Trials@uspto.gov
571-272-7822

Paper 10
Date: February 7, 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.

IPR2023-01232
Patent 11,389,310 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 1, "Pet") requesting *inter partes* review of claims 1–3, 5, 7, and 11–13 of U.S. Patent No. 11,389,310 B2 (Ex. 1001, "the '310 patent"). Pet. 1, 17. Aortic Innovation LLC ("Patent Owner") filed a Preliminary Response (Paper 9, "Prelim. Resp.").

Patent Owner has since disclaimed claims 1–10 of the '310 patent. *See* Ex. 2138; Prelim. Resp. 75; 35 U.S.C. § 253(a). *Inter partes* review may not be ordered for the disclaimed claims. *See* 37 C.F.R. § 42.107(e) ("No *inter partes* review will be instituted on disclaimed claims."); *Vectra Fitness, Inc. v. TWNK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) ("This court has interpreted the term 'considered as part of the original patent' in section 253 to mean that the patent is treated as though the disclaimed claims never existed."). Of the challenged claims, claims 11–13 remain.

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 11–13 of the '310 patent.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC as the real parties-in-interest. Pet. 90. Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

B. Related Matters

The parties identify the following lawsuit involving assertion of the '310 patent (along with other asserted patents): *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, 23-cv-00158 (D. Del.); Pet. 91; Paper 4, 1.

Petitioner identifies related matters filed with the Board involving the same parties and related patents. Pet. 90–91. Those matters include: IPR2021-01527; IPR2021-01584; IPR2022-00193; IPR2022-00034; IPR2022-00556; IPR2022-00549; and IPR2023-01151. *Id.*; *see also id.* at 4 (identifying the earlier-filed IPRs and their status).[1]

C. The '310 Patent

The '310 patent is titled "Device for Aortic Repair and Method of Using the Same." Ex. 1001, code (54). The '310 patent issued from U.S. Application No. 16/941,117, filed July 28, 2020, which claims priority through a series of related applications. *Id.* at codes (21), (22), (60). The earliest applications in the '310 patent's identified priority chain are two U.S. provisional applications filed November 7, 2012, and December 6, 2011. *Id.* at 2 (labeled code (60)).[2]

According to the '310 patent, no devices in clinical use for endovascular repair of ascending aortic aneurysms "have been designed with

[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 and 1151 cases. Exs. 1120, 1121, 2124; IPR2023-01151, Paper 12.

[2] The '310 patent includes two different paragraphs labeled code "(60)." *Compare* Ex. 1001, 1 (cover page), *with id.* at 2 (cover page continuation).

the purpose of endovascular repair of multiple types of ascending aortic aneurysms." *Id.* at 2:28–32.

The '310 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 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 2:33–41.

The '310 patent discloses an endograft device, including a transcatheter heart valve for endovascular repair of ascending aortic aneurysms. Ex. 1001, 2:45–47. 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 2:47–55. "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 2:60–62. Moreover, the second prosthetic component may include "a self-expanding frame that is connected to the balloon-expandable frame." *Id.* at 2:55–59. Both parties agree that the challenged claims in this *inter partes* review relate to the heart-valve component. *See, e.g.*, Pet. 2.

Figure 11 of the '310 patent is reproduced below.

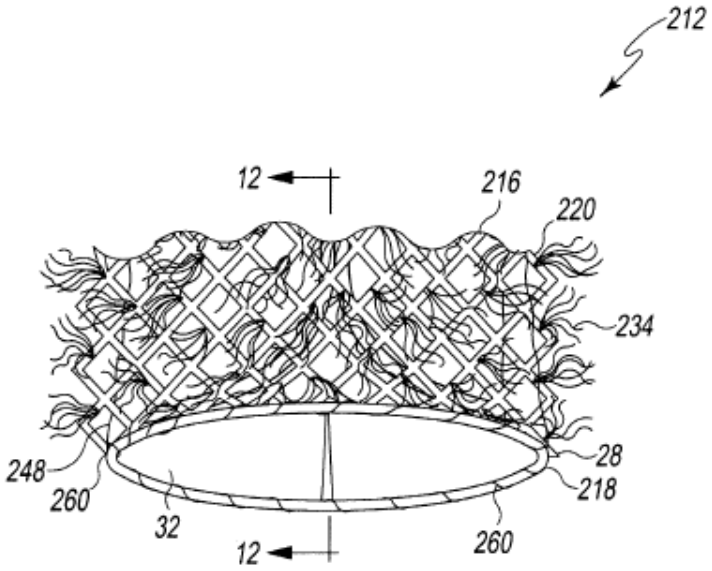


Fig. 11

Ex. 1001, Fig. 11. Figure 11 is a perspective view of a proximal end of the proximal prosthetic component 212 of the endovascular device. *Id.* at 5:46–47. 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 14:3–10. Figure 11 also shows fibers 234 attached to the outer frame 216. *Id.* at 14:10–13.

Figure 13 of the '310 patent is reproduced below.

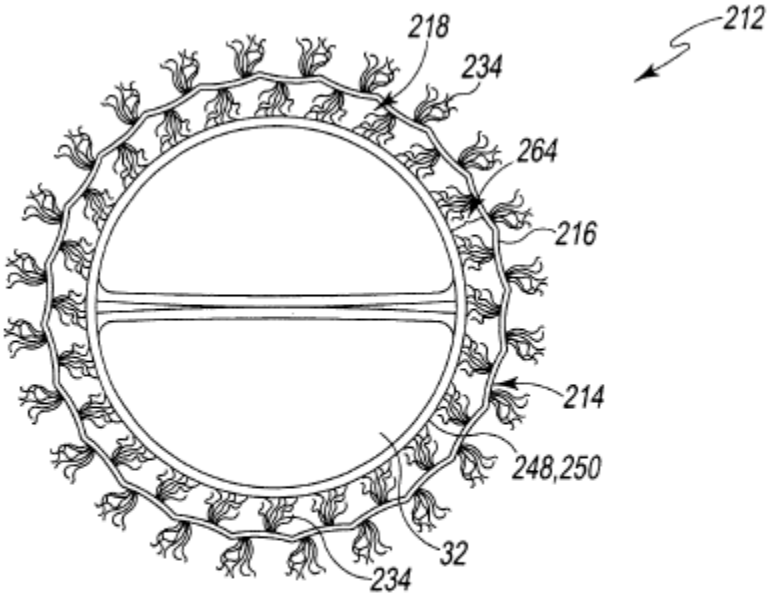


Fig. 13

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 5:51–53. 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 14:10–13; *see also id.* at 18:23–25 (describing alternative embodiment with outwardly and inwardly extending fibers). In the unexpanded state, a gap 264 is defined between the inner and outer frames. *Id.* at 14:10–15.

The '310 patent discloses that the "[b]alloon-expandable frame 218" may be embodied as a "balloon-expandable tubular stent 244." Ex. 1001, 13:38–41. "[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 13:43–45. "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, 14:10–13. 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), 14:16–29.

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 14:55–61 (disclosing that the combined engagement of the frames seals the annulus and prevents paravalvular leakage). According to the '310 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 18:20–23.

