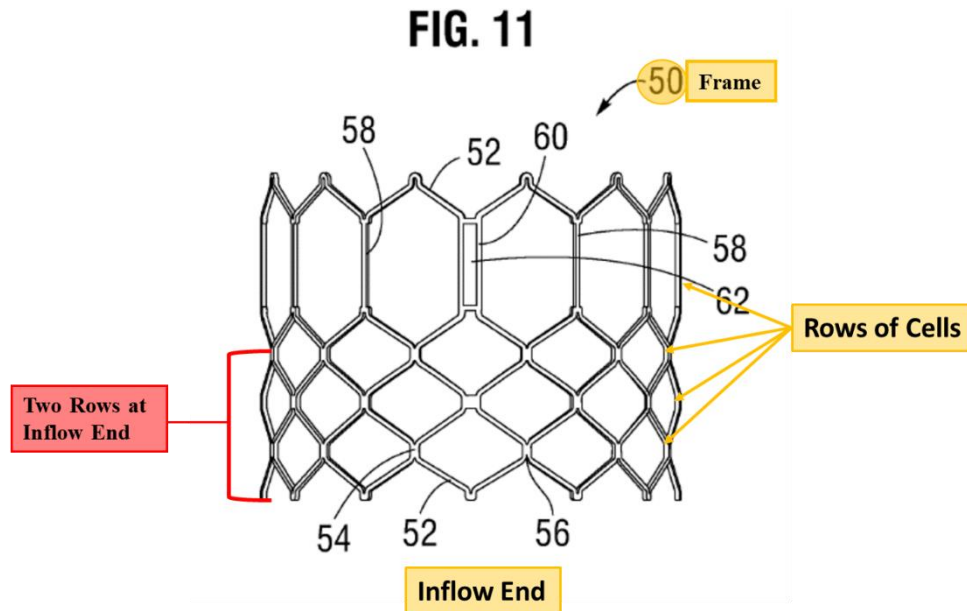
Spenser and Levi disclose “a frame formed of a plurality of cells, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” (Ex. 1003, ¶¶106-108.)

Spenser’s Figure 44a illustrates “an implantable prosthetic valve” that includes “frame 575”:



(Ex. 1010, 19:5-13, 26:30-34.) The frame is formed of a plurality of cells, including two rows of cells at the inflow end of the frame. (*Id.*, Fig. 44a-44b; Ex. 1003, ¶107.) Spenser’s valve, including the frame, “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.)

Levi also discloses a frame formed from a plurality of cells, including two rows of cells at the inflow end of the frame:

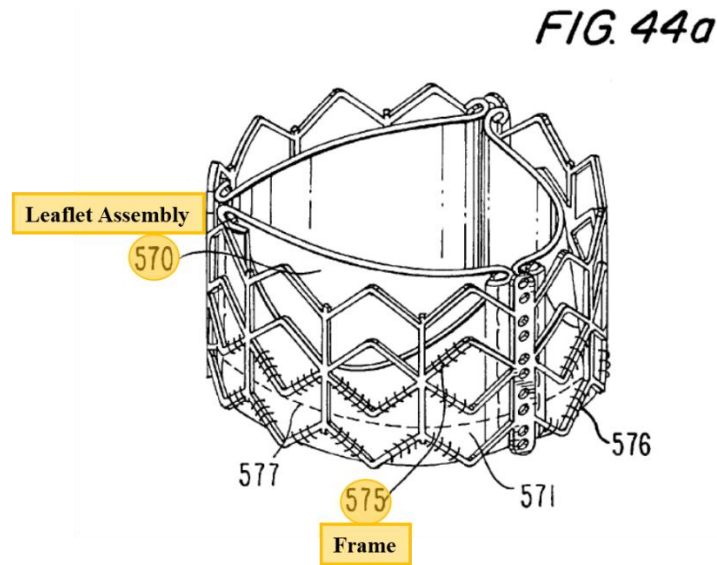


(Ex. 1008, 6:17-7:3, Fig. 11; Ex. 1003, ¶108.) Levi’s frame is “radially collapsible and expandable.” (Ex. 1008, Abstract, 6:20-24.)

c. Leaflet Assembly

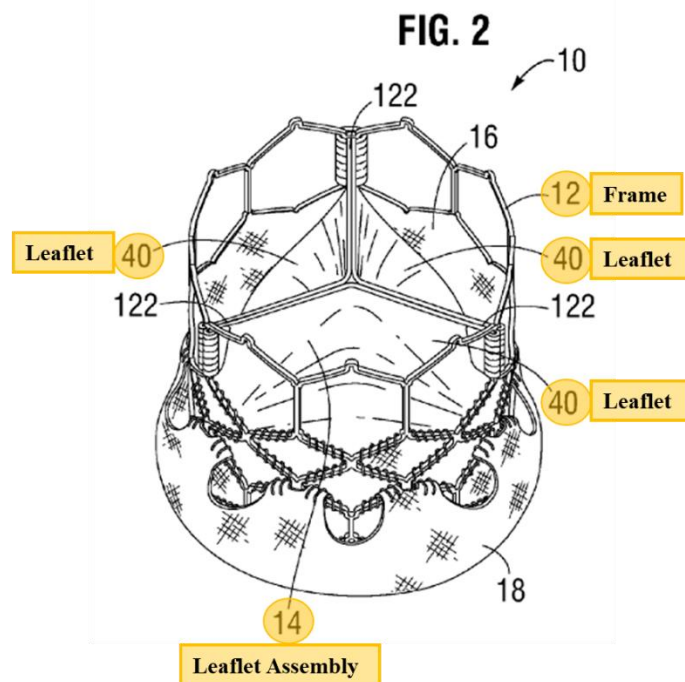
Spenser and Levi disclose “a leaflet assembly within the frame.” (Ex. 1003, ¶¶109-111.)

Spenser’s Figure 44a includes “pericardial leaflets 570,” which are a “leaflet assembly” within frame 575:



(Ex. 1010, 26:34-37, Figs. 44a-44c; Ex. 1003, ¶110.)

Levi discloses a “valvular structure 14 [that] can comprise three leaflets 40,” forming a leaflet assembly within frame 12:

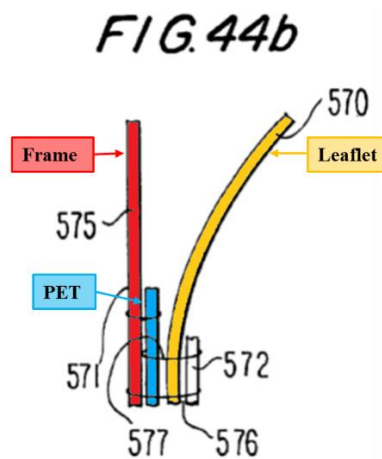


(Ex. 1008, 5:59-60, Fig. 2; Ex. 1003, ¶111.)

d. Polymer Covering

Spenser and Levi disclose “a polymer covering about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage.” (Ex. 1003, ¶¶112-116.)

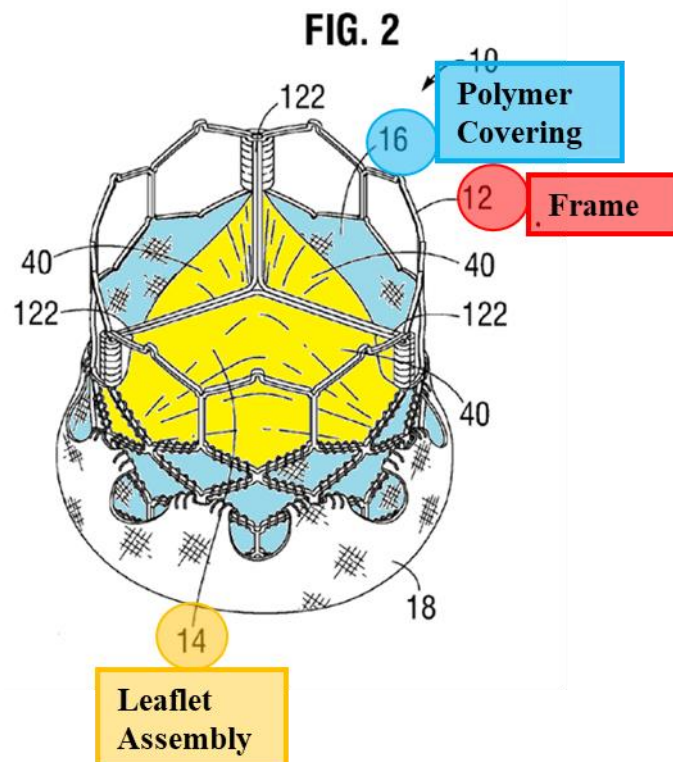
Spenser’s Figure 44a includes “additional pieces of PET” for “sealing and protecting the pericardium.” (Ex. 1010, 26:30-34, Figs. 44a-44c.) The “pericardium” includes a leaflet assembly formed of leaflets 570, and the piece of PET 571 is a “polymer covering.” (*Id.*, 26:30-54; Ex. 1003, ¶113.) As shown below, PET 571³ [blue] is attached to the leaflets via suture 577 and positioned radially inwardly of the frame 575:



³ In Fig. 44b, the lead line for 571 points to the frame [red]. This is a drafter’s error. The lead line for PET layer 571 should point to the PET middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶114 n.4.)

(Ex. 1010, 26:30-54, Fig. 44b (PET 571 is positioned “between the leaflets [570 yellow] and frame [575 red]”); *see also id.*, Fig. 44a.)

Levi discloses an “inner skirt 16 ... to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets.” (Ex. 1008, 9:7-11.) The inner skirt may be constructed of “polyethylene terephthalate (PET)” and is a “polymer covering.” (*Id.*, 9:11-16; Ex. 1003, ¶116.) The inner skirt is attached to the leaflet assembly “via one or more thin PET reinforcing strips.” (Ex. 1008, 9:25-29.) Levi’s inner skirt [blue] is positioned radially inwardly of the frame [red]:

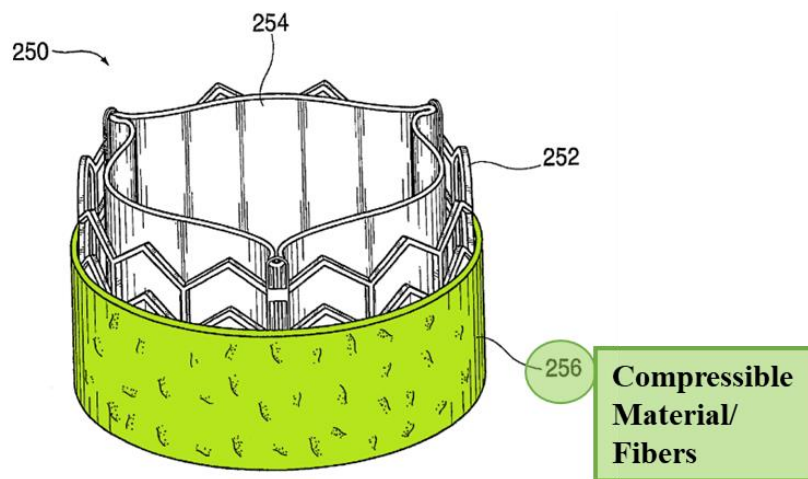


(Ex. 1008, Fig. 2; Ex. 1003, ¶116.)

e. Sealing Assembly

Spenser *or* Levi in combination with Spenser II renders obvious “a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage, wherein the sealing assembly extends over each of the at least two rows of cells.” (Ex. 1003, ¶¶117-131.)

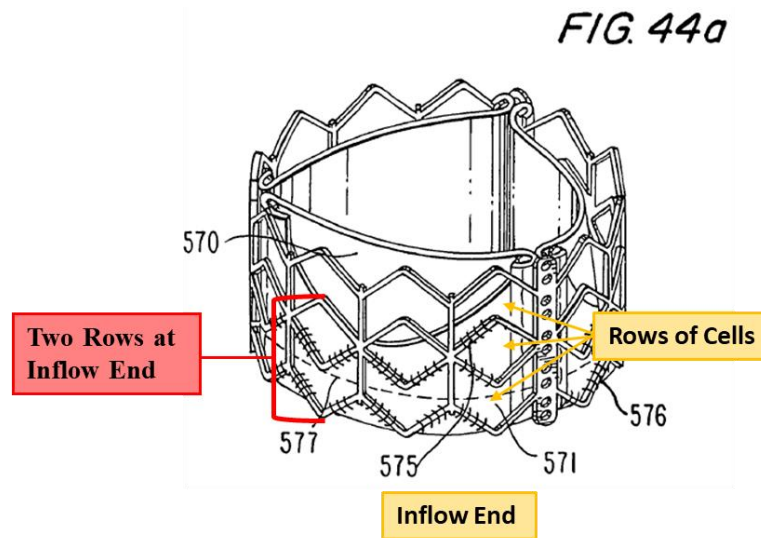
Spenser II discloses, “[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252”:



(Ex. 1011, [00145], Fig. 22.) “In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.” (*Id.*) The fibers “may be straight, curved or hook-shaped.” (*Id.*) Spenser II’s compressible material is therefore a “sealing assembly” as claimed in claim 1. (Ex. 1003, ¶119.)

