Trials@uspto.gov
571-272-7822

Paper 12
Date: February 22, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS LLC,
Patent Owner.

IPR2023-01325
Patent 11,491,033 B2

Before JOHN G. NEW, RYAN H. FLAX, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively "Petitioner") filed a Petition (Paper 2, "Pet") requesting *inter partes* review of claims 1, 2, and 4–6 of U.S. Patent No. 11,491,033 B2 (Ex. 1001, "the '033 patent"). Pet. 1, 18. Aortic Innovation LLC ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp."). Petitioner also filed a Preliminary Reply (Paper 9) and Patent Owner filed a Preliminary Sur-reply (Paper 11), both papers providing further argument and evidence about the "spacing" claim limitation, which we discuss below.

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For reasons discussed below, we do not institute review of claims 1, 4, and 4–6 of the '033 patent.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC as the real parties-in-interest. Pet. 83. Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

B. Related Matters

The parties identify as a related matter the following lawsuit involving the '033 patent (and other patents): *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, 23-cv-00158 (D. Del.); Pet. 84–85; Paper 4, 1.

Petitioner also identifies related matters filed with the Board involving the same parties and related patents. Pet. 83–84. Those matters include: IPR2021-01527; IPR2021-01584; IPR2022-00193; IPR2022-00034; IPR2022-00556; IPR2022-00549; IPR2023-01151; and IPR2023-01232.

Id.; *see also id.* at 6–9 (identifying the earlier-filed IPRs and their status).[1] Petitioner states that the '033 patent is part of the same family and shares a specification with the patents at issue in the IPRs listed above. *Id.* at 83–84.

C. The '033 Patent

The '033 patent is entitled "Transcatheter Valve Repair Having Improved Paravalvular Seal." Ex. 1001, code (54). The '033 patent issued from U.S. Application No. 17/719,160, filed April 12, 2022, which claims priority through a series of related applications. *Id.* at codes (21), (22), (60). The earliest applications in the '033 patent's identified priority chain are two U.S. provisional applications filed November 7, 2012, and December 6, 2011. *Id.* at code (60).[2]

According to the '033 patent, no devices in clinical use for endovascular repair of ascending aortic aneurysms "have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms." *Id.* at 2:40–44.

The patent describes a need for a device

> that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device

[1] In final written decisions, the Board determined that all challenged claims were unpatentable in the 1527 and 1584 cases and that some challenged claims were unpatentable in the 0193 case. Exs. 1117, 1118, 1119. The Board concluded that no challenged claims were proved unpatentable in the 0034 and 0556 cases, and the Board denied institution in the 0549, 1151, and 1232 cases. Exs. 1120, 1121, 2124; IPR2023-01151, Paper 12; IPR2023-01232, Paper 10.

[2] The '033 patent includes two different paragraphs labeled code "(60)." *Compare* Ex. 1001, 1 (cover page), *with id.* at 2 (cover page continuation).

> is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

Id. at 2:44–53.

The ’033 patent discloses an endograft device, including a transcatheter heart valve for endovascular repair of ascending aortic aneurysms. Ex. 1001, 2:57–59. The patent discloses that the device includes first and second prosthetic components, in which the first prosthetic component has a proximal frame and the second prosthetic component is secured to the first prosthetic component. *Id.* at 2:59–67. “The endograft device also includes a valve element that is secured to [a] balloon-expandable frame at the proximal end of the second prosthetic component.” *Id.* at 3:5–7. Moreover, the second prosthetic component may include “a self-expanding frame that is connected to the balloon-expandable frame.” *Id.* at 2:67–3:4.

Figure 11 of the ’033 patent is reproduced below.

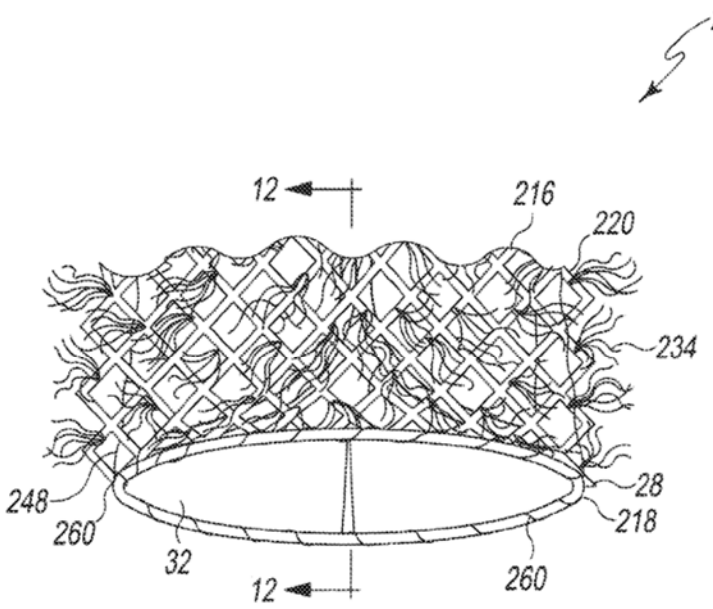
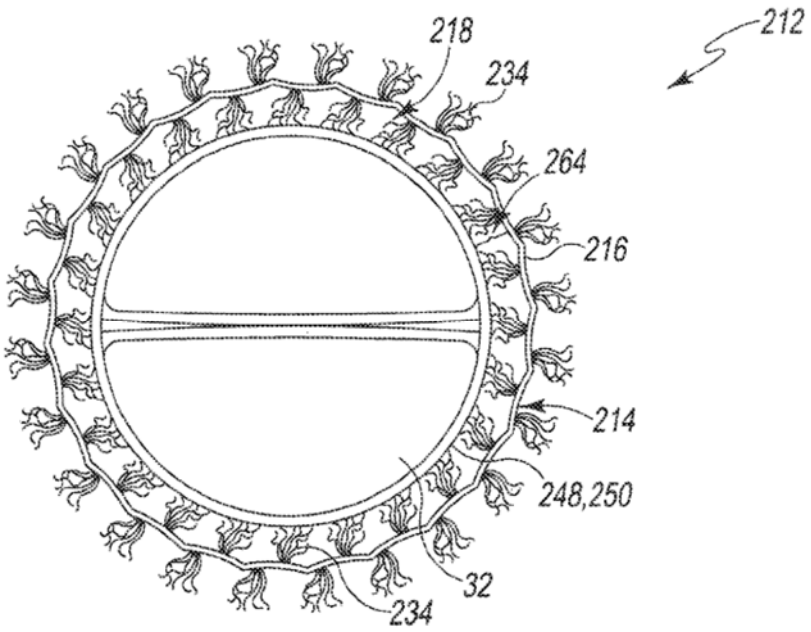


Fig. 11

Id. at Fig. 11. Figure 11, as shown above, is a perspective view of a proximal end of the proximal prosthetic component 212 of the endovascular device. *Id.* at 5:58–59. Figure 11 shows the prosthetic component with an outer “self-expanding” frame 216 and an inner frame 218 and valve component 32 disposed within the outer frame 216. *Id*. at 14:23–28. Figure 11 also shows fibers 234 attached to the outer frame 216. *Id.*

Figure 13 of the ’033 patent is reproduced below.



Id. at Fig. 13. Figure 13 is a longitudinal view of the proximal prosthetic component 212, again including outer frame 216, inner frame 218, and valve component 32, with the inner frame shown in an unexpanded state. *Id.* at 5:63–65. Figure 13 shows pluralities of fibers 234 attached to the outer frame—some fibers extending outwardly and some fibers extending inwardly from that frame. *Id.* at 14:25–28. In the unexpanded state, a gap 264 is defined between the inner and outer frames. *Id.* at 14:25–30.

The '033 patent discloses that the "[b]alloon-expandable frame 218" may be embodied as a "balloon-expandable tubular stent 244." Ex. 1001, 13:54–56. "[S]tent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an opencell configuration." *Id.* at 13:58–60. "When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216." *Id.* at Fig. 13, 14:25–28. When inner frame 218 is expanded, outer surface 248 of stent 244 engages fibers 234 through covering material 250, thereby closing gap 264 so that fibers

234 and covering material 250 create a seal between inner frame 218 and outer frame 216. *Id.* at Figs. 13, 14 (view in expanded state), 14:31–44.

Moreover, expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 216, compressing the fiber-coated proximal section 220 of the outer frame 216 against the patient's aortic annulus. *Id.* at 15:3–9 (disclosing that the combined engagement of the frames seals the annulus and prevents paravalvular leakage). According to the '033 patent, in embodiments, fibers 234 attached to the proximal section 220 aid in preventing paravalvular leaks and valve migration within the aortic walls. *Id.* at 18:34–37.

D. Challenged Claims

Claim 1 is the only challenged independent claim. It reads:

> 1. An endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient, comprising:
>
> a frame formed of a plurality of cells,
>
> wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,
>
> wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
>
> a leaflet assembly within the frame;
>
> a polymer covering about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage; and
>
> a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage,
>
> wherein the sealing assembly extends over each of the at least two rows of cells,
>
> wherein the sealing assembly lays against the frame when the prosthetic valve assembly is in the radially compressed orientation and the radially expanded orientation,

> wherein the prosthetic heart valve assembly is sized and shaped to be endovascularly deployed through a femoral artery of the patient,
>
> wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state,
>
> wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state:
>
> presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers relative to the spacings thereby reducing the spacings; and
>
> expands the polymer covering radially outwardly,
>
> wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.

Ex. 1001, 21:27–22:29.

Challenged claims 2 and 4–6 depend from claim 1. Claim 2 adds that the frame is "self-expanding"; claim 4 adds that the plurality of cells are "a same shape"; claim 5 adds that the frame is "integrally formed"; and claim 6 adds that the plurality of fibers extend outwardly "to a tip of each respective fiber." *Id.* at 22:30–32, 22:35–42.

E. Prosecution History

1. Prosecution History for U.S. Patent No. 11,337,834

U.S. Patent No. 11,337,834 ("the '834 patent" (Ex. 2143)) is the parent of the '033 patent. Ex. 1001, code (60) (indicating the application that issued as the '033 patent is a continuation to the application that issued as the '834 patent).

