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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.

IPR2023-01232
Patent No. 11,389,310

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,389,310**

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Exhibit No.	Description
1001	U.S. Patent No. 11,389,310 B2 (“ ’310 patent ”)
1002	Excerpts from the prosecution history of the ’310 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“Walther”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	Reserved
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ Spenser ”)
1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
1012	Reserved
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.
1016	Reserved

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1017	Cheung, Anson, et al., <i>Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human</i> , Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020-1021	Reserved
1022	Smith, Craig R., et al., <i>Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients</i> , 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., <i>Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches</i> , Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Reserved
1025	Cribier, Alain, et al., <i>Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis</i> , 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al.
1027-1029	Reserved
1030	Cribier, Alain, et al., <i>Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis</i> , 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)

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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	Preliminary Amendment for Patent Application No. 17/096,253 Submitted November 30, 2020
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	Reserved
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dkt. 1, Complaint (Sept. 28, 2021)

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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”)
1107	Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)

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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 Collogen Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)
1112	Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”)
1113-1115	Reserved
1116	U.S. Patent Pub. No. 2002/0151958 to Chuter (“ Chuter ”)
1117	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01527, Final Written Decision (“172 FWD”)
1118	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584, Final Written Decision (“011 FWD”)
1119	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00193, Final Written Decision (“538 FWD”)
1120	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00034, Final Written Decision (“846 FWD”)

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

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Exhibit No.	Description
1135	U.S. Pat. No. 3,878,565 (“Sauvage”)
1136	Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”)
1137	U.S. Pat. Pub. No. 2005/0273155 (“Bahler”)
1138	U.S. Pat. Pub. No. 2012/0143324 (“Rankin”)
1139	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dat. 83, Plaintiff Aortic Innovations’ Opening Claim Construction Brief (Nov. 21, 2021)
1140	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dkt. 1, Claim Construction Order (Sept. 28, 2021)

Petitioners Edwards Lifesciences Corp. and Edwards Lifesciences LLC (“Petitioner”) request *inter partes* review (“IPR”) of claims 1-3, 5, 7-8, and 11-13 (“the challenged claims”) of U.S. Patent No. 11,389,310 (“the ’310 patent”) to Aortic Innovations, LLC (“PO” or “Patent Owner”).

I. SUMMARY OF THE ARGUMENT

The ’310 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 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 '310 patent claims a heart valve having: (1) an outer frame [red], (2) a graft covering [blue], (3) prosthetic heart valve leaflets, and (4) a sealing material including fibers that extend outwardly of the outer frame [green].

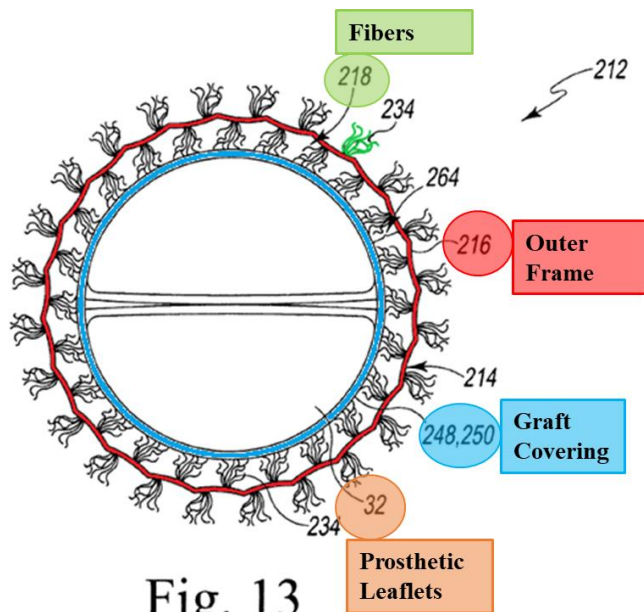


Fig. 13

In attempting to distinguish the '310 patent from the claims previously found unpatentable, PO included limitations requiring (1) that the fibers are “in contact” with the outer frame when the valve is compressed and expanded, and (2) that the valve assembly may be “deployed endovascularly through the femoral artery.” These litigation-driven limitations do not distinguish the challenged claims from the prior art.²

² Petitioner reserves its right to challenge whether the '310 patent claims satisfy 35 U.S.C. §112 in future proceedings.

Spenser II, which the Board relied upon for its unpatentability findings in the prior IPRs, 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.” (Ex. 1011, [00145].) As shown in Figure 22 below, the compressible material may extend entirely around the frame in the form of a sleeve:

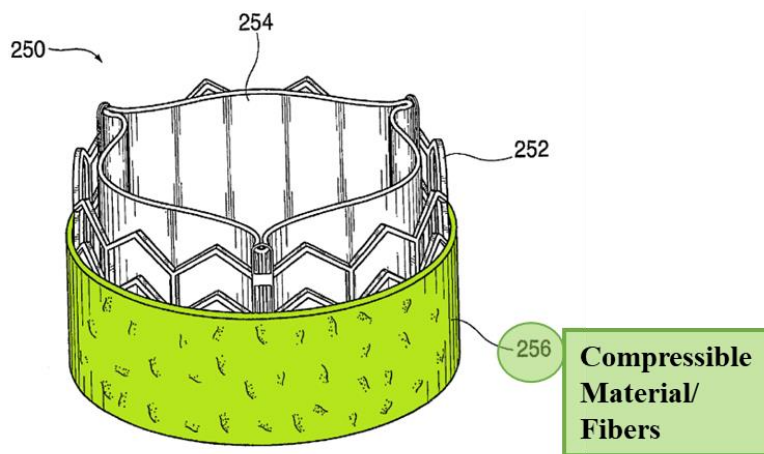


FIG. 22

Notably, the Board has already found, and PO is precluded from challenging, that POSITAs would have found it obvious to add Spenser II’s compressible material to the **Spenser** valves, which disclose every other limitation of the challenged claims.

Accordingly, the challenged claims would have been obvious under the same prior art, factual findings, and analysis that the Board has already applied in the prior IPRs. In addition, as explained below, the challenged claims also would have been obvious in view of an additional prior art reference, **Chuter**, that was not before the

Examiner during prosecution of the '310 patent, and was not considered in the prior IPRs resulting in Final Written Decisions.

II. PRIOR IPRS OF RELATED PATENTS

Petitioner has previously filed seven IPRs (“prior IPRs”) challenging patents having the same specification and drawings as the '310 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
IPR2023-1151	11,337,834	Filed June 29, 2023

The Board found every challenged claim in Petitioner’s prior IPRs that 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.” *Id.* (internal quotation marks omitted). Accordingly, PO is precluded from challenging at least the following issues for the ’310 patent:

- POSITAs would have been motivated to add Spenser II’s compressible material to Spenser’s transcatheter heart valves (“THVs”) (Ex. 1117,

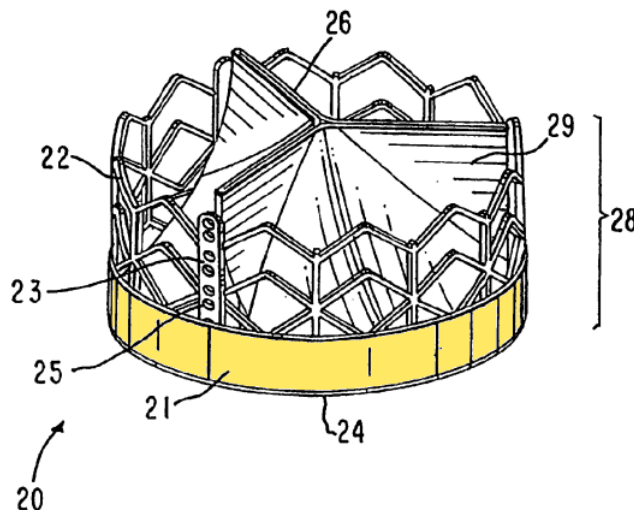
64-66; Ex. 1118, 67-70);

- 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).

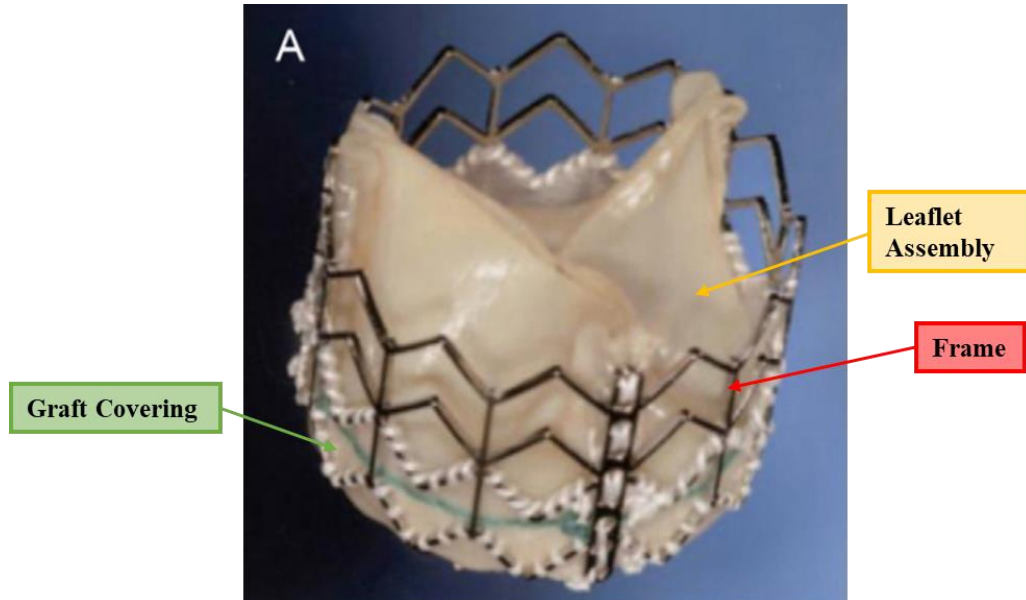
III. STATE OF THE ART

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.) **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) prosthetic heart valve leaflets:



(Ex. 1023, 154, Fig. 3A (excerpt); Ex. 1003, ¶69.)

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:

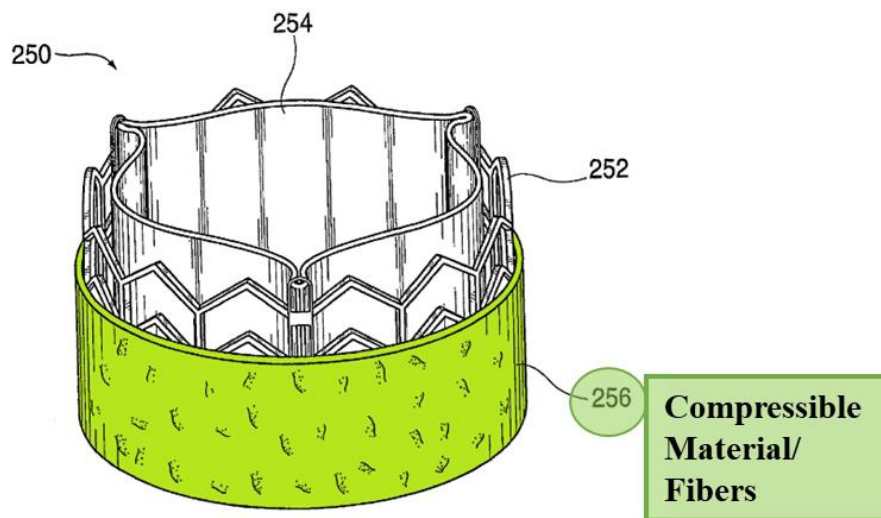
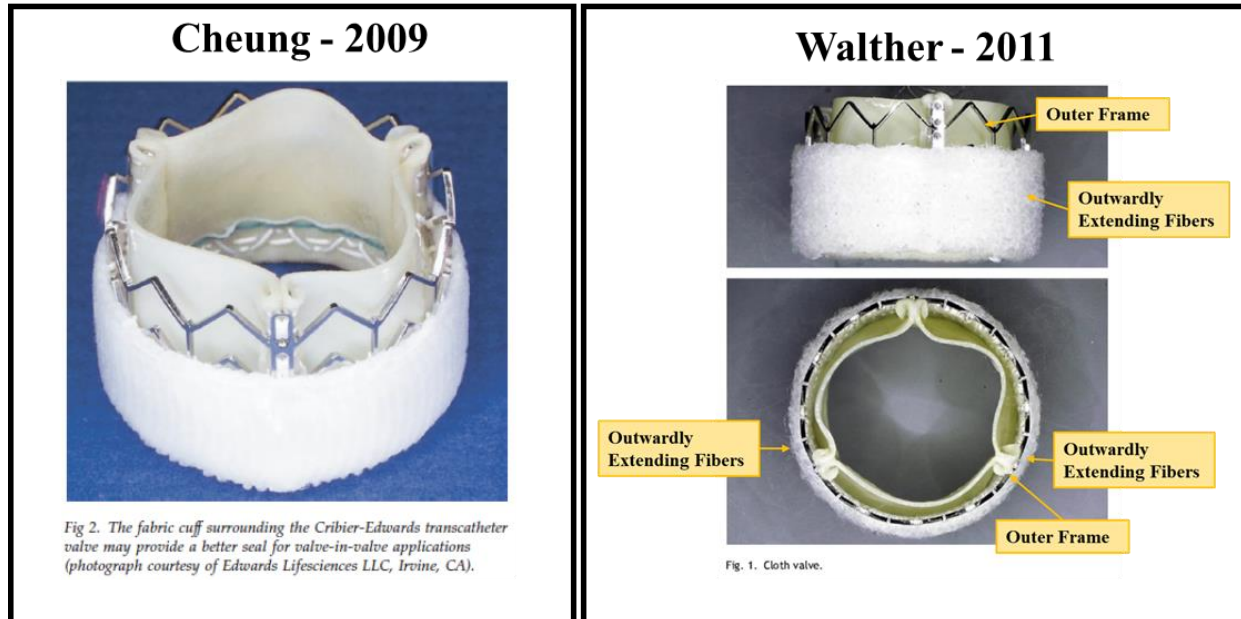


FIG. 22

(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶70-71.)

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 and velour-like fabrics as outer sealing materials in cardiovascular implants for decades prior to the November 2012 critical date of the '310 patent. (See Ex. 1107; Ex. 1106, 158; Ex 1110, 172; Ex. 1003, ¶¶78, 83.) They

adopted 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, ¶78, 83.)

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.”

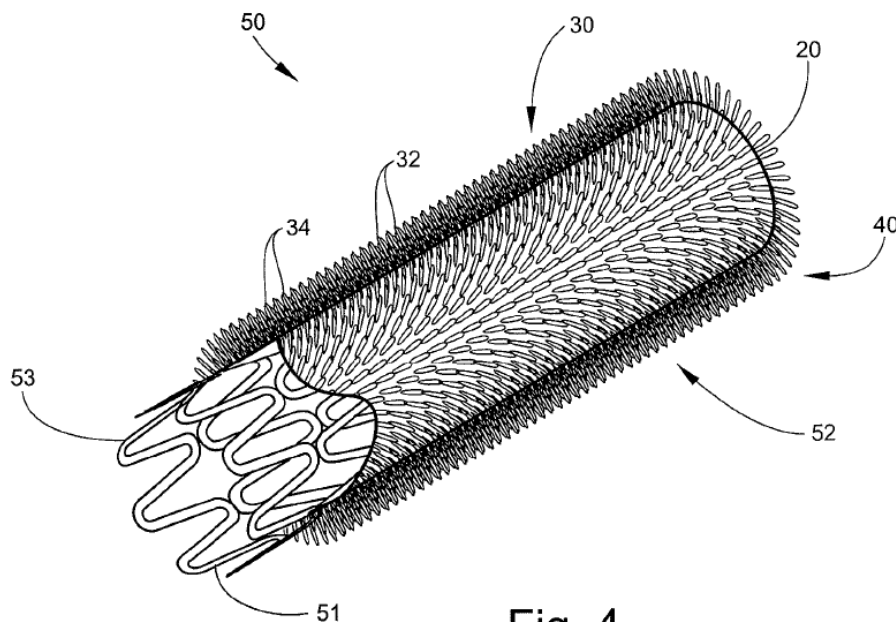
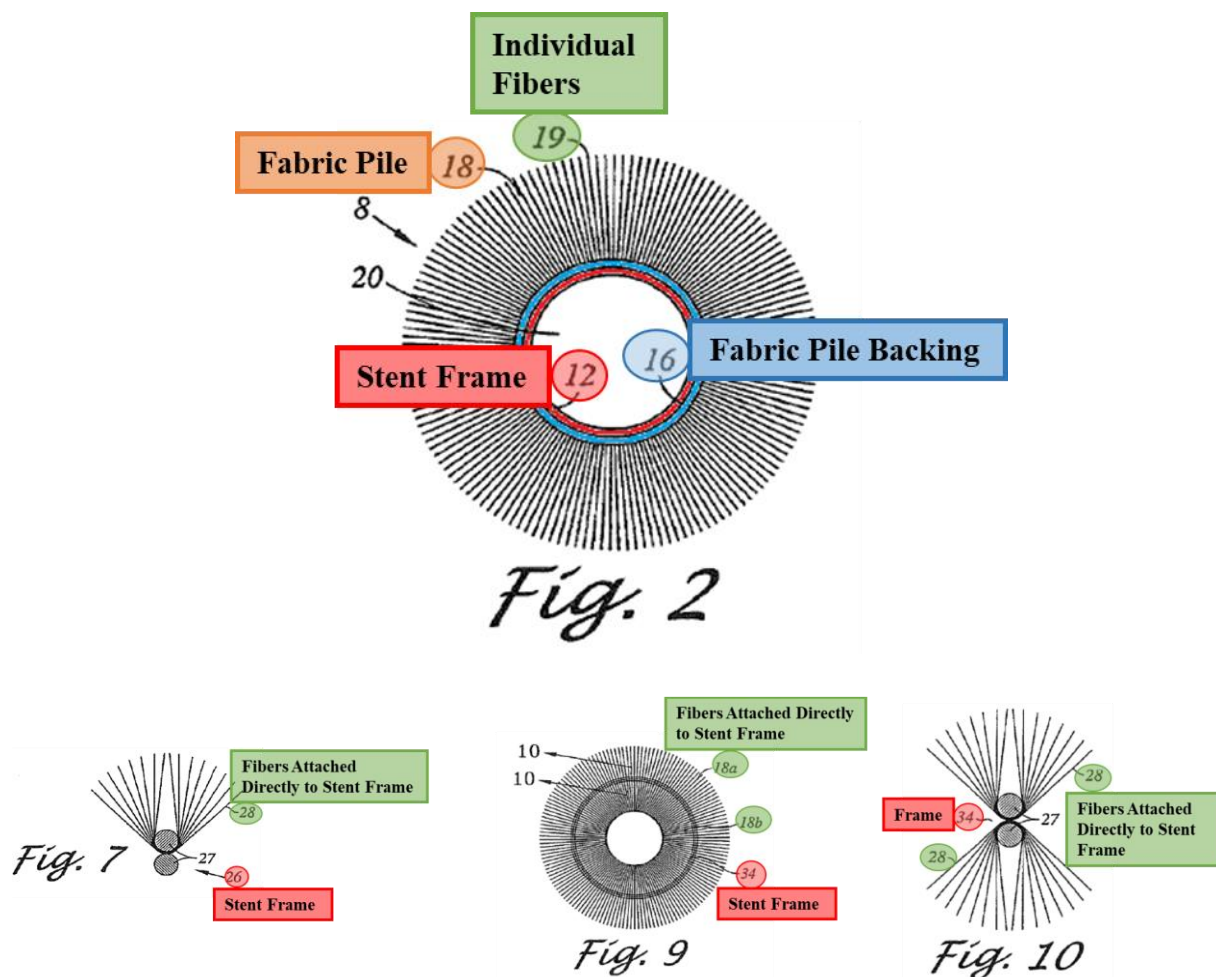


