

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

**REPLY DECLARATION OF NIGEL BULLER, M.D.
IN SUPPORT OF PETITIONER'S REPLY**

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1001	U.S. Patent No. 10,792,172 B2 (“ 236 patent ”)
1002	Excerpts from the prosecution history of the ’236 patent
1003	Declaration of Nigel P. Buller, M.D.
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)
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., <i>Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach</i> , Herz, 34:347-56 (2009) (“ Cribier ”)
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.

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1016	Alkashkari, MD, et al., <i>Percutaneous Pulmonary Valve Implantation for RVOT Defects</i> , Cardiac Interventions Today, 21-29 (September/October 2010) (“Alkashkari”)
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	Yuksel, Uygur, <i>Balloon-Expandable Transcatheter Aortic Valve Implantation</i> , Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., <i>Transapical Minimally Invasive Aortic Valve Implantation</i> , 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) (“Walther II”)
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	Zajarias, Alan and Cribier, Alain G., <i>Outcomes and Safety of Percutaneous Aortic Valve Replacement</i> , 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) (“Zajarias”)
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. (“Spenser Parent”)

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1027	Roselli, E.E., <i>Engineering transcatheter aortic valve devices: a surgeon's perspective</i> , 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., <i>Yarn structure and properties from different spinning techniques</i> , ("Tyagi")
1029	Kothari, V K, <i>Hairiness properties of polyester-cotton blended yarns</i> , 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
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)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," <i>Transcatheter Aortic Valve Implantation</i> , 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)
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)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.

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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.
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., <i>In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry</i> , 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., <i>Transcatheter aortic valve implantation: first trans-iliac experience in Japan</i> , General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, <i>Iliac Arterial Conduits for Endovascular Access: Technical Considerations</i> , J. Endovasc. Ther. 14:347-351 (2007)
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., <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	WO 2011/051043 A1 to Essinger et al.

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1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from <i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall (“Birdsall”)
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD
1060	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 (November 2011), obtained from the University of California Los Angeles Library
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
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1065	Azadani, Ali N., <i>Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation</i> , Cir Cardiovascular Intervention 4:621-628 (2011).
1066	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), obtained from the British Library
1067	Herz MARC Record from the British Library
1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD
1071	Reserved
1072	Deposition Transcript of Stephen Brecker from August 30, 2022
1073	Deposition Transcript of Stephen Brecker from August 31, 2022
1074	U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)
1075-1103	Reserved
1104	Second Declaration of Dr. Nigel Buller, M.D.
1105	Deposition Transcript of Stephen Brecker from February 8, 2023
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”)

Exhibit No.	Description
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	PMA P140031/S112: FDA Summary of Safety and Effectiveness Data - Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System

I, Dr. Nigel Buller, M.D., do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, “Edwards” or “Petitioner”) to provide my opinion regarding the patentability of claims 1-4 of U.S. Patent No. 10,987,236 (“the ’236 patent”). As discussed herein, and for the reasons set out in my previous Declaration submitted in this IPR (Ex. 1003), I have concluded that claims 1-4 of the ’236 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Declaration supports Petitioner’s Reply for the above-captioned *inter partes* review (“IPR”) of the ’236 patent. I have reviewed Petitioner’s Reply and agree with the unpatentability arguments contained therein.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me.

4. I am being compensated at my customary hourly rate 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.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is included as Exhibit 1004.

6. I have also provided a summary of some of my relevant experience in my previous Declaration submitted in this IPR. *See* Ex. 1003 at ¶¶ 5-24. After I submitted my previous Declaration, I have become aware that Patent Owner has questioned my qualifications to provide opinions from the perspective of a person of ordinary skill in the art for the '236 patent in November 2012. I disagree with Patent Owner's assertion that I am not qualified to provide such opinions, and in response I provide additional details on my relevant experience.

7. Beginning in the 1980's I became involved in the research and development of cardiovascular stent implant devices, and I gained hands on experience with some of the first stent devices implanted in patient's hearts. Subsequently, I also implanted the first coated stents, early stent grafts and drug eluting stents. As such I am very familiar with the concepts used in the design of stent frames and graft coverings including metals, polymers, polyesters, PET and ePTFE. As I discuss later in this Declaration, covering materials had been used on stent devices for decades prior to 2012, and I have personal experience implanting many such devices.

8. When Henning Andersen et al. published their seminal work on a permanently implantable stent mounted biological aortic heart valve in the 1990's, I was an advisory board member to several major medical device companies including Medinol, Scimed/Boston Scientific, JJIS/Cordis, Medtronic and Baxter. In that role, I advised many companies on the prospects for catheter-based valve delivery and met with engineers to discuss design, materials, and feasibility. In that role I also worked with Alain Cribier who subsequently performed the first-in-man TAVR procedure using the PVT/Aran device in 2002. I have followed the development of TAVR in the literature, at meetings, and at hands-on training sessions to this day.