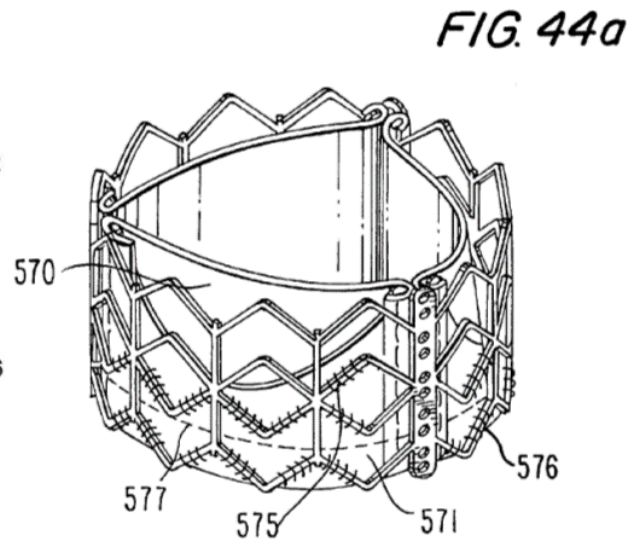
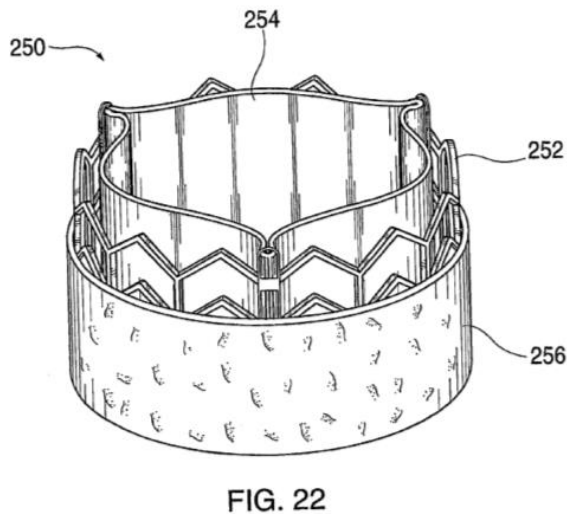
i. Spenser and Spenser II

Spenser's Figure 44a includes a frame that has two rows of cells at the inflow end:



(Ex. 1010, Fig. 44a; Ex. 1003, ¶124.)

Spenser's Figure 44a and Spenser II's Figure 22 include similar frames having the same number of rows. When added to Spenser's Figure 44a, Spenser II's compressible material would cover at least the two rows of cells at the inflow end of the frame, as shown by comparing Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



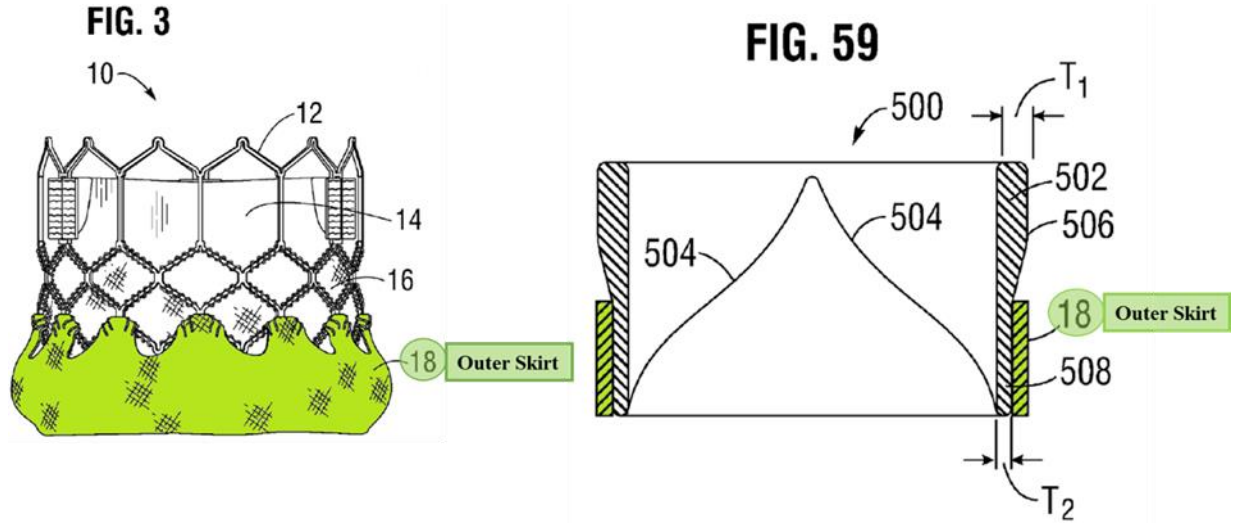
(Ex. 1010, Fig. 44a; Fig. 1011, Fig. 22; Ex. 1003, ¶124.) If PO argues that this limitation requires the compressible material to *entirely* extend over two rows of cells in the vertical direction, POSITAs would have found it obvious to slightly increase the height of Spenser II’s compressible material, as taught in Levi’s Figure 42, and given the finite number of options for the height of the material. (Ex. 1003, ¶125.)

The Board previously found that “Spenser II provides, and the prior art Norris provide ample motivation for combining a compressible cloth, as a sealing material, with the TAVR disclosed by Spenser.” (Ex. 1117, 64; *see also* Ex. 1118, 68; Ex. 1119, 80-81.) Spenser and Spenser II are closely related patents, sharing three common inventors, and Spenser II explicitly proposes improvements to the valves described in Spenser’s U.S. Publication No. 2003/0153974 (Ex. 1015). (See Ex.

1011, [0009-00010] (explaining that Spenser’s parent application describes similar heart valves but does not address “leaks that can occur around the implanted valve”).) Given this relationship, POSITAs would have reasonably expected that features described in one patent would apply to the other. (Ex. 1003, ¶¶122-123.) Moreover, the valves in Spenser and Spenser II comprise balloon-expandable, metallic, gridded frames that surround leaflet assemblies. (*Id.*) Given these similarities, POSITAs would have reasonably expected that the valve features described in one reference would apply to the valves described in another, and POSITAs would have been motivated to use Spenser II’s compressible material to reduce PVL with Spenser’s valves. (*Id.*) Further, adding Spenser II’s compressible material to Spenser’s valves would merely entail applying Spenser II’s known technique for reducing PVL (adding an outer compressible material) to Spenser’s known valves, which were ready for improvement and would yield predictable results. *KSR Int’l Co. v. Teleflex. Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶122.)

ii. Levi and Spenser II

Levi discloses an outer fabric skirt 18 secured to the exterior surface of the frame for preventing PVL. (Ex. 1008, 13:49-53, 13:62-66, 16:51-54, 17:12-18.)



(*Id.*, Figs. 3, 59.)

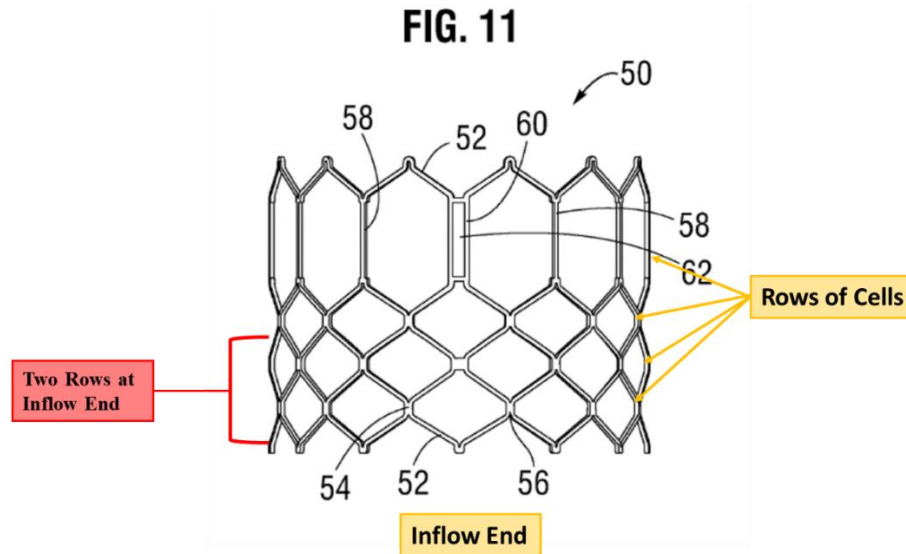
POSITAs would have found it obvious to replace Levi's outer PET skirt with Spenser II's compressible material because the skirt and material are interchangeable. (Ex. 1003, ¶¶127-128.) While the specific materials have slightly different constructions, they were both designed for use with balloon-expandable heart valves to prevent PVL. (*Id.*; Ex. 1011, [00144], Ex. 1008, 6:17-28.)

Moreover, a finite number of methods to address PVL existed in November 2012. (Ex. 1003, ¶128.) Spenser II and Levi disclose two such methods. (*Id.*) POSITAs would have found it obvious to select one of these finite, predictable solutions and would have reasonably expected success in doing so. (*Id.*) POSITAs would have found it obvious to try each material because the different constructions provide potential advantages. (*Id.*) For example, Spenser II's compressible material "may be adapted to encourage coagulation of blood to further fill the gaps and

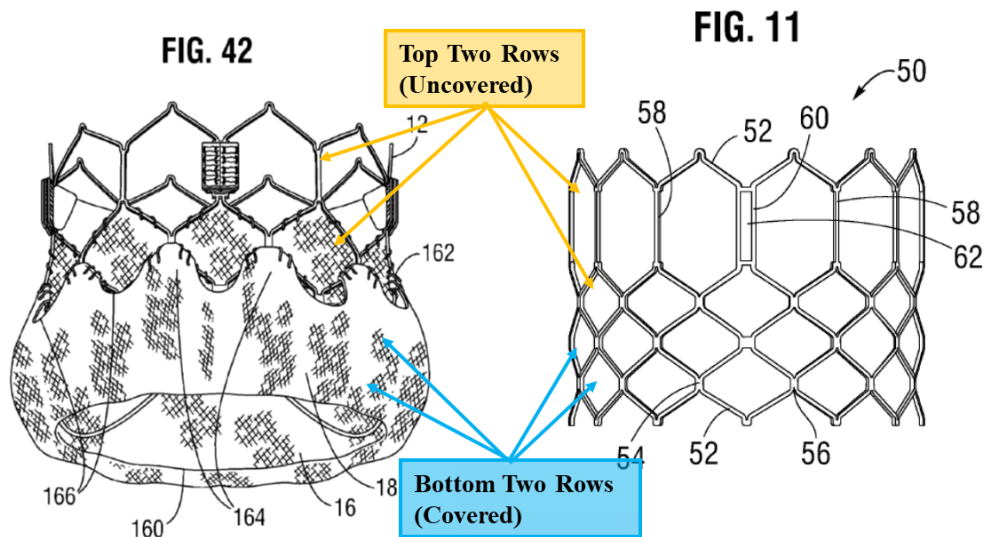
prevent leakage.” (Ex. 1011, [00145].) Ultimately, the combination of Levi with Spenser II would have merely entailed substitution of one known element (Spenser II’s compressible material) for another (Levi’s outer skirt) to yield the predictable results of reducing PVL. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶¶127-128.)

POSITAs would have reasonably expected success in substituting Spenser II’s compressible material for Levi’s outer skirt. (Ex. 1003, ¶¶129-130.) The valve frames in Spenser II and Levi share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. (*Id.*) Moreover, Levi suggests adding other components, like an outer skirt or seal, to the inflow portion of the frame, stating “if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component.” (Ex. 1008, 16:41-45.) Levi discloses methods to reduce the frame’s diameter at the inlet, or to modify the leaflets to reduce the frame size, to create room for an outer seal. (*Id.*, 16:24-17:18.) POSITAs would have understood they could utilize one or more of these methods to substitute Spenser II’s compressible material for Levi’s outer skirt. (Ex. 1003, ¶¶129-130.)

Levi’s frame includes two rows of cells at the inflow end of the frame:



(Ex. 1008, Fig. 11.) A comparison of Figures 11 and 42 shows that Levi's outer skirt covers the bottom two rows at the inflow end:



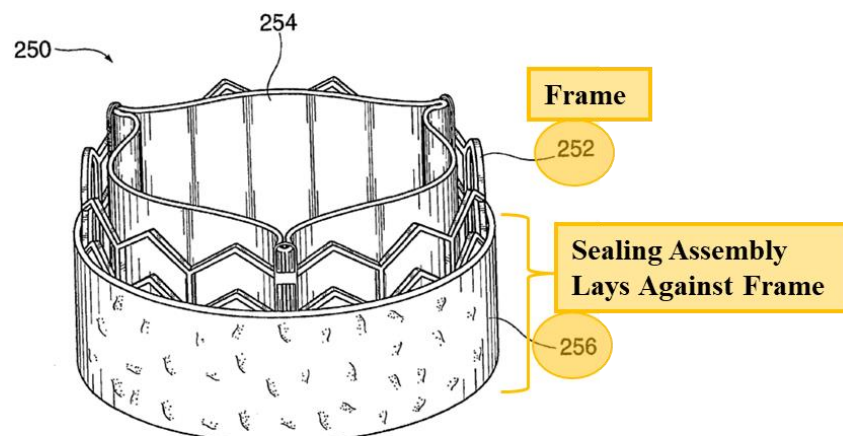
(*Id.*, Figs. 11, 42; Ex. 1003, ¶131.) Spenser II discloses a sealing material that covers the bottom two rows of cells formed by the frame. (*Supra* §VIII.A.1.e.) POSITAs would have been motivated to attach Spenser II's compressible material to Levi's frame in the same location, and expected success in doing so, because the references

demonstrate that covering the bottom two rows creates an effective seal. (Ex. 1003, ¶131.)

f. Sealing Assembly Lays Against the Frame

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation.” (Ex. 1003, ¶¶132-134.) Notably, because the sealing assembly must include “fibers that extend away from the frame,” this limitation cannot require that all parts or portions of the sealing assembly are in-contact with or touching the frame at all times.

