

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.

IPR2022-00556
Patent 10,987,236 B2

Before JOHN G. NEW, JASON W. MELVIN, and RYAN H. FLAX,
Administrative Patent Judges.

NEW, *Administrative Patent Judge.*

DECISION

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner Edwards Lifesciences Corporation, And Edwards Lifesciences LLC (“Petitioner”) has filed a Petition (Paper 1, “Pet.”) seeking *inter partes* review of claims 1–4 (all claims) of US Patent 10,987,236 B2 (Ex. 1001, the “’236 patent”). Patent Owner Aortic Innovations, LLC (“Patent Owner”) timely filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

Under 35 U.S.C. § 314, the Board “may not authorize an *inter partes* review to be instituted unless ... the information presented in the petition ... and any response ... 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.” Upon consideration of the Petition and the Preliminary Response, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims of the ’236 patent.

II. BACKGROUND

A. *Real Parties in Interest*

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC, as the real parties-in-interest. Pet. 111. Patent Owner identifies Aortic Innovations, LLC as the real party-in-interest. Paper 4, 1.

B. *Related Matters*

Petitioner represents that it has filed a Petition for *inter partes* review of U.S. Patent No. 10,792,172 (the “’172 patent”) in *Edwards Lifesciences*

Corp. v. Aortic Innovations, LLC, IPR2021-01527 (Filed Sept. 10, 2021).

Pet. 108. Petitioner states that it has also filed a Petition for *inter partes* review of U.S. Patent No. 10,857,011 (“the ’011 patent”) in *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021). *Id.* at 108–109. Petitioner has additionally filed a Petition for *inter partes* review of U.S. Patent No. 10,966,846 (the “’846 patent”), *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00034 (Filed Oct. 11, 2021). *Id.* at 109. Petitioner has also filed a Petition for *inter partes* review of U.S. Patent No. 10,881,538 (the “’538 patent”), *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00193 (Filed Nov. 11, 2021). *Id.* Petitioner has also filed a Petition for *inter partes* review of U.S. Patent No. 11,129,735 (the “’735 patent”), *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-0549 (Filed February 4, 2022). *Id.* Petitioner asserts that the ’236 patent is part of the same patent family and shares a common specification with the ’172, ’011, ’846, ’538, and ’735 patents. *Id.*

Further, Petitioner and Patent Owner both identify *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1-21-CV-01377 (D. Del., filed Sept. 28, 2021), in which Patent Owner alleges infringement of the ’735 patent, ’538 patent, the ’846 patent, and ’236 patents by Petitioner. Pet. 109; Paper 3, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–4 of the ’236 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–4	103	Cribier ¹ , Walther ²
2	1–4	103	Spenser ³ , Walther
3	1–4	103	Spenser, Spenser II ⁴
4	1–4	102(e)	Levi ⁵
5	1–4	103	Levi
6	1–4	103	Levi, Walther
7	1–4	103	Levi, Spenser II

Petitioner also relies upon, *inter alia*, the Declarations of Dr. Nigel P. Buller (the “Buller Declaration,” Ex. 1003) and Sylvia D. Hall-Ellis (the “Hall-Ellis Declaration,” Ex. 1059). Patent Owner relies upon, *inter alia*, the Declarations of Dr. Stephen J.D. Brecker (the “Brecker Declaration,” Ex. 2002).

¹ A. Cribier et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien® Heart Valve Using the Transfemoral Approach*, 34 HERZ 347–56 (2009) (“Cribier”) Ex. 1012.

² T. Walther et al., *Trans-Catheter Valve-in-Valve Implantation: in vitro Hydrodynamic Performance of the SAPIEN + Cloth Trans-Catheter Heart Valve in the Carpentier-Edwards Perimount Valves*, 40 EUR. JOUR. CARDIO-THORACIC SURG. 1120–26 (2011) (“Walther”) Ex. 1007.

³ Spenser et al. (US 7,510,575 B2, March 31, 2009) (“Spenser”) Ex. 1010.

⁴ Spenser et al. (WO 2006/005015 A2, January 12, 2006) (“Spenser II”) Ex. 1011.

⁵ Levi et al. (US 9,393,110 B2, July 19, 2016) (“Levi”) Ex. 1008.

D. The '236 Patent

The '236 patent is titled “Transcatheter Aortic Valve Repair Having Improved Paravalvular Seal.” Ex. 1001, code (54). The '236 patent issued from Appl. No. 17/131,869 (the “’869 application”), which claims priority through a series of continuation and divisional applications to Appl. No. 13/706,896, filed on December 6, 2012. *Id.* at codes (21), (60). The '236 patent also claims priority to Provisional Appl. No. 61/723,446, filed on Nov. 7, 2012, and Provisional Appl. No. 61/567,458, filed on Dec. 6, 2011. *Id.* at code (60).⁶

The '236 patent discloses an endograft device, including a transcatheter heart valve, used for endovascular repair of ascending aortic aneurysms. Ex. 1001, col. 2, ll. 51–52. Specifically, the Specification discloses that “[t]he endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component.” *Id.* at col. 2, ll. 65–67. According to the

⁶ According to Petitioner, “[d]uring prosecution of U.S. Patent No. 10,792,172 (the “’172 patent), a parent to the '236 patent, Patent Owner stated that the application’s ‘effective filing date . . . is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012.’” Pet. 26 (quoting Ex. 1049, 274).

Petitioner argues that “the '236 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '236 patent’s claims.” Pet. 21 (citing *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)). Petitioner contends that “Patent Owner first added the disclosure of outwardly extending fibers in the November 2012 provisional.” Pet. 26 (citing Ex. 1006 ¶ 24). Because all the asserted references bear a publication or filing date that antedates the earlier priority date of the '458 provisional, we need not address at this stage whether the '172 patent claims are entitled to claim priority to the '458 provisional.

Specification, none of the 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 col. 2, ll. 35–37. The Specification describes a need for a device:

[T]hat 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 col. 2, ll. 37–46.

Figure 11 of the '236 patent is reproduced below.

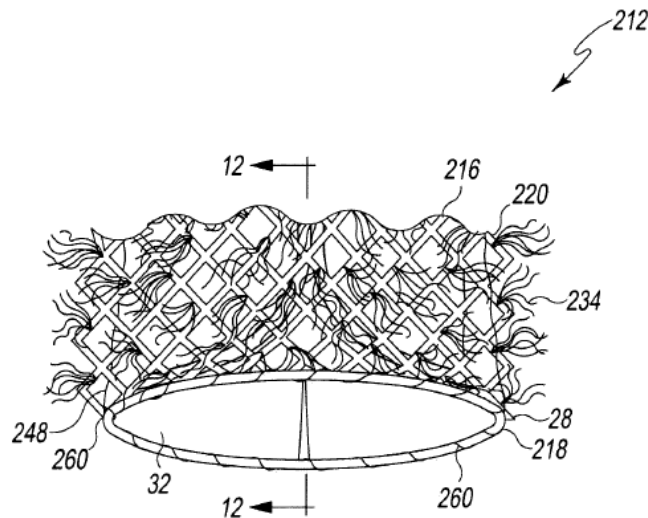


Fig. 11

Figure 11 of the '236 patent is a perspective view a proximal end of the proximal prosthetic component

As shown above, component 212 includes a dual-frame structure with circular inner frame 218 secured to circular outer frame 216 via a plurality of stitches 260. *Id.* at Fig. 11, col. 14, ll. 6–9.

Figure 13 of the '236 patent depicts a different view of the relevant portion of the same embodiment as Figure 11 and is reproduced below.

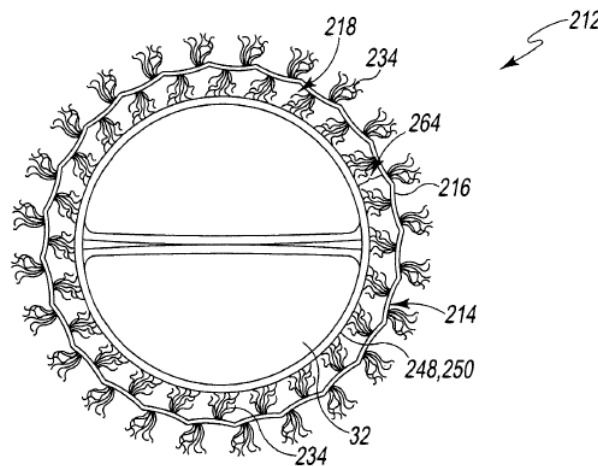


Fig. 13

Figure 13 of the '236 patent is a plan view of the proximal prosthetic component showing the inner frame in an unexpanded position

As shown above, the device with circular dual frame component 214 includes outer frame 216 secured to balloon-expandable inner frame 218. *Id.* at Fig. 13, 14, ll. 6–8.

As also shown in Figures 11 and 13, inner frame 218 houses prosthetic valve 32. *Id.* at Figs. 11, 13, col. 13, ll. 42. Collagen fibers 234 extend outwardly and inwardly from outer frame 216. *See id.* at Fig. 13, col. 12, ll. 43, 46–48. Outer frame 216 is a grid with diagonally oriented members as compared to those at the proximal end of the device. *See* Fig. 11. Figures 11 and 13 further illustrate fibers 234 extending outwardly from proximal section 220 and inwardly into the passageway formed by the stent. *Id.* at Figs. 11, 13, col. 14, ll. 30–33. According to the Specification, these collagen fibers 234 “aid in preventing paravalvular leaks and migration of

the proximal component 212 within the aortic walls.” *Id.* at col. 12, ll. 43–45.

The Specification further describes “[b]alloon-expandable frame 218 ... as a balloon-expandable tubular stent 244.” *Id.* at col. 13, ll. 41–43. “[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 open-cell configuration.” *Id.* at col. 13, ll. 46–48. “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, col. 14, ll. 13–16. 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 Fig. 13, col. 14, ll. 19–32.

E. The Challenged Claims

Claims 1–4 are the challenged claims in this proceeding. *See* Section II.D. above. Claim 1, the sole independent claim, recites:

1. A transcatheter aortic valve assembly comprising:

an outer frame formed from a metallic material;

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching;

a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,

wherein the first portion of fibers extend radially outwardly of the outer frame,

wherein the first portion of fibers is non-metallic;

and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

Id. at cols. 21–22, ll. 14–19.

F. Prosecution History of the '236 Patent

The '236 patent matured from U.S. Appl. Ser. No. 17/131,869, which was filed on December 23, 2020, with original claims 1–10. Ex. 1001, codes (21), (22); Ex. 1002, 253–355. The applicant filed a Preliminary Amendment on January 26, 2021, replacing the original claims with new claims 11–14. *Id.* at 235–36.

On February 11, 2021 and March 17, 2021, Patent Owner submitted terminal disclaimers to obviate a double patenting rejection over prior U.S. Patents 10,792,172 B2, 10,857,011 B2, 10,881,538 B1, and 10,888,441 B1. Ex. 1002, 205-207.

