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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC**

Petitioners,

v.

AORTIC INNOVATIONS, LLC

Patent Owner.

IPR2022-00556
Patent No. 10,987,236

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“ Walther ”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	Conradi, Lenard, et al., <i>Transcatheter aortic and mitral valve interventions: update 2010</i> , 2(4) Interventional Cardiology 513-523 (2010)
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1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
1012	Cribier, Alain, et al., <i>Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach</i> , Herz, 34:347-56 (2009) (“ Cribier ”)
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1106	Estridge, Trudy & Dale Feldman, <i>Quantification of Vascular Ingrowth into Dacron® Velour</i> , 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”)
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I. INTRODUCTION

PO argues that the fibrous outer cloths in Walther and Spenser II do not satisfy two claim limitations: (1) “free of an outer graft covering” and (2) “second portion of fibers.” The Board should reject PO’s arguments.

First, PO improperly equates “graft covering” with a “backing layer.” (*See e.g.*, POR, 7.) PO then speculates that Walther’s and Spenser II’s outer sealing materials have a backing layer and argues this means the materials are not “free of an outer graft covering.” (*Id.*) In making these arguments, PO is construing “graft covering” to mean “backing layer.” Yet, the ’236 patent does not use the term “backing layer,” and PO has not identified any disclosure that equates a graft covering with a backing layer. In fact, both parties’ experts agree that not all backing layers are graft coverings. (Ex. 1104, ¶¶22, 55.)

The term “graft covering” appears in the claims but not the specification. The only material described in the specification corresponding to a “graft covering” is a “nonporous covering material that prevents fluid from passing through the surface.” (*See e.g.*, Ex. 1001, 15:50-53.) Even if Walther and Spenser II have an alleged “backing layer,” it would not be a graft covering under the proper meaning. Rather, POSITAs would have understood Walther’s and Spenser II’s outer sealing materials

to be porous to perform their stated purposes of preventing PVL and promoting tissue ingrowth, and thus are free of an outer graft covering. (Ex. 1104, §§II.B-C.)

Second, Walther's and Spenser II's outer sealing materials have outward- and inwardly-facing surfaces formed of fibers. (*See e.g.*, Pet. 72.) The inward-facing fibers satisfy the "second portion of fibers" limitation. (*Id.*) PO counters that Walther's and Spenser II's sealing materials "have a solid backing layer with no inwardly-facing fibers" and, therefore, lack a "second portion of fibers." (*See e.g.*, POR, 46.) Although PO never fully explains its argument, PO appears to equate inwardly-facing fibers with *radially* inwardly-*extending* fibers. Yet, while the claims state "the *first* portion of fibers extend radially outwardly of the outer frame," no such limitation exists for the "second portion of fibers." Thus, even assuming Walther and Spenser II disclose a "solid backing layer," the backing layer is made of PET fibers "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst." Thus, the backing layer satisfies the "second portion of fibers" limitation.

Moreover, PO inconsistently construes "graft covering" and "second portion of fibers" depending on whether PO is applying the claims to (1) Walther and Spenser II or (2) Petitioner's accused SAPIEN 3 Ultra ("S3U") valve. When addressing the prior art, PO argues that a "backing layer" constitutes a "graft

covering” but not a “second portion of fibers.” (POR, 6-9, 45-47, 63-67.) In contrast, when addressing the S3U valve, PO argues that not all backing layers constitute a graft covering, that a porous “base layer” *would not* constitute a “graft covering,” and that the S3U valve’s backing layer *is* a second portion of fibers. (POR, 85 n.7; Ex. 1050, ¶82.) If the same claim scope that PO applies to the S3U valve is applied to the prior art, Walther and Spenser II meet the claim limitations, regardless of whether they have a backing layer.

II. THE PRIOR ART DISCLOSES A VALVE ASSEMBLY “FREE OF AN OUTER GRAFT COVERING”

A. The Claimed “Graft Covering” Is A Nonporous Covering Material

The Board has stated that the issue regarding the “free of an outer graft covering” limitation turns on the nature of Walther’s and Spenser II’s outer materials. (D.I. 33-34, 44-47.) This is true. But the issue also turns on the meaning of “graft covering” used in the claims. PO raised this claim construction issue by contending in the POR that “graft covering” means “backing layer.” (POR 7.) However, the claims require the absence of an outer graft covering *independent* of fibers and never describes a cloth having a backing layer. Thus, in attempting to read graft covering on a fibrous cloth, PO effectively reads “free of an outer graft covering” out of the claims.

Moreover, whether Walther and Spenser II have a backing layer is not determinative of whether they have a graft covering. Both parties' experts agree that not all backing layers are graft coverings. (Ex. 1104, ¶¶22, 55; Ex. 1105, 37:15-17, 39:3-4, 40:4-8, 41:5-11, 42:3-8, 47:3-11, 60:11-20, 172:5-12.))

To develop this issue further, as expected by the Board, Petitioner deposed Dr. Brecker, where he testified that "something that is porous with holes wouldn't be a graft cover." (Ex. 1105, 39:3-4.) Likewise, PO argued in the POR that a "highly porous skirt does not constitute a graft covering," but "a tightly-woven, tightly-knitted, or non-porous, dense felt layer may well constitute a graft." (POR, 85 n. 7.) Petitioner's expert, Dr. Buller, agrees, testifying that a porous covering would not constitute a graft covering because the graft covering claimed in the '236 patent is a "nonporous covering material that prevents fluid from passing through the surface." (Ex. 1104, ¶¶14-18.) Thus, there should be no dispute that a "graft covering" is a nonporous material that prevents fluid from passing through the surface.

This construction is consistent with the intrinsic record. Claim 1 uses "graft covering" in two limitations: "inner graft covering" and "free of an outer graft covering." The "inner graft covering," which provides "sealing to the prosthetic heart valve," can do so only if it prevents fluid from passing through its surface. "Graft covering" should have the same meaning in both limitations. *Paragon Sols.*,

LLC v. Timex Corp., 566 F.3d 1075, 1087 (Fed. Cir. 2009). Thus, the claims require the “graft covering” to be a “nonporous covering material that prevents fluid from passing through the surface.”

