

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.

IPR2021-01584
Patent 10,857,011 B2

Before JOHN G. NEW, CHRISTOPHER G. PAULRAJ, and
JASON W. MELVIN, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background and Summary*

Edwards Lifesciences Corp. and Edwards Lifesciences LLC (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–12 of U.S. Patent Number 10,857,011 B2 (Ex. 1001, “the ’011 patent”). Paper 1 (“Petition” or “Pet.”). Aortic Innovations LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). Along with its Preliminary Response, Patent Owner filed a Statutory Disclaimer of claims 1–6 and 8–11 of the ’011 patent. Prelim. Resp. 1, 82–83; Ex. 2011. Pursuant to our authorization, Petitioner filed a Preliminary Reply and Patent Owner filed a Preliminary Sur-Reply addressing the prior art status of certain references relied upon in the Petition. Paper 10 (“Prelim. Reply”); Paper 12 (“Prelim. Sur-Reply”).

In view of Patent Owner’s statutory disclaimer, we treat claims 1–6 and 8–11 as having never been part of the ’011 patent, such that Petitioner cannot seek *inter partes* review of those claims. *See Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (“This court has interpreted the term ‘considered as part of the original patent’ in section 253 to mean that the patent is treated as though the disclaimed claims never existed.”) (*citing Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996)); 37 C.F.R. § 42.107(e) (“No *inter partes* review will be instituted based on disclaimed claims.”). And because no *inter partes* review will be instituted based on disclaimed claims, we do not consider claims 1–6 and 8–11 to be within the scope of this proceeding. *Cf. General Elec. Co. v. United Techs. Corp.*, IPR2017-00491, Paper 9 (PTAB July 6, 2017) (precedential) (denying institution of *inter partes* review based on disclaimer of *all*

challenged claims). We base our decision to institute on the remaining challenged claims that have not been disclaimed.

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. §42.4(a). We may not institute an *inter partes* review “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). In view of the above, we address the merits of the issues raised by the parties regarding claims 7 and 12 of the ’011 patent. For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the ’011 patent is unpatentable, we institute an *inter partes* review of all the remaining challenged claims—claims 7 and 12—based on the grounds set forth in the Petition.

B. Real Parties in Interest

Petitioner identifies itself, Edwards Lifesciences Corp. and Edwards Lifesciences LLC, as the real parties-in-interest (“RPI”). Pet. 113. Patent Owner identifies only itself as the RPI. Paper 4, 1. There is no dispute over the RPIs in this proceeding.

C. Related Matters

As a related matter, Petitioner identifies IPR2021-01527, challenging claims of U.S. Patent Number 10,792,172 B2, which is a parent of the ’011 patent. *Id.* We also note two additional *inter partes* review proceedings concerning related patents filed by Petitioner. IPR2022-00034; IPR2022-00193.

D. The '011 Patent (Ex. 1001)

1. Specification

The '011 patent is titled “Device for Endovascular Aortic Repair and Method of Using the Same.” Ex. 1001, code (54). The '011 patent issued from Appl. No. 16/910,189, which claims priority through a series of continuation and divisional applications to Appl. No. 13/706,896, filed on Dec. 6, 2012. *Id.* at codes (21), (60). The '011 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).¹

The '011 patent discloses an endograft device, i.e., a transcatheter heart valve, used for endovascular repair of ascending aortic aneurysms. *Id.* 2:43–45. According to the 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 2:28–30. The Specification describes a need for a device “that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions.” *Id.* at 2:31–35. “A device is also needed that would allow

¹ According to Petitioner, “[d]uring prosecution of the '011 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. 21 (quoting Ex. 1002, 274). Petitioner asserts that “the '011 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '011 patent’s claims.” *Id.* 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 '011 patent claims are entitled to claim priority to the '458 provisional.

for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.” *Id.* at 2:35–39.

Figure 11 illustrates a perspective view of a proximal end of a prosthetic component, and is reproduced below.

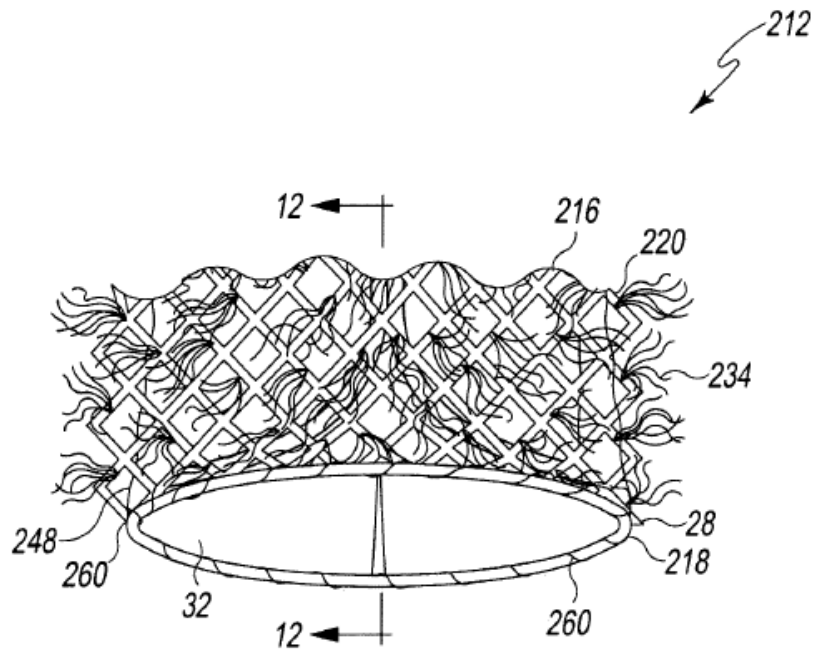


Fig. 11

As shown above, the component 212 includes a dual-frame structure with a circular inner frame 218 secured to circular outer frame 216 via a plurality of stitches 260. *Id.* at Fig. 11, 13:61–63.

Figure 13 illustrates a plan view of the prosthetic device, and is reproduced below.

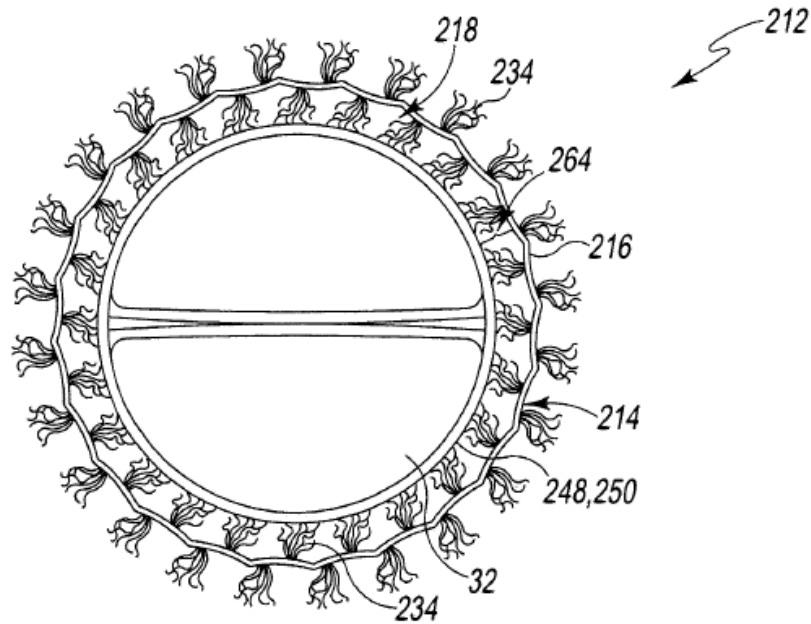


Fig. 13

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, 13:26–28.

Also shown in the figures above, the inner frame 218 houses valve 32. *Id.* at Fig. 13, 13:28–29, 66–7:1. Fibers 234 extend outwardly and inwardly from outer frame 216. *See id.* at Fig. 13, 12:31–41, 13:3–4. Outer frame 216 is a grid with diagonally oriented lines as compared to 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, 12:31–36. 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 12:31–34.

The Specification further describes “[b]alloon-expandable frame 218 . . . as a balloon-expandable tubular stent 244.” *Id.* at 13:29–31. “[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 13:34–36. “When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216.” *Id.* at Fig. 13, 14:1–4. 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, 14:7–20.

2. *Relevant Prosecution History*

The ’011 patent was filed as Appl. No. 16/910,189 on June 24, 2020, with original claims 1–10. Ex. 1002, 313–357. The Applicant filed a Preliminary Amendment on May 1, 2020, replacing the original claims with new claims 11–21. *See id.* at 295–298. The Applicant also filed a terminal disclaimer disclaiming the term of the ’011 patent beyond the expiration of the ’172 patent. *Id.* at 288.

In a Non-Final Office Action, the Examiner rejected the claims as indefinite and obvious over either Nguyen et al. (WO/2006/124649) or Braido et al. (US 2011/0098802) in view of Greenhalgh (US 2002/0052649). *Id.* at 218–224. The Examiner reasoned it would have been obvious to modify Nguyen et al. and Braido to include a sealing material external with radially extending fibers, as taught in Greenhalgh, “in order to further improve the seal of the device once implanted and prevent leakage.” *Id.* at 221, 223.

In response, the Applicant amended claim 11 as follows to require, *inter alia*, a “cylindrically extending graft,” “a plurality of stitches at a proximal end of the graft covering and a plurality of stitches at a proximal end of the outer frame,” “wherein the fibers cover at least a first two proximal, circumferentially extending rows of grids formed in the gridded configuration,” and “wherein the valve assembly is balloon expandable.”

Id. at 202 (underlying in original to show added limitations). The Applicant argued that “Nguyen could not be modified such that the fibers cover at least a first two proximal, circumferentially extending rows of grids formed in the gridded configuration,” that “Nguyen already teaches an outer seal,” that the combination of “an inner frame that is a graft material and an outer frame that includes radially extending fibers provides diversity in sealing the claimed heart valve,” that “a self expanding frame like Nguyen is unlikely to use a fiber based outer seal due to increased thrombus risk,” and that “Braido does not teach an inner frame that is a graft material.” *Id.* at 203–206. The Applicant also distinguished other prior art of record, including Spenser II² on the basis that “that there is no graft forming the inner frame, thus the inner sealing is missing.” *Id.* at 212.

The Examiner subsequently issued a notice of allowance without comment on the reasons for allowance. *Id.* at 145. Thereafter, the Applicant filed a request for continued examination (RCE), submitted additional prior art in an information disclosure statement (IDS), and further amended claim 11 to require, *inter alia*, that the outer frame defines an “open cell configuration,” that the inner frame “engages a prosthetic heart valve,” that the outer frame is secured to the graft covering by stitching,” and “wherein

² Spenser et al., WO 2006/005015 A1, published Jan. 12, 2006 (Ex. 1011).

the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” *Id.* at 113 (underlying in original to show added limitations). Claims 12 and 20 were cancelled, and new dependent claims 22 and 23 were added. *Id.* at 114–115. In the remarks accompanying the amendment, the Applicant distinguished Spenser II and Levi³ (two of the references relied upon in the current Petition) on the basis that the references only disclosed that “the seal was made below the native leaflets in the patient, but not against the leaflets.” *Id.* at 117. Once again, the Examiner allowed these amended claims without comment on the reasons for allowance. *Id.* at 3, 20. The ’011 patent issued thereafter. *Id.* at 1.