The Examiner issued a Notice of Allowance for claims 11 and 14–16, as claims 1–4 on March 24, 2021. Ex. 2002, 7–9. In the Reasons for Allowance, the Examiner stated that:

[T]he prior art of record does not disclose or render obvious a first portion of fibers positioned radially outwardly of the outer frame and a second portion of fibers carried by the outer frame wherein the first portion of fibers and second portion of fibers are in overlapping radial alignment; the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame in combination with the other recited features.

Id. at 8.

III. ANALYSIS

A. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms “are generally

given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence may also be considered, but is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner proposes a construction for any claim terms apart from their plain and customary meaning. Pet. 29; *see generally* Prelim. Resp. Nor do we perceive, at this stage of the proceeding, a need to construe any claim terms of the ’236 patent for purposes of determining whether to institute trial. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that “only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy”); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

B. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. Pet. 28. Petitioner contends that this

skilled artisan would, where necessary, work as a member of a team in combination with a medical device engineer to experiment with or manufacture a prosthetic heart valve. *Id.* at 28–29 (citing Ex. 1003 ¶ 45). Patent Owner does not argue otherwise or propose an alternative definition. *See generally* Prelim. Resp.

At this stage of the proceeding and for purposes of our analysis in this Decision, we adopt Petitioner’s definition because we find that that definition is consistent with the level of skill in the art, as reflected by the prior art. *See, e.g.*, Exs. 1007–1012; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Grounds 1 and 2: Obviousness over Cribier or Spenser and Walther

In each of the related cases IPR2021-01527, IPR2021-01584, IPR2022-00034, IPR2022-00193 (*see supra* Section II.B), each of the independent claims of the challenged patents recites some or all of the same, or substantially the same, limitations of claim 1 of the ’236 patent reciting:

1. an outer frame formed from a metallic material;
2. an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

3. wherein the outer frame is secured to the inner graft covering by stitching;
4. a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,
5. wherein the first portion of fibers extend radially outwardly of the outer frame,
6. wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,
7. wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,
8. wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
9. wherein the valve assembly is balloon expandable to the radially expanded orientation

See IPR2021-01527, Ex. 1001 col. 21, ll. 7–23 (reciting limitations 1, 2, 3, 4, 5), cols. 21–22, ll. 48–15 (reciting limitations 1, 2, 3, 4, 5); IPR2021-01584, Ex. 1001 col. 21, ll. 4–30 (reciting limitations 1, 2, 3, 4, 5, 9), col. 22, ll. 12–44 (reciting limitations 1, 2, 3, 4, 5, 6, 9); IPR2022-00034, Ex. 1001 cols. 21–22, ll. 15–6 (reciting limitations 1, 2, 3, 4, 5, 6, 7, 8, 9); IPR2021-00193 cols. 21, ll. 14–55 (reciting limitations 1, 2, 3, 4, 5, 6, 8, 9), col. 22, ll. 15–55 (reciting limitations 1, 2, 3, 4, 5, 6, 8, 9).

In each of these related cases, we instituted *inter partes* review, finding that Petitioner had demonstrated a reasonable likelihood that at least

one of the challenged claims reciting these same, or substantially the same, limitations of claim 1 of the '236 patent, are obvious over at least one of the proposed Grounds, which rely upon the same combinations of references cited in the present Petition's Grounds 1–7. *See, e.g.*, IPR2022-00034 Paper 14 at 4, 61 (Grounds 1 and 3–8 same as the present Petition Grounds 1–7); IPR2022-00193 Paper 15 at 4, 67 (Grounds 1–6 same as present Grounds 1–6). For these reasons and for consistency, our reasons for granting institution in these related cases is relevant here and we incorporate by reference herein our reasoning and conclusions from our Decisions to Institute in the related cases with respect to limitations 1–9 above of Claim 1 of the '236 patent. *See, e.g.*, IPR2022-00034 Paper 14 at 13–27; 31–43, 51–55, Paper 22 at 6–10; IPR2022-00193 Paper 15 at 18–33, 37–50, 59–66, Paper 21 at 8–11, 15–18.

Challenged claim 1 of the '236 patent additionally recites:

a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

...

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

...

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface

Claim 1 also requires that the first and second portions of the fibers are non-metallic. Ex. 1001 col. 21, l. 31, col. 22, l. 2.

These limitations are not present in the claims of the challenged patents of the related *inter partes* reviews listed above. Therefore, the issue of whether Petitioner has demonstrated a reasonable likelihood of success of prevailing at trial here with respect to these specific limitations is dispositive of our Decision to Institute in the present case. Indeed, these additional limitations are the only ones Patent Owner disputes in the present proceeding in its Preliminary Response. *See generally* Prelim. Resp. We address these limitations, Petitioner's related contentions, and Patent Owner's arguments below.

1. Claim 1: first and second portion of radially positioned fibers forming a first and second sealing interface in overlapping radial alignment to form the respective first sealing interface and second sealing interface

- a. Introduction

Claim 1 is the sole independent claim of the '236 patent. Claim 1 recites, *inter alia*, the following limitations:

a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,

wherein the first portion of fibers extend radially outwardly of the outer frame,

...

and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the

outer frame when the second portion of fibers is compressed thereagainst

Ex. 1001 col. 21, ll. 25–35. Petitioner argues that each of Walther, Spenser II, and Levi, teaches these limitations. *See* Pet. 36–47, 63–74, 88–97. We begin our analysis with Walther.

b. Overview of Walther (Ex. 1007)

Walther is an article published in the European Journal of Cardiothoracic Surgery that bears a copyright date of 2011. Ex. 1007, 1120.

Petitioner contends that Walther was published online on April 3, 2011, and qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). Pet. 22.

Walther is directed to a method of deploying a trans-catheter valve in a previously implanted degenerative bioprosthetic valve. Ex. 1007, 1120. Specifically, Walther describes implanting an Edwards SAPIEN THV cloth valve, “which is identical to the SAPIEN model, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve.” *Id.* Walther discloses that:

The CEP surgical valves are made with a base that is more rigid than other valves. When a SAPIENTM valve is expanded in the CEP valve, the rigid base does not easily conform to the profile of the expanded stent frame, which leaves gaps between the two valves, resulting in higher paravalvular leak. The addition of an outer cloth to the SAPIENTM cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better ‘fit’ within surgical Perimount valves.

Id. Additionally, Walther discloses that the outer cloth “reduce[s] paravalvular leak,” “increase[s] ‘fit’ within EW Perimount valves [a

benchtop valve],” and “promote[s] tissue ingrowth, which further decreases paravalvular leakage.” *Id.*

Figure 1 of Walther is reproduced below:

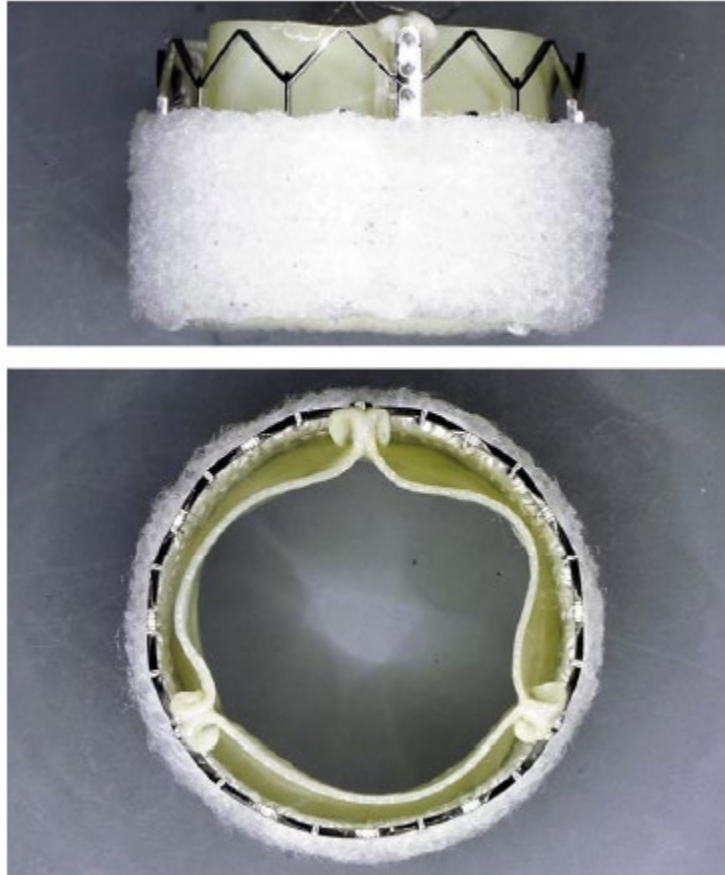


Fig. 1. Cloth valve.

Figure 1 of Walther depicts two views of the SAPIEN THV

Figure 1 of Walther provides two photographic views (side view at top and top-down view at bottom) of the SAPIEN THV with a cloth encircling approximately the lower two thirds of the valve. *Id.* at Fig. 1, 1121. Walther describes deploying the SAPIEN valves inside “various CEP valves” *via* the 33 F Ascendra catheter system. *Id.* at 1121.

- c. Petitioner's contentions with respect to Walther
 - i. "a first portion of [non-metallic] fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets"

Petitioner argues that Walther teaches that its outer PET cloth is positioned radially outwardly of the outer frame, and is formed of nonmetallic, PET (i.e., non-metallic) fibers that extend radially outwardly of the outer frame.⁷ Pet. 36–37 (citing Ex. 1007, 1121, Fig. 1; Ex. 1003 ¶ 115). Petitioner contends that Walther's outer fibers are configured to form a sealing interface against the cardiac annulus and native valve leaflets when compressed against them. *Id.* at 37 (citing Ex. 1003 ¶¶ 118–120). Petitioner's witness, Dr. Buller, explains that Walther describes implanting the cloth-covered SAPIEN within a surgical valve, and that the fibrous outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves" by compressing the radially extending fibers against the surgical valve's annulus and leaflets. *Id.* (citing Ex. 1003 ¶¶ 1120–1121; Ex. 1007 Fig. 2).

Petitioner asserts that a person of ordinary skill in the art would have understood that expanding Walther's cloth-covered SAPIEN within a native aortic valve would form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed against it. Pet. 38 (citing Ex. 1003 ¶ 118). Petitioner points to Cribier, which, Petitioner contends, teaches that the SAPIEN THV presses against the aortic valve's annulus and native leaflets upon implantation. *Id.*

⁷ We understand PET to refer to polyethylene terephthalate.

Specifically, Petitioner argues that Cribier teaches states that the SAPIEN valve is “advanced to the native aortic valve[,] ... positioned across the aortic annulus, and delivered by balloon inflation[.]” *Id.* at 39 (citing Ex. 1012, 347). According to Petitioner, Cribier instructs that “before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion.” *Id.* (citing Ex. 1012, 353).