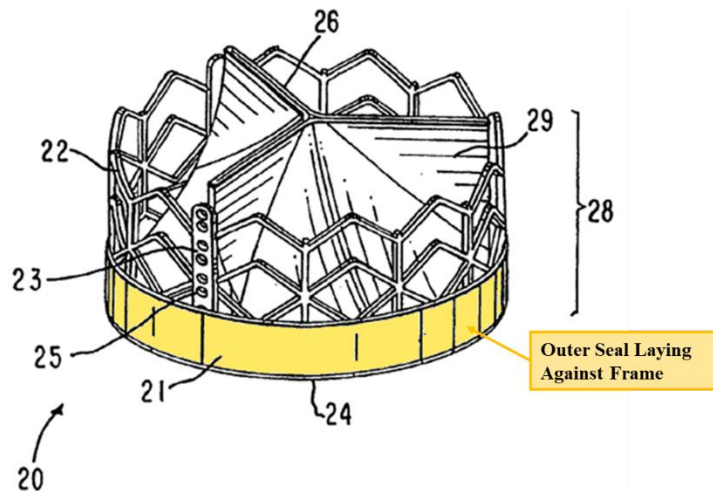
Spenser II’s compressible material is “disposed along an outer surface of the stent structure 252,” and therefore, “lays against the frame” of the valve in the compressed and expanded orientations. Figure 22 illustrates the material laying against the frame in the expanded orientation:



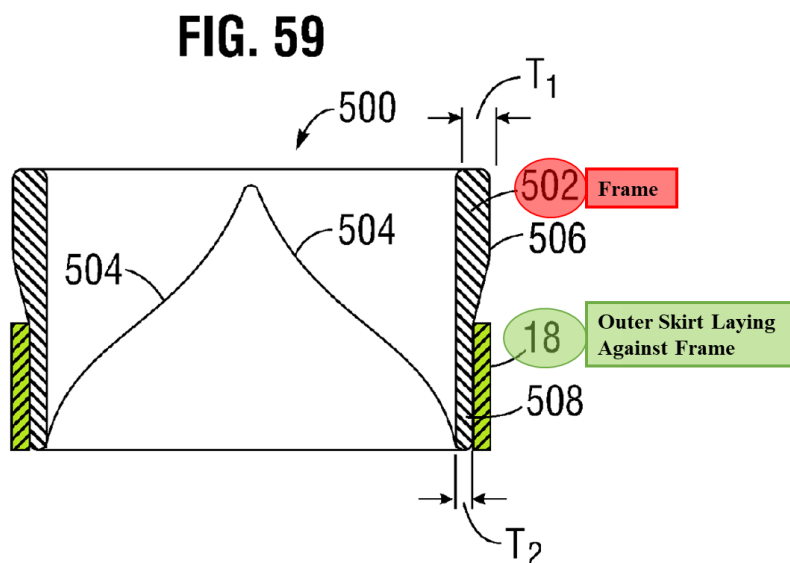
(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶133.) The compressible material similarly lays against the frame when the valve is in its compressed orientation. (Ex. 1003, ¶133.) When the material is compressed, the fibers are forced closer together thereby reducing the spacings between the fibers and decreasing the surface area of the material. (See *e.g.*, Ex. 1074, 8:45-50 (“the ground layer 20 can have a porosity that can provide some space into which the loops can be compressed”).) Consequently, the fibers of the compressible material are more densely packed but are still laying against the frame, particularly when the valve is loaded into a crimping apparatus or delivery sheath. (See *id.*, 5:7-22 (noting delivery catheter applies “a compressive pressure”); Ex. 1003, ¶133.)

Additionally, POSITAs would have understood that the compressible material is sutured to the frame like Spenser’s inner skirt and, therefore, cannot separate from the frame. (Ex. 1010, 26:29-54, Figs. 44a-44c; Ex. 1011, [00142], [00145], Figs. 20e-20f, 22; Ex. 1003, ¶133; *see also* Ex. 1007, 2 (explaining “cloth was stitched onto the perimeter of each SAPIEN valve”).) POSITAs would have been motivated and expected success in suturing Spenser II’s compressible material to Spenser’s Figure 44a or Levi’s valve in the same way, such that the material would lay against the frame of Spenser’s Figure 44a or Levi’s valve. (Ex. 1003, ¶133.)

Both Spenser and Levi disclose embodiments that would have motivated a POSITA to position Spenser II's compressible material so that it lays against the frame when added to either valve. (*Id.*, ¶134.) Spenser discloses an embodiment having an outer seal that lays against the frame:



(Ex. 1010, 13:22-25, Fig. 1.) Levi also discloses embodiments having an outer skirt that lays against the frame:



(Ex. 1008, 16:51-54, Fig. 59.) Thus, each reference suggests a sealing assembly that lays against the frame and would have given a POSITA a reasonable expectation of success in combining Spenser II's compressible material with Spenser or Levi's valves. (Ex. 1003, ¶134.)

g. Endovascularly Deployed

Claim 1 next recites, “wherein the prosthetic heart valve assembly is sized and shaped to be endovascularly deployed through a femoral artery of the patient.”⁴ This statement of intended use is not limiting. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018). However, if it is limiting, Spenser **or** Levi in combination with Spenser II renders this limitation obvious. (Ex. 1003, ¶¶135-149.)

i. Spenser and Spenser II

The Board previously concluded that POSITAs would have expected the THV formed from combining Spenser's frame and Spenser II's compressible material would be sized and shaped for endovascular deployment. (Ex. 1117, 53-64; Ex. 1118, 57-68; Ex. 1119, 69-80.) The Board explained, “the 12F (4.0 mm) diameter of the valve taught by Spenser ... is well within the maximum allowable diameter

⁴ Petitioner reserves the right to argue that this limitation renders the claims indefinite.

of 24F [for transfemoral delivery] argued by [PO], such that [POSITAs] could reasonably understand that there would be sufficient additional space to accommodate the ‘compressible ... cloth or fabric,’ which Spenser II teaches can also be delivered endovascularly.” (Ex. 1117, 57.) Thus, the Board determined the combined valve would be reasonably understood to have a crimped profile less than 24F, which would permit endovascular delivery through the femoral artery. (*See id.*) PO did not appeal this determination and, therefore, is estopped from contesting it here. *Supra* §II.

The Board’s findings are correct. Spenser states, “the present invention deals with the possibility of implanting the valve percutaneously, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location via a large blood vessel such as the femoral artery, in a procedure similar to other known interventional cardiovascular procedures.” (Ex. 1010, 2:6-12.) Further, Spenser’s valve may be crimped to a diameter that is “suitable for percutaneous catheterization and deployment.” (*Id.*, 14:12-14; *see also id.*, 12:8-17, 12:28-36, 13:26-54.) Spenser also discloses endovascularly implanting the prosthetic valve in a patient’s native aortic valve using a balloon catheter that is guided through the patient’s vasculature to the patient’s valve. (*Id.*, 5:17-6:36, 17:19-18:43; Ex. 1003, ¶¶137-138.)

Spenser's Figure 44a illustrates a "preferred embodiment of the present invention[.]" (Ex. 1010, 26:30-34.) Based on the above disclosures, POSITAs would have understood Spenser's disclosure of endovascular delivery through the femoral artery applies to Figure 44a. (*See id.*, 2:6-12, 26:30-34; Ex. 1003, ¶138.)

Similarly, Spenser II discloses, "The present invention provides a series of new percutaneous concepts of paravalvular repairs including ... built-in means for leak prevention[.]" (Ex. 1011, Abstract; *see also id.*, [0014].) Spenser II explains, "[p]ercutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation." (*Id.*, [0012].) Introduction of the valve through a small perforation in the groin area refers to, at least, endovascular delivery through the femoral artery. (Ex. 1003, ¶139.)

POSITAs would have reasonably expected Spenser's valve to remain suitable for endovascular delivery through the femoral artery after the addition of Spenser II's compressible material. (Ex. 1003, ¶140.) Spenser teaches 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 discloses “in one preferred embodiment,” the compressible material “has a thickness ranging from about 1 to 5 mm” when the material is uncompressed. (Ex. 1011, [00145].) POSITAs would have reasonably expected that adding an uncompressed, compressible material 1 mm thick to Spenser’s 4 mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery. (Ex. 1003, ¶141; *see also* Ex. 1117, 57.) Additionally, POSITAs would have recognized Spenser II encompasses thin and highly compressible materials that will result in a low profile. (Ex. 1003, ¶141.) Thus, POSITAs would have reasonably expected the combination of Spenser II’s compressible material, or a similar but thinner or more compressible material, and Spenser’s Figure 44a to be endovascularly deliverable through the femoral artery. (*Id.*) “This becomes particularly evident when one looks to the teachings of ... Norris.” (Ex. 1117, 58; Ex. 1118, 62.)

Norris discloses a fabric, suitable for sealing a heart valve, which is highly compressible to enable “a small enough delivery catheter to reach a target implant site.” (Ex. 1074, 8:23-39.) Norris explains, “[i]n the non-compressed configuration 40, some embodiments of the fabric 10 can have a thickness 43 of about 1-5mm” and “[i]n the compressed configuration 41, the fabric 10 can have a thickness 44 of about 0.004–0.008 inches [0.102–0.203 mm],” which “can allow the fabric 10 to be

easily inserted into a delivery catheter along with an intraluminal medical device.” (*Id.*, 4:54-60, 7:66-8:3.) Norris’s teachings would have reinforced the reasonable expectation of success in endovascularly delivering Spenser’s valve with Spenser II’s compressible material through the femoral artery. (Ex. 1003, ¶142.)

Additionally, POSITAs would have recognized that Spenser II’s disclosure is broad and that fibrous, compressible sealing materials with a range of thicknesses and porosities could be used consistent with Spenser II’s teachings. (Ex. 1003, ¶141.) POSITAs would have found it obvious to select one of the finite, existing compressible materials to enable endovascular delivery through the femoral artery, particularly given the disclosure of such delivery in Spenser and Spenser II. (*Id.*, ¶141.)

ii. Levi and Spenser II

Levi discloses “collapsible transcatheter heart valves [that] 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.) POSITAs would have understood Levi’s percutaneous delivery to include transfemoral delivery because Levi states that the “diameter of the crimped profile is important because it directly influences the physician’s ability to advance the transcatheter heart valve through the femoral artery or vein.” (*Id.*,

2:3-5.) Levi also incorporates by reference the percutaneous methods described in U.S. Patent No. 6,730,118 (Spenser’s parent), which include endovascular delivery through the femoral artery. (Ex. 1008, 1:57-67; Ex. 1051, 2:3-13.) Indeed, during the prior IPRs, PO admitted Levi discloses transfemoral delivery. (Ex. 1124, 37.)

Levi also discloses several features to enable endovascular delivery through the femoral artery, including: a low-profile frame constructed of nickel-cobalt-chromium-molybdenum alloy; larger open cells in the frame’s uppermost row that allow portions of the prosthetic leaflets to protrude outwardly when crimped; a frame with varied thickness along its length; window frame portions that are depressed radially inwardly relative to other portions of the frame; low-profile tapered leaflets; and an inner skirt with non-perpendicular fibers to allow for greater axial elongation. (See Ex. 1008, 6:46-49, 7:10-12; Ex. 1003, ¶¶145-146.)

POSITAs would have reasonably expected that, after replacing Levi’s outer skirt with Spenser II’s compressible material, the resulting device would remain suitable for endovascular delivery through the femoral artery. (Ex. 1003, ¶¶147-148.) Levi discloses, “When 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.) POSITAs would have had a finite number of locations to attach Spenser II's compressible material to Levi's frame and would have at least found it obvious to try covering the reduced diameter region so that the compressible material would not disadvantageously increase the crimp profile. (*Id.*, 8:46-54; Ex. 1003, ¶148.)

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; *see also* Ex. 1003, ¶149.) POSITAs would have understood “additional component[s]” to include Spenser II's compressible material. For these reasons, POSITAs would have reasonably expected success in adding Spenser II's compressible material to Levi's valve and endovascularly delivering the combined valve through a patient's femoral artery. (Ex. 1003, ¶¶147-149.)

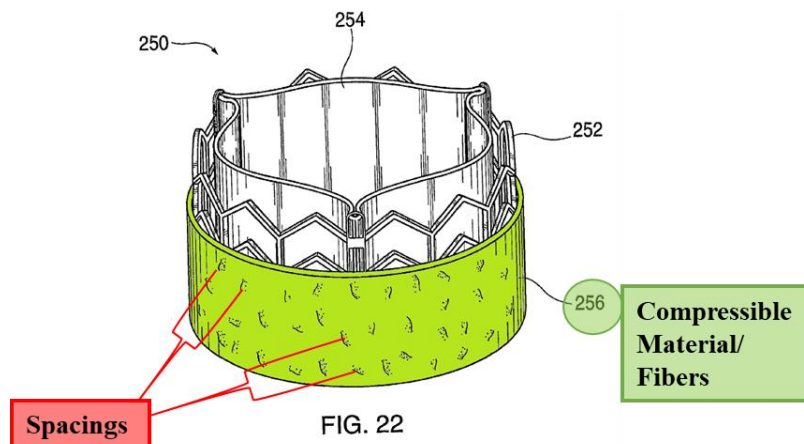
Additionally, POSITAs would have been aware of fibrous, compressible sealing materials with a range of thicknesses and porosities that could be used consistent with Spenser II's teaching and would have found it obvious to select an appropriate compressible material from the finite group of available materials that

would enable endovascular delivery through a patient’s femoral artery, particularly given the disclosure of such delivery in Levi and Spenser II. (*Id.*, ¶141.)

h. Spacings in the Sealing Assembly

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state.” (Ex. 1003, ¶¶**.)