D. Illustrative Claims

Claim 11 is the only non-disclaimed, independent claim that remains challenged. Claim 11 reads:

> 11. A transcatheter aortic heart valve assembly comprising:
>
> a graft covering engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the prosthetic heart valve leaflets;
>
> a frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering; and
>
> a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall to prevent paravalvular leaks,
>
> wherein the sealing material is attached to the frame,
>
> wherein the sealing material defines a height that extends over at least a first two rows of cells in the frame,

> wherein the sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame;
>
> wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,
>
> wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,
>
> wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the outwardly extending fibers into engagement with native leaflets of the aorta of the patient,
>
> wherein the plurality of fibers is in contact with the 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. 1001, 22:50–23:14. Challenged claims 12 and 13 depend from claim 11 and recite, respectively, that the frame's cells are "a square shape," and that the "graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve." *Id.* at 23:15–19.

E. Prosecution History

The application (U.S. Application 16/941,117) that matured into the '310 patent was filed on July 28, 2020. Ex. 1001, code (22).

On October 12, 2021, applicant submitted a preliminary amendment that canceled application claims 1–30, amended application claim 31 (ultimately issued as claim 1) and added new claims 32–35. Ex. 1002, 686–689. Claim 31, as then amended, was drawn to a transcatheter heart valve assembly that required, *inter alia*, a sealing material positioned externally to an outer frame, that "the sealing material is attached to the outer frame" and "includes a plurality of radially extending fibers that extend outwardly of the outer frame," and that the valve assembly is "configured to be deployed endovascularly through a femoral artery of [a] patient" *Id.* at 687. At that

time, applicant also provided "Remarks" concerning "transcatheter aortic valve replacement (TAVR)" technology, to which the claimed subject matter relates, and contrasted the claimed subject from existing TAVR, valve, and stent graft devices. *Id.* at 690–710. In those remarks, applicant discussed the Levi, Spenser, and Spenser II references (asserted by Petitioner here and filed as Exhibits 1008, 1010, and 1011; *infra* Section II(F)). *See, e.g.*, *id.* at 698–700 (stating, e.g., Spenser II[3] "teach[es] a thick band with fibers emanating therefrom in FIG. 22").

On October 26, 2021, the Examiner rejected the claims as obvious over multiple prior art combinations, including combinations based on Spenser, Spenser II, and Levi. *See, e.g.*, *id.* at 585–587 (rejecting claim 31 over Spenser combined with Spenser II), 590–592 (rejecting other claims over a combination of Spenser, Spenser II, and Levi). In response, applicant argued that the Examiner's proposed combinations would create a valve assembly too large to be deployed endovascularly via the femoral artery as claimed. *Id.* at 566–577.

The Examiner entered another non-final rejection dated December 13, 2021, stating that applicant's arguments were "moot" in light of "new rejections" over a combination of Levi and Spenser II. *Id.* at 454–458. In short, the Examiner proposed modifying Levi's transcatheter heart valve assembly having a frame, inner graft material, and outer sealing material to include Spenser II's outer "sealing member" and plurality of outwardly extending fibers. *Id.* at 458. In response, applicant amended and canceled certain claims, added additional new claims (including application claim 44

[3] Spenser II (WO 2006/005015) was also referred to as "Dehdashtian" during prosecution. *See, e.g.*, Ex. 1002, 585.

(issued claim 11)) and essentially repeated its arguments that a proposed combination of Levi and Spenser II would render the modified device unsuitable for femoral artery delivery. *Id.* at 434–447 (arguing, *inter alia*, that Spenser II teaches an "outer band/sleeve with a thickness that ranges from 1 mm to 5 mm[,] . . . greater than what Levi teaches is allowable").

Additional back-and-forth between the applicant and Examiner followed. On February 4, 2022, the Examiner repeated the rejection for obviousness, but added another reference ("Rankin") as further support that delivering valves percutaneously was known. *Id.* at 324–335. Applicant responded with declaration testimony, and restated the argument that Levi and Spenser II could not be combined as proposed to meet the claim limitations, with emphasis on whether the modified device could be delivered through the femoral artery and whether the modification would render the device inoperable. *Id.* at 276–283 (declaration from Dr. Stephen J.D. Brecker), 289–319 (Remarks). Applicant's response prompted the Examiner to clarify the rejection. In an Office Action dated April 19, 2022, the Examiner explained:

> [A]dding to and/or replacing the band of Levi with that of [Spenser II] appears to change the functionality of Levi. . . . However, the Examiner meant to focus on the "fibers" in [Spenser II] that provide enhanced sealing. The fibers are separate components on the device of [Spenser II] . . . [and] the modification to Levi et al. is not to add to and/or replace the band in Levi with the band in [Spenser II], but 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. . . . The rejection has been clarified as the entire band of [Spenser II] is not added to the device of Levi.

Id. at 166–167. With this "clarification" the Examiner maintained the obviousness rejection over Levi, Spenser II, and Rankin. *Id.* at 167–175.

Examiner and applicant then held an interview where prospective claim amendments were discussed. *Id.* at 125 (summary of May 10, 2022, interview). And, on May 11, 2022, applicant amended application claims 31 and 44 (issued as claims 1 and 11) to require, *inter alia*, that "the plurality of fibers is in contact with the [] 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.* at 138–139, 141; *see also id.* at 143 (stating that it was agreed that the amendments would overcome the obviousness rejection; asserting that the newly-added claim language was supported in the Specification, citing Figures 20–22 and stating "[a]s illustrated, the fibers maintain contact with the frame").

After this amendment, the Examiner allowed the pending claims. *Id.* at 20. In doing so, the Examiner stated:

> The following is an examiner's statement of reasons for allowance: 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. at 21.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 11–13[4] are unpatentable based on the following grounds:

[4] As noted above, Patent Owner disclaimed challenged claims 1–10 after the Petition was filed; we do not discuss the disclaimed claims. Ex. 2138 (Disclaimer dated Nov. 9, 2023).

Claims Challenged	35 U.S.C. §[5]	References/Basis
11–13	103	Spenser,[6] Spenser II[7]
11, 13	103	Levi,[8] Spenser II
11–13	103	Spenser, Chuter[9]
11, 13	103	Levi, Chuter
11–13	103	Spenser, Chuter, Spenser II
11, 13	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

[5] 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 '310 patent is November 7, 2012. Pet. 16. Because that date precedes the effective date of the applicable AIA amendments, we apply the pre-AIA versions of §§ 102, 103.

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

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

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

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

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.[10] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Moreover, "[a]n obviousness determination requires finding

[10] The parties did not present substantive argument on secondary considerations. Pet. 84 ("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. 74 (citing, e.g., 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.

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. 21 (citing Ex. 1003 ¶ 50). Patent Owner does not 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 '310 patent require construction to resolve the patentability issues herein." Pet. 19. Also, Petitioner contends, its "grounds are based on [Patent Owner's] allegations that the '310 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, 262–476).[11]

Patent Owner does not propose any express claim construction. Instead, Patent Owner contends that the claims should be interpreted according to their ordinary and customary meaning. *See, e.g.*, Prelim. Resp. 18–19, 35–36 (asserting that Petitioner's mapping of the claims is, in respects, contrary to the "plain language" of the claims).