E. Illustrative Claims

Petitioner challenges claims 7 and 12 of the ’011 patent.⁴ Claim 12 is representative of the challenged claims and recites:

12. An endovascularly deployed heart valve assembly comprising:

an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration;

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic heart valve and

³ Levi et al., US 9,393,110 B2, issued July 19, 2016 (Ex. 1008). At this point during prosecution, Levi had not yet issued as a patent and the applicant was referencing the corresponding published patent application, 2012/0123529, in the remarks to the examiner.

⁴ Claim 7 is treated as independent by virtue of its dependency on disclaimed claim 1. The limitations of claim 1 are therefore incorporated into, and considered part of, claim 7.

radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame;

a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to treat paravalvular leaks, wherein the sealing material includes a plurality of radially extending fibers that form a circumferential surface that extends outwardly of the outer frame,

wherein the fibers cover at least two circumferentially extending rows of grids formed in the open cell configuration and the at least two circumferentially extending rows radially overlap with the prosthetic leaflets,

wherein the valve assembly is balloon expandable during endovascular deployment,

wherein expansion of the valve assembly presses the sealing material against native valve leaflets of the patient.

Ex. 1001, 22:12–44. Claim 7 is directed to a heart valve assembly with the same basic structure recited in claim 12, “wherein the valve assembly is delivered endovascularly.” *Id.* at 21:5–29, 42–43.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 7 and 12 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	7, 12	103 ⁵	Spenser ⁶ , Walther ⁷
2	7, 12	103	Spenser, Spenser II
3	7, 12	103	Cribier '321 ⁸ , Walther
4	7, 12	103	Cribier '321, Spenser II
5	7, 12	102(e)	Levi
6	7, 12	103	Levi
7	7, 12	103	Levi, Walther
8	7, 12	103	Levi, Spenser II
9	7, 12	103	Levi, Cribier '321
10	7, 12	103	Levi, Spenser
11	7, 12	103	Levi, Cribier '321, Walther
12	7, 12	103	Levi, Cribier '321, Spenser II
13	7, 12	103	Levi, Spenser, Walther
14	7, 12	103	Levi, Spenser, Spenser II

Petitioner relies on the declaration of Nigel Buller, M.D. (Ex. 1003).

Patent Owner relies on a declaration of Stephen J.D. Brecker, M.D. (Ex. 2002).

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Petitioner proposes that a person of ordinary skill in the art (“POSITA”) “would have been an interventional cardiologist with a working

⁵ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '172 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

⁶ Spenser et al., US 7,510,575 B2, issued Mar. 31, 2009 (Ex. 1010).

⁷ 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. J. CARDIO-THORACIC SURGERY 1120–1126 (2011) (Ex. 1007).

⁸ Cribier, US 7,585,321 B2, issued Sep. 8, 2009 (Ex. 1045).

knowledge of heart valve designs and endovascular prostheses. This POSITA would, where necessary, work as a team with a medical device engineer to experiment with or manufacture a prosthetic heart valve.” Pet. 24 (citing Ex. 1003 ¶ 47). Patent Owner does not argue otherwise. *See generally* Prelim. Resp.

At this stage of the proceeding and for purposes of our analysis in this Decision, we adopt Petitioner’s definition as that definition is consistent with the level of skill in the art reflected by the prior art. *See 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))).

B. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). This standard requires that we construe claims “in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Neither Petitioner nor Patent Owner proposes a construction for any claim terms apart from their plain and customary meaning. Pet. 24; *see generally* Prelim. Resp. We also do not perceive a need to construe any claim terms of the ’011 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).

C. Overview of Asserted References

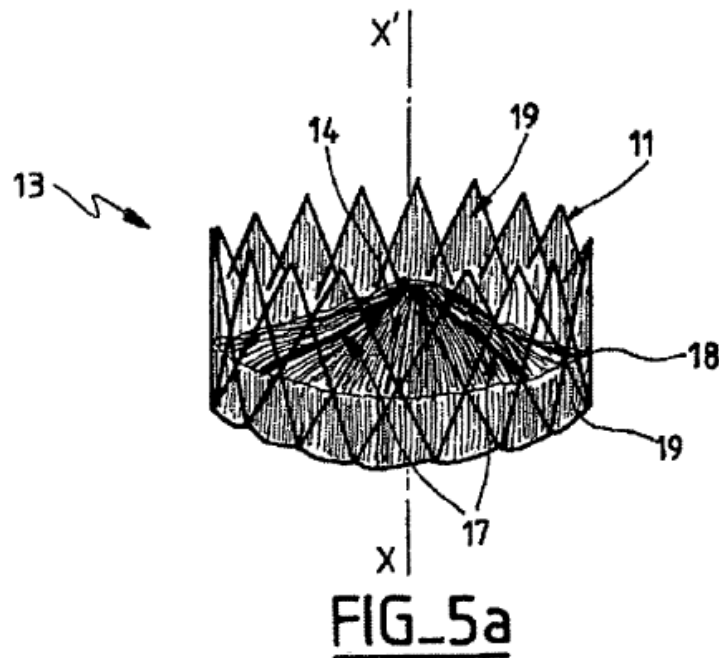
1. Overview of Cribier '321 (Ex. 1045)

Cribier '321 is a U.S. patent that issued on Sep. 8, 2009. Ex. 1010, codes (10), (12), (45). Thus, on its face, Cribier '321 qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Cribier '321 is directed to a prosthetic heart valve with a structure composed of “physiologically compatible valvular tissue” that “forms a continuous surface and is provided with strut members that create stiffened zones which induce the valvular structure to follow a patterned movement in its expansion to its opened state and in its turning back to its closed state.”

Id., Abstract.

Figure 5a of Cribier '321 is reproduced below:



Id., Fig. 5a. Illustrated above is an implantable valve (“IV”) 13 in its expanded position with a frame comprised of “intercrossing linear bars 11,” “a soft and mobile tissue constituting the valvular structure 14[, wherein] the tissue is fastened to the bars 11 of the frame at its base 16,” and an “internal cover 19” that is “fixed on the internal wall of the frame 10” and “prevents any passage of blood through the spaces between the bars 11 of the frame.” *Id.* at 8:46–48, 10:66–7:1; 11:13–16, 12:28–32; *see also id.*, Figs. 4a (illustrating embodiment in compressed position).

“The frame is preferably a metallic frame, preferably made of steel. It constitutes a frame with a grate type design able to support the valvular structure and to behave as a strong scaffold for the open stenosed aortic orifice.” *Id.* at 9:27–30. The valvular tissue may be made of “synthetic biocompatible material such as TEFLON® or DACRON®, polyethylene, polyamide,” and the internal cover “is preferably made with the same tissue as the valvular structure.” *Id.* at 5:15–17, 13:13–16. The internal cover may be secured to the “upper and lower extremities of the frame 10 on the upper and lower zig-zag lines of the intercrossing bars 11” by “sewing” the internal cover onto the bars of the frame. *Id.* at 13:54–56, 14:22–26, 14:31–35, 14:45–47. Additionally, the internal cover may be “extended at its lower end 19’ to an external cover 19[’] which is rolled up to be applied on the external wall of the stent 10.” *Id.* at 13:28–30, Fig. 6d.

Cribier ’321 discloses:

Since it is aimed at being positioned in the heart after having been introduced by a catheterization technique by a transcutaneous route in a peripheral artery, mainly the femoral artery, the IV should preferably have the smallest possible external diameter. Ideally, it should be able to be introduced in the femoral artery through a 14 F (4.5 mm) size arterial introducer which is the size of the arterial introducer commonly

used to perform an aortic dilatation. However, a 16 F (5.1 mm) or even a 18 F (5.7 mm) introducer would also be acceptable. *Id.* at 14:56–65. “Above this size, the introduction of the IV in the femoral artery should probably be done by a surgical technique.” *Id.* at 14:66–67; *see also id.* at 9:19–22 (“When folded by compression, the diameter of said frame is about 4 to 5 millimeters, in view of its transcutaneous introduction in the femoral artery through an arterial sheath of 14 to 16 F.”).

2. Overview of Walther (*Ex. 1007*)

Walther is a journal article that bears a copyright date of 2011. *Ex. 1007, 1120*. Petitioner argues that Walther was published online on April 3, 2011, and qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). *Pet. 21*. Patent Owner argues that Petitioner has failed to demonstrate that Walther is available as prior art. *Prelim. Resp. 77–80*.

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,” and

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

Figure 1 of Walther is reproduced below:

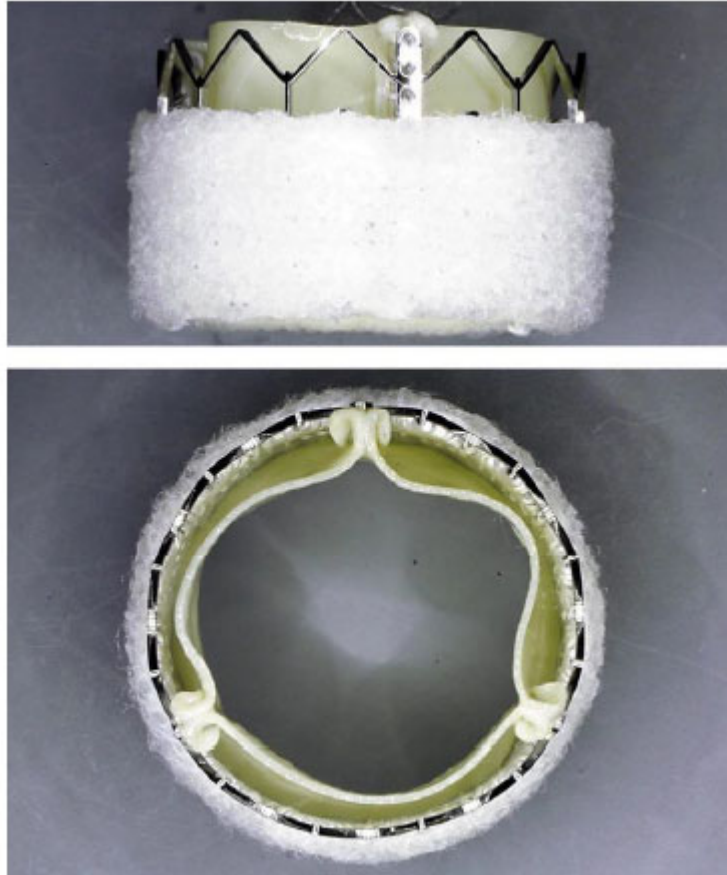


Fig. 1. Cloth valve.

