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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.

IPR2022-00034
Patent No. 10,966,846

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1008	U.S. Patent No. 9,393,110 B2 to Levi et al. ("**Levi**")
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1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. ("**Spenser**")
1011	WO 2006/005015 A2 to Spenser et al. ("**Spenser II**")
1012	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach,* Herz, 34:347-56 (2009) ("**Cribier**")
1013	U.S. Patent No. 3,365,728 to Edwards et al.
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1017	Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,* Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020	Yuksel, Uygar, *Balloon-Expandable Transcatheter Aortic Valve Implantation,* Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation,* 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) ("Walther II")
1022	Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients,* 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches,* Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement,* 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) ("Zajarias")

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1025	Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis,* 1006 Circulation 3006-3008 (December 10, 2002)
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1027	Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., *Yarn structure and properties from different spinning techniques*, ("Tyagi")
1029	Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
1030	Cribier, Alain, et al., *Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis,* 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation,* edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)

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1034	Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.
1036	Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems,* Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., *In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry,* EuroIntervention 15:1240-1247 (2020)
1042	Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010)
1043	Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan,* General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations,* J. Endovasc. Ther. 14:347-351 (2007)

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1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. ("**Cribier '321**")
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020
1047	Piazza, Nicolo, et al., *Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve*, Cir Cardiovascular Intervention 1:74-81 (2008).
1048	WO 2011/051043 A1 to Essinger et al.
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1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
1063	Library of Congress subject heading sh85099890
1064	Library of Congress subject heading sh85023143

Exhibit No.	Description
1065	Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach*, Herz, 34:347-56 (2009), obtained from the British Library
1067	Herz MARC Record from the British Library
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1075	Definition of "felt" from Merriam-Webster available at https://www.merriam-webster.com/dictionary/felt.
1076	BD Cardiovascular Fabrics, Surgical Felts, Pledgets and Tapes
1077	Grube, Eberhard, et al., *First Report on a Human Percutaneous Transluminal Implantation of a Self-Expanding Valve Prosthesis for Interventional Treatment of Aortic Valve Stenosis,* Catheterization and Cardiovascular Interventions 66:465-469 (2005).

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1078	Horejs, David, et al., *Normal Aortoiliac Diameters by CT,* J. of Computer Assisted Tomography Vol. 12, No. 4, 602-603 (July/August 1988).
1079	Decision Granting Institution of *Inter Partes* Review in *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2022-00556 (Paper 10, Sept. 8, 2022).
1080	Patent Owner's Preliminary Response in *Edwards Lifesciences Corp. v. Aortic Innovations, LLC,* IPR2022-00556 (Paper 8, June 10, 2022)
1081	Kilic, Teoman, et al., *Transcatheter aortic valve implantation: a revolution in the therapy of elderly high-risk patients with severe aortic stenosis,* Journal of Geriatric Cardiology 14:204-217 (2017).
1082	Joh, Jin Hyun, et al., *Reference Diameters of the Abdominal Aorta and Iliac Arteries in the Korean Population,* Yonsei Med. J. 54(1):48-54 (2013).
1083-1100	Reserved
1101	Linke, Axel, et al., *Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study,* European Heart Journal 35:2672-2684 (2014).

I. INTRODUCTION

Patent Owner's ("PO") arguments to distinguish the prior art rest entirely upon features that are neither disclosed nor claimed in the '846 patent. PO argues that the '846 patent discloses a transcatheter heart valve ("THV") having a "novel outer-seal made of sparsely distributed fibers and without an outer graft." (POR, 1.) According to PO, these "sparsely distributed fibers" enable endovascular delivery of the THV and solve a long felt but unmet need. (*Id.*) Yet, the only remaining challenged claim (Claim 6) merely requires "fibers," not "sparsely distributed fibers." Moreover, the patent specification never uses the term "sparsely distributed fibers" nor provides any information regarding fiber density, sizing, or spacing.

The '846 patent also does not disclose how the fibers allegedly enable endovascular delivery. Aside from using the word "endovascular," the patent provides no dimensions, such as the THV's crimped diameter or the delivery catheter diameter, nor any other guidance regarding how the claimed THV is endovascularly deliverable. To the contrary, the patent discloses that the claimed THV having inner and outer frames has a ***larger*** delivery diameter than the prior art. PO's argument that Petitioner has allegedly not identified specific sizes (e.g., the "crimped diameter") for the combined prior art valves should be rejected given the '846 patent's omission of similar details. Likewise, the Board should reject PO's

arguments that the claimed THV solved a long-felt need, because PO has failed to show either that any valve practices the claimed invention, or that the claimed invention solved paravalvular leak ("PVL").

For these reasons, and those provided below and in the Petition, Petitioner has demonstrated that the remaining challenged claim (Claim 6) is unpatentable.