Spenser II’s Figure 22 illustrates an embodiment of the compressible material having small fibers extending from the surface of its compressible material. (Ex. 1011, [00145].) The figure illustrates “spacings” between the fibers. (Ex. 1003, ¶152.) Moreover, the “spacings” extend through “a thickness of the sealing assembly,” where the “thickness” is at least the length of the fibers. (*Id.*) As illustrated, the valve in Figure 22 is not implanted in a native heart valve and, therefore, is in an “undeployed state.” (*Id.*)



The “spacings” illustrated in Figure 22 are consistent with Spenser II’s written description. Spenser II describes a “*compressible* material,” which informs a POSITA that the material must have spacings through a thickness of the material to permit compression. (Ex. 1003, ¶153; *see also* Ex. 1109, 1048; Ex. 1074, 8:3-7, 8:45-48.) Spenser II also discloses that the compressible material “expands after deployment at a treatment site” and that “[a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.” (Ex. 1011, [00145].) Once again, the compressible material must have spacings between the fibers in the undeployed state if the material can expand. (Ex. 1003, ¶154.) Spenser II also explains that the fibers can “encourage coagulation of blood to further fill the gaps and prevent leakage.” (Ex. 1011, [00145].) POSITAs would have understood that blood can coagulate within the material only if the material has spacings to accept the blood. (Ex. 1003, ¶155.)

POSITAs would have understood that fluid can pass through Spenser II’s compressible material when the prosthetic heart valve assembly is in an undeployed state for at least three reasons. (Ex. 1003, ¶156.) First, Spenser II’s compressible material must have spacings in the undeployed state to accommodate the compression that occurs when the valve is crimped to its compressed orientation. (*Id.*) POSITAs would have understood that the spacings that permit compression

also mean that the material is porous and would permit the flow of fluid therethrough. (*Id.*)

Second, Spenser II explains that the “compressible material expands after deployment at the treatment site” and “fills gaps between the stented valve and the surrounding tissue.” (Ex. 1011, [00145].) Spenser II explains that this compression against the surrounding tissue “creates a mechanical seal that prevents paravalvular leakage.” (*Id.*) POSITAs would have appreciated that this compression does not occur in the undeployed state and, therefore, no seal is formed, and fluid could pass through the sealing material. (Ex. 1003, ¶156.)

Third, Spenser II discloses, “the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.” (Ex. 1011, [00145].) Spenser II also discloses, “a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps.” (*Id.*) POSITAs would have understood that promoting blood coagulation and tissue ingrowth into the compressible material would have only been possible, and necessary, if the material were porous and did not, on its own, prevent the flow of fluid therethrough. (Ex. 1003, ¶156.) Moreover, POSITAs would have understood that the spacings necessary to promote tissue ingrowth into a fibrous material were in the range of 40-

100 μm , far larger than the size of a spacing necessary to allow passage of fluid therethrough. (*Id.*; Ex. 1106, 158.) Finally, Spenser II does not contain any suggestion that the porous, compressible material must prevent the flow of fluid thereof in its undeployed state. (Ex. 1003, ¶156.)

Even if Spenser II does not disclose the “spacings” limitation, POSITAs would have been motivated to use, and expected success in using, a porous fabric or cloth, such as a knitted or woven velour-like fabric, as the compressible material taught by Spenser II. (Ex. 1003, ¶¶157-159.) Such fabrics were well-known and successfully used in the art as sealing materials for cardiovascular devices prior to November 2012. (*Id.*, ¶157.) POSITAs would have been motivated to use such a fabric as the compressible material because they were known to be compressible, stretchable, and provide enhanced tissue ingrowth when used on cardiovascular devices. (*Id.*, ¶157.) POSITAs would have understood that porous velour-like cloths/fabrics would have spacings extending through a thickness of the cloth/fabric that would allow fluid to pass therethrough when the fabric is uncompressed. (*Id.*, ¶158.) Indeed, the art taught that because of their porosity, velour-like fabrics were often “pre-clotted” with blood or treated with a nonporous material, such as collagen, to prevent blood from leaking through the fabric when they were used in situations where such leakage needed to be minimized. (*Id.*)

Notably, the '033 patent does not claim or disclose how to size or arrange the fibers to provide the claimed “spacings.” (*Id.*, ¶151.) For example, the '033 patent does not use the term “spacings” and never discloses the length or width of the fibers, the density or number of the fibers, or any particular arrangement of the fibers. (*Id.*) Nor does the '033 patent disclose that fluid can pass through any “spacings” or through any “sealing assembly.” Consequently, PO cannot argue that the selection of materials and adaptation of the compressible material to provide such spacings would have been beyond a POSITA’s skill. *See e.g., Smith & Nephew, Inc.*, 721 F.3d at 1380-81 (“[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.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988); *TorPharm, Inc.*, 336 F.3d at 1331.

During prosecution of the '033 patent, PO argued under the guise of claim construction that the Board erred in its Institution Decision for PO’s '236 patent when it found that “small openings inherently exist between the radially extending fibers” of the prior art. (Ex. 1002, 28-30.) PO argued that the “specification illustrates spacing [sic] between fibers that are an intentionally placed spacing, i.e., not just the spacing that may be inherent between radially extending fibers such as those that appear to be found in the Walther reference.” (*Id.*, 29.) PO’s argument

that the claims should be construed to require a spacing that is “intentionally placed” and/or a spacing having a specific size is unsupported by the intrinsic record and should be rejected.

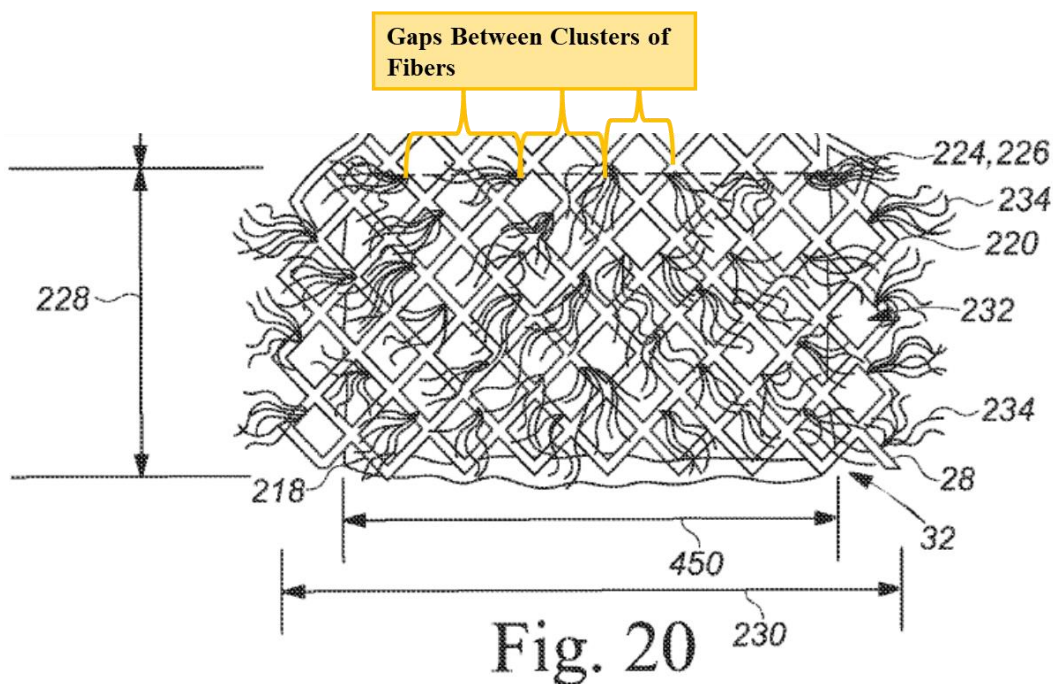
The '033 patent does not describe the “spacings” anywhere in the specification, much less require specific dimensions for the “spacings.” (See Ex. 1001.) PO’s proposed claim construction also improperly attempts to inject an intent element into the construction by requiring that the spacings be “intentionally placed.” Such a construction would frustrate the efforts of POSITAs, as well as the general public, in understanding the scope of the claim and evaluating both the prior art and accused products because the intent behind a particular invention is typically not public. See *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346-1347 (Fed. Cir. 2008) (holding inventor’s subjective intent is irrelevant to claim construction).

Moreover, the construction “intentionally placed” is vague. Walther’s outer cloth was created by design to have a particular density; yet PO still argued in prosecution that Walther did not have “intentionally placed” spacings. (Ex. 1002, 28-30.)

PO’s attempt to exclude “inherent spacings between fibers” is improper for the same reasons. The '033 patent does not exclude “inherent spacings” from the

invention's scope or distinguish "inherent spacings" from spacings "intentionally placed." If such a construction were adopted, POSITAs would have no meaningful definition to apply.

To the extent PO argues that the claims require spacings of equivalent size to those illustrated in the figures of the '033 patent, its argument is inconsistent with its infringement contentions against Petitioner's accused SAPIEN 3 Ultra valve. The figures of the '033 patent illustrate fibers that are arranged in groups or clusters around the outer frame, with gaps between the clusters that span at least the width of the open cells of the frame:

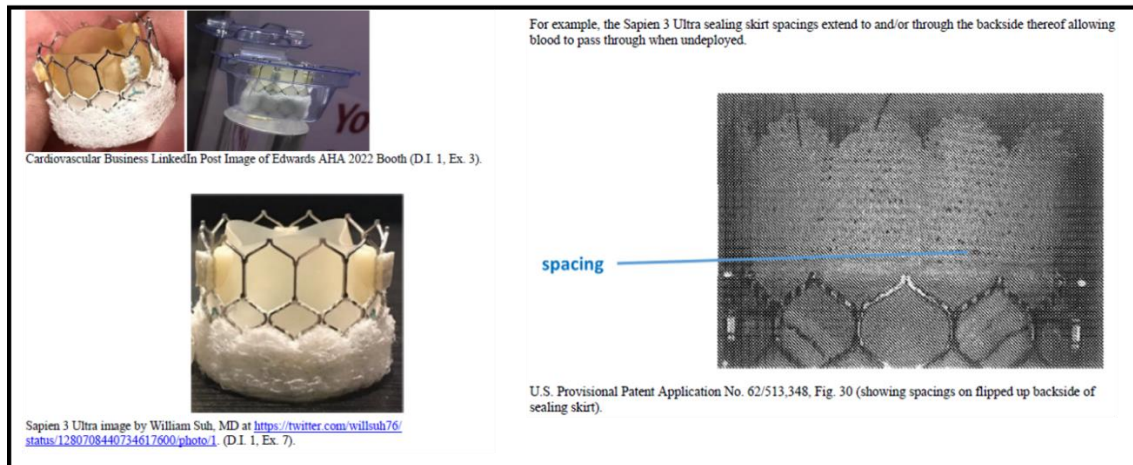


(Ex. 1001, Fig. 20; Ex. 1003, ¶95.) In contrast, the outer skirt of the SAPIEN 3 Ultra valve spans across the cells of the frame; there are no spacings between the fibers

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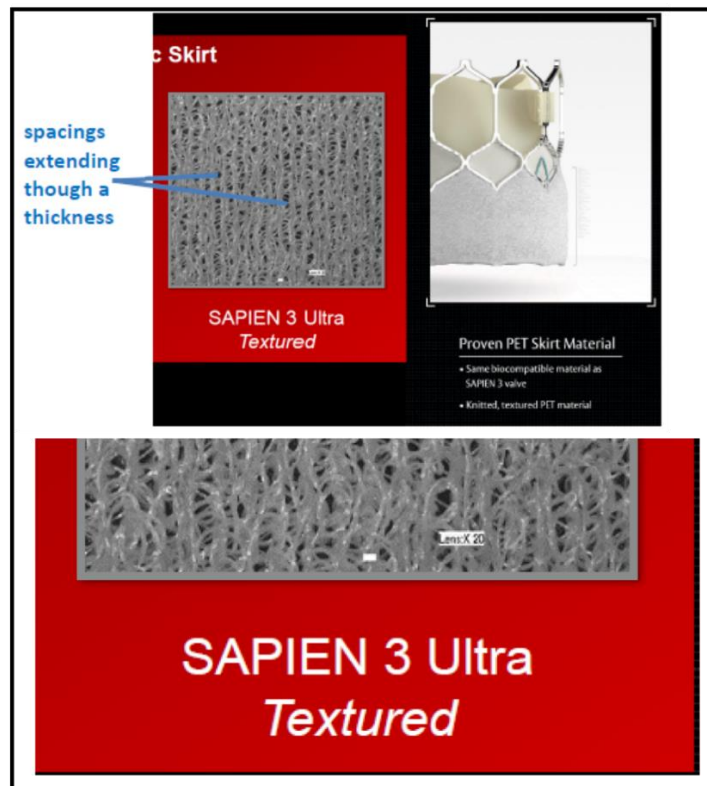
that are the width of the open cells:

Patent Owner's Infringement Contentions



(Ex. 1123, 543-544.) Indeed, PO relies on an alleged image of the SAPIEN 3 Ultra valve's outer skirt that appears to be magnified at least **20 times** in an attempt to identify "spacings" in the outer skirt:

Patent Owner's Infringement Contentions



(*Id.*, 542.) As shown, PO has taken inconsistent and irreconcilable positions regarding the size of the “spacings” required by the claims when addressing the prior art versus Petitioner’s SAPIEN 3 Ultra valve. “A patent may not, like a nose of wax, be twisted one way to avoid anticipation and another to find infringement.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (citations and internal quotation marks omitted). If the SAPIEN 3 Ultra valve’s outer skirt includes “spacings,” as PO has alleged, then the prior art, including Spenser II’s compressible material, also has spacings.