[11] Petitioner identifies a claim construction order in related litigation where the district court construed an "outer frame" as a "self-expanding frame." Pet. 19 (citing Ex. 1140, 17). We need not further construe the "outer frame" term here because Petitioner contends, without dispute, that the prior art discloses self-expanding frames. *Id.* at 19–20, 26. Moreover, Patent Owner states that it has disclaimed those claims reciting the term "outer frame" to reduce the number of issues before the Board. Prelim. Resp. 75.

Insofar as the parties' arguments may suggest a further disagreement about the scope of the claims, we address those arguments below in our discussion of the mapping of claims to the asserted prior art.

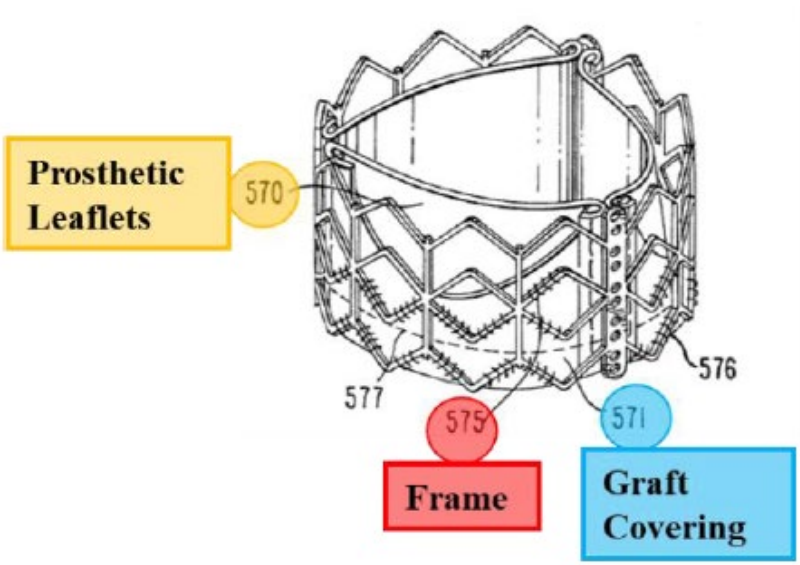
D. Asserted References

Assuming, as Petitioner does, a critical date of November 7, 2012, for the '310 patent's claims, each of the references below is prior art. Pet. 16. 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.

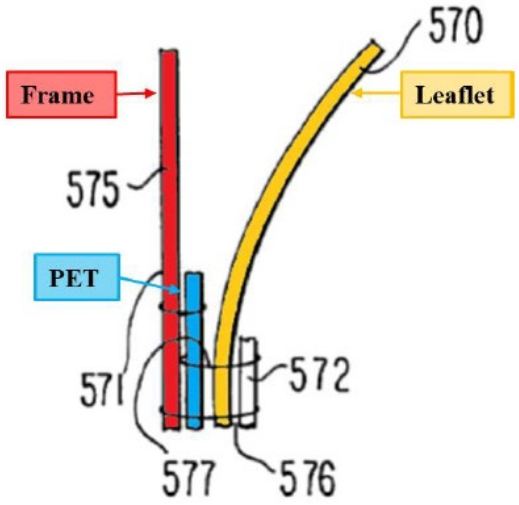


Pet. 20 (reproducing Fig. 44a of Spenser (Ex. 1010) with Petitioner's additional labeling and color-coding). Spenser's Figure 44a shows a

perspective view of an implantable valve with three pericardial leaflets 570 (labeled "Prosthetic Leaflets" 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 "Graft 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. 23 (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,

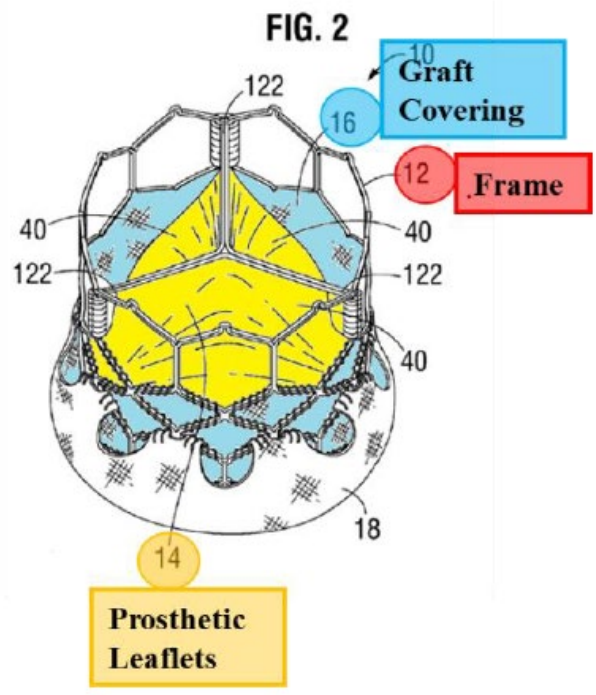
> connects the three layers, the leaflet and both PET layers to the frame and forms a strong sealing line. An upper suture 578 connects the outer PET layer 571 to frame 575.

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. 22 (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 "Prosthetic Leaflets" 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 "Graft 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 (annotated by Petitioner) is reproduced below.

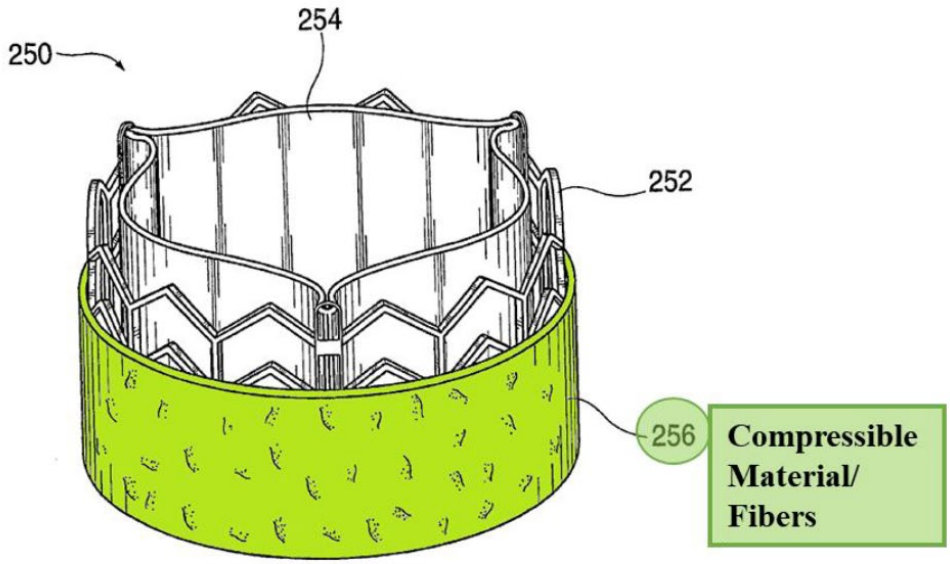


FIG. 22

Pet. 21 (reproducing Fig. 22 of Spenser II (Ex. 1011) with Petitioner's additional labeling and maintained color-coding). Figure 22 of Spenser II, shown above, is a perspective view of a preferred embodiment of the Spenser II prosthetic valve. Ex. 1011 ¶ 85. 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 includes circular layer of compressible material 256 (colored green and labeled "Compressible Material/Fibers" by Petitioner) 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.*