Fig. 4

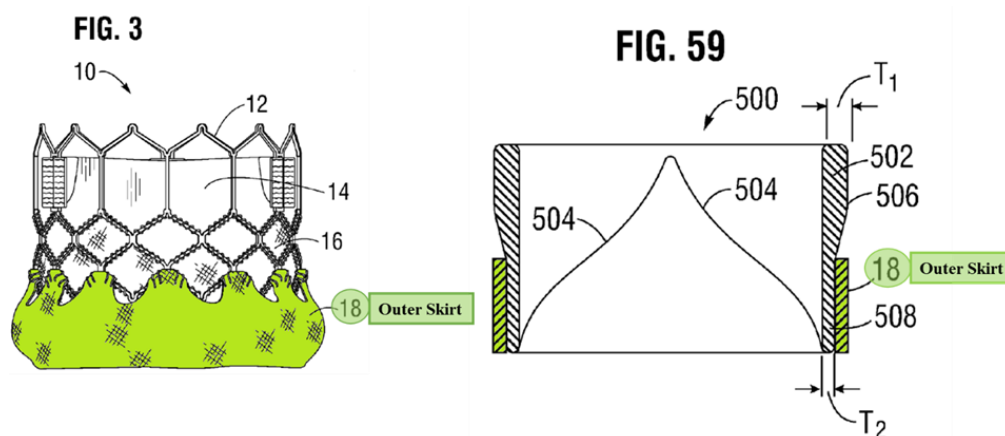
(Ex. 1074, 4:22-26, 9:18-21, Fig. 4.) Norris’s fabric helps prevent blood from leaking around the implanted device. (*Id.*, 9:18-26.) Norris’s fabric is highly compressible to minimize the crimped profile of the device to which it was added, enabling endovascular delivery. (*Id.*, 8:23-39, 10:6-13.)

Chuter, a 2002 patent publication, provides another example of compressible materials for sealing cardiovascular implants. Chuter discloses embodiments of endovascularly-delivered intravascular stents having a “fiber pile” made of individual fibers that are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” (Ex. 1116, [0017]-[0022], Figs 1-10.) The individual fibers of the “fiber pile” can extend from a “fabric pile backing” layer 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 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, 17:12-18, Figs. 3, 59.) Levi also discloses several ways to minimize the impact of any outer seal on the crimped profile so the valve can be delivered transfemorally. (*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 '310 PATENT

A. Overview

The '310 patent describes a “valve assembly” having a “dual-frame” for replacing an aortic heart valve. (Ex. 1001, 17:36-45.) 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”:

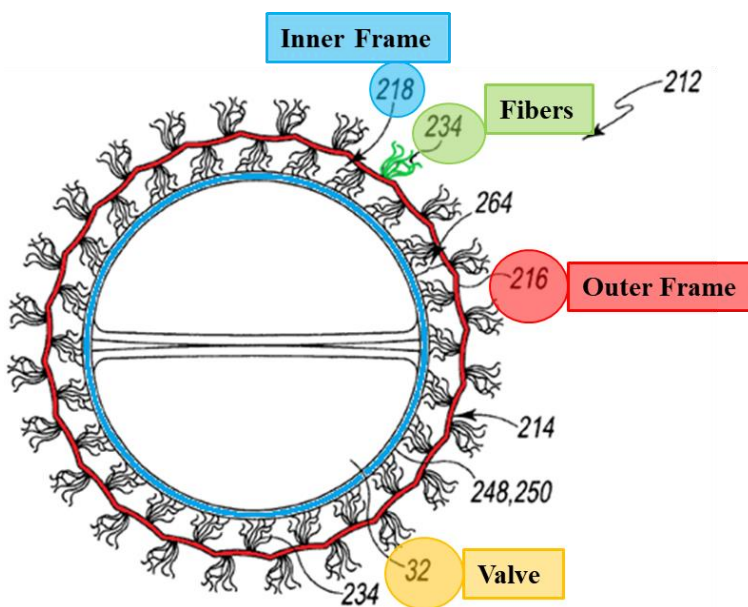


Fig. 13

(*Id.*, 17:54-57, Fig. 13.)

The outer frame [red] includes an “open cell-stent configuration” and radially extending collagen fibers [green] attached to the frame to aid in preventing PVL and migration of the valve. (*Id.*, 17:57-62, 18:2-3, 18:20-23, Fig. 9.) The inner frame [blue] is a “balloon-expandable tubular stent.” (*Id.*, 13:38-48.) The outer surface of

the inner frame may be covered with a non-porous covering material. (*Id.*, 13:48-54.)

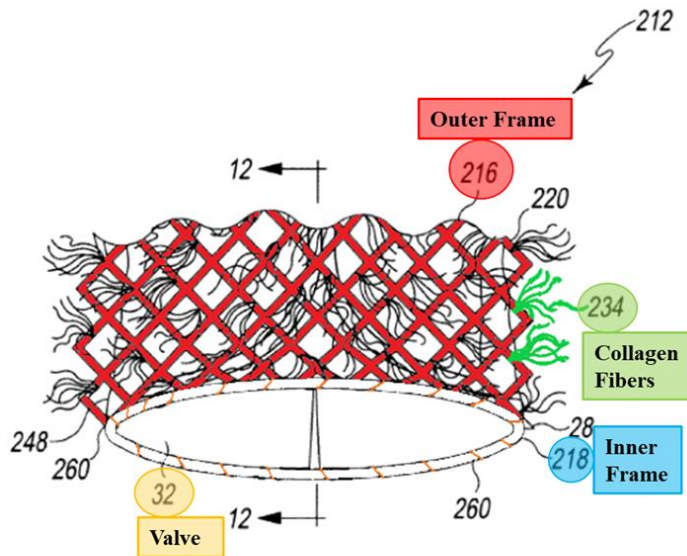


Fig. 11

B. Prosecution History

The Examiner rejected the pending claims in a Non-Final Rejection as obvious over Spenser in combination with Spenser II³ in further combination with U.S. Pat. Pub. No. 2005/0273155 (“Bahler”) or Levi. (Ex. 1002, 585-592; Ex. 1137.) In response, PO argued that the combination of Spenser or Levi with Spenser II would not result in a valve that could be endovascularly delivered via the femoral artery. (Ex. 1002, 567-577.) The Examiner again rejected the pending claims as

³ The Examiner referred to Spenser II, which is WO 2006/005015, as “Dehdashtian” throughout the prosecution history.

obvious over Levi combined with Spenser II following PO's arguments. (*Id.*, 455-459.) After another amendment by PO repeating similar arguments regarding endovascular delivery via the femoral artery, the Examiner rejected the claims as obvious over Levi in combination with Spenser II and U.S. Pat. Pub. No. 2012/0143324 ("Rankin"). (Ex. 1002, 327-336, 434-447; Ex. 1138.) PO then submitted an additional amendment and an affidavit by Dr. Stephen Brecker again arguing that the combination of Levi and Spenser II would not result in a valve that could be transfemorally delivered and would not press the sealing material against the patient's native leaflets. (Ex. 1002, 276-319.) The Examiner issued a fourth Non-Final Rejection following this amendment asserting the same prior art references as the prior rejection and clarifying the proposed prior art combination to "utilize the fibers from [Spenser II] in the device of Levi in order to aid in engagement with native leaflets of the aorta of a patient and to help with preventing leakage." (*Id.*, 166-175.) In response, PO amended the claims to require "the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation." (*Id.*, 138-139.) PO argued that Levi required a "billowing" outer skirt to allow for endovascular delivery and that if Spenser II's compressible material were added to Levi's valve, the resulting valve would not be

capable of endovascular delivery through the femoral artery. (*Id.*, 144-148.) The Examiner subsequently allowed the amended claims, concluding that the “prior art does not disclose or render obvious wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation in combination with the recited claim features.” (*Id.*, 21.) As explained below, that conclusion was materially erroneous. (*Infra* §X.)

C. The Critical Date

The '310 patent claims priority to two provisional applications: application No. 61/567,458 (“the '458 provisional”), filed December 6, 2011; and application No. 61/723,446 (“the '446 provisional”), filed November 7, 2012. (Ex. 1001.) During prosecution, the Examiner determined that the '310 patent is not entitled to the benefit of the earlier application because it “fails to disclosure [sic] or support for any ‘fibers’” and thus determined that the effective priority date of the '310 patent is November 7, 2012. (Ex. 1002, 326.) 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	1-3, 5, 7-8, 11-13	103	Spenser + Spenser II
2	1, 3, 5, 8, 11, 13	103	Levi + Spenser II
3	1-3, 5, 7-8, 11-13	103	Spenser + Chuter
4	1, 3, 5, 8, 11, 13	103	Levi + Chuter
5	1-3, 5, 7-8, 11-13	103	Spenser + Chuter + Spenser II
6	1, 3, 5, 8, 11, 13	103	Levi + Chuter + Spenser II

B. The Asserted References Are Prior Art

The Critical Date of the '310 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 '310 patent, e.g., cardiovascular implant devices, including endografts and transcatheter heart valves. (Ex. 1003, ¶41.) 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, ¶50.)

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 '310 patent require construction to resolve the patentability issues herein. Petitioner's grounds are based on PO's allegations that the '310 patent covers Petitioner's SAPIEN 3 Ultra valve and the scope of the claims asserted by PO in litigation. (Ex. 1122; Ex. 1123, 2, 262-476); *see also 10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00087, Paper 9, at 9-10, 15-19 (P.T.A.B. Apr. 27, 2020) ("[W]e see no problem with Petitioner relying on statements by [PO] in the related district court action in which [PO] took a position on the scope of a challenged claim."); *Nintendo Co. v. Gamevice, Inc.*, IPR2018-01521, Paper 7, at 7 n. 5 (P.T.A.B. Mar. 11, 2019). Petitioner reserves its right to propose claim constructions for the '310 patent in district court and to contest PO's infringement allegations.

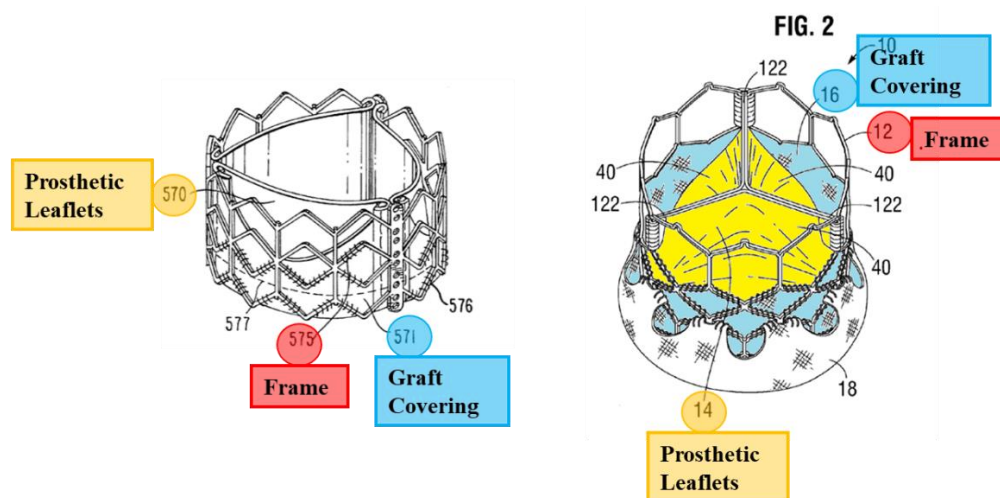
In litigation of related patents, the district court construed the term "outer frame" to mean a "self-expanding frame." (See Ex. 1140, 17.) Notwithstanding the district court's construction, PO has asserted that Petitioner's SAPIEN 3 Ultra valve infringes the '310 patent, even though SAPIEN 3 Ultra does not include a self-expanding frame. (Ex. 1122.) Petitioner has relied on PO's continued contention that the term "outer frame" is not limited to self-expanding frames and identified disclosures in the prior art that include balloon-expandable frames. However, the references relied upon herein also disclose self-expanding frames and, thus,

Petitioner’s grounds render the claims unpatentable under either interpretation of “outer frame.”

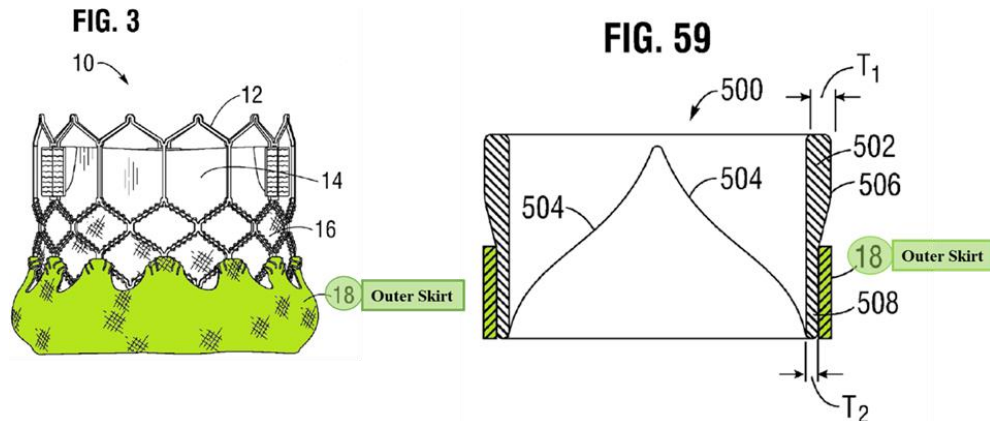
VIII. PROPOSED GROUNDS FOR UNPATENTABILITY

A. Grounds 1-2: Claims 1, 3, 5, 8, 11, 13 Obvious Over Spenser or Levi and Spenser II

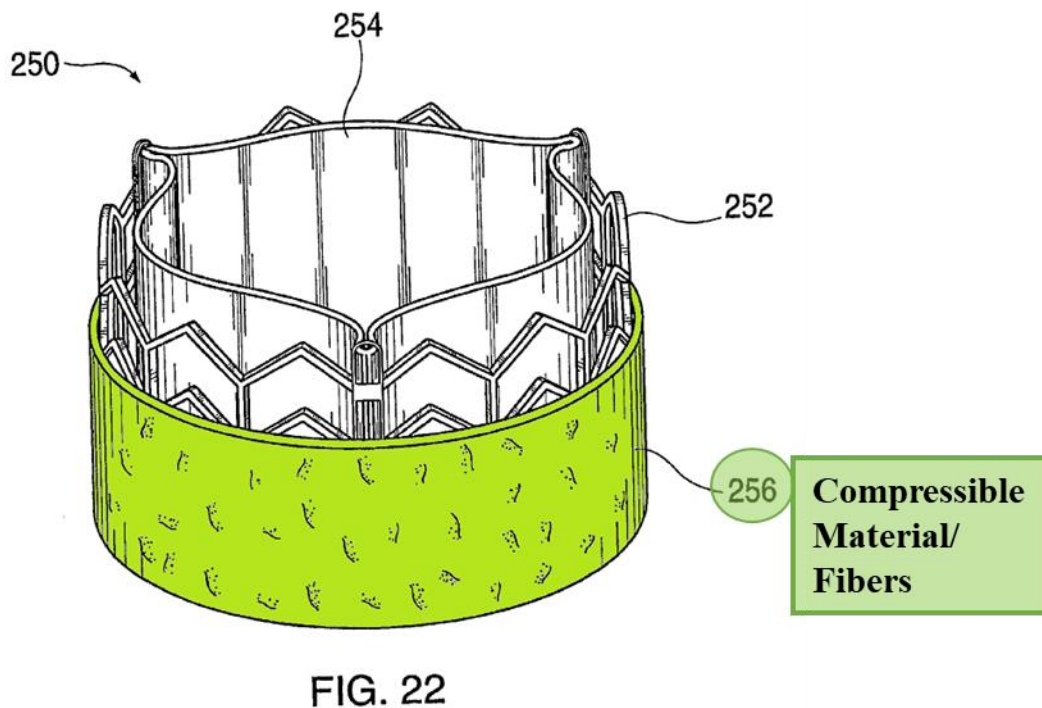
Spenser (left) and Levi (right) describe heart valves having a frame, a graft covering, and prosthetic heart valve leaflets:



(Ex. 1010, 11:66-12:17, Fig. 44a; Ex. 1008, Fig. 2.) Levi also discloses an outer fabric skirt secured to the frame’s exterior surface for preventing PVL. (Ex. 1008, 13:50-66, 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.)

In the prior IPRs, the Board 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, ¶¶131-136; *infra* §VIII.A.1.f.ii.) Thus, Spenser *or* Levi combined with Spenser II renders claims 1, 3, 5, 8, 11, and 13 obvious. (Ex. 1003, ¶¶106-218.)