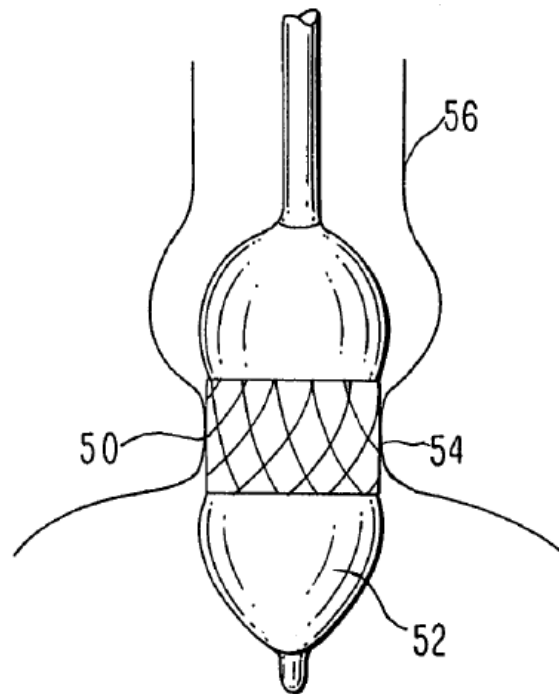
i. Sealing Assembly Presses Against Native Leaflets

Spenser **or** Levi and Spenser II render obvious “wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers relative to the spacings thereby reducing the spacings.” (Ex. 1003, ¶¶160-166.)

i. Spenser and Spenser II

The Board found that Spenser and Spenser II render this limitation obvious in a prior IPR. (Ex. 1119, 83-86.) The Board found POSITAs “reading Spenser II, would understand that, if the compressible material that is disposed along the outer surface of the stent extends entirely around the stent, then it would, necessarily, be in radial alignment with the native leaflets around the circumference of where the outer frame presses the native leaflets laterally.” (*Id.*) PO did not appeal this finding and, therefore, is estopped from challenging it here. (*Supra* §II.)

The Board’s finding was correct. Spenser’s Figure 4 (below) shows the valve deployed “in a natural aortic valve position in accordance with the present invention”:



(Ex. 1010, 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b.) As shown, at least two rows of the valve's frame press against the patient's aortic annulus. (Ex. 1003, ¶162.) Although not shown in Figure 4, POSITAs would have understood the valve also presses against the patient's native leaflets, which are attached to the annulus and extend distally therefrom. (*Id.*)

Spenser II's compressible material expands upon implantation and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." (Ex. 1011, [00145].) When added to Spenser's valve, the compressible material would extend over at least the bottom two rows of grids formed by the frame, as shown in the below comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):

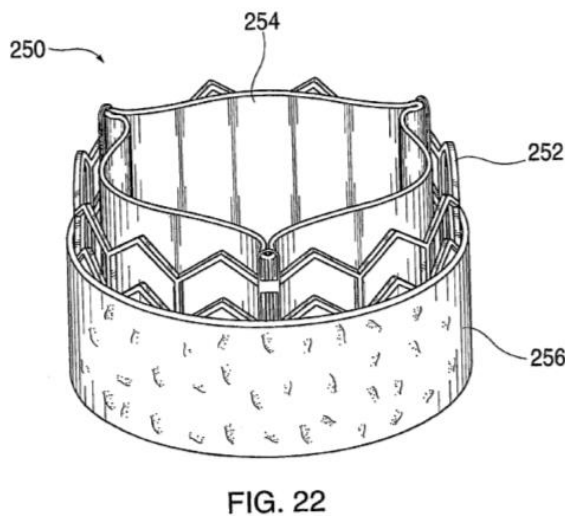
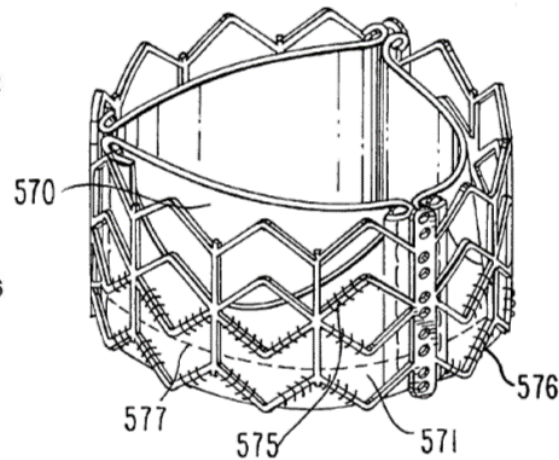


FIG. 44a



(Ex. 1010, Fig. 44a; Fig. 1011, Fig. 22; Ex. 1003, ¶163.) Thus, when added to Spenser’s Figure 44a valve, the compressible material would press against the native annulus and aortic leaflets. (Ex. 1003, ¶164.) This would “impart compression of the sealing assembly [compressible material] that compresses the plurality of fibers relative to the spacings thereby reducing the spacings.” (*Id.*)

ii. Levi and Spenser II

Levi’s outer skirt “fill[s] in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” (Ex. 1008, 14:3-7.) When the outer skirt “form[s] a good fluid-tight seal between the valve and the native annulus,” the fibers of the outer skirt also seal against the native leaflets, which are attached to the native annulus and extend distally therefrom. (Ex. 1003, ¶165.) PO has previously admitted Levi’s outer skirt

would “extend[] into crevices created by the native leaflets.” (Ex. 1046, 21.)

If Levi’s outer skirt were replaced with Spenser II’s compressible material, the compressible material, rather than the outer skirt, would press against the native leaflets. (Ex. 1003, ¶166.) POSITAs would have been motivated and had a reasonable expectation of success in covering the same portion of the valve with Spenser II’s compressible material as is covered with Levi’s outer skirt. (*Id.*) Thus, if Levi’s outer skirt presses against the leaflets, as admitted by PO, then so would Spenser II’s compressible material. (*Id.*) This would “impart compression of the sealing assembly [compressible material] that compresses the plurality of fibers relative to the spacings thereby reducing the spacings.” (*Id.*)

j. Polymer Covering Expands Radially Outwardly

Spenser and Levi disclose “wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: ... expands the polymer covering radially outwardly.” (Ex. 1003, ¶¶167-168.)

Spenser’s PET 571 (i.e., polymer covering) is attached to the inner surface of the frame with stitches. (*Supra* §VIII.A.1.d.) Levi’s inner skirt (i.e., polymer covering) is also attached to the inner surface of its frame with stitches. (*Id.*) Consequently, when Spenser’s or Levi’s valve is expanded from the compressed orientation to the expanded orientation, the polymer covering, which is sutured to

the frame, also “expands ... radially outwardly.” (Ex. 1003, ¶168.)

k. Compression Creates Paravalvular Seal

Spenser *or* Levi and Spenser II render obvious “wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.” (Ex. 1003, ¶¶169-170.)

Spenser II discloses a compressible material disposed along the frame of a THV “[t]o reduce or prevent paravalvular leakage.” (Ex. 1011, [00145].) As explained above, Spenser II illustrates, and POSITAs would have understood, that Spenser II’s compressible material has spacings between the fibers of the material. (*Supra* §VIII.A.1.h.) Spenser II further teaches that “[t]he compressible material expands after deployment at a treatment site [and a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue” which “creates a mechanical seal that prevents paravalvular leakage.” (Ex. 1011, [00145].) POSITAs would have understood from these teachings that the fibers of Spenser II’s compressible material would be compressed relative to the spacings between the fibers of the material, reducing the spacings between the fibers and creating the paravalvular seal around the valve. (Ex. 1003, ¶170.)

As explained above, both Spenser and Levi disclose polymer coverings for sealing around the leaflet assembly. *Supra* §VIII.A.1.d. POSITAs would have understood that when Spenser II's compressible material is added to Spenser's or Levi's valve, the compressible material and the inner polymer covering would "cooperatively create a paravalvular seal about the frame and the native leaflets." (Ex. 1003, ¶171.)

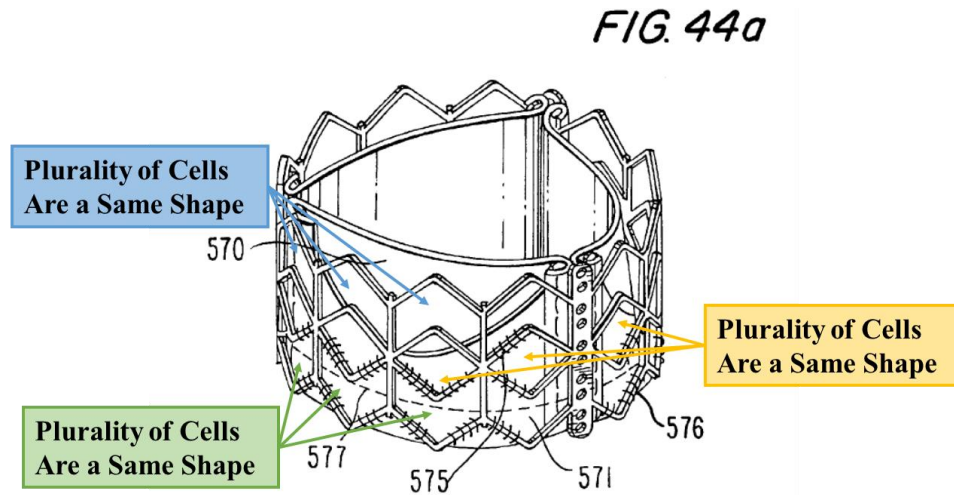
2. Claim 2

Spenser and Levi disclose "wherein the frame is self-expanding." (Ex. 1003, ¶¶172-174.) Spenser and Levi both disclose that the described frames can be self-expanding or balloon expandable. (Ex. 1010, 21:15-34, 26:1-37, Figs. 26a-c, 43a, 44a; Ex. 1008, 6:17-30; Ex. 1003, ¶¶173-174.)

3. Claim 4

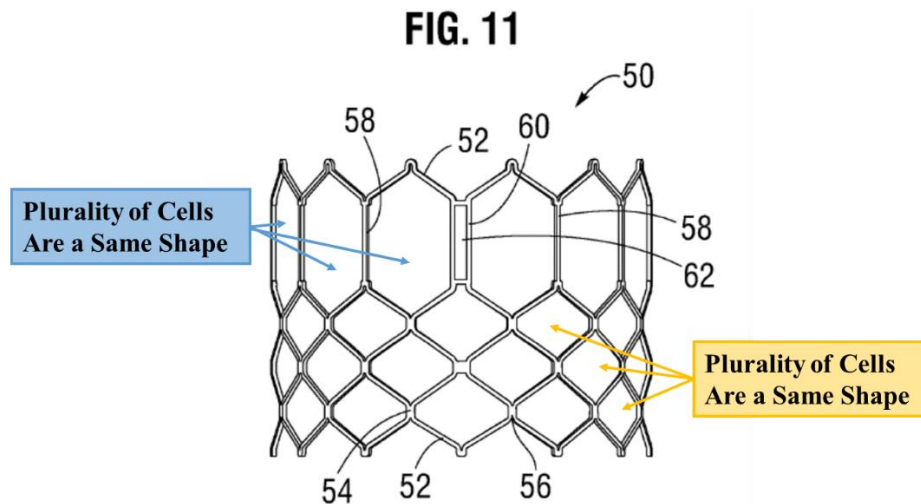
Spenser and Levi disclose "wherein the plurality of cells are a same shape." (Ex. 1003, ¶¶175-177.)

Spenser discloses a frame having a plurality of cells that are a same shape:



(Ex. 1010, Fig. 44a; Ex. 1003, ¶176.)

Levi also discloses a frame having a plurality of cells that are a same shape:

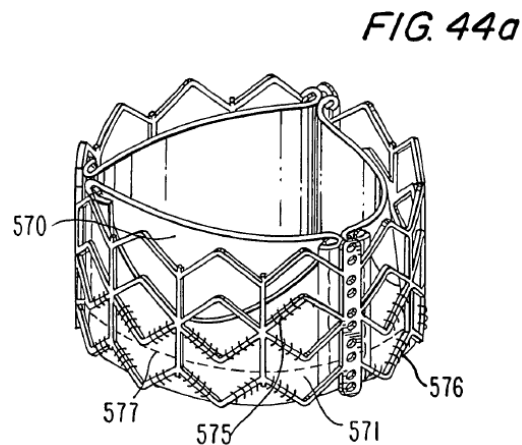


(Ex. 1008, Fig. 11; Ex. 1003, ¶177.)

4. Claim 5

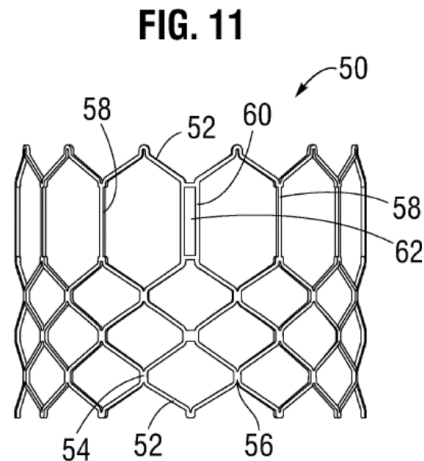
Spenser and Levi disclose “wherein the frame is integrally formed.” (Ex. 1003, ¶¶178-181.)

The Board found that Spenser’s frame is a singular, integral component in a prior IPR. (Ex. 1119, 37, 90.) Spenser’s Figure 44a includes “frame 575,” which is integrally formed:



(Ex. 1010, 26:30-34, 19:5-13, Figs. 44a-44b; Ex. 1003, ¶180.)

Levi’s frame is also integrally formed:



(Ex. 1008, 6:50-7:17, 9:4-6, Figs. 4-14; Ex. 1003, ¶181.)