II. THE ASSERTED PRIOR ART DISCLOSES AND RENDERS OBVIOUS AN ENDOVASCULARLY DELIVERED VALVE

A. PO Improperly Tries To Distinguish The Prior Art Based On Unclaimed And Undisclosed Features

The Board preliminarily determined that Claim 6 is unpatentable in view of at least Walther or Spenser II in combination with Levi. (D.I. 31-43.) PO argues these prior art combinations, in addition to combinations of Spenser/Cribier with Walther/Spenser II, would not yield a valve capable of endovascular delivery. (POR, 11-54.) However, PO's argument improperly relies on unclaimed and undisclosed features that, under *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013), cannot form the basis for finding the '846 patent nonobvious.

PO argues that endovascularly-deliverable THVs with outer seals comprised of outwardly extending fibers to prevent PVL were unknown in the prior art, and that combinations of prior art seals and THVs would have been inoperable for

endovascular delivery. (POR, 11-13.) Yet, as the Federal Circuit stated in *Smith & Nephew,* "This naturally raises the question of how [PO] managed to make such a combination work" for endovascular delivery. *Smith & Nephew,* 721 F.3d at 1381. PO argues that an endovascularly-deliverable valve was only possible by using an outer seal with a "sparse distribution of fibers." (Ex. 2051, ¶39; POR, 1, 6-12, 49.)

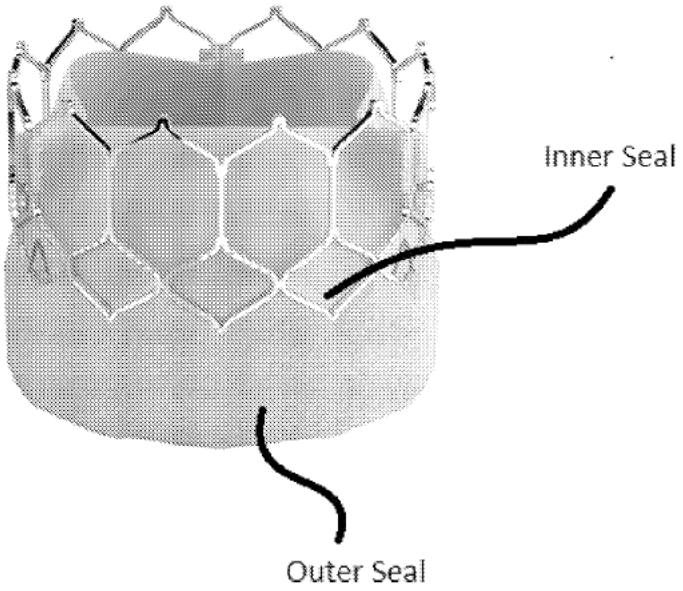
However, the '846 patent does not claim or disclose an outer seal with a "sparse distribution of fibers." Indeed, the '846 patent does not disclose or claim ***any*** sizing, density, or arrangement of fibers; the specification merely discloses that the fibers are "attached" to the frame.[1] (Ex. 1001, 18:2-25.) PO's expert, Dr. Brecker, confirmed that the patent does not provide any numerical measurements for the fibers. (Ex. 1073, 318:2-11.) When asked to further define a "sparse distribution of fibers," Dr. Brecker merely referenced drawings in the patent and argued that the fibers appeared "countable." (*Id.*, 315:19-319:20; *see also infra,* §III (Dr. Buller testified that prior art seals were conceptually the same as the '846 patent).) He could not provide any information on how dense or spaced-apart the fibers needed to be to

[1] PO criticizes Petitioner for not providing exact crimped profiles for the prior art combinations. (POR, 13.) But the '846 patent does not disclose the crimped profile for any of its embodiments, much less the claimed embodiment that includes fibers and both inner and outer frames.

qualify as a "sparse distribution" because the '846 patent provides no such information.

Further, PO never requested a claim construction for "fibers" or "endovascularly" that includes density or sparsity. PO undoubtedly recognized that such a construction would be too vague and unquantifiable to satisfy the definiteness requirement and would have insufficient support to satisfy the written description requirement. Because PO has not proposed any construction that includes density or sparsity, PO's arguments to distinguish the prior art on this basis are irrelevant.

PO's arguments are further weakened by the '846 patent's prosecution history. During prosecution, PO argued that Petitioner's SAPIEN 3 Ultra THV "appears to be covered by the claimed invention." (Ex. 1002, 145-146.) However, as shown by the below figure submitted by PO during prosecution, SAPIEN 3 Ultra has a dense, fibrous PET outer skirt (labeled "outer seal") and not a "sparse distribution" of fibers.



(*Id.*, 146; *see also* Ex. 2052, 227:18-228:2 (testifying SAPIEN 3 Ultra's outer skirt is similar to Spenser II).) While PO argues the differences between the '846 patent's fiber density and Walther/Spenser II are meaningful, PO ignores these same differences in the SAPIEN 3 Ultra.

The patent figures alone cannot support the importation of a "sparse distribution" of fibers into the claims, because nothing in the patent indicates that the figures are to-scale or accurately represent the arrangement of fibers necessary to enable endovascular delivery. *See Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.").