Petitioner reasons that the '236 patent identifies the annulus as the point where the leaflets begin and that when expanded in this location, SAPIEN presses against and displaces the patient's native aortic leaflets. *Id.* (Ex. 1001 col. 1, ll. 58–60, Fig. 2; Ex. 1003 ¶ 119; *see also* Ex. 1047, 74 (describing SAPIEN as “crush[ing] the leaflets of the native valve against the wall.”)). Petitioner contends that expanding Walther's cloth-covered SAPIEN in a native aortic valve would press Walther's fibers against the patient's annulus and native leaflets to form a sealing interface. *Id.* at 41 (Ex. 1003 ¶ 121). According to Petitioner, if one-third to one-half of Walther's cloth-covered SAPIEN THV rested above the annulus and the remainder in the LVOT, the central fibers would press against the annulus and the fibers “above the annulus” would press against the leaflets. *Id.* (citing Ex. 1003 ¶ 121; Ex. 1047, 74).

Petitioner contends that a skilled artisan would have found it obvious to deploy the valve within a patient's native valve so that the outer cloth forms a sealing interface with the annulus and native leaflets, and would have been motivated to apply Walther's outer cloth covering to reduce paravalvular leakage (“PVL”), a problem well known in the contemporaneous art. Pet. 42 (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S.

398, 416 (2007); Ex. 1003 ¶¶ 122, 124). Petitioner argues that a person of skill in the art would also have had a reasonable expectation of success in deploying the cloth-covered SAPIEN in a patient's native aortic valve based upon Walther's teaching of a successful balloon deployment of the cloth-covered SAPIEN that "demonstrated excellent hydrodynamic performance" and that an in-patient procedure "is feasible." *Id.* (citing Ex. 1007, 1125; Ex. 1003 ¶ 125).

- ii. a second portion of [non-metallic] fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame

With respect to this limitation of independent claim 1, Petitioner argues that Walther's outer cloth also includes inwardly facing fibers on the inward-facing surface of the cloth that form a sealing interface against the outer frame. Pet. 43 (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 132). Petitioner points to a portion of Walther's Figure 1, which is reproduced, as annotated by Petitioner, below:

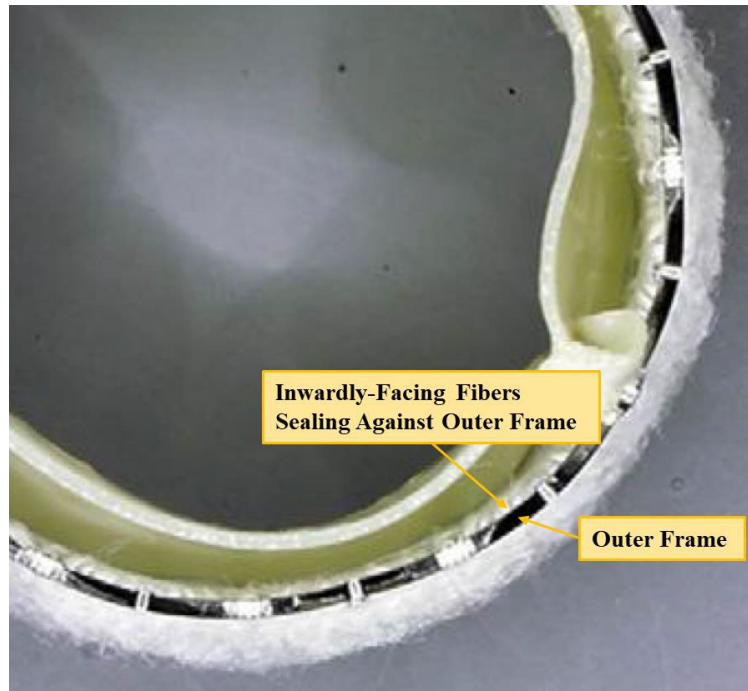


Figure 1 of Walther (annotated by Petitioner) depicts a magnified plan view of a portion of Walther's cloth-covered SAPIEN THV

Petitioner asserts that Figure 1 depicts some of the inwardly facing fibers pressing through the open cells of the outer frame and extending radially inwardly of the outer frame, and annotates the figure with two text boxes labeling these features. Pet. 44 (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 132). According to Petitioner, the inwardly facing fibers that do not pass through the open cells of the outer frame instead press against and form a sealing interface with the outer frame. *Id.* (citing Ex. 1003 ¶ 132). These fibers, Petitioner argues, are the “second portion of fibers” recited by claim 1. *Id.*

Petitioner notes that Walther teaches that the outer cloth is “stitched onto the perimeter of each SAPIEN valve,” and carried by the outer frame, and that the inwardly facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded.

Pet. 45 (citing Ex. 1007, 1121, Fig. 1; Ex. 1003 ¶¶ 133–134). Petitioner reasons that these inwardly facing fibers must form a sealing interface with the frame in the expanded state, because Walther discloses that the cloth prevents PVL, which could not happen if blood could leak between the cloth and expanded frame. *Id.* (citing Ex. 1003 ¶ 134).

- iii. “wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment”

Petitioner asserts further that Walther’s first and second portion of fibers are interwoven and part of a single PET cloth and, therefore, are in overlapping radial alignment. Pet. 46. Petitioner also notes, as discussed above, that Walther’s cloth-covered SAPIEN is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal against them. *Id.* at 47.

- iv. “wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface”

Petitioner argues that Walther’s cloth-covered SAPIEN is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface, as argued above. Pet. 50.

d. Patent Owner's Preliminary Response

Patent Owner argues that Petitioner fails to clearly identify “a second portion of fibers,” that is “configured to form a second sealing interface” or that is in “overlapping radial alignment” with the claimed “first portion of fibers.” Prelim. Resp. 31. Specifically, Patent Owner contends that Petitioner’s reliance upon Walther’s Figure 1 to allege disclosure of a “second portion of fibers” is misplaced. *Id.* at 32–33 (citing Pet. 43–45). Patent Owner argues that it is unclear what is shown in that Figure, and that it is possible that the Petitioner is pointing to the white fabric on the inside of the black “outer frame,” which is, Patent Owner asserts, the inner PET cuff that the Petition identifies as the claimed “polymeric graft covering,” i.e., the inner frame of claim 1, as depicted in Figure 1 of Cribier. *Id.* (citing Pet. 34). As such, Patent Owner contends it presumptively cannot also satisfy the separate “second portion of fibers” limitation, because there is a “strong” and “clear implication” that when two structures are separately named in a claim “the named entities are not one and the same structure.” *Id.* at 34. (citing *HTC Corp. v. Cellular Commc’ns Equip., LLC*, 701 F. App’x 978, 982 (Fed. Cir. 2017); *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010)).

Furthermore, argues Patent Owner, the arrow added by Petitioner to Walther’s Figure 1 appears to point to the sutures that secure the inner graft covering to the frame, which, Patent Owner contends, are different from the more visible stitches that secure the outer graft covering to the frame. Prelim. Resp. 35. (citing Pet. 44). Patent Owner asserts that these are the same stitches that the Petitioner asserts satisfy the limitation, “the outer frame is secured to the inner graft covering by stitching.” Prelim. Resp. 35.

Patent Owner repeats that there is a strong implication that the same structure cannot satisfy two different claim limitations. *Id.*

Patent Owner disputes Petitioner's contention that "[a]s shown [in Petitioner's annotated Figure 1 of Walther], some of the inwardly facing fibers are pressed through the open cells of the outer frame and extend radially inwardly of the outer frame." Prelim. Resp. 35–36 (quoting Pet. 44). Patent Owner asserts that this is not shown, and that Petitioner does not explain how the fibers could push through the open cells of the outer frame given the presence of the inner frame. *Id.* at 36. Patent Owner points to the Declaration of its expert, Dr. Brecker, who states that:

The image is very blurry and difficult to discern. To the extent this blurry image shows any fibers that appear on the inside of the frame, the fibers may just as well be stray fibers from the stitching on top of the frame or may emanate from the outer surface of the PET cloth and wrapped over the top of the outer frame when the cloth was cut.

Id. (quoting Ex. 2002 ¶ 45). Patent Owner contends that any such "stray fibers" cannot constitute "a second sealing interface against the outer frame when the second portion of fibers is compressed [against it]" give the '236 patent's disclosure that "the fibers 234 and the covering material 250 create a seal between the inner frame 218 and the other frame 216." *Id.* at 37 (quoting Ex. 1001, col. 14, ll. 31–32).

Patent Owner further contends that the testimony of Petitioner's witness, Dr. Buller, with respect to this issue is conclusory, and thus insufficient to establish a disclosure. Prelim. Resp. 37 (citing Ex. 1003 ¶ 132; also citing 37 C.F.R. §42.65(a); *Ericsson Inc. v. Intellectual Ventures I, LLC*, 890 F.3d 1336, 1346 (Fed. Cir. 2018)). Furthermore, Patent

Owner's witness, Dr. Brecker, directly disputes Dr. Buller's conclusion. *Id.* (citing Ex. 2002 ¶¶ 46–49).

Patent Owner also argues that Petitioner fails to prove that Walther's alleged "second" portion of fibers are in "overlapping radial alignment" with the "first portion of fibers" as required by the claims. Prelim. Resp. 40. Patent Owner notes that the Petition states that, "Walther's first and second portion of fibers are interwoven and part of a single PET cloth, as illustrated in Figure 1 below, and, therefore, are in overlapping radial alignment." *Id.* (quoting Pet. 46). Patent Owner repeats its previous observation that only a few stray fibers of indeterminate origin are visible in Walther's Figure 1, which, therefore does not show that "the first portion of fibers and the second portion of fibers are in overlapping radial alignment." *Id.* at 40–41.

e. Analysis

We find that Petitioner has demonstrated a reasonable likelihood of prevailing at trial with respect to these limitations, and that Patent Owner's arguments, as developed at this stage of the proceeding, are insufficient to overcome that likelihood. Nevertheless, we acknowledge that a degree of uncertainty remains, and we expect this issue to be further developed at trial.