9. Because of my involvement in stent design and my interest in TAVR, I was first invited to act as a consultant to Edwards Lifesciences in 2007. I am very familiar with the concepts of stents, graft coverings, and TAVR, and I believe that I am well placed to represent a person of ordinary skill in the art in the context of the Aortic Innovations' patents at issue in this IPR and the related IPRs in which I've opined.

10. I do not agree with Dr. Brecker's opinion that clinical use of TAVR devices is necessary to provide relevant opinions regarding the validity of the '236 patent. Based on my review, none of the technology or concepts claimed in the '236 patent, or any of the other Aortic Innovations patents I have reviewed for

related IPRs, were new as of 2012. To the contrary, the claimed technology and concepts were known in the art since the late 1990's and early 2000's, before Dr. Brecker had ever implanted a TAVR device.

11. I am also aware that Dr. Brecker has opined that clinical use of TAVR devices in the 2010 to 2012 timeframe is necessary to qualify as a person of ordinary skill in the art. *See, e.g.*, Ex. 2103 (Second Brecker Decl.) at ¶¶20-21. I disagree. Both the issue of paravalvular leak and the concept of preventing paravalvular leak by attaching a fibrous material to the outside of a prosthetic heart valve were known in the art well before 2010-2012. For example, the Spenser II reference has a priority date of 2004 (and was published in 2006) and expressly discloses embodiments for addressing paravalvular leak in percutaneous heart valves, including an embodiment using a fibrous “compressible material” attached to the outer surface of the stented valve. *See* Ex. 1003 (Buller Decl.) at Section VII.A.

C. Materials Considered

12. In preparing this Declaration, I have considered the materials referenced in this Declaration, my previous Declaration, and the attached list of exhibits.

13. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '236 patent.

II. “OUTER GRAFT COVERING BETWEEN THE FIRST PORTION OF FIBERS AND THE OUTER FRAME”

A. The “Graft Covering” Claimed In The ’236 Patent Must Be Dense And Nonporous And Thereby Prevents Fluid From Passing Through The Surface

14. Patent Owner and Dr. Brecker dispute that the prior art references, including Walther and Spenser II, are “free of an outer graft covering,” as required by claim 1 of the ’236 patent. Dr. Brecker bases his argument on a construction of “graft covering” that requires a dense, nonporous material. *See, e.g.*, Ex. 1105 (Brecker Dep.) at 39:3-4 (Dr. Brecker testifying that “something that is porous with holes wouldn’t be a graft cover”); *see also id.*, 37:15-17, 40:4-8, 41:5-11, 42:3-8, 47:3-11, 60:11-20, 172:5-12. In view of Dr. Brecker’s claim construction, I believe it is helpful to clarify how a person of ordinary skill in the art would understand the term “graft covering” as used in claim 1 of the ’236 patent. As I explain below, I agree with Dr. Brecker’s construction of “graft covering”; however, I disagree with Dr. Brecker’s application of this construction to Walther and Spenser II because neither reference discloses a dense, nonporous “graft covering” as part of its outer seal.

15. As I explained during my deposition, in my opinion, a person of ordinary skill in the art would understand the term “graft covering” in claim 1 of the ’236 patent to mean a nonporous covering material that prevents fluid from

passing through the outer surface. *See* Ex. 2104 (Buller Depo) at 72:20-73:1, 135:8-12. I am aware that Dr. Brecker testified in this IPR that one of the characteristics of the claimed “graft covering” is that it prevents fluid from passing through the material, and that a porous material would not be a graft covering. Ex. 1105 (Brecker Dep.) 39:2-4, 60:11-20. Thus, Dr. Brecker appears to agree that a “graft covering” as claimed in the ’236 patent must be a nonporous covering material that prevents fluid from passing through the surface.

16. My understanding of the meaning of “graft covering” in the claims of the ’236 patent is informed by, and consistent with the specification of the ’236 patent. The specification of the ’236 patent does not use the term “graft covering.” However, the specification describes “covering materials” attached to the outer surface of a stent to prevent the flow of fluid through the stent. Ex. 1001 (’236 patent) at 7:21-27, 8:42-46, 9:26-28, 13:25-29, 13:51-57, 15:50-55, 16:61-65, 19:5-8. In each instance, the ’236 patent describes those covering materials as “nonporous.” *See id.* For example, with respect to Figure 10, the patent discloses that the outer surface 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” or that the stent may alternatively be covered with “standard polyester, ePTFE or *other nonporous materials.*” *Id.* at 13:51-57. Given this repeated and consistent