Indeed, the ’846 patent does not disclose that the claimed valve assembly having inner and outer frames and outwardly extending fibers can be endovascularly delivered. The patent merely states that the dual-frame valve assembly is implanted by “a stiff wire . . . passed through the aortic valve 202 and into the left ventricle 204” and “[t]he delivery system for the valve component 412 is then passed through the valve 202.” (Ex. 1001, 19:23-26; *see also id.*, 6:43-47 (explaining the “transcatheter valve” embodiments are in Figs. 17-22).) This description does not mention endovascular delivery and applies equally to non-endovascular delivery, such as direct-aortic procedures, which Dr. Brecker characterized as a “very important” implant route prior to 2012 that surgeons “quite like[d].” (Ex. 1072, 127:12-135:1.) Notably, the description of the claimed dual-frame valve assembly stands in stark contrast to the descriptions of other embodiments, which lack fibers and dual frames but are described as being endovascularly delivered through a patient’s femoral artery. (*See e.g.,* Ex. 1001, 17:9-37 (describing that the embodiment in Figures 17-19 includes only a single balloon-expandable frame 34).)

Further, the few dimensions provided in the ’846 patent reveal that the claimed dual-frame valve would have a ***larger*** crimped diameter than the prior art. Figure 13 depicts the outer frame in the expanded configuration and the inner frame in the “unexpanded position.” (Ex. 1001, 5:56-58, 14:13-18, Fig. 13.)

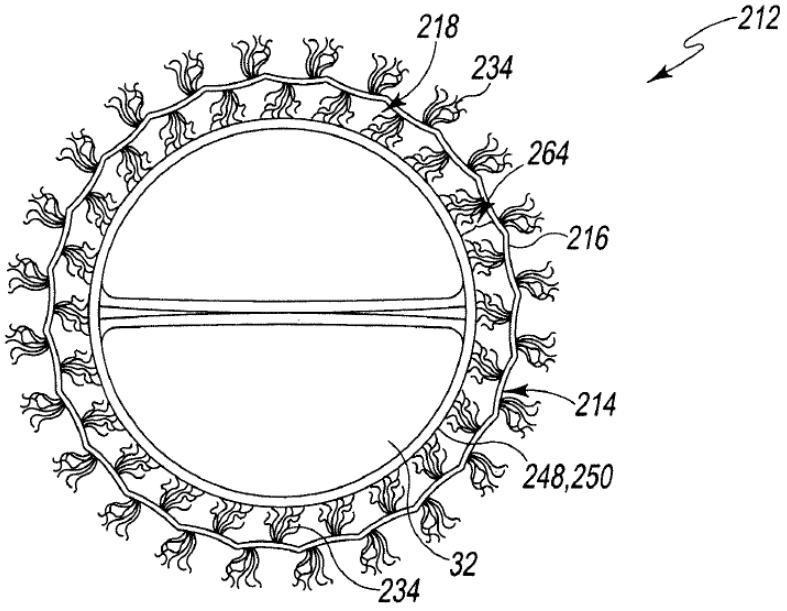


Fig. 13

The patent explains that the expanded diameter of the outer frame is approximately 26mm and the gap 264 between the expanded outer frame and unexpanded inner frame is "about 2 mm to about 3 mm." (*Id.*, 13:62-64, 14:16-18.) Applying a 3mm gap to the left and right sides of the valve means that the "***unexpanded***" inner frame has a diameter of approximately 20mm (or ***60F***). This is ***much*** larger than any of the cited prior art. (*See e.g.,* POR 18 (alleging Walther is delivered through a 33F catheter).)

Therefore, as in *Smith & Nephew*:

> The problem with [PO's] argument is that it is contending that [combining prior art fibrous seals with prior art THVs] would be inoperative to obtain [endovascular delivery], while at the same time

> claiming that it managed to achieve exactly that objective, all through the *deus ex machina* of a [seal with a "sparse distribution" of fibers]. But an unclaimed and undisclosed feature such as the [sparse distribution of fibers] cannot be the basis for finding [PO's] patent to be non-obvious over the prior art.

Smith & Nephew, 721 F.3d at 1381.

B. <u>PO Ignores The Compressibility Of Walther And Spenser II's Cloths</u>

PO's argument that combinations involving Walther and Spenser II would not render Claim 6 obvious depends on Dr. Brecker's erroneous calculations, which completely ignore the compressibility of Walther's PET outer cloth and Spenser II's "compressible material." For example, in his "rough estimate" of the crimped profile of Spenser II's compressible material, Dr. Brecker's calculation expressly relies on the "uncompressed Spenser II outer cloth." (Ex. 2051, ¶63; *see also* Ex. 1073, 350:16-21; Ex. 1072, 191:15-192:5 (Dr. Brecker testified he did not conduct any research on the compressibility of PET fabrics).) This is a critical error that undermines the reliability of both Dr. Brecker's and PO's analysis.