Figure 13 of the '236 patent depicts the "first portion of fibers positioned radially outwardly of the outer frame" and the "second portion of fibers carried by the outer frame," as recited by claim 1. Figure 13 is reproduced below:

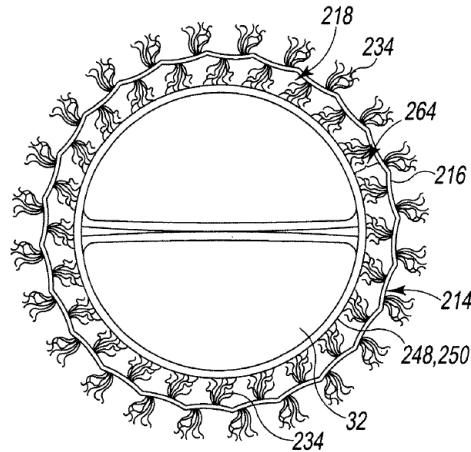


FIG. 13 of the '236 patent is a plan view of the proximal prosthetic component showing the inner frame in an unexpanded position

The collagen fibers 234 of Figure 13 constitute the first portion of fibers positioned radially outwardly of the outer frame (*see also* Figure 14) and the second portion of the fibers carried by the outer frame that are recited in claim 1. Petitioner argues that the outer cloth taught by Walther contains the first portion of fibers positioned radially outward of the outer frame, and that these fibers form a first sealing interface against the cardiac annulus and native leaflets when the prosthetic valve is positioned and expanded in place at the cardiac-aortic junction. On the present record, we agree with Petitioner that a person of ordinary skill in the art would understand that Walther teaches this limitation.

This issue of whether Walther teaches the remaining limitations in question turns on the nature of the “outer cloth” taught by Walther that is added to the SAPIEN valve. *See* Ex. 1007, 1120, 1121. Walther minimally describes the nature of this added outer cloth, stating only that it comprises a “poly(ethylene terephthalate) (PET) cloth ... stitched onto the perimeter of each SAPIEN valve.” *Id.* at 1121.

Figure 1 of Walther, as magnified and annotated by Petitioner is again reproduced below:

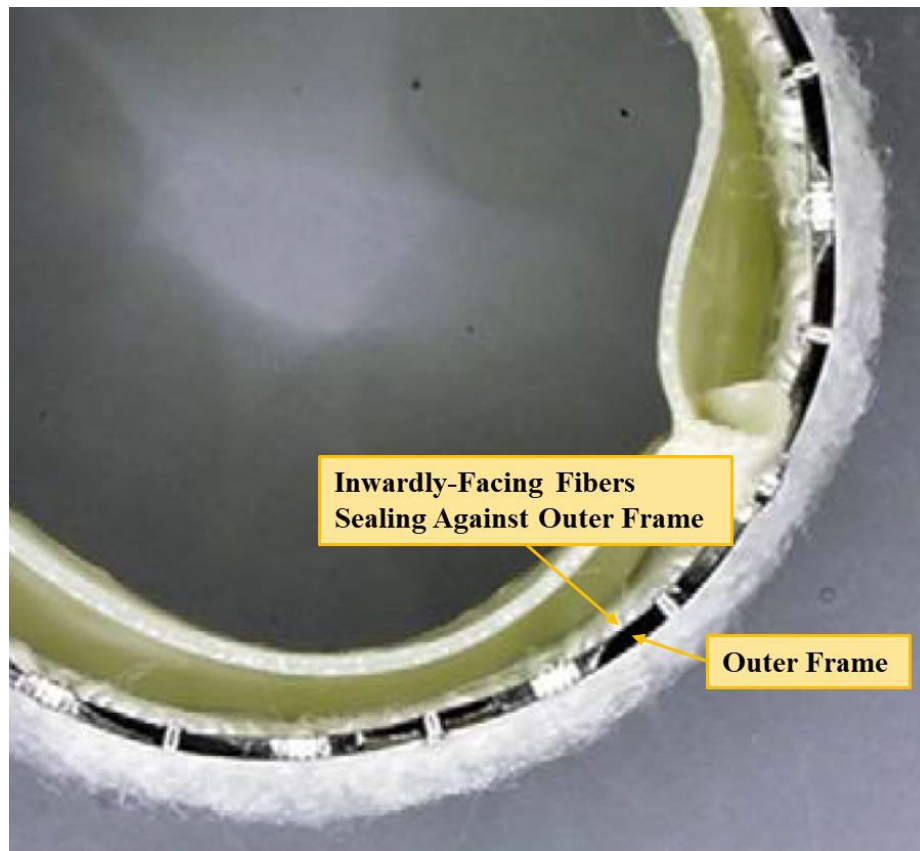


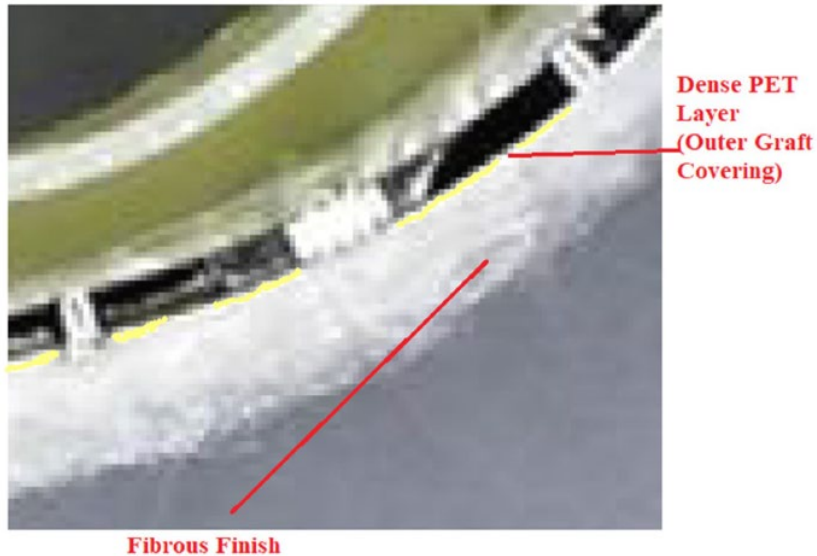
Figure 1 of Walther (annotated by Petitioner) depicts a magnified plan view of a portion of Walther's cloth-covered SAPIEN THV

Petitioner argues that “the inwardly-facing fibers press[] through the open cells of the outer frame and extending radially inwardly of the outer frame” and that these “inwardly-facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded.” Pet. 44–45. We interpret Petitioner’s argument to mean that, either due to the elastic nature of the PET cloth or, when expanded *in situ* into the annulus of the aortic valve, the resulting inward force of the pressure exerted on the outer cloth of the valve by the annulus and native leaflets of

the aortic valve would force some of the fibers of the outer cloth inwards through the interstices of the metallic outer frame against the inner frame, thus forming a second portion of inward facing fibers, and forming a second sealing interface between the inner and outer frames. In any event, the figure from Walther above appears to show fibers on the inside and on the outside of the metallic frame.

This analysis depends at least in part upon the nature of Walther's outer cloth. A close inspection of Walther's Figure 1 could lead an individual to conclude that the outer cloth comprises an outer fibrous layer and a solid woven "backing layer" that forms the inner surface of the cloth. This could be interpreted as being the brighter white line forming the inner surface of the outer cloth. Such a backing layer would prevent any of the outer fibers from penetrating inwardly through the interstices of the outer frame and also from forming a second sealing interface between inner and outer frames. Dr. Brecker opines that such a backing layer indeed exists:

If we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the second image) sandwiched beneath a fibrous finish and the black metal frame.



Second image of Dr. Brecker's annotated, magnified Figure 1
of Walther

I note that Dr. Buller acknowledges that graft material can be made of polyesters, which include PET and repeatedly relies on a dense PET layer/cloth/skirt as the claimed "inner graft covering." Ex. 1003 [Buller-Decl.] ¶¶ 60, 109, 174, 232. ... I also understand that Dr. Buller relies on the fibrous finish for the claimed "first portion of fibers positioned radially outwardly of the outer frame." *Id.*, ¶¶ 115-117.

Ex. 2002 ¶ 37.

By contrast, Petitioner's expert, Dr. Buller, discerns no such dense backing layer/cloth/skirt, stating that:

Expansion of Walther's cloth-covered SAPIEN within a patient's native aortic valve would similarly compress the outwardly extending fibers of the outward-facing surface of the cloth (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and the inwardly extending fibers of the inward-facing surface of the cloth (i.e., second portion) against SAPIEN's outer frame to form a second sealing interface.

Ex. 1003 ¶ 147.

What we are left with, at this stage of the proceeding, is the parties' two declarants squinting at a magnified, pixelated image from Walther's Figure 1 and, without significant additional evidence of record, opining as to what it is that they think they see in Walther's outer cloth. As we have mentioned, Walther itself offers us minimal help with respect to the issue of the nature of its outer cloth. No other relevant evidence of record with respect to how a skilled artisan would understand the cloth actually used in Walther has been presented in the record at this stage.

Furthermore, if the outer cloth of Walther contains both outward facing (a first portion of fibers) and an inward facing portion of fibers unconstrained by a dense backing layer of woven PET (the second portion), then the inward and outward facing fibers would be "in overlapping radial alignment," as required by claim 1.

We expect that both parties will further develop this issue at trial. Nevertheless, at this stage of the proceeding, we conclude that Petitioner has presented a plausible interpretation of Walther, which, if supported by the trial record, would demonstrate that Walther teaches the limitations of claim 1 reciting:

- a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,
- wherein the first portion of fibers is non-metallic;
- and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,
wherein the first portion of fibers and the second portion of fibers
are in overlapping radial alignment.

We conclude that Petitioner has, therefore, demonstrated a
reasonable likelihood of prevailing at trial upon this issue.

2. Claim 1: “wherein the valve assembly is free of an outer graft
covering between the first portion of fibers and the outer frame”

- a. Petitioner’s contentions with respect to Walther

Pointing again to Figure 1 of Walther, Petitioner argues that Walther teaches that the outer cloth, which is stitched to the valve’s perimeter, was the only modification made to SAPIEN. Pet. 47 (citing Ex. 1007, 1120). Petitioner notes that Walther does not state that the outer cloth includes a “graft covering” and contends that the cloth does not include any visible graft covering. *Id.* (citing Ex. 1012, Fig. 1; Ex. 1003 ¶ 140). Petitioner therefore asserts that a person of ordinary skill in the art would have understood that Walther’s cloth-covered SAPIEN is free of an outer graft covering between the first portion of fibers and the outer frame. *Id.* at 49 (Ex. 1003 ¶ 140).

- b. Patent Owner’s Preliminary Response

Patent Owner responds that Petitioner and its witness, Dr. Buller, confirm that PET fabric or cloth are used to make graft coverings, and that Petitioner relies on PET fabrics to meet the “inner graft covering” limitation. Prelim. Resp. 15. According to Patent Owner, Petitioner acknowledges that PET fabric can be a graft covering. *Id.* Furthermore, argues Patent Owner, the Board has found, in a related proceeding, and after evaluating arguments

very similar to those made in this proceeding, that Levi's woven PET outer skirt is an "outer graft covering." *Id.* (citing Ex. 2043, 27); *compare* Ex. 2047 85–86, *with* Pet. 97–98.