1. Claim 1

Spenser *or* Levi combined with Spenser II renders claim 1 obvious. (Ex. 1003, ¶¶109-177.)

a. Preamble

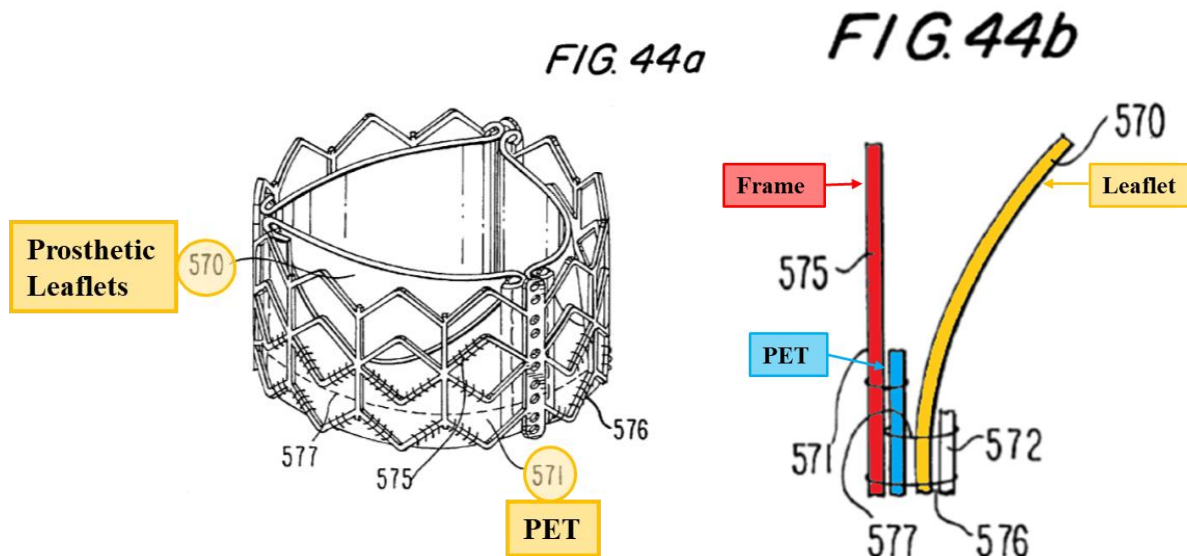
If the preamble is limiting, Spenser, Levi, and Spenser II disclose a “transcatheter heart valve assembly.” (Ex. 1010, 2:6-12; Ex. 1011, [0009], [0014], [0017], [00144]-[00145]; Ex. 1008, 1:57-2:7; Ex. 1003, ¶¶110-112.)

b. Graft Covering

Spenser and Levi disclose a “graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the heart valve leaflets.” (Ex. 1003, ¶¶113-117.)

Spenser's Figure 44a includes “additional pieces of PET” for “sealing and protecting the pericardium.” (Ex. 1010, 26:30-34, Figs. 44a-44c.) The “pericardium” includes prosthetic leaflets 570, and the piece of PET 571 is a “graft

covering.” (*Id.*, 26:30-54; Ex. 1003, ¶114.) As shown below, PET 571⁴ [blue] extends around the prosthetic heart valve leaflets 570 and is attached to the leaflets via suture 577:

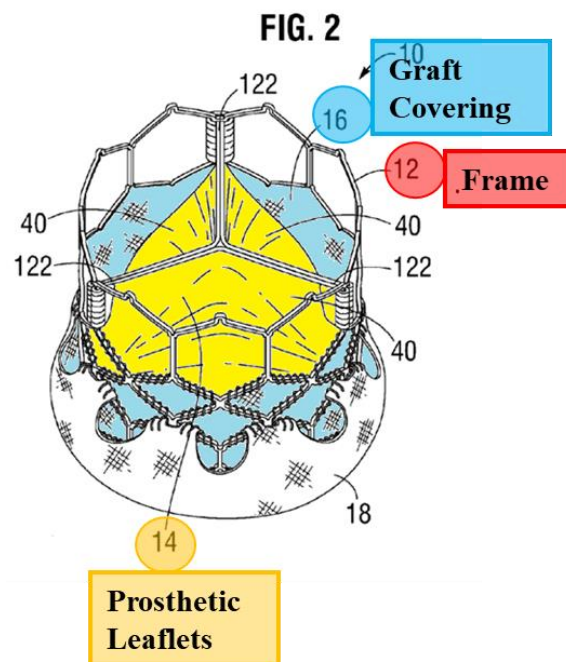


(Ex. 1010, 26:30-54, Fig. 44a-b (PET 571 is positioned “between the leaflets [570 yellow] and frame [575 red]”).)

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

⁴ 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 middle layer [blue]. (Ex. 1010, 26:40-42; Ex. 1003, ¶115 n. 5.)

skirt may be constructed of “polyethylene terephthalate (PET).” (*Id.*, 9:11-16.) Levi’s inner skirt is a “graft covering.” (Ex. 1003, ¶117.) The inner skirt is attached to the prosthetic leaflets “via one or more thin PET reinforcing strips.” (Ex. 1008, 9:25-29.) Levi’s inner skirt 16 [blue] extends around the prosthetic leaflets [yellow] and houses the leaflets:



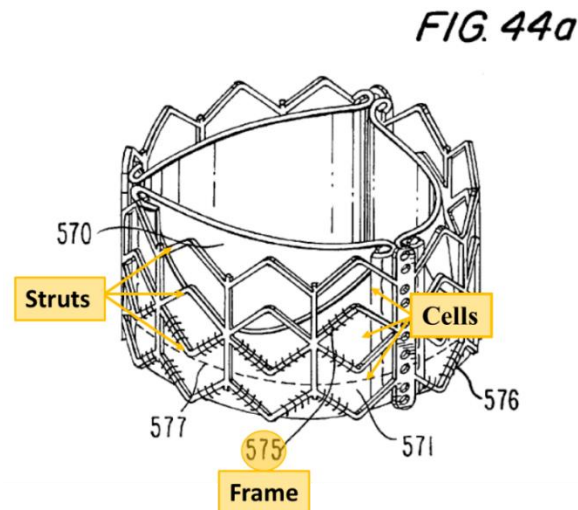
(Ex. 1008, Fig. 2; Ex. 1003, ¶117.)

c. **Outer Frame**

Spenser and Levi disclose “an outer frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering.”

(Ex. 1003, ¶¶118-122.)⁵

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



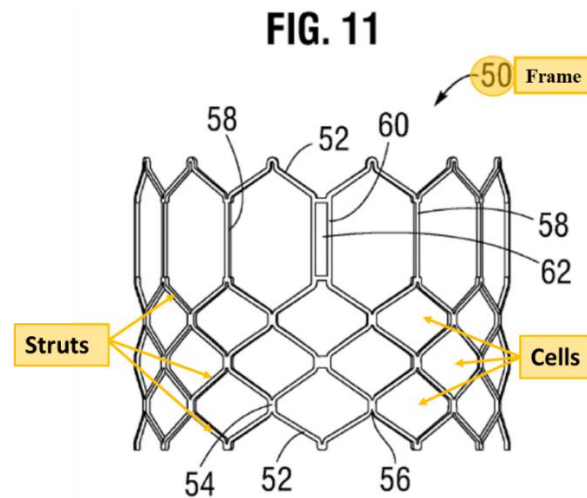
(Ex. 1010, 19:5-13, 26:30-34.) Frame 575 defines an open cell configuration and is made from metal. (Ex. 1010, 12:28-31, Fig. 44a-44b.) The frame 575 is an outer frame because it surrounds the prosthetic leaflets 570 and inner graft covering 571. (*Id.*; Ex. 1003, ¶119.) Frame 575 is secured to PET 571 via sutures. (Ex. 1010, 26:45-47, Figs. 44a-44c.)

Spenser discloses that the valve in Figure 44a “resembles the valve shown in

⁵ Petitioner’s unpatentability arguments are based on PO’s continued assertion in litigation that the “outer frame” in the ’310 patent need not be a self-expanding frame.

FIG. 43,” which “is inflated by a balloon.” (Ex. 1010, 26:19-28, 26:34-37.) However, Spenser also discloses that valves having frames like Figure 44a can be self-expanding. (*Id.*, 21:15-34, Figs. 26a-c.) Consequently, POSITAs would have understood that the frame in Figure 44a can be balloon expandable or self-expanding. (Ex. 1003, ¶120.)

Levi also discloses a metal frame defining an open cell configuration:



(Ex. 1008, 6:17-7:3, Fig. 11; Ex. 1003, ¶122.) Levi’s inner skirt is secured to the frame via sutures. (Ex. 1008 9:24-25, 10:11-30.) As in Spenser, Levi discloses that the described frames can be self-expanding or balloon expandable. (Ex. 1008, 6:17-49; Ex. 1003, ¶122.)

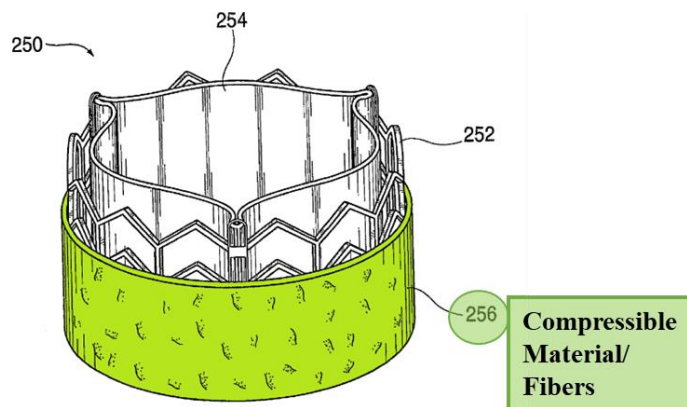
d. Sealing Material

Spenser *or* Levi in combination with Spenser II renders obvious “a sealing material positioned externally to the outer frame for providing sealing between the

outer frame and a patient's anatomical wall to prevent paravalvular leaks, wherein the sealing material is attached to the outer frame, wherein the sealing material defines a height that partially extends over at least a first two rows of cells in the outer frame, wherein the sealing material includes a plurality of radially extending, arcuate fibers that extend outwardly of the outer frame.” (Ex. 1003, ¶¶123-136.)

The recited intended use for the sealing material: “for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks,” is not limiting. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018). However, even if the intended use is limiting, Spenser II discloses this limitation.

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 of the compressible material “may be straight, curved or hook-shaped.” (*Id.*, [00145].)

i. Spenser and Spenser II

Spenser II’s compressible material defines a height that partially extends over at least a first two rows of cells in the frame:

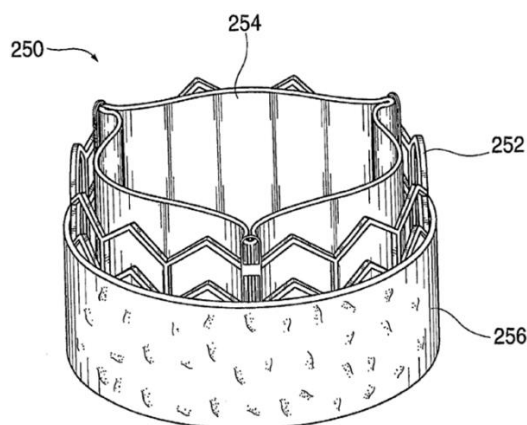
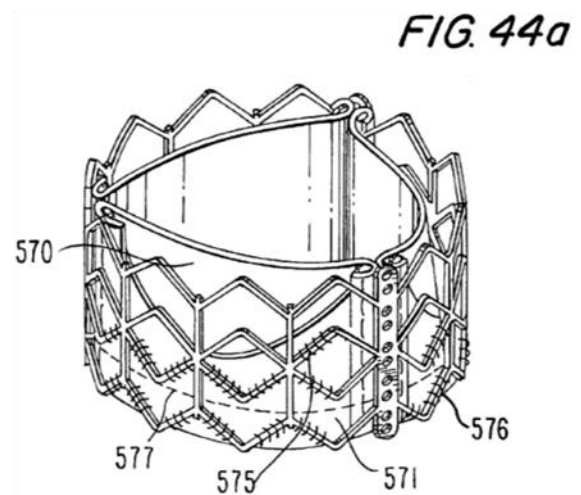
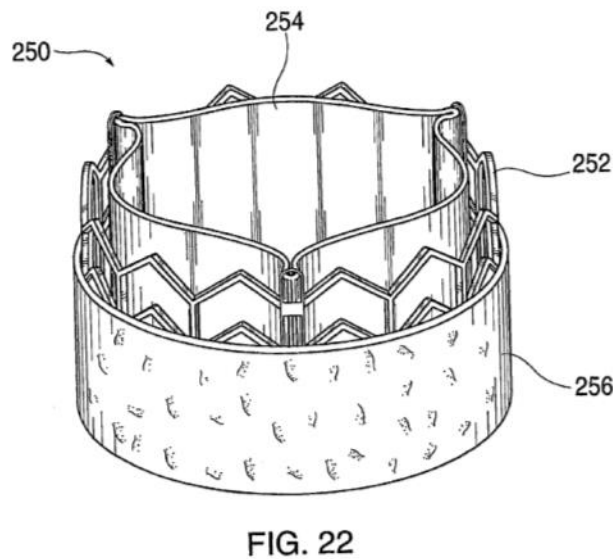


FIG. 22

(Ex. 1011, Fig. 22; Ex. 1003, ¶126.)

If Spenser II’s compressible material were added to Spenser’s Figure 44a valve in the same way, the material would partially extend over a first two rows of cells. (Ex. 1003, ¶126.) A comparison of Spenser II’s Figure 22 (left) and Spenser’s Figure 44a (right) confirms that the stent structures are similar and that the compressible material would at least partially cover two rows of Figure 44a:



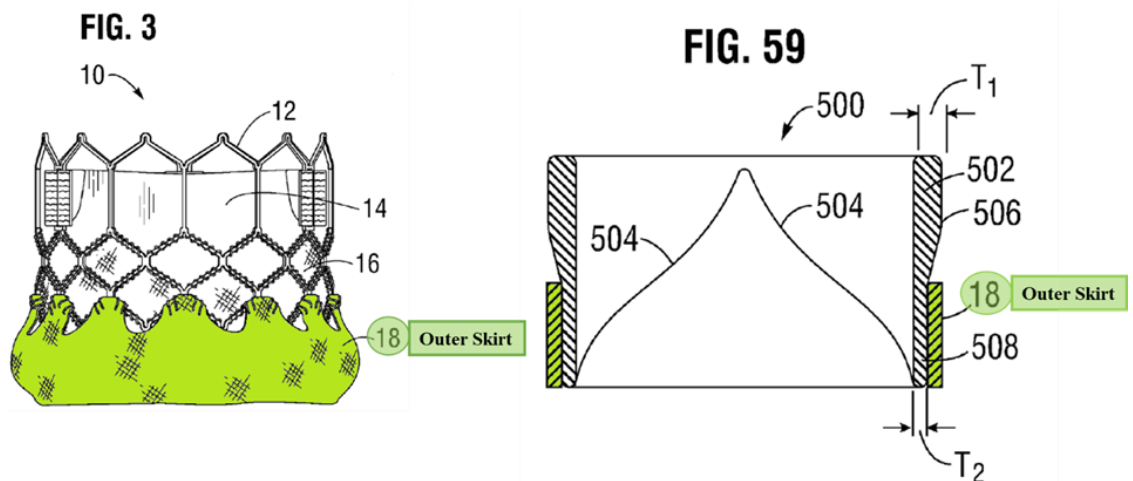
(Fig. 1011, Fig. 22; Ex. 1010, Fig. 44a; Ex. 1003, ¶126.)

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 close relationship, POSITAs would have reasonably expected that features described in one patent would apply to the other. (Ex. 1003, ¶¶128-130.) Moreover, the valves in Spenser and Spenser II comprise balloon-expandable,

metallic, gridded frames that surround prosthetic leaflets. (*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, ¶129.)

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, 13:50-53, 13:62-66, 16:51-54, 17:12-18.)



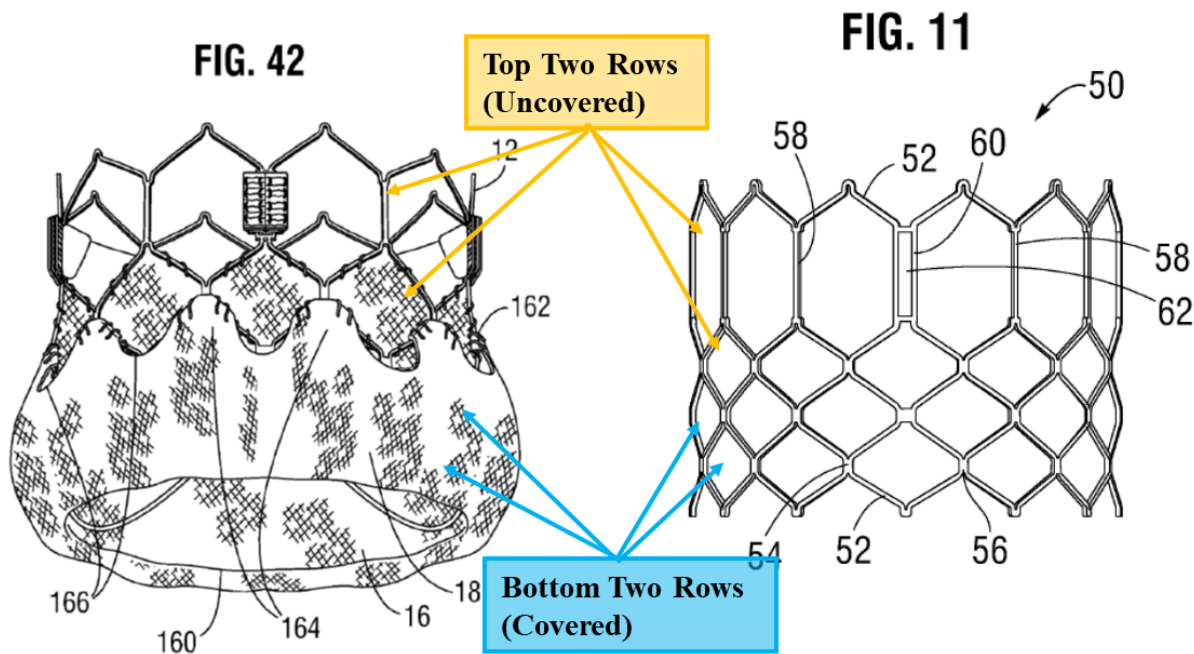
(*Id.*, Figs. 3, 59.)