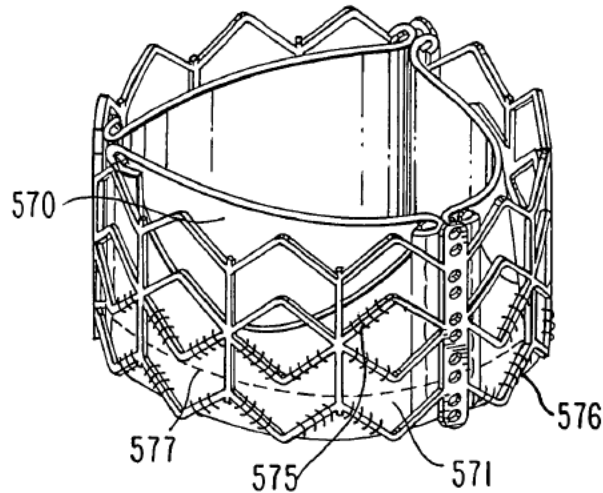
Shown above are two photographs (side view and top-down view) of the SAPIEN THV with a cloth encircling the lower two thirds of the valve. *Id.* at Fig. 1, 1121. Walther describes deploying the SAPIEN valves inside “various CEP valves” via the 33F Ascendra system. *Id.* at 1121.

3. Overview of Spenser (Ex. 1010)

Spenser is a U.S. patent that issued on Mar. 31, 2009. Ex. 1010, codes (10), (12), (45). Thus, on its face, Spenser qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Spenser is directed to an implantable prosthetic valve for cardiac implantation. Ex. 1010, 1:13–15. Figure 44a of Spenser is reproduced below:

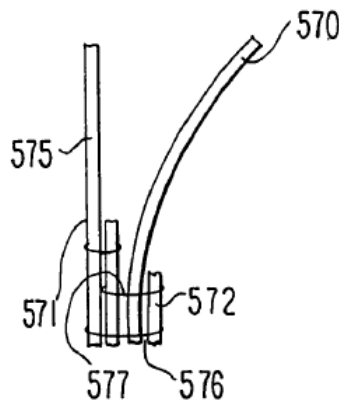
FIG. 44a



Spenser's Figure 44a illustrates an isometric view of an implantable prosthetic valve with additional pieces of PET used for sealing and protecting the pericardium. *Id.* at 11:32–35. Specifically, Figure 44a illustrates an implantable valve with three pericardial leaflets 570, located within a gridded circular frame 575. *Id.* at 26:30–37.

Figure 44b of Spenser is reproduced below:

FIG. 44b



Spenser's Figure 44b illustrates a view of an implantable prosthetic valve including a pre-shaped PET tube and leaflet-tube attachments. *Id.* at 11:36–40. Figure 44b illustrates four layers from left to right, including frame 575, PET layer 571, valve leaflet 570, and PET 572. *See id.* at Fig. 44b, 26:40–42. Spenser discloses that

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

Id. at 26:40–48.

4. *Overview of Spenser II (Ex. 1011)*

Spenser II is a PCT Publication that published on Jan. 12, 2006. Ex. 1011, codes (10), (43). Thus, on its face, Spenser II 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:

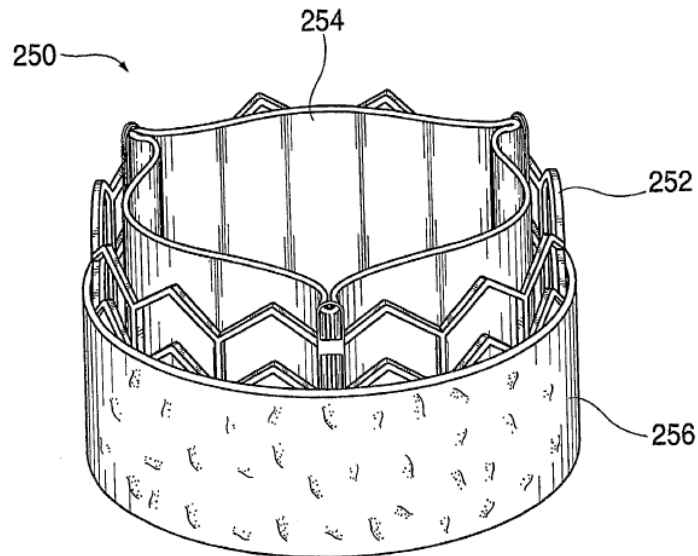


FIG. 22

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 a stented valve 250 including a circular stent structure 252 surrounding a valvular structure 254. *Id.* at Fig. 22, ¶ 144. “[S]tent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.” *Id.* ¶ 145. 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

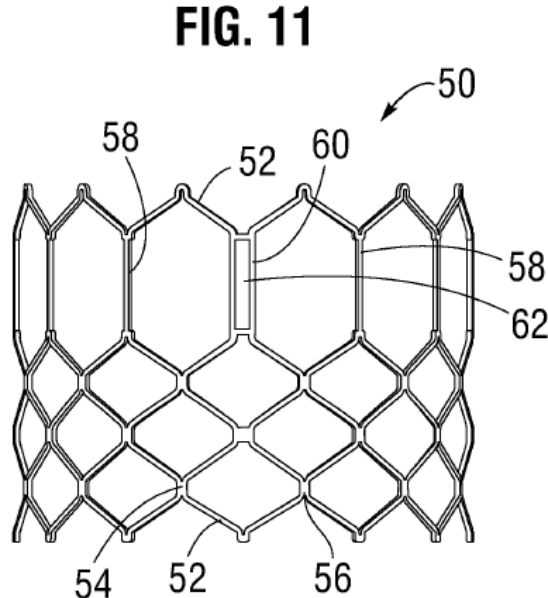
“creates a mechanical seal that prevents paravalvular leakage.” *Id.* “In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.” *Id.*

5. *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, 1:16–18.

Figure 11 of Levi is reproduced below:

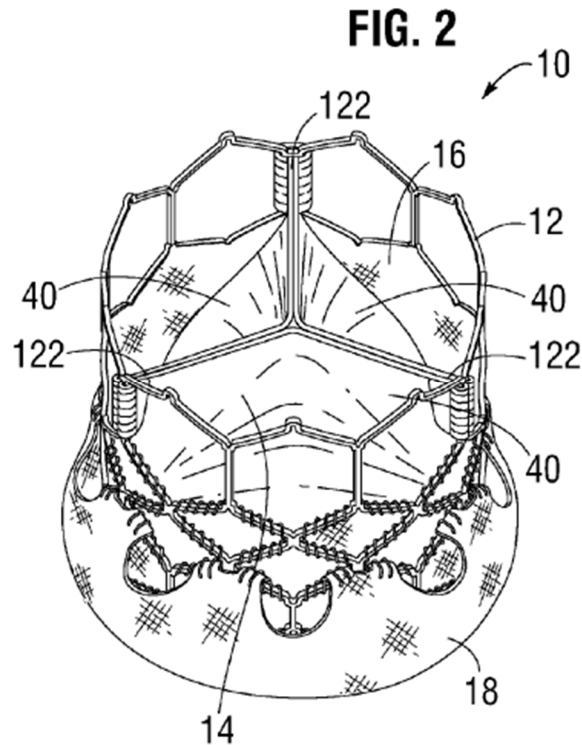


Illustrated above is a frame for use in a prosthetic heart valve. *Id.* at Fig. 11, 4:61–62. Specifically, Figure 11 illustrates frame 50 that

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 8:61–9:3.

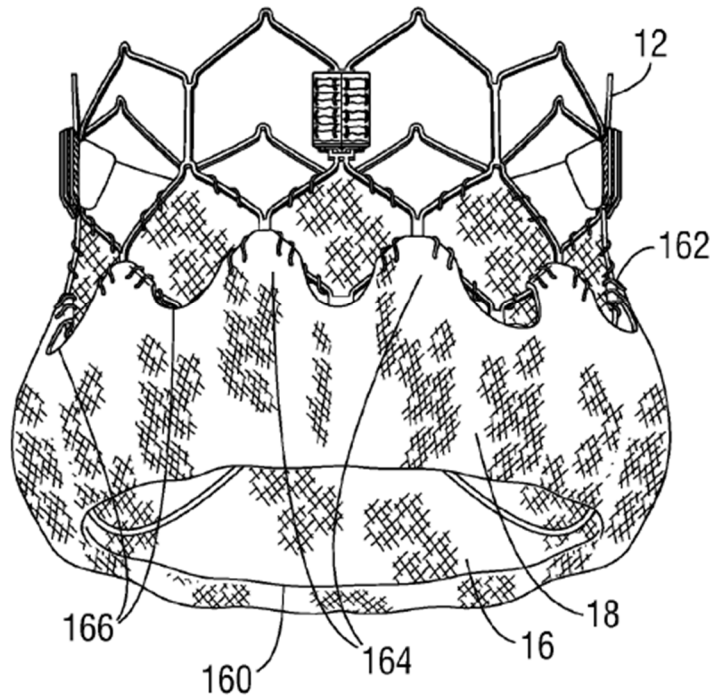
Figure 2 of Levi is reproduced below:



Illustrated above is prosthetic heart valve 10 including valvular structure 16, surrounded by circular stent or frame 12. *Id.* at Fig. 2, 5:52–58. 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, 5:52–58, 9:24–25, 13:49–50. 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, 5:59–61. “[L]eaflets 40 are secured to one another at their adjacent sides to form commissures 122 of the leaflet structures.” *Id.* at 11:35–37.

Figure 20 of Levi is reproduced below:

FIG. 42



Illustrated above is a valve that includes outer skirt 18 with projections 164 that are sutured to the outer side of frame 12. *Id.* at Fig. 42, 13:54–61. 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, 13:62–66. 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 14:4–9.

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

Patent Owner argues that we should 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. 60–78. Petitioner argues that the Board should not deny institution under 35 U.S.C. § 325(d). Pet. 112–113. We address the parties’ arguments below.

1. Legal Framework

Pursuant to 35 U.S.C. § 325(d), in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” The Board evaluates two issues in addressing 35 U.S.C. § 325(d):

- (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 [the] 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.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”). With respect to the first issue, previously “presented” art includes, among other things, “art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.* at 7–8. With respect to the second issue, institution generally will be denied if a “petitioner fails to make a showing of material error,” and “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at 8–9.

“[T]his framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

The Board also considers the following non-exclusive factors when exercising discretion under § 325(d):

(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 & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

2. *Was the Same or Substantially the Same Art or Arguments Presented to the Office?*

It is undisputed that Levi and Spenser II were cited to the Examiner during prosecution. *See* Pet. 112–113; Prelim. Resp. 61 (citing Ex. 1002, 117–118, 212). Accordingly, Levi and Spenser II are deemed to have been previously presented to the Office. *See Advanced Bionics*, Paper 6, at 7–8. Petitioner contends, however, that “Cribier, Walther, and Spenser were not cited during prosecution of the ’011 patent.” Pet. 112.

In response, Patent Owner contends that “[t]he portions of Cribier ’321, Walther, and Spenser relied upon by Petitioner are . . . substantially

similar to the very portions of Levi and Spenser II specifically brought to the Examiners' attention." Prelim. Resp. 69. Specifically, Patent Owner argues that "each of Levi, Cribier '321, Walther, and Spenser are related to SAPIEN valves." *Id.* (citing Ex. 2022, 26; Ex. 1007, 1; Ex. 2027, 29; Ex. 2028, 8; Ex. 2029, 8, 29). Patent Owner further argues that: 1) "Levi's outer frame is substantially similar to Cribier '321's and Spenser's alleged outer frames"; 2) "Levi's inner skirt 16 (the alleged 'inner frame') is similar to Cribier '321's (internal cover 19) and Spenser's (PET layer 571) alleged inner frames"; 3) "Levi's sutures 70 (the alleged 'stitches') are essentially identical to Spenser's stitches" and "Cribier '321 likewise discloses that the valvular structure (which includes internal cover 19) can be fastened to the bars by sewing"; and 4) "Spenser II's compressible material 256 (the alleged 'sealing material') is essentially identical to Walther's outer cloth in both the configuration and the material." *Id.* at 72–75.