The application that matured into the '834 patent was filed on May 22, 2021. Ex. 2143, code (22). We incorporate-by-reference in its entirety the summary of the '834 patent's prosecution from our earlier decision addressing Petitioner's challenge to claims of that patent. IPR2023-01151, Paper 12, 8–13; *see also* Ex. 2140 (file history for the '834 patent).[3]

For brevity, we note here that: (i) Levi and Spenser II (references asserted in this IPR, and filed as Exhibits 1008 and 1011) were discussed and identified to the Examiner during that prosecution (Ex. 2140, 1143–1144); (ii) applicant amended the claims to recite a "spacing" limitation (with similar but not identical language compared to the corresponding limitation in the challenged claims here) (*id.* at 995, 997–999); (iii) applicant argued that the "spacing" limitation was supported by at least Figure 12 of the Specification, and that Spenser II did not disclose this "spacing" (*id.* at 1000–1002); and (iv) the Examiner found that the prior art did not disclose or render obvious the "spacing" limitation as then claimed—allowing the claims of the '834 patent to issue (*id.* at 850).

2. Prosecution History for the '033 Patent

The application that issued as the '033 patent was filed April 12, 2022. Ex. 1001, code (22).

On July 21, 2022, the Examiner rejected the sole pending application claim, which included no "spacing" limitation at that time, as obvious over the Nguyen (Ex. 1052) and Greenhalgh (Ex. 1053) references. Ex. 1002, 305–306 (preliminary amendment presenting application claim 2), 184–187 (obviousness rejection). According to the Examiner, the claimed subject

[3] The file history for the '834 patent in IPR2023-01151 was submitted as Exhibit 1002 in that case.

matter would have been obvious by modifying Nguyen's heart valve assembly to add Greenhalgh's graft sealing material positioned externally to a frame and that included outwardly-extending fibers. *Id.* at 186–187.

In a response dated July 31, 2022, applicant canceled the rejected claim and added new independent application claim 3 (ultimately issued as claim 1) and application claims 4–9, which depended from claim 3. *Id.* at 51, 165–166. Newly-presented application claim 3 included, *inter alia*, the limitation reciting: "wherein the prosthetic heart valve defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state." *Id.* at 165. Applicant argued that claim 3 and this "spacings" limitation was supported by description, including figures, in the November 7, 2012, provisional application to which the '033 patent claims priority. *Id.* at 168–173. Applicant also argued that Nguyen taught away from including Greenhalgh's sealing material, that adding such material would require significant and possibly detrimental design changes, and that such changes would likely create a valve profile too large for delivery through the femoral artery as claimed. *Id.* at 174–180.

The Examiner then entered a Non-Final Office Action dated August 23, 2022. *Id.* at 91–98. The Examiner indicated that "[c]laims 3–8 [were then] allowed over the prior art of record," and the Examiner rejected application claim 9 (for reasons not significant to this IPR). *Id.* at 95–96; *see also id.* at 87 (canceling claim 9). The Examiner also "note[d] that the large number of references in the attached IDS [(Information Disclosure Statement)] have been considered" but "requested [applicant] to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action."

Id. at 93; *see also id.* at 135–139 (Examiner-signed IDS listing, e.g., Spenser, Levi, Spenser II, and Chuter (i.e., the asserted prior art in this IPR, filed as Exhibits 1008, 1010, 1011, and 1116); *see infra* Section II(F))).

Applicant promptly responded to the Examiner's office action, including the inquiry concerning the IDS and number of references listed. *Id.* at 82–88 (response dated Aug. 23, 2022; canceling claim 9). Applicant stated that "the most relevant references may be Spenser I (USPN 7,510,575, see FIG. 44a), Spenser II (WO 2006005015, see FIG. 22), [and] Levi (USPN 9,393,110, generally)." *Id.* at 86 (identifying Norris (Ex. 1074), Greenhalgh (Ex. 1053), Walther (Ex. 1007), and Cheung (Ex. 1017) as well in this list of "most relevant" references).

After the Examiner entered the notice of allowance, but before the '033 patent issued, applicant submitted another IDS, identifying the Board's institution decisions in related matters, IPR2022-00556 (institution), and IPR2022-00549 (denial of institution). Ex. 1002 (IDS and Remarks dated Sept. 11, 2022), 27–35, 44–46 (Notice of Allowance dated Sept. 1, 2022). With that submission, applicant added "Remarks" about the term "openings" that appeared in certain dependent claims subject to the Board's related decisions. *Id.* at 28 (asserting "[t]hese limitations have a parallel to the claims presented herein as the claims recite similar term 'spaces'"). Applicant argued that the "specification illustrates spacing between fibers that are an intentionally placed spacing, i.e., not just the spacing that may be inherent between radially extending fibers such as those that appear to be found in the Walther reference." *Id.* at 29 (citing the Specification's Fig. 11, with applicant's annotation of a "Spacing"). Moreover, applicant stated, "[t]he benefit to this [claimed] design is that the lesser density construction allows for a smaller crimp profile" and "[t]hese limitations are clearly not

shown in the Walther reference." *Id.* at 29–30 (reproducing an image of the Walther valve and further arguing that "spaces" as claimed are "not shown in the references of record").

The Examiner then entered a Corrected Notice of Allowance. *Id.* at 13–16. In that entry, the Examiner stated "[t]he allowability of claims 3–8 is confirmed" and "[n]othing cited on the newly presented IDS altered the previous determination of the allowable subject matter." *Id.* at 15.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1, 2, and 4–6 are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §[4]	References/Basis
1, 2, 4–6	103	Spenser,[5] Spenser II[6]
1, 2, 4–6	103	Levi,[7] Spenser II
1, 2, 4–6	103	Spenser, Chuter[8]

[4] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. Petitioner asserts that the critical date of the '033 patent is November 7, 2012. Pet. 18–19. Because that date precedes the effective date of the applicable AIA amendments, we apply the pre-AIA version of § 103 here.

[5] Spenser et al., US 7,510,575 B2, iss. Mar. 31, 2009 (Ex. 1010 ("Spenser")).

[6] Spenser et al., WO 2006/005015 A2, pub. Jan. 12, 2006 (Ex. 1011 ("Spenser II")).

[7] Levi et al., US 9,393,110 B2, iss. July 19, 2016, from an application filed Oct. 5, 2011 (Ex. 1008 ("Levi")).

[8] Chuter, US 2002/0151958 A1, pub. Oct. 17, 2002 (Ex. 1116 ("Chuter")).

Claims Challenged	35 U.S.C. §[4]	References/Basis
1, 2, 4–6	103	Levi, Chuter
1, 2, 4–6	103	Spenser, Chuter, Spenser II
1, 2, 4–6	103	Levi, Chuter, Spenser II

Petitioner relies on testimony from Nigel Buller, M.D., in support of its challenges. Ex. 1003 (Buller Decl.). In response, Patent Owner submits testimony from Stephen J.D. Brecker, M.D. Ex. 2002 (Brecker Decl.). The parties additionally submit testimony from Drs. Buller and Brecker from related proceedings. *See supra* Section II(B).

III. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and

(4) objective indicia (also called secondary considerations) of nonobviousness when presented.[9] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Moreover, "[a]n obviousness determination requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks and citation omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the problems encountered in the art, the art's solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner proposes that the person of ordinary skill in the art ("POSA") in November 2012 "would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This [POSA] would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve." Pet. 19 (citing Ex. 1003 ¶ 49). Patent Owner does not

[9] The parties did not present substantive argument on secondary considerations. Pet. 80 ("Petitioner is not aware of any evidence of secondary considerations"). Patent Owner mentions the Board's alleged "credit[ing]" of Dr. Brecker's testimony in related matters referencing an "unexpected result." Prelim. Resp. 72 (citing Ex. 2124, 33–34). This overstates the Board's citation to a paragraph of testimony from Dr. Brecker, which the Board cited for a claim construction issue and, in no way, was this citation a finding that any unexpected result had been established. Ex. 2124, 33–34. Patent Owner, in any case, presents no argument on nexus issues.

expressly contest Petitioner's proposed definition or offer an alternative. *See generally* Prelim. Resp.

For this Decision, we apply Petitioner's proposed POSA level, which appears to be consistent with the level of skill shown in the prior art of record. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). This POSA level is also consistent with the level the Board applied in earlier decisions involving the same parties and related patents. *See, e.g.*, Ex. 2124, 11; Ex. 1120, 11–12.

C. Claim Construction

In *inter partes* review, we construe claims using the same claim construction standard used to construe claims in a civil action before the courts under 35 U.S.C. § 282(b), including construing claims' language in accordance with its ordinary and customary meaning as understood by the POSA, in view of the patent's specification and considering the patent's prosecution history. 37 C.F.R. § 42.100(b). We need only construe terms that are in controversy and only as needed to resolve the matters in dispute. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

Petitioner contends that "[n]o terms of the '033 patent require construction to resolve the patentability issues herein." Pet. 20. Also, according to Petitioner, its "grounds are based on [Patent Owner's] allegations that the '033 patent covers Petitioner's SAPIEN 3 Ultra valve and the scope of the claims asserted by [Patent Owner] in litigation." *Id.* (citing Ex. 1122 (Complaint); Ex. 1123 (Infringement Contentions), 2, 477–564); Paper 9, 1–5 (addressing the "spacings" limitation and asserting that Spenser II discloses this limitation "under the plain and ordinary meaning").

Patent Owner does not propose any express claim construction and, instead, contends the claims should be interpreted according to their plain

and ordinary meaning in light of the '033 patent's Specification and prosecution history. *See generally* Prelim. Resp.; Paper 11, 3–4.

Based on the parties' arguments, it is, however, evident that they dispute the meaning of the term "spacings" in claim 1 and the application of this term to the prior art. *See, e.g.*, Paper 11, 1–3 (arguing Spenser II was expressly distinguished and disclaimed as lacking the "spacings" as claimed during prosecution of U.S. Patent No. 11,337,834 ("the '834 patent" (Ex. 2143)), which is the parent of the '033 patent); Paper 9, 1–5 (arguing that all fibrous cloths have "spacings" between fibers and against any disclaimer of Spenser II). We discuss the arguments below when addressing the asserted mapping of the claims to the prior art. *Infra* Section III(E)(1).

