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On behalf of **Edwards Lifesciences Corporation and
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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.

IPR2023-01151

Patent No. 11,337,834

**PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S
PRELIMINARY 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	Reserved
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	Reserved
1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.
1016	Reserved

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1017	Cheung, Anson, et al., <i>Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human</i> , 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.
1020-1021	Reserved
1022	Smith, Craig R., et al., <i>Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients</i> , 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., <i>Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches</i> , Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Reserved
1025	Cribier, Alain, et al., <i>Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis</i> , 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al.
1027-1029	Reserved
1030	Cribier, Alain, et al., <i>Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis</i> , 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)

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1034	Andersen, Henning, et al., <i>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</i> , European Heart Journal, 13:704-08 (1992)
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1036	Nietlispach, Fabian, et al., <i>Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems</i> , Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
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1046	Preliminary Amendment for Patent Application No. 17/096,253 Submitted November 30, 2020
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	Reserved
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1074	U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)
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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”)
1107	Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)

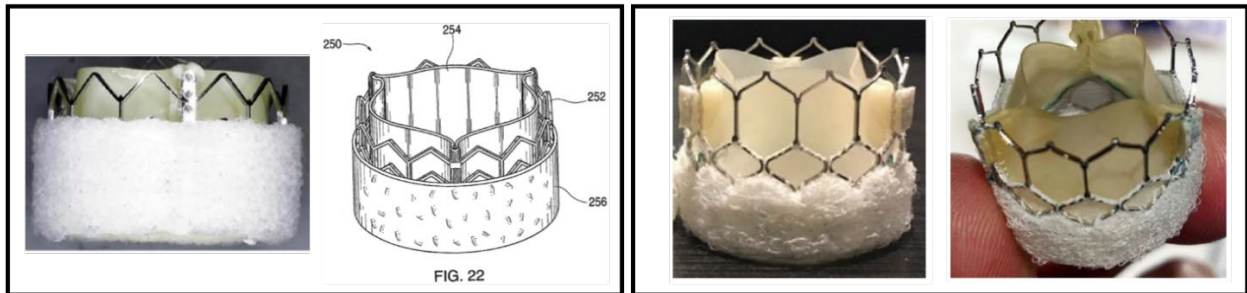
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1108	Jonas, Richard A. et al., <i>Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments</i> , 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”)
1109	Ko, Frank K., <i>Fabrics</i> , Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”)
1110	Pourdeyhimi, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyhimi”)
1111	Scott, Steward M. et al., <i>A Collogen Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)
1112	Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”)
1113-1115	Reserved
1116	U.S. Patent Pub. No. 2002/0151958 to Chuter (“ Chuter ”)
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1122	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Dkt. 13, Second Amended Complaint (Apr. 10, 2023)
1123	Aortic Innovations LLC’s Disclosure of Asserted Claims and Infringement Contentions, C.A. No. 1-23--CV-00158 (JPM) (“PO Infringement Contentions”)
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1125	U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment
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1127	U.S. Pat. No. 5,102,417 to Palmaz
1128	Deposition Transcript of Dr. Nigel Buller from November 11, 2012
1129	C. C. Chu, <i>Understanding Implantable Textiles</i> , Advanced Textiles Source (May 21, 2018) (“Chu”)
1130	“Distinct,” Merriam Webster Online Dictionary, <i>available at</i> https://www.merriam-webster.com/dictionary/distinct
1131-1138	Reserved
1139	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dat. 83, Plaintiff Aortic Innovations’ Opening Claim Construction Brief (Nov. 21, 2021)
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1145	Declaration of Dr. Stephen J.D. Brecker Regarding Claim Construction submitted in Case No. 1-23-cv-00158 (D. Del.)
1146	Deposition Transcript of Stephen Brecker from February 8, 2023
1147	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Aortic Innovations LLC's Identification of Preliminary Claim Constructions and Evidence (Oct. 13, 2023)
1148	Amendment for U.S. Patent App. No. 17/213,251 submitted May 17, 2022
1149	Amendment for U.S. Patent App. No. 17/469,391 submitted May 18, 2022

PO asserts inconsistent constructions of “spacings” before the Board and the district court. In this IPR, PO argues that disclaimers during prosecution require a narrow construction that excludes the fibrous cloths on the prior art valves (below left). Yet, in the district court, PO argues that it made no disclaimer, and that the plain and ordinary meaning should apply so that the claims encompass the fibrous cloth on Petitioner’s SAPIEN 3 Ultra valve (below right).

Prior Art (Walther and Spenser II) Accused Product (SAPIEN 3 Ultra)



“A patent may not, like a ‘nose of wax,’ be twisted one way to avoid [invalidity] and another to find infringement.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (internal quotation omitted); *see also Ericsson v. Intellectual Ventures II LLC*, IPR2014-00915, Paper 37 at 8 (P.T.A.B. Dec. 7, 2015) (criticizing inconsistent positions). Yet, that is what PO is doing here. PO’s transparent attempt to construe “spacings” to exclude whatever is in the prior art but include the accused product is improper.

While PO resists the plain and ordinary meaning of “spacings” in this IPR, PO never affirmatively offers an alternative construction. Nor can it because the

'834 patent specification does not even include the term “spacings.” PO introduced the term during prosecution and relied on the '834 patent figures alone for written description support. (Ex. 1002, 1000.) However, the figures are not to scale and, therefore, cannot narrow the claim scope. PO also argued during prosecution that the prior art cloths do not have “spacings.” Yet, PO and its expert have now conceded that all cloths have spacings between their fibers. PO never explains why the spacings in the prior art cloths are outside the claims but the spacings in the SAPIEN 3 Ultra cloth are covered. Here, the Board should apply the plain and ordinary meaning of “spacings” because it is the only affirmative definition offered in this IPR and PO has advocated for this construction in the district court.