We agree with Patent Owner that at least some portions of the Cribier '321, Walther, and Spenser references are substantially similar to the Levi and Spenser II references considered by the Examiner insofar as each of these references disclose the basic structure of the Edwards SAPIEN valve. We also agree that Walther discloses the use of an outer cloth over the SAPIEN valve to reduce paravalvular leaks in a manner that is substantially similar to Spenser II's disclosures regarding the Figure 22 embodiment that includes a layer of compressible material. As such, we find that the prior art relied upon in the Petition is the same or substantially the same as the prior art that was before the Examiner.

Nonetheless, insofar as the remaining challenged claims of the '011 patent specifically require the heart valve to be delivered "endovascularly," we are not persuaded that the Examiner considered the prior art teachings

and arguments presented in the Petition as to why the prior art valves disclosed in these references are sized or could otherwise be modified, if needed, to satisfy that particular requirement. *See, e.g.*, Pet. 60–64. We address the Examiner’s consideration of the prior art under the second part of the *Advanced Bionics* framework.

3. *Did the Office Err in a Manner Material to the Patentability of Challenged Claims?*

In view of our determination that at least some of the prior art relied upon in the Petition is the same or substantially the same as what was previously presented to the Office, we turn to the second part of the *Advanced Bionics* framework, which requires an assessment of whether Petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Petitioner contends that “[t]he Examiner never addressed the combination of Spenser II with Spenser or Levi. Consequently, Patent Owner’s statements should not form a basis to deny institution under §325(d).” Pet. 112. Petitioner further points out that the basis upon which Patent Owner distinguished Spenser II and Levi, i.e., that “the seal was made below the native leaflets in the patient, but not against the leaflets,” is not a requirement in most of the challenged claims. *Id.* at 112–113.

Patent Owner contends “Petitioner does not explain how an allegedly incorrect statement [made by the applicant during prosecution] could have caused a ‘material error’ where the Examiners had already considered the art and issued a notice of allowance prior to the alleged misstatement.” Prelim. Resp. 68. Patent owner also argues “Because Petitioner notes that Cribier ’321, Walther, and Spenser were not cited during prosecution (Pet., 112) but does not address whether those references are ‘substantially similar’ to Levi

and Spenser II, Petitioner does not even attempt to show any ‘material error’ on the Examiner’s part as to Grounds 1–4, 7, and 9–14.” *Id.* at 78.

Having considered the arguments of record, we find that the Examiner materially erred during prosecution by failing to fully consider the prior art teachings regarding the claim requirement for a “sealing material.” Indeed, although Spenser II and Levi were presented to the Examiner, the Examiner did not issue *any* rejections during prosecution based on that prior art despite teachings that are closely related to the subject matter and claims of the ’011 patent. For example, we find that the Examiner erred by failing to address why Spenser II’s Figure 22 embodiment did not suggest the claimed “sealing material.” *See, e.g.*, Ex. 1011 ¶ 145, Fig. 22 (Spenser II’s Figure 22 embodiment showing an outer layer of compressible material made of fabric or cloth that can reduce paravalvular leakage). We also find that the Examiner erred by failing to address whether the prior art taught or suggested the requirement that the valves be delivered endovascularly as recited in challenged claims 7 and 12. *See, e.g.*, Ex. 1008, 2:1–5 (Levi discussing that the diameter of the crimped profile of the heart valve is an important design parameter to allow for transfemoral delivery).

In view of this material error by the Examiner, we decline to deny institution under 35 U.S.C. § 325(d).

E. Prior Art Status of Walther

Before we turn to the merits of Petitioner’s unpatentability grounds, we first address Patent Owner’s argument that Petitioner has failed to demonstrate that the Walther reference was publicly accessible. Prelim. Resp. 79–82. Patent Owner argues that, under Board precedent, “*the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible* before the

critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Id.* at 79 (citing *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, 13 (PTAB Dec. 20, 2019) (precedential) (“*Hulu*”). Patent Owner contends that “Petitioner provides no librarian declaration or other supporting evidence, and no explanation for its conclusory assertion” that the Walther reference was “published” as of a particular date. *Id.* at 79–80. Although recognizing that the first page in Walther states “[a]vailable online 3 April 2011,” Patent Owner argues that “nothing in the document lists the URL of where Walther was allegedly available online, or provides any indication that Walther was available ‘to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.’” *Id.* at 80 (citing *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008)).

In its Preliminary Reply, Petitioner contends that the evidence presented in the Petition establishes that Walther qualifies as prior art. Petitioner points out that the reference itself bears sufficient indicia of publication, including the fact that it is a medical journal article published in the European Journal of Cardio-thoracic Surgery (“EJCS”), and states on its face that it was available online as of April 3, 2011. Prelim. Reply 1 (citing Ex. 1007, 1120). Additionally, Petitioner notes that “Walther states that it was accepted for publication by the EJCS on February 21, 2011” and that that the article’s contents were “[p]resented at the 24th annual meeting of the European Association for Cardio-thoracic Surgery, Geneva Switzerland, September 11–15, 2010.” *Id.* was published in volume 34 of the journal *Herz* in 2009. *Id.* at 1–2. Petitioner also submits a declaration by Dr. Sylvia Hall-Ellis, who points to additional evidence supporting publication of both

references, including Machine-Readable Cataloging (“MARC”) records, archived webpages from the “Wayback Machine,” and a later publication citing to Walther. *Id.* at 3 (citing Exs. 1059–1070).

Patent Owner, in its Preliminary Sur-Reply, argues that publication evidence relied upon by Petitioner in its Reply was not “identified, with particularity *in the Petition*.” Prelim. Sur-Reply 1. Patent Owner also argues that Petitioner improperly shifts the burden to Patent Owner. *Id.* at 2.

Based on the present record, we find that Petitioner has satisfied the threshold standard set forth in *Hulu* to identify, with particularity, evidence sufficient to establish a reasonable likelihood that the Walther reference was publicly accessible before the priority date of the ’011 patent. As noted by Petitioner, Walther is an article published in a known journal with dates and other indicia of publication on the face of the reference itself. The *Hulu* decision specifically notes that “the indicia on the face of a reference, such as printed dated and stamps, are considered part of the totality of the evidence” that should be taken into account. *Hulu*, 17–18; *see also id.* at 19 (noting that “the face of Dougherty bears a copyright date of 1990, a printing date of November 1992, and an ISBN date of 8/94” and the fact that the book was from “an established publisher”). We also take into account that journal articles, unlike perhaps other disputed publications, are “the type[s] of document[s] intended for public dissemination,” and that the Walther reference “bears no designations, such as ‘draft’ or ‘confidential,’ that might suggest that it was not intended for public distribution.” *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1377 (Fed. Cir. 2018). Additionally, we have considered the declaration of Dr. Hall-Ellis and the

supporting evidence cited therein as further evidence of public accessibility.⁹ We find that it was appropriate for Petitioner to submit this evidence with its Preliminary Reply. Indeed, the *Hulu* case recognizes that a petitioner may provide additional evidence “in a reply to a patent owner preliminary response,” and “if the patent owner challenges a reference’s status as a printed publication, a petitioner may submit a supporting declaration with its reply to further support its argument that a reference qualifies as a printed publication.” *Hulu* at 14–15. Here, we determined that Petitioner satisfied the good cause requirement of 37 C.F.R. § 42.108(c) for submitting its Preliminary Reply with the Hall-Ellis declaration and other supporting evidence in order to respond to Patent Owner’s challenge to the printed publication status of Walther. *See* Ex. 1071, 13:23–14:4 (Transcript of teleconference call from February 14, 2022).

Accordingly, in view of the totality of the evidence currently in the record, we find that Petitioner has established a reasonable likelihood that both the Walther reference is a printed publication that was publicly accessible before the priority date of the ’011 patent.

F. Analysis of Grounds 5–14: Anticipation or Obviousness Based on Levi

In Ground 5, as presented in the Petition, Petitioner asserts that claims 7 and 12 were anticipated by the teachings of Levi. Pet. 80–103. Alternatively, in Grounds 6–14, Petitioner asserts that the same claims would have been obvious over the teachings of Levi alone, or with various

⁹ Contrary to Patent Owner’s arguments, we are not of the view that a librarian declaration is always necessary to show public accessibility of a journal article, especially where the article itself bears credible indicia of publication.

combinations of Walther, Spenser II, Cribier '321, and/or Spenser. *Id.* As our analysis with regard to the Levi-based grounds will be relevant to Petitioner's other obviousness challenges, we address those grounds first.

The challenged claims require a "heart valve assembly" with the following common structural requirements:

- 1) "an outer frame . . . formed from a metallic material [that] defines an open-cell configuration" (i.e., the "outer frame" requirement) (Ex. 1001, 21:6–7, 22:14–16);
- 2) "an inner frame [that is or includes] a cylindrically extending 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" (i.e., the "inner frame" requirement) (*id.* at 21:9–14, 22:17–23)¹⁰,
- 3) "wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame" (i.e., the "stitching" requirement) (*id.* at 21:15–17, 22:24–26);
- 4) "wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame" (i.e., the "graft extension" requirement) (*id.* at 21:18–20, 22:27–29);
- 5) "a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to treat paravalvular leaks, wherein the sealing

¹⁰ Claim 12 additionally specifies that the inner frame "ha[s] prosthetic leaflets." *Id.* at 22:18.

material includes a plurality of radially extending fibers that form a circumferential surface that extends outwardly of the outer frame” (i.e., the “sealing material” requirement) (*id.* at 21:21–26, 22:30–35); and

- 6) “wherein the fibers cover at least two circumferentially extending rows of grids formed in the open cell configuration” (i.e., the “fiber coverage” requirement) (*id.* at 21:27–29, 22:36–38).¹¹

In addition to the foregoing structural requirements, the claims require that this valve assembly is delivered “endovascularly” and is “balloon-expandable.” *Id.* at 21:30, 21:42–43, 22:12, 22:40–40–41.¹²

Petitioner relies primarily upon Levi as teaching or otherwise suggesting most of these limitations, but also relies upon Spenser and Cribier ’321 as further suggesting the claimed graft extension requirement and relies upon Walther and Spenser II as further suggesting the claimed sealing material requirement. Given the mostly similar claim requirements, we treat claims 7 and 12 together for purposes of our analysis, but address any differences as needed below. We address the grounds relying upon Levi alone first before turning to Petitioner’s reliance on Walther and Spenser II in combination with Levi.

¹¹ Claim 12 additionally requires that “the at least two circumferentially extending rows radially overlap with the prosthetic leaflets.” *Id.* at 22:38–39.