POSITAs would have found it obvious to replace Levi's outer skirt with Spenser II's compressible material because the skirt and material are interchangeable. (Ex. 1003, ¶¶132-133.) 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, while Levi discloses embodiments of the outer skirt that billow away from the frame after expansion, Levi also discloses embodiments where the outer skirt is in contact with the frame after expansion. (*See e.g.*, Ex. 1011, Fig. 59.)

Moreover, a finite number of methods to address PVL existed in November 2012. (Ex. 1003, ¶133.) 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, ¶¶132-133.)

POSITAs would have reasonably expected success in substituting Spenser II's compressible material for Levi's outer skirt. (Ex. 1003, ¶¶134-135.) The valve frames in Spenser II and Levi share many common features, including being compressible and 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, ¶¶134-135.)

Levi discloses that the outer skirt may be mounted to the "lower half" of the valve, which encompasses the proximal two rows of cells of the frame, as shown in Figure 42:



(Ex. 1008, 16:38-45, Fig. 42.) Spenser II also discloses a sealing material having a height that partially extends over at least a first two rows of cells. (*Supra* §VIII.A.1.d.i.) POSITAs would have been motivated to attach Spenser II’s outer compressible material to Levi’s outer frame at the same height, and expected success in doing so, because the references demonstrate that a height that partially extends over at least a first two rows of cells creates an effective seal. (Ex. 1003, ¶136.)

e. Polyester Graft Covering

Spenser and Levi disclose a “wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer.” (Ex. 1003, ¶¶137-138.) Spenser and Levi disclose PET graft coverings. (*Supra* §VIII.A.1.b.) PET is a polymer and a polyester. (Ex. 1003, ¶138.)

f. Endovascularly Deployed

Claim 1 next recites “wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient.”⁶ This statement of intended use is not limiting. *See ParkerVision, Inc.*, 903 F.3d at 1361. However, if the intended use is limiting, Spenser *or* Levi in combination with Spenser II renders this limitation obvious. (Ex. 1003, ¶¶139-155.)

i. Spenser and Spenser II

The Board previously concluded that POSITAs would have expected the THV formed from combining Spenser and Spenser II’s compressible material could be delivered endovascularly. (Ex. 1117, 53-64; Ex. 1118, 57-68; Ex. 1119, 69-80.) The Board explained, “the 12F (4.0 mm) diameter of the valve taught by Spenser ... is well within the maximum allowable diameter of 24F [for transfemoral delivery] argued by [PO], such that [POSITAs] could reasonabl[y] understand that there would be sufficient additional space to accommodate the ‘compressible ... cloth or fabric,’ which Spenser II teaches can also be delivered endovascularly.” (Ex. 1117, 57.) Thus, the Board has already determined that the combination of Spenser and

⁶ Petitioner reserves the right to argue that this limitation renders the claims indefinite.

Spenser II would be reasonably understood to have a crimped profile of less than 24F and permit endovascular delivery through the femoral artery. (*See id.*)

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.) Spenser’s valve may be crimped to a small 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, ¶142.)

Spenser’s Figure 44a illustrates a “preferred embodiment of the present invention[.]” (Ex. 1010, 26:30-34.) Therefore, 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, ¶143.)

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, ¶144.)

POSITAs would have reasonably expected Spenser’s valve would remain suitable for endovascular delivery after the addition of Spenser II’s compressible material. (Ex. 1003, ¶145.) 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 a compressible material 1 mm thick to Spenser’s 4-mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery. (Ex. 1003, ¶146; *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, ¶146.) Thus, POSITAs would have reasonably expected the combination of Spenser II’s 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 compressible to enable “a small enough delivery catheter to reach a target implant site.” (Ex. 1074, 8:23-39.) Norris explains, “In the compressed configuration 41, the fabric 10 can have a thickness 44 in the range of about 0.004–0.008 inches [0.102–0.203 mm] ... [which] can allow the fabric 10 to be easily inserted into a delivery catheter along with an intraluminal medical device.” (*Id.*, 7:66-8:3.) Norris’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, ¶147.)

Additionally, POSITAs would have recognized that Spenser II’s disclosure is broad, and that many types of fibrous, compressible sealing materials with a range of thicknesses and porosities could be used consistent with Spenser II’s teachings. (Ex. 1003, ¶146.) 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.*, ¶142-148.)

ii. Levi and Spenser II

Levi discloses “collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent.” (Ex. 1008, 1:57-67.) POSITAs would have understood Levi’s percutaneous delivery to include transfemoral delivery given Levi’s disclosure 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 having: 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, ¶¶150-151.)

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. (*Id.*) 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, ¶153.)

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, ¶154.) 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, ¶154.)

Additionally, POSITAs would have been aware of many types 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 that would enable endovascular delivery through a patient’s femoral artery, particularly given the disclosure of such delivery in Levi and Spenser II. (*Id.*, ¶155.)

g. Radially Expandable

Spenser and Levi disclose “wherein the heart valve assembly has a radially compressed and a radially expanded orientation.” (Ex. 1003, ¶¶156-157.)

Spenser’s valve “has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation].” (Ex. 1010, 27:67-28:2.) Similarly, Levi’s valve is “radially collapsible and expandable.” (Ex. 1008, Abstract.) Levi teaches that “[w]hen constructed of a plastically-expandable

material, the frame 12 (and thus the valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon or equivalent expansion mechanism.” (*Id.*, 6:20-24.)

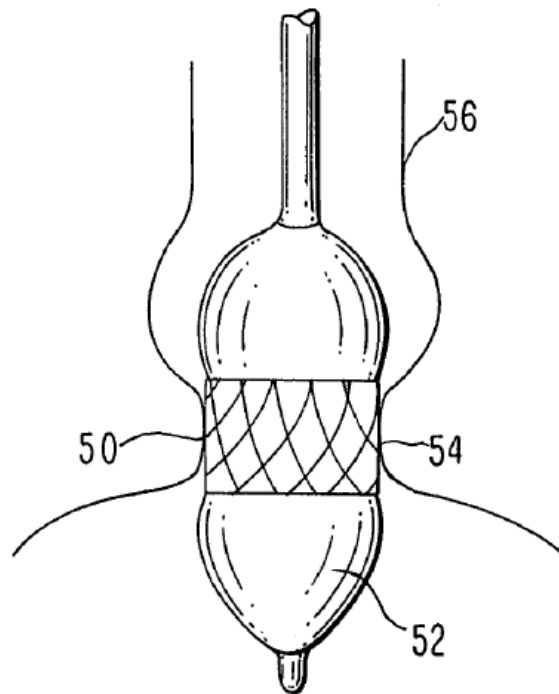
h. Fibers Pressed Against Native Leaflets

Spenser *or* Levi combined with Spenser II renders obvious “wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the radially extending fibers into engagement with native leaflets of the aorta of the patient.” (Ex. 1003, ¶158-164.)

i. Spenser and Spenser II

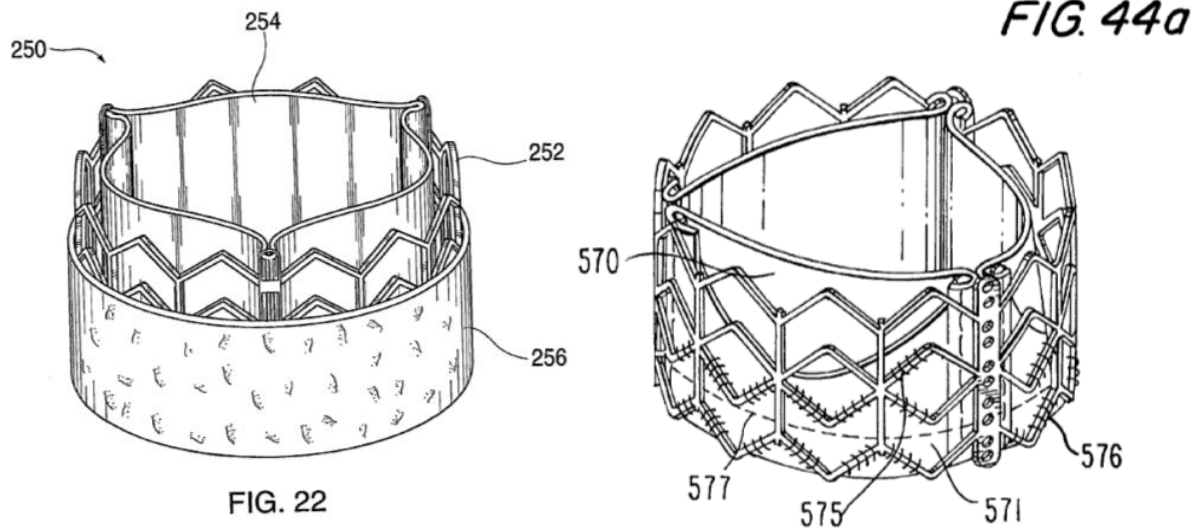
The Board found Spenser and Spenser II render this limitation obvious in a prior IPR. (Ex. 1119, 83-86.) The Board found POSITAs “reading Spenser II, would understand that, if the compressible material that is disposed along the outer surface of the stent extends entirely around the stent, then it would, necessarily, be in radial alignment with the native leaflets around the circumference of where the outer frame presses the native leaflets laterally.” (*Id.*)

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 frame press against the patient's aortic annulus. (Ex. 1003, ¶160.) Although not shown in Figure 4, POSITAs would have understood that 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):



(Ex. 1010, Fig. 44a; Fig. 1011, Fig. 22; Ex. 1003, ¶161.) Thus, when added to Spenser 44a's valve, the compressible material would press against the native annulus and aortic leaflets. (Ex. 1003, ¶162.)

ii. Levi and Spenser II

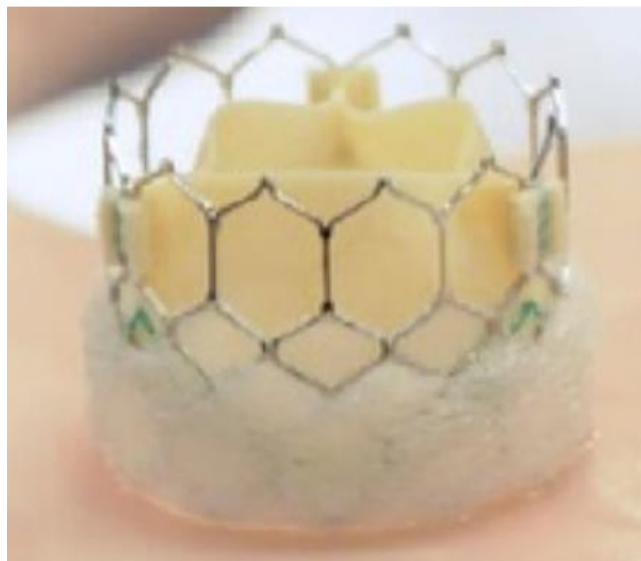
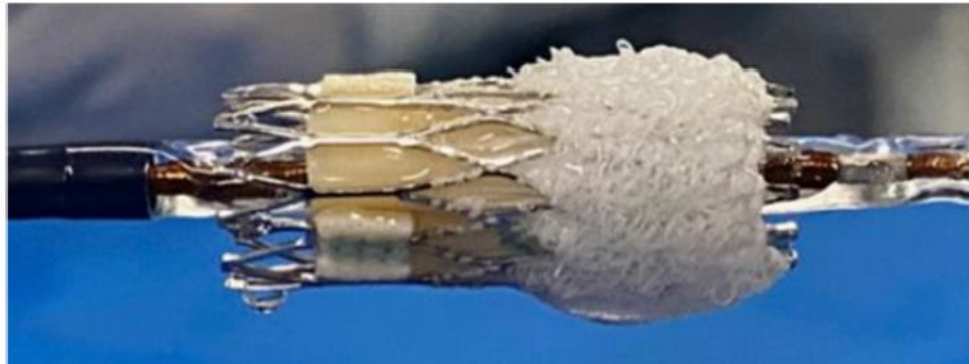
Levi's outer skirt "fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus." (Ex. 1008, 14:3-7.) When the outer skirt "form[s] a good fluid-tight seal between the valve and the native annulus," the fibers of the outer skirt would also seal against the native leaflets, which are attached to the native annulus and extend distally therefrom. (Ex. 1003, ¶163.) 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, ¶164.) 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 because Spenser II and Levi both disclose that level of covering is effective at creating a seal. (*Id.*) Thus, if the outer skirt presses against the leaflets, as admitted by PO, then so would the compressible material. (*Id.*)

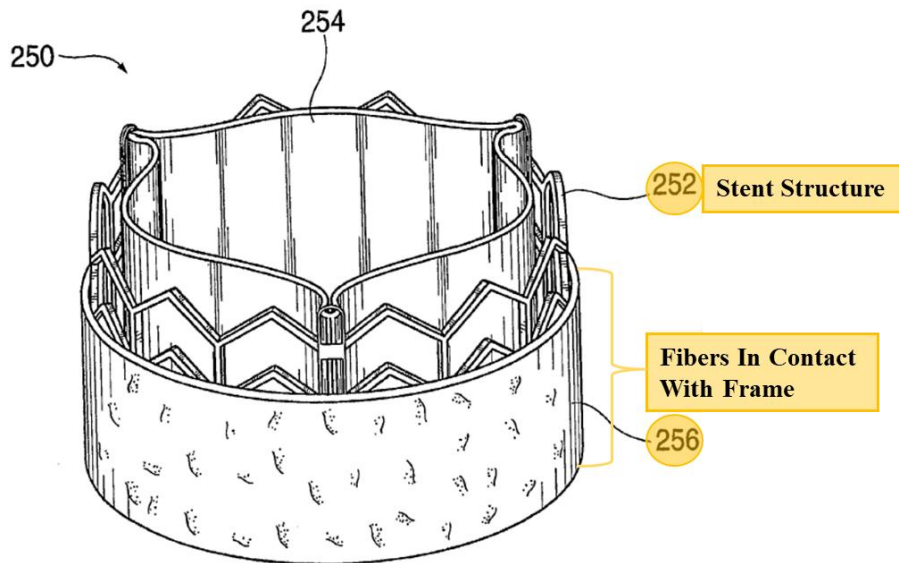
i. Fibers In Contact With Frame

Spenser *or* Levi combined with Spenser II render obvious “wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.” (Ex. 1003, ¶165-174.)

During prosecution, PO suggested that this limitation is met if the “sealing material is in contact with the outer frame.” (See Ex. 1002, 147-148.) PO's infringement contentions regarding Petitioner's SAPIEN 3 Ultra valve, which rely on the photos below, rely on a similar application of the limitation.



(See Ex. 1123, 329-330.) Spenser II discloses this limitation as applied by PO. Spenser II's compressible material is “disposed along an outer surface of the stent structure 252,” and therefore, the compressible material (sealing material) is in contact with the stent structure along the height of the sealing material in the radially expanded orientation, as shown in Fig. 22:

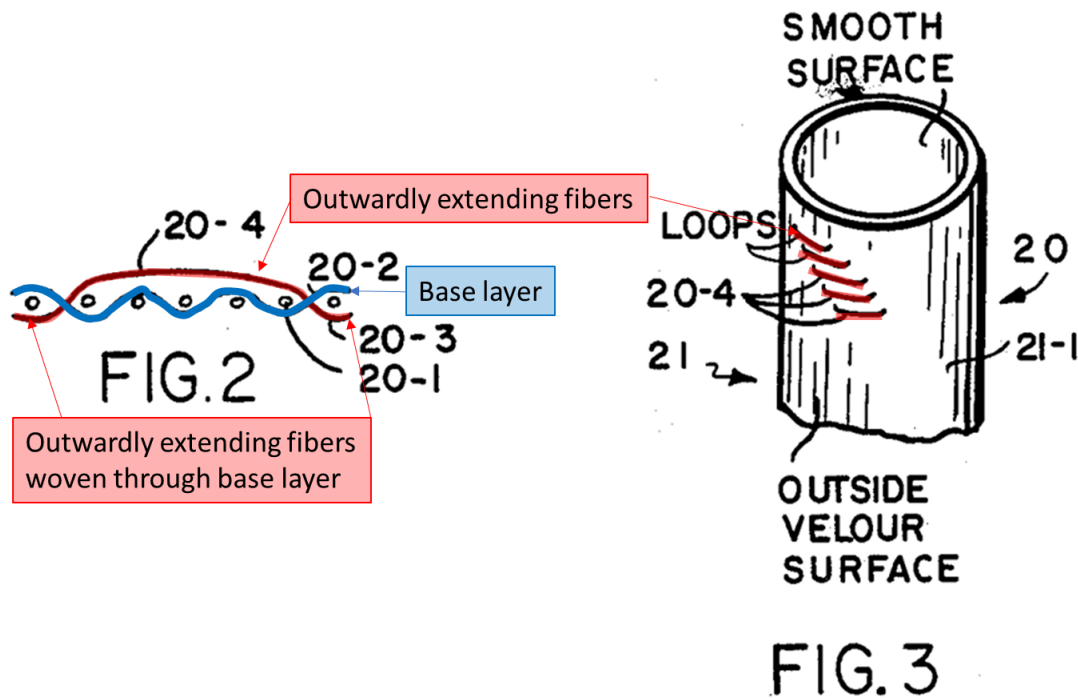


(Ex. 1011, [00145], Fig. 22; Ex. 1003, ¶166.)

The compressible material similarly contacts the outer frame along the height of the sealing material when the valve is crimped to its radially compressed orientation. When the material is compressed, the fibers are forced closer together thereby reducing the spaces 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 pressed into contact with the frame along the height of the sealing material, 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, ¶166.) Additionally, POSITAs would have appreciated 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, ¶166; *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 attaching Spenser II’s compressible material to Spenser’s Figure 44a or Levi’s valve in the same way, such that the material would be in contact with the frame of Figure 44a or Levi’s valve. (Ex. 1003, ¶166.) Thus, the radially extending fibers of the compressible material are “in contact with” the frame.

