

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC,	)	
	)	
Plaintiff,	)	Case No. 1:23-cv-00158-JPM
	)	
v.	)	
	)	
EDWARDS LIFESCIENCES	)	
CORPORATION, EDWARDS	)	
LIFESCIENCES LLC, and EDWARDS	)	
LIFESCIENCES (U.S.) INC.,	)	
	)	
Defendants.	)	

INITIAL EXPERT CLAIM CONTRUCTION DECLARATION OF DAVID
BROOKSTEIN, Sc.D.

I, David Brookstein, Sc.D., hereby declare as follows:

1. I have been retained by counsel for Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively, “Edwards”) to provide expert opinions in this action.

2. I understand that this action involves claims by Plaintiff Aortic Innovations LLC that Edwards infringes U.S. Patent Nos. 11,337,834 (the “’834 patent”); 11,389,310 (the “’310 patent”); 11,491,033 (the “’033 patent”); 11,497,634 (the “’634 patent”); and 11,523,918 (the “’918 patent”), which I collectively refer to herein as the “Asserted Patents.”

3. I have reviewed the Asserted Patents, and I see that they are identical except for the recitation of priority at the beginning of the specifications and the claims. Accordingly, for convenience and brevity, when discussing the Asserted Patents herein, I refer and cite to the specification of the ’834 patent. However, my opinions apply equally to the other Asserted Patents.

I. QUALIFICATIONS AND EXPERIENCE

4. I was awarded a Bachelor of Textile Engineering from the Georgia Institute of Technology (“Georgia Tech”) in 1971, a Master of Science in Textile Technology from the Massachusetts Institute of Technology (“MIT”) in 1973, and a Doctor of Science in the field of Mechanical Engineering from MIT in 1976. My doctoral thesis focused on polyester materials such as yarns. My current curriculum vitae is attached as Appendix A. A summary of my expert witness professional services is attached as Appendix B.

5. I was a professor of Textile Engineering at Georgia Tech from 1975 to 1980. I was the Associate Director of Albany International Research Co. (formerly Fabric Research Laboratories, Inc.) from 1980 to 1994. While I was at Albany International Research Co., I worked on many contract research programs, including one program to develop textile-based fabric leaflets for prosthetic aortic heart valves. I also was the research leader for a project funded by Meadox

Medicals, Inc. that led to U.S. Patent 5,697,969 titled “Vascular Prosthesis and Method of Implanting.” The invention was directed towards a vascular prosthesis that comprises a braided tubular fabric having a plurality of braid layers, wherein each layer includes at least one interlocking yarn that extends from that layer into another layer to form an interlock therewith. In one aspect of the invention, the plurality of braid layers included a substantially non-absorbable first surface layer and a substantially resorbable second surface layer. One of the disclosed resorbable materials was reconstituted collagen fibers. See U.S. Patent No. 5,697,949 at 2:13-17 (describing collagen embodiment).

6. While at Albany International Research Co., I also conducted research on other biomedical devices such as sutures, resorbable bone reinforcement plates, textile-fabric substitutes for native aortic heart valve replacements, textile-based artificial arteries, and synthetic anterior cruciate ligaments (ACL). My work on ACLs resulted in U.S. Patent 5,004,474 titled “Prosthetic Anterior Cruciate Ligament Design,” which discloses an artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones. One of the textile elements in the synthetic ACL was a woven fabric of Dacron® polyester yarns that was made from continuous filament fibers. My work on textile-based artificial arteries resulted in U.S. Patent 5,697,969 titled “Vascular Prosthesis and Method for Implanting.”

7. I was Dean of the School of Engineering and Textiles and Executive Director of Research at Philadelphia University (formerly Philadelphia College of Textiles and Science) from 1994 to 2010. At both Georgia Tech and Philadelphia University, I taught courses involving yarn and fabric mechanics.

8. In 2010, I was appointed Executive Dean for University Research at Philadelphia University and served in that position through June 2012. In July 2012, I became Dean of the

Science, Technology, Engineering, and Mathematics Division of Montgomery County Community College in Pennsylvania. At Philadelphia University, I regularly taught courses that included instruction in textile-based biomedical devices. I also founded the Biomedical Textile Structures Laboratory, where I supervised and conducted research on tissue engineering for synthetic myocardial structures that resulted in U.S. Patent 9,668,846, titled “Textile-Templated Electro Spun Anisotropic Scaffolds for Tissue Engineering and Regenerative Medicine.”