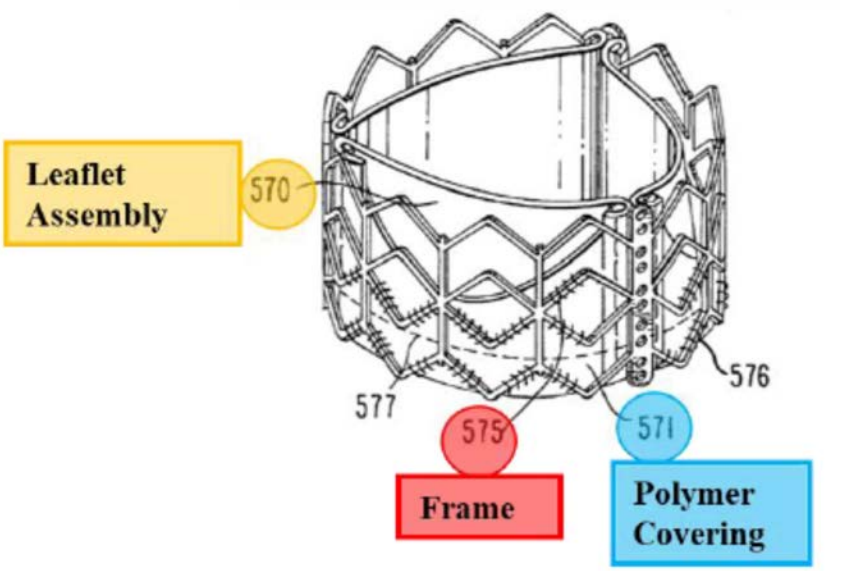
D. Asserted References

Assuming, as Petitioner does, a critical date of November 7, 2012, for the '033 patent, each of the references below is prior art. Pet. 18–19. Patent Owner does not contest the prior-art status of these references.

1. Spenser (Ex. 1010)

Spenser is a U.S. patent titled "Implantable Prosthetic Valve" that issued on March 31, 2009. Ex. 1010, codes (10), (12), (45), (54). Spenser therefore qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

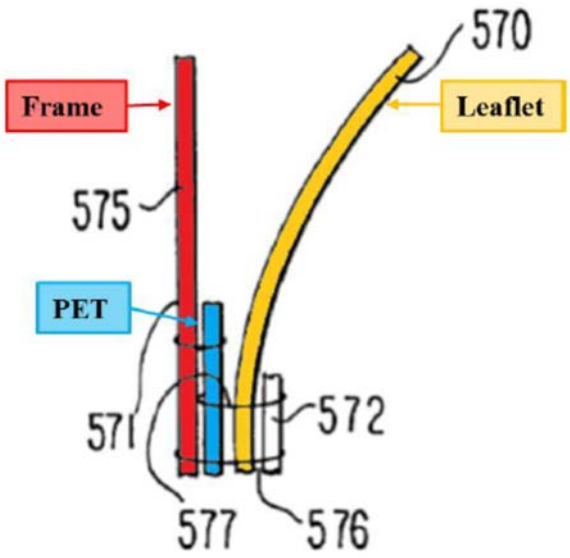
Spenser relates to a prosthetic valve for cardiac implantation. *Id.* at 1:13–15. Figure 44a of Spenser (with Petitioner's annotations) is reproduced below.



Pet. 21 (reproducing Fig. 44a of Spenser (Ex. 1010) with Petitioner's additional labeling and color-coding). Spenser's Figure 44a shows a perspective view of an implantable valve with three pericardial leaflets 570 (labeled "Leaflet Assembly" and colored yellow), located within a gridded circular frame 575 (labeled "Frame" and colored red). Ex. 1010, 26:30–37. As shown, Figure 44a also includes a polyethylene terephthalate (PET) layer 571 (labeled "Polymer Covering" and colored blue) that connects the leaflets to the frame. *Id.* at 26:30–42.

Spenser's Figure 44b (with Petitioner's annotations) is also reproduced below.

FIG. 44b



Pet. 27 (reproducing Fig. 44b of Ex. 1010 with Petitioner's labeling and maintained color-coding). Figure 44b (as annotated) shows a partial cross-sectional view of the valve assembly including the connections between the frame 575 (red), PET layers 571 and 572 (blue and white) and leaflet 570 (yellow). Ex. 1010, 11:36–40. Spenser discloses:

> PET 571 and 572 are used for connecting pericardial leaflets 570 to frame 575, while they are assembled in between the leaflets and the frame. A suture 577 connects pericardium leaflet 570 in between two layers of PET, while the inner layer of PET 572 is short and the outer layer is longer. Bottom attachment suture 576, connects the three layers, the leaflet and both PET layers to the frame and forms a strong sealing line. An upper suture 578 connects the outer PET layer 571 to frame 575.

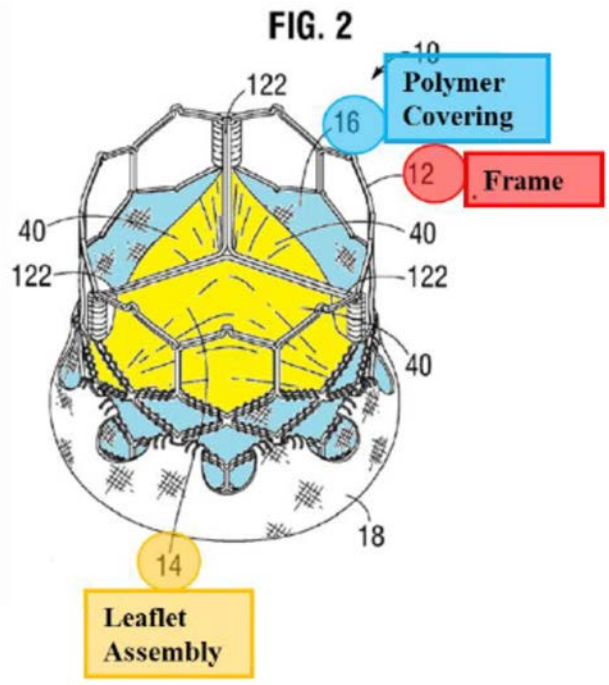
Id. at 26:40–48.

2. Levi (Ex. 1008)

Levi is a U.S. patent titled "Prosthetic Heart Valve" that issued on July 19, 2016, from an application filed on October 5, 2011. Ex. 1008,

codes (10), (22), (45), (54). Levi, thus, qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

Levi is directed to an expandable prosthetic heart valve. Ex. 1008, Abstr., 1:16–18. Figure 2 of Levi is reproduced below (as annotated by Petitioner in a similar fashion to the figures of Spenser, above).



Pet. 21 (reproducing Fig. 2 of Levi (Ex. 1008) with Petitioner's additional labeling and maintained color-coding). Figure 2 of Levi, as annotated above, is a perspective view of an exemplary heart valve 10 including valvular structure 14 (labeled "Leaflet Assembly" and colored yellow) within a circular stent or frame 12 (labeled "Frame" and colored red). Ex. 1008, Fig. 2, 4:57–58, 5:52–58. As shown, the valve also includes inner skirt 16 (labeled "Polymer Covering" and colored blue) and outer skirt 18. *Id.* at 5:56–58. According to Levi, "[t]he illustrated valve is adapted to be implanted in the native aortic annulus." *Id.* at 5:53–56.

3. Spenser II (Ex. 1011)

Spenser II is a PCT publication titled "Paravalvular Leak Detection, Sealing and Prevention" that published on January 12, 2006. Ex. 1011, codes (10), (43), (54). Spenser II, therefore, qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Spenser II is directed to "the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses." Ex. 1011 ¶ 1. Spenser II teaches that prosthetic valves may be implanted "either through open heart surgery or by use of newer percutaneous methods," but "[w]ith both methods paravalvular leaks are a known side effect." *Id.* ¶ 11. Spenser II notes that "[p]ercutaneous introduction of medical devices is a preferred surgical procedure" that is "safer and less invasive." *Id.* ¶ 12.

Figure 22 of Spenser II is reproduced below.

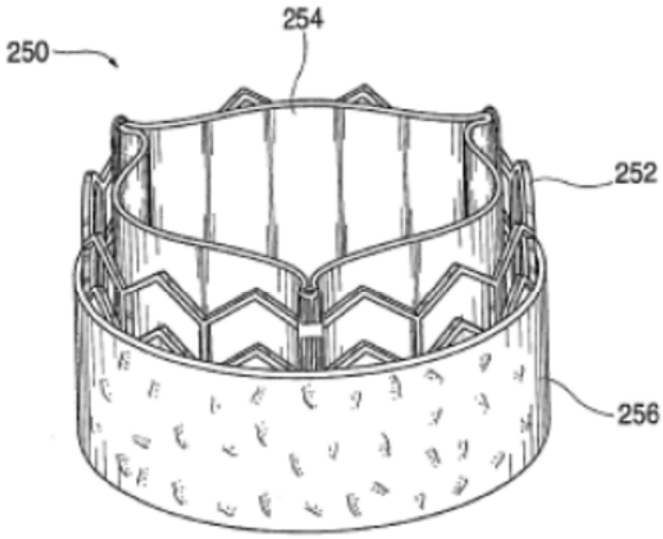


FIG. 22

Id. at Fig. 22. Figure 22 of Spenser II, shown above, is a perspective view of a preferred embodiment of the Spenser II prosthetic valve. *Id.* ¶ 85. More specifically, Spenser II's Figure 22 shows an embodiment including a layer of compressible material, such as a cloth material, along an exterior surface

of a stented valve. *Id.* The stented valve 250 includes a circular stent structure 252 surrounding a valvular structure 254. *Id.* at Fig. 22, ¶ 144. "[S]tent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration." *Id.* ¶ 144. The device further includes circular layer of compressible material 256 surrounding the outside of stent structure 252. *Id.* at Fig. 22, ¶ 145. "The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve." *Id.* "[T]he compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." *Id.*

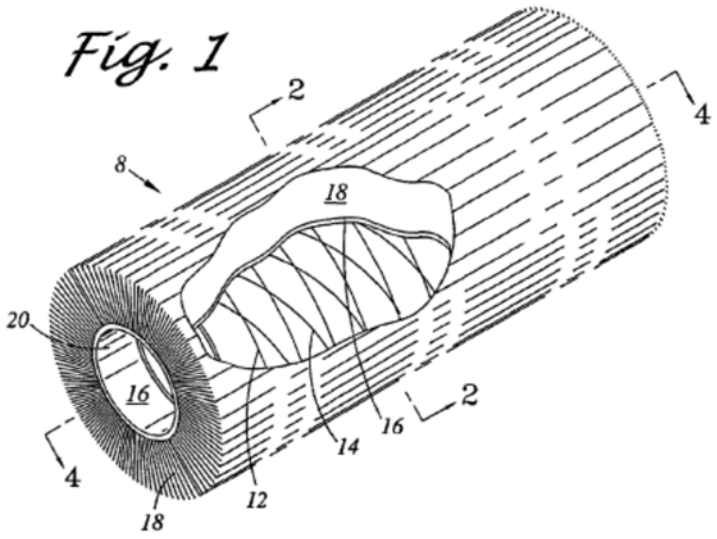
Spenser II discloses that the "compressible material expands after deployment at a treatment site" and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* "In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.*

4. Chuter (Ex. 1116)

Chuter is a published U.S. patent application titled "Large Vessel Stents and Occluders." Ex. 1116, code (54). Chuter published October 17, 2002, and is prior art under pre-AIA 35 U.S.C. § 102(b). *Id.* at code (43).