¹² Claim 12 additionally requires that the “expansion of the valve assembly presses the sealing material against native valve leaflets of the patient.” *Id.* at 22:42–44.

*1. Whether Levi Alone Anticipates or Renders Obvious
Claims 7 and 12 (Grounds 5 and 6)*

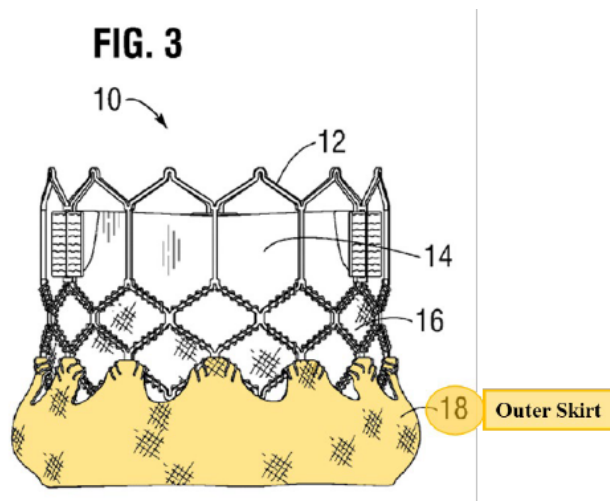
Petitioner contends that Levi discloses a heart valve assembly having a metal frame that defines an open cell structure, i.e., the claimed outer frame requirement. Pet. 80–81 (citing Ex. 1008, 6:17–24, Fig. 11; Ex. 1003 ¶ 275). Petitioner further contends that Levi discloses an “inner skirt,” constructed of a tough material such as polyethylene terephthalate (PET), that extends around a prosthetic valve and is secured to the frame by stitches, i.e., the claimed inner frame and stitching requirements. *Id.* at 81–83 (citing Ex. 1008, 9:7–11, 9:11–16, 9:24–29, 10:11–30, Figs. 2, 20, 39; Ex. 1003 ¶¶ 277–278). Petitioner contends that “if an inner frame can be a graft covering, Levi’s inner skirt is an inner frame that is a graft covering.” *Id.* at 82.

Petitioner also contends that Levi discloses the claimed graft extension requirement, or at least renders that limitation obvious,¹³ based on its teaching that “the lower edge 160 of the skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.” *Id.* at 84–86 (citing Ex. 1008, 13:55–58, Figs. 20 and 42; Ex. 1003 ¶ 282). According to Petitioner, “[b]ecause the inner skirt extends beyond the proximal end of the

¹³ Petitioner also contends that if Levi does not disclose the claimed graft extension requirement, Spenser and Cribier ’321 do, and POSITAs would have found it obvious to apply Spenser’s or Cribier ’321’s teaching to Levi’s inner skirt. Pet. 86–88 (citing Ex., 14:6–9, Fig. 2; Ex. 1045, Fig. 6d; Ex. 1003 ¶¶ 356–358). Because Patent Owner does not present any separate arguments as to whether this combination satisfies the graft extension requirement, and in view of our determination below that Petitioner has sufficiently shown that Levi alone teaches this requirement, we do not address at this stage Petitioner’s arguments relying upon Spenser and Cribier ’321 for this requirement.

outer frame, the attachment of the skirt necessarily causes the lower edge of the inner skirt 16 to extend over and cover the proximal end of the outer frame,” and “[t]his is particularly true when the outer skirt bulges outwardly from blood and pulls the proximal portion of the inner skirt over the distal end of the frame.” *Id.* at 85 (citing Ex. 1003 ¶ 282).

Petitioner further contends that Levi discloses the claimed sealing material requirement, or at least renders that limitation obvious, based on its disclosure of an “outer skirt” of a woven PET fabric secured to the exterior surface of the frame in Figure 3, as reproduced below:

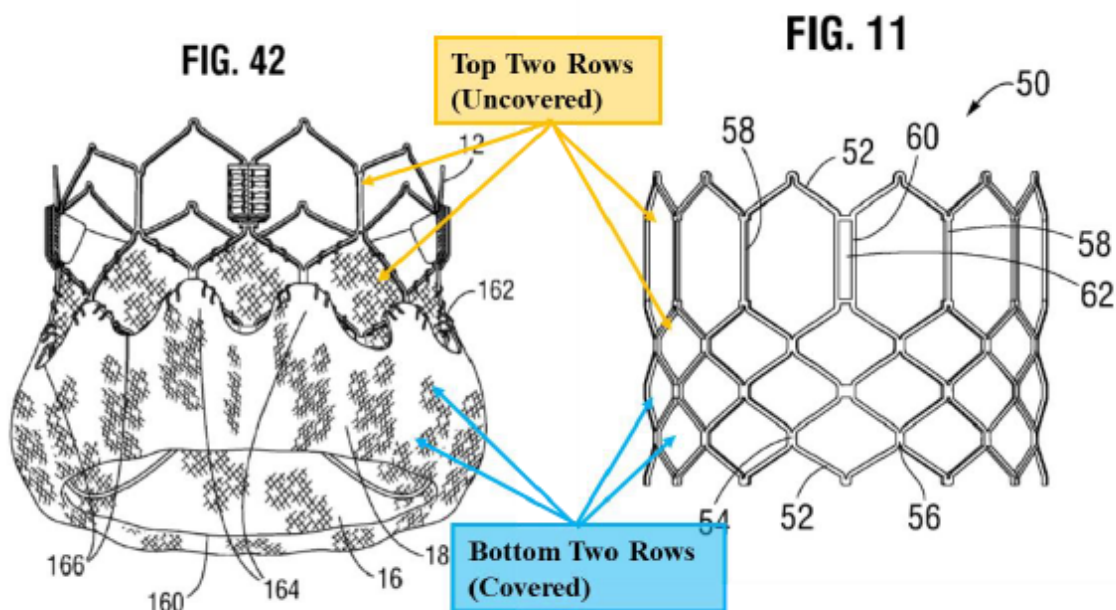


Shown above is a prosthetic heart valve with Petitioner’s annotations highlighting outer skirt 18 surrounding an outer portion of frame 12. *Id.* at 89–90 (citing Ex. 1008, 9:52–56, 13:50–53, 13:62–14:7, Fig. 3; Ex. 1003 ¶¶ 286–287). Petitioner argues Levi discloses that the outer skirt fills “gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” *Id.* at 89 (citing Ex. 1008, 14:3–7).

Petitioner further contends that Levi’s outer skirt meets the requirement for a sealing material with radially extending fibers that extend outwardly of the outer frame because Levi discloses that the outer skirt

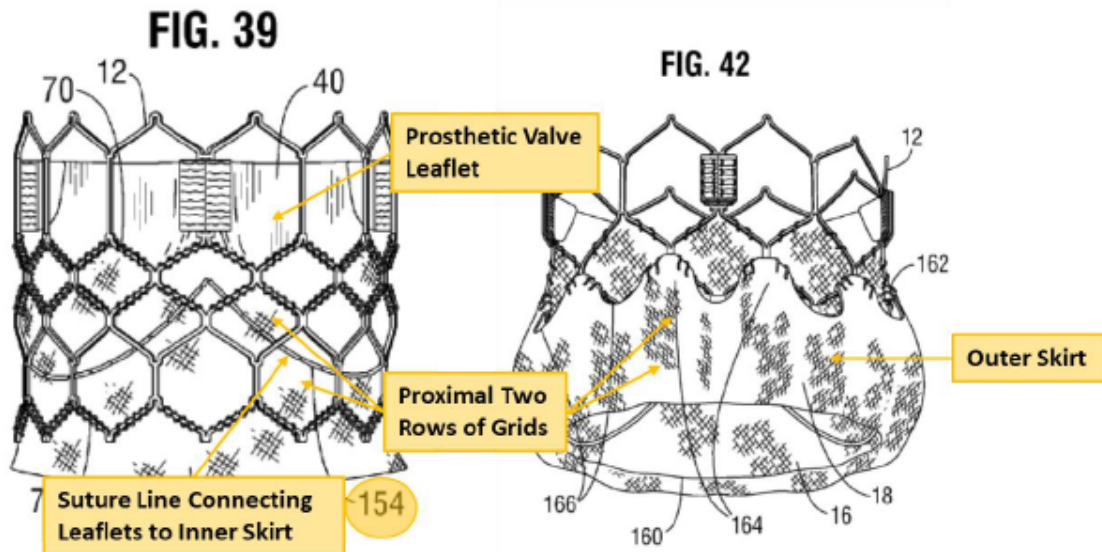
“bulge[s] outwardly” from the outer frame. *Id.* at 90 (citing Ex. 1003 ¶ 286). Petitioner also contends that a “POSITAs would have understood that the outer surface of the woven PET fabric would not be entirely smooth, but would necessarily have fibers, or strands, that extend radially outwardly from the surface of the fabric,” because PET yarn was known to exhibit some level of “hairiness.” *Id.* at 90–91 (citing Ex. 1028, 124; Ex. 1029, 32; Ex. 1003 ¶ 287).

Petitioner contends that Levi discloses the claimed fiber coverage requirement based on the following side-by-side comparison of Figures 11 and 42 of Levi:



The above figures show an embodiment of Levi’s device with outer skirt 18 (Fig. 42 on the left) and Levi’s frame 50 without any outer skirt (Fig. 11 on the right) with Petitioner’s annotations showing the top two rows being uncovered and the bottom two rows being covered. *Id.* at 95 (citing Ex. 1008, Fig. 42, Fig. 11, Fig. 22; Ex. 1003 ¶ 296).

With regard to claim 12's additional requirement that "the at least two circumferentially extending rows radially overlap with the prosthetic leaflets," Petitioner points to the following comparison of Levi's Figures 39 and 42:



Petitioner also contends that Levi's device is balloon expandable based on its disclosure that "the frame 12 (and thus the valve 10) can be . . . expanded inside a patient by an inflatable balloon." *Id.* at 96 (citing Ex. 1008, 6:17–28; Ex. 1003 ¶ 298).

Finally, with regard to the requirement for endovascular delivery, Petitioner contends that Levi discloses "collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent." *Id.* at 96 (citing Ex. 1008, 1:57–67, 6:46–49; Ex. 1003 ¶ 315). Petitioner contends "Levi discloses several features to enable such endovascular delivery," including the use of a nickel-cobalt-chromium-molybdenum alloy that "allows for less material to

be used so that ‘the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body.’” *Id.* (citing Ex. 1008, 6:46–49, 7:10–12). Petitioner further contends that Levi discloses minimizing the diameter of the valve to contain the valve assembly within a smaller diameter catheter to be passed through smaller vessels in the body, and that a POSITA would have expected success in delivering Levi’s valve endovascularly. *Id.* at 102 (citing Ex. 1008, 14:60–64, 16:24–17:18; Ex. 1003 ¶ 319).