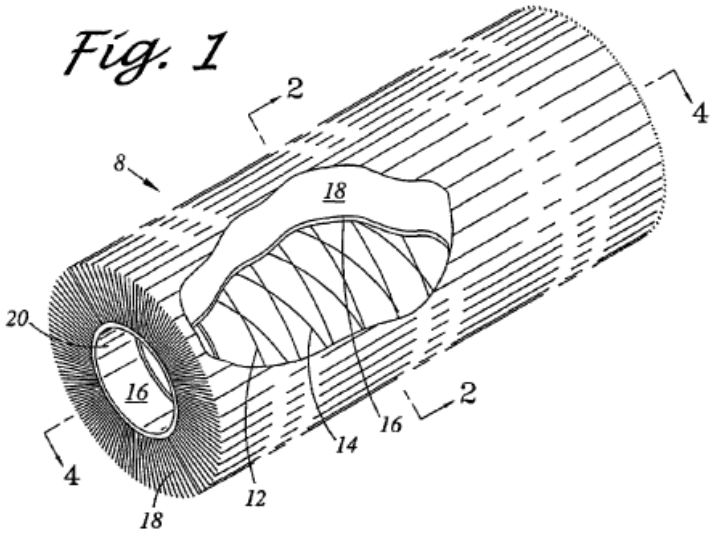
Spenser II discloses that the "compressible material expands after deployment at a treatment site" and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* "In one preferred embodiment, the compressible material 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).

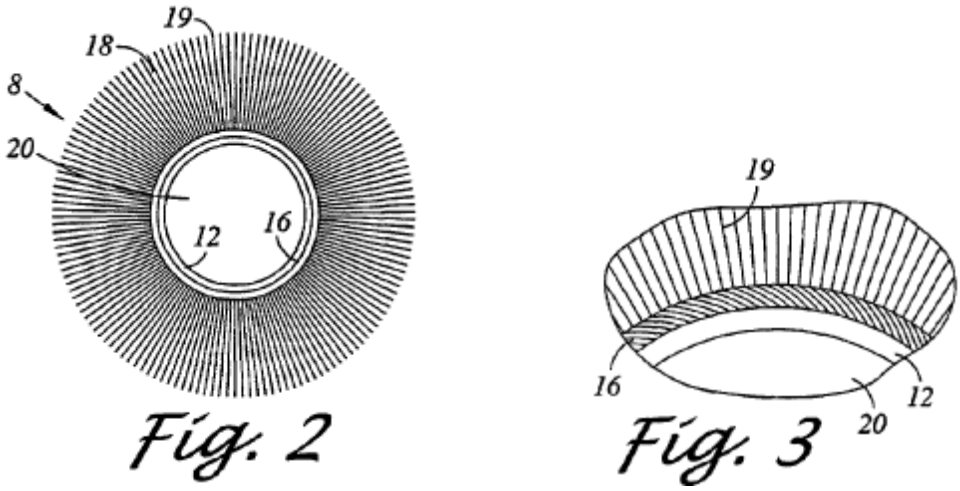
Chuter discloses "[a]n endovascular stent for vascular vessels which can be used to occlude the vessel or which can be used to bridge damaged areas in the vessel." *Id.* at Abstr.

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.

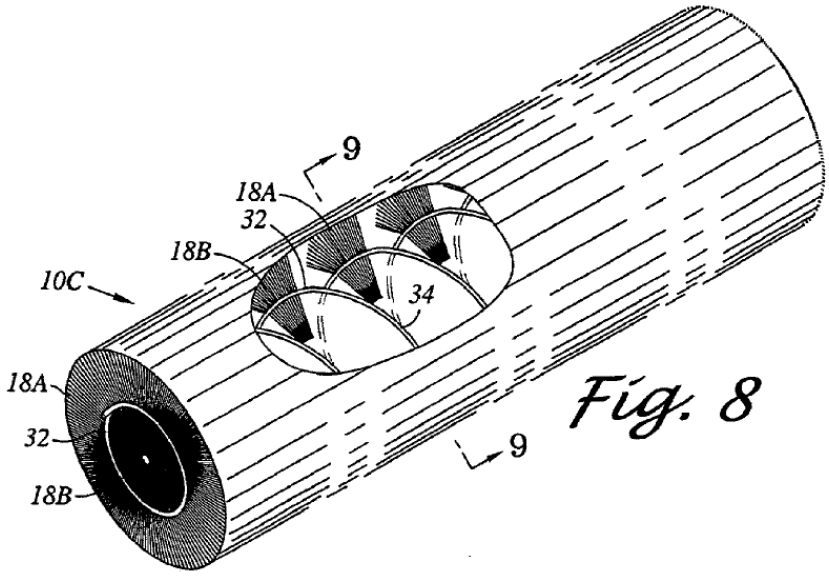


Fig. 8

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.

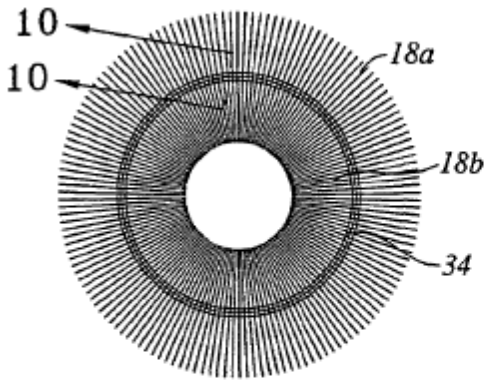


Fig. 9

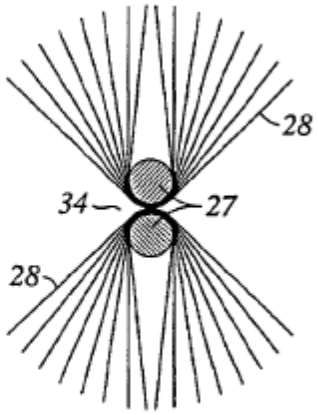


Fig. 10

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 11–13 would have been obvious over Spenser and Spenser II, and that claims 11 and 13 would have been obvious over a combination of Levi and Spenser II. Pet. 65–67.[12] Patent Owner opposes these arguments. Prelim. Resp. 3–37.

[12] Petitioner's claim 11 analysis largely relies on its analysis for claim 1. Pet. 65–66 (citing Pet. § VIII.A).

1. Claim 11

Whether Petitioner has shown sufficiently that the combination of Spenser or Levi with Spenser II discloses that the plurality of outwardly-extending fibers are "in contact with the frame" as claimed 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 argues that Spenser or Levi disclose most of the limitations of claim 1 (and similarly claim 11). Pet. 22–54 (analysis for claim 1 (now disclaimed)), 65–66 (noting three minor differences between claims 1 and 11, with assertion that such differences would have been obvious over Spenser, Levi, and Spenser II for similar reasons as explained for claim 1). For example, Petitioner alleges that Spenser discloses a transcatheter heart valve assembly with an inner "graft covering" and "leaflets" as claimed. Pet. 22–23 (citing, *e.g.*, Ex. 1010, Fig. 44a–44c); *id.* at 23–24 (citing, e.g., Fig. 2 of Levi as showing similar structures meeting these limitations). Petitioner contends that both Spenser and Levi disclose metallic frames with an open-cell configuration that surround and are secured to the graft covering and leaflets. *Id.* at 24–26 (annotating Fig. 44a of Spenser and Fig. 11 of Levi to show the claimed features).