Patent Owner contends that, just as Levi's woven PET is an "outer graft covering," so too is Walther's outer PET cloth. Prelim. Resp. 21 (citing Ex. 2046, 7–10). According to Patent Owner, Walther teaches that "outer cloth" is "[a]n added poly(ethylene terephthalate) (PET) cloth ... stitched onto the perimeter of each SAPIEN valve." *Id.* (citing Ex. 1007, 1120, 1121). Petitioner notes that, for Grounds 1, 2, and 6, Petitioner relies on Walther's outer PET cloth as carrying the "first portion of fibers." *Id.* (citing Pet. 36–37, 63–64, 90–91).

Petitioner contends that Walther does not need to explicitly state that the outer cloth includes a "graft covering" because the outer cloth is made of PET, which Petitioner's own expert testifies is a "graft material." Pet. 22 (citing Ex. 1003 ¶ 60 (further citing Ex. 1035, col. 5, ll. 53–59). Patent Owner asserts that PET is also the same material its witness testifies is a "polymeric graft covering." *Id.* (citing Ex. 1003 ¶ 109).

Patent Owner disputes Petitioner's assertion that the cloth does not include any visible graft covering. Prelim Resp. 22. Patent Owner contends that the distinction between the '236's figures (free of an outer graft covering) and Figure 1 of Walther (including an outer graft covering) is readily apparent. *Id.* (citing Ex. 1001 Fig. 11; Ex. 1007, Fig. 1). Patent Owner points to Dr. Brecker's opinion that Walther's outer cloth includes a dense layer of PET that acts as the "outer graft covering" and is located between the frame and the alleged "first portion of fibers":

If we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the

second image) sandwiched beneath a fibrous finish and the black metal frame. Ex. 1007 Fig 1. (excerpted, magnified, annotated) (yellow highlighting added). I note that Dr. Buller acknowledges that graft material can be made of polyesters, which include PET and repeatedly relies on a dense PET layer/cloth/skirt as the claimed “inner graft covering.” Ex. 1003 ¶¶ 60, 109, 174, 232. This is consistent with my understanding that conventional densely woven PET cloth constitutes a “graft covering.” I also understand that Dr. Buller relies on the fibrous finish for the claimed “first portion of fibers positioned radially outwardly of the outer frame.” *Id.*, ¶¶ 115-117. Accordingly, a POSITA would understand that the dense PET layer underneath the outer PET cloth’s fibrous finish would be an “outer graft covering between the first portion of the fibers and the outer frame.”

Prelim. Resp. 23–25 (quoting Ex. 2002 ¶ 37; *see* second image of Dr. Brecker’s annotated, magnified Figure 1 of Walther, reproduced above).

Patent Owner asserts that there is therefore no support for Petitioner’s assertion that a person of ordinary skill in the art would have understood that Walther’s cloth-covered SAPIEN is “free of an outer graft covering between the first portion of fibers and the outer frame.” Prelim. Resp. 25 (quoting Pet. 49). Rather, argues Patent Owner, a skilled artisan would have understood that Walther’s outer PET cloth is an “outer graft covering,” and that, as shown in Figure 1 of Walther, this PET cloth is located “between the first portion of fibers and the outer frame” as precluded by the claims. *Id.*

c. Analysis

Our analysis with respect to this limitation mirrors our previous analysis with respect to the first and second portions of, respectively, inward and radially outward facing fibers, overlapping and aligned radially, and forming first and second sealing interfaces. To put the matter succinctly, the issue turns on the nature of Walther’s outer cloth. If the outer cloth

possesses a woven PET “backing layer” on the inner surface of the outer cloth, interposed between the fibrous portion of the outer cloth and the metallic outer frame, such a woven layer of PET could reasonably be interpreted as constituting an “outer graft covering.” If, on the other hand, there is no such layer, and the outer cloth of Walther is simply a mass of PET fibers without a woven “backing layer” of, e.g., PET cloth, then there would be no outer graft covering, and the fibrous outer PET cloth of Walther would, as we have explained above, constitute the first and second portions of fibers recited in claim 1. It is difficult to tell solely from the magnified and pixelated Figure 1 of Walther whether skilled artisans would understand such a layer to actually exist and, the experts’ testimony notwithstanding, there is not sufficient evidence of record to determine whether there is a layer constituting the “outer graft covering” that is excluded by claim 1. However, the figure appears to show fibers on the outside and on the inside of Walther’s metallic scaffold.

We repeat that this is an issue that we expect the parties to develop at trial. At this stage of the proceedings, however, we conclude that Petitioner has made a plausible and reasonable, if not conclusive, showing that it would likely prevail at trial in demonstrating that this negative limitation would have been obvious over Walther.

3. Conclusion

Incorporating our reasoning with respect to the remaining limitations from our Decisions to Institute in the previous, related *inter partes* reviews (see, e.g., IPR2021-01584, Paper 15; IPR2021-00193, Papers 14, 22) we conclude that, for the purposes of this Decision, on this record Petitioner has established a reasonable likelihood of prevailing at trial in showing that

claim 1 is obvious over the combination of at least Cribier and Walther (Ground 1) and Spenser and Walther (Ground 2). We address the remaining grounds of the Petition below in a more limited manner to provide additional guidance for the parties during trial. We have considered and also address below in Section III.F Patent Owner's arguments concerning objective indicia of nonobviousness.

4. Dependent claims 2–4

Claim 2 depends from independent claim 1 and recites: “wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.” Ex. 1001 col. 22, ll. 20–25. Petitioner contends that Cribier shows that SAPIEN's inner PET fabric cuff (i.e., inner graft covering) extends to the proximal inflow end of SAPIEN's outer frame. Pet. 51 (citing Ex. 1012, 348, Fig. 1; Ex. 1003 ¶ 149). We agree with Petitioner that this is a reasonable interpretation of the teachings of Cribier and we find that there is a reasonable likelihood of Petitioner prevailing at trial with respect to this claim. Patent Owner does not expressly contest this claim at this stage of the proceeding.

Claim 3 depends from claim 1 and recites “wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.” Ex. 1001 col. 22, ll. 26–29. Similarly, claim 4 also depends from claim 1 and recites “wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers,

wherein the opening extends to the outer frame.” Ex. 1001 col. 22, ll. 30–35.

Petitioner argues that Walther’s cloth-covered SAPIEN includes radially extending first portion of fibers. Pet. 54. Petitioner contends that a person of ordinary skill in the art would have understood that small openings inherently exist between the radially extending fibers that are formed by spacing between the adjacent fibers. *Id.* (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 152). According to Petitioner, Figure 1 of Walther shows that the fibers of the outer cloth are dense enough to prevent blood from flowing through the fibers, but still loose enough to create small gaps. *Id.* (citing Ex. 1003 ¶ 153). Petitioner argues that these small gaps define a plurality of “opening[s] extending through a thickness” of the radially extending fibers, as recited in claim 3. *Id.* Patent Owner does not expressly contest claim 3 or 4 at this stage of the proceeding.

We agree with Petitioner that this is a reasonable interpretation of the teachings of Walther and we find that there is a reasonable likelihood of Petitioner prevailing at trial with respect to these claims. Again, Patent Owner has not yet addressed these claims. *See generally* Prelim. Resp.

D. Ground 3: Spenser and Spenser II

1. Claim 1: first and second portion of radially positioned fibers forming a first and second sealing interface in overlapping radial alignment to form the respective first sealing interface and second sealing interface

- a. Introduction

Petitioner relies upon Spenser as teaching a heart valve assembly similar to the SAPIEN prosthetic valve, but which lacks radially extending

fibers forming the sealing interfaces. Pet. 56. For the reasons explained in Section III.C above, we agree with Petitioner that it has demonstrated a reasonable likelihood of prevailing in showing that Spenser teaches these limitations. As with its reliance upon Walther in Grounds 1 and 2, under Ground 3 Petitioner relies upon Spenser II as teaching the limitations of claim 1 reciting:

a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

...

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

...

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

We thus turn to the question of whether Petitioner has demonstrated a reasonable likelihood of prevailing at trial in proving that these limitations are obvious over Spenser II.

b. Overview of Spenser II (Ex. 1011)

Spenser II is a PCT Publication that published on Jan. 12, 2006. Ex. 1011, codes (10), (43). Spenser II facially 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 discloses that prosthetic valves may be implanted “either through open heart surgery or by use of newer percutaneous methods,” but with “both methods paravalvular leaks are a known side effect.” *Id.* ¶ 11. Spenser II further notes that “[p]ercutaneous introduction of medical devices is a preferred surgical procedure” and “considered safer and less invasive.” *Id.* ¶ 12.

Figure 22 of Spenser II is reproduced below:

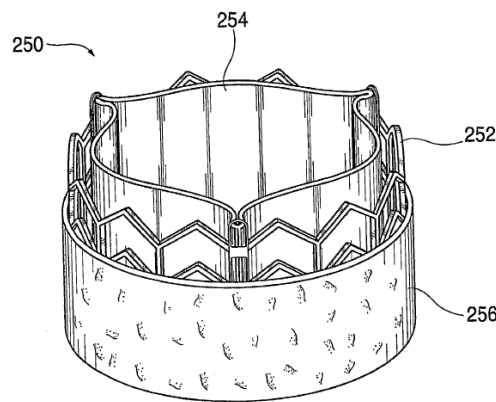


FIG. 22

Figure 22 illustrates a valve device, in accordance with a preferred embodiment

Spenser II’s Figure 22 embodiment, as shown above, includes a layer of compressible material, such as a cloth material, along an exterior surface of a stented valve. *Id.* ¶ 85.

Specifically, Figure 22 illustrates stented (artificial) valve 250 including circular stent structure 252 surrounding 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,” and may be formed of PET. *Id.* “[T]he compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.” *Id.* This “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.*

- c. Petitioner’s contentions with respect to Walther
 - i. “a first portion of [non-metallic] fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets”

Petitioner argues that Spenser II teaches that “[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.” Pet. 67 (citing Ex. 1011 ¶ 145, Fig. 22). Petitioner also notes that Spenser II teaches that the compressible material “may resemble a cloth or fabric having small fibers extending from the surface of the material.” *Id.* Petitioner asserts that the fibers extending outwardly from the compressible material are the “first portion of fibers” required by claim 1. *Id.* (citing Ex. 1003 ¶ 187). Petitioner also notes that, in a preferred embodiment, Spenser II teaches that the compressible material

is formed of nonmetallic PET fibers. *Id.* at 68 (Ex. 1011 ¶ 145; Ex. 1003 ¶ 187).

Petitioner contends that Spenser II's compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." Pet. 68 (citing Ex. 1011 ¶ 145).