9. In May 2013, I took a sabbatical from academia and consulted full-time in areas associated with textiles, apparel, and textile manufacturing.

10. In July 2014, I was appointed Professor of Mechanical Engineering and Director of Undergraduate Affairs at Temple University College of Engineering in Philadelphia. In 2015, I was promoted to Associate Dean for Undergraduate Studies in the College of Engineering at Temple University. In 2017, I was promoted to Senior Associate Dean for Undergraduate Studies in the College of Engineering at Temple University. At Temple University, where I am now Senior Associate Dean of Engineering and Professor of Mechanical Engineering, I regularly give lectures on the concept of “Design Thinking” and include in those lectures the development of bio-prosthetic heart valves.

11. I was elected a Fellow of the American Society of Mechanical Engineers in 1995 and a Fellow of the Textile Institute (U.K.) in 1992.

12. In 1998 I was awarded the ASTM Committee D-13 Textiles Harold DeWitt Smith Award for Distinguished Achievement in the field of textile fiber utilization.

13. I am a named inventor on thirteen (13) U.S. patents dealing with textile materials and textile manufacturing, including three that deal with biomedical devices. I have over 45 years of experience in the field of textile and apparel research, development, and manufacturing.

II. COMPENSATION

14. I am being compensated at my customary hourly rate of \$400/hour for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

III. MATERIALS CONSIDERED

15. In forming my opinions, I have considered the materials cited in and/or attached to this Declaration and the following documents, which either I have obtained or have been provided to me:

- The Asserted Patents;
- The parties' claim construction documents; and
- The materials referenced herein and attached to this Declaration as Appendix C.

16. I also previously offered claim construction opinions in a prior lawsuit between the parties, which I will refer to as *Aortic I*. In offering those opinions, I considered the patent-in-suit, U.S. Patent No. 11,129,735 ("the '735 patent"), the claim construction documents submitted by the parties, and other materials identified in my declaration. I understand that the '735 patent includes the same specification and drawings as the Asserted Patents in this case. I have also reviewed the Court's Claim Construction Order. To the extent relevant to my opinions, I have considered the materials from *Aortic I*.

17. In addition to the materials identified above, I have also relied on my own education, training, experience, research, and knowledge in the field of engineering, textiles, and textile fabric-based medical devices.

18. I may rely on any of these materials, experiences, and knowledge, in addition to the evidence specifically cited as supportive examples in particular sections of this Declaration, as additional support for my opinions.

19. I have been asked by counsel to offer opinions regarding how a person of ordinary skill in the art (“POSA”) would have understood the terms “fibers” and “spacing(s)” in the claims of the Asserted Patents.

20. I reserve the right to supplement or amend this Declaration if additional facts and information affecting my opinions become available.

IV. LEVEL OF ORDINARY SKILL IN THE ART

21. It is my understanding that patent claims are interpreted from the viewpoint of a POSA at the time of the invention to which the Asserted Patents pertain.

22. I have been instructed by counsel that a POSA would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This POSA would, where necessary, work as a team in combination with an engineer to experiment with or manufacture a prosthetic heart valve. Alternatively, a POSA would have been an engineer with a working knowledge of heart valve designs and endovascular prostheses. The POSA would collaborate as a team with an interventional cardiologist to experiment with or manufacture a prosthetic heart valve. I believe counsel’s instructions are consistent with the skill level of the audience for whom the Asserted Patents are written. I have worked and done research in teams like those identified above and, through those experiences, am qualified to offer opinions regarding the knowledge of a POSA. I am at least a POSA.

V. CLAIM TERMS

A. Fibers

23. The claims of the Asserted Patents require “fibers that extend away from the frame,” or a similar “fibers” limitation. ’834 patent at claim 17; *see also id.* at claims 2, 18.