Spenser II discloses that its outer seal is "compressible" and teaches that its solutions are intended for percutaneously delivered valves. (Ex. 1011, Abstract, [00145].) Dr. Buller also testified that POSITAs would have understood that Walther's outer cloth was "very compressible," and POSITAs would have understood that the compressibility of Walther's cloth and Spenser II's compressible

material would result in much thinner profiles when the valve is compressed for delivery. (Ex. 2052, 102:22-103:15, 104:5-24, 123:19-25, 181:14-18.) Thus, PO's calculations of Walther and Spenser II's dimensions, and PO's repeated characterizations of Walther's and Spenser II's materials as "bulky" or "thick," ignore the teachings of the references and are entitled to no weight.

Dr. Buller's testimony is corroborated not only by Walther and Spenser II, but by other prior art, such as U.S. Patent No. 7,921,678 ("Norris"), which discloses a "compressible resilient fabric" that can be used "in vascular and endovascular implants such as stents, stent-grafts, and heart valves." (Ex. 1074, 10:45-49.) Norris discloses that in some embodiments, its fabric can have a non-compressed thickness of about 1-5mm (the same dimensions as Spenser II's compressible material), and when compressed, the fabric can have a thickness of about 0.004-0.008 inches (i.e., 0.1016 – 0.2032mm), roughly 10-25 times thinner than its uncompressed thickness. (*Id.*, 4:54-58.) Because Norris describes fabrics intended for use with endovascular-deliverable heart valves, Norris would have reinforced a POSITA's reasonable expectation that Walther's outer cloth and Spenser II's compressible material would be compatible with an endovascularly-delivered THV.

PO's argument that Walther and Spenser II's cloths would "bunch" like the device in the non-prior art Russell article is without merit. First, Russell is not prior

art and it would have been unknown to a POSITA at the priority date. Second, Russell's outer cloth is ***not*** a compressible PET fabric; it is a dense, matted felt material. (Ex. 2009, 1440; *see also* Ex. 1075 (defining felt); Ex. 1076 (distinguishing "cardiovascular fabrics" from Russell's "surgical felt").) Russell describes a ***surgical mitral valve*** replacement procedure, not a TAVR procedure, and the selection of dense felt reflects the significant differences between those procedures. (*See* Ex. 2009, 1442-43; *see also* Ex. 1072, 186:8-187:12, 188:9-191:14, 195:6-198:19.) Indeed, Russell discloses that the modified valve does not need to be "fully crimped" for the procedure. (Ex. 2009, 1442-43.)

Moreover, Russell's felt was not meant to compress and expand to fill gaps between the valve and the native tissue like Walther and Spenser II; it merely provides a sturdy base for suturing the Russell valve to the patient's native mitral valve. (Ex. 2009, 1443, Fig. 4F; *see also* Ex. 1072, 197:9-198:19; Ex. 1076 (surgical felt is a suture "buttress").) Dr. Brecker did not address these material differences between Russell and the TAVR valves in Walther and Spenser II and admitted that he did not consider the manufacturing or lack of compressibility of Russell's felt. (Ex. 1072, 191:5-192:5.) Thus, PO has failed to show that the alleged "bunching" in Russell's device would occur with the compressible PET cloths in Walther and

Spenser II or that such "bunching" would make them unsuitable for endovascular delivery.

Additionally, like the POPR, the POR erroneously focuses entirely on the bodily incorporation of Walther's outer cloth or Spenser II's compressible material onto the valves disclosed in Cribier, Spenser, and Levi. (*See* D.I. 42-43.) As explained in the Petition and by Dr. Buller, even if bodily incorporation of Walther's outer cloth or Spenser II's compressible material would not be suitable for endovascular delivery, POSITAs would have had access to a range of suitable cloths and could have selected an appropriately dimensioned cloth for endovascular delivery. (Petition, 40, 68; Ex. 1003, ¶¶153, 222.) The prior art demonstrates the range of cloths and outer sealing materials that were known, including fabrics that are highly compressible to minimize valve profile. (*See, e.g.,* Ex. 1011 [00055], [00145]; Ex. 1008, 13:49-53; Ex. 1007, 1021; Ex. 1017, 1-2; Ex. 1074, 4:54-58, 10:45-49; Ex. 2056, [0033]-[0034].) Even the non-prior art Russell article demonstrates that those in the art knew how to select different types of fabrics for outer sealing materials for different types of applications. (Ex. 2009, 1443.)

PO does not dispute that POSITAs would have had access to a variety of suitable cloth materials and could have utilized the many methods described in Levi to reduce crimp profile. Instead, PO consistently underestimates the skill level and

ingenuity of a POSITA. PO's low standards for the POSITA are particularly suspect in view of the high standards PO wants applied to Dr. Buller. In reality, a POSITA, as defined by either party, would not have immediately given up if the dimensions of Walther's or Spenser II's materials were slightly too large for a specific type of delivery. Rather, a POSITA would have found it obvious to try the available cloth fibers and tools in Levi to resolve a straightforward sizing problem.