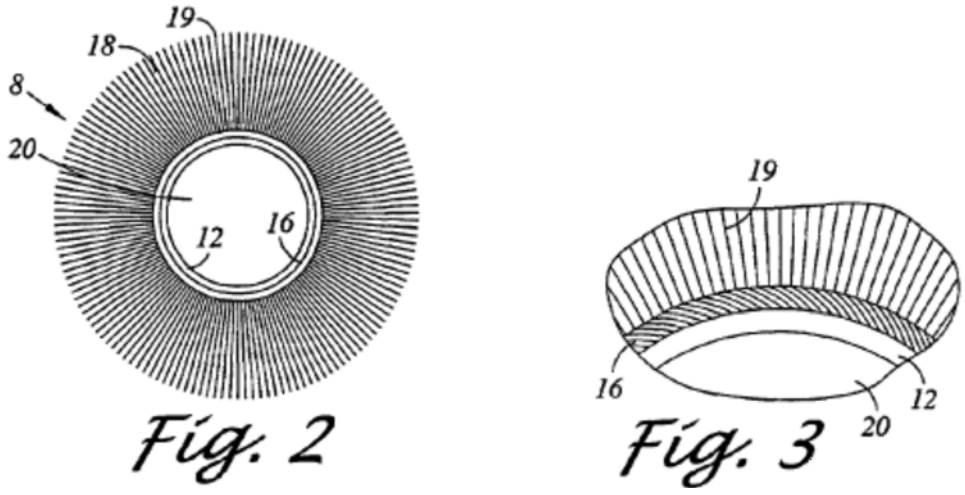
Chuter discloses "[a]n endovascular stent for vascular vessels which can be used to occlude the vessel or which can be used to bridge damaged areas in the vessel." *Id.* at Abstr.

Chuter describes a "graft" embodiment, such as shown in Figures 1–3 of Chuter. *Id.* ¶¶ 28–30, Figs. 1–3. Chuter's Figure 1 is reproduced below.



Id. at Fig. 1. Figure 1, depicted above, is a perspective view of Chuter's graft 8, comprising a stent 12 frame formed from wires 14, which frame supports a fabric pile backing 16. *Id.* ¶ 54. Chuter teaches that, "[e]xtending circumferentially outwardly from the backing 16 is a fabric pile 18 made up of individual fibers 19." *Id.* Also, "[t]he graft has a longitudinal lumen or bore 20 extending its length to permit blood to flow." *Id.*

Figures 2 and 3 of Chuter, providing different views of the graft embodiment of Figure 1, are reproduced side-by-side below.



Id. at Figs. 2 and 3. Figure 2 above is a cross-sectional end-view, and Figure 3 is an enlarged sectional view of the graft 8, showing stent 12 and

fiber pile backing 16 surrounding lumen 20. *Id.* ¶ 54. The figures also show fabric pile 18 comprising individual fibers 19 extending outwardly from the fiber pile backing 16. *Id.*

Chuter also describes several "occluder" embodiments. *See, e.g.*, *id.* at Figs. 4–12, ¶¶ 54–57. An example "occluder" embodiment is shown in Figure 8 of Chuter, reproduced below.

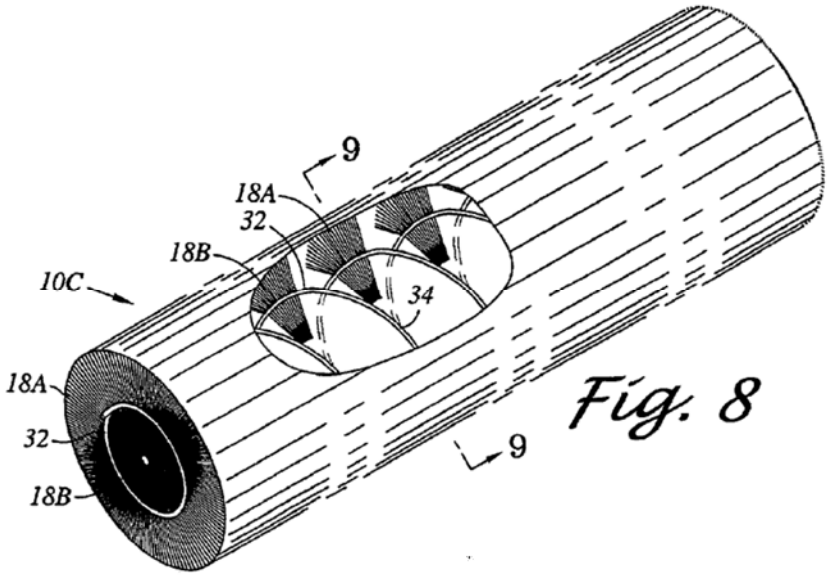


Fig. 8

Id. at Fig. 8. Figure 8 above is a perspective view of an "occluder." *Id.* ¶ 35. Chuter teaches that this embodiment includes occluder 10C comprising a stent 32 made from a helical wire frame that includes wire strand 34. *Id.* ¶ 57. In the depicted embodiment, "the wire strand has fabric threads 28 extending both outwardly and inwardly circumferentially of the stent . . . to form fabric piles extending outwardly from the occluder and inwardly of the stent to form a fabric pile 'plug.'" *Id.* As shown, fibers 18A are outwardly extending fibers, and 18B comprise inwardly extending fibers. *Id.* at Figs. 9, 12 (showing end and cross-sectional views of an occluder like represented in Fig. 8).

Chuter's Figures 9 and 10 are reproduced below.

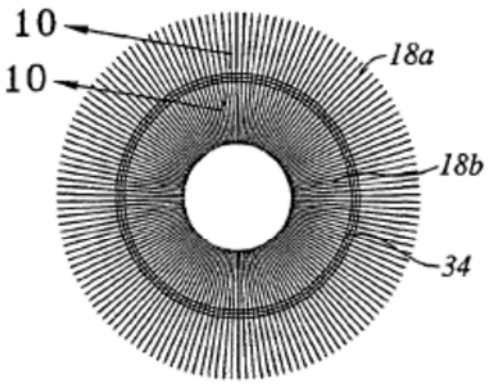


Fig. 9

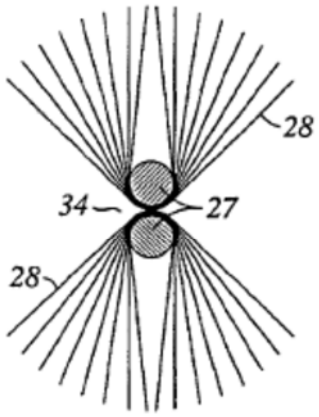


Fig. 10

Id. at Figs. 9, 10. Figure 9, shown above, is an end view of the occluder of Figure 8 and shows fibers 18a and 18b extending outwardly and inwardly from wire strand 34. *Id.* ¶ 57. Figure 10 is an enlarged cross-sectional view along lines 10-10 of Figure 9, depicting wire strand 34, comprised of at least two twisted wires 27 such that fabric threads 28 extend from those wires. *Id.* ¶¶ 56–57; *see also id.* at Figs. 5, 6, 7 (depicting an occluder comprising at least one helically wound double wire strand 26 similar to the wire strands 27 of Fig. 10). Chuter teaches that the fibers are made of biocompatible materials such as polyester. *Id.* ¶ 22.

E. Spenser II Combinations (Grounds 1 and 2)

Petitioner argues that claims 1, 2, and 4–6 would have been obvious over either Spenser or Levi, in further combination with Spenser II. Pet. 21–63; *see id.* at 21–60 (claim 1). Patent Owner opposes those arguments. Prelim. Resp. 1–38.

1. Claim 1

Whether Petitioner has shown sufficiently that the combination of Spenser or Levi with Spenser II discloses claim 1's limitation reciting

"wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state" is a determinative issue on this record. Before turning to the parties' arguments and our analysis on this issue, however, we provide a brief overview of other aspects of Petitioner's challenge for context.

Petitioner contends that Spenser or Levi discloses most of claim 1's limitations. Pet. 22–60. Petitioner argues that Spenser, for example, discloses a prosthetic heart valve meeting the claimed "frame," "leaflet assembly," and "polymer covering" limitations and further teaches that its valve may be placed percutaneously via the femoral artery as claimed. *Id.* at 23–28 (citing, e.g., Ex. 1010, Fig. 44a, 2:6–12, 19:5–13, 26:30–54, 27:67–28:2); *see supra* Section III(D)(1) (Petitioner's annotations of Spenser's Fig. 44a and 44b showing features of Spenser's valve). Petitioner supports these contentions with testimony from Dr. Buller. *See, e.g.*, Ex. 1003 ¶¶ 106–108, 110–111, 112–116, 137–138; *see also id*. ¶¶ 137–142 (testifying a POSA would have expected the modified Spenser-Spenser II valve could be delivered endovascularly through the femoral artery).