24. The Asserted Patents disclose the material composition of the “fibers” in only four instances. In each instance, the Asserted Patents disclose that the fibers are collagen fibers. *See* ’834 patent at 12:53-58 (“In the illustrative embodiment, collagen fibers **234** are attached to the proximal section **220** to aid in preventing paravalvular leaks and migration of the proximal component **212** within the aortic walls. The fibers **234** extend outwardly from the proximal section **220** and inwardly into the passageway **232**.”); *id.* at 15:1-5 (“Expansion of the balloon-expandable inner frame **218** engages the inner frame **218** with the outer frame **216** and compresses the collagen fiber/hydrogel coated proximal section **220** of the outer frame **216** against the aortic annulus **210**.”); *id.* at 18:34-39 (“In the illustrative embodiment, collagen fibers **234** are attached to the proximal section **220** to aid in preventing paravalvular leaks and migration of the valve component **412** within the aortic walls. The fibers **234** extend outwardly from the proximal section **220** and inwardly into the passageway **232**.”); *id.* at 19:48-52 (“Expansion of the balloon-expandable inner frame **218** engages the inner frame **218** with the outer frame **416** and compresses the collagen fiber/hydrogel coated proximal section **220** of the outer frame **416** against the aortic annulus **210**.”). Thus, collagen fibers are the only types of fibers disclosed in the specification.

25. A POSA would have understood that collagen fibers are resorbable fibers. A resorbable fiber can be degraded and absorbed in a patient’s body. Collagen fibers are distinct from other materials disclosed in the Asserted Patents, such as polyester. Polyester is a non-resorbable material, meaning it would not be degraded in a patient’s body, even if in the form of a fiber.

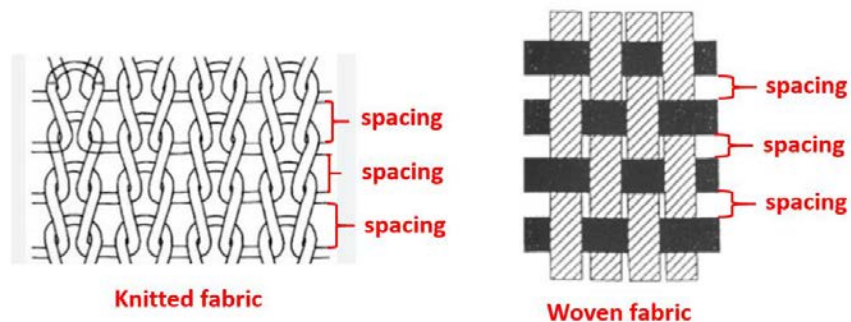
26. Due to the unique characteristics of collagen fibers, a POSA would have found Aortic Innovations' decision to specifically identify "collagen fibers" in the specification meaningful and important to interpreting the Asserted Patents. In my experience, collagen fibers are not interchangeable with non-resorbable fibers, like those made of polyester. A POSA, having read the specification, would not have understood the claim term "fibers" to encompass both collagen fibers and other types of non-resorbable fibers. To the contrary, a POSA would have understood that collagen fibers were specifically identified because their characteristics were important to the described devices. The specification of the Asserted Patents reinforces this conclusion by disclosing non-resorbable covering materials that lack "fibers," such as polyester. See '834 patent at 7:30-36, 8:51-55, 9:35-37, 13:35-39, 13:61-67, 15:60-65, 17:6-10, 19:17-20. Because the specification refers to resorbable and non-resorbable materials, but specifically describes the "fibers" as only "collagen fibers," a POSA would have understood the claim term "fibers" to encompass only "collagen fibers."

27. I also offered the above opinions in *Aortic I*. My opinions have not changed since *Aortic I* and the above testimony continues to be an accurate expression of my opinions. I am aware that the Court construed the term "fibers" in *Aortic I* to have its "plain and ordinary meaning" and rejected Edwards' proposed construction that "fibers" mean "discrete bundles of collagen threads or filaments."