Petitioner argues that the compressible material is "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst," as required by claim 1. *Id.* (citing Ex. 1003 ¶ 188). Petitioner contends that a person of ordinary skill in the art would have been motivated to adopt Spenser II's compressible material to reduce PVL, which was a known problem of THV implantation. *Id.*

ii. Second portion of fibers

Petitioner argues that, in addition to an outward facing surface, the compressible material of Spenser II possesses an inward-facing surface also formed of non-metallic fibers. Pet. 72 (citing Ex. 1011 ¶ 145, Fig. 22; Ex. 1003 ¶ 195). According to Petitioner, the inward-facing fibers are the "second portion of fibers" required by claim 1. Petitioner points to Spenser II's Figure 22 as showing that the inwardly facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded. *Id.* (citing Ex. 1003 ¶ 195).

iii. First and second portions of fibers in overlapping radial alignment

Petitioner also argues that Spenser II teaches that its compressible material “may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material.” Pet. 73 (citing Ex. 1011 ¶ 145). According to Petitioner, a skilled artisan would understand that such a PET cloth or fabric would include fibers on both its outward-facing surface (a first portion) and on its inward-facing surface (a second portion). *Id.* Petitioner asserts that, because the two portions of fibers are part of a single PET cloth disposed along the exterior of the outer frame, a person of ordinary skill in the art would understand that the two portions of fibers, located on opposite surfaces of the compressible material, are in overlapping radial alignment. *Id.*

iv. Compress fibers to form a sealing interface

Petitioner contends that Spenser II’s compressible material, in combination with the valve of Spenser’s Figure 44a, is configured, upon expansion of the valve, to: (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. Pet. 78.

v. Free of an outer graft covering

Petitioner asserts that Spenser II teaches that its compressible material, “may resemble a cloth or fabric having small fibers extending from the surface of the material” that is “disposed along an outer surface” of the stent. Pet. 75 (citing Ex. 1011 ¶ 145). Petitioner asserts that Spenser II does not disclose or suggest any “outer graft covering” between the outwardly

extending fibers of the outward-facing surface of the compressible material (i.e., first portion) and the stent. *Id.* at 75–76 (citing Ex. 1003 ¶ 205).

Petitioner concludes that a skilled artisan would have understood that there is therefore no “outer graft covering” between the fibers of the compressible material and the outer frame. *Id.*

d. Patent Owner’s Preliminary Response

i. a first portion of inward facing fibers and a second portion of outward facing fibers

Patent Owner responds that there is no evidence that Spenser II’s compressible material sleeve has “a second portion of fibers ... configure[d] to form a second sealing interface” and that is “in overlapping radial alignment” with the “first portion of fibers.” Prelim. Resp. 41. Patent Owner contends that Spenser II’s Figure 22 shows only the outer surface of compressible material sleeve 256. *Id.* at 42. According to Patent Owner, no “inwardly-facing fibers” are visible in Figure 22, nor are they otherwise mentioned by Spenser II. *Id.* Patent Owner argues that, because Petitioner does not rely upon any actual disclosure in Spenser II, its argument necessarily lies in inherency but, constitutes mere conjecture. *Id.*

Patent Owner acknowledges that Spenser II indicates that the compressible material “may resemble a cloth or fabric having small fibers extending from the surface of the material.” Prelim. Resp. 43 (citing Ex. 1011 ¶ 145). Patent Owner notes that, in Figure 22 these fibers are depicted as the curved lines on the outer surface of element 256, but no other fibers are visible or described. *Id.* Nor, Patent Owner asserts, were any such fibers mentioned by Petitioner during the prosecution of the Spenser II application. *Id.* at 43–44. Patent Owner therefore contends that Petitioner

has failed to meet its burden of showing that the inward facing fibers are necessarily present.

Similarly, argues Patent Owner, because the “second portion of fibers” in Spenser II are not visible, Petitioner’s argument that “the first portion of fibers and the second portion of fibers are in overlapping radial alignment,” is based upon what a POSITA would allegedly understand about a PET cloth or fabric. Prelim. Resp. 46 (citing Pet. 73). Patent Owner contends that Petitioner cannot, however, demonstrate that such fibers are “necessarily” present at all, and therefore also cannot show that the fibers are in overlapping radial alignment with the first portion of fibers. *Id.*

ii. Free of an outer graft covering

Patent Owner next argues that Spenser II’s compressible material sleeve is an “outer graft covering between the first portion of fibers and the outer frame” that is expressly precluded from claim 1. Prelim. Resp. 26. Patent Owner notes that Spenser II’s Figure 22 was discussed at length in prosecution where the Applicant argued, and the Examiner agreed, that Spenser II did not disclose or render obvious the “free of an outer graft covering” limitation. *Id.* (citing Ex. 1002, 196) (“Spenser [II] appears to include an outer graft covering between the fibers and the outer frame”), *see also id.* at 8 (“The following is an examiner’s statement of reasons for allowance: the prior art of record does not disclose or render obvious ... the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame”)).

Patent Owner contends that Petitioner’s argument that the “free of an outer graft covering” limitation is contrary to Spenser II’s express teaching. Prelim. Resp. 27 (quoting Pet. 75–76). Patent Owner points out that

Petitioner and its witness, Dr. Buller, explicitly rely on a PET fabric cuff as forming an “inner graft covering.” *Id.* (citing Pet. 34, 60). Patent Owner notes that Petitioner and its expert do not explain why Spenser II’s compressible material sleeve made of PET is not also a graft covering. *Id.* Patent Owner points to the following explanation by its witness, Dr. Brecker:

Similar to Walther, a POSITA would understand Spenser II’s compressible material sleeve as illustrated to be a PET cloth with fibers on top of the denser PET layer. See Ex. 1011 [Spenser II] ¶ 145 (“the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.”). This dense PET layer forms an “outer graft covering.” It is located between the alleged “first portion of fibers,” located on the outer surface of the PET sleeve, and the outer frame. Thus, Spenser II is not “free of an outer graft covering between the first portion of fibers and the outer frame.” Ex. 1011 [Spenser II] Fig. 22 (annotated in red). It is also notable that Dr. Buller, in his declaration in IPR2022-00034, repeatedly stated that “Spenser II does not disclose any additional ‘outer graft covering’ between the fibrous fabric of the compressible material and the stent frame.” Ex. 2042 [IPR2022-00034 Buller-Decl.] ¶¶ 92, 193. Dr. Buller does not state that Spenser II’s sleeve is not itself an “outer graft covering.”

Id. at 28–29 (citing Ex. 2002 ¶ 40 (figure omitted)). Patent Owner concludes that, because Spenser II’s PET sleeve is itself “an outer graft covering between the first portion of the fibers and the outer frame,” it does not meet the requirement of claim 1 that “the valve assembly is free of” such an “outer graft covering.” *Id.* at 29.

e. Analysis

Based upon the evidence of record at this stage of the proceeding, we have questions whether Petitioner is reasonably likely to prevail at trial in

showing that Spenser II teaches a second portion of inward facing fibers forming a second sealing interface. Further, on this record, whether the compressible material of Spenser II constitutes an outer graft covering or not is similarly not susceptible of easy resolution.

With respect to these issues, Spenser II teaches:

In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot[h] or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

Ex. 1011 ¶ 55. Spenser II further teaches that:

To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. 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. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of

tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

Id. ¶ 145.

The “cloth” or “fabric” of compressible material 256 of Spenser II thus may have “small fibers extending from the surface of the material.” Spenser II does not expressly state that such fibers extend only from the *outer* surface of the material, it merely states that the fibers extend from the “surface,” and a person of ordinary skill in the art could reasonably conclude that the fibers of the material extend from both inner and outer surfaces of the cloth or fabric material. As such, these fibers could be reasonably interpreted as corresponding to the claimed first and second portions of inward and outward facing fibers, respectively.

On the other hand, Spenser II also teaches that, in certain configurations, “the compressible material 256 may resemble a cloth or fabric,” and may be formed of PET. Ex. 1011 ¶¶ 55, 145. PET is a polymeric material that, as the evidence of record shows, may constitute a fabric-like weave (*see, e.g.*, Ex. 2019⁸ Fig. 1A; *see also* Ex. 2020⁹, 23–24,

⁸ B. A. Meslmani, *Development of thrombus-resistant and cell compatible crimped polyethylene terephthalate cardiovascular grafts using surface co-immobilized heparin and collagen*, 43 MATERIALS SCI. AND ENG’G C 538–46 (2014) (“Meslmani”) Ex. 2019.

⁹ A. Rodrigues et al., *Mechanical Behavior of PET Fibers and Textiles for Stent-Grafts Using Video Extensometry and Image Analysis*, 30 SCI. AND TECH. OF MATERIALS 23–33 (2018) (“Rodrigues”) Ex. 2020.

Fig. 8; Ex. 2021¹⁰, Fig. 1.18A) or may be fibrous or “hairy” in appearance, as depicted in Walther (*see* Ex. 1007, Figs 1, 2; *see also* Ex. 1028¹¹, 124 (stating that PET yarn can exhibit “hairiness”), or possibly some combination thereof, as suggested by Dr. Brecker. *See* Ex. 2002 ¶ 37. Indeed, Spenser II directly suggests the latter (“hairiness”) when it discloses that the compressible material may “resemble a cloth or fabric having small fibers extending from the surface of the material.”

As we have explained, such extending fibers could reasonably be interpreted by a skilled artisan as constituting the first and second portions of inward and outward facing fibers recited in claim 1. However, the “cloth or fabric” from which the fibers extend could also be reasonably interpreted as constituting the “outer graft covering between the first portion of fibers and the outer frame” that is precluded by claim 1. We have previously found, in a related *inter partes* review, that the densely woven outer PET skirt of Levi constitutes an outer graft covering. *See* IPR2022-00034 Paper 14, at 27. Spenser II’s description of a fabric or cloth compressible material suggests a similar outer graft covering. We expect that the parties will wish to develop this argument further at trial.

¹⁰ S. De Bock, A (Bio)MECHANICAL ANALYSIS OF STENT GRAFTS FOR THE TREATMENT OF ABDOMINAL AORTIC ANEURYSMS, Doctoral Dissertation, Faculteit Ingenieurswetenschappen en Architectuur, Universiteit Ghent (Academic Year 2013-2014) (“De Bock”) Ex. 2021.

¹¹ G.K. Tyagi, *Yarn Structure and Properties From Different Spinning Techniques*, 119–154, in C.A. Lawrence, ed., ADVANCES IN YARN SPINNING TECHNOLOGY (2010) (“Tyagi”) Ex. 1028.

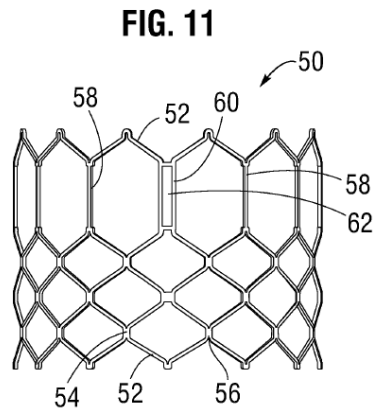
E. Grounds 4–7: Anticipation by (Ground 4), or Obviousness (Ground 5) over Levi, and over Levi and Walther (Ground 6) or Levi and Spenser II (Ground 7)

1. Overview of Levi (Ex. 1008)

Levi is a U.S. Patent that issued on July 19, 2016, from an application filed on October 5, 2011. Ex. 1008, codes (10), (22), (45). Thus, on its face, Levi qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

Levi is directed to a prosthetic heart valve. Ex. 1008, col. 1, ll. 16–18.