The '236 patent specification further confirms this construction. While the specification never uses the term “graft covering,” it repeatedly discloses coverings for the frames made of “low-profile polyester, ePTFE, or ***other nonporous covering material 44 that prevents fluid from passing through the outer surface.***” (Ex. 1001, 7:21-27 (emphasis added); *see also id.*, 8:42-46, 9:26-28, 13:25-29, 13:51-57, 15:50-55, 16:61-65, 19:5-8 (same).) The word “other” indicates that the listed materials are part of the same group, i.e., “nonporous covering materials that prevent fluid from passing through the outer surface.” If some of the listed materials were porous, the word “other” would not make sense.

The prosecution history also confirms this construction. PO identified the following disclosure as allegedly providing written description support for “inner graft covering”:

In the illustrative embodiment, the outer surface 248 of the stent 244 is covered with low-profile polyester, ePTFE, ***or other nonporous covering material 250 that prevents fluid from passing through the outer surface 248.*** However, it should be appreciated that the stent 244

may be covered with standard polyester, ePTFE *or other nonporous materials*.

(Ex. 1002, 237-238 (emphasis added).)

Accordingly, the intrinsic evidence confirms that “graft covering” is “a nonporous covering material that prevents fluid from passing through the surface.”

B. PO Misstates The Standards For Negative Limitations

PO argues that Walther’s and Spenser II’s silence regarding an outer graft covering “is a problem for Petitioner” because silence cannot satisfy Petitioner’s burden. (POR, 5.) PO argues that Petitioner must show the prior art is “inherently ‘free of a graft covering’” to meet its burden. (*Id.*) PO misstates the legal standard.

“[A] reference need not state a feature’s absence in order to disclose a negative limitation.” *AC Techs. S.A. v. Amazon.com, Inc.*, 912 F.3d 1358, 1367 (Fed. Cir. 2019); *see also Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 273-74 (Fed. Cir. 2022) (affirming Board finding that reference which did “not indicate that any of its formulations include adapalene” was sufficient to disclose negative limitation requiring absence of adapalene). When a reference does not disclose the feature excluded by the negative limitation, as here, the proper inquiry is whether the prior art *requires* the feature. *See e.g., Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1004-05 (Fed. Cir. 2009) (assessing whether prior art “requires the use

of adhesive coatings”); *Wag Acquisition, LLC v. WebPower, Inc.*, 781 Fed. App’x 1007, 1013 (Fed. Cir. 2019) (“While Carmel does not specify that a pointer is *not* used, nothing in the record suggests that a pointer *must* be used.” (emphasis in original)).

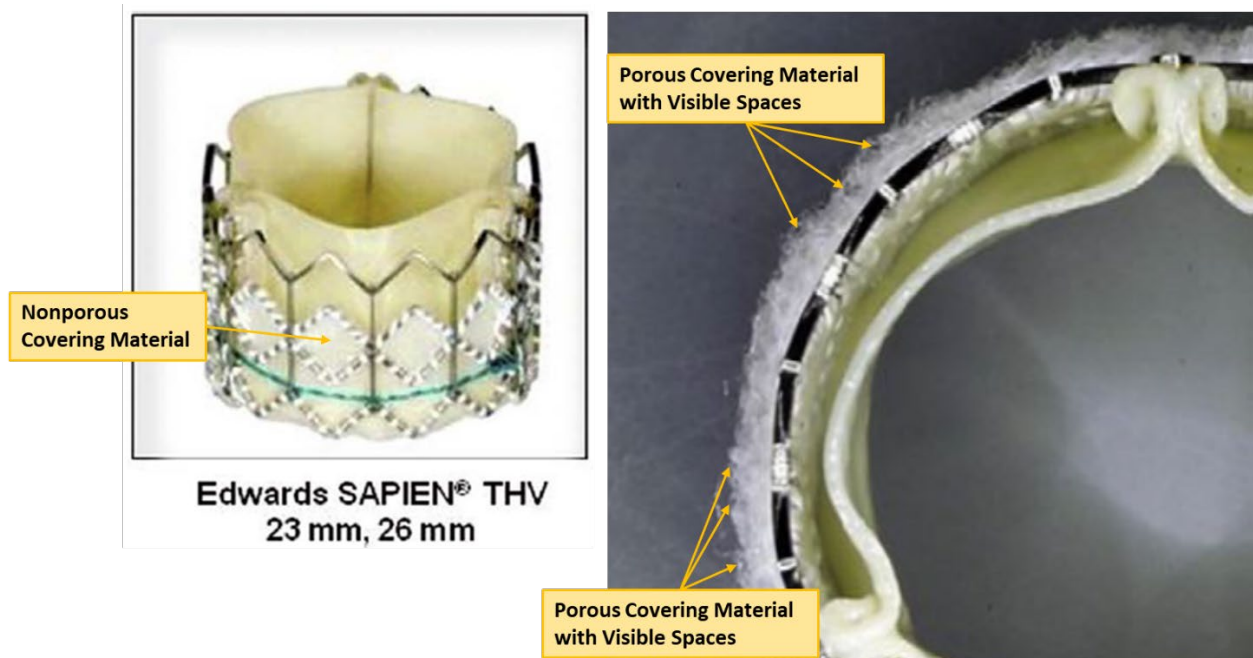
Here, PO has failed to show, or even allege, that Walther or Spenser II require an outer graft covering.

C. Walther Is Free Of An Outer Graft Covering

1. Walther’s Outer Cloth Is A Porous Material

Walther discloses a SAPIEN valve having an outer PET cloth. (Ex. 1007, 1121.) Walther does not describe a backing layer, nor does it describe any portion of the outer cloth as being a nonporous covering material that prevents the flow of fluid through the surface. To the contrary, POSITAs would have had several reasons to conclude that Walther’s outer cloth is porous and would not prevent the flow of fluid through the surface, regardless of whether it has a backing layer. (Ex. 1104, ¶¶20-48.)

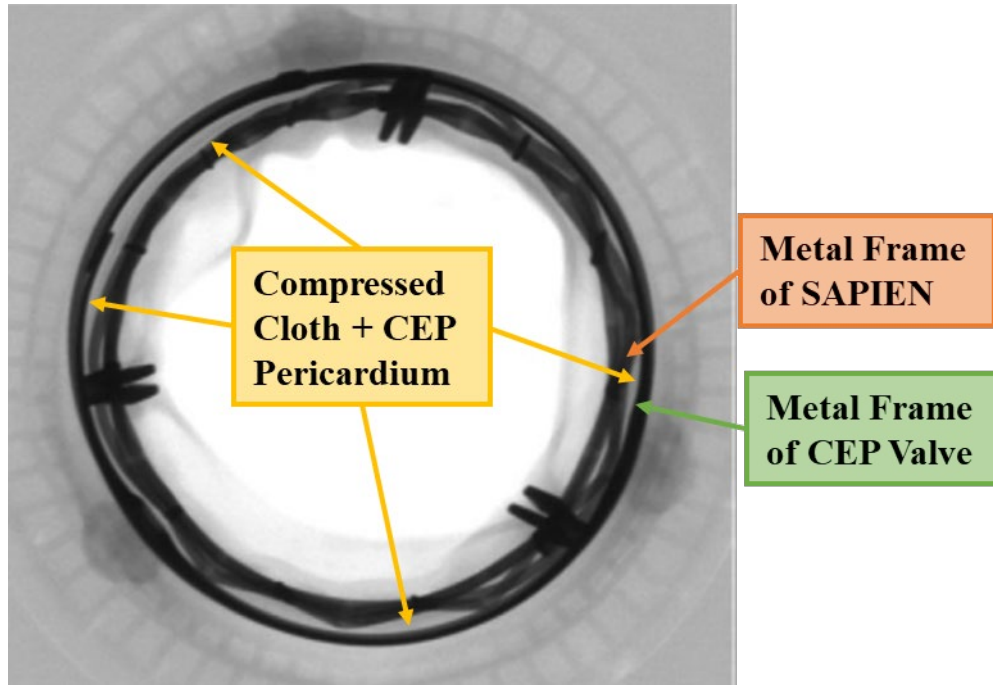
First, Walther’s outer cloth has loosely-arranged fibers with visible spaces therebetween. (*Id.*, ¶32.) Walther’s outer cloth is fuzzy and not dense like SAPIEN valve’s inner skirt, which the parties agree is a graft covering:



(*Id.*) Walther's loosely-arranged fibers would have led a POSITA to conclude that the outer cloth is porous and would not prevent the flow of fluid through the surface.

(*Id.*)

Second, Walther's outer cloth is highly compressible. (*Id.*, ¶33.) Figure 3 illustrates the implanted Walther valve and shows very little space between the SAPIEN and CEP frames. A larger, continuous gap would exist between the frames if Walther's outer cloth, which is between the frames, were dense and incompressible.



(*Id.*) The high compressibility of Walther's outer cloth further teaches a porous material that would not prevent the flow of fluid through the surface. (*Id.*, ¶¶33, 45; *see also* Ex. 1109, 1048; Ex. 1074, 8:3-7, 8:45-48.)

Third, Walther's outer cloth: (1) increases the fit between the SAPIEN and CEP valves and (2) promotes tissue ingrowth. (Ex. 1007, 1120.) The prior art demonstrates that a flexible, porous cloth is necessary to accomplish these purposes. (Ex. 1104, ¶¶34-43.) For example, tissue ingrowth requires a porous cloth with spaces between the fibers for the tissue to grow into. (*Id.*, ¶¶38-39.) Thus, applications for Walther's outer cloth further teach a porous material that would not prevent the flow of fluid through the surface. (*Id.*)

Dr. Brecker's argument that a porous cloth would not reduce PVL is unsupported and directly contradicted by numerous prior art references. (*See* Ex. 1105, 128:7-17 (Dr. Brecker testifying that a porous cloth could not prevent PVL); Ex. 2103, ¶160 (similar); *see also* Ex. 1107, 180-181; Ex. 1109, 1049; Ex. 1108, 657; Ex. 1106, 158.) Even Chu, cited by Dr. Brecker, contradicts his testimony. (Ex. 2057, 4 (the "main disadvantages of woven vascular fabrics are their very low healing porosity leading to poor healing").) The Board should therefore accord Dr. Brecker's testimony little weight. *See, e.g., Unified Patents, LLC v. JustService.net LLC*, IPR2020-01258, Paper 41, at 39-40 (P.T.A.B. Feb. 16, 2022) (rejecting unsupported expert testimony in favor of testimony offered by petitioner which was corroborated by prior art); *see also Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1022 (Fed. Cir. 2017) (affirming Board's decision giving little weight to conclusory expert testimony); *Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (noting that the Board may accord little weight to "broad conclusory statements" that are "unsupported by corroborating references").

The Board should also accord Dr. Brecker's testimony limited weight because he failed to consider whether Walther's outer cloth would be "free of an outer graft covering" if the cloth is porous. (Ex. 1105, 154:3-155:12.) This is critical, given that Dr. Brecker testified that the S3U valve's outer skirt lacks an "outer graft covering"

because it is porous and admitted that porous fabrics could not be graft coverings. (*Id.*, 39:2-4; Ex. 2103, ¶148.)

Fourth, Walther's valve includes an inner skirt, which the parties agree is a graft covering. (Pet., 32-35.) Consequently, Walther's outer cloth does not need to be nonporous and block fluid flow through the frame because the inner graft covering already does this. (Ex. 1104, ¶¶41-42; Ex. 1105, 102:12-104:9.)

Fifth, the experts agree that Walther's outer cloth is "velour-like."¹ (Ex. 1104, ¶26; Ex. 2103, ¶¶44, 47.) Velour and velour-like fabrics were known to be porous materials, not nonporous "graft coverings." (Ex. 1104, ¶¶26-29.) Chu, a publication cited by PO, confirms that POSITAs adopted woven or knitted velour-like fabrics for their porosity, a point corroborated by other decades-old references. (*Id.*, ¶¶27-29; Ex. 2057, 4 ("to improve the healing porosity and compliance of woven vascular fabrics, velour woven vascular fabrics were introduced"); Ex. 1107; Ex. 1106, ("The most commonly used porous soft tissue biomaterial is Dacron velour."); Ex. 1110, 172.) Indeed, to make velour-like fabrics nonporous, physicians had to pre-clot the cloth with blood or coat the cloth with a nonporous material, such as collagen or

¹ Dr. Buller testified that Walther's outer cloth may also be knitted. (Ex. 1104, ¶26; Ex. 2052, 93:22-94:22.)

Silastic (rubber). (Ex. 1104, ¶29; Ex. 1108, 657; Ex. 1111, Summary; Ex. 1112, Summary.) Walther's outer cloth was not coated with any substances. For this additional reason, POSITAs would have understood that Walther's outer cloth is a porous material that would not prevent fluid flow through the surface and, therefore, is free of an outer graft covering.

2. PO Fails To Show That Walther Has An Outer Graft Covering

PO's argument that Walther includes a graft covering relies on the incorrect construction of "graft covering" and is inconsistent with PO's other arguments. For example, PO argues that Walther has a graft covering because Walther has a "velour-like woven PET cloth." (POR, 7.) Similarly, PO argues that a statement made during prosecution "confirms that a 'velour-like woven PET' covering would not satisfy the 'free of an outer graft covering' limitation." (POR, 10.) Yet, later in the POR, PO admits that not "all 'woven' bases would necessarily constitute a graft" and argues that the S3U valve, which includes a velour-like cloth and base layer, does not have an outer graft covering. (*Id.*, 85 n.7, 89; Ex. 1113.)

Moreover, PO did not clearly and unmistakably disclaim velour-like woven PET cloths while discussing "Hartley" during prosecution. The only prosecution statement mentioning Hartley says, "[Hartley] teaches a velour band at a distal end of the stent graft." (Ex. 1002, 191.) Later, after discussing other stent grafts, PO

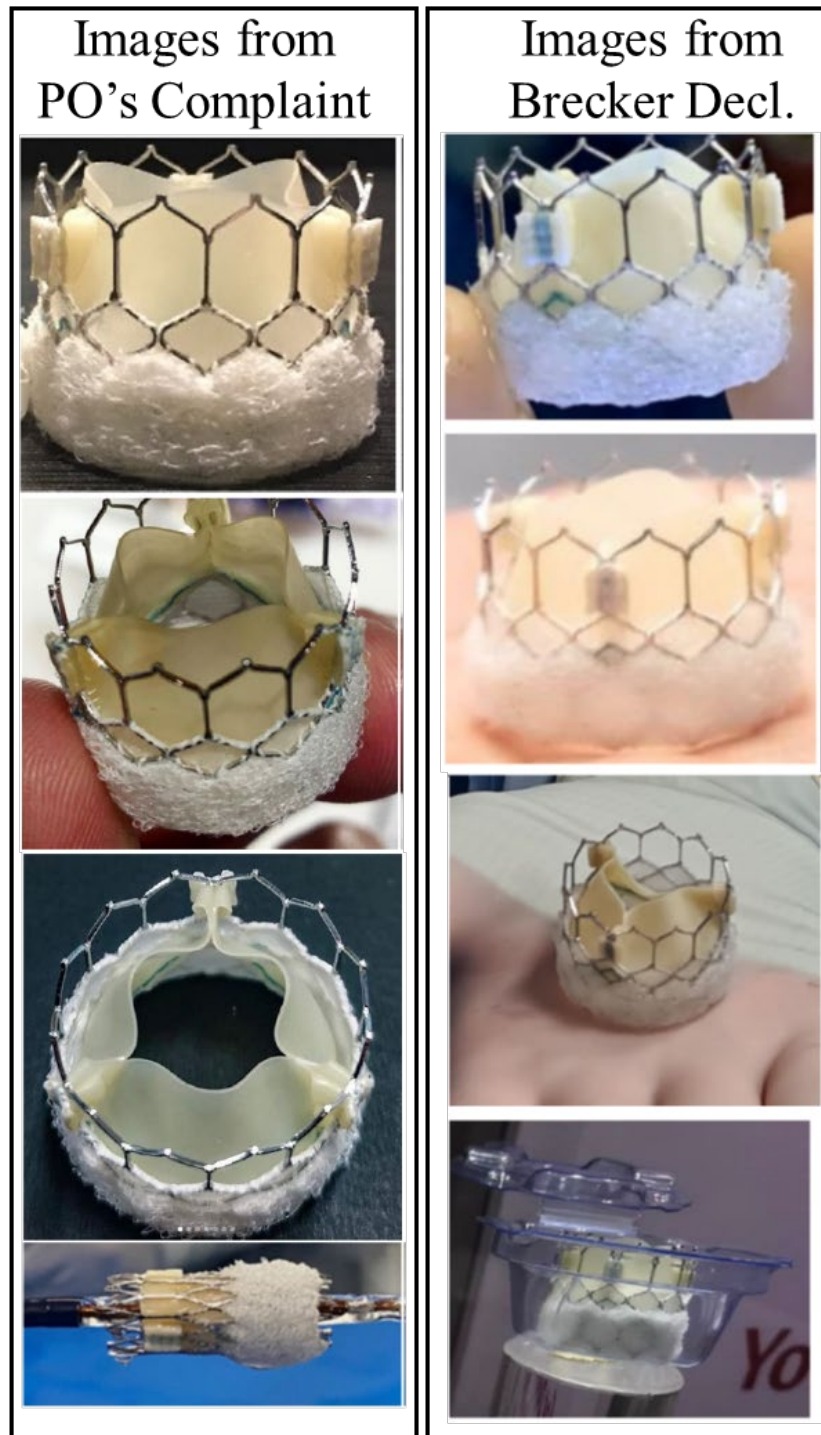
argued that “stent graft technology generally appears to teach a graft covering on the outside of the metal stent frame, and the fibers extend from the graft covering.” (*Id.*, 197.) Notably, PO does not mention Hartley in this general statement, nor does PO clearly equate Hartley’s velour band with a graft covering. PO’s vague argument is not a clear and unmistakable disclaimer of velour-like woven PET cloths. *See, e.g., Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (noting courts refuse to find disclaimer where disavowal is ambiguous or amenable to multiple reasonable interpretations).

Additionally, PO misinterprets Hartley’s disclosure about the velour band. Hartley discloses an embodiment having “a continuous band of velour material 20 fastened to the graft 1 by stitching.” (Ex. 1104, ¶46; Ex. 2056, [0035], Fig. 2.) Thus, the “band of velour 20” is distinct from the “graft 1.” (Ex. 1104, ¶46.) Accordingly, POSITAs would have had no basis to conclude that Hartley’s velour band is a “graft covering.” Unlike Hartley, Walther’s outer cloth was not fastened to underlying “graft” material.

PO also argues that Walther’s outer cloth is a graft covering because SAPIEN and Levi’s *inner* PET skirts are graft coverings. (POR, 1.) However, “PET can have a range of finishes.” (Ex. 1003, ¶116; *see also supra* §II.C.1 (comparing references).) Merely being made of PET does not mean a material is a graft covering, as PO

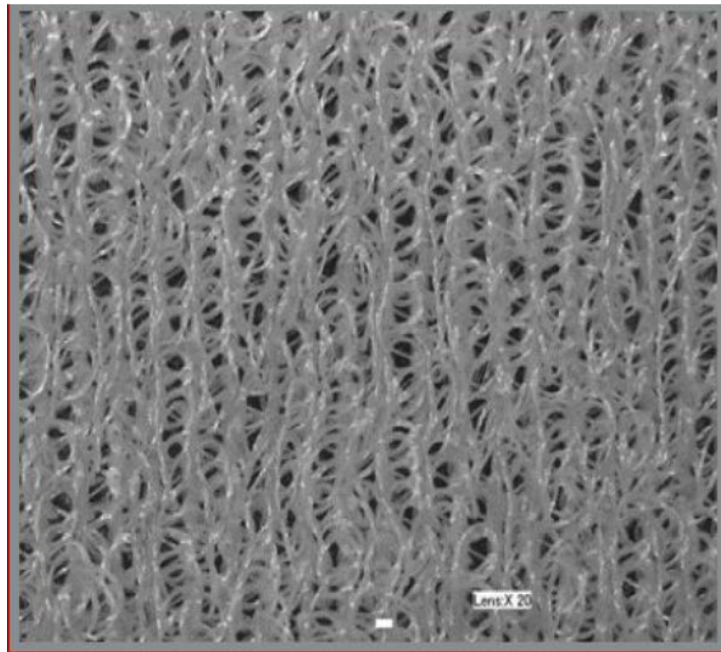
acknowledges by alleging that the S3U valve's outer PET skirt is "free of an outer graft covering." (*See also* Ex. 1105, 97:14-21.)

PO also argues that Walther's outer cloth includes an "outer graft covering" because the cloth is opaque, while also arguing that the S3U valve lacks a graft covering because its outer skirt is "translucent." (POR, 91-93.) Yet, nothing in the patent claims or specification correlate a graft covering with opacity or translucency. Moreover, PO ignores that opacity/translucency depends on many factors, including lighting and moisture. (Ex. 1104, ¶51.) By changing the conditions, a fabric can appear more translucent, as illustrated by the S3U valve images selected by PO in its Complaint (left) and POR (right):

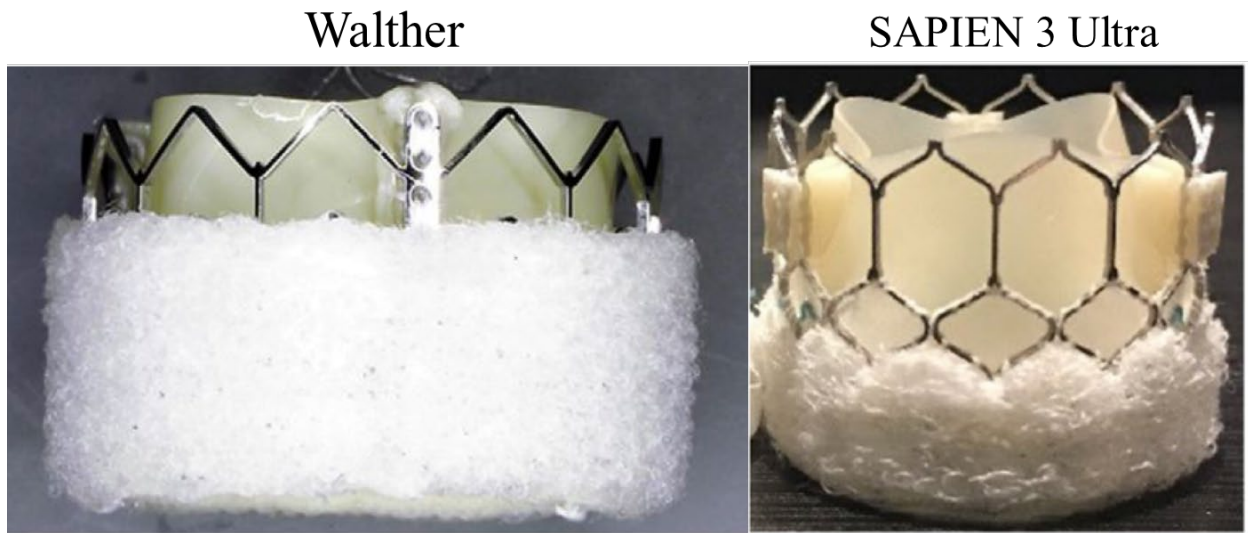


(Ex. 1050, ¶¶6, 62, 85; POR, 91-92.) As shown, the valve's outer skirt is opaque in the Complaint and, at best, slightly translucent in the POR.

PO also attempts to distinguish the S3U valve from Walther's outer cloth based on alleged "clear holes" in the S3U valve's outer skirt. Yet, the alleged "clear holes" are only visible under 20x magnification:



(POR, 91-93.) Even nonporous cloths will have "holes" at sufficiently high magnifications, so the magnified image is not probative of porosity. Further, PO compares this highly-magnified image to a non-magnified image of Walther to conclude that Walther does not have "clear holes." (*Id.*) Naturally, a comparison of vastly different magnifications lacks probative weight. A fairer comparison shows the striking similarities between the cloths:



(Compare Ex. 1007, Fig. 1 with Ex. 1050, ¶¶6.) Moreover, POSITAs would have understood that Walther’s outer cloth includes spaces/holes between its fibers due to its porosity. (Ex. 1104, ¶¶88-89.)

PO also attempts to draw conclusions about Walther based on other valves (Cheung and Apogee). (POR, 15-26.) PO’s arguments suffer from numerous deficiencies. First, PO fails to establish that the outer cloths on the other valves are identical to Walther. (*Id.*) Second, PO incorrectly describes Cheung’s and Apogee’s outer cloths as “smooth” without “inwardly-extending fibers.” (*Id.*) Dr. Buller explained in his deposition that neither reference describes a “smooth backing layer.” (Ex. 2104, 8:17-23, 36:11-14.) Moreover, whether the cloths have “inwardly-extending fibers” is irrelevant because the claims do not require them. Third, even assuming PO is correct that the references depict a “smooth backing layer,” PO has

not shown that the backing layers are nonporous materials that prevent fluid flow through the surface. (*Id.*) Accordingly, PO has not shown that Cheung and Apogee are probative of whether Walther is free of an outer graft covering.

PO also argues that Walther's outer cloth includes a "graft covering" based on the unrelated Dehdashtian patent. (POR, 26-33.) PO's argument is wild speculation. The only connection is that Mark Dehdashtian is a co-author of Walther and a co-inventor on Dehdashtian; there is no other overlap of co-authors and Dehdashtian. Walther does not mention Dehdashtian or use the same terminology. Whereas Dehdashtian discloses a "graft" with fibers woven into a "graft," Walther discloses a cloth and never mentions a "graft." (Ex. 1104, ¶25.) PO also ignores that Dehdashtian is a named inventor on over 80 U.S. patents and published patent applications, most of which relate to cardiovascular devices, demonstrating that he has worked on numerous different inventions. Accordingly, PO fails to show that a POSITA would have considered Dehdashtian relevant to Walther. (*Id.*, ¶¶62-68.)

Finally, PO insinuates that Petitioner is withholding nonpublic information regarding Walther. But even if additional, nonpublic information regarding Walther's outer cloth exists, it would be irrelevant to how POSITAs would understand Walther because nonpublic information would not have been available to them.

PO has failed to demonstrate that Walther requires a nonporous outer cloth. Consequently, PO has failed to rebut Petitioner's evidence that Walther's outer cloth is "free of an outer graft covering."

D. Spenser II Is Free Of An Outer Graft Covering

Spenser II's compressible material is also "free of an outer graft covering." Spenser II discloses that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material." (Ex. 1011, [00145].) Spenser II never describes the compressible material as including a graft covering or backing layer. However, as discussed above, even if Spenser II's compressible material included a "backing layer," it would not mean that the material was a graft covering. (*Supra* §II.A-C.) Rather, the relevant inquiry is whether Spenser II *requires* the compressible material to be a nonporous covering material that prevents fluid flow through the surface. Spenser II includes no such requirement. To the contrary, a POSITA would have understood Spenser II's material to be porous for several reasons. (Ex. 1104, ¶¶54-61.)

First, Spenser II does not describe the compressible material as nonporous, nor does Spenser II restrict the compressible material to dense materials. (*Id.*, ¶60.) Spenser II's description of the material is broad and encompasses loose, porous materials. (Ex. 1011, [00145].) Second, Spenser II's material is expressly described

as “compressible,” which teaches a porous material to a POSITA. (*Id.*, ¶57; *supra* §II.C.1.) Third, Spenser II discloses that the compressible material “expands after deployment at a treatment site” and that “[a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.” (Ex. 1011, [00145].) The compressible material could expand to “fill[] the gaps” only if it was a porous, compressible material. (Ex. 1104, ¶58.) Fourth, Spenser II explains that the fibers can “encourage coagulation of blood to further fill the gaps and prevent leakage.” (Ex. 1011, [00145].) Accordingly, a POSITA would have understood that the compressible material must be loose and porous to create spaces/openings for the coagulation. (Ex. 1104, ¶59.)

PO argues that Spenser II includes an “outer graft covering” because it describes “small *fibers extending from the surface of the [compressible] material.*” (POR, 36-37, 41.) PO equates the “surface of the material” with a “graft covering” and speculates that the compressible material includes a “dense PET layer.” (*Id.*) Yet, Spenser II never equates the compressible material with a “graft covering,” nor does it describe the compressible material as dense or nonporous. (Ex. 1011, [00145]; Ex. 1104, ¶60.) Thus, PO’s characterization of Spenser II is unsupported.

Additionally, PO did not clearly and unmistakably disclaim claim scope when discussing Spenser II during prosecution. (POR, 41.) PO argued, “the seal of Spenser

appears to be relatively thick in construction, including a graft covering or sleeve with fibers extending from the sleeve.” (Ex. 1002, 196.) First, PO acknowledged that Spenser II does not necessarily disclose a “graft covering” by using the word “appears” and identifying the alternative “sleeve.” Second, PO never distinguished the claims based on this speculative characterization. Third, PO’s self-serving characterization lacks specificity regarding which features allegedly form the “graft covering” and why those features qualify as a “graft covering.” For at least these reasons, PO has not demonstrated that it clearly and unmistakably disclaimed claim scope during prosecution. *See, e.g., Avid Tech.*, 812 F.3d at 1045 (ambiguous statements do not result in disclaimer).

PO’s argument that Dehdashtian includes teachings relevant to Spenser II fails for the same reasons explained for Walther. (*Supra* §II.C.2.) The *only* relation between Dehdashtian and Spenser II is that Mark Dehdashtian is a co-inventor on both references. Spenser II does not incorporate Dehdashtian by reference, or even mention Dehdashtian. (Ex. 1011, [0003]-[0009].) Spenser II also does not use the “towel-like graft” terminology in Dehdashtian. Moreover, Spenser II does not disclose a “graft” as part of the compressible material, nor does it describe the compressible material as “towel-like” or including “floaters.” Also, as noted above, Dehdashtian is a named inventor on many patents and publications in this field.

Accordingly, a POSITA would have had no basis to believe Spenser II's compressible material is anything like Dehdashtian's graft material. (Ex. 1104, ¶¶62-68.)

III. WALTHER AND SPENSER II DISCLOSE A “SECOND PORTION OF FIBERS”

The '236 patent claims require, *inter alia*, a “second portion of fibers” that is: (1) carried by the outer frame and (2) configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst. (Ex. 1001, claim 1.) Walther and Spenser II satisfy these limitations.

Walther's and Spenser II's outer materials include two surfaces: (1) an outward-facing surface and (2) an inward-facing surface.² (Ex. 1104, ¶¶71-72, 80-83.) Both surfaces are made of PET fibers. (*Id.*) Dr. Brecker admitted that the alleged “dense PET layer” in Walther's outer cloth was made of PET fibers. (Ex. 1105, 133:18-134:7.) He also admitted that Spenser II discloses a “woven PET compressible material” and that “woven PET is made of woven PET fibers.” (*Id.*,

² PO dismisses this basic understanding as “nonsense,” but fails to provide any reasonable alternative. (POR, 64.)

134:6-7; Ex. 2103, ¶123.) Thus, the experts agree that the outer materials are made from a single material, PET fibers.

In both references, the fibers forming the inward-facing surface of the material are attached to and carried by the frame, and those fibers press against the frame when the valve is implanted, forming a sealing interface thereagainst. (Ex. 1104, ¶¶72-73, 80-82; *see also* Ex. 1105, 142:19-148:20 (Dr. Brecker testifying that Walther's outer cloth is "attached" to the frame and that the purpose of the cloth "is to seal the space between the two valves").) Accordingly, the fibers forming the inward-facing surface of Walther's and Spenser II's sealing materials are the claimed "second portion of fibers." (Ex. 1104, ¶¶69-82.)³

Most of PO's arguments responses address whether the fibers on the inward-facing surface of Walther's or Spenser II's sealing material are "extending" from the material. (POR, 43-66.) But the claims do not require the "second portion of fibers" to be "extending." Thus, PO's arguments are irrelevant to Petitioner's grounds.

³ PO also asserts that Petitioner relies on inherency. (POR, 44.) PO is wrong. Petitioner's arguments rely on a POSITA's understanding of the disclosures in Walther and Spenser II regarding the cloth or compressible material.

IV. THE PRIOR ART RENDERS CLAIM 4 UNPATENTABLE

A. PO's Construction Of "Opening" Is Incorrect

The Board should reject PO's construction of "opening" in claim 4 because it is ambiguous and unsupported by the intrinsic record.

PO argues that the "opening" must be "relatively larger and created by design, rather than mere inherent spaces between fibers." (POR, 82.) However, the '236 patent does not describe the claimed "opening" anywhere in the specification, much less require specific dimensions for the "opening," and PO fails to identify any guideposts from which a POSITA could determine if an opening is "relatively larger." Dr. Brecker's deposition testimony illustrates the problem with the construction. When asked what he meant by "relatively larger," Dr. Brecker responded that "I haven't put a size on it," but that he could "get a sense" from looking at the patent's figures. (Ex. 1105, 179:4-17.) Yet, the '236 patent never discloses that the figures are drawn to-scale or reflect the precise dimensions of the openings. (Ex. 1104, ¶85); *see also Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000).

PO also attempts to inject an intent element into the construction by requiring that the opening be "created by design." Such a construction would hopelessly frustrate the efforts of POSITAs in evaluating the prior art because the intent behind

a particular invention is typically not public. *See Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346-1347 (Fed. Cir. 2008) (holding inventor’s subjective intent is irrelevant to claim construction). Moreover, the term “created by design” is vague. Walther’s outer cloth was created by design to have a particular density and, yet PO still contends that it does not have openings.

PO’s attempt to exclude “inherent spaces between fibers” is improper for the same reasons. The ’236 patent does not exclude “inherent spaces” from the invention’s scope or distinguish “inherent spaces” from spaces “created by design.” If such a construction were adopted, POSITAs would have no meaningful definition to apply.

For these reasons, the Board should not adopt PO’s proposed construction of the “opening.” Instead, the Board should apply the plain and ordinary meaning.

B. Walther And Spenser II Disclose An “Opening”

POSITAs would have understood that Walther’s outer PET cloth and Spenser II’s compressible material are porous materials. *Supra* §§II.C-D. These outer materials could not accomplish their stated functions of promoting tissue ingrowth and encouraging blood coagulation if spaces did not exist between adjacent fibers. (*Supra* §§II.C-D; Ex. 1104, ¶¶26-45, 54-59; Ex. 1106, 158.)

POSITAs would have further understood that the fibers forming the inwardly-facing surface of Walther's and Spenser II's sealing materials (i.e., "second portion of fibers") would also include "spacings" between the adjacent fibers, which form "openings" extending through a thickness of the fabric. (Ex. 1104, ¶¶88-89.) Again, such "openings" are necessary for the sealing materials to achieve their stated purposes of promoting tissue ingrowth and preventing PVL. (*Id.*) They are also necessary for the sealing material to effectively compress and stretch. (*Id.*) When the porous material is sutured/attached to a valve frame, those openings "extend to the outer frame" because they directly abut the frame. (*Id.*) Accordingly, both Walther and Spenser II disclose and render obvious the limitations in claim 4. (*Id.*)

PO decries this analysis as requiring "imagination." (POR, 77.) It does not. The concept of having spaces between adjacent fibers was ubiquitous, not complex. PO simply ignores the skills and knowledge of POSITAs when analyzing the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.") Moreover, Dr. Buller's expert testimony regarding the openings between the fibers in Walther or Spenser II is un rebutted. (Ex. 1104, ¶¶88-89.) Dr. Brecker admitted that he has not opined regarding the spacing between the fibers in Walther or Spenser II. (Ex. 1105, 198:22-199:19.)

V. DR. BULLER IS A POSITA

Dr. Buller is a highly-respected cardiologist with over 25 years of practice, and has conducted or supervised more than 8,000 diagnostic and therapeutic non-surgical catheterization procedures. (Ex. 1003, ¶¶6-7.) Dr. Buller has also received hands-on training on the use and delivery of TAVR devices. (Ex. 1104, ¶8.) The Board has previously found Dr. Buller qualified to offer expert opinions in a related IPR and has even credited Dr. Buller's opinions over those of Dr. Brecker in a prior IPR. *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01527, Paper 52, at 51-53; *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc.*, IPR2017-00060, Paper 64, at 11. The Board should do so again here.

VI. DR. BULLER'S TESTIMONY IS CREDIBLE AND CONSISTENT

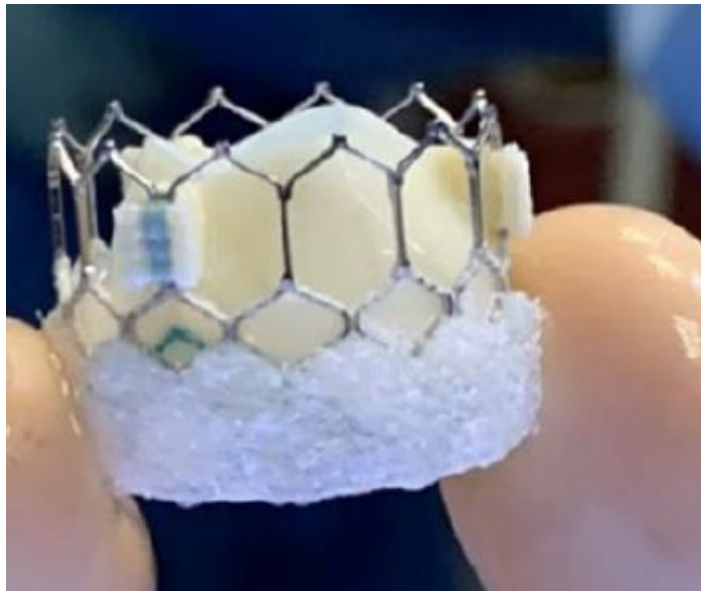
Dr. Buller has provided consistent, credible expert testimony in this IPR. PO fails to show otherwise.

Regarding the "opaqueness" of Spenser II's compressible material, Dr. Buller correctly and consistently testified that he does not judge the density or opaqueness of the compressible material based only on Figure 22. (*See, e.g.*, Ex. 2052, 156:9-12, 160:17-20, 168:9-11; 174:11-14.) Dr. Buller's interpretation of patent drawings comports with Federal Circuit precedent and is consistent with Dr. Brecker's testimony regarding Spenser II's Figure 22. *See, e.g., Hockerson-Halberstadt*, 222

F.3d at 956; (Ex. 1073, 357:11-359:8 (Dr. Brecker testifying he had not made “any assumption” regarding the density of fibers in Spenser II’s compressible material).)

Regarding the S3U valve’s outer skirt, Dr. Buller testified that it would not constitute an outer graft covering, as claimed, because it is porous. (Ex. 2104, 133:7-21.) This testimony is consistent with his testimony that Walther and Spenser II lack an “outer graft covering” because they disclose porous cloths. (Ex. 1104, §§II.B-C; Ex. 2104, 71:16-73:1, 136:10-19.)

During his deposition, Dr. Buller was asked whether he could clearly see the bars of the frame through the outer skirt in the below image:



(Ex. 2104, 98:21-24.) Dr. Buller responded, “I can’t clearly see them. I can see some areas that probably has darkness for bars. So I can’t clearly see the design of the stent.” (*Id.*, 98:25-99:2; *see also id.*, 99:24-100:4.) Dr. Buller’s testimony accurately

describes the image and is consistent with the remainder of his testimony, including his testimony that POSITAs would not draw conclusions regarding translucence/opaqueness based on a single photo because translucence depends on many factors. (Ex. 1104, ¶51.)

Finally, PO criticizes Dr. Buller’s testimony that the collagen fibers in Figure 9 “could be seen as a graft covering, but a loose one.” (Ex. 2052, 154:5-155:1; POR, 95.) First, Dr. Buller appropriately did not limit the density or opaqueness of the claimed fibers based on the patent figures because the ’236 patent does not describe or otherwise limit the density of the collagen fibers. (*See, e.g.*, Ex. 2052, 158:21-25, 161:6-12, 173:1-9.) Second, Dr. Buller was *not* asked whether the collagen fibers in Figure 9 constitute an “outer graft covering” as that term is used in the claims, and he did not testify that they would. Dr. Buller has testified that the collagen fibers would not constitute the claimed “graft covering” because they are not nonporous. (Ex. 1104, ¶18.) This is consistent with Dr. Buller’s testimony regarding the lack of an outer graft covering in Walther and Spenser II.

Accordingly, PO has failed to show that any of Dr. Buller’s testimony is inconsistent or lacks credibility.

**VII. PO FAILS TO ESTABLISH SECONDARY CONSIDERATIONS
OF NONOBVIOUSNESS**

PO's argument that the '236 patent solved a long-felt but unmet need and yield unexpected results merits no weight. (POR, 99-106.) PO raised nearly identical arguments in its Preliminary Response, and the Board properly rejected them. (Institution Decision, 55); *see also Edwards Lifesciences*, IPR2021-01527, Paper 52, at 66-70 (rejecting similar arguments). PO fails to present any evidence establishing the alleged secondary considerations and, therefore, has failed to meet its burden of production. *See, e.g., Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018).

VIII. CONCLUSION

Petitioner has established by a preponderance of the evidence that the challenged claims are unpatentable and, therefore, requests that the Board cancel the claims.

Respectfully submitted,

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Dated: March 13, 2023

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing **PETITIONER’S REPLY TO PATENT OWNER’S RESPONSE**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 5,599 words and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE** and **EXHIBITS 1072 – 1074 and 1104-1113** are being served on March 13, 2023, via electronic mail pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Patent Owner as addressed below:

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