B. Spacings

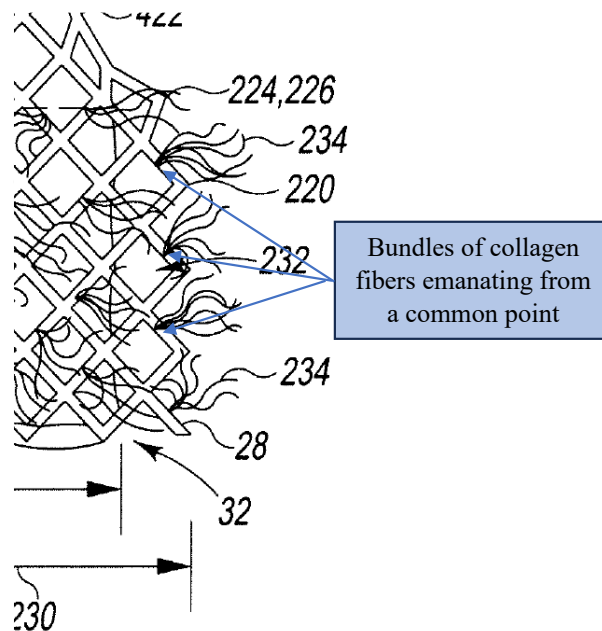
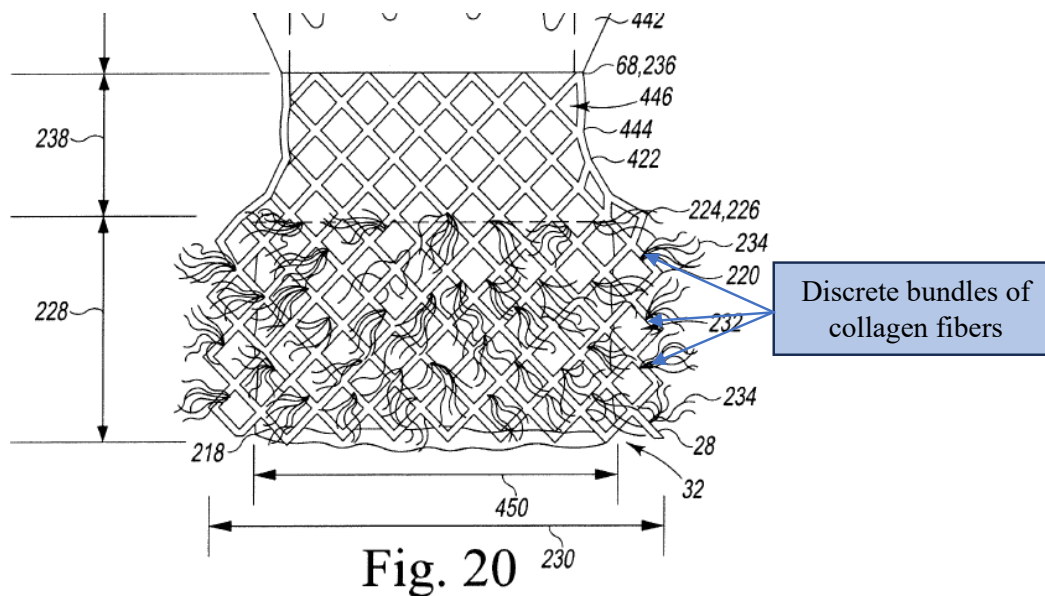
28. Many of the claims of the Asserted Patents require "a spacing extending through a thickness of the plurality of fibers," or a similar "spacing" limitation. '834 patent at claim 18; see also *id.* at claims 2, 17; '033 patent at claims 1, 5; '634 patent at claims 1-7, 9; '918 patent at claims 1, 4-10, 16-17, 20-22, 26.

29. Based on my experience, a POSA would typically have understood spacings between fibers in textile engineered structures, including medical devices that comprise textile cloths or fabrics, to mean the spacings between threads in a woven or knitted fabric. For example, the area density of a woven or knitted fabric can be varied by changing the linear density of the yarns or threads by altering the thread spacing. Examples of “spacings” in textile fabrics are shown below:



A POSA would not have understood the claim term “spacings” to indicate a specific distance, or range of distances, between fibers or threads.

30. However, after reviewing the Asserted Patents and the prosecution histories, I see that Aortic Innovations does not use spacings in the way I am accustomed to as a POSA. The Asserted Patents illustrate a different arrangement of fibers than one would find in the cloths used for cardiovascular devices. The figures of the Asserted Patents illustrate discrete bundles of collagen fibers **234**, with the individual collagen fibers that make up each bundle emanating from their terminal ends at a common point on the frame:



Id. at Figs. 20 (excerpt) (annotations added). The “spacings” that exist between the fibers result from the arrangement of the discrete bundles.