In response, Patent Owner contends that Levi does not disclose or teach a sealing material with “radially extending fibers.” *See* Prelim. Resp. 42–57. Specifically, Patent Owner argues that Levi “has no discussion of fibers that ‘radially extend’ or ‘extend outwardly’ from its ‘outer skirt.’” *Id.* at 45. Instead, Patent Owner argues that “Levi’s description of its ‘laser cut’ ‘outer skirt’ confirms the absence of any such fibers.” *Id.* (citing Ex. 1008, 13:50–54). Patent Owner argues that Levi’s outer skirt and claimed sealing material are visually distinguishable based on a comparison of Figure 3 of Levi and Figure 9 of the ’172 patent. *Id.* (citing Ex. 2002 ¶ 74).

Patent Owner further contends that Petitioner fails to show that Levi inherently discloses radially extending fibers. *Id.* at 46. First, Patent Owner argues that Levi’s disclosed bulging outer skirt does not mention radially extending fibers. *Id.* at 47 (citing Ex. 1008, 13:62–14:2). For example, Patent Owner argues that “neither Petitioner nor its expert proffer any explanation of why this ‘bulging’ would cause any fibers to extend radially particularly as no such radially extending fibers are mentioned or are apparent from Levi’s figures.” *Id.* (citing Ex. 1008, Fig. 3).

Second, Patent Owner argues that “[i]t is widely recognized in the field that woven PET,” such as that disclosed by Levi for the outer skirt, “is

smooth with no ‘hairiness’ or radially extending fibers.” *Id.* at 49. Patent Owner submits Meslmani¹⁴ as evidence that woven PET utilized for cardiovascular applications includes tightly wound fibers with a smooth surface. *Id.* (citing Ex. 2019, Fig. 1A). Patent Owner contends that similar examples of woven PET utilized in aortic stent grafts are characterized by smooth surfaces with fibers that do not radially extend from the surface. *See id.* at 50–51 (citing Ex. 2020, 23–24; Ex. 2021, Fig. 1.18A). In contrast, Patent Owner contends that Petitioner’s “hairiness” argument relies on a reference directed to yarns suitable for clothing a clothing and knitted goods, not aortic valve repair. *Id.* at 51 (citing Ex. 1028, 5, 11–12, 20, 25, 32, 33). Patent Owner argues that the art discloses various yarns, only one of which is “hairy,” and that “‘hairiness’ is a ‘desirable property in certain circumstances’ such as textiles used for ‘thermal insulation’ and ‘undesirable in other circumstances, depending upon the type of end-use and application of the resultant fabric.’” *Id.* at 54 (citing Ex. 1028, 10).

Additionally, Patent Owner argues that “Levi is one of the patents covering [Petitioner’s] SAPIEN 3” product, and SAPIEN 3 is characterized by a “flat woven” outer skirt. *Id.* at 55 (citing Ex. 2022, 26; Ex. 2023, 97, 220; Ex. 2024, 131, 260; Ex. 2025, 143). Patent Owner contends that the SAPIEN 3 outer skirt, corresponding to Levi’s “woven PET” outer skirt, “is not hairy.” *Id.* at 55–57 (citing Ex. 2026, 3, 8; Ex. 1028; Ex. 2002 ¶ 76).

Furthermore, with regard to all the grounds set forth in the Petition, Patent Owner argues generally that

¹⁴ B. A. Al Meslmani, *Development of thrombus-resistant and cell compatible crimped polyethylene terephthalate cardiovascular grafts using surface co-immobilized heparin and collagen*, 43 MATS. SCI. ENG. C 538–546 (2014) (Ex. 2019).

Petitioner never contends that any of the asserted references teach an “inner frame [that] *is* a graft covering.” Instead, Petitioner qualifies its arguments with a hypothetical, stating that “*if* an ‘inner frame’ can be a graft covering”—implicitly alluding to its prior statement that a “inner frame cannot be a graft covering”—then the reference teaches this limitation.

Id. at 58–59 (citing Pet. 31, 32, 82). Patent Owner further argues that “Petitioner nor its expert provide *any* evidence or explanation as to *why* any of the alleged graft coverings it identifies are an ‘inner frame.’” *Id.* at 59 (citing Ex. 1003 ¶¶ 102, 206, 277).

Based on the present record, we find that Petitioner has demonstrated sufficiently that Levi teaches all the claim requirements *except* for the requirement of a sealing material with radially extending fibers. In particular, we agree with Petitioner that Levi discloses a heart valve with a metallic frame 12 that meets the claimed outer frame requirement, a polymeric inner skirt 16 that meets the claimed inner frame requirement, and sutures 70 that meet the claimed stitching requirement. *See, e.g.*, Ex. 1008, 6:12–8:7; 9:7–35. We also agree with Petitioner that Levi discloses the claimed graft extension requirement based on its disclosure that the inner skirt 16 extends beyond the proximal end of the frame, as shown in Fig. 20. *Id.*, Fig. 20, 12:55–58. Additionally, we agree with Petitioner that Levi teaches the outer skirt covers at least two rows of the gridded configuration based on a comparison of Figures 11 and 42 of Levi. *Id.*, Fig. 42, Fig. 11.

We disagree with Patent Owner’s insinuation that Petitioner has not met its burden merely because it seeks to preserve arguments that a graft covering cannot be an “inner frame.” Pet. 31 n. 5. Notwithstanding Petitioner’s qualification “if an inner frame can be a graft covering” (*id.* at 82), the claims plainly equate the claimed inner frame with a graft covering,

and Petitioner has pointed to Levi's inner skirt that Patent Owner does not otherwise dispute satisfies the claim requirements for both a graft covering and inner frame. It is also undisputed that Levi teaches that the device is delivered endovascularly, i.e., percutaneously. Ex. 1008, 1:57–67, 6:46–49.

We do not, however, find persuasive Petitioner's contention that Levi's disclosure of an outer skirt made of a woven PET fabric that “bulge[s] outwardly” from the frame meets the requirements of a sealing material with radially extending fibers. We understand the requirement for “radially 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 in the figures of the '172 patent.¹⁵ See Ex. 1001, Figs. 8, 9, 11–14, 20. 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. Ex. 1028, 10. In this regard, we take into account the evidence cited by Patent Owner showing that the type of woven PET fibers utilized for cardiovascular applications are tightly wound and do not radially extend from the surface. Prelim. Resp. 49–51 (citing Ex. 2019, Fig. 1A; Ex. 2020, Fig. 8; Ex. 2021, Fig. 1.18A).

Based on the present record, we do not find that Levi alone teaches, or otherwise provides a motivation to incorporate, a sealing material with

¹⁵ To the extent this is a disputed issue, the parties are encouraged to address the proper construction of “radially extending” in their post-institution briefing.

radially extending fibers. Accordingly, we are not persuaded that Petitioner is likely to prevail with regard to Grounds 5 and 6.

2. *Whether Levi in Combination with Walther or Spenser II Renders Obvious Claims 7 and 12 (Grounds 7 and 8)*

We now turn to Petitioner’s alternative contentions that a POSITA would have found it obvious to replace Levi’s outer skirt with either Walther’s outer cloth or Spenser II’s compressible material to satisfy the claimed sealing material requirement. Pet. 92–94.

Petitioner contends that “POSITAs would have been motivated to use Walther’s outer cloth because the cloth prevents paravalvular leakage and promotes tissue ingrowth.” *Id.* at 92 (citing Ex. 1007, 1120; Ex. 1003 ¶ 289). Petitioner also contends that a “POSITAs would have been to use Spenser II’s compressible material because its radially extending fibers reduce or prevent paravalvular leakage and ‘may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.’” *Id.* (citing Ex. 1001 ¶ 145; Ex. 1003 ¶ 289). With respect to both these grounds, Petitioner contends that modifying Levi with Walther or Spenser II “would merely entail substitution of one known element,” i.e., Walther’s outer cloth or Spenser II’s compressible material, “for another (Levi’s outer skirt) to yield the predictable results of reducing paravalvular leakage” and there would have been a reasonable expectation of success in making these substitutions. *Id.* at 92–93 (citing Ex. 1003 ¶¶ 290–293).

Petitioner contends that “POSITAs would have understood that after replacing Levi’s outer skirt with Walther’s outer cloth or Spenser II’s compressible material, the resulting device would remain suitable for endovascular delivery” through, for example, the common iliac artery. *Id.* at 102–103 (citing Ex. 1003 ¶ 320). To facilitate such endovascular delivery,

Petitioner contends that Levi teaches crimping frame 12 to form a reduced diameter region corresponding to the area covered by outer skirt 18 so that the outer skirt “does not increase the overall crimp profile of the valve.” *Id.* at 103 (citing Ex. 1008, 8:46–54; 2:22–35, 14:22–35, 16:38–45, 17:14–18).

Petitioner further contends that “Walther’s outer cloth or Spenser II’s compressible material would also cover the reduced diameter region, which would reduce any risk that the outer cloth/compressible material would disadvantageously increase the crimp profile.” *Id.* (citing Ex. 1008, 8:46–54; Ex. 1003 ¶ 321). According to Petitioner, Levi explains that the reduced profile of the inflow portion of the valve “can help offset or minimize the increase in diameter” caused by mounting additional components, such as Walther’s outer cloth or Spenser II’s compressible material. *Id.* at 103 (citing Ex. 1008, 16:41–45; Ex. 1003 ¶¶ 322–323).

Petitioner argues that “if POSITAs wanted to deliver the combined valves through smaller blood vessels, POSITAs would have possessed the skills necessary to adapt the outer sealing material or valve for the particular vessel.” *Id.* at 62 (citing Ex. 1003 ¶¶ 166, 244). First, Petitioner contends that a POSITA could have selected an appropriately dimensioned cloth from a range of available cloths having varying thicknesses and densities. *Id.* Second, Petitioner contends that “by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN,” permitting endovascular delivery of a valve having a greater diameter than SAPIEN alone. *Id.* (citing Ex. 1036, 295–297; Ex. 1037 ¶¶ 5–6). Third, petitioner argues that “by 2012, Petitioner had developed a variety of ways to adapt a heart valve’s outer frame and leaflets to create additional space for an outer cloth.” *Id.* (citing Ex. 1008, 6:31–49, 16:24–17:18).

Petitioner contends that one of ordinary skill would have had a reasonable expectation of success in endovascularly delivering a cloth-covered SAPIEN because “Levi discloses methods to reduce the diameter of the valve frame at the inlet, or to modify the leaflets to reduce the frame size, to create room for a cloth sealing material,” and “POSITAs would have understood they could utilize one or more of these strategies to add Walther’s outer cloth or Spenser II’s compressible material to Levi’s frame if the access vessel required a smaller valve.” *Id.* at 94 (citing Ex. 2008, 16:24–17:18; Ex. 1003 ¶ 294). Petitioner further contends that “Walther discloses that the cloth-covered SAPIEN valves displayed ‘excellent hydrodynamic performance’ and that *in vivo* implantation of the valve ‘is feasible,’ suggesting that other cloth-covered valves would have similar results.” *Id.* at 93 (citing Ex. 1007, 1125; Ex. 1003 ¶ 291). Additionally, Petitioner contends that and other endovascular approaches (e.g., through the common iliac artery) were known to accommodate larger valves. *Id.* at 61 (citing Ex. 1043, 273; Ex. 1003 ¶ 165). In particular, Petitioner cites Kianuma¹⁶ as evidence of a SAPIEN valve being successfully delivered through the common iliac artery, which is a larger artery that can accommodate bigger devices. *Id.*

With regard to all the obviousness grounds relying upon the teachings of Walther or Spenser II for the claimed sealing material, Patent Owner contends that “adding the outer cloth of Walther or Spenser II . . . would make the resultant combination far too large to be ‘delivered endovascularly’ as required.” Prelim. Resp. 5; *see generally id.* at 3–42.