For claim 11's limitations relating to a "sealing material" with that material's various claimed features, Petitioner turns to Spenser II. To summarize, claim 11 also requires, *inter alia*: "a sealing material positioned externally to the frame" and "attached to the frame;" the sealing material "defines a height that extends over at least a first two rows of cells in the frame;" the "sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame," and "engage[] with native

leaflets of the aorta" upon the valve assembly's expansion; and, "the *plurality of fibers is in contact with the frame along the height of the sealing material*" when the heart valve assembly is in both a radially compressed and radially expanded orientation. *See supra* Section II(D) (emphasis added).

Petitioner cites Spenser II's Figure 22 and related disclosure about Spenser II's "compressible material" and "fibers" as meeting the claimed "sealing material" limitations in a proposed combination with the valves assemblies of Spenser or Levi. Pet. 26–33 (citing Ex. 1011, Fig. 22, ¶ 145). 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. 27–28 (annotating Fig. 22); 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. 27–28 (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, for the purposes of preventing paravalvular leakage (PVL). Pet. 28–30, 30–33. Petitioner contends that its asserted motivation here is consistent with the Board's findings on the motivation issue for the Spenser-Spenser II combination in related proceedings and, for the Levi and Spenser II combination, involves swapping interchangeable features that serve similar purposes. *Id.* at 29–33 (citing, e.g., Ex. 1117, 64; Ex. 1003 ¶¶ 123–136).

With these changes, Petitioner contends, the modified valve devices would include the various "sealing material" limitations, such as the requirement that the sealing material have a height that extends over the first two rows of frame's cells. *See, e.g.*, Pet. 28 ("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."), 30–32 (showing Levi's to-be-replaced outer skirt extending over the bottom two rows of Levi's frame, which Petitioner argues would be substituted for Spenser II's compressible material attached "at the same height").

Petitioner further contends that the combination of Spenser or Levi with Spenser II meets claim 11's limitation of "the plurality of fibers is in contact with the frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation."[13] Pet. 44–51 (citing Ex. 1003 ¶¶ 165–174). In support, Petitioner makes three arguments. Petitioner's first argument hinges on a broader claim interpretation where this limitation is met if the sealing material, but not necessarily the fibers, contacts the frame. Petitioner's second and third arguments presume that this limitation requires the fibers directly contact the frame. We address these arguments in turn below.

First, Petitioner argues that, based on Patent Owner's suggestion during prosecution and its infringement contentions in related litigation, this limitation may be met so long as the "sealing material is in contact with the

[13] Petitioner uses the shorthand "fibers in contact with frame" to describe this limitation and we may do likewise herein, or simply refer to it as the "fibers in contact" or "in contact" limitation. *See, e.g.*, Pet. 44.

outer frame." Pet. 44–45 (citing Ex. 1002, 147–148; Ex. 1123, 329–330). Petitioner contends that, in Petitioner's proposed modification of the prior art, Spenser II's compressible material is attached to, and would otherwise contact the Spenser or Levi stent frame along the material's height, thus meeting the limitation. *Id.* at 45–47.

We are unpersuaded. The language of claim 11 states the "sealing material is attached to the frame," but also that it is the plurality of outwardly-extending "***fibers***" that maintain "contact with the frame along the height of the sealing material" whether the valve assembly is compressed or expanded. *Supra* Section II(D). Thus, according to this plain language, Petitioner must demonstrate that Spenser II's identified *fibers* contact with the frame in its modification of Spenser or Levi—not just that some portion of Spenser II's compressible material be attached to and contact the frame. On this record, we agree with Patent Owner that Petitioner's contrary interpretation is "at-odds with the plain language of the claims." Prelim. Resp. 18, 35.

The cited excerpt from the prosecution history does not support Petitioner's position that the "in contact" limitation is met if the sealing material—but not necessarily the fibers—contacts the frame. Petitioner cites an assertion by applicant during prosecution that modifying Levi's valve so that the "sealing material" is in contact with the frame would not show that the claimed subject matter is obvious. Pet. 44 (citing Ex. 1002, 147–148). In its more complete context, however, applicant's prosecution argument was made in furtherance of applicant's repeated assertion that replacing Levi's loosely-fit, "billowing" skirt with a tightly-held and bulky sleeve would change Levi's principle of operation and make it too large and

unsuitable for transfemoral delivery. Ex. 1002, 144–148[14]; *see also* Prelim. Resp. 35–36 (arguing applicant's position is also "consistent" with claims' plain language because, if Levi's billowing skirt included outwardly-extending fibers, such fibers could not contact the frame along the skirt's height when it billows out from the frame).[15] Applicant's argument does not rise to a concession that the "fibers in contact with the frame" limitation can be met so long as the sealing material contacts the frame. At best for Petitioner, the relevant prosecution history could be characterized as ambiguous; it does not justify rewriting claim 11's plain language. *See, e.g.*, Ex. 1002, 127–128 (earlier version of proposed amendment to application claim 31, reciting "the sealing material is in contact with the outer frame"), 138–139 (later version of the proposed and as-entered amendment, expressly changing the language to require "the plurality of fibers is in contact with the outer frame").

Patent Owner's infringement contentions likewise do not support interpreting claim 11's "fibers in contact" limitation contrary to its plain meaning. It is not apparent that Patent Owner's interpretation of the claims in related litigation requires only a "sealing material" contact the frame. Prelim. Resp. 36 ("Patent Owner never proposed or relied upon Petitioner's imagined construction"). Patent Owner has asserted that Petitioner's

[14] The responsiveness of this argument at that stage of prosecution is questionable because, by that point, the Examiner had clarified that the combination involved adding only Spenser II's outer-extending fibers to Levi's outer skirt, not Spenser II's entire compressible band, which fibers and band the Examiner considered as distinct components of Spenser II. *See supra* Section II(E); Ex. 1002, 166–167.

[15] Petitioner adduces no evidence here that Levi's skirt includes outwardly-extending fibers like those claimed.

SAPIEN 3 Ultra valve infringes the '310 patent, and contends that such valve includes claim 1's (and analogously claim 11's) "***fibers*** in contact with the [] frame" limitation. Ex. 1123, 329–330 ("showing plurality of ***fibers*** in contact with outer frame in compressed orientaiton [sic]") (emphasis added).[16] If the alleged "sealing material" in the SAPIEN 3 Ultra device includes multiple distinct components or, alternatively, is wholly comprised of outwardly-extending fibers that contact the frame, it is not clear to us on this record. Petitioner presumes, but does not show, that Spenser II's compressible material with its surface-extending fibers is the same as the alleged sealing material of SAPIEN 3 Ultra. Pet. 45–46.[17] We see no adequate evidentiary basis here to support that conclusion.