Figure 11 of Levi is reproduced below:



Levi's Figure 11 depicts a frame for use in a prosthetic heart valve.

Specifically, Figure 11 illustrates frame 50, which:

comprises multiple rows of circumferentially extending, angled struts **52** that are connected to each other at nodes, or connecting portions, **54** and **56**. The uppermost row of struts **52** are connected to an adjacent row of struts by a plurality of axially extending struts **58** and commissure window frame portions **60**. Each commissure frame portion **60** defines a slot, or commissure window, **62** for mounting a respective commissure of the valvular structure.

Id. at cols. 8–9, ll. 61–3.

Figure 2 of Levi is reproduced below:

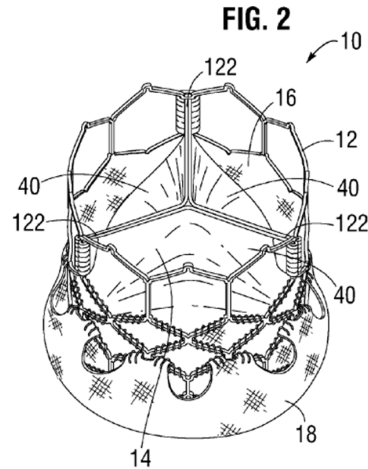


Figure 2 of Levi depicts an exemplary embodiment of a prosthetic heart valve

Figure 2 depicts a prosthetic heart valve 10 including valvular structure 16, surrounded by circular stent or frame 12. *Id.* at Fig. 2, col. 5, ll. 52–58. The bottom portion of frame 12 is covered by inner skirt 16 on the inside of frame 12 and outer skirt 18 on the outside of frame 12. *See id.* at Fig. 2, col. 5, ll. 52–58, col. 9, ll. 24–25, col. 13, ll. 49–50. Valvular structure 16 includes “three leaflets 40, collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement.” *Id.* at Fig. 2, col. 5, ll. 59–61. “[L]eaflets 40 are secured to one another at their adjacent sides to form commissures 122 of the leaflet structures.” *Id.* at col. 11, ll. 35–37.

Figure 20 of Levi is reproduced below:

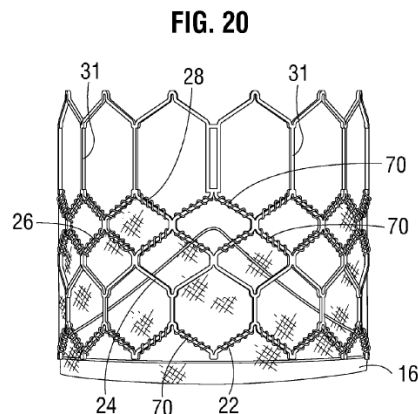


Figure 20 of Levi depicts the assembly of the inner skirt and frame of a prosthetic heart valve

Figure 20 depicts a valve with skirt 16 arranged on frame 12. *Id.* at Fig. 20, col. 10, ll. 5–17. Specifically, frame 12 includes struts 22, 24, 26, and 28. *Id.* at Fig. 20, col. 7, ll. 16–21. “[S]econd, third, and fourth rows of structures 24, 26, and 28 define two intermediate rows of cells defining openings 38. The fourth and fifth rows of struts 28 and 32, along with frame portions 30 and 31, define an upper row of cells defining openings 40.” *Id.* at Fig. 20, col. 7, ll. 19–23. “[T]he upper edge of skirt 16 can be tightly secured to structures 28 with sutures 70.” *Id.* at Fig. 20, col. 10, ll. 16–18. “[S]kirt 16 can also be secured to the first, second, and third rows of struts 22, 24, and 26, respectively, with sutures 70.” *Id.* at col. 10, ll. 28–30.

Figure 42 of Levi is reproduced below:

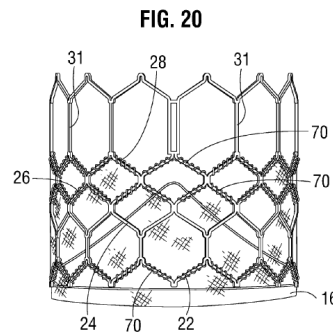


Figure 42 of Levi depicts aspects of an exemplary embodiment of a prosthetic heart valve

Figure 42 illustrates portions of the valve assembly including an outer skirt 18 with projections 164 that are sutured to the outer side of frame 12. *Id.* at Fig. 42, col. 13, ll. 54–61. Skirt 18 includes lower edge 160 that can be sutured to the lower edge of inner skirt 16 at the inflow end of the valve. *Id.* Outer skirt 12 includes excess material between the lower and upper edges. *Id.* at Figs. 2, 43, col. 13, ll. 62–66. Levi discloses that when

valve **10** is deployed within the body the excess material of the outer skirt **18** can fill in gaps **5** between the frame **12** and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus. The outer skirt **18** therefore cooperates with the inner skirt **16** to avoid perivalvular leakage after implantation of the valve **10**.

Id. at col. 14, ll. 4–9.

2. Analysis

In our Decision to Institute in related IPR2022-00034, we found that Petitioner was unlikely to prevail at trial in demonstrating that: (1) the woven fabric of Levi possessed *outwardly extending fibers* that form a first sealing interface, and (2) that the outer skirt of Levi was an “outer graft covering” which precluded by the present claim 1. *See, e.g.*, IPR2022-00034, Paper 14 at 13–27; *see also* Prelim. Resp. 14. Specifically, with respect to (1), we found that:

We understand the requirement for “outwardly extending,” in accordance with its plain and customary meaning, to mean that the tips of the fibers must extend in a generally outward direction from the frame as shown, for example, in Figures 8, 9, 11–14, and 20 of the ’846 patent. We agree with Patent Owner that nothing in Levi suggests that the “woven PET fabric” used to form the outer skirt expressly or inherently meets this requirement. We are not persuaded by Petitioner’s contention that the laser-cut woven PET disclosed for use in Levi’s outer skirt would necessarily exhibit the type of “hairiness” described for PET yarn used in other textile applications.

IPR2022-00034, Paper 14 at 26 (citations omitted). With respect to (2) we found that:

Similarly, Petitioner provides no persuasive evidence that Levi discloses the limitation of disclaimed independent claim 1 (from which challenged claim 6 depends) reciting “wherein the outer

seal is free of an outer graft covering between the fibers and the outer frame.” We agree with Patent Owner that, having argued that “Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt” and “Levi does not include any ‘outer graft covering’ on the exterior of the outer frame,” Petitioner has failed to recognize that Levi’s outer skirt is an “outer graft covering.”

Id. at 27. We incorporate here that same reasoning from those Decisions and similarly conclude that, for those same reasons, Petitioner is unlikely to prevail at trial upon Grounds 4 and 5.

With respect to Ground 6 (obviousness over Levi and Walther), Petitioner argues that it would have been obvious to replace Levi’s outer skirt, with the outer cloth covering of Walther or the compressible material of Spenser II. Pet. 90–91, 95–99. We have explained above our reasoning as to why we conclude that Petitioner has established a reasonable likelihood of success at trial, at least with respect to the Walther-based Grounds 1 and 2, of demonstrating that Walther teaches the limitations of claim 1 reciting the first and second portions of non-metallic fibers forming first and second sealing interfaces and positioned in overlapping radial alignment and does not teach or suggest an outer graft covering. We have also explained our similar reasoning with respect to Spenser II in Petitioner’s Ground 3. We find that this reasoning applies equally to Grounds 6 and 7, and we conclude that Petitioner has demonstrated a reasonable likelihood of success in demonstrating that at least claim 1 is obvious over the combinations of Walther or Spenser II and Levi. We expect that the parties will continue to develop their arguments with respect to these Grounds at trial.

F. Objective Indicia of Nonobviousness

Patent Owner also argues that evidence of objective indicia strongly supports a finding of nonobviousness (and, thus, denial of institution).

Prelim. Resp. 2. Patent Owner argues that its claimed invention meets a “long-felt need to reduce PVL while maintaining a small valve profile.” *Id.* at 6 (quoting Ex. 1002, 185).

Patent Owner explains that paraventricular leakage (“PVL”) around implanted transcatheter aortic valve replacements was a major cause of mortality and rehospitalization. Prelim. Resp. 3 (citing, *e.g.*, Ex. 1002, 183, 185). A competing problem was designing a prosthetic valve that is small enough in its crimped state to permit endovascular delivery. *Id.*

Patent Owner relates that, by 2012, a blood impermeable, dense “outer seal” was employed in the art to reduce paravalvular leakage. Prelim. Resp. 4 (citing Ex. 1002, 186). According to Patent Owner, these outer seals often were composed of a blood impermeable graft material made of a woven fabric such as PET. *Id.* (citing Ex. 1035, col. 5, ll. 53-59). Patent Owner argues that those of skill in the art also recognized, however, that such outer seals formed of a dense woven PET “tend[ed] to deform the struts of the frame and prevents uniform crimping.” *Id.* Ex. 1002, 183. The resulting structures were also too large and bulky in the crimped position and could not be delivered endovascularly. *Id.* Patent Owner points to Walther, for example, as teaching a thick, bulky, outer cloth. *Id.*

Patent Owner contends the claimed invention provides a solution to these problems through a combination of features found in the claimed inventions. Prelim. Resp. 6 (citing Ex. 1002, 195). Patent Owner provides four reasons why its invention met this long-felt need. *Id.*

First, argues Patent Owner, the claimed invention greatly reduced the crimped profile of the device by not using a graft material and requiring that “the valve assembly” be “free of an outer graft covering between the first portion of fibers and the outer frame.” Prelim. Resp. 6–7 (citing Ex. 1001, claim 1). Patent Owner states that, by omitting the impermeable outer seal of the prior art, this not only reduced the crimped profile by removing bulky material, but also prevented deformation of the struts of the frame and allowed for more uniform crimping. *Id.* at 7.

Second, Patent Owner contends, to create adequate sealing to prevent PVL in the absence of an outer graft covering, the claimed invention provides two sets of fibers that create two separate “sealing interfaces . . . when those fibers are compressed.” *Id.*

The third reason Patent Owner advances is that, for the “first portion of fibers” to adequately “form a first sealing interface against the annulus and native valve leaflets of the patient,” the claimed inventions require the fibers to “extend radially outwardly of the outer frame.” *Id.* at 11.