I. PO’S INCONSISTENT POSITIONS ON “SPACINGS”

In this IPR, PO argues that “[t]he Applicant’s specific identification of Spenser II’s compressible material as *not* disclosing ‘spacings’ operates as a disclaimer.” POPR, 11 (emphasis in original).¹ For support, PO cites attorney arguments made during prosecution purportedly contrasting the fibers in the '834

¹ While PO’s arguments can constitute a disclaimer in subsequent proceedings, such as district court litigation, PO’s arguments do not create a binding disclaimer in this IPR. *Cupp Computing AS v. Trend Micro Inc.*, 53 F.4th 1376, 1383 (Fed. Cir. 2022).

patent's figures with Walther and Spenser II. *Id.* at 9. PO's argument fails.

First, PO and its expert, Dr. Brecker, propose a contrary construction in district court. There, PO asserts that "spacings" should be given its plain and ordinary meaning, and Dr. Brecker declared with respect to the "spacings" limitation, "I did not see any disavowal or disclaimer in the specification, claims, for [sic] the prosecution history requiring that all sleeves, layers, and cloths be excluded from the term 'spacings.'" Ex. 1147 at 44-47; Ex. 1145 at ¶92.

The Board has repeatedly applied patent owners' district court constructions in IPRs. *10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00087, Paper 9, at 9-10, 15-19 (P.T.A.B. Apr. 27, 2020); *Nintendo Co. v. Gamevice, Inc.*, IPR2018-01521, Paper 7, at 7, n.5 (P.T.A.B. Mar. 11, 2019). Precluding petitioners from relying on a patent owner's "inconsistent constructions would usurp the Board's rule obligating parties to disclose 'information that is inconsistent with a position advanced by the party during the proceeding.'" *Nintendo*, IPR2018-01521, Paper 7, at 7, n.5 (quoting 37 C.F.R. §42.51(b)(1)(iii)). Thus, while Petitioner disagrees with PO's infringement allegations and proposes a construction of "spacings" in the district court that excludes the SAPIEN 3 Ultra valve or finds the term indefinite, it is nonetheless appropriate for the Board to rely on **PO's constructions** in this IPR.

Second, if a disclaimer occurred, PO inaccurately describes the disclaimer.

PO did not limit its prosecution arguments to Spenser II, as it suggests here. Rather, PO argued the spacings in *any* “very tightly knitted outer seal made of tightly knitted fibers” were outside the claims, and merely cited Spenser II and Walther as examples. (Ex. 1002, 1001.) PO also generically distinguished the claims from spacings found in “grafts,” “graft coverings,” “sleeves,” and “cloths.” (Ex. 1148, 7-8, 12-13; Ex. 1149, 8-9, 13-14; Ex. 1002, 1001.) In this IPR, PO again argues that Spenser II’s compressible material lacks spacings because it “forms a tight outer seal, which is confirmed by its description as a ‘sleeve,’ ‘layer,’ or ‘cloth.’” (*Id.*, 10.) Thus, if a disclaimer occurred, it is much broader than just Spenser II and, at least, includes materials like the cloth on Petitioner’s accused SAPIEN 3 Ultra valve, which has “tightly knitted fibers” and/or is a “graft covering,” “sleeve,” or “cloth.”

Third, PO’s prosecution statements do not provide any objective boundaries for the “spacings.” See *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371-73 (Fed. Cir. 2014). PO and its expert admit that all cloths have spacings between their fibers. *Infra* §II. Yet, PO never identifies any boundaries that would enable POSITAs to determine which spacings are within the claims. PO’s prosecution argument that the claims exclude “tightly knitted fibers” is too vague to define “spacings.” PO never defines “tightly knitted,” and, more importantly, the ’834 patent does not exclude, or even mention, “tightly knitted” fibers. In fact, the ’834

patent does not contain any disclosure regarding fiber density. For these added reasons, the Board should apply the plain and ordinary meaning of spacings here.

II. ALL FIBROUS CLOTHS HAVE “SPACINGS”

Both PO and Dr. Brecker have admitted that all fibrous cloths have “spacings” between their fibers. In a related IPR, Dr. Brecker testified that “[a]ny piece of fabric would have spaces between the fibers however it was produced.” (Ex. 1146, 185:18-20.) Similarly, when discussing Spenser II’s fibrous cloth during prosecution of related patents, PO acknowledged that “all fibers have some degree of being spaced-apart.” (Ex. 1148, 13; Ex. 1149, 14.) PO argued that “Applicant’s claimed invention clearly requires some level more spacing.” (*Id.*) However, PO never defined “some level more spacing” and never identified any disclosure in the ’834 patent creating such a requirement. As shown above, PO’s admissions were unqualified and encompass all fibers in a cloth, including those extending outwardly from the cloth’s surface (i.e., the first plurality) and those in any base layer (i.e., the second plurality).

Given these admissions, PO cannot dispute that Spenser II discloses the claimed “spacings” under the plain and ordinary meaning. For this reason and those in the Petition, the Board should institute this IPR and cancel the challenged claims.

Respectfully submitted,

Dated: November 22, 2023

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONER'S
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RESPONSE** is being served via electronic mail pursuant to 37 C.F.R. § 42.6(e) and
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