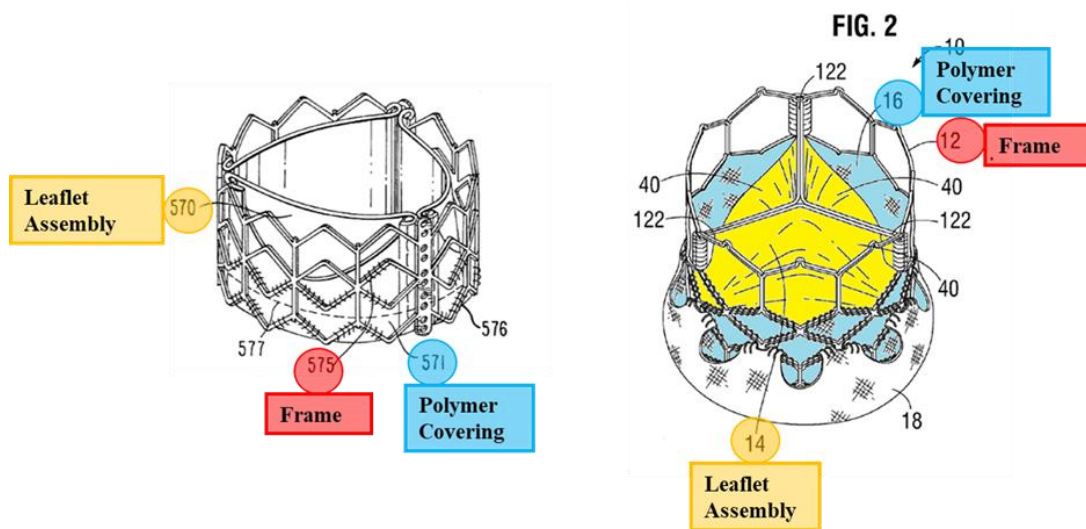
5. Claim 6

Spenser *or* Levi and Spenser II render obvious “wherein the plurality of fibers define fibers that extend outwardly to a tip of each respective fiber.” (Ex. 1003, ¶182-183.)

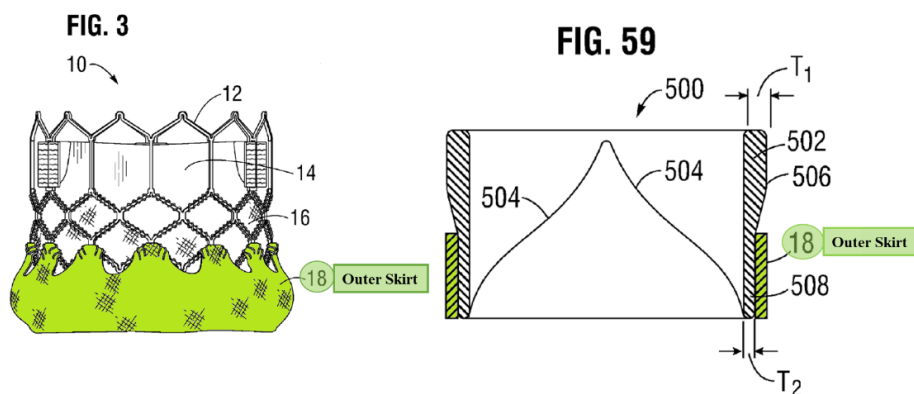
Spenser II discloses a compressible material (i.e., sealing assembly) disposed along the frame of a TVH that “[i]n certain configurations may resemble a cloth or fabric having small fibers extending from the surface of the material.” (Ex. 1011, [00145].) The fibers “may be straight, curved or hook-shaped.” (*Id.*) Spenser II’s “straight, curved or hook-shaped” fibers that extend from the compressible material would “extend outwardly to a tip of each respective fiber.” (Ex. 1003, ¶183.)

B. Grounds 2-4: Claims 1-2 and 4-6 Obvious Over Spenser or Levi in Combination with Chuter

Spenser (left) and Levi (right) describe heart valves having a frame, a polymer covering, and a leaflet assembly:

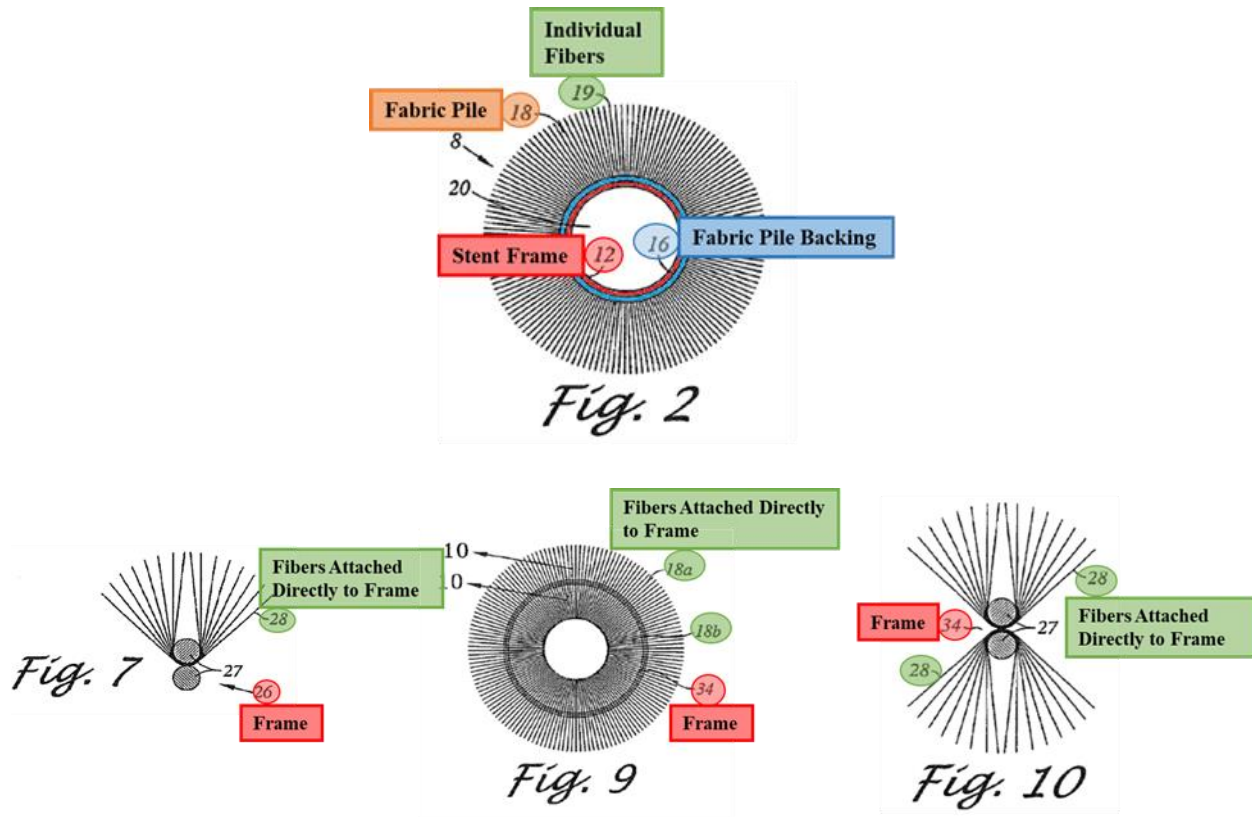


(Ex. 1010, 11:66-12:17, Fig. 44a; Ex. 1008, Fig. 2.) Levi also discloses a fabric skirt 18 secured to the frame’s exterior surface for preventing PVL. (Ex. 1008, 13:49-66, 16:51-54, 17:12-18, Figs. 3, 59.)



Chuter describes various embodiments of endovascularly deliverable “intervascular stents for maintaining vascular patency” or occluding diseased vessels. (See Ex. 1116, Abstract, [001].) Chuter’s stents include a “fiber pile” composed of outwardly extending individual fibers that are “adapted to form a

foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.”



(*Id.*, [0017]-[0022], Figs 1-10.) The individual fibers can extend from a “fabric pile backing” (Fig. 2) or directly from the frame without any backing (Figs. 7, 9-10).

(*Id.*, [0054]-[0057], Figs. 1-10.) Chuter also discloses embodiments having individual fibers extending outwardly and inwardly from the frame (Figs. 9-10).

(*Id.*, [0057], Figs. 8-10.)

As discussed below, POSITAs would have found it obvious to add Chuter’s “fiber pile” to Spenser’s valves or replace Levi’s outer skirt with Chuter’s “fiber

pile.” (Ex. 1003, ¶¶192-205.) POSITAs would have been motivated to do so given the well-known problem of PVL and Chuter’s teachings that the fiber pile encourages tissue ingrowth and prevents blood from leaking between the frame and the patient’s native tissue. (*Id.*) Accordingly, Spenser *or* Levi in combination with Chuter renders the challenged claims obvious. (*Id.*, ¶¶184-228.)

1. Claim 1

Spenser *or* Levi in combination with Chuter renders claim 1 obvious. (Ex. 1003, ¶¶187-223.)

a. Preamble

If the preamble is limiting, Levi and Spenser combined with Chuter disclose this limitation as explained in Grounds 1-2 above (*supra* §VIII.A.1.a) and sections VIII.B.1.e-g below.

b. Frame

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.b.)

c. Leaflet Assembly

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* § VIII.A.1.c.)

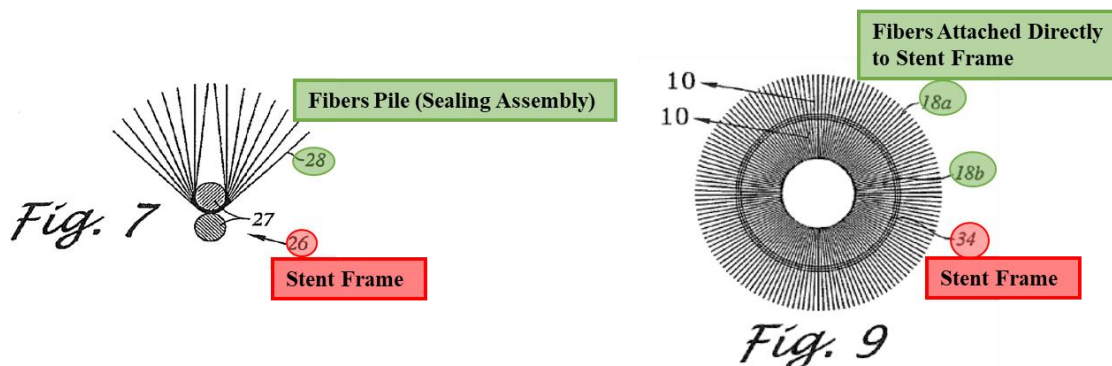
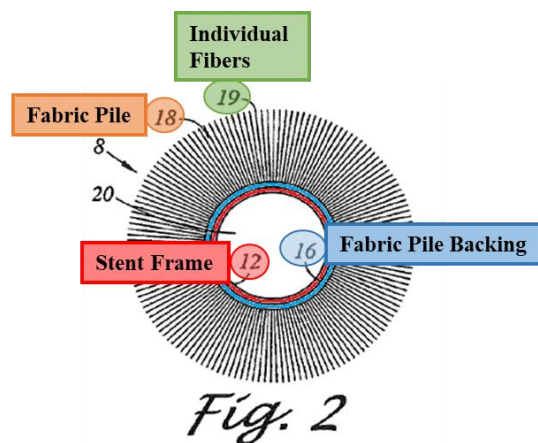
d. Polymer Covering

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* § VIII.A.1.d.)

e. Sealing Assembly

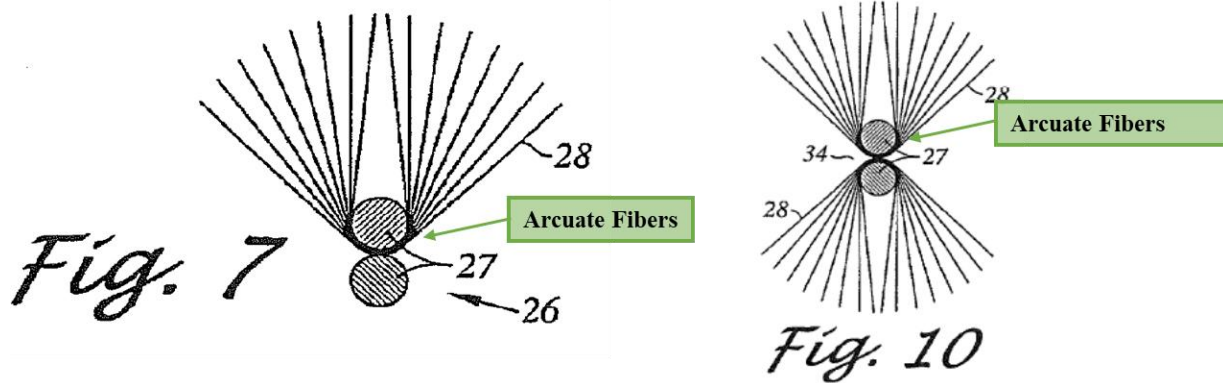
Spenser *or* Levi in combination with Chuter renders the sealing assembly limitations obvious. (Ex. 1003, ¶192-205.)

Chuter’s “fiber pile” includes a plurality of fibers that extend away from the frame and “form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel”:



(Ex. 1116, [0017]-[0022], Figs 1-10.)

In Chuter's embodiments lacking the fabric pile backing, Chuter's figures depict the fibers curving and wrapping around the stent frame:



(*Id.*, Figs. 7, 10.) The illustrated fibers are therefore arcuate. (Ex. 1003, ¶194.)

In Chuter's embodiments having individual outwardly extending fibers that extend from a backing, POSITAs would have understood that the individual outwardly extending fibers would be curved (i.e., arcuate) at least where they are secured to the backing, such as by weaving or knitting the fibers into the backing. (*Id.*, ¶195.)

Chuter also discloses that the “fibers of the fiber pile are biocompatible fibers which are known to the art” and may “include nylon fibers, polyester fibers, Mylar brand fibers and the like” and further teaches that the fibers are flexible and get “push[ed] down” when the device is crimped. (Ex. 1116, [0022], [0062].) POSITAs would therefore have understood that while Chuter's figures illustrate portions of the fibers as straight, not all (and likely none) of the fibers would have been perfectly

straight, and at least some of the flexible fibers would have an arcuate shape, particularly during delivery and deployment. (Ex. 1003, ¶196.)

i. Spenser and Chuter

POSITAs would have also been motivated to add Chuter's fiber pile to Spenser's valve to prevent PVL. (Ex. 1003, ¶197.) Chuter's fiber pile forms "a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel" and also "fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel." (Ex. 1116, [0012]-[0013], [0017]-[0020], [0064].) POSITAs would have recognized that Spenser's THVs would benefit from Chuter's fiber pile. (Ex. 1003, ¶197.) In fact, Spenser II expressly discloses that Spenser's valve could benefit from improved PVL protection, which was a well-known issue, and suggests supplementing Spenser with a sealing material. (*Id.*; *see also* Ex. 1011, [0009]-[0010].) Further, adding Chuter's fiber pile to Spenser's valves would merely entail applying Chuter's known technique for reducing leaks around a frame (adding a fabric pile) to Spenser's known frames, which were ready for improvement and, as discussed below, would yield predictable results. *KSR Int'l Co. v. Teleflex. Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1003, ¶197.)