PO's argument that Petitioner relies on hindsight is incorrect. (POR, 33.) The prior art expressly disclosed using fibrous outer sealing materials in THVs to reduce PVL and promote tissue ingrowth. (Ex. 1003, ¶¶114, 189, 265-270.) The prior art also disclosed adding sealing materials to valves intended for endovascular delivery. (*See e.g.,* Ex. 1003, ¶¶148-154, 218-220, 305-306 (describing Walther/Spenser II/Levi valves).) Levi also teaches many features to reduce the valve's crimped profile to accommodate an outer skirt or another "additional component" on the outside of the valve, including modifying the frame wall thickness, cell shape, and material. (*Id.*, ¶¶309-312.) Levi's additional features reduced the valve's crimped diameter but had nothing to do with the selection of the outer skirt or its properties. Additionally, the prior art also disclosed that in 2012, endovascular delivery was preferred to other more invasive delivery routes, such as trans-apical. (*Id.*, ¶152.) Given these ample teachings, POSITAs would have been motivated to combine the

endovascularly delivered THV with the known fibrous outer seals. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015); *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc).

C. PO Fails To Rebut Evidence That POSITAs Could Endovascularly Deliver THVs Via The Common Iliac Artery

PO incorrectly asserts that POSITAs would not have delivered a THV with a fibrous outer seal via a patient's common iliac artery. Ironically, PO ignores that the '846 patent itself corroborates delivery through the "iliac arteries or an iliac conduit." (Ex. 1001, 10:44-47.) Kainuma also provides objective evidence that delivery through the common iliac artery was performed successfully. (Ex. 1043, 2; *see also* Ex. 1077, 465-467 (successful delivery through the common iliac artery).) Because some patients were not eligible for transfemoral delivery due to disease or having naturally smaller femoral arteries, delivery through the common iliac artery provided a preferable alternative for such patients. (Ex. 1044, 347; Ex. 1043, 2.)

PO criticizes Kainuma because the delivery sheath used in the procedure measured 22F. Kainuma used the 22F sheath to deliver the SAPIEN valve because that was the sheath used for delivering SAPIEN at the time. POSITAs would not have concluded from Kainuma that 22F was the maximum diameter sheath that the common iliac artery could accommodate. (Ex. 1003, ¶¶148-154.) To the contrary,

POSITAs would have been aware that the common iliac artery has a generally larger diameter than the common femoral artery and could therefore accommodate a device with a larger crimped diameter. (*See* Ex. 1078, 602-603 (demonstrating iliac arteries larger than femoral arteries); Ex. 1082, 51 (confirming size of iliac arteries).)

PO's criticisms of Craido are equally unavailing. Craido discloses that "[i]liac access conduits are valuable tools to facilitate ***endovascular*** arterial access in a number of clinical situations that tend to share 2 things in common: the presence of small and/or diseased (calcified) femoral and external iliac arteries (EIA) and the need for introduction of a large-bore sheath or catheter, size ≥ 22-F, in the majority of cases." (Ex. 1044, 347 (emphasis added).) Craido thus confirms that larger devices, such as those requiring ≥ 22F sheaths, may be delivered via the iliac artery. Craido also teaches that "the basic procedural requirements [for access via the iliac artery] tend to be straightforward from a surgical perspective," further confirming such delivery as a viable option. (*Id.*, 348.)

Dr. Brecker's characterization of delivery through the common iliac artery as "perverse" is also flatly contradicted by his own articles. (Ex. 2051, ¶69.) For example, a prior art publication co-authored by Dr. Brecker expressly discloses TAVR implantations "via the iliac approach." (Ex. 1101, 2674.) The article does not include any disclosure that the implantations were unsafe.

III. DR. BULLER'S DEPOSITION TESTIMONY WAS FACTUALLY AND LEGALLY CORRECT

PO's allegation that Dr. Buller's testimony was "implausible on significant matters" is incorrect. (POR, 47.) Dr. Buller repeatedly explained that he does not interpret a patent drawing of a single embodiment to limit the dimensions of an outer seal, such as those disclosed in Spenser II or the challenged patents. (*See, e.g.*, Ex. 2052, 174:11-14 (testifying Figure 11 of the '846 patent "is a diagram. I don't think it is limiting or really teaching the density of fibers that you would achieve on an actual device. It's a diagram."); *see also id.*, 156:9-12, 160:17-20, 168:9-11; 174:11-14.) Dr. Buller's interpretation of patent drawings comports with well-settled Federal Circuit precedent. *See, e.g., Hockerson-Halberstadt,* 222 F.3d at 956.