31. In contrast, the fibers in medical cloths are interconnected, most often by weaving or knitting, to form a unitary, planar structure. Edwards’ Walther article illustrates an example of such a cloth. Walther describes an Edwards’ SAPIEN heart valve that has a polyethylene terephthalate (PET) cloth stitched to the perimeter of the valve, as shown in Figure 1 of the article:

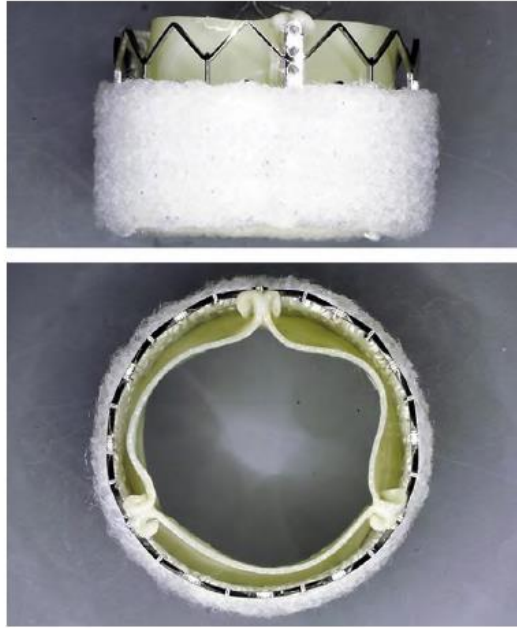


Fig. 1. Cloth valve.

Appendix C, Ex. 4 (Walther) at 1121, Figure 1. Edwards' prior art patent application, WO 2006/005015 ("Spenser II"), provides another example. Spenser II discloses prosthetic heart valves having a "layer of compressible material 256 ... disposed along an outer surface of the stent structure" and further explains that the "compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material" that "may extend entirely around the stent structure, such as in the form of a sleeve":

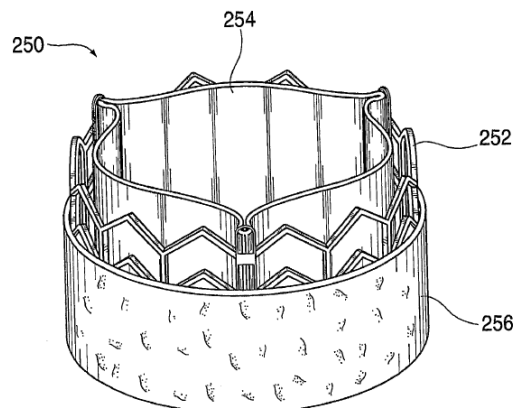


FIG. 22

Appendix C, Ex. 5 (Spenser II) at [00145], Fig. 22.

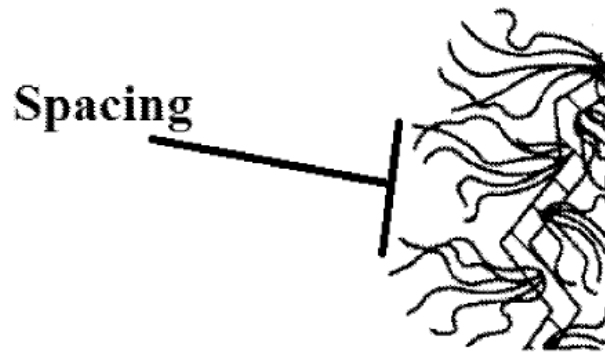
32. The cloths illustrated and described in Walther and Spenser II are like the cloths I have used and observed in my experience as a textile engineering researcher in both academia and in industry. These medical cloths have some degree of spacings between the woven or knitted yarns that make up the cloth.¹ While the distance between the yarns can vary based on several factors, such as the width or density of yarns in the knit or weave, spacings exist between the yarns. I see that Aortic Innovations agreed during prosecution of the '634 and '918 patents that spacings exist between the fibers in all cloths, stating that “all fibers have some degree of being spaced-apart.” Appendix C, Ex. 8 ('391 App., May 18, 2022 Amend.) at 14; Appendix C, Ex. 9 ('251 App., May 17, 2022 Amend.) at 13. Cloths, like those discussed in Walther and Spenser II, were well known in the cardiovascular field, and used with heart valves before November 2012. Yet, the Asserted Patents do not mention cloths. This omission would have been significant for a POSA interpreting the Asserted Patents, especially when considering the patent figures, which illustrate spacings between discrete bundles of collagen fibers.