Second, Petitioner argues that, although Spenser II discloses embodiments where the compressible material is a cloth or fabric, a POSA would understand Spenser II discloses other embodiments where the outwardly-extending fibers are attached directly to the frame, as opposed to

[16] We take no position on Patent Owner's assertion that SAPIEN 3 Ultra meets this limitation or infringes any claim of the '310 patent.

[17] Petitioner further suggests that Spenser II's compressible material and its "fibers" would be "pressed into contact" with the frame upon compression. Pet. 46 (citing Ex. 1074 ("Norris"), 8:45–50). Spenser II does not evidence that any surface-extending fibers would be pressed into contact with the frame, much less pressed into contact with the frame along the height of Spenser II's compressible material. Even considering Norris for the proposition that pores could or would exist in a compressible material's ground layer, it is not shown that any pores, as contemplated by Petitioner, pass through that layer and would necessarily result in surface-extending fibers contacting the frame along the material's height. *See* Ex. 1074, Fig. 2, 4:64–67 (teaching knitting the ground layer "with a uniform density" so "gaps and voids in the knit pattern can be avoided"); Ex. 2002 ¶ 62 (Brecker testimony addressing Norris and the absence of any "contact" as claimed).

the surface of a cloth.[18] Pet. 50–51 (citing Ex. 1003 ¶ 173). According to Petitioner, "[i]n embodiments where the fibers are attached directly to Spenser II's frame, the fibers are in contact with the frame." *Id.*

We disagree with Petitioner's interpretation of Spenser II. The argument that Spenser II discloses attaching the fibers directly to the frame is wanting for evidentiary support. Dr. Buller's cited testimony lacks any persuasive corroboration. Ex. 1003 ¶ 173. That Spenser II may describe, as exemplary, its compressible material as comprising a layer, sleeve, cloth, or fabric does not, absent hindsight, disclose attaching outwardly-extending fibers directly to the stent's surface. Nowhere in Spenser II is such a design taught or suggested. Ex. 2002 ¶¶ 38–43, 63 (testimony of Dr. Brecker that "[t]here is no disclosure or suggestion . . . that these fibers residing on the compressible material's outer surface do or could contact the frame, which is on the opposite surface of the compressible material").

Petitioner's argument was also already rejected in substance by the Board in related matters, and is inconsistent with argument about Spenser II raised elsewhere by Petitioner. In IPR2022-00034, for example, Petitioner argued that Spenser II's compressible material was free of any outer graft covering between the fibers and frame because Spenser II never depicts or mentions any covering between the fibers and frame. Ex. 1120 (034 FWD), 24 (summarizing Petitioner argument); *see also* IPR2022-00034, Paper 2, 57–58. The Board, however, found that Spenser II "discloses that any fibers extending outwardly from the cloth arise from the surface of the cloth, ***and***

[18] Petitioner raises its additional arguments (labeled "Second" and "Third" in this Decision) as alternatives "[i]f 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." Pet. 47–51.

are not attached directly to the frame." Ex. 1120, 48 (emphasis added) (finding that a POSA would understand Spenser II includes a sleeve-like cloth/fabric "between its fibers and its outer frame, and such a covering would be between Spenser II's surface fibers and its metallic outer frame"). Moreover, as pointed out by Patent Owner, in opposition proceedings, Petitioner (or its affiliate[19]) argued against the notion that Spenser II's counterpart patent described and claimed fibers starting at, and extending outwardly from, the stent frame. Prelim. Resp. 25–26 (citing Ex. 2040, 149; Ex. 2002 ¶ 59 (Dr. Brecker's testimony on opposition papers)). Petitioner suggested such interpretation was "unfounded" and the "only reasonable interpretation" is that the fibers extend, not from the stent surface, but from the outer surface of the compressible material itself. Ex. 2040, 149; *see also* Prelim. Resp. 24–25 (citing Petitioner's argument in IPR2022-00556 that Spenser II's compressible material included an inwardly-facing fibrous layer that pressed against the frame, as distinct from the outwardly-extending fibers, which Petitioner now argues would be attached to and contact the frame); Ex. 2002 ¶¶ 57–58 (testimony of Dr. Brecker that, under Petitioner's and Dr. Buller's prior positions, "an intervening compressible material/graft covering and the allegedly inwardly extending fibers would instead [(and contrary to Petitioner's present argument)] be positioned between the outwardly extending fibers and the frame").

[19] Exhibit 2040 comprises correspondence and briefing before the European Patent Office concerning the European counterpart patent to Spenser II. *See, e.g.*, Ex. 2040, 141–142 (cover letter of correspondence/briefing from Edwards Lifesciences PVT, Inc., noting that Spenser II is the published "parent application" of the opposed European patent); Ex. 1011 (Spenser II), codes (71), (74) (listing Edwards Lifesciences PVT, Inc. as the applicant, and a representative from Edwards Lifesciences LLC as the agent).

Third, Petitioner argues that, even in Spenser II's embodiments having a cloth/fabric with fibers extending from the cloth's surface, a POSA "would have understood that at least some fibers extending from the surface would be in contact with the frame." Pet 47–48 (citing Ex. 1003 ¶ 168). Continuing, Petitioner argues, a POSA "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 allegedly taught in three additional references. *Id.* at 48–50 (citing Exs. 1134 ("Koch"), 1074 ("Norris"), and 1135 ("Sauvage")).

Petitioner's argument is unavailing on this record. As an initial matter, we find that Petitioner's argument is in tension with the Board's findings and Petitioner's positions about the scope and content of Spenser II in related matters, as explained above. *See, e.g.*, Ex. 1120 (034 FWD), 48 (finding that Spenser II includes an intervening cloth or fabric graft material between its outer fibers and frame). We find, consistent with Dr. Brecker's testimony, that Spenser II depicts and discloses that outwardly-extending fibers extend from the compressible material's "outer surface"—i.e., the outer surface of the depicted base layer or sleeve. Ex. 2002 ¶¶ 50–55 ("This is entirely consistent with what we see in Fig. 22 [of Spenser II], fibers extending from the outer surface of a base layer"); Ex. 1011 ¶ 145 ("the compressible material 256 may resemble a cloth or fabric having small fibers extending ***from the surface of the material***") (emphasis added).

Petitioner's argument, which at least partly invokes a theory of inherency, is self-contradictory and undermined by Petitioner's own evidence. Prelim. Resp. 19–24. Petitioner, on the one hand, argues that at least some of Spenser II's fibers "***would be***" in contact with the frame despite the presence of an intervening cloth/fabric base layer. Pet. 47

(emphasis added). Yet, on the other, Petitioner also contends the "in contact" limitation is met because the outwardly-extending fibers "***may be***" attached to the base layer by weaving those fibers through the base layer to its inner surface. *Id.* (emphasis added). Even if such means of attachment were possible, the law is clear—inherency is not established by possibilities or probabilities. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195–1196 (Fed. Cir. 2014) (explaining the "high standard" involved in showing obviousness by inherency and confirming that "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient"). No such weaving of the fibers through the entire depth of the compressible material is taught or suggested in Spenser II as already explained. And other evidence, such as Norris, show fibers extending from a ground layer without traversing through the ground layer or contacting any frame. Prelim. Resp. 27–28 (reproducing Figs. 1–3 of Norris with annotations; arguing that Norris' figures plainly show fibers knitted into the ground layer "without contacting the frame"); Ex. 2002 ¶ 62 (testimony of Dr. Brecker that "Norris, which, like Spenser II and Dehdas[h]tian[20] teaches fibers/loops extending outwardly from an intervening graft . . . ***without*** contacting the frame").