Dr. Buller correctly explained that "[t]here is no requirement on the exact density and how opaque or...not opaque these things are in either of the[] teachings" of Spenser II or the challenged patents. (Ex. 2052, 158:22-25; *see also id.*,160:17-20, 161:6-12, 167:2-9, 168:9-11.) Notably, Dr. Brecker appears to agree, as he testified that he had "not made a quantitative assessment of how many fibers there are on Spenser II" and had not made any "assumption" beyond Spenser II's description of the compressible material. (Ex. 1073, 357:11-359:8.) Dr. Buller also correctly explained that Spenser II's "compressible material" in Figure 22 teaches

the same concept as the figures of the challenged patents, as both figures disclose fibers disposed on the outside of the frame and do not otherwise limit the fiber arrangement or density. (Ex. 2052, 158:2-7.) Dr. Buller's refusal to adopt PO's unsupported characterization of the '846 patent as having "sparsely distributed fibers" was proper, not discrediting.

PO also misrepresents Dr. Buller's testimony by incorrectly asserting that "[b]oth experts agree that the Patent teaches an outer seal formed of a relatively sparse distribution of outwardly extending fibers that was unlike any they had seen in the prior art." (POR, 48.) Dr. Buller made no such statement and did not agree that the challenged patents teach a valve with a "sparse distribution" of fibers. To the contrary, Dr. Buller repeatedly explained that a POSITA cannot draw limiting conclusions regarding the dimensions of fibers from a patent drawing of a single embodiment. (Ex. 2052, 156:9-12, 160:17-20, 168:9-11.) Dr. Buller also explained that the challenged patents fail to inform a POSITA on the "density of the fibers, the width of the fibers, [or] the length of the fibers," and thus there is "no teaching that allows you to come to any real conclusion about what [the valve] would collapse down to." (*Id.*, 173:1-9, 174:11-14.)

IV. DR. BULLER IS A POSITA

In an effort to discredit Dr. Buller's testimony, PO proffers an overly narrow definition of a POSITA that is inconsistent with the evidence. For example, PO argues that a POSITA must have been an interventional cardiologist who implanted TAVRs in the 2010-2012 timeframe. (POR, 95.) However, Dr. Brecker testified that several individuals ***other than*** the implanting cardiologist, such as cardio-vascular surgeons, imaging cardiologists, and ICU doctors, were also involved in TAVR procedures, including determining which valve to implant. (Ex. 1072, 125:3-127:2.) PO fails to explain why a POSITA should not encompass the "multidisciplinary team" involved in TAVR procedures. The Board should adopt Petitioner's proposed definition of a POSITA because it more accurately captures the level of ***ordinary*** skill in the art.

Moreover, the Board has previously rejected similarly baseless attacks against Dr. Buller's qualifications and found him qualified to provide opinions regarding similar subject matter. *Edwards Lifesciences Corp. v Boston Scientific Scimed, Inc.*, IPR2017-00060, Paper 64, at 4. Like this case, IPR2017-00060 (the "Boston IPR") involved a patent directed to "methods and apparatus for endovascularly replacing a patient's heart valve," and Drs. Buller and Brecker were experts on opposite sides

of the case.[2] *Id.* The patentee in the Boston IPR also argued that Dr. Buller lacked "experience in the relevant technologies" because "he has never performed a valve replacement procedure and has never implanted stent grafts." *Id.* at 10. The Board rejected these arguments, noting that the patentee "fail[ed] to provide a persuasive justification for why the fact that Dr. Buller has never performed a valve replacement procedure and has never implanted stent grafts matters, such that Dr. Buller's testimony should be given 'little or no weight.'" *Id.* PO has similarly failed to provide any such justification here.

Dr. Buller is a highly-respected cardiologist with over 25 years of practice, and has conducted or directly supervised more than 8,000 diagnostic and therapeutic non-surgical catheterization procedures. (Ex. 1003, ¶¶6-7.) Given his extensive qualifications, the Board has already found Dr. Buller qualified to offer expert opinions on nearly identical subject matter. *Edwards Lifesciences Corp.*, IPR2017-00060, Paper 64, at 11. The Board should do so again here.

[2] Notably, the Board credited Dr. Buller's testimony over Dr. Brecker's testimony in the FWD. *See e.g., Edwards Lifesciences Corp.*, IPR2017-00060, Paper 64, 27, n.10.

V. THE PRIOR ART DISCLOSES AN OUTER SEAL "FREE OF AN OUTER GRAFT COVERING"

The challenged claim requires the outer seal to be "free of an outer graft covering between the fibers and the outer frame." (Ex. 1001, claim 1.) As explained in the Petition, Walther and Spenser II satisfy this limitation because their outer cloths are free of an outer graft covering. (Petition, 30-31, 52-59.) PO's arguments to the contrary are unsupported. There is no dispute that Walther and Spenser II ***do not*** describe an outer graft covering and that the outer cloths look homogeneous and are described as being formed from a single material (i.e., PET and a "compressible material"). (*Id.*)

Lacking any contrary evidence, PO resorts to demonstratives using a highly-magnified figure in Walther to allegedly depict a "dense PET layer." (POR, 78.) PO's demonstrative is unauthenticated and uncorroborated. Dr. Brecker confirmed during his deposition that he did not create the image and did not know the alleged level of magnification. (Ex. 1073, 351:2-352:6.) Moreover, Dr. Brecker admits to speculating about the demonstrative, stating, "if we magnify Walther's Figure 1, we can identify what ***appears to be*** the dense woven PET base layer…." (Ex. 2051, ¶136 (emphasis added).) While the demonstrative images are so heavily blurred and

pixelated that they are not reliable, the images still show the outer fibers directly abutting the frame as demonstrated in the Petition. (Petition 30-31.)