33. Moreover, there does not appear to be any dispute that the Asserted Patents do not include cloths like those described in Walther and Spenser II. During prosecution, I see that Aortic Innovations repeatedly distinguished the claimed “spacing(s)” from spacings between fibers that are present in a “cloth,” “sleeve,” “graft,” or “graft covering,” including the cloths and materials disclosed in Walther and Spenser II. I have identified several examples of these distinguishing statements below.

34. Example 1: During prosecution of the '834 patent, Aortic Innovations (referred to during prosecution as “the Applicant”) represented to the Patent Office that “[w]hat the Applicant

¹ Yarns are typically made of multiple threads. Threads are typically made of multiple fibers.

is claiming is the spacing between segments of some fibers” and argued that “Applicant submits that FIG. 12 of the Application as filed illustrates this spacing.” Aortic Innovations included the following “annotated version” of Figure 12 to show a “spacing”:



Appendix C, Ex. 6 ('673 Appl. Sept. 28, 2021 Amend.) at 8-9 (annotations in original). Aortic Innovations also included an annotated version of Figure 11 to show a “spacing” between the points where the bundles of fibers are attached to the outer frame 216:

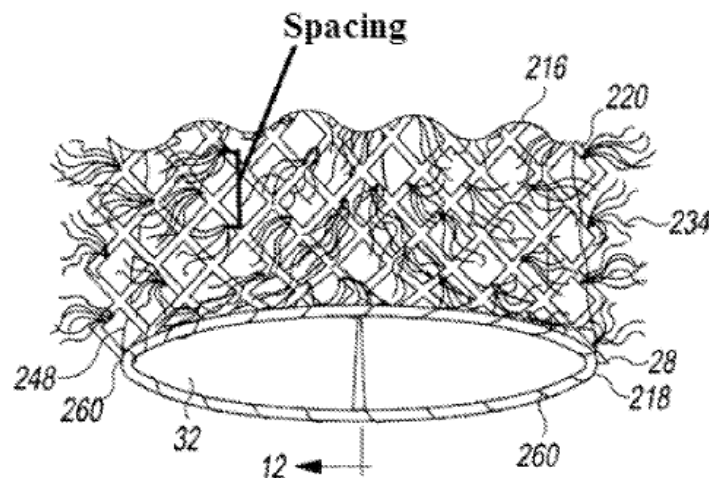


Fig. 11

Id. at 9 (annotations in original).

35. Aortic Innovations also argued:

“As the MPEP makes clear, drawings alone may provide a ‘written description’ of an invention as required by Sec. 112. This is the case in this instance, where the fibers are shown with spacings therebetween. This advantage is not shown in the prior art.”

Id. (emphasis in original). Aortic Innovations argued that the collagen fibers in the Asserted Patents were distinguishable from the prior art because the prior art (including Walther and Spenser II) allegedly included a “very tightly knitted outer seal made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, or WIPO Publication 2006005015A2 to Spenser, with reference to Figure 22) . . . [sic] there the lack of ‘spacings’ between some fibers would not allow for compression of the outwardly extending fibers.” *Id.* at 8.² Aortic Innovations further distinguished the claimed “spacings” from a “tight outer seal such as a graft” and asserted that the “spacing provides a lesser rigidity than a graft covering (as one example, a graft covering cannot foreshorten during crimping expansion to the same degree as a loosely defined fiber structure).” *Id.*

36. Example 2: During prosecution of the ’033 patent, Aortic Innovations represented to the Patent Office that the “specification illustrates spacings between fibers that are an intentionally placed spacing, i.e., not just the spacing that may be inherent between radially

² I do not agree with Aortic Innovations’ characterization of the compressible material in Spenser II or the outer cloth in Walther as “tightly knitted” or made of “tightly knitted fibers.” I have reviewed both references, and I do not see any statement or suggestion in either that the materials are “tightly knitted.” I also do not agree with Aortic Innovations’ statement that the arrangement of the outer fibers in Spenser II and Walther would not allow for compression of the outwardly extending fibers. Walther includes pictures of the compressed fibers and Spenser II expressly discloses a “compressible material.” Moreover, in my experience, all knitted and woven cloths have some degree of spacings between the fibers – in other words, the spacings cannot be completely eliminated.

extending fibers such as those that appear to be found in the Walther reference.” Appendix C, Ex. 7 (’160 App., Sept. 11, 2022 Comments with IDS) at 3. Aortic Innovations included the following annotated image of Figure 11 to illustrate a “spacing”:

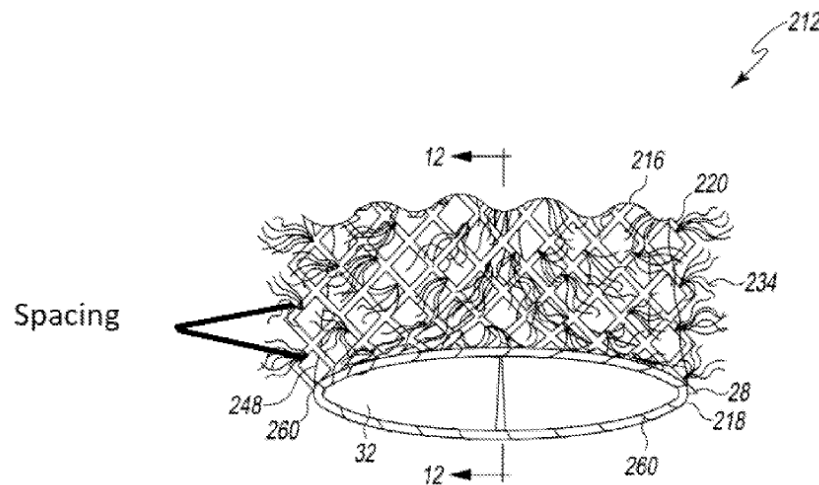


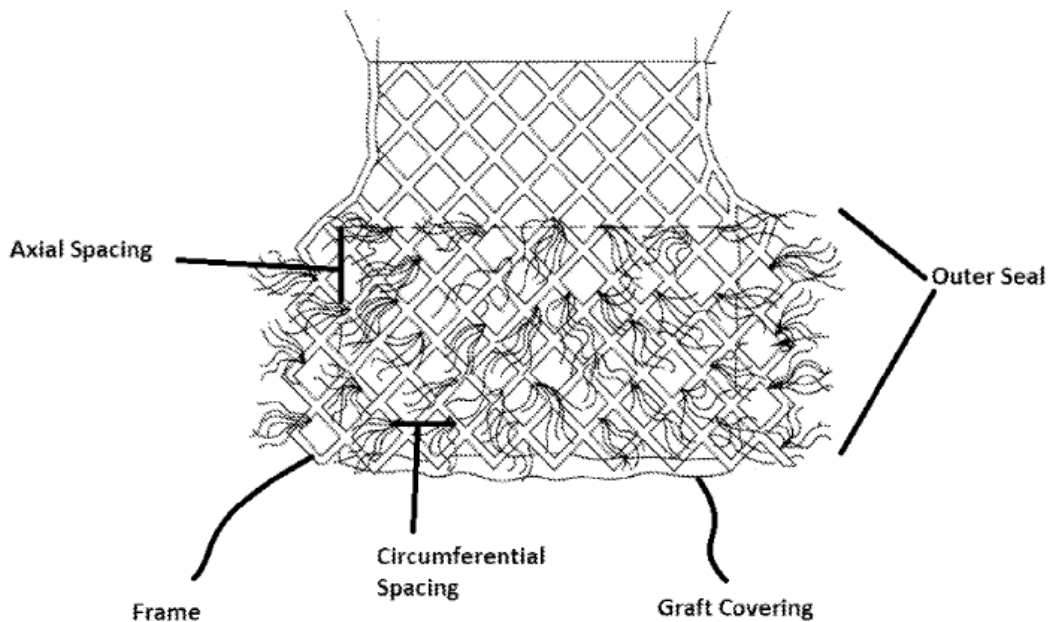
Fig. 11

Id. (annotations in original).

37. Example 3: During prosecution of the ’634 patent, Aortic Innovations represented to the Patent Office that by having a “second plurality of fibers defining spacing therebetween . . . the overall fiber construction is loosely structured (compared to a band/sleeve/cloth as shown in Dehdashtian).”³ Appendix C, Ex. 8 (’391 App., Jan. 4, 2022 Amend.) at 14.

38. Example 4: During prosecution of the ’634 and ’918 patents, Aortic Innovations submitted the following annotated version of Figure 20 to illustrate the claim elements, including the “spacing(s)”:

³ Aortic Innovations referred to Spenser II as “Dehdashtian” in this amendment.