If this limitation has a different scope than PO has alleged, and requires the ***radially extending fibers*** of the sealing material to be in direct contact with the frame, then Spenser II still discloses this limitation in two ways. First, in Spenser II’s embodiments having a cloth/fabric with fibers extending from the surface, POSITAs would have understood that at least some of the fibers extending from the surface would be in direct contact with the frame. (Ex. 1003, ¶168.) In a cloth/fabric with fibers extending from a base layer embodiment, a POSITA would have understood that the radially extending fibers may be attached to the base layer by weaving or knitting the fibers through the base layer, as illustrated in Koch:

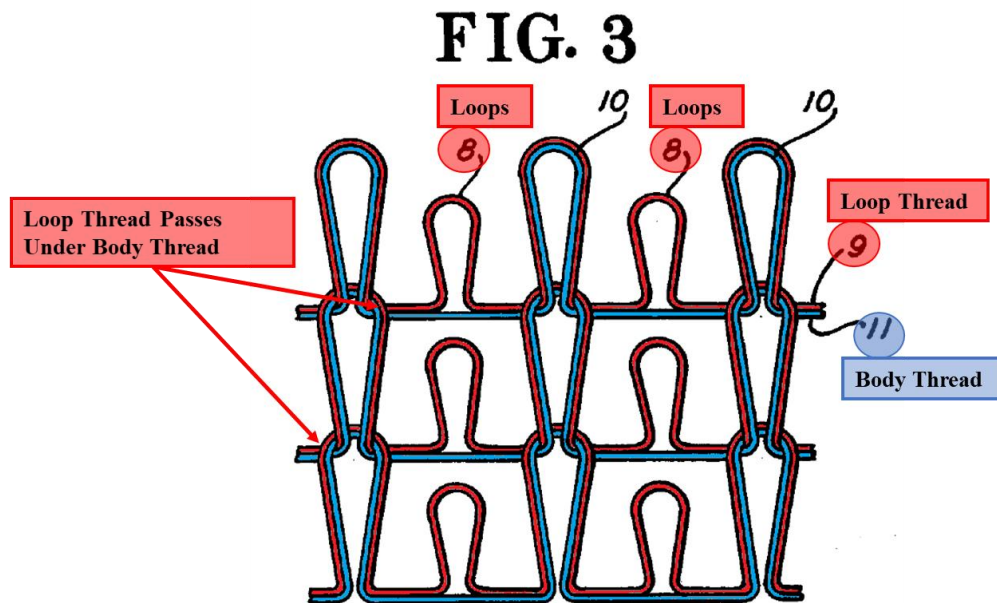


(Ex. 1134, 2:55-3:9, Figs. 2-3; Ex. 1003, ¶168.) As shown, the radially extending fibers (loops 20-4) extend through the base layer and, therefore, would be in contact with the frame when disposed along the exterior of a THV, as Spenser II teaches. (Ex. 1003, ¶168.) The prior art disclosed many fabrics having such a configuration, such as woven and knitted velours, that were used in cardiovascular implant devices prior to November 2012 and reflect the state of the art for the '310 patent.

For example, Norris, which the Board has relied upon in prior IPRs, describes making a “compressible resilient fabric 10” using the method illustrated in Koch above. (Ex. 1074, 13:31-41; Ex. 1003, ¶169.) Norris explains that embodiments of the compressible resilient fabric can be woven to include loops 32 formed of “floated

yarns.” *Id.*

As a further example, Sauvage discloses a “tubular prosthesis [that] is knitted with pile loops on the inside, as is customary with available knitting machines, and is then turned inside out” to provide a “velour exterior surface to enhance the retention of clotted blood and improve the rate of growth of tissue within the confines of the length thereof.” (Ex. 1135, 1:44-60.) Sauvage’s Figure 3 illustrates that the threads 9 forming the extending loops (radially extending fibers) repeatedly pass underneath the threads 11 forming the body of the fabric (backing layer) as the fabric is knitted:



(*Id.*, Fig. 3; Ex. 1003, ¶170.) As a result of this knitting pattern, the threads/fibers that make up the outwardly extending loops would extend all the way to the inside of the fabric once it is turned inside-out after knitting, and those fibers would be in

direct contact with the frame when the fabric is disposed along the exterior of a THV, as taught by Spenser II. (Ex. 1003, ¶170.) Once again, Norris discloses that its “compressible resilient fabric” can be made using similar knitting techniques. *Id.*

Koch, Sauvage, and Norris are representative of the state of the relevant art of velour fabrics for vascular prostheses prior to November 2012. POSITAs would have been motivated, and found it obvious, to make Spenser II’s compressible material out of such velour fabrics due to their known benefits. (Ex. 1003, ¶172.) Both Koch and Sauvage disclose that velour fabrics can promote tissue ingrowth, and Sauvage additionally teaches that its velour can enhance blood coagulation. (Ex. 1134, 1:26-30; Ex. 1135, 1:56-60.) Norris teaches that its velour fabrics can be highly compressible, allowing for smaller delivery profiles when added to cardiovascular devices. (Ex. 1074, 4:54-60, 9:18-39.) POSITAs would have reasonably expected success in using woven or knitted velour fabrics as Spenser II’s compressible material given their ubiquitous use and the predictability of those fabrics. (Ex. 1003, ¶172.)

Second, while Spenser II discloses embodiments where the compressible material is a cloth or fabric, a POSITA would have understood Spenser II to also disclose embodiments where the compressible fibers are attached directly to the frame, as opposed to the surface of a cloth. (Ex. 1003, ¶173.) Spenser II broadly

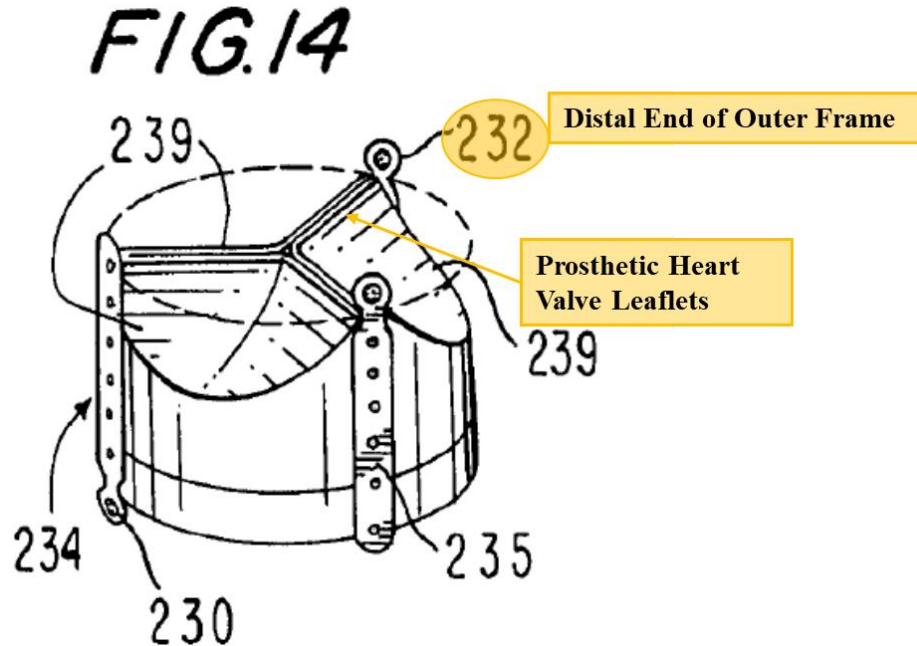
describes a “layer of compressible material.” (Ex. 1011, [00145].) Spenser II also makes clear that the cloth/fabric applies only “[i]n certain configurations,” and further discloses that the compressible material “**may** extend partially around the stent structure or **may** extend entirely around the stent structure, such as in the form of a sleeve.” (*Id.* (emphasis added).) In the embodiments where the fibers are attached directly to Spenser II’s frame, the fibers are in contact with the frame. (Ex. 1003, ¶173.)

j. Outer Frame Distally Further Than Leaflets

Spenser and Levi disclose “wherein the outer frame extends distally further than the prosthetic heart valve leaflets.” (Ex. 1003, ¶¶175-178.)

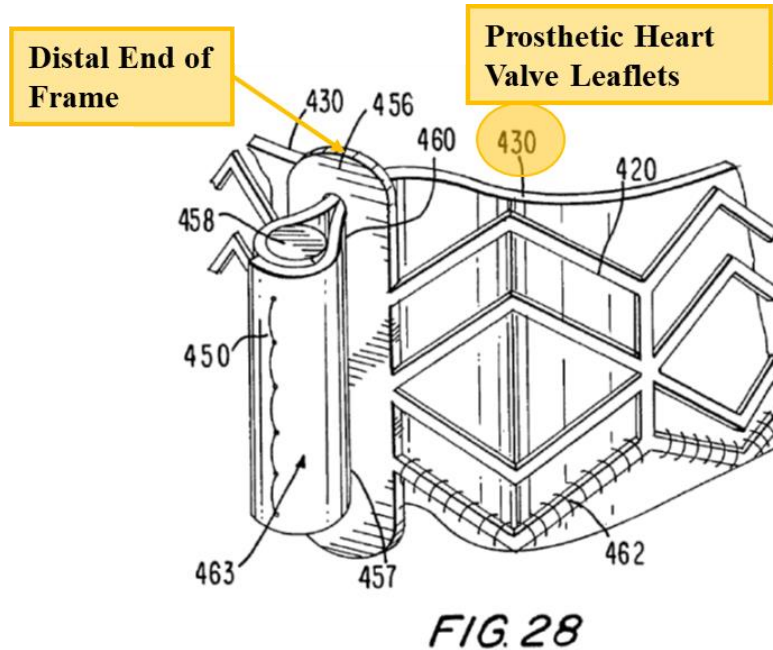
i. Spenser

Spenser discloses this limitation in two ways. (Ex. 1003, ¶¶176-177.) First, Spenser illustrates valves having “heavy metal markers [232] on the stent,” which allow visualization of the device during delivery:



(Ex. 1010, 16:27-51, Figs. 14-14a.) The portion of the frame having the marker extends distally further than the leaflets. (Ex. 1003, ¶176.) POSITAs would have been motivated to add markers to the Figure 44a stent to better visualize the stent during deployment. (*Id.*) POSITAs would have reasonably expected success in adding the markers because Spenser describes using the markers with stents like Figure 44a and metal markers were common in the field by 2012. (*Id.*)

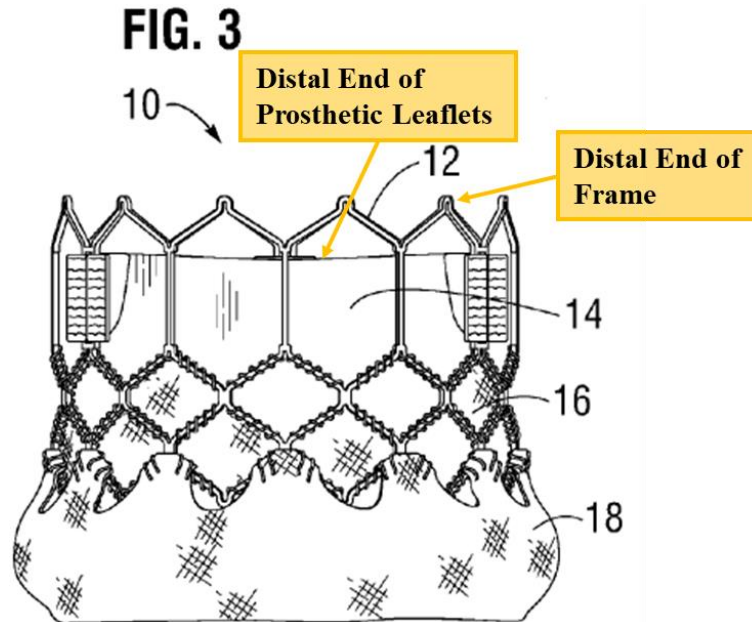
Second, Spenser illustrates a method of attaching the leaflets 430 to the frame 420:



(Ex. 1010, 21:46-67, Fig. 28.) The frame portion 456 extends distally further than the leaflet assembly. (Ex. 1003, ¶177.) POSITAs would have been motivated to use this method of attachment in Figure 44a to reduce stress points and abrasion on the leaflets. (Ex. 1010, 21:60-67, Ex. 1003, ¶177.) POSITAs would have reasonably expected success in using this method with Figure 44a because Spenser discloses using the method with a valve like Figure 44a. (Ex. 1003, ¶177.)

ii. Levi

“To protect against over-expansion of the leaflet structure 14,” Levi teaches that the “leaflet structure desirably is secured to the frame 12 below the upper row of struts 32.” (Ex. 1008, 8:11-13.) As shown below, the frame 12 extends distally further than the leaflets:



(*Id.*, Fig. 3; Ex. 1003, ¶178.)

2. Claim 3

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve.” (Ex. 1003, ¶¶179-180.)

Spenser and Levi disclose PET graft coverings that extend around and are attached to the prosthetic heart valve leaflets. *Supra* §VIII.A.1.b. Because the graft coverings are sutured to the leaflets, POSITAs would have understood that Spenser’s and Levi’s graft coverings “support[]” the leaflets. (Ex. 1003, ¶180.) Therefore, if a graft covering can be an inner frame, Spenser’s PET 571 and Levi’s inner skirt form

an inner frame for supporting the prosthetic heart valve. (*Id.*, ¶180.)⁷

3. Claim 5

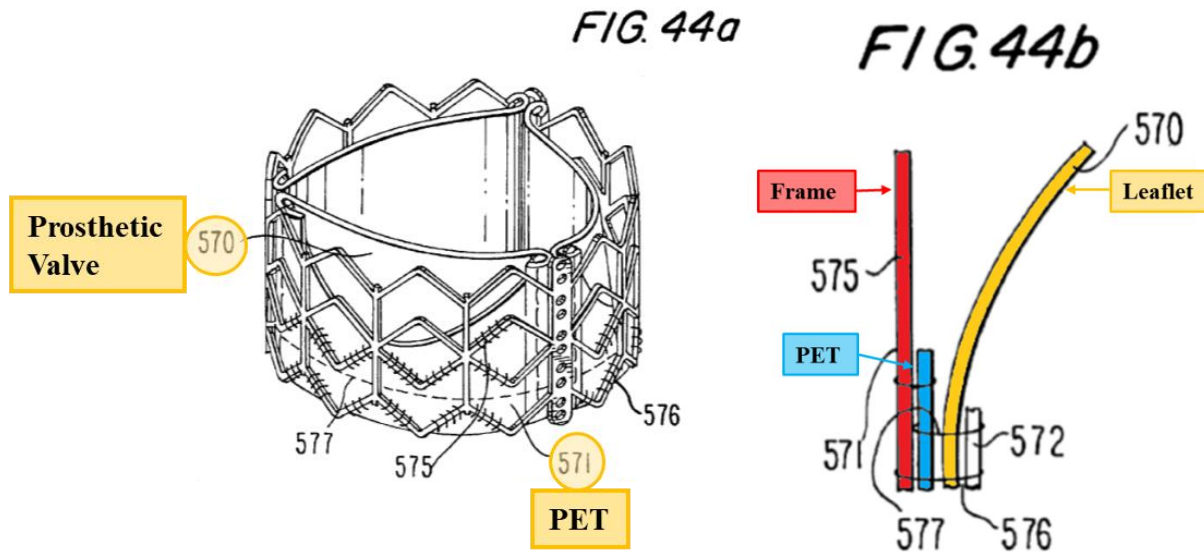
Claim 5 is an independent claim that includes many of the limitations in claim 1. Spenser **or** Levi in combination with Spenser II renders those limitations obvious as explained in claim 1. *Supra* §VIII.A.1. Spenser **or** Levi in combination with Spenser II renders obvious the additional limitations of claim 5 for the reasons explained below.

a. Graft Covering

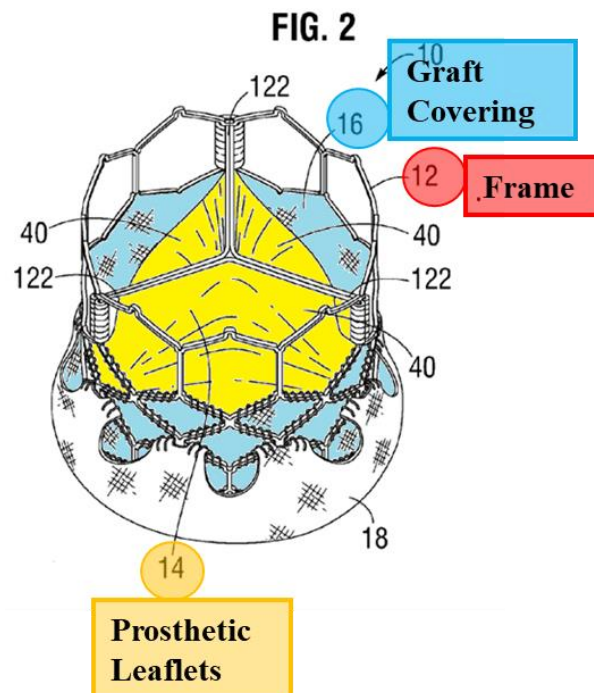
Spenser and Levi disclose “a graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends radially outwardly around the prosthetic heart valve leaflets and radially inwardly of an outer frame for providing sealing to the prosthetic heart valve leaflets.” (Ex. 1003, ¶¶183-186.)

Spenser’s PET 571 (graft covering) extends radially outwardly around the prosthetic heart valve leaflets and radially inwardly of the outer frame:

⁷ Petitioner preserves arguments that the ’310 patent does not describe a graft covering that forms an “inner frame” and that a graft covering cannot be an “inner frame.”



(Ex. 1010, 26:30-34, Fig. 44a-b; Ex. 1003, ¶184.) Levi's inner skirt also extends radially outwardly around the prosthetic heart valve leaflets and radially inwardly of the outer frame:



(Ex. 1008, Fig. 2; Ex. 1003, ¶¶185-186.)

Spenser and Levi disclose the other recited features of the graft covering for the reasons explained in claim 1. *Supra* §VIII.A.1.b.