Inasmuch as Petitioner is suggesting that Spenser II's compressible material should be changed further based on, for example, fabrics described in Koch or Sauvage, Patent Owner contends that Petitioner's challenge should still fail. Pet. 47–50; Prelim. Resp. 26–34. According to Patent

[20] Dehdashtian, cited here, is Exhibit 2101, which Dr. Brecker explains discloses that fibers can be "partially integrated into the weave" and "placed on the exterior of the graft body." Ex. 2002 ¶ 62 (citing Ex. 2101, 5:12–24, 3:7–16, 3:37–41).

Owner, such "examples" do not show outwardly-extending fibers of any velour-like woven/knitted fabrics necessarily meeting the "in contact" limitation. Prelim. Resp. 26–28 (citing, e.g., Ex. 1074, Figs. 1–3, 4:22–26). Patent Owner also contends Petitioner fails to show that a POSA would be motivated to modify Spenser II so that the extending fibers are in contact with the frame. *Id.* at 29–33 (citing, e.g., Ex. 2002 ¶¶ 66, 69–71 (testimony of Dr. Brecker that alleged benefits including compressibility and enhanced blood coagulation are already present in Spenser II without fibers contacting the frame as claimed, and would not suggest any proposed change based on, e.g., Norris or Koch: "these benefits, already described in Spenser II, would not motivate the [POSA] to alter Spenser II in any way")). Moreover, Patent Owner argues, although Petitioner purports to modify Spenser II in view of Norris, Koch, or Sauvage, Petitioner never included those references in any of its asserted prior art combinations—further undermining any alleged motivation and revealing that Petitioner's argument is driven by hindsight. Prelim. Resp. 33–34 (*citing, e.g.*, *RPX Corp. v. Parity Networks, LLC*, IPR2018-00097, Paper 7, 14 (PTAB Apr. 24, 2018)).

We agree, on balance, with Patent Owner on this record. It could be the case that further modifications to Spenser II according to embodiments noted in Koch, Sauvage, or Norris would result in the "in contact" limitation being met. But, Petitioner has not shown persuasively that is necessarily true. Take, for example, Sauvage. Petitioner contends that the knitting pattern in Sauvage's Figure 3, where portions of what Petitioner has labeled "Loop Thread" (annotated red) purport to pass under what Petitioner has labeled "Body Thread" (annotated blue). Pet. 49 (citing Ex. 1135, Fig. 3). According to Petitioner, with this pattern, thread that makes up the loops "would extend all the way to the inside of the fabric once the fabric is turned

inside-out after knitting" and that thread "would be in direct contact with the frame" if the fabric were disposed along the exterior of a THV. *Id.* at 49–50 (citing Ex. 1003 ¶ 170[21]). Sauvage, however, does not clearly describe the alleged loop thread extending all the way through and to the inside of the fabric when turned inside out—Figures 1C and 2B, illustrating synthetic graft once turned "inside-out" do not show this. Ex. 1135, Figs. 1C, 2B, 2:65–3:4. And we are left to speculate whether, even if some loop thread appeared on the inside fabric, that thread would contact the metallic lattice-like, open-cellular frame along the height of the sealing material as claimed in a further modified Spenser or Levi device. That is particularly true because: (i) Sauvage describes a synthetic (textile-based) tubular stent and does not show any connection to a metal substructure or frame; and (ii) even crediting Petitioner's annotated drawing, it appears that only small portions of the loop thread pass under the body thread, and only intermittently so.

Petitioner's rationale to modify Spenser II based on inchoate and unasserted combinations is also unpersuasive. Pet. 50 (citing blood coagulation, compressibility, and tissue ingrowth as reasons to consider other fabrics). As Dr. Brecker credibly explains, Norris, for example, is characterized as providing a compressible fabric and as promoting clot formation and enhanced cellular ingrowth without any need for loops or fibers passing through a ground layer to a frame. Ex. 2002 ¶ 66 (citing, e.g., Ex. 1074, 6:6–8, 5: 57–62, 10:14–16, 8:50–52, Figs. 1–3; Pet. 10, 50). Furthermore, these "benefits" are already conferred in Spenser II's "compressible material" and its surface-extending fibers without those fibers

[21] We do not doubt Dr. Buller's qualifications as an interventional cardiologist, but the details of Sauvage here seem to more aptly call for testimony from a witness with expertise in textile engineering.

contacting the frame along the sealing material's height. *Id.* ¶¶ 68–72 (testifying, "[n]or is there any need for outwardly extending fibers to contact the frame to confer these pre-existing benefits" that are expressly described in Spenser II) (citing Ex. 1011 ¶¶ 55, 145; Ex. 2101, 5:12–24, 3:7–16, 3:37–41). The notion that Spenser II's compressible material would be further changed in the manner urged by Petitioner suggests, on this record, a hindsight bias.

Altogether, based on the argument and evidence of record, we find that Petitioner has not met its burden and established that it is reasonably likely to prevail on its challenge to claim 11 over Spenser or Levi, in combination with Spenser II.[22]

2. Claims 12 and 13

Claims 12 and 13 depend from independent claim 11. Ex. 1001, 23:15–19. Petitioner's challenge to claims 12 and 13 relies on Petitioner's threshold analysis for claim 11, and Petitioner does not argue or show that its challenge to those dependent claims makes up for above-noted deficiencies on claim 11. Pet. 66–67. Thus, Petitioner is not reasonably likely to prevail on its challenge to claims 12 and 13. *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 11, 12, or 13 would have

[22] Because we deny Petitioner's Spenser-II based challenge for other reasons, we need not decide whether 35 U.S.C. § 325(d) or collateral estoppel should bar Petitioner's challenge. Prelim Resp. 3–14.

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 11–13 would have been obvious over Spenser combined with Chuter (Grounds 3) and that claims 11 and 13 would have been obvious over Levi combined with Chuter (Ground 4). Pet. 67–83; *see id.* at 82 (claim 11, cross-citing analysis for claim 1 (now disclaimed)). Petitioner's argument under Grounds 5 and 6 mirrors the argument for Grounds 3 and 4, differing only in that Petitioner asserts Spenser II would have provided "additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves." *Id.* at 83 (citing Ex. 1003 ¶¶ 282–283).

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. 68–69, 71, 77–79; Prelim. Resp. 37–48; Ex. 1116, Fig. 2; *see supra* Section III(D)(4). The second 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 5–10 of Chuter. *See, e.g.*, Pet. 68–69, 71, 79; Prelim. Resp. 54–75; Ex. 1116, Figs. 8–10.