POSITAs would have reasonably expected success in adding Chuter's fiber pile to Spenser's valve. Chuter discloses that "[v]irtually any expanding stent" can be adapted to include the described "fiber pile on its external surface about the tubular side wall of the stent." (Ex. 1116, [0012].) Chuter specifically identifies a variety of self-expanding and balloon-expandable frames that can be combined with the fiber pile. (Ex. 1116, [0003].) Indeed, Chuter discloses combining the fiber pile with the same balloon-expandable frames incorporated into the '033 patent. (*Compare* Ex. 1001, 7:46:53 (incorporating U.S. Pat. No. 5,102,417) *with* Ex. 1116, [0003] (incorporating the parent of the '417 patent); *see also* Ex. 1126-1127). Some of these frames are like the frames described in Spenser. (*See* Ex. 1126.) Thus, while the preferred embodiment in Chuter includes a double-wire frame, Chuter's invention is not limited to such frames and expressly encompasses many other frames. (Ex. 1003, ¶¶199-200.)

Notably, the '033 patent never discloses how to attach its collagen fibers, or any other fibers, to the valve frame. (*See* Ex. 1001, 12:53-56.) Rather, the '033 patent presumes POSITAs possessed the know-how to attach fibers to THV frames. Indeed, PO's expert admitted that the '033 patent specification does not provide "an explicit description of how [the fibers] are attached or secured other than stating that they are attached and secured, and the assumption is that that would be by known

biomedical engineering methods.” (Ex. 1073, 313:18-314:1.) Therefore, PO cannot dispute that POSITAs would have possessed the knowledge to attach Chuter’s fiber pile to Spenser’s frame. *See e.g., Smith & Nephew, Inc.*, 721 F.3d at 1380-81; *see also E.I. du Pont de Nemours & Co.*, 849 F.2d at 1433; *TorPharm, Inc.*, 336 F.3d at 1331.

Spenser discloses two rows of cells at the inflow end of the frame as explained in Grounds 1-2. (*Supra* §VIII.A.1.e.i.) POSITA’s would have found it obvious to position Chuter’s fiber pile over at least the proximal two rows of cells on Spenser’s valves. (Ex. 1003, ¶202.) POSITAs would have been motivated to do so because there are a finite number of places to position the material such that the fiber pile would overlap with, and press against, the patient’s diseased native leaflets to form a seal and fill gaps between the native leaflets and the valve. (*Id.*)

ii. Levi and Chuter

POSITAs would have been motivated to replace Levi’s outer skirt with Chuter’s fiber pile, and reasonably expected success in doing so, for the reasons explained in Grounds 1-2 for Spenser II and for the reasons discussed immediately above. (*Supra* §§VIII.A.1.e.ii, VIII.B.1.e.i.) POSITAs would have also been motivated to add Chuter’s fiber pile to Levi based on Chuter’s disclosure that the fiber pile promotes tissue ingrowth, which can contribute to a further reduction in PVL.

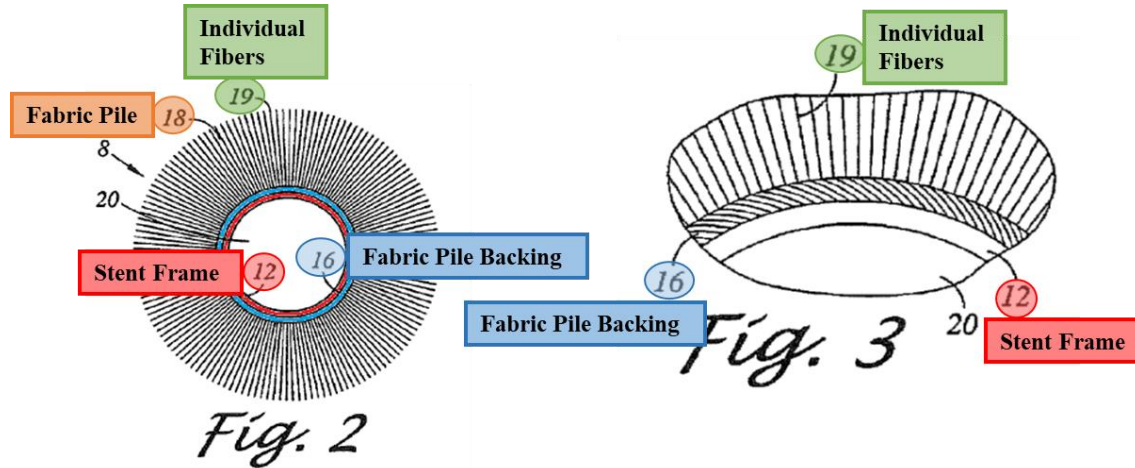
(Ex. 1116 [Chuter], [0012]-[0013], [0017]-[0020], [0064]; Ex. 1003, ¶203.)

Levi discloses two rows of cells at the inflow end of the frame as explained in Grounds 1-2. (*Supra* §VIII.A.1.e.ii.) POSITA's would have found it obvious to position Chuter's fiber pile over at least the proximal two rows of cells on Levi's valves. (Ex. 1003, ¶205.) POSITAs would have been motivated to do so because there are a finite number of places to position the material such that the fiber pile would overlap with, and press against, the patient's diseased native leaflets to form a seal and fill gaps between the native leaflets and the valve. (*Id.*) Additionally, Levi already discloses a sealing material extending over the proximal two rows of cells, providing POSITAs with further motivation to select such an arrangement. (*Id.*)

f. Sealing Assembly Lays Against the Frame

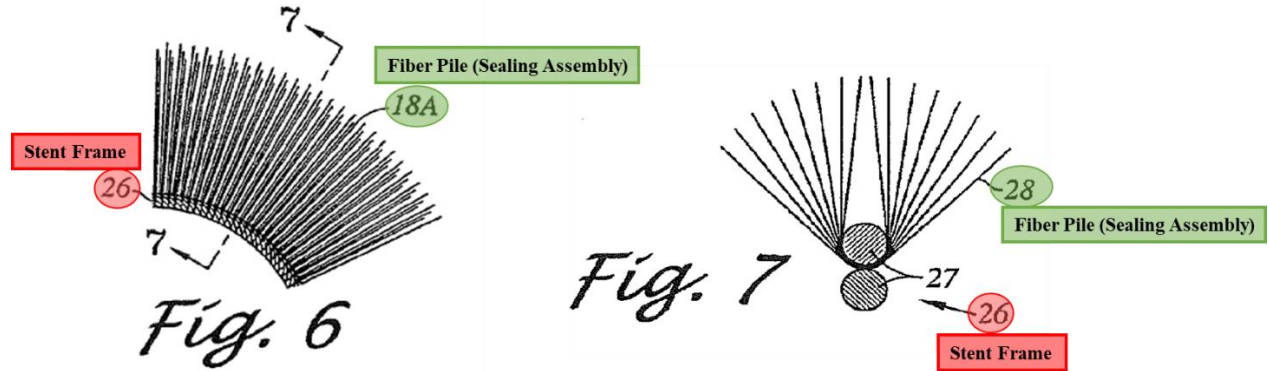
Spenser *or* Levi in combination with Chuter renders this limitation obvious. (Ex. 1003, ¶¶206-209.)

Chuter discloses this limitation in two ways. (Ex. 1003, ¶207.) First, Chuter teaches embodiments having a “fabric pile backing” that includes “a fabric pile 18 made up of individually extending fibers 19” that “[e]xtend[s] circumferentially outwardly from the backing.”

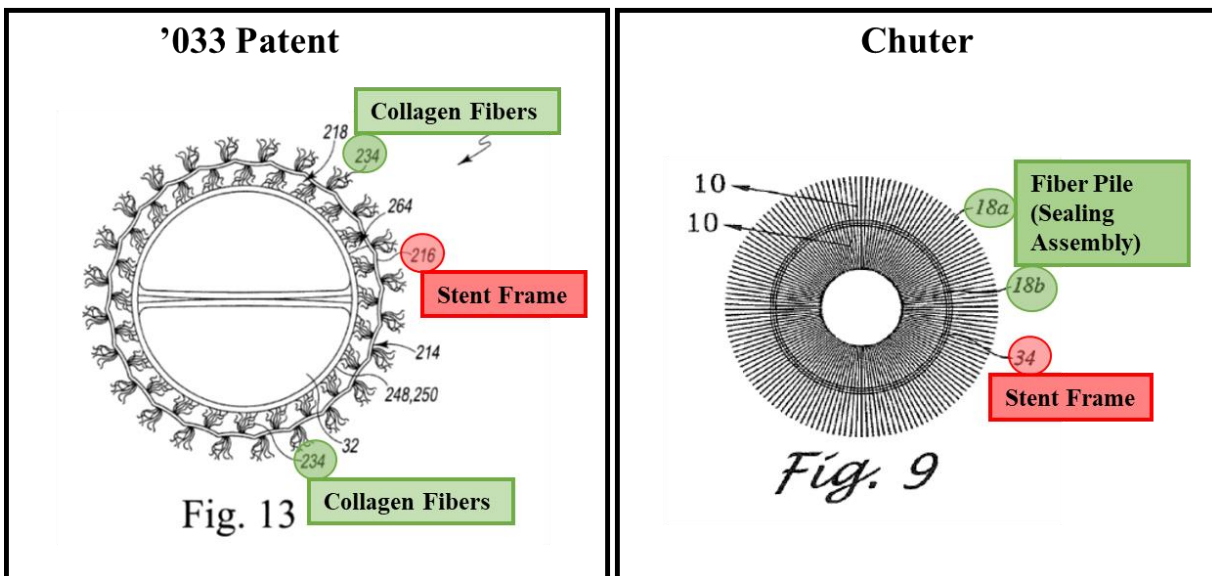


(Ex. 1116, [0054]-[0055], Figs. 2-3.) The “fabric pile backing” is part of the “sealing assembly” and, as illustrated in Figures 2 and 3 above, is in direct contact with, and lays against, the frame. (*Id.*, Figs. 2-3; Ex. 1003, ¶208.) POSITAs would have understood that this would be the case when Chuter’s fiber pile is added to Spenser’s and Levi’s valves, both when the valves are compressed and expanded, because Chuter discloses that the backing is attached directly to the frame and POSITAs would have been motivated to attach Chuter’s fiber pile to Spenser’s and Levi’s valves in the same way. (Ex. 1003, ¶208.) POSITAs would have understood that the fiber pile would be securely attached to the frame to prevent the fibers from separating in the patient and, therefore, would lay against the frame when the valve is compressed or expanded. (*Id.*)

Second, Chuter also discloses embodiments having individual fibers attached directly to the stent frame without the backing:



(Ex. 1116, [0056]-[0057], Figs. 5-10.) As illustrated in Figures 6-7, the fibers (i.e., sealing assembly) are in contact with, and lay against, the frame. (Ex. 1116, [0057], Figs. 9-10; Ex. 1003, ¶209.) Indeed, in such embodiments, Chuter's fibers lay against the frame in the same way as the collagen fibers disclosed in the '033 patent:



(Compare Ex. 1001, Fig. 13 with Ex. 1116, Fig. 9; Ex. 1003, ¶209.) POSITAs would have understood that this would be the case when Chuter's fiber pile is added to Spenser's and Levi's valves because Chuter teaches attaching the fibers directly to

the frame and POSITAs would have been motivated to secure the fiber pile to Spenser's and Levi's valves in the same way. (Ex. 1003, ¶209.) POSITAs would have understood that the fiber pile would be secured to the frame, and therefore cannot separate from the frame, when the valve is compressed or expanded, so the fibers would lay against the frame in both positions. (*Id.*)

g. Endovascularly Deployed

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.g.) POSITAs would have reasonably expected that Spenser's and Levi's valves would remain suitable for endovascular delivery through the femoral artery after adding Chuter's fiber pile. (Ex. 1003, ¶211.)

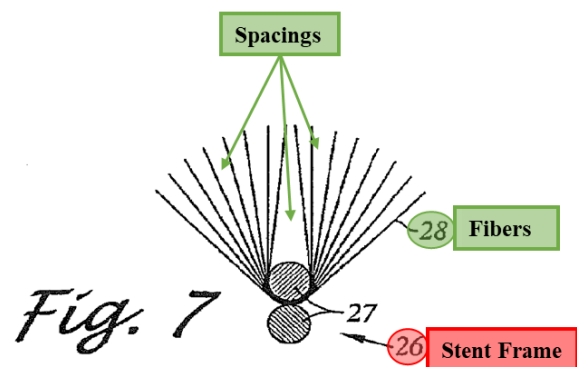
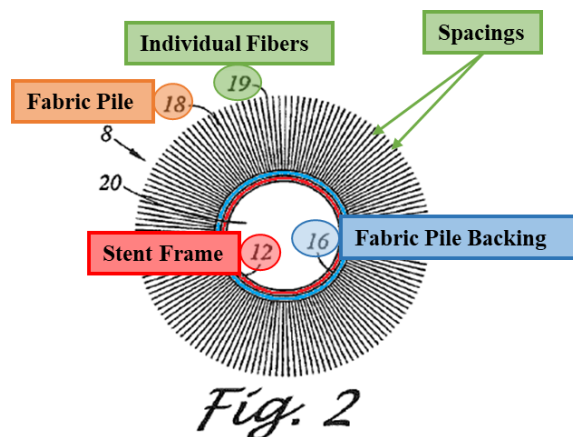
Chuter's stents are "delivered through catheters" inserted into the patient through "a distal branch of the arterial system" that "will normally be one of the arteries in the legs or in the arms." (Ex. 1116, [0062].) POSITAs would have understood these arteries to include the femoral artery. (Ex. 1003, ¶212.) Chuter further teaches that the stents are compressed when placed in the catheter and the "compression compresses the stent and pushes down the fabric pile" to allow for endovascular delivery. (Ex. 1116, [0062].) Given these teachings, POSITAs would have reasonably expected Chuter's fabric pile to similarly compress when added to Spenser's or Levi's valve, allowing for continued endovascular delivery of the valve

through the femoral artery. (Ex. 1003, ¶¶212-214.) Additionally, POSITAs would have understood that the lengths and densities of the fabric pile could be optimized for delivery through the femoral artery. (*Id.*)

h. Spacings in the Sealing Assembly

Spenser *or* Levi in combination with Chuter renders this limitation obvious. (Ex. 1003, ¶¶215-217.)