¹⁶ S. Kainuma et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan*, GENERAL THORACIC CARDIOVASCULAR SURGERY 59:273-276 (2011) (Ex. 1043).

Patent Owner argues that 8 mm is the maximum size of a catheter for transfemoral endovascular delivery of a valve. *Id.* at 8–9 (citing Ex. 1010, 27:65–67; Ex. 1003 ¶ 167; Ex. 2002 ¶ 37; Ex. 2004, 4). Patent Owner also contends that there would be no motivation to add Walther’s or Spenser II’s outer cloth because the SAPIEN devices were designed to have a narrow profile suitable for transfemoral delivery, and the combination would render the devices inoperable for their intended purpose. *Id.* at 35–42.

With regard to combining Walther’s teachings in particular, Patent Owner argues that “Walther’s thick outer cloth was not designed to be used on an endovascularly delivered device” because “Walther uses an 11 mm (33 French) delivery catheter for its cloth valve.” *Id.* at 10 (citing Ex. 1007, 2, 6). Patent Owner further argues that, rather than endovascular delivery, Walther describes a transapical delivery approach where “tight crimping” of the cloth “is not an issue.” *Id.* at 11 (*citing* Ex. 2002 ¶ 42). According to Patent Owner, “if Walther’s outer cloth were added to a valve assembly (in the expanded state) and that valve assembly were then crimped, the cloth would bunch, adding significantly to the diameter of the crimped delivery profile” as shown in Spenser Figure 26c. *Id.* (citing Ex. 2002 ¶ 43; Ex. 1010, Fig. 26c). Patent Owner argues that similar bunching was shown in Russell¹⁷ which also included an outer cloth attached to a valve assembly and was implanted “using a trans-atrial route (*i.e.*, not endovascular).” *Id.* at 11–16 (citing Ex. 2009, Fig. 4; Ex. 2010; Ex. 1007, Fig. 1; Ex. 2002 ¶ 44). Patent Owner argues that “Petitioner does not account for the bunching that occurs when a cloth covered valve is crimped or even attempt to explain

¹⁷ H. M. Russell et al., *Open Atrial Transcatheter Mitral Valve Replacement in Patients With Mitral Annular Calcification*, J. AM. COLLEGE CARDIOLOGY, Sept. 25, 2018, Vol. 72, No. 13, pp. 1437-1448 (Ex. 2009).

how the valve could remain suitable for endovascular delivery with a bunched outer cloth.” *Id.* at 16. Patent Owner cites another Federal Circuit decision as showing a similar failure concerning the size of a prosthetic heart valve in the exact same field. *Id.* at 17–18 (citing *Snyders Heart Valve LLC v. St. Jude Med., LLC*, 977 F.3d 1232 (Fed. Cir. 2020)).

Likewise, with regard to combining Spenser II’s teachings, Patent Owner contends that “a POSITA would know that Spenser II’s outer cloth would bunch up when the valve is crimped, significantly increasing the delivery profile,” thereby making it unsuitable for endovascular delivery. *Id.* at 18. As further support, Patent Owner cites the testimony of its expert Dr. Brecker, who calculates that Petitioner’s proposed combinations with Spenser II would require 81.68 mm² of outer cloth for a given cross-sectional area when the device is in a fully expanded state, and that this would result in a device with “a diameter of at least 10.96 mm (when the valve is crimped and the cloth uncompressed)—similar to Walther’s 11 mm delivery—over 36% too large for transfemoral delivery.” *Id.* at 19–22 (citing Ex. 2002 ¶¶ 48–52).¹⁸

Patent Owner also disputes Petitioner’s contention that any larger device resulting from the proposed combinations could be endovascularly delivered through the common iliac artery, noting that “Petitioner does not identify the maximum allowable delivery profile for the iliac artery.” *Id.* at 23. In this regard, Patent Owner contends that Petitioner’s citation to Kainuma is irrelevant as it does not mention a cloth-covered valve like

¹⁸ Although Dr. Brecker’s calculations are based on a combination of Spenser II’s outer cloth (assuming a 1 mm thickness) with Spenser’s valve (assuming a 25 mm diameter when fully expanded), he reaches the same conclusion based on a combination of Spenser II with Levi. Ex. 2002 ¶ 52.

Walther's, and that Kainuma "used a 7.3 mm sheath, less than the 8 mm maximum for endovascular transfemoral delivery." *Id.* (citing Ex. 2002 ¶ 54). Moreover, even assuming that any of the Walther combinations could be delivered via the common iliac artery, Patent Owner argues that a POSITA would not have been motivated to do so because the common iliac artery is only accessible through a more invasive vascular surgery associated with numerous complications. *Id.* at 25–27 (citing Ex. 2002 ¶¶ 57–58).

Based on the present record, we determine that Petitioner has made a persuasive showing that a POSITA would have found it obvious to substitute the woven PET outer skirt taught by Levi with a fibrous material, such as the outer cloth taught by Walther or the compressible material taught by Spenser II, to arrive at a heart valve structure that meets the claimed structural requirements. We further determine, on the present record, that Petitioner has persuasively shown that a POSITA would have been motivated to deliver such a modified device endovascularly, either using the transfemoral approach or through the common iliac artery, with a reasonable expectation of success. We find that the modification to Levi's device proposed by Petitioner would entail the "simple substitution of one known element for another" to obtain predictable results. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). In this regard, we note that Walther's outer cloth, Spenser II's compressible material, and Levi's outer skirt all serve similar functions of helping reduce paravalvular leakage for a prosthetic heart valve. Ex. 1007, 1; Ex. 1008, 14:7–9, Ex. 1011 ¶ 145. Walther and Spenser II provide an additional motivation to incorporate fibrous cloth materials as the outer layer insofar as they teach that the fibers may encourage blood coagulation and tissue ingrowth to further fill in the gaps and prevent leakage. *Id.*

We have considered, but are not persuaded by Patent Owner's arguments to the contrary at this stage. In particular, we are not persuaded by Patent Owner's arguments that the resultant combination would necessarily be too large to be delivered endovascularly. We note that Levi itself expressly teaches that its device can be delivered percutaneously (endovascularly) notwithstanding its inclusion of an outer skirt layer with bulging PET fibers, and that this is possible due to the reduced crimped profile of the frame made of a thinner alloy. *Id.* at 6:46–49. Levi also recognizes that “an important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile . . . because this directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein.” Ex. 1008, 2:1–5. There is nothing of record to suggest that the outer cloth of Walter or the compressible material of Spenser II would be significantly thicker than Levi's outer skirt material such that their addition would render Levi's device unsuitable for endovascular delivery. In any event, to the extent that the thickness of the outer layer material could increase the overall diameter and affect the crimped profile of the device, Levi recognizes that other aspects of the devices, including the particular materials selected (such as the use of a thinner metal alloy for the frame), could compensate for such thickness and be among the “design parameters” that a POSITA would account for to ensure endovascular delivery.

We specifically note that Levi expressly teaches that:

The diameter of region **174** is reduced compared to the diameter of the upper portion of the frame (which is not covered by the outer skirt) such that the outer skirt **18** does not increase the overall crimp profile of the valve. In one example, the frame of a 26-mm valve, when crimped, had a diameter D of 14 French

at the outflow end of the valve and a diameter D of 12 French at the inflow end of the valve.

Ex. 1008, col. 8, ll. 51–59. Nietlispach¹⁹ teaches that femoral arterial diameters of 7 mm and 8 mm can accommodate catheter delivery systems of 22 F and 24 F, respectively (Ex. 1036, 1, 3), which, even allowing for the thickness of the sheath wall, a POSITA would understand allows considerable leeway for additional catheter diameter to accommodate the outer cloth of Walther or the compressible material of Spenser II.

We do not find that a POSITA would have been discouraged from the proposed combination in view of Walther’s disclosure that its SAPIEN + cloth THV device was implanted using a transapical approach rather than the claimed endovascular delivery approach. To be sure, in response to a question about “how much the cloth increases the delivery system size,” Dr. Walther responds: “I think it will be an advantage, at least for the transapical approach, where tight crimping is not an issue. You need a slightly larger sheath, but you have a valve that could better seal off against irregular aortic calcifications, even primary aortic valve implantations.” Ex. 1007, 1126. We do not interpret Dr. Walther’s response that the device will be an advantage “at least” for the transapical approach to foreclose the possibility that the SAPIEN + cloth device could be modified, if needed, to allow for endovascular delivery.

In this regard, Spenser II further supports the feasibility of using such a device for endovascular delivery. Patent Owner acknowledges that “Spenser II’s compressible material 256 (the alleged ‘sealing material’) is

¹⁹ F. Nietlispach et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems*, 75 CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS 295–300 (2010) (“Nietlispach”) Ex. 1036.

essentially identical to Walther's outer cloth in both the configuration and the material." Prelim. Resp. 75. Notwithstanding its disclosure of an embodiment that includes an outer compressible material that is 1 to 5 mm thick, Spenser II also teaches that percutaneous introduction of medical devices is a preferred approach as it is considered safer and less invasive. Ex. 1011 ¶¶ 11–13, 145. That is, Spenser II does not suggest that its Figure 22 embodiment is only capable of being delivered using a transapical approach. Dr. Brecker's calculation that the incorporation of Spenser II's compressible material would result in an overall diameter that is too large for endovascular deliver is also unpersuasive at this stage. Ex. 2002 ¶¶ 48–52. Dr. Brecker appears to assume that the 1–5 mm thickness disclosed for Spenser II's compressible material would be the thickness of the outer layer when the device is in its fully expanded state. But there is no support cited for that assumption. It is unclear whether the thickness range described in Spenser II for the compressible material is for the device in its crimped or expanded state. We will consider this issue further once the record is more fully developed after institution.

We have also considered, but are not persuaded by, Patent Owner's arguments against delivering the modified device endovascularly through the common iliac artery. First, we note that Petitioner points to the common iliac artery as merely an alternative means for endovascular delivery that was recognized in the art. Second, although Kianuma recognizes "transfemoral access as the technique of choice because it is less invasive than the transapical approach," it also notes there may be "anatomical constraints" in certain patients for transfemoral delivery. Ex. 1043, 275. Based on the successful implantation of a SAPIEN valve through the common iliac artery, Kianuma concludes that "[t]rans-iliac [implantation]

might be less invasive, safe, and the alternative approach for patients with inappropriate anatomical aspects for transfemoral” implantation. *Id.* at 276. As such, on the current record, we find that Petitioner sufficiently shows that a POSITA would have known that any larger diameter device resulting from the combination could potentially be delivered through the common iliac artery for patients with anatomical constraints that would make transfemoral delivery unsuitable.