For claim 1's limitations relating to a "sealing assembly" with that assembly's several claimed sub-features, Petitioner turns to Spenser II. Claim 1 requires, *inter alia*: "a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame"; that the "sealing assembly extends over each of the at least two rows of cells" at the frame's inflow end; and the "sealing assembly lays against the frame" when the heart valve is both radially compressed and radially expanded. *See supra* Section II(D). Moreover, claim 1 requires that the prosthetic heart valve assembly "defines spacings extending through a thickness of the sealing assembly that allow

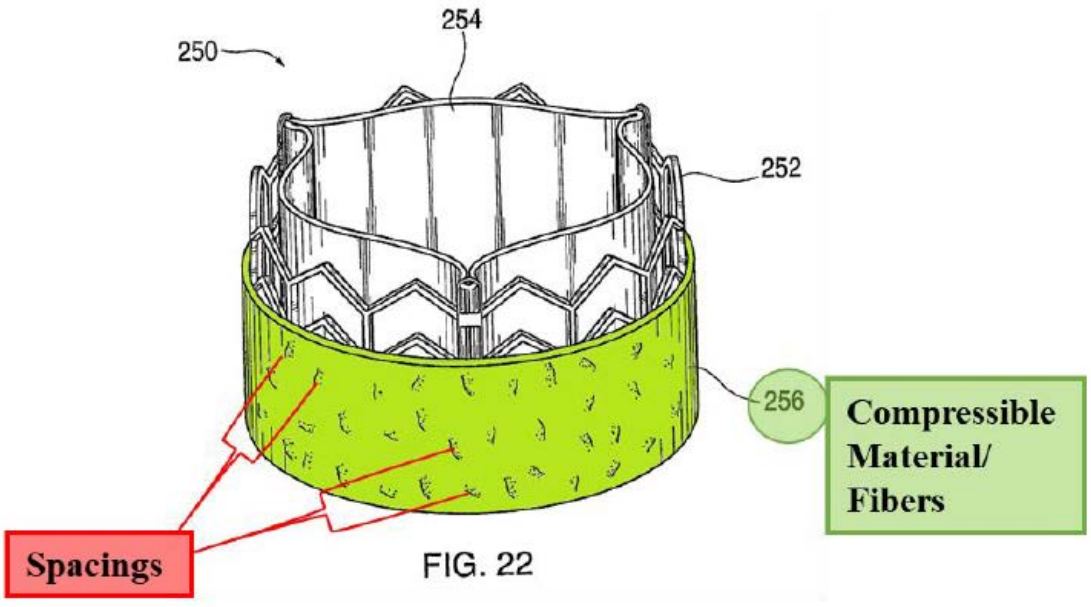
fluid to pass therethrough" when the valve assembly is in an "undeployed state." *Id.*

Petitioner cites Spenser II's Figure 22 and related disclosure about Spenser II's "compressible material" and "fibers" as meeting the claimed "sealing assembly" limitations in a proposed combination with the valves of Spenser or Levi. Pet. 29–39 (citing Ex. 1011, Fig. 22, ¶ 145; Ex. 1003 ¶¶ 117–131). More specifically, Petitioner points to Spenser II's teaching that to "reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252," as shown in Figure 22. Pet. 29–31 (annotating Fig. 22 of Spenser II and Fig. 44a of Spenser); Ex. 1011 ¶ 145; *see supra* Section III(D)(3). As noted by Petitioner, Spenser II teaches that "[i]n certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material," which fibers may be "straight, curved or hook-shaped." Pet. 29 (citing Ex. 1011 ¶ 145).

Petitioner argues that a POSA would have been motivated to add Spenser II's compressible material to Spenser's valves, or to replace Levi's outer skirt on Levi's valves with Spenser II's compressible material, to prevent paravalvular leakage (PVL). Pet. 31–36, 37–39 (addressing alleged motivation and reasonable expectation of success in suturing Spenser II's compressible material to the frames of Spenser or Levi such that it lays flat against said frames). Petitioner also contends that its asserted motivation is consistent with the Board's findings on the motivation issue for the Spenser-Spenser II combination in related proceedings and, for the Levi-Spenser II combination, involves swapping interchangeable features that serve similar purposes. *Id.* at 31–34 (citing, e.g., Ex. 1117, 64; Ex. 1003 ¶¶ 122–123, 127–128). With these changes, Petitioner contends, the modified valves

would include the "sealing assembly" limitations, such as the requirement of "arcuate fibers" that extend away from the frame and a sealing assembly that extends over two or more rows of cells. *See, e.g.*, Pet. 29–31 (identifying Spenser II's compressible material and the small fibers extending from that material's surface; noting rows of Spenser's frame to be covered with Spenser II's compressible material (comparing Spenser (Fig. 44a) and Spenser II (Fig. 22) side-by-side to show similar frames); Pet. 35 (asserting a POSA would have been motivated to attach Spenser II's compressible material to Levi's valve at the "same location" as Levi's outer skirt, thus covering the bottom two rows of the frame's cells).

For claim 1's limitation of "spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state," Petitioner argues Spenser II teaches this limitation. Pet. 46–54. Petitioner provides an annotated version of Spenser II's Figure 22, which is reproduced below.



Pet. 46. This annotation shows Spenser II's Figure 22, with the compressible material 256 colored green by Petitioner. *Id.* Petitioner labels,

with red brackets, alleged "Spacings" between what purport to be distinct groupings of fibers extending from the surface of Spenser II's compressible material. *Id.* According to Petitioner, "[t]he figure illustrates 'spacings' between the fibers" and those spacings extend through a thickness that is "at least the length of the fibers." *Id.* (citing Ex. 1003 ¶ 152).

Petitioner urges further reasons why the Board should find the "spacings" term is met. Petitioner contends Spenser II's compressible material must have "spacings" so that Spenser II's material can compress and expand. *Id.* at 47 (citing Ex. 1011 ¶ 145; Ex. 1003 ¶¶ 154–155). Petitioner asserts that the '033 patent does not disclose how to size or arrange the fibers to provide "spacings" as claimed. *Id.* at 50. Petitioner contends that, during prosecution, the applicant advanced "vague" arguments about what the "spacings" term means. *Id.* at 50–52 (citing Ex. 1002, 28–30); Paper 9, 1–5 (arguing, *inter alia*, that there was no prosecution disclaimer that excludes Spenser II's compressible material; that, if there was a disclaimer, it is broader than Patent Owner argues now; and, Patent Owner's alleged "plain meaning" interpretation lacks "objective boundaries"). Petitioner also contends Patent Owner cannot simultaneously maintain that Petitioner's SAPIEN 3 Ultra valve includes "spacings" and infringes the '033 patent's claims while arguing that such "spacings" are missing in Spenser's II's compressible material. Pet. 53–54 (providing images of SAPIEN 3 Ultra from Patent Owner's infringement contentions); Paper 9, 1–2 (same).

Much like we discussed in our decision addressing Petitioner's challenge to claims of the parent '834 patent, based on the record before us, the meaning of the term "spacings" remains elusive here. IPR2023-01151, Paper 12, 29–34 (summarizing Petitioner's and Patent Owner's arguments

about the corresponding "spacing" limitation, which arguments largely mirror arguments raised here against the '033 patent's claims), 34–41 (analysis explaining why, in the absence of coherent construction for the "spacing" limitation, the Board was unable to conduct the required prior-art analysis relative to Petitioner's Spenser II-based challenge). We discuss below.

As was argued in the related matter against the '834 patent's claims, Patent Owner repeats its contention that Spenser II was distinguished and disclaimed during prosecution. Prelim. Resp. 2–13 (citing alleged disclaimer over Spenser II and Walther (Ex. 1007) during the '834 patent's prosecution (Ex. 2140, 1001), and "parallel" disclaimer of Spenser II's "real-world embodiment" (i.e., Walther) during the '033 patent's prosecution (Ex. 1002, 29–30)); Ex. 2052, 104:17–105:7 (Buller testimony about Walther); Paper 11, 1–5. Petitioner also repeats its argument that Patent Owner advances inconsistent positions before the Board and the district court under the banner of a "plain meaning" interpretation of "spacings" to avoid Spenser II while also trying to capture Petitioner's SAPIEN 3 Ultra valve product. Paper 9, 1–5 (arguing against the alleged disclaimer and asserting that, if subject matter was disclaimed, it extends to Petitioner's allegedly infringing product too). Moreover, like was argued in the related matter, Petitioner contends that all fibrous cloths have "spacings" between fibers, while Patent Owner contends that such "inherent" spaces are not what is being claimed. Paper 9, 5 (citing Ex. 1146, 185:18–20); Prelim. Resp. 11, 30–32 (citing Ex. 1002, 29; Ex. 2141 ¶ 36).

There is some support in this record for the alleged disclaimer as argued by Patent Owner. Indeed, during the '834 patent's prosecution, applicant argued expressly that Spenser II described a "very tightly knitted

outer seal made of tightly knitted fibers" and, thus, "lack[ed]" spacings as claimed.[10] Ex. 2140, 1001. The Examiner subsequently allowed the claims and remarked that the claimed "spacings" were not disclosed by or obvious over the prior art. Ex. 2140, 850, 995–1002. Similarly, during the '033 patent's prosecution, applicant argued the claimed "spacings" were missing in Walther, which Petitioner's expert, Dr. Buller, characterized as Spenser II's "real-world embodiment." Ex. 1002, 29–30 (applicant arguing it "does not appear than any such spacings are visible or disclosed in the Walther reference"); Ex. 2052, 104:17–105:7 (Dr. Buller testifying that Walther is a real-world embodiment of Spenser II). And, Petitioner's expert in the related litigation, Dr. Brookstein, testified that "there does not appear to be any dispute that the Asserted Patents do not include cloths like those described in Walther and Spenser II." Ex. 2141 ¶¶ 33–39 (citing "example" distinctions made by applicant during the '834 and '033 patents' respective prosecutions).[11]

---

[10] Relative to the alleged disclaimer, neither party draws a substantive distinction based on the fact that the "spacing" or "spacings" limitations in the challenged claims of the '834 and '033 patent are not identical. *Compare* claim 1 (*supra* Section II(D)), *with* Ex. 2143 ('834 patent), 21:52–56 (claim 2: reciting "the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame"), 24:8–12 (claim 18: reciting "the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame").

[11] For reasons discussed in our decision on the related '834 patent, which apply equally here, we are not persuaded that the "spacings" limitation should be interpreted to cover all fibrous cloths attached to a frame (as any cloth has inherent spaces) or, if any disclaimer is credited, that it must extend to all cloth-like sleeves including the structure allegedly used with Petitioner's allegedly infringing device. IPR2023-01151, Paper 12, 34–38.