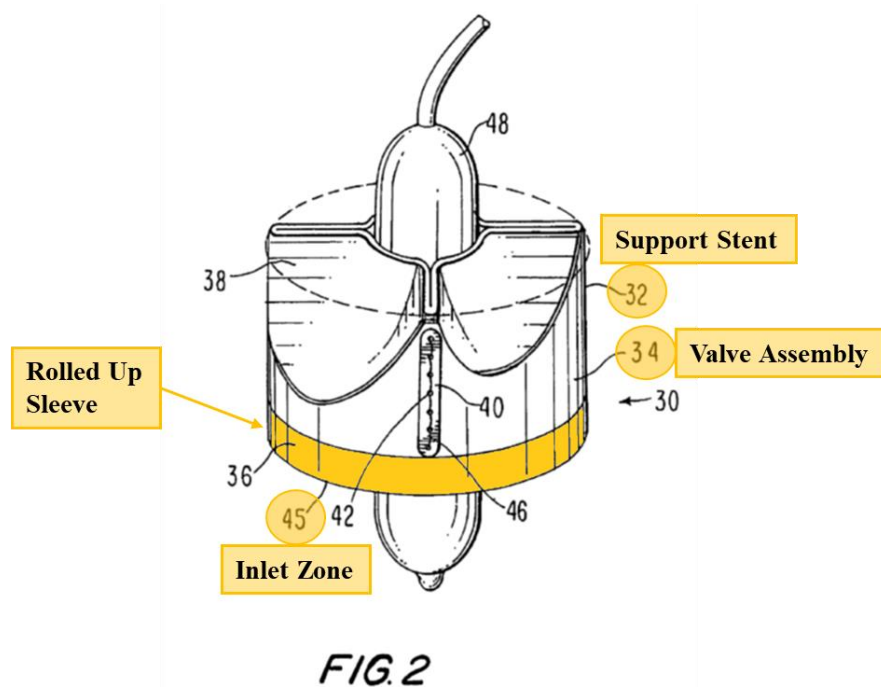
b. Extending Graft Covering

Spenser and Levi disclose “wherein the graft covering extends beyond a proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” (Ex. 1003, ¶¶189-196.)

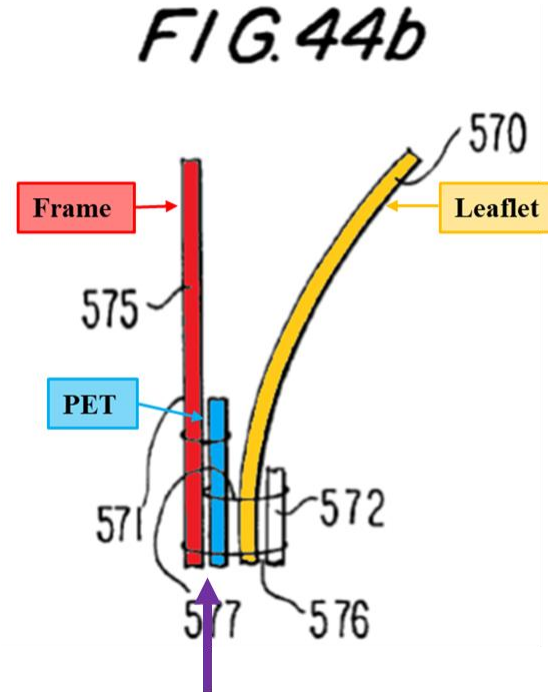
i. Spenser

The Board found Spenser and Spenser II render this limitation obvious in a prior IPR. (Ex. 1118, 22-23, 74.) The Board’s finding was correct. Spenser discloses a “portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve [yellow], which enhances the sealing of the device at the valve inlet”⁸:

⁸ In Figure 2, the dashed lines indicate the support stent 32, which is not shown in full. (Ex. 1010, 13:63-66.)



(Ex. 1010, 14:6-9, Fig. 2; *see also* 12:51-53.) POSITAs would have found it obvious to add this feature to Figure 44a by extending Figure 44a’s inner PET 571 proximally further than the proximal end of the outer frame. (Ex. 1003, ¶192.) POSITAs would have been motivated to extend PET 571 to further “enhance[] the sealing of the device at the valve inlet.” (Ex. 1010, 14:6-9, 12:51-53; Ex. 1003, ¶192.) POSITAs would have understood that extending the inner PET fabric over the frame’s proximal end would prevent blood from leaking between the PET 571 and frame 575 (*see* purple arrow). (Ex. 1003, ¶192.)



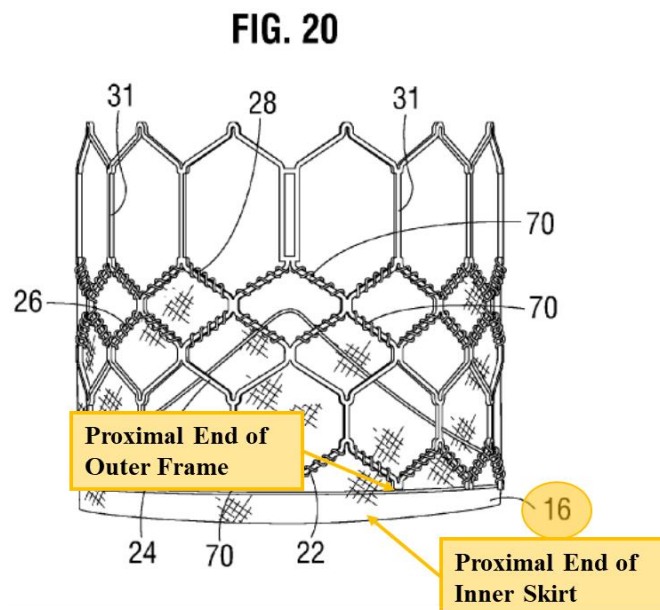
This motivation would not have been affected by the addition of Spenser II's compressible material because the compressible material serves a different purpose than the extended graft covering. Extending the graft covering over the outer frame's proximal end prevents blood from leaking between the graft covering and outer frame. (Ex. 1003, ¶192.) In contrast, the compressible material prevents blood from leaking between the THV and surrounding tissue. (Ex. 1007, 1120; Ex. 1011, [00145].)

POSITAs would have reasonably expected success in extending Figure 44a's PET 571 because Spenser's Figures 2 and 44a describe similar THVs. (See Ex. 1010, 14:41-44, 26:30-54; Ex. 1003, ¶193.) Both THVs include an inner PET layer that is stitched to a balloon-expandable frame that has three parallel support beams

for attaching the leaflets. (Ex. 1010, 13:62-14:3; 26:30-54, Figs. 2, 44a; *see also* 9a-9f.) POSITAs would have reasonably expected that the teachings of Figure 2 would also apply to Figure 44a due to these similarities. (Ex. 1003, ¶193.)

ii. **Levi**

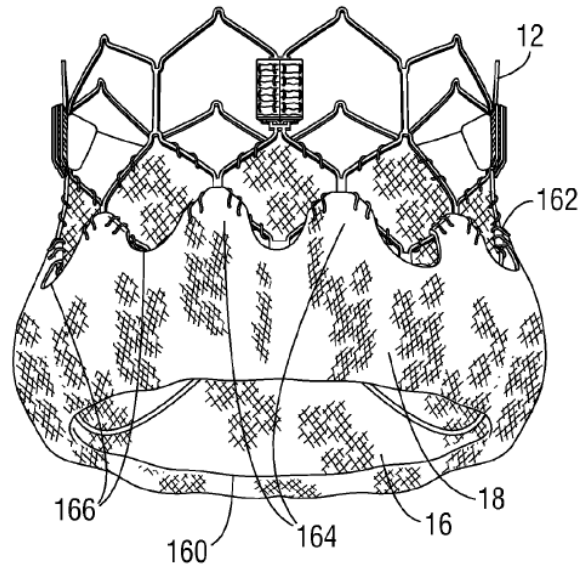
Levi discloses an inner PET skirt sutured to the interior surface of the frame. *Supra* §VIII.B.1.b. The lower edge of Levi's inner skirt extends beyond the proximal end of the frame:



(Ex. 1008, Fig. 20.)

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

FIG. 42



Because the inner skirt extends beyond the proximal end of the outer frame, the attachment of the outer skirt necessarily causes the lower edge of the inner skirt 16 to extend over and cover the proximal end of the outer frame. (Ex. 1003, ¶195.)

Alternatively, POSITAs would have found it obvious to extend Levi's inner skirt over the proximal end of the frame to cover the proximal end. (*Id.*, ¶196.) Levi discloses that the "upper edge portion [distal] of the [inner] skirt is wrapped around the upper surfaces of struts 28 and secured in place with sutures 70." (Ex. 1008, 10:12-26, Fig. 20.) The wrapping "provides for a stronger and more durable attachment of the skirt to the frame." (*Id.*, 10:26-28.) POSITAs would have been motivated to apply this technique to the lower (proximal) edge of the inner skirt to create a stronger attachment between the inner skirt and frame. (Ex. 1003, ¶196.)

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

c. Circumferential Surface

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the plurality of radially extending fibers form a circumferential surface that extends outwardly of the outer frame.” (Ex. 1003, ¶¶197-198.)

Spenser II's Figure 22 discloses such a “circumferential surface”:

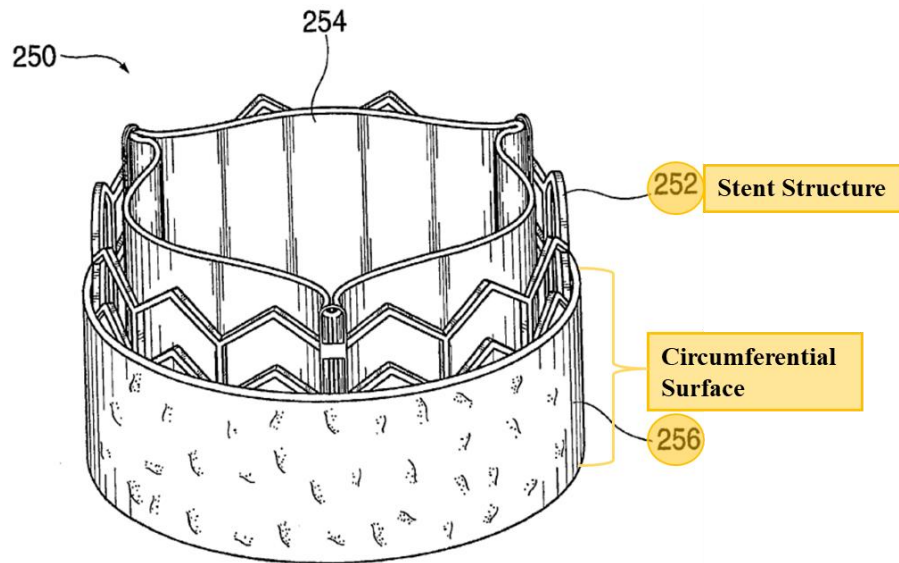


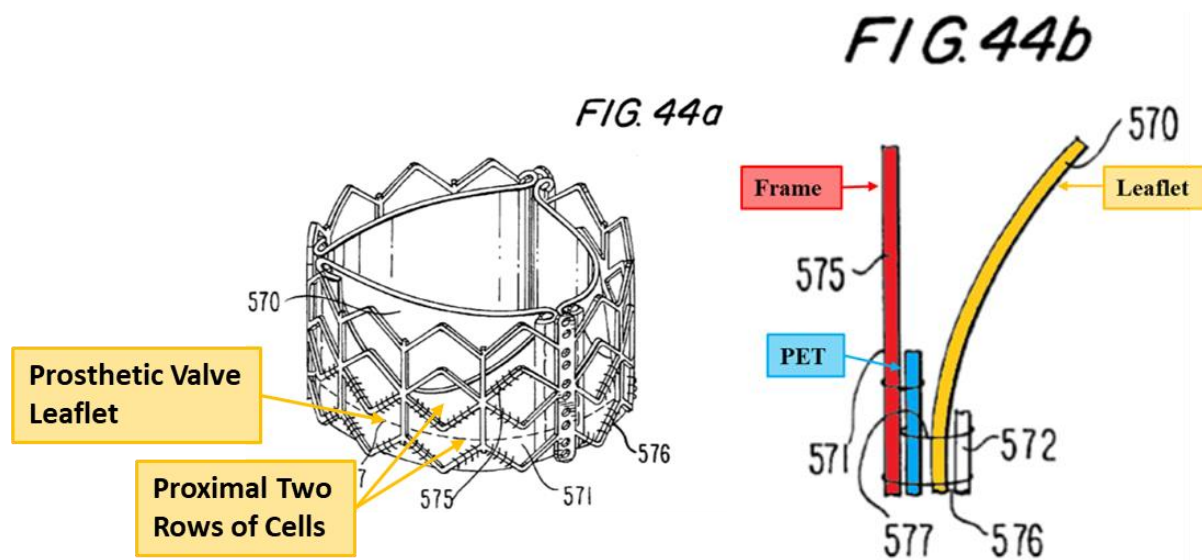
FIG. 22

(Ex. 1011, Fig. 22; Ex. 1003, ¶198.)

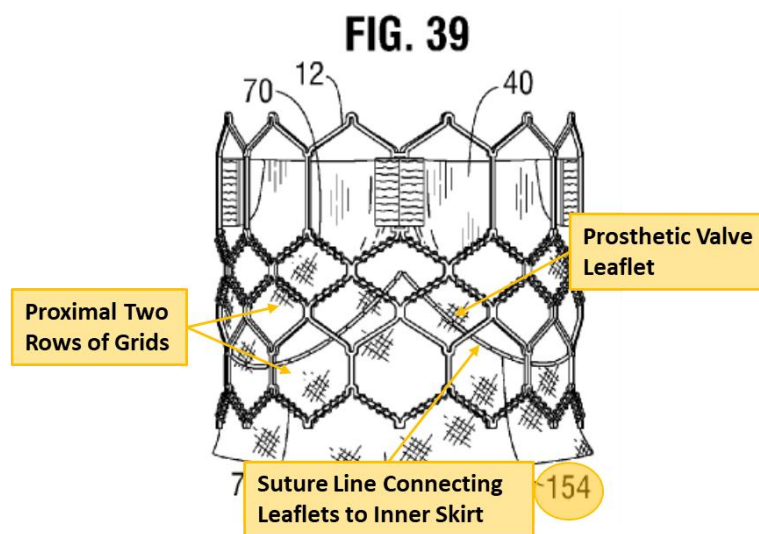
d. Radial Overlap With Prosthetic Leaflets

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the fibers radially overlap with the prosthetic heart valve leaflets.” (Ex. 1003, ¶¶199-200.)

If Spenser II’s compressible material were added to Spenser’s Figure 44a or Levi’s valve, the compressible material would extend over at least the two proximal rows of cells in the frame. *Supra* §VIII.A.1.d. Spenser’s prosthetic leaflets extend to the proximal end of the frame and, therefore, overlap with the first two rows of cells:



(Ex. 1010, Fig. 44a-b.) Similarly, Levi's prosthetic valve leaflets are stitched to the inner skirt at the suture line in Figure 39, which overlaps with the proximal two rows of cells:



(Ex. 1008, Fig. 39; Ex. 1003, ¶200.)

e. Expandable Assembly

Spenser and Levi disclose “wherein the valve assembly is expandable during endovascular deployment” as explained in claim 1. *Supra* §§VIII.A.1.f-g.

f. Fibers In Contact With Frame

Spenser *or* Levi in combination with Spenser II renders obvious “wherein the plurality of fibers is in contact with the at least a first two proximal circumferentially extending rows of cells along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation” as explained in claim 1. *Supra* §§VIII.A.1.d, VIII.A.1.i.

4. Claim 8

If a graft covering can be an inner frame, Spenser and Levi disclose “wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve” as explained in claim 3. *Supra* §VIII.A.3.

5. Claim 11

Claim 11 is an independent claim that includes the limitations of claim 1 with three exceptions: claim 11 recites (1) a graft covering “engaging prosthetic heart valve leaflets” instead of “housing” the leaflets; (2) a “frame” rather than an “outer frame”; and (3) a sealing material with “outwardly extending” fibers instead of “radially extending” fibers. Spenser *or* Levi in combination with Spenser II renders

the limitations of claim 1 obvious for the reasons previously explained. *Supra* §VIII.A.1.

As for the three exceptions, Spenser’s PET 571 is attached to the prosthetic leaflets via suture 577 and therefore “engag[es]” the leaflets. (Ex. 1010, 26:30-54, Fig. 44b; Ex. 1003, ¶209.) Similarly, Levi’s inner skirt is sutured to, and therefore “engag[es]” the prosthetic leaflets. *Supra* §VIII.A.1.b.

Spenser and Levi disclose a “frame,” as recited in claim 11, for the same reasons they disclose an “outer frame,” as explained in claim 1. *Supra* §VIII.A.1.c.

Spenser II discloses a sealing material with “outwardly extending” fibers for the same reasons it discloses “radially extending” fibers, as explained in claim 1. *Supra* §VIII.A.1.d.

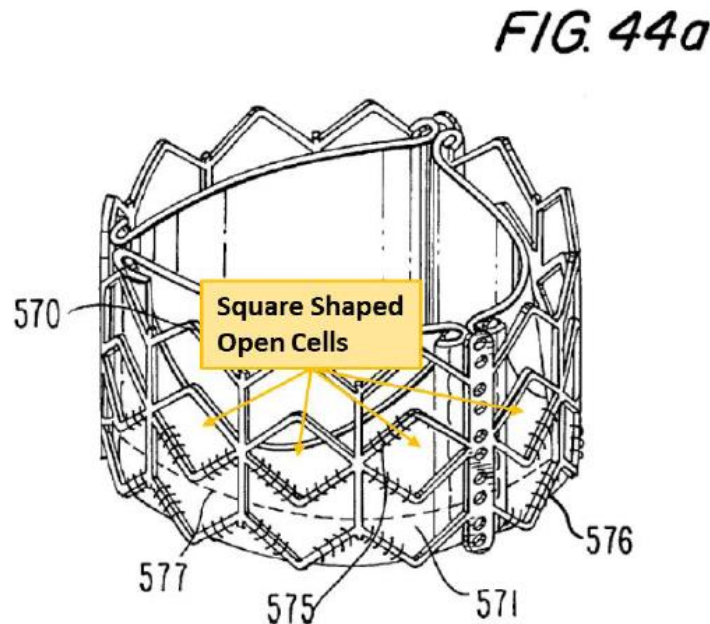
6. Claim 13

If a graft covering can be an inner frame, Spenser and Levi disclose “wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve” as explained in claim 3. *Supra* §VIII.A.3.