Finally, we note that many of Patent Owner’s arguments focus on the bodily incorporation of Walther’s outer cloth or Spenser II’s compressible material onto the SAPIEN device. But that is not the standard for obviousness. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.”). In this regard, we are persuaded by Petitioner’s contention based on the present record that “POSITAs would have possessed the skills necessary to adapt the outer sealing material or valve for the particular vessel,” and “would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected an appropriately dimensioned cloth for the selected vessel.” Pet. 62 (citing Ex. 1003 ¶¶ 166, 244). After all, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421.

3. *Additional Obviousness Grounds Based on Levi in Combination with Cribier ’321 or Spenser (Grounds 9–14)*

Petitioner also contends that if Levi does not disclose the claimed graft extension requirement, Spenser and Cribier ’321 do, and POSITAs would have found it obvious to apply Spenser’s or Cribier ’321’s teaching to Levi’s inner skirt. Pet. 86–88 (citing Ex., 14:6–9, Fig. 2; Ex. 1045, Fig. 6d;

Ex. 1003 ¶¶ 356–358). In particular, Petitioner contends that “POSITAs would have been motivated to use Levi’s inner skirt to cover the proximal end of the frame to further ‘enhance[] the sealing of [Levi’s] device at the valve inlet,’” and “would have understood that extending Levi’s inner skirt over the proximal end of the outer frame would prevent leaks between the inner skirt and frame.” *Id.* at 88 (citing Ex. 1010, 14:6–9; Ex. 1003 ¶ 358). According to Petitioner, “[t]his modification would have merely entailed applying a known technique (extending the skirt) to a known device (Levi’s valve) ready for improvement (enhanced sealing).” *Id.* (citing *KSR Int’l Co.*, 550 U.S. at 416).

Patent Owner does not present any separate arguments as to whether this combination satisfies the graft extension requirement. In view of our determination above that Petitioner has sufficiently shown that Levi alone teaches or suggests this requirement, we do not address at this stage Petitioner’s arguments relying upon Spenser or Cribier ’321. To the extent necessary, we will consider these grounds after a full record is developed during trial.

4. *Conclusion for Levi-Based Grounds*

As set forth above, we are not persuaded at this stage that Petitioner is likely to prevail on its Ground 5 and Ground 6 challenges (anticipation or obviousness based on Levi alone). However, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing with regard to at least independent claims 7 and 12 in view of its Ground 7 (Levi + Walther) and Ground 8 (Levi + Spenser II) challenges. We do not at this stage find it necessary to address the merits of Petitioner’s Ground 10–14 challenges relying upon the additional teachings of Spenser or Cribier ’321.

Accordingly, we institute an *inter partes* review of all challenged claims of the '172 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”). We address the remaining grounds of the Petition below in a more cursory manner to provide some additional guidance for the parties during trial.

G. Analysis of Grounds 1–4: Obviousness over Cribier '321 or Spenser Combined with Either Walther or Spenser II

In Grounds 1–4, Petitioner asserts that claims 7 and 12 would have been obvious over Cribier '321 or Spenser combined with either Walther or Spenser II. Pet. 24–79. Cribier '321 and Spenser are relied upon in the Petition for similar teachings concerning the basic structure of SAPIEN heart valve assembly, which are alleged to meet most of the claimed structural requirements except for the sealing material and fiber coverage requirements. Also, in the same manner as with the Levi-based grounds discussed above, Walther and Spenser II are relied upon in these grounds for similar teachings concerning the incorporation a cloth layer onto the SAPIEN valve assembly. We therefore consider these grounds together.

With respect to the outer frame requirement, Petitioner points to frame 575 as shown in Spenser's Figure 44 and “intercrossing linear bars 11” in Cribier '321. Pet. 27–28 (citing Ex. 1010, 19:5–13, 26:30–34, Fig. 44a; Ex. 1045, 8:46–64, 9:27–30, Figs. 2a, 5a; Ex. 1003 ¶¶ 99, 203). With respect to the claimed inner frame requirement, Petitioner points to Spenser's disclosure of “additional piece[] of PET” 571 for “sealing and protecting the pericardium” and Cribier '321's disclosure of an “internal cover 19” that is

“fixed on the internal wall of the frame 10” and “prevents any passage of blood through the spaces between the bars 11 of the frame.” *Id.* at 29–32 (citing Ex. 1010, 26:30–54, Figs. 44a–44c; Ex. 1045, 5:15–17, 12:28–32, 13:13–16, 14:22–26, Figs. 6d, 7; Ex. 1003 ¶¶ 101, 205, 206). With respect to the claimed stitching requirement, Petitioner points to Spenser’s disclosure that that a “[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame” and Cribier ’321’s disclosure that the internal cover [19] may be secured to the “lower [proximal] extremities of the frame 10 on the . . . lower zig-zag lines of the intercrossing bars 11” by “sewing, molding or gluing.” *Id.* at 32–34 (citing Ex. 1010, 26:45–47, Figs. 44a–44c; Ex. 1045, 14:31–35, 14:45–47, 13:54–56, Figs. 5a, 8a)).

With respect to the claimed graft extension requirement, Petitioner points to Spenser’s disclosure that a “portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve [yellow], which enhances the sealing of the device at the valve inlet.” *Id.* at 35 (citing Ex. 1010, 12:51–53, 14:6–9, Fig. 2). Petitioner contends that POSITAs would have been motivated to extend PET 571 to further “enhance[] the sealing of the device at the valve inlet” and “prevent blood from leaking between the inner PET 571 and the frame 575.” *Id.* at 36 (citing Ex. 1003 ¶ 111). Petitioner further contends that “POSITAs would have reasonably expected success in extending Figure 44a’s inner PET 571 because Figure 2 and Figure 44a describe similar heart valves.” *Id.* at 37 (citing Ex. 1010, 14:41–44, 26:30–54; Ex. 1003 ¶ 112). Petitioner also points to Cribier ’321’s disclosure that its internal cover 19 may be “extended at its lower end 19’ to an external cover 19” which is rolled up to

be applied on the external wall of the stent 10.” *Id.* at 38 (citing Ex. 1045, 13:28–30, Fig. 6d; Ex. 1003 ¶ 210).

Petitioner points to disclosures showing that both the devices of Spenser and Cribier ’321 are balloon-expandable. *Id.* at 50–51 (citing Ex. 1010, 26:19–22, 26:34–35; Ex. 1045, 9:23–26, 11:5–7, Figs. 13a–13l; Ex. 1003 ¶¶ 145, 146, 226, 228). Additionally, with respect to the requirement for endovascular delivery, Petitioner points to Spenser’s disclosure that “[a]n aspect of the present invention deals with the possibility of *implanting the valve percutaneously . . . via a large blood vessel such as the femoral artery*” and Cribier ’321’s disclosure of utilizing a “*transcutaneous catheterization technique*” and “*transcutaneous introduction in the femoral artery through and arterial sheath of 14 to 16 F.*” *Id.* at 60–61 (citing Ex. 1010, 2:6–12; Ex. 1045, 1:22–25, 9:19–22, 10:27–29, 14:56–65, 17:18–22:45) (emphasis by Petitioner).

Petitioner acknowledges that neither Cribier ’321 nor Spenser teach the claim requirements for a “sealing material” that includes a plurality of radially extending fibers that extend outwardly of the outer frame. Thus, Petitioner turns to the teachings of Walther or Spenser II, in the same manner as discussed above in combination with Levi, to assert that the incorporation of such a sealing material would have been obvious.

Petitioner argues that a “POSITAs would have been motivated to combine Walther’s outer cloth with the valves in Spenser or Cribier ’321 for several reasons,” including the fact that 1) “all three references describe similar heart valves,” 2) “Walther expressly describes combining an outer cloth with valves (SAPIENS) similar (if not identical) to Spenser’s Figure 44a and Cribier ’321’s Figures 5a/6d,” 3) “Spenser describes combining an outer sealing cuff 21 with valves similar (if not identical) to Spenser’s

Figure 44a and Cribier '321's Figures 5a/6d," and 4) "because Walther's outer cloth serves a different purpose than the extended graft covering," i.e., to "prevent[] blood from leaking between the valve and surrounding tissue." *Id.* at 40–42; *see also id.* at 43 (discussing motivation based on reducing paravalvular leakage). Petitioner contends that POSITA would have had reasonable expectation in making such a combination "because Walther explains how to combine the outer cloth with a similar valve, provides images of the combined device, and concludes that the cloth-covered valve 'demonstrated excellent hydrodynamic performance.'" *Id.* at 42.

Petitioner identifies a similar rationale to combine Spenser II's compressible material. *Id.* at 45–46. Petitioner further contends that Spenser II discloses a compressible material having a "thickness ranging from about 1 to about 5 mm," and Spenser teaches a prosthetic valve that can change its diameter from about 4 mm to about 25 mm. *Id.* at 63 (citing Ex. 1011 ¶ 145). Petitioner contends that a "POSITA would have reasonably expected that adding a compressible material 1 mm thick to Spenser's 4-mm valve would have resulted in a device suitable for endovascular delivery." *Id.* (citing Ex. 1003 ¶ 167).

With respect to the claimed fiber coverage requirement, Petitioner contends that if Walther's outer cloth were added to either Spenser's Figure 44 or Cribier '321's valve in the same way, the cloth would cover at least two rows of grids, and also that "POSITAs would have found it obvious to add or subtract rows as necessary." *Id.* at 46–48 (citing Ex. 1003 ¶ 224; comparing Ex. 1007, Fig. 1 with Ex. 1010, Fig. 44a and Ex. 1045, Fig. 13k). Petitioner provides a similar rationale for covering at least two circumferentially extending rows of grids with Spenser II's compressible

material. *Id.* at 48–50 (citing Ex. 10023 ¶ 143; comparing Ex. 1011, Fig. 22 with Ex. 1010, Fig. 22 and Ex. 1045, Fig. 13k).

Patent Owner does not raise any additional arguments with regard to Grounds 1–4 that we have not already considered with regard to the Levi-based grounds discussed above. *See* Prelim. Resp. 3–42 (arguing Grounds 1–4, 7, 8 and 11–14 together). We do not find Patent Owner’s arguments persuasive for the reasons discussed above. We recognize, however, that Petitioner’s grounds relying upon Cribier ’321 and Spenser are somewhat weaker because neither reference discloses a structure, such as Levi’s outer skirt, that a POSITA may consider equivalent to Walther’s or Spenser II’s outer cloth layers. Nonetheless, even without a motivation based on “simple substitution of one known element for another,” *KSR*, 550 U.S. at 417, a POSITA may have possessed a sufficient independent motivation to incorporate an outer cloth layer to Cribier ’321’s and Spenser’s SAPIEN valve structures in view of Walther’s and Spenser II’s teachings that such a layer could help reduce paravalvular leakage. As we have already decided to institute an *inter partes* review in view of our preliminary assessment of Grounds 7 and 8, we will consider these issues more thoroughly and make a final assessment of the merits of Grounds 1–4 (along with the other grounds in the Petition) after a complete trial record.

III. CONCLUSION

For the foregoing reasons, Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the ’011 patent would have been obvious over the prior art of record. Accordingly, we institute an *inter partes* review on all claims and all grounds set forth in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on all non-disclaimed claims and 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 '011 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2021-01584
Patent 10,857,011 B2

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