On the other hand, as we pointed out in our related decision concerning the '834 patent, the intrinsic evidence is minimally helpful in revealing an affirmative meaning for the claims' "spacing(s)" terms. IPR2023-01151, Paper 12, 39–41. The Specification does not use the term "spacings" in relation to the positioning of adjacent fibers; the drawings might be helpful, but neither party proposes a specific construction that is reliant on them. And, portions of the prosecution record are arguably confounding. For example, the applicant distinguished claimed "spacings" from "tightly knitted fibers." Ex. 2140, 1001 (suggesting a more "loosely defined fiber structure" may be covered); *see also* Ex. 1002, 29–30 (asserting the claimed design has "a lesser [fiber] density construction" compared to Walther). This begs the question, at what point does a cloth of "tightly knitted fibers" convert to a cloth having a "loosely defined" fiber structure that would come within the scope of the claimed "spacings?" The record does not answer. Applicant's suggestion during prosecution that the claimed spacings between fibers are "intentionally placed" about the frame and not simply "the spacing that may be inherent" in fibrous cloths is also unavailing on this record in clearly defining the metes and bounds of the term. Ex. 1002, 28–29. Whether the alleged absence of "objective boundaries" for the term "spacings" supports a conclusion that the claims are invalid as indefinite would be a question for the court. Paper 11, 5 (arguing

There is insufficient technical detail available to determine whether the SAPIEN 3 Ultra does or does not include "spacings" as claimed and we take no position on whether such device infringes any claim of the '033 patent.

that a conclusion that the claims are indefinite is "outside the Board's [IPR] jurisdiction").[12]

Notwithstanding the lack of any express claim construction for the "spacings" term from either party, claim 1 of the '033 patent requires something more than just "spacings." Claim 1 requires "spacings extending through a thickness of the sealing assembly that *allow fluid to pass therethrough* when the prosthetic heart valve assembly is in an undeployed state." Ex. 1001, 22:11–15 (emphasis added). In other words, the spacings must allow fluid to pass through the sealing assembly's thickness when the valve is undeployed. For reasons discussed below, we are not persuaded on this record that Petitioner is reasonably likely to prevail in showing that this limitation is met—particularly the fluid-passing element—in the proposed combinations of Spenser or Levi with Spenser II.

Petitioner argues that fluid can pass through Spenser II's compressible material "for three reasons" in its proposed combination of the asserted art. Pet. 47–49. We address those reasons in turn below.

First, argues Petitioner, Spenser II's compressible material "must have spacings" to allow compression, which would mean the material is porous and permits flow of fluid therethrough. *Id.* at 47–48 (citing Ex. 1003 ¶ 156). Petitioner does not persuade us that the relevant limitation is satisfied. As explained by Dr. Brecker, "no mention is made of any 'spacings'" in Spenser II's compressible material, which instead is described and depicted as "a thick, opaque sealing without any spacings extending through the compressible material," much less any spacings (even if "hypothetical" or "imagined") that would allow fluid to pass through Spenser II's graft

[12] We express no opinion here on the legal question of indefiniteness.

material when undeployed. Ex. 2002 ¶¶ 59–60 (annotating Spenser II's Fig. 22); Ex. 1011 ¶ 145. Dr. Brecker further testifies, and we agree, Petitioner's position is at odds with Dr. Brecker's earlier testimony (and the Board's crediting of that testimony) describing Spenser II's compressible material as a "solid, ***non-porous***, graft material." Ex. 2002 ¶ 60 (citing Ex. 2124 (556 FWD), 38, quoting Ex. 2103 ¶ 160). Moreover, the Board recently rejected Petitioner's challenge to claims of the '033 patent's parent—holding (based on a similar record) that Spenser II includes a ***non-porous*** (i.e., ***fluid impermeable***) graft covering material between the outwardly-extending surface fibers and the frame. IPR2023-01151, Paper 12, 43–44.

Petitioner's argument is also contradicted by its own expert's testimony in prior proceedings. Although Petitioner now argues that fluid could or would pass through Spenser II's compressible material, Dr. Buller previously testified that Spenser II's compressible material would be "sufficiently dense to prevent blood from leaking through the cloth/fabric." Ex. 2128 ¶ 222.[13] On this point, Dr. Brecker agrees—POSAs "would understand that the compressible material would be 'sufficiently dense' to prevent blood from leaking because that is its principal purpose." Ex. 2002 ¶¶ 62–63 (testifying "a thick, sleeve-like PET layer as depicted in FIG. 22 [of Spenser II] would not suggest, much less necessarily indicate, a 'porous'

[13] As discussed in related proceedings, Dr. Buller testified that non-porous, as used in his prior testimony and in the Specification of the '033 patent, means "fluid would not pass through it." Ex. 2122, 20:2–21:3, 21:17–22:1. Dr. Buller also confirmed that, relevant to the challenged patent here, fluid means plasma (i.e., blood and water). *Id.* at 22:2–8.

covering"). Petitioner's and Dr. Buller's contradictory positions undermine Petitioner's present argument.

Second, Petitioner contends that Spenser II's compressible material expands after deployment to create a mechanical seal. Pet. 48 (citing Ex. 1003 ¶ 156; Ex. 1011 ¶ 145). From this, Petitioner contends, POSAs "would have appreciated" that compression and sealing does not occur in an undeployed state and "fluid could pass through the sealing material." *Id.*

This argument from Petitioner fares no better. It is inconsistent with Dr. Buller's prior testimony and the Board's findings in prior matters, as already explained. Moreover, the cited portions of Spenser II relate to the compressible material filling gaps and creating a seal "between the stented valve and the [patient's] surrounding tissue." Ex. 1011 ¶ 145 ("As the compressible material expands, it fills gaps between the stented valve and the surrounding tissue."). Put differently, this disclosure relates to sealing around the prosthetic valve's outer periphery—in the case of aortic valve placement, between the compressible material and fibers and the patient's native aortic leaflets. This disclosure does not suggest, much less necessarily show, that fluid would pass through the thickness of Spenser II's compressible material when it is undeployed. Ex. 2002 ¶¶ 65–66 (testimony of Dr. Brecker that there is "no basis" in Spenser II to conclude fluid would pass through its compressible material and that real-world embodiments of Spenser II, like Walther, are described as compressible and promoting coagulation and sealing without spacings that allow fluid to pass through Walther's outer cloth); Ex. 1007, 1, 7; Ex. 1128, 72:8–9 (testimony of Dr. Buller that blood clots in Walther's outer cloth).

Third, Petitioner contends that Spenser II's "compressible material, and especially the fibers, may be adapted to encourage coagulation of blood

to further fill the gaps and prevent leakage." Pet. 48–49 (citing Ex. 1003 ¶ 156; Ex. 1011 ¶ 145 (disclosing "a tissue growth factor may be applied to the compressible material for promoting growth of tissue into the material, thereby further sealing the gaps")). According to Petitioner, POSAs "would have understood" that the spacings needed to promote tissue ingrowth would be in the "range of 40–100 μm" and larger than needed to allow fluid to flow. *Id.* (citing Ex. 1106, 158).

Petitioner's argument is unavailing. The notion that Spenser II's compressible material would allow fluid flow through it is inconsistent with Petitioner's and Dr. Buller's past positions, as explained above. Inasmuch as Petitioner is suggesting that the claim is met if fluid moves between the outwardly-extending fibers or may seep to some degree into the cloth/fabric of the compressible material itself, we are unpersuaded that would necessarily meet the relevant claim language—the sealing assembly has a thickness, and claim 1 requires spacings such that fluid is allowed to "pass" through the sealing assembly's thickness. Moreover, as Patent Owner argues, Petitioner's evidence "does not even speak to fluid permeability." Prelim. Resp. 29–30 (citing Ex. 2002 ¶ 72; Ex. 1106, 157–158). Indeed, Dr. Brecker testifies, Petitioner's evidence "appears to be referring to "healing porosity" (tissue ingrowth) and not "bleeding porosity" (relating to fluid permeability). Ex. 2002 ¶ 72 (citing Ex. 1106, 157 and Dr. Buller's testimony (Ex. 2122, 43:8–45:2) distinguishing tissue growth into a fabric and passage of fluids through it). On the record before us, we are unpersuaded that Petitioner has shown sufficiently that Spenser II's compressible material, when added to the valves of Levi or Spenser, would necessarily allow fluid to pass through that material in an undeployed state.

Lastly, Petitioner contends that, even if Spenser II does not disclose claim 1's "spacings" limitation, a POSA would have used some other "porous" fabric or cloth, such as a woven or knitted velour-like material, that allegedly would allow fluid to pass therethrough when the fabric is uncompressed. Pet. 49 (citing Ex. 1003 ¶¶ 157–159). According to Petitioner, a POSA would have done so because such materials are compressible, stretchable, and allow tissue ingrowth. *Id.*

We reject this backstop argument. Petitioner's challenge under Grounds 1 and 2 is based on the combination of either Levi and Spenser II, or Spenser and Spenser II. Yet Petitioner purports to modify Spenser II's compressible material, or supplant it with something else, based on "porous" fabrics allegedly known elsewhere in the art, which art is not identified in the Petition itself as part of any asserted combination. Pet. 49. To see what specific modifications or combinations Petitioner might be suggesting, requires we look to three paragraphs of Dr. Buller's Declaration, cited but not discussed by Petitioner, where eight additional references are mentioned. Ex. 1003 ¶¶ 157–159 (identifying Exs. 1106–1112, and 1129).

This format is an improper incorporation-by-reference of argument and evidence that, had Petitioner wanted to pursue some other combination of asserted art beyond Levi, Spenser, and Spenser II, needed to be set forth explicitly in the Petition. 37 C.F.R. § 42.6(a)(3). Moreover, it leaves the record unclear and forces Patent Owner, the Board, and the public to guess at what combination(s) are, in fact, being urged.

We also find that Petitioner's position reveals a hindsight bias insofar as it suggests, with the aim of arriving at the claimed subject matter, removing Spenser II's "sufficiently dense" and fluid impermeable compressible material (Ex. 2128 ¶ 222) in favor of some other sufficiently

"porous" and fluid permeable material. Hindsight is further evidenced because Spenser II's cited material is already described as being compressible and adapted to allow coagulation and tissue ingrowth—factors cited by Patent Owner as allegedly motivating a change to some other material. Ex. 1011 ¶ 145. Altogether, we find unpersuasive Petitioner's position based on unspecified combinations of unasserted prior art to achieve benefits that Spenser II's existing compressible material already provides.