B. Ground 1: Spenser and Spenser II Also Render Obvious Claims 2, 7, and 12

Claims 2, 7, and 12 are dependent claims that depend from claims 1, 5, and 11 respectively and require that the “open cells of the open cell configuration are a

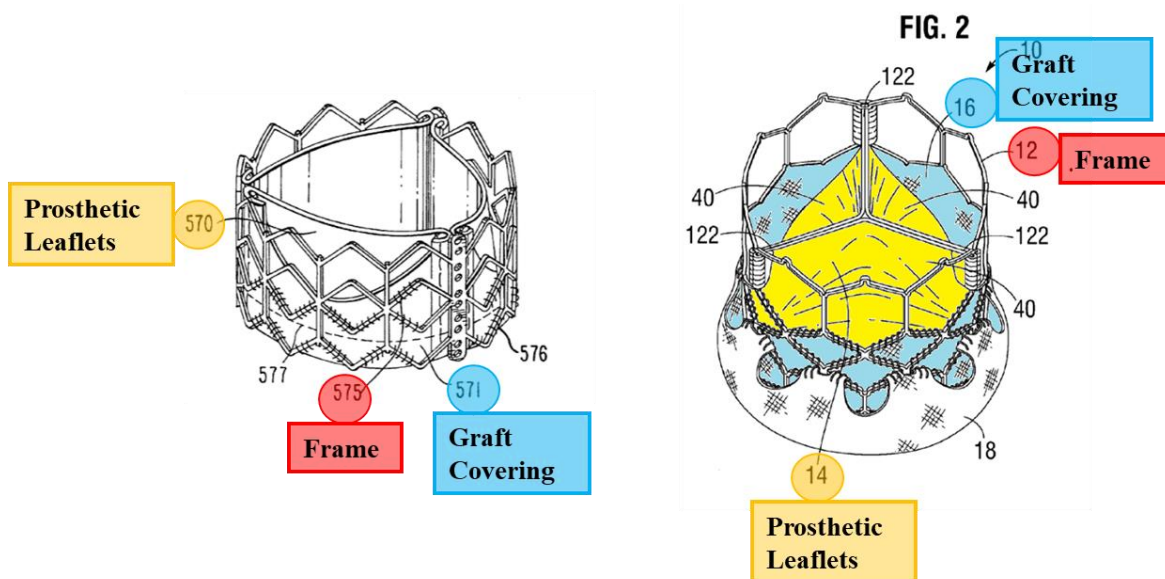
square shape.” Spenser discloses this limitation. Figure 44a’s outer frame comprises three rows of open cells, and the middle cells are a square shape:



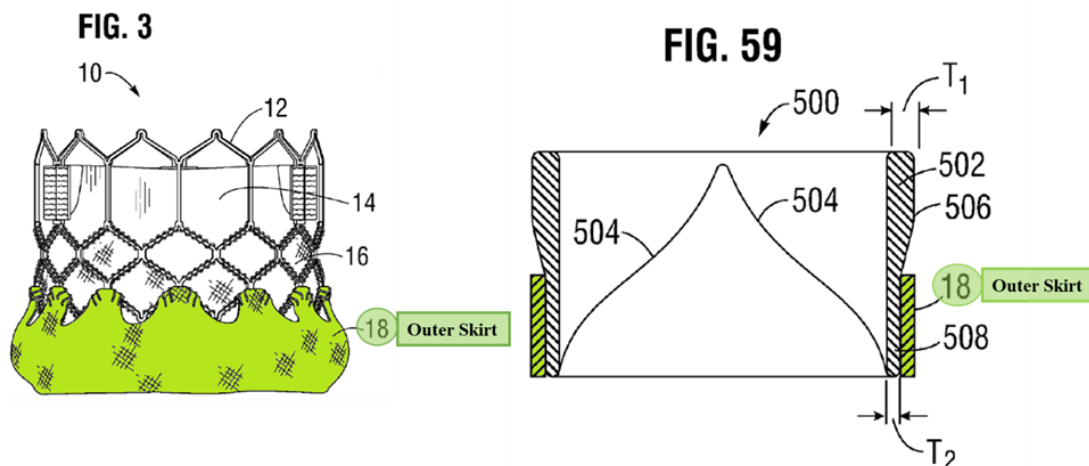
(Ex. 1010, Fig. 44a; Ex. 1003, ¶218.) Spenser and Spenser II render the remaining limitations of claims 2, 7, and 12 obvious for the reasons explained in Grounds 1-2 above. *Supra* §VIII.A. Accordingly, claims 2, 7, and 12 would have been obvious in view of Spenser and Spenser II. (Ex. 1003, ¶219.)

C. Grounds 3-4: Claims 1, 3, 5, 8, 11, 13 Obvious Over Spenser or Levi in Combination with Chuter

As discussed above, Spenser (left) and Levi (right) describe heart valves having a frame, a graft covering, and prosthetic leaflets:

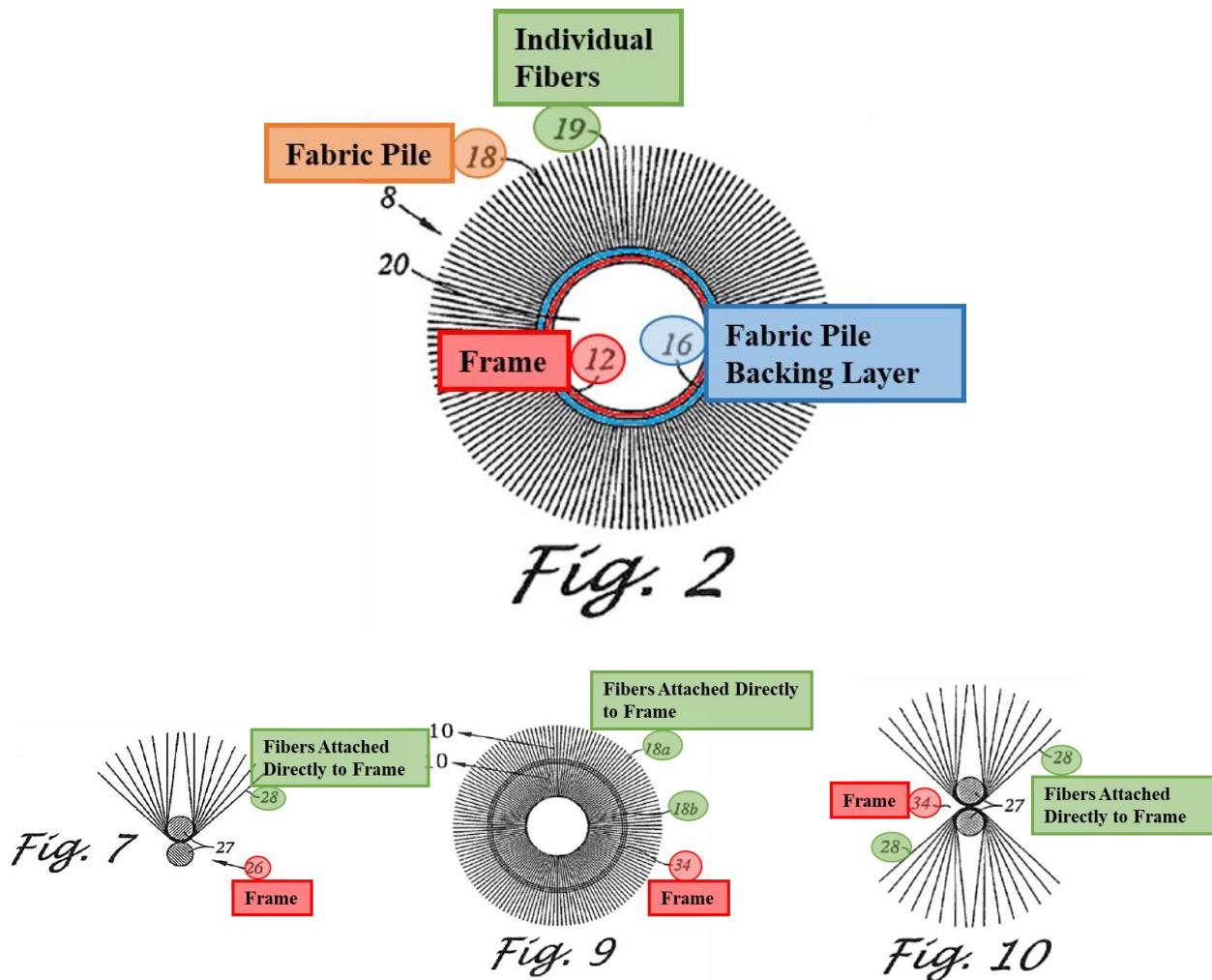


(Ex. 1010, 11:66-12:17, Fig. 44a; Ex. 1008, Fig. 2.) Levi also discloses a fabric skirt secured to the frame's exterior surface for preventing PVL. (Ex. 1008, 13:50-66, 16:51-54, 17:12-18, Figs. 3, 59.)



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” layer (Fig. 2) or extend directly from the frame without any backing layer (Figs. 7, 9-10). (*Id.*, [0054]-[0057], Figs. 1-10.)

As discussed below, POSITAs would have found it obvious to add Chuter’s “fiber pile” to Spenser’s valves or to replace Levi’s outer skirt with Chuter’s “fiber pile.” (Ex. 1003, ¶¶227-240.) 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 claims 1, 3, 5, 8, 11, and 13 obvious.

1. Claim 1

Spenser **or** Levi in combination with Chuter renders claim 1 obvious. (Ex. 1003, ¶¶223-254.)

a. Preamble

If the preamble is limiting, Spenser and Levi disclose this limitation as explained in Grounds 1-2. *Supra* §VIII.A.1.a.

b. Graft Covering

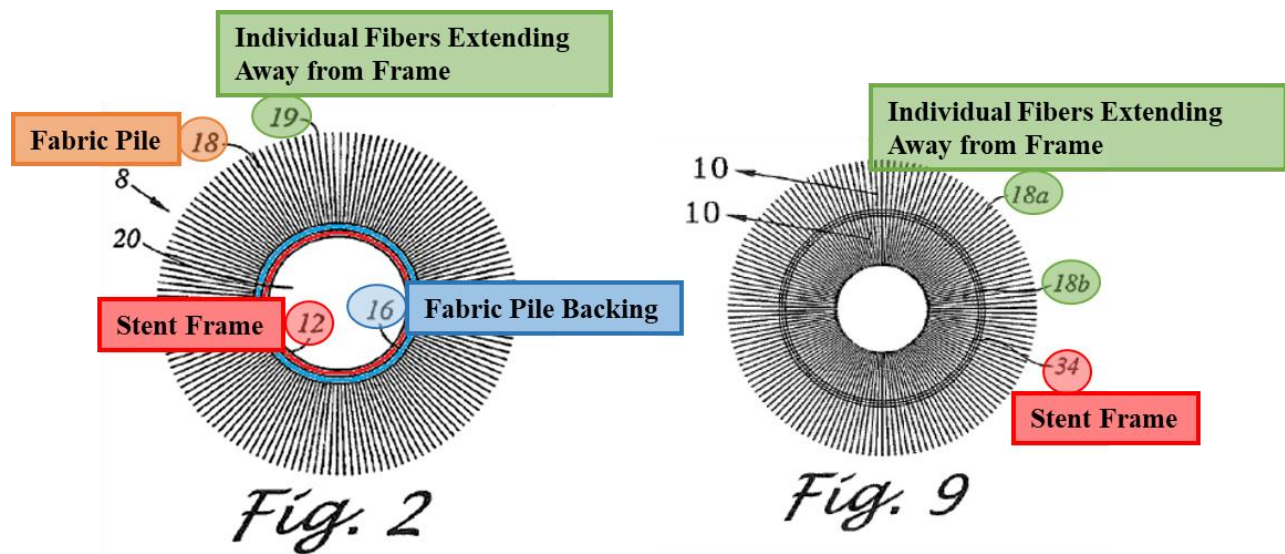
Spenser and Levi disclose this limitation as explained in Grounds 1-2. *Supra* § VIII.A.1.b.

c. Outer Frame

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

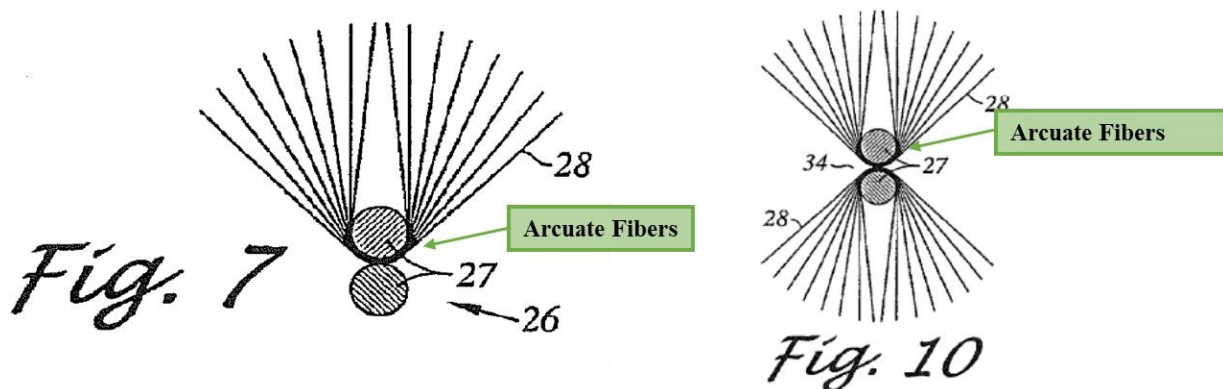
d. Sealing Material

Chuter’s “fiber pile” includes individual 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 layer, 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, ¶229.)

In Chuter’s embodiments having individual outwardly extending fibers that extend from a backing layer, 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 layer, likely by weaving or knitting the fibers into the backing layer. (*Id.*, ¶230.)

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. (Ex. 1003, ¶231.)

i. Spenser and Chuter

POSITAs would have recognized that Spenser’s THVs would benefit from Chuter’s fiber pile. (Ex. 1003, ¶232.) 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 PVL (adding a fabric pile) to Spenser’s known valves, 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, ¶232.)

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 and “employed in the present invention,” which POSITAs would have understood to encompass the embodiments of the fiber having a “backing” layer and embodiments lacking the “backing” layer. (Ex. 1116, [0003]; Ex. 1003, ¶234.) Indeed, Chuter discloses combining the fiber pile with the same balloon-expandable frames incorporated into the ’310 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). Thus, while the preferred embodiment in Chuter includes a double-wire frame, Chuter’s invention is not limited to such frames and encompasses many frames. (Ex. 1003, ¶¶233-235.)

Additionally, the ’310 patent never discloses how to attach the collagen fibers,

or any other fibers, to the frame. (See Ex. 1001, 12:53-56.) Rather, the '310 patent presumes POSITAs possessed the know-how to attach fibers to THV frames. Indeed, PO's expert admitted that the '310 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.

Spenser discloses two rows of cells at the inflow end of the frame as explained in Grounds 1-2. (*Supra* §VIII.A.1.d.i.) POSITAs would have found it obvious to position Chuter's fiber pile to have a height that partially extends over at least the proximal two rows of cells on Spenser's valves. (Ex. 1003, ¶237.) POSITAs would have been motivated to do so to ensure that the extending fibers of the fiber pile would overlap with, and press against, the patient's diseased native aortic leaflets when the valve was implanted so that the fibers could form a seal and fill gaps between the native leaflets and the THV. (*Id.*) Moreover, multiple references, including Levi and Spenser II, disclosed that covering two rows of cells provided effective sealing. (Ex. 1011, [00145], Fig. 22; Ex. 1008, Fig. 42.)

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.d.ii, VIII.B.1.d.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, ¶238.)

Levi discloses two rows of cells at the inflow end of the frame as explained in Grounds 1-2. (*Supra* §VIII.A.1.d.ii.) POSITAs would have found it obvious to position Chuter's fiber pile to have a height that partially extends over at least the proximal two rows of cells on Levi's valves. (Ex. 1003, ¶240.) POSITAs would have been motivated to do so to ensure that the extending fibers of the fiber pile would overlap with, and press against, the patient's diseased native aortic leaflets when the valve was implanted so that the fibers could form a seal and fill gaps between the native leaflets and the THV. (*Id.*) Additionally, Levi discloses a sealing material extending over the proximal two rows of cells, providing POSITAs with further motivation to select such an arrangement for Chuter's fiber pile. (*Id.*)

e. Polyester Graft Covering

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

f. Endovascularly Deployed

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.f.) 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, ¶¶242-246.)

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 this disclosure to include the femoral artery. (Ex. 1003, ¶244.) 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, ¶244.) Additionally, POSITAs would have understood that the lengths and densities of the fabric pile could be optimized for

delivery through the femoral artery. (*Id.*)

g. Radially Expandable

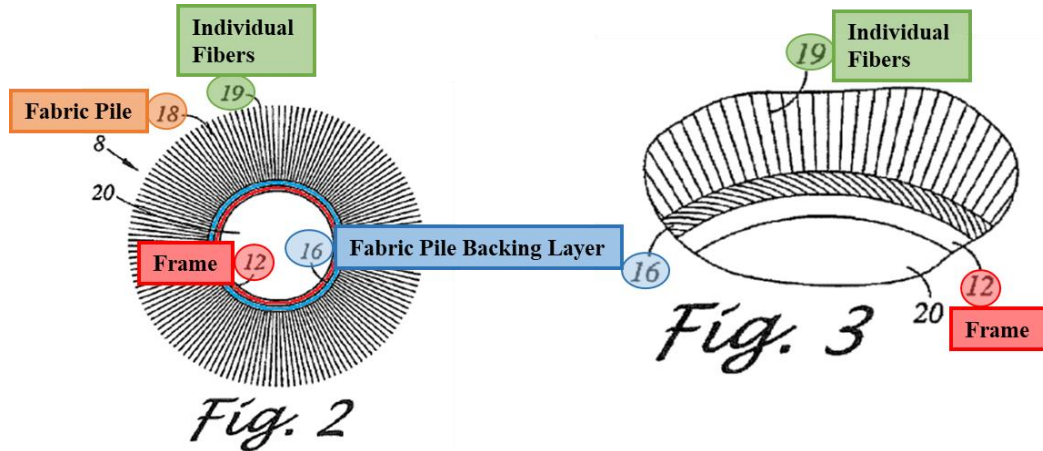
Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.g.)

h. Fibers Pressed Against Native Leaflets

Levi and Spenser disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.1.h.) Chuter’s radially 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, ¶249.)

i. Fibers In Contact With Frame

Chuter discloses this limitation in two ways. (Ex. 1003, ¶¶250-253.) First, Chuter describes embodiments having a “fabric pile backing” layer 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” layer is composed of fibers, as illustrated in Chuter’s Figure 3. (*Id.*, Fig. 3; Ex. 1003, ¶251.) Such a configuration was known in the art, as taught by Norris.