PO provides even less argument with respect to Spenser II. PO argues that Spenser II's compressible material includes multiple layers. (POR, 83.) However, Spenser II directly contradicts that argument by disclosing, "***a layer*** of compressible material 256 is disposed along an outer surface of the stent structure 252." (Ex. 1011, [00145] (emphasis added).) PO also argues that the "fibers extending from the surface of the material" must be separate from the alleged dense layer. (POR, 81-83.) However, as the Board has previously noted, "it is far from evident to us from the schematic Figure 22 of Spenser II that the 'dense PET layer' is 'distinct from the fibers on top of it.' Figure 22 does not clearly show any such demarcation within the structure of the compressible material." (Paper 22, 9-10.) To the contrary, Spenser II describes the compressible material as "a layer" that is made of a single material, PET. (Ex. 1011, [00145].)

PO also argues that the prior art outer cloths are analogous to carpet. (POR, 77.) However, this analogy actually supports Petitioner's position that there is no "base" layer in Walther or Spenser II. In carpet, the base and pile fabric are ***different*** materials creating a clear line of demarcation. (*Id.*) The cloths of Walther and

Spenser II are all the ***same*** material (PET) and, thus, do not have a separate "base" layer like carpet. (Ex. 1007, 1121; Ex. 1011, [00145].)

PO also argues that the Examiner agreed, "that Hartley's band of velour material is not 'free of an outer graft covering.'" (POR 75-76; *see also id.,* 70.) This is not correct. The Examiner found that Hartley did not satisfy all of the limitations of the claim. (Ex. 1002, 20.) The Examiner did not specifically determine that Hartley's velour material was not free of an outer graft covering. (*Id*.)

The prosecution history also contradicts PO's argument on this limitation. There, PO argued that Petitioner's SAPIEN 3 Ultra THV "appears to be covered by the claimed invention." (Ex. 1002, 145.) Yet, PO now asserts that any velour-like PET fabric includes an "outer graft covering" between its extending fibers and the frame, and also suggests that an opaque outer seal cannot satisfy this limitation. (*See* POR, 9-10, 49-53, 75-89; *see also* Ex. 1073, 338:10-340:21.) But this is the structure of the outer skirt on Petitioner's SAPIEN 3 Ultra, which is a velour-like PET fabric and opaque. (*See e.g.,* Ex. 2026, 8-9.) PO's contradictory arguments are improper.

VI. PO FAILS TO ESTABLISH SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

PO argues that the '846 patent solved a long-felt but unmet need for an endovascularly delivered THV that addressed PVL by disclosing a THV with an

outer seal of "sparsely distributed fibers" that is free of an "outer graft covering." (POR, 3-11.) PO's argument is legally and factually deficient for several reasons.

A. PO Has Not Provided Any Objective Evidence That The '846 Patent Solved An Alleged Long-Felt Need

PO "bears the burden of production with respect to evidence of secondary considerations of nonobviousness." *Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018). PO fails to meet that burden because it has not provided ***any*** objective evidence that the valve disclosed and claimed in the '846 patent reduces or prevents PVL.

The Board has already dismissed PO's secondary-considerations arguments in its decision to institute IPR of the related '236 patent. (Ex. 1079, 54-55.) There, the Board noted:

> Virtually all of Patent Owner's arguments with respect to its meeting a long-felt unmet need derive support from arguments made by Patent Owner (the then-Applicant) during the prosecution of the '236 patent, arguments which are necessarily, of their very nature, self-serving. . . . Patent Owner presents no evidence that its valve met a need that had not been previously met by the prior art (i.e., by the art upon which Grounds 1–6 are based, particularly Walther and Spenser II.)

(*Id.*, 55). The same is true here. The POR provides no additional evidence or arguments beyond the rejected arguments from the '236 IPR. (*Compare* Ex. 1080, 2-12, *with* POR, 1-11.)

As in the ’236 IPR, PO has not identified any evidence that a THV with “sparsely distributed” fibers attached to the outside of the frame would reduce or prevent PVL. *See e.g., Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1333 (Fed. Cir. 2009). PO does not even identify the existence of any such valve, much less cite any tests demonstrating the valve reduces PVL. Dr. Brecker makes a conclusory assertion that the “sparsely distributed” fibers shown in the patent’s figures “address PVL,” but he does not cite to any objective evidence supporting this bare conclusion. (Ex. 2051, ¶38.) Indeed, Dr. Brecker testified that he has never seen, much less implanted, ***any*** valve that is designed like the valves disclosed in the ’846 patent. (Ex. 1073, 308:5-309:21, 312:10-19.)