Appendix C, Ex. 8 ('391 App., May 18, 2022 Amend.) at 7-8 (annotations in original); *see also* Appendix C, Ex. 9 ('251 App. May 17, 2022 Amend.) at 7. Aortic Innovations argued that “[t]he benefit to this claimed design is by using a lesser number of fibers than are found in, for example, a graft or sleeve,⁴ there is not so much fiber structure.” Appendix C, Ex. 8 ('391 App., May 18, 2022 Amend.) at 8 (footnote in original); *see also* Appendix C, Ex. 9 ('251 App. May 17, 2022 Amend.) at 7. Aortic Innovations further argued that “[p]roposed outer seals for a transcatheter valve before Applicant’s claimed invention were traditionally blood impermeable cardiovascular cloths or grafts . . . [that] could have different finishes including a fibrous finish . . . [but] [d]ue to the attachment of the graft to the stent frame, the graft impedes efficient elongation of the TAVR assembly because the outer seal cloth cannot stretch and thereby impedes effective elongation.” Appendix C, Ex. 8 ('391 App., May 18, 2022 Amend.) at 9; *see also* Appendix C, Ex. 9 ('251 App. May 17, 2022 Amend.) at 8. In those same amendments while discussing the Spenser II reference, Aortic Innovations represented that “[w]hile all fibers have some degree of being

⁴ “See Dehdashtian, Levi, and NPL of Walther.”

spaced-apart, the construction from Applicant's claimed invention clearly requires some level more spacing [sic]." Appendix C, Ex. 8 ('391 App., May 18, 2022 Amend.) at 14; *see also* Appendix C, Ex. 9 ('251 App. May 17, 2022 Amend.) at 13.

39. As shown by the above examples, Aortic Innovations argued during prosecution that the "spacings" required by the claims do not include the spacings between the fibers that occur in a cloth, sleeve, or graft covering. While Aortic Innovations identified the materials that are *not* covered by the claims, Aortic Innovations never identified the materials having "spacings" that *would* fall within the claims, other than the specific embodiments illustrated solely in the figures of the Asserted Patents. For example, the term "spacing" does not appear in the Asserted Patents other than in the patent claims. I also do not see any part of the specification of the Asserted Patents that discusses any spacings between the collagen fibers that are attached to the frame. With respect to the arrangement of the collagen fibers, the specification merely states:

"In the illustrative embodiment, collagen fibers **234** are attached to the proximal section **220** to aid in preventing paravalvular leaks and migration of the valve component **412** within the aortic walls. The fibers **234** extend outwardly from the proximal section **220** and inwardly into the passageway **232**."

'834 patent at 18:34-39; *see also id.* at 12:53-58.

40. I see that some claims of the Asserted Patents recite that the spacing(s) between the fibers "allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state." *See e.g.*, '033 patent at claim 1. However, in my opinion, this limitation would not have led a POSA to understand that the claims cover "cloths," particularly in view of Aortic Innovations' arguments during prosecution that the Asserted Patents do not cover cloths. Many, if not most, cloths used in the field of cardiovascular devices and prosthetic heart valves, including

those described in Walther and Spenser II, had spacings between the fibers of sufficient size to allow fluid to pass therethrough when the cloth is uncompressed. For example, fluid-permeable velour cloths were commonly used in the prior art. *See, e.g.*, Appendix C, Ex. 2 (Hall) (1967 article discussing the use of velour fabrics in cardiovascular implants); Appendix C, Ex. 1 (Estridge) at 158 (“The most commonly used porous soft tissue biomaterial is Dacron velour. This material has been used extensively as an artificial vascular graft material and in percutaneous devices.”); Appendix C, Ex. 3 (Mathisen) at Table 1 (article reporting water porosity testing of eight currently used arterial prostheses, including five prostheses with a velour construction). Yet, Aortic Innovations clearly argued during prosecution that these types of cloths were not covered by the Asserted Patents.

41. In conclusion, based on the absence of any specialized meaning for the term “spacings,” the lack of guidance in the specification, and Aortic Innovations’ arguments during prosecution, the best understanding a POSA would have as to the meaning of “spacings” would be a distance between fibers such that the fibers do not form a sleeve, graft covering, or cloth.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 27, 2023, in Philadelphia, Pennsylvania.



David Brookstein, Sc.D.