For the above reasons, we conclude that Petitioner has not established it is reasonably likely to prevail in showing that claim 1 is unpatentable as obvious over Spenser or Levi, combined with Spenser II.[14]

2. Dependent claims

Claims 2 and 4–6 depend from independent claim 1. Ex. 1001, 22:31–42. Petitioner's challenge to those dependent claims relies on Petitioner's threshold showing for claim 1, and Petitioner does not argue or show that its challenge to those dependent claims makes up for above-noted deficiencies on claim 1. Pet. 60–63. Thus, Petitioner is not reasonably likely to prevail on its challenge to claims 2 and 4–6. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.").

3. Conclusion

On this record, Petitioner has not shown it is reasonably likely to prevail in establishing that at least one of claims 1, 2, and 4–6 would have

[14] Because we deny Petitioner's Spenser-II based challenge for other reasons, we do not further address Patent Owner's contention that 35 U.S.C. § 325(d) should bar consideration of such challenge. Prelim Resp. 13–17.

been obvious over Spenser or Levi in further combination with Spenser II under asserted Grounds 1 and 2.

F. Chuter Combinations (Grounds 3–6)

Petitioner contends that claims 1, 2, and 4–6 would have been obvious over either Spenser or Levi, in further combination with Chuter (Grounds 3 and 4). Pet. 63–79. Petitioner also contends that claims 1, 2, and 4–6 would have been obvious over either Spenser or Levi, in further combination with Chuter and Spenser II (Grounds 5 and 6). *Id.* at 79–80.[15] Petitioner's argument under Grounds 5 and 6 mirrors the argument for Grounds 3 and 4, differing only insofar as Petitioner asserts that Spenser II would have provided "additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves." *Id.* (citing Ex. 1003 ¶¶ 229–230).

As we discuss below, Petitioner's challenge, as well as Patent Owner's counterargument, focus on two embodiments of Chuter relied upon in the proposed combination with either Spenser or Levi. One of those embodiments is a graft that includes a stent frame covered by a fabric pile backing layer, and with a fabric pile of individual fibers extending outwardly from the backing layer, such as shown in Figures 1–3 of Chuter. *See, e.g.*, Pet. 64–65, 67, 73–74, 76–77; Prelim. Resp. 41–51; Ex. 1116, Figs. 1–2; *see supra* Section III(D)(4). The second Chuter embodiment (or set of embodiments) is an "occluder," with individual fibers disposed outwardly and inwardly, or only outwardly, from a frame, such as shown in Figures 5–

[15] For the Chuter-based grounds, the Petition uses headings "Grounds 2–4," and "Grounds 4–6," which appear to be typographical errors. *Compare* Pet. 63, 79, *with* Ex. 1003, 114, 137 (corresponding pages from Dr. Buller's Declaration, using the headings "Grounds 3–4" and "Grounds 5–6").

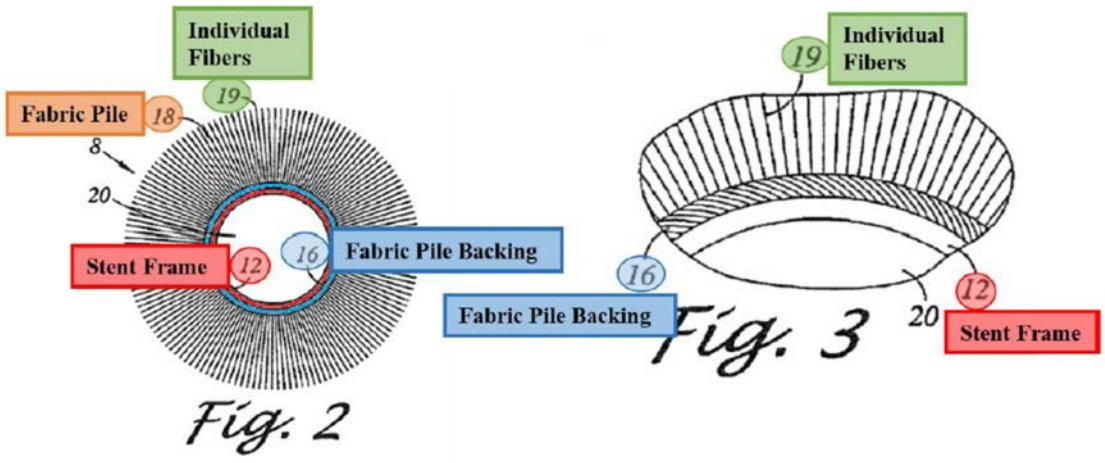
10 of Chuter. *See, e.g.*, Pet. 67–68, 73–74; Prelim. Resp. 51–74; Ex. 1116, Figs. 5–10.

1. Analysis

a) Chuter Graft/Backing-Layer Embodiment (all challenged claims)

Petitioner's challenge based on the combination of Spenser or Levi with Chuter's backing-layer embodiment resembles Petitioner's challenge based on the combination of Spenser, Levi, and Spenser II from above. Petitioner relies on Chuter in much the same way as it relied on Spenser II—citing Spenser or Levi for most of claim 1's limitations and relying on Chuter as teaching the claim requirements concerning the "sealing assembly" including the limitation of "spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough" when the valve is undeployed. Pet. 66–78; *see id.* at 76–77 (argument about "spacings" limitation).

Petitioner's annotated version of Chuter's Figures 2 and 3 are reproduced below.



Pet. 73. Figures 2 and 3 of Chuter are, respectively, longitudinal end and partial expanded views of Chuter's backing-layer embodiment and, according to Petitioner, show an internal frame (red), a fabric pile backing

layer (blue) surrounding the frame, and individual fibers (green) making up a fabric pile (orange) that extends outwardly from the backing layer. *Id.* at 73 (citing Ex. 1116 ¶¶ 54–55, Figs. 2–3).

As with Petitioner's argument based on Spenser II above (*supra* Section III(E)(1)), Petitioner contends a POSA would have been motivated to add Chuter's fiber pile to Spenser, and to replace Levi's outer skirt with the fiber pile to promote tissue ingrowth and reduce PVL around the valve. *Id.* at 69–71.

According to Petitioner, in Chuter's embodiments "wherein the fiber pile includes a fabric pile backing . . . [,] spacings exist between the fibers that 'extend through a thickness' of the fiber pile (i.e., sealing assembly) and would 'allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state." Pet. 76 (citing Ex. 1116, Fig. 2; Ex. 1003 ¶ 216). For reasons explained below, we do not agree.

Petitioner's assertion that claim 1's "spacing" limitation including the "fluid to pass" sub-element is met by Chuter's embodiments having a backing layer is wanting for evidentiary support. Petitioner's conclusory assertion that Chuter discloses this limitation is accompanied by an equally conclusory opinion from Petitioner's declarant, Dr. Buller. Ex. 1003 ¶ 216. Indeed, from Dr. Buller's conclusory opinion, he jumps abruptly to Chuter's *alternative* embodiment where fibers are "attached directly" to a frame as "illustrated in [Chuter's] Figure 7." *Id.* In that embodiment, if allegedly combined with Levi or Spenser, Dr. Buller opines that "there would be no fibers, or other material, traversing openings between the struts" and, thus, fluid could pass through spacings spanning the width of a frame's open cells when undeployed. *Id.* Yet, Petitioner provides neither evidence nor technical analysis that explains how this limitation is met in embodiments

with a backing-layer, where there ***would be material*** covering any openings between struts of the frame. *See, e.g.*, Ex. 1116, Figs. 1–4 (showing backing layer 16 and 16A). Dr. Brecker identifies this flaw in Petitioner's showing. Ex. 2002 ¶ 108. And, we agree on this record with Dr. Brecker's testimony that, if anything, Chuter suggests the fabric-pile backing layer would prevent passage of fluid therethrough. *Id.* ¶¶ 105–109 (citing, for example, Chuter's disclosures where a "fabric pile backing is utilized to occlude the blood vessel . . .[,] indicat[ing] that fluid may not pass therethrough"); *see, e.g.*, Ex. 1116, Fig. 11 (showing a fabric pile backing layer (16A) enclosing the sides and one open end of a stent, in a sock-like fashion).

We are, thus, not persuaded that Petitioner is reasonably likely to prevail in establishing that claim 1 (or dependent claims 2 and 4–6) is unpatentable based on the argument and evidence before us. *In re Fritch*, 972 F.2d at 1266.

b) Chuter Occluder Embodiments (all challenged claims)

As an alternative, Petitioner cites Chuter's embodiments lacking the fabric pile backing layer and having individual fibers that extend directly from a frame. Pet. 65, 67–68, 76. Chuter's Figures 7, 9, and 10, as annotated by Petitioner, are provided below.

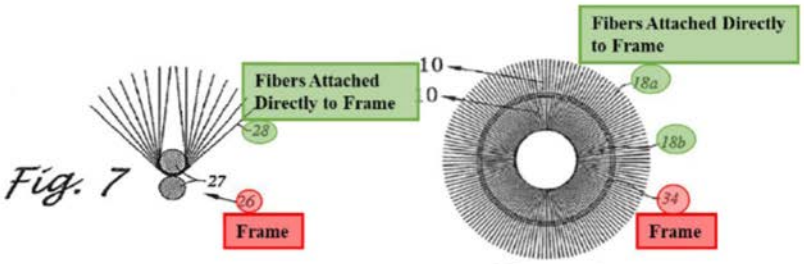


Fig. 7

Fig. 9

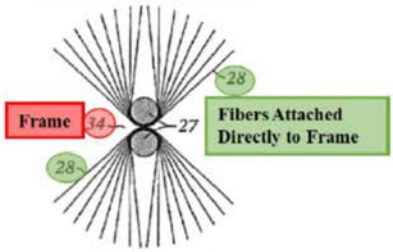


Fig. 10

Pet. 65; Ex. 1116, Figs. 7, 9, 10. As shown above, Petitioner contends that the above embodiment of Chuter discloses a frame (red annotation) and first (green annotation) and fibers attached directly to the frame (green). Pet. 65.