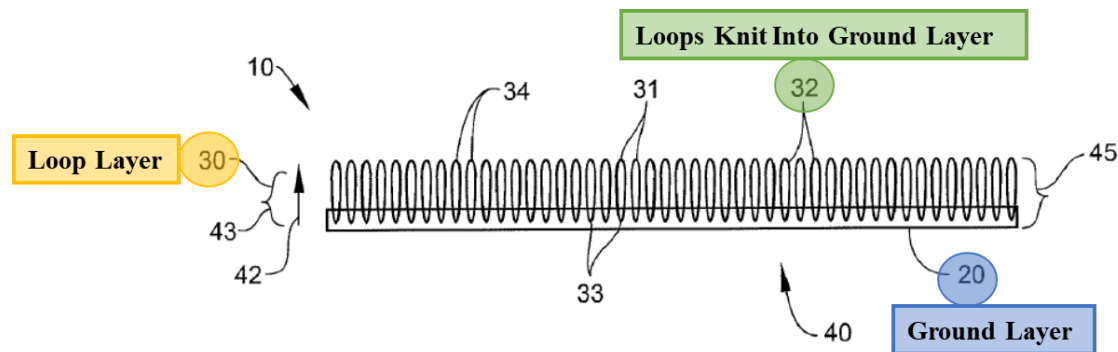


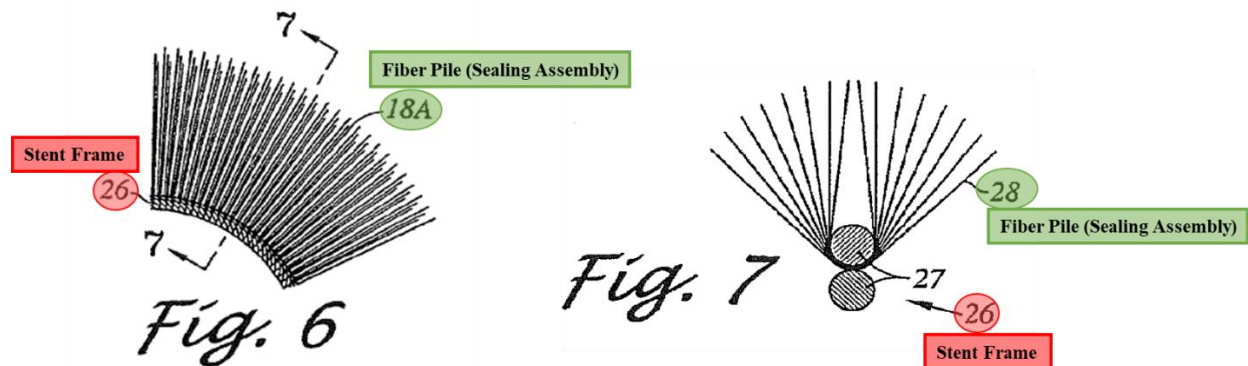
Fig. 1

(Ex. 1074, 4:22-26, Fig. 1 (disclosing a compressible fabric for stents and heart valves comprising a ground layer of knitted fibers with loops of fibers extending therefrom).)

The fibers of Chuter’s fabric pile backing layer are in contact with the stent frame. (Ex. 1116, Figs. 2-3; Ex. 1003, ¶251.) Moreover, as explained previously

for Spenser II, POSITAs would have understood that the individual fibers extending from Chuter's fabric pile backing layer would have been woven or knitted all the way through the thickness of the backing layer, consistent with numerous examples in the prior art. (*Supra* §VIII.A.1.i.) Accordingly, if this limitation requires the radially extending fibers of the sealing material to be in direct contact with the frame, POSITAs would have understood that the individual fibers extending from Chuter's backing layer would be "in contact" with the frame for the same reasons explained with respect to Spenser II's compressible material. (*Id.*)

Second, Chuter discloses embodiments without the "backing layer," where individual fibers are attached directly to the frame:



(Ex. 1116, [0056]-[0057], Figs. 5-10.) As illustrated in Figures 6 and 7, the fibers in these embodiments are in contact with the frame. (Ex. 1116, [0057], Figs. 6-7; Ex. 1003, ¶253.)

j. Outer Frame Distally Further Than Leaflets

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

2. Claim 3

If a graft covering can be an inner frame, Spenser and Levi disclose the limitations of claim 3 as explained in Grounds 1-2. (*Supra* §VIII.A.3.)

3. Claim 5

Claim 5 is an independent claim that includes many of the limitations in claim 1. Spenser *or* Levi in combination with Chuter renders those limitations obvious as explained in claim 1. (*Supra* §VIII.B.1.) Spenser *or* Levi in combination with Chuter renders obvious the additional limitations of claim 5 for the reasons discussed below.

a. Graft Covering

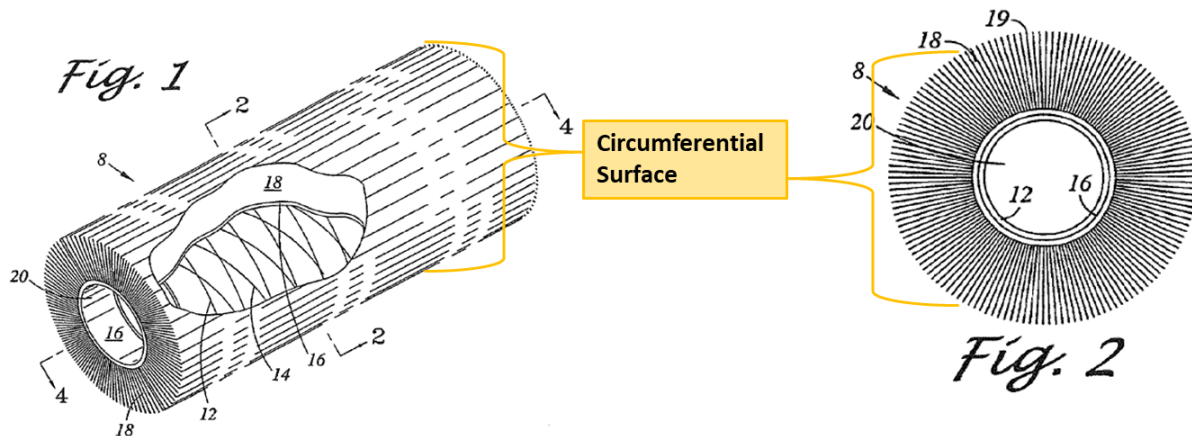
Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.4.a.)

b. Extending Graft Covering

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.4.b.)

c. Circumferential Surface

The radially extending fibers of Chuter’s fiber pile “form a circumferential surface that extends outwardly of the outer frame,” as shown in Figures 1 and 2:



(Ex. 1116, Figs. 1 & 2; Ex. 1003, ¶263.)

d. Radial Overlap With Prosthetic Leaflets

POSITAs would have found it obvious to position Chuter’s fiber pile over at least the proximal two rows of cells of Spenser’s and Levi’s valves for the reasons explained in claim 1. (*Supra* §VIII.B.1.d.) Such positioning would cause the fibers of Chuter’s fiber pile to radially overlap with the prosthetic leaflets for the reasons explained in Grounds 1-2. (*Supra* §VIII.A.4.d.)

e. Expandable Assembly

Spenser and Levi disclose this limitation as explained in Grounds 1-2. (*Supra* §VIII.A.4.e.)

f. Fibers In Contact With Frame

Spenser *or* Levi in combination with Chuter renders this limitation obvious for the reasons explained in claim 1. (*Supra* §VIII.B.1.i.)

4. Claim 8

If a graft covering can be an inner frame, Spenser and Levi disclose the limitations of claim 3 as explained in Grounds 1-2. (*Supra* §VIII.A.6.)

5. Claim 11

Claim 11 is an independent claim that includes the limitations of claim 1 with three exceptions as explained in Grounds 1-2. Spenser *or* Levi in combination with Chuter renders obvious the limitations of claim 1 for the reasons explained previously. (*Supra* §VIII.B.1.) With respect to the exceptions, Spenser and Levi disclose a graft covering that “engag[es]” the prosthetic leaflets instead of “housing” the leaflets. (*Supra* §VIII.A.7.) Spenser and Levi also disclose the “frame” recited in claim 11 for the same reasons explained in Grounds 1-2. (*Id.*) Finally, Chuter discloses “outwardly extending” fibers for the same reasons explained in claim 1 with respect to “radially extending” fibers. (*Supra* §VIII.B.1.d.)

6. Claim 13

If a graft covering can be an inner frame, Spenser and Levi disclose the limitations of claim 13 as explained in Grounds 1-2. (*Supra* §VIII.A.9.)

D. Ground 3: Spenser and Chuter Also Render Claims 2, 7, 12 Obvious

Spenser discloses square-shaped open cells as explained in Ground 3. *Supra* §VIII.B. Spenser in combination with Chuter renders the remaining limitations of claims 2, 7, and 12 obvious as explained above. *Supra* §VIII.C. Accordingly, claims 2, 7, and 12 would have been obvious in view of Spenser in combination with Chuter. (Ex. 1003, ¶281.)

E. Grounds 5-6: Claims 1, 3, 5, 8, 11, 13 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, 3, 5, 8, 11, and 13 because those combinations disclose every claim element 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.C.) Spenser II would have provided POSITAs additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves. (Ex. 1003, ¶282.) Spenser II teaches the addition of compressible materials to the outside of THVs for preventing PVL. (Ex. 1011, [00145].) POSITAs would have recognized Chuter's fiber pile as a type of compressible material that could be combined with THV's to prevent PVL according to Spenser II's teachings. (Ex. 1003, ¶283.)

Accordingly, claims 1, 3, 5, 8, 11, and 13 would have been obvious over the combination of Spenser *or* Levi with Chuter and Spenser II. (*Id.*)

F. Ground 5: Spenser in Combination With Chuter and Spenser II Also Renders Claims 2, 7, 12 Obvious

Spenser discloses square-shaped open cells as explained in Ground 3. *Supra* §VIII.B. Spenser in combination with Chuter and Spenser II renders the remaining limitations of claims 2, 7, and 12 obvious as explained in Grounds 5-6. *Supra* §VIII.E. Accordingly, claims 2, 7, and 12 would have been obvious in view of Spenser in combination with Chuter and Spenser II. (Ex. 1003, ¶284.)

IX. SECONDARY CONSIDERATIONS

Petitioner understands that PO does not practice the '310 patent or sell any products covered by the '310 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶285-286.) If PO asserts that the '310 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)

Chuter was not considered by the Examiner during prosecution of the '310 patent and, therefore, the Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d).

The Board should also not exercise its discretion to deny institution under 35 U.S.C. §325(d) because the Examiner erred in a manner material to the patentability of the challenged claims. For example, in the Notice of Allowance, the Examiner stated that the “prior art does not disclose or render obvious wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material in the radially compressed orientation and the radially expanded orientation in combination with the recited features.” (Ex. 1002, 21.) That finding was material error. As detailed above, Spenser II and Chuter both disclose that limitation. Thus, the Examiner failed to fully consider the teachings of the prior art.

Additionally, the Examiner initially rejected the pending claims of the '310 patent as obvious over the combination of Spenser and Spenser II. (*Id.*, 585-587.) In response to that rejection, PO argued that the combination of Spenser and Spenser II would not be capable of endovascular delivery through a femoral artery of a patient, presenting the same cross-area calculations PO presented in the prior IPRs.

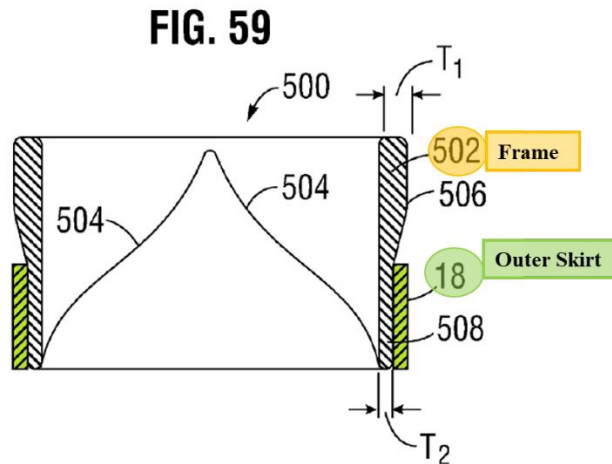
(*See id.*, 567-577.) The Examiner subsequently withdrew the rejection over Spenser and Spenser II. (*Id.*, 454-459.) That was material error. The Board has already rejected the same analysis and calculations PO presented to the Examiner to argue that the combination of Spenser and Spenser II does not enable endovascular delivery, and PO is precluded from challenging the Board’s findings and rejection of those arguments. (*See supra* §II.) Thus, the Examiner materially erred in withdrawing the rejection based on Spenser and Spenser II.

PO also erroneously asserted that Spenser II’s compressible material would restrict foreshortening of the stent during expansion, arguing that the compressible material must be “tightly held against the frame” and argued that such a “tightly held” sealing material would restrict foreshortening. (Ex. 1002 at 298-300, 441-443.) PO also submitted a declaration by Dr. Stephen Brecker, which asserted that Spenser II’s compressible material “appears dense and tightly held against the frame.” (*Id.*, 280.) PO’s and Dr. Brecker’s arguments are not supported by Spenser II’s disclosure. Spenser II never describes the compressible material as “dense” or restrict the compressible material to any particular density. (*See* Ex. 1011, [00145].) Nor does Spenser II require that the compressible material to be “tightly held” against the frame. (*Id.*) Additionally, PO and Dr. Brecker ignore that a compressible material would be capable of stretching to accommodate foreshortening and

expansion of the valve. Indeed, POSITAs would have understood that the THV in Spenser II's Figure 22 would have necessarily elongated when crimped due to its geometry, yet Spenser II expressly discloses using a compressible material that may be a cloth or fabric with such a THV. (*Id.*; Ex. 1003, ¶96.)

Real world practice demonstrates the error in PO's and Dr. Brecker's analysis. For example, Walther discloses a valve with an outer cloth stitched to the perimeter of the frame. Walther states that the resulting valve demonstrated "excellent hydrodynamic performance" and does not report any issues related to under-expansion or foreshortening. (*See* Ex. 1007, 1121-1125; *see also* Ex. 1017.) Moreover, the prior art was replete with examples of porous, stretchable, and compressible materials used to provide sealing and promote tissue ingrowth on cardiovascular devices for decades prior to November 2012. (Ex. 1003, ¶96.)

PO and Dr. Brecker also erroneously asserted that Levi ***requires*** a billowing outer skirt. (Ex. 1002, 279-280, 307-308.) PO's and Dr. Brecker's characterizations of Levi are inaccurate. Although Levi discloses embodiments with a bulging outer skirt, Levi also discloses embodiments with an outer skirt attached to the frame that does not bulge outwardly therefrom:



(Ex. 1008, 16:51-54, 17:12-18, Fig. 59.)

Both PO and Dr. Brecker also erroneously relied on a non-prior art article, Russell (Ex. 1131), to assert that Spenser II's compressible material could not be used on a valve delivered endovascularly via the femoral artery. (See Ex. 1002 ('310 prosecution history excerpt) at 444-446, 574-575.) PO and Dr. Brecker both suggested that Russell discloses a sealing material similar to Spenser II's compressible material. (See *id.*) This argument was previously presented to the Board, but not adopted. And rightly so because the argument is incorrect. Russell's sealing material is a strip of Bard PTFE Felt Ref. 007976, which is made of dense, compacted fibers that have very little compressibility. (Ex. 1131, 1440; Ex. 1003, ¶¶99.) Unlike Spenser II's compressible material, the felt used in Russell cannot extend into gaps formed between the patient's native tissue and the THV. (Ex. 1003, ¶¶99.) Nor was it intended for such a purpose. Russell's felt strip was used to provide

a sturdy, tear-resistant base for suturing the Russell valve to the patient’s mitral valve during an open-heart surgical procedure. (*Id.*) POSITAs would not use a dense, non-compressible fabric such as PTFE felt as an outer seal for a TAVR valve given its lack of flexibility and compressibility. (*Id.*) Given the significant differences between TAVR procedures and the open-heart mitral valve procedure in Russell, and the significant differences between the properties of the materials disclosed in Russell and Spenser II, PO’s reliance on Russell is misplaced and PO’s suggestion that Russell embodies Spenser II and/or discloses a “similar” sealing material is incorrect and misleading.

Accordingly, none of PO’s arguments during prosecution should form the basis for the Board to exercise its discretion to deny institution under §325(d).

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 of the ’310 patent. The Examiner thus materially erred in allowing the claims over Spenser, Spenser II, and Levi. Given this material error, and also because Chuter was not of-record during prosecution, 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 has also filed a Petition for *Inter Partes* Review of U.S. Patent No. 11,129,735 (“the ’735 patent”). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-000549 (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 July 10, 2023). The ’310 patent is part of the same patent family and shares a specification with the ’172, ’011, ’846, ’538, ’735, ’236, and ’834 patents. The status and outcomes of Edwards’ prior IPRs is summarized previously in section II.

PO also recently filed suit against Petitioner alleging infringement of the ’310 patent, as well as U.S. Patent Nos. 11,523,918; 11,491,033; 11,497,634; and 11,337,834 by Petitioner’s SAPIEN 3 Ultra valve. *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1:23-00158-JPM (D. Del., filed Feb. 13, 2023). The court has not set a trial date in the litigation. The court has scheduled a claim construction hearing 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 BoxEdwards28-2@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 BoxEdwards28-2@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 '310 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: July 20, 2023

By: /Joshua J. Stowell/

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

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

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

Customer No. 20,995

Attorneys for Petitioners

EDWARDS LIFESCIENCES CORP. AND

EDWARDS LIFESCIENCES LLC

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,389,310,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,748
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: July 20, 2023

By: /Joshua J. Stowell/
Craig S. Summers (Reg. No. 31,430)
Joshua J. Stowell (Reg. No. 64,096)
Brian C. Barnes (Reg. No. 75,805)
Customer No. 20,995

Attorneys for Petitioners
EDWARDS LIFESCIENCES CORP. AND
EDWARDS LIFESCIENCES LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,389,310** and **EXHIBITS
1001 – 1140** are being served on July 20, 2023 via Federal Express overnight mail
on counsel of record for U.S. Patent 11,389,310 as addressed below:

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

Dated: July 20, 2023

By: /Joshua J. Stowell/

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