Finally, argues Patent Owner, a fourth limitation of the invention requires that “the first portion of fibers and the second portion of fibers are in overlapping radial alignment” as shown, e.g., in Figures 13 and 14 of the ’236 patent. Aligning these fibers aligns the seals and thus prevents blood leakage after the fibers have been compressed. *Id.*

Patent Owner therefore contends that this collection of limitations, addresses a long-felt need by allowing for a TAVR with a narrow profile that can be endovascularly delivered while still limiting PVL. *Id.* at 11–12.

Objective evidence that an invention satisfied a long-felt and unmet need that existed before the patent’s filing date supports that an invention is non-obvious. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324,

1332 (Fed. Cir. 2009). We find that, at this stage of the proceeding, Patent Owner has not provided sufficient *objective* evidence to show the existence of a “long-felt, unmet need alleviated by the patent.” *Id.*

Virtually all of Patent Owner’s arguments with respect to its meeting a long-felt unmet need derive support from arguments made by Patent Owner (the then-Applicant) during the prosecution of the ’236 patent, arguments which are necessarily, of their very nature, self-serving. Patent Owner points to little objective evidence that its invention was recognized as having met a long-felt need, rather, its arguments were directed to showing only that a putative need existed and had not yet been met. Patent Owner presents no evidence that its valve met a need that had not been previously met by the prior art (i.e., by the art upon which Grounds 1–6 are based, particularly Walther and Spenser II.

Patent Owner may develop this argument and evidence further at trial, but for the purpose of this Decision, we find that a lack of sufficient, persuasive objective evidence supporting that the invention met a long-felt need that outweighs Petitioner’s assertions and the present evidentiary record showing obviousness.

G. Discretionary Denial under 35 U.S.C. § 325(d)

Finally, Patent Owner urges us to exercise our discretion under § 325(d) to deny institution because the same or substantially the same prior art or arguments were previously presented to the Office. Prelim. Resp. 70–81. Petitioner takes a contrary position, arguing that the Board should not deny institution under 35 U.S.C. § 325(d). Pet. 104–1088. We address the parties’ arguments below.

1. Legal standard

Under § 325(d), we have discretion to deny a petition that presents the same or substantially the same prior art or arguments as previously presented to the Office. *See* 35 U.S.C. § 325(d). In evaluating whether the factual predicate under § 325(d) is met, we consider a number of non-exclusive factors, as set forth in our decision in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential) (“the *Becton, Dickinson* factors”):

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, IPR2017-01586, Paper 8 at 17–18.

In performing an analysis under § 325(d):

[T]he Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented

to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.... If, after review of [*Becton, Dickinson*] factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

Consequently, we first turn to an analysis of *Becton, Dickinson* factors (a), (b), and (d) under this framework to determine whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.

2. Part One of the *Advanced Bionics* Analysis

Patent Owner argues that Levi and Spenser II were before, and were considered by, the Examiner during prosecution. Prelim Resp. 71–72. Patent Owner acknowledges that Spenser, Walther, and Cribier were not specifically before the Examiner, but argues that the portions of those references relied upon by Petitioner are “substantially similar” to the considered portions of Levi and Spenser II. *Id.* at 74.

As noted by Patent Owner, in the related IPRs, the Board found that Spenser, Walther, and Cribier are substantially similar to Levi and Spenser II. Prelim. Resp. 74; *see* IPR2021-01527, Paper 15 at 24; IPR2022-00034, Paper 14 at 58; *see also* IPR2021-01584, Paper 15 at 26 (holding that a different Cribier reference, Walther, and Spenser were substantially similar to Levi and Spenser II). We incorporate the reasoning from those Decisions

herein, finding that Spenser, Walther, and Cribier are substantially similar to Levi and Spenser II.

We next turn to examine whether the Examiner materially erred in his consideration of the references.

3. Part Two of the *Advanced Bionics* Analysis

Petitioner notes that Walther was not before the Examiner during prosecution of the '869 application. Petitioner argues that the Examiner erred in failing to consider whether any reference (or combination of references) that were before the Examiner disclosed Walther's combination of a prosthetic heart valve having: (1) a fibrous outer seal stitched to the exterior of a balloon-expandable stent frame and (2) an "inner graft covering" stitched to the interior of the stent frame. Pet. 104.

Original claim 11, which became independent claim 1, was added by amendment to the '869 application on January 26, 2021. Claim 11 recited "wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame." Ex. 1002, 235–236. In a claim chart accompanying the claim when added, Patent Owner (the then-Applicant) explained this limitation as follows:

The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

Id. at 240.

In remarks to the Examiner on February 16, 2021, Patent Owner discussed both Levi and Spenser II. In prosecution, Patent Owner stated:

Thus, as these studies show, PVL is a long-felt problem and a method of addressing them has been needed.... However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion, and crossing of the aorta. The claimed invention addresses these problems.

...

There were multiple TAVRs available in 2012 at the effective filing date of this application, however, none of TAVRs known to Applicant taught a fiber outer seal.

....

[Levi] appears to teach an inner and outer seal in FIG. 42. [Spenser II] appears to teach a thick band with fibers emanating therefrom in FIG. 22, however, there is no graft forming the inner frame, thus the inner sealing is missing.

....

The combination of a balloon expandable transcatheter stent valve with an outer seal with outwardly extending fibers, along with the other limitations found in the claims, presented an improvement over the prior art, with particular reference to the unexpected results of products covered by claims in prosecution of the '137 Application (Now USPN 10,792,172). Applicant submits that it was not obvious to combine the seal found in the references submitted with the information disclosure statement with the TAVR technology of record to seal against the native leaflets of the patient with a fiber outer seal.

Ex. 1002, 185–194.

Patent Owner concluded during prosecution that:

Additionally, placing outer seal bands as disclosed by Spencer, Cribier and Levi, creates significant technical limitations in the functionality of the TAVR device during loading of the device into a sheath and deployment of the devices *in vivo*. These disclosures show balloon- expandable stent frames. A balloon-expandable frame has a dynamic length, where in an undeployed crimped state, the frame is taller and gradually shortens as the frame is ballooned and expanded to be placed in its final *in vivo*

position. Applicant submits that the density of this outer seal band (Spenser II, Cribier, and Levi) restricts the necessary foreshortening of the stent frame during deployment in vivo and can cause PVL, migration, under-deployment and malfunction of the valve leaflets.

Ex. 1002, 195. Patent Owner thus argued that the outer graft coverings of Spenser II and Levi were disadvantageous for mechanical reasons in a balloon-expandable THV, but did not consider whether the “compressible material” of Spenser II *itself* comprised the first and second portions of fibers forming the first and second interfaces in overlapping radial alignment.

In a Non-Final Office Action, issued on February 26, 2021, the Examiner rejected Patent Owner’s original claims 11–14 as unpatentable under 35 U.S.C. § 103 as being obvious over the combination of Nguyen et al. (WO 2006/124649), Greenhalgh (US 2002/0052649) and Braido et al. (US 2011/0098802).¹² Ex. 1002, 104. The Examiner found that Nguyen teaches an aortic valve assembly comprising a radially-expandable outer frame and inner frame corresponding to Patent Owner’s claimed invention. *Id.* The Examiner also found that Nguyen did not teach first and second portions of fibers forming first and second sealing interfaces aligned radially and overlapping. *Id.* at 104-105.

The Examiner found that Greenhalgh teaches a stent graft with a “sealing material” (22) positioned outside of a stent graft area (frame/stent 20) (Fig. 1). Ex. 1002, 105. The Examiner found that Greenhalgh thus

¹² The Examiner also rejected the claims as unpatentable over 35 U.S.C. §§ 101 and 112(b) as being indefinite. Exs. 1002, 1003. These rejections were subsequently overcome by Patent Owner, and we do not consider them here.

discloses a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed against it, in which the first portion of fibers extend radially outwardly of the outer frame, and a second portion of fibers carried by the outer frame forming a second sealing interface against the outer frame when the second portion of fibers are compressed against it. *Id.* The Examiner concluded that it would have been obvious to a person of ordinary skill in the art modify Nguyen to include radially extending fibers, as taught by Greenhalgh, to further improve the seal of the device once implanted and prevent leakage. *Id.*

The Examiner also found that Braido teaches a heart valve assembly in the same field of endeavor that comprises an outer graft covering that covers an exterior surface of an outer frame, in which the outer graft covering is distinct from the inner graft covering. Ex. 1002, 105. The Examiner concluded that it would have been obvious to a skilled artisan to combine the teachings of Braido with those of Nguyen and Greenhalgh to comprise an outer covering, that covers an exterior surface of an outer frame, as taught by Braido, to further improve the seal of the device once implanted and prevent leakage. *Id.*

Patent Owner responded to the Examiner's rejection by amending independent claim 11 (which, as noted, became the present claim 1) as follows "wherein the valve assembly is free of a ~~polymeric~~ an outer graft covering between the first portion of fibers and the outer frame ~~that covers an exterior surface of the outer frame~~. Ex. 1002, 94 (strikethroughs indicate deletions, underlining indicates additions). Patent Owner argued that:

Nguyen, however, is not modifiable to add the stent graft of Greenhaulgh and achieve acceptable performance. As the name

“stent graft” implies, Greenhaulgh includes a graft material, which is what the fibers extend from.

[0024] Stent graft 10 comprises a thin, flexible, biocompatible substrate 18, preferably tubular and having stents 20 located at either end. Stents 20 are spring-like supports which hold the graft open and allow the ends to be sealingly attached to the wall 16 of the artery to either side of aneurysm 12.

Independent claim 11, however, requires that the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame. Thus, Greenhalgh, teaches away from the claimed invention. Similarly, Braido teaches the presence of an outer graft covering and also teaches away from the claimed invention.

Id.

The Examiner subsequently allowed the claims, stating in a Notice of Allowance, issued on March 24, 2021, that:

[T]he prior art of record does not disclose or render obvious a first portion of fibers positioned radially outwardly of the outer frame and a second portion of fibers carried by the outer frame wherein the first portion of fibers and second portion of fibers are in overlapping radial alignment; the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame in combination with the other recited features.

Ex. 1002, 8.

We agree with Petitioner and conclude that the Examiner erred in the examination of the '869 application. Specifically, we do not find that the Examiner considered the question of whether the compressible material of Spenser II itself constituted the first and second portion of fibers forming first and second sealing interfaces, and was *not*, in fact, an outer graft covering. Rather, the compressible material of Spenser II (the “thick band”)

was argued by Patent Owner as constituting an outer graft covering, an argument accepted by the Examiner.

We have explained above why we find that this is a central question posed by the Petition before us, and one the Examiner failed to adequately consider. In view of this error by the Examiner, we decline to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

IV. CONCLUSION

For the forgoing reasons, Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the '236 patent would have been obvious over the prior art of record. Accordingly, we institute an *inter partes* review of all challenged claims of the '236 patent, based on all of the grounds identified in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, *inter partes* review is instituted on all claims and all Grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '236 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2022-0556

Patent 10,987,236 B2

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