Petitioner's reasons for combining Chuter's fiber pile as illustrated above to the frames and valves of Spenser or Levi is essentially the same as discussed with the backing-layer embodiment. Pet. 69–72 (arguing a POSA would be motivated to add this fiber pile to Spenser's valve, or to replace Levi's outer skirt with Chuter's fiber pile, to reduce PVL); Ex. 1003 ¶¶ 197–205. Petitioner further contends that, although Chuter's embodiments without a backing layer use double-wire frames, Chuter suggests other frames may be used. Pet. 70 (citing Ex. 1116 ¶¶ 3, 12). Petitioner also asserts that, based on a dearth of detail in the '033 patent about how fibers are attached to the frame, the POSA would know how that could be done. *Id.* at 70–71 (citing Ex. 1001, 12:53–56); Ex. 1073, 313:18–314:1 (Buller testimony about the Specification not providing an explicit description of how fibers are attached).

Petitioner contends the "spacings" limitation is met in Petitioner's proposed combination relying on Chuter's directly-attached fibers. Pet. 76–77 (citing Ex. 1116, Fig. 7). According to Petitioner, a POSA "would have been motivated to attach the fiber pile to Spenser's or Levi's frames in the same way they are attached to Chuter's frame." *Id.* (citing Ex. 1003 ¶¶ 216–217). In support, Dr. Buller testifies that attaching fibers directly in this way to a frame would leave spaces between adjacent fibers and no material traversing openings in the frame/struts when undeployed, such that fluid would pass through such openings. Ex. 1003 ¶ 216.

Petitioner's argument supporting this alternative combination with Chuter is unpersuasive. Petitioner sidesteps the fact that the cited Chuter

embodiments without a backing layer and with directly attached fibers are described as addressing a different purpose—***occlusion of the blood vessel***. *See, e.g.*, Ex. 1116 ¶¶ 5, 18, 56–57, Figs. 5–10. As argued by Patent Owner, "Chuter's occluder, used in a bypass procedure, is intended to stop ***all*** blood from passing" and "is antithetical to a TAVR which is designed to allow blood to pass through the channel." Prelim. Resp. 52–53. Moreover, as explained by Dr. Brecker, "[t]he principal function of an occluder, including Chuter's occluder, is to 'prevent all blood flow into' a vessel." Ex. 2002 ¶¶ 118–120 (citing, e.g., Ex. 1116 ¶¶ 5, 18, 57). By contrast, "TAVRs, ***must*** leave the aorta (a large vessel) unobstructed to allow blood flow through the aortic artery and prosthetic leaflets." *Id.* And, Dr. Brecker testifies, "[t]he twisted wire loop stent of Chuter is . . . uniquely designed for the specific purpose of adapting to the diseased vessels and causing occlusion." *Id.* ¶ 120; *see also id.* ¶¶ 125–128 (citing Ex. 1116, Figs. 5, 8, ¶¶ 17–18, 56–57, and contrasting Chuter's twisted-wire design with lattice-like stents of Spenser and Levi (Ex. 1008, Fig. 20; Ex. 1010, Fig. 44a)).

We, thus, find Dr. Brecker's testimony more credible that "[i]t would, accordingly, be counterintuitive for a [POSA] to look to a device designed to occlude a blood vessel when designing a TAVR." *Id.* ¶¶ 119–120 (testifying "[n]o [POSA] would look to this [occluder] design when considering a TAVR valve and . . . would further have concerns about the pro-thrombotic potential of the arrangement of fibers in Chuter"). Where a proposed combination would run counter to the primary reference's stated purpose, the POSA would not generally be motivated to make that combination. *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069–70 (Fed. Cir. 2018).

The unsuitability of Chuter's occluder features in the TAVR environment is especially evident in embodiments where the fibers extend both outwardly and inwardly from the stent. But even in embodiments with only outwardly-extending fibers, Dr. Brecker testifies that the fibers must be densely arranged and have sufficient length to traverse the stent's inner bore to form a seal and stop all blood from flowing through the vessel—otherwise the device could not perform its necessary function. Ex. 2002 ¶ 120 (citing Ex. 2126 (Chuter file history), 145, 165, 170–172, 186 (distinguishing Chuter from prior art meshes on the basis that Chuter's fiber pile must be long enough to bridge the stent lumen). We question Dr. Brecker's testimony on this point (also, no authority is cited for the proposition that arguments made during prosecution of applied prior art necessarily inform that art's teachings). It would seem, for example, that the occlusion function, may be provided by the combination of outwardly-oriented and directly attached fibers in combination with the shape of the helical stent itself (i.e., "conical"). Ex. 1116 ¶ 57 (describing Figures 5-7 as "conical shaped occluder"). Nevertheless, we have greater doubts that a POSA would, absent hindsight, have culled the directly attached fibers from Chuter's occluder embodiments (e.g., Ex. 1116, Figs. 6–7, ¶¶ 56–57) and applied that feature in a TAVR environment where it was not intended; nor does Chuter suggest that it may be applied in that environment.

In addition, we are unpersuaded by Petitioner's contention that a POSA would have been motivated to, and reasonably expected success in, combining the unique, direct fiber-attachment design of Chuter for use in the stents of Spenser or Levi, much less done so by attaching fibers "***in the same way*** they are attached to Chuter's frame." Pet. 76–77. As Patent Owner highlights, "Chuter's occluding fiber pile . . . is formed when the individual

fibers are secured by the twisted, helically wound double wires of Chuter's frame." Prelim. Resp. 58. Indeed, Dr. Brecker testifies that "[t]he only 'technique' or 'method' Chuter teaches for attaching fibers to this helical loop, [(e.g., as depicted in the spring or coil-like structure of Fig. 5 of Chuter),] is by 'inner dispos[ing]' or 'secur[ing]' the fibers between the twisted, helically wound metal wires." Ex. 2002 ¶¶ 126–127. We agree with Dr. Brecker that such a helical, wound-wire structure bears no resemblance to the gridded or lattice-like open-celled frames of Spenser or Levi. *Id.* ¶ 128 (showing the relevant structures of Chuter, Spenser, and Levi side-by-side).[16] We also find persuasive, on this record, Dr. Brecker's testimony that Chuter's disclosure about its fabric pile being compatible with other expanding stents is more reasonably read as limited to Chuter's backing-layer embodiments. *Id.* ¶¶ 137–138 (citing, e.g., Ex. 1116 ¶¶ 12–13, and noting that Chuter's cited disclosure was expressly made for embodiments with a backing layer).

It is true, as Petitioner contends, that the '033 patent is short on details about how fibers are attached to a frame. But, as a threshold matter, Petitioner must still establish a sufficient motivation to change the Levi or Spenser frame to include Chuter's directly-attached fibers and do so, in Petitioner's words, "in the same way" as shown in Chuter. Pet. 76–77. We find evidence for such a motivation lacking on this record, especially given

[16] We also agree with Dr. Brecker that Chuter's disclosure criticizes known constant-diameter stents and its prosecution history sought to distinguish such stents, including those with lattice-like configurations (more like Spenser or Levi's frames) from the relied-upon occluder embodiments. Ex. 2002 ¶¶ 134–135 (citing Ex. 1116 ¶ 9; Ex. 2126, 200).

Chuter's different purpose and unique stent design involved where fibers are directly attached, as discussed above.

In addition, Petitioner's assertions that POSAs could "optimize[]" fiber lengths, densities, or distributions for delivery via the femoral artery lack detail and do not outweigh the evidence that detracts from the proposed motivation in the first instance, as discussed above. Pet. 75–76; *InTouch Tech., Inc. v. VGO Comm., Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (finding hindsight bias in testimony that "primarily consisted of conclusory references to [the] belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so"). And, Petitioner's unspecified modifications leave important questions unanswered. *Sisvel Int'l. S.A. v. Sierra Wireless, Inc.*, 82 F.4th 1355, 1364 (Fed. Cir. 2023) (affirming Board's rejection of obviousness rationales that "were too conclusory, lacked clarity, or suffered from both problems"); Prelim. Resp. 68–74.

Dr. Brecker testifies, for example, that "adding Chuter's occluding fibers to the frame of Spenser I or Levi would not allow for transfemoral delivery" as "Chuter's dense fibers are accommodated via Chuter's [distinct] helical loop frame" with "no valve structure or graft covering housing the native leaflets within the stent to inhibit crimping." Ex. 2002 ¶¶ 143–145 (testifying, in apparent agreement with Petitioner's declarant, Dr. Buller, that Chuter's fiber pile could not be added to Spenser or Levi without further (unspecified) changes). Yet, Dr. Brecker testifies, "no specifics are proffered [by Dr. Buller] for what modifications would be made or how the resulting combination would still be transfemorally deliverable," as claimed while also providing fibers "dense enough to prevent PVL." *Id.*

Lastly, the "additional motivation" allegedly supplied by Spenser II for adding Chuter's fiber pile does not change the result here. Pet. 80. Petitioner contends "Spenser II teaches the addition of compressible materials to the outside of THVs for preventing PVL." *Id.* (citing Ex. 1011 ¶ 145; Ex. 1003 ¶¶ 229–230). This rationale provides no persuasive support for adding Chuter's directly-attached fibers to Spenser's or Levi's devices for reasons discussed above. No such fibers are suggested in Spenser II, which describes only fibers extending externally from the surface of a compressible material (e.g., fabric/cloth base layer). And, even assuming Spenser II provided a motivation for considering Chuter's embodiments where a fibrous backing-layer is included (as akin to Spenser II's compressible material), we are unpersuaded a modification of Spenser or Levi to include a fibrous pile backing layer as described in Chuter would allow fluid to pass and meet the "spacings" limitation, as explained above.[17]

2. Conclusion

On this record and for the reasons above, Petitioner has not shown under Grounds 3–6 that it is reasonably likely to prevail in establishing that at least one of claims 1, 2, and 4–6 would have been obvious over Spenser or Levi in further combination with Chuter (even considering the alleged "additional motivation" supplied by Spenser II).

IV. CONCLUSION

For the reasons explained above, Petitioner has not established a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims is unpatentable based on the grounds advanced.

[17] Because we deny Petitioner's Chuter-based challenges for other reasons, we do not further address Patent Owner's contention that 35 U.S.C. § 325(d) should bar consideration of such challenges. Prelim Resp. 39–41.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and we do not institute *inter partes* review of any claim of the ’033 patent based on the grounds asserted in this Petition.

FOR PETITIONER:

Joshua Stowell
Craig Summers
Brian Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
2jys@knobbe.com
2css@knobbe.com
2bcb@knobbe.com

FOR PATENT OWNER:

Kenneth Weatherwax
LOWENSTEIN & WEATHERWAX LLP
weatherwax@lowensteinweatherwax.com