As explained above, Chuter discloses embodiments wherein the fiber pile includes a fabric pile backing and embodiments wherein the individual fibers of the fiber pile are attached directly to the frame. *Supra* §VIII.B.1.e. In both embodiments, spacings exist between the fibers that “extend through a thickness” of the fiber pile (i.e., sealing assembly) and would “allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state.” (See Ex. 1116, Figs. 2, 10; Ex. 1003, ¶216.) These spacings are illustrated in Chuter’s Figures 2 and 7, which illustrate the assembly in an undeployed state:



(Ex. 1116, Figs. 2, 7.) Adding Chuter’s fiber pile to Spenser’s or Levi’s valve would not change the spacings or porosity of the spacings when the valve is undeployed. A POSITA would have been motivated to attach the fiber pile to Spenser’s or Levi’s frames in the same way they are attached to Chuter’s frame. (Ex. 1003, ¶217.)

i. Sealing Assembly Presses Against Native Leaflets

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.i.) Chuter’s outwardly extending fibers would press against the patient’s native leaflets when added to Spenser’s or Levi’s valve for the same reasons discussed in Grounds 1-2 for Spenser II. (*Id.*) POSITAs would have been motivated to position Chuter’s fiber pile on Spenser’s or Levi’s valve such that the fibers could fill the gaps between the valve and the diseased leaflets to prevent PVL. (*See* Ex. 1116, [0064]; Ex. 1003, ¶219.)

POSITAs would have understood that when Chuter’s fibers are pressed against the patient’s native leaflets, this would “impart compression” of the fibers relative to the spacings thereby reducing the spacings. (Ex. 1003, ¶219.)

j. Polymer Covering Expands Radially Outwardly

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.j.)

k. Compression Creates Paravalvular Seal

Spenser *or* Levi in combination with Chuter renders this limitation obvious.
(Ex. 1003, ¶¶221-223.)

As explained above, Chuter discloses intravascular stents having a fiber pile comprised of outwardly extending fibers that “press against the inner luminal wall” of the native tissue to form a seal when the stent is implanted. (Ex. 1116, [0059].) POSITAs would have understood that when Chuter’s fiber pile is added to Spenser’s or Levi’s valves, the fiber pile would press against the patient’s native aortic leaflets when the valves are implanted, reducing the spacings between the fibers of the fiber pile and forming a paravalvular seal. (Ex. 1003, ¶222.) Further, as explained above, both Spenser and Levi disclose polymer coverings for sealing around the leaflet assembly. (*Supra* §VIII.A.1.d.) POSITAs would therefore have understood that when Chuter’s fiber pile is added to Spenser’s or Levi’s valve, the fiber pile and the inner polymer covering would “cooperatively create a paravalvular seal about the frame and the native leaflets.” (Ex. 1003, ¶223.)

2. Claim 2

Spenser and Levi disclose the limitations of claim 2 as explained in Grounds 1-2. *Supra* §VIII.A.2.

3. **Claim 4**

Spenser and Levi disclose the limitations of claim 4 as explained in Grounds 1-2. *Supra* §VIII.A.3.

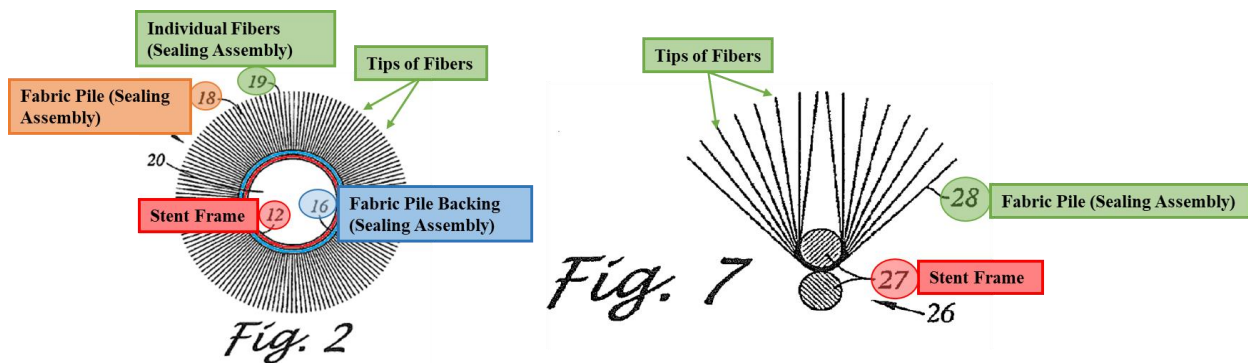
4. **Claim 5**

Spenser and Levi disclose the limitations of claim 5 as explained in Grounds 1-2. *Supra* §VIII.A.4.

5. **Claim 6**

Spenser *or* Levi and Chuter render claim 6 obvious. (Ex. 1003, ¶¶227-228.)

The individual extending fibers of Chuter's fiber pile (i.e., sealing assembly) extend outwardly to a tip of each respective fiber, as illustrated in Figures 2 and 7:



(Ex. 1116, Figs. 2, 7; Ex. 1003, ¶228.)

C. **Grounds 4-6: Claims 1-2 and 4-6 Obvious Over Spenser in Combination with Chuter and Spenser II *or* Levi in Combination with Chuter and Spenser II**

As explained above, Spenser *or* Levi in combination with Chuter renders

obvious claims 1-2 and 4-6 because those combinations disclose every limitation of the claims and POSITAs would have been motivated to add Chuter's fiber pile to Spenser's and Levi's valves to prevent PVL with a reasonable expectation of success. (*Supra* §VIII.B.) Spenser II would have provided POSITAs additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves. (Ex. 1003, ¶229.) Spenser II teaches the addition of a compressible material to the outside of a THV for preventing PVL. (Ex. 1011, [00145].) POSITAs would have recognized Chuter's fiber pile as one such compressible material that could be used on THV's to prevent PVL according to Spenser II's teachings. (Ex. 1003, ¶230.) Accordingly, claims 1-2 and 4-6 would have been obvious over the combination of Spenser *or* Levi with Chuter and Spenser II. (*Id.*, ¶230.)

IX. SECONDARY CONSIDERATIONS

Petitioner understands that PO does not practice the '033 patent or sell any products covered by the '033 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶231-232.) If PO asserts that the '033 patent solved a long-felt but unmet need, the Board has repeatedly rejected that argument in the prior IPRs. (Ex. 1117, 66-70; Ex. 1118, 71-74; Ex. 1119, 86-89.) If PO identifies any other alleged evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

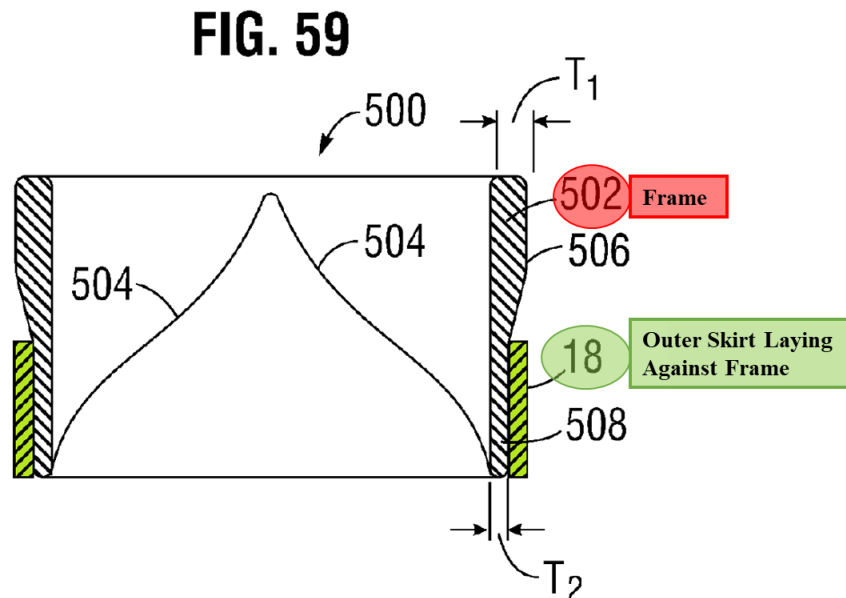
X. THE BOARD SHOULD NOT DENY INSTITUTION

UNDER 35 U.S.C. §325(d)

The Board should not exercise its discretion to deny institution under §325(d) because the Examiner erred in a manner material to the patentability of the challenged claims. The challenged claims would have been obvious in view of the asserted prior art for the reasons explained above. Thus, the Examiner failed to fully consider the teachings of the prior art. This was material error. Notably, as discussed previously, the Board has determined in prior IPRs filed by Petitioner that the same prior art references asserted herein render highly similar claims obvious. *Supra* §II. Moreover, the Board should not deny institution based on the inclusion of Spenser, Spenser II, Chuter, and Levi on an IDS because the Examiner never applied those references. (Ex. 1002); *see e.g., Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining to deny institution under §325(d) because prior art was not applied).

PO also made arguments mischaracterizing Levi during prosecution. For example, PO asserted that “Levi discloses that known fabric skirts such as those in Greenhalgh cannot be secured on the exterior of the frame in a ‘lay flat’ position as claimed or else the valve cannot be crimped properly.” (Ex. 1002, 179.) Levi

contains no such disclosure. To the contrary, Levi discloses embodiments having an outer sealing material in a “lay flat” position as claimed in the ’033 patent:



(Ex. 1008, 16:51-54, Fig. 59.) Thus, PO’s erroneous arguments during prosecution should not form the basis to deny institution under §325(d).

The Examiner also appears to have allowed the claims of the ’033 patent based on PO’s erroneous arguments that the combined prior art would not be capable of endovascular delivery through the femoral artery. (See Ex. 1002, 93-98, 167-180.) That was material error. As explained above, the Board has already determined that the combination of Spenser and Spenser II would result in a valve that is endovascularly deliverable through the femoral artery. (*Supra* §VIII.A.1.g.) Thus, the Examiner materially erred in allowing the claims over at least Spenser and Spenser II based on endovascular delivery.

As discussed previously, the Board has determined in prior IPRs that the same prior art references asserted herein render highly similar claims obvious. (*Supra* §II.) There is no material difference between the scope of the claims found unpatentable in those IPRs and the challenged claims here. The Examiner thus materially erred in allowing the claims over Spenser, Spenser II, Chuter, and Levi. Given this material error, the Board should not exercise its discretion to deny institution under §325(d).

XI. MANDATORY NOTICES UNDER 37 C.F.R. §42.8(a)(1)

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Edwards Lifesciences Corp. and Edwards Lifesciences LLC are the real parties in interest.

B. Related Matters (37 C.F.R. §42.8(b)(2))

Petitioner has filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,792,172 (“’172 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01527 (Filed Sept. 10, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,857,011 (“the ’011 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No.

10,966,846 (“the ’846 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00034 (Filed Oct. 11, 2021). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,881,538 (“the ’538 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00193 (Filed Nov. 11, 2021). Petitioner also filed a Petition for *Inter Partes* Review of U.S. Patent No. 11,129,735 (“the ’735 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-000549 (Filed February 4, 2022). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 10,987,236 (“the ’236 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00556 (Filed February 7, 2022). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 11,337,834 (“the ’834 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2023-01151 (Filed June 29, 2023). Petitioner has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 11,389,310 (“the ’310 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2023-01232 (Filed July 20, 2023). The ’033 patent is part of the same patent family and shares a specification with the ’172, ’011, ’846, ’538, ’735, ’236, ’834, and ’310 patents. The status and outcomes of Edwards’ prior IPRs is summarized previously in section II.

PO recently filed suit against Petitioner alleging infringement of the ’033 patent, as well as U.S. Patent Nos. 11,523,918; 11,337,834; 11,497,634; and

11,389,310, by Petitioner’s SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1:23-00158-JPM (D. Del., filed Feb. 13, 2023). The court has not set a trial date in the litigation. The court has scheduled a claim construction hearing on March 21, 2024.

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

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

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

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com BoxEdwards28-3@knobbe.com <u>Postal and Hand-Delivery Address:</u> Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com <u>Postal and Hand-Delivery Address:</u> Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

D. Service Information Under 37 C.F.R. §42.8(b)(4)

Please address all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxEdwards28-3@knobbe.com.

XII. FEES

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

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

Petitioner certifies that the '033 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims on the identified grounds.

XIV. CONCLUSION

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

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 14, 2023

By: /Joshua J. Stowell/

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

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

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

Customer No. 20,995

Attorneys for Petitioners

EDWARDS LIFESCIENCES CORP. AND

EDWARDS LIFESCIENCES LLC

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,491,033**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 12,626 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: August 14, 2023

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. 11,491,033** and **EXHIBITS
1001 – 1136** are being served on, via Federal Express overnight mail on counsel of
record for U.S. Patent 11,491,033 as addressed below:

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