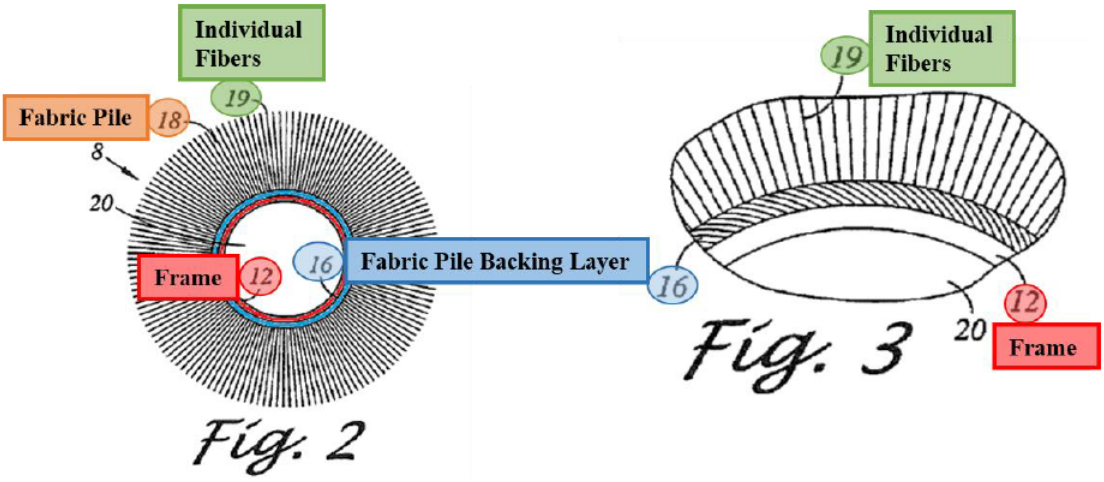
1. Analysis

a) Chuter Graft/Backing-Layer Embodiment

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 11's limitations and relying on Chuter as teaching the claim requirements concerning the "sealing material" and "fibers . . . in contact with the frame" limitations. Pet. 70–80; *see id.* at 77–79 (argument about "in contact" limitation).

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



Pet. 78. Figures 2 and 3 of Chuter are, respectively, longitudinal 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 77–78 (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 72–75.

Petitioner argues that Chuter's "fabric pile backing layer" with a fabric pile extending outwardly from that backing layer, as shown above, discloses the "in contact" limitation. Pet. 77–78. According to Petitioner, "[t]he fibers of Chuter's fabric pile backing layer are in contact with the stent frame." *Id.* at 78. And, Petitioner contends, invoking its Spenser II arguments, POSAs "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." *Id.* at 79.

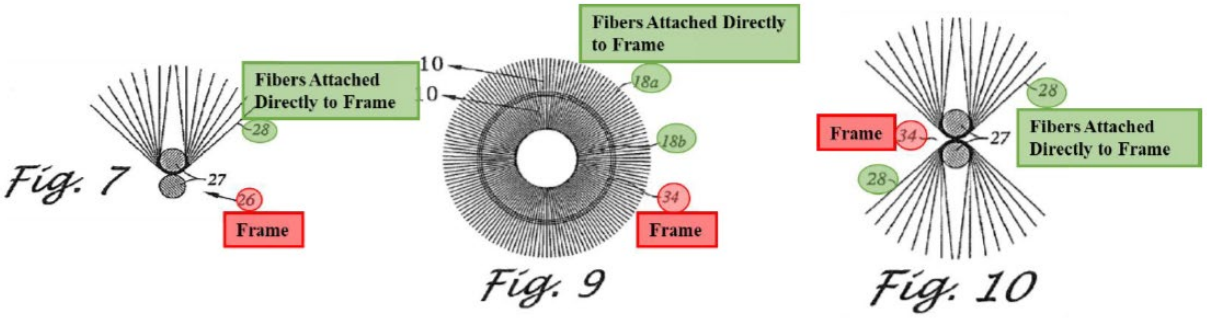
Petitioner's challenge here fails for similar reasons to the Spenser II-based grounds (Grounds 1 and 2). We agree with Patent Owner and Dr. Brecker on this record that Chuter neither depicts nor describes its outwardly-extending fibers in the graft/backing-layer embodiments as being in contact with the frame—the backing layer is plainly disposed between any fibers and the frame. Prelim. Resp. 40–41 (citing Ex. 2002 ¶¶ 81–82). The notion that Chuter inherently discloses the "in contact" limitation or that its backing-layer embodiment would be changed to knit the fibers all the way through the backing layer based on unasserted prior art combinations is flawed, speculative, and hindsight-driven like we explained for Grounds 1 and 2. Prelim. Resp. 44–48 (repeating counterargument).

We are, thus, not persuaded that Petitioner is reasonably likely to prevail in establishing that at least one of claim 11 (or dependent claims 12 or 13) are unpatentable based on the argument and evidence presently before us. *In re Fritch*, 972 F.2d at 1266.

b) Chuter Occluder Embodiments

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. 69, 71, 79. Chuter's Figures 7, 9, and 10, as annotated by Petitioner, are provided below.



Pet. 69; 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. 69.

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. 72–75 (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 ¶¶ 232–240. Petitioner further contends that, although Chuter's embodiments without a backing layer use double-wire frames, Chuter suggests other frames may be used. Pet. 73 (citing Ex. 1116 ¶¶ 3, 12). Petitioner also asserts that, based on a dearth of detail in the '310 patent about how fibers are attached to the frame, the POSA would know how that could be done. *Id.* at 73–74 (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 "fibers in contact with the frame" limitation is met in Petitioner's proposed combination because Chuter's embodiments,

such as shown in Chuter's Figure 7, show fibers attached directly to the frame. Pet. 79 (citing Ex. 1116, Figs. 5–10, ¶¶ 56–57; Ex. 1003 ¶ 253).

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. 55. 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 ¶¶ 100–102 (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.* ¶ 101; *see also id.* ¶¶ 106–107 (citing Ex. 1116, Figs. 5, 8, ¶¶ 17–18, 56–57).

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.* (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 ¶ 101 (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. 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. 60. 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 Fig. 5 of Chuter),] is by 'inner dispos[ing]' or 'secur[ing]' the fibers between the twisted, helically wound metal wires." Ex. 2002 ¶¶ 105–109, 115 n.4 (testifying this helical loop construction resembles a spring coil and is visibly different from Chuter's graft embodiments like in Figs. 1 and 4). 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.* ¶ 115 (showing the relevant structures of Chuter, Spenser, and Levi side-by-side).[23] 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.* ¶¶ 117–118 (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 '310 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 fibers in direct contact with such frames. We find evidence for such a motivation lacking on this record, especially given

[23] 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 ¶¶ 114–116 (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. 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. 70–75. 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 polymer covering within the stent to inhibit crimping." Ex. 2002 ¶¶ 123–125 (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. 83.

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 ¶¶ 282–283). This rationale provides no persuasive support for adding Chuter's directly-attached fibers to Spenser' or Levi' valves 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 graft/backing-layer embodiment as having a feature akin to Spenser II's compressible material, we are unpersuaded a modification of Spenser or Levi based on that embodiment meets the "fibers in contact" limitation, as explained above.

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 11, 12, or 13 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.

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 '310 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
brian.barnes@knobbe.com

FOR PATENT OWNER:

Kenneth Weatherwax
LOWENSTEIN & WEATHERWAX LLP
weatherwax@lowensteinweatherwax.com