Nor is it inherent that the allegedly “sparsely distributed” fibers in the patent’s figures would create a seal that prevents PVL, as even Dr. Brecker characterized such a result as “counter-intuitive.” (Ex. 2051, ¶39; Ex. 1073, 330:11-334:4.) Dr. Brecker also testified that POSITAs are often mistaken about how a particular aspect of a valve will function before actually testing the valve, and that he didn’t know whether a POSITA could determine whether fibers would be too sparsely distributed to prevent PVL based on a visual inspection. (Ex. 1073, 332:19-334:13.)

The only data regarding PVL that PO cites allegedly relates to a comparison between the mild PVL rates for Petitioner’s SAPIEN 3 and SAPIEN 3 Ultra THVs.

(POR, 5.) However, PO provides no objective evidentiary support for the alleged PVL rates. (*Id.*) PO does not cite to any publication that discloses the mild PVL rates, but rather cites to attorney argument made during prosecution of the '846 patent. (*Id.*) During prosecution, PO asserted that SAPIEN 3 had "mild PVL in 22.3% of cases, whereas, the Ultra had in only 7.2%." (Ex. 1002, 145.) However, the article relied upon for this statement does not disclose the cited PVL numbers, and it does ***not even mention*** SAPIEN 3 Ultra. (*See* Ex. 1081.)

Notably, however, the article ***does*** disclose that "trace and mild PVL after TAVI is often considered to be acceptable and benign." (*Id.*, 210.) Thus, even if PO's unsupported mild PVL rates are assumed to be true, PO fails to explain how reduction in an "acceptable and benign" level of PVL demonstrates that the '846 patent solved a long-felt but unmet need. (*See* Ex. 1072, 224:16-21 ("And I think our feeling now is, for the majority of patients, mild PVL doesn't -- really mild or trace -- doesn't matter…."), 231:7-232:22.)

Moreover, the article also establishes that moderate and severe PVL had been addressed by solutions ***other than*** "outwardly extending" fibers. (*See* Ex. 1081, 210 (listing features that decrease PVL).) In this regard, Dr. Brecker testified that "a lot of factors" contribute to resolving PVL, including the sizing of the valve, the implant depth, the patient's anatomy, whether the valve is bicuspid or tricuspid, and radial

force of the valve. (Ex. 1072, 209:18-220:17.) At the very least, the evidence reflects that addressing PVL was not as simple as adding "outwardly extending fibers" to the outside of the valve; it required a multitude of design changes and considerations that are not claimed in the '846 patent and were not novel in 2012. Indeed, when asked during his deposition to identify the factors that contributed to whether PVL occurs with a THV, Dr. Brecker stated that there were "a lot of factors" but tellingly ***did not*** identify the presence of radially or outwardly extending fibers as one of those factors. (*Id.*) Even the '846 patent discloses that PVL is prevented by "combined engagement of the frames 218, 416 [which] seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage." (Ex. 1001, 19:41-43.)

B. <u>PO Has Not Established A Nexus Between SAPIEN 3 Ultra And The Challenged Claim</u>

"In order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have a 'nexus' to the claims, i.e., there must be 'a legally and factually sufficient connection' between the evidence and the patented invention." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal quotations omitted). PO bears the burden of proving a nexus. *Id.* To the extent PO is attempting to rely on Petitioner's

SAPIEN 3 Ultra THV as evidence of secondary considerations, PO has not established a nexus between SAPIEN 3 Ultra and the challenged claim.

PO has not attempted to prove that SAPIEN 3 Ultra embodies the claimed features of the ’846 patent and is coextensive with them, so PO is not entitled to a presumption of nexus. *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018). PO also has not attempted to show that SAPIEN 3 Ultra’s performance is a “direct result of the unique characteristics of the claimed invention.” *Fox Factory, Inc.*, 944 F.3d at 1373-74 (internal quotations omitted). To the contrary, PO attempts to distinguish the asserted prior art on the basis that the outer seals taught by the prior art were “opaque due to density” and included “graft coverings.” (*See* POR, 9-10, 49-53, 75-89.) Yet, SAPIEN 3 Ultra’s outer skirt is also opaque and made of a knitted PET velour fabric, which PO has repeatedly asserted constitutes an “outer graft covering.” As the claims specify the absence of such a covering, PO cannot have it both ways. (*Id.*; Ex. 1002, 146.)

Because PO has not carried its burden to establish a nexus, to the extent PO is relying on SAPIEN 3 Ultra as evidence of secondary considerations, the Board should not afford PO’s arguments any weight.

VII. CONCLUSION

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

Respectfully submitted,

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Dated: October 3, 2022

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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 5,591 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 – 1082 and 1101** are being served on October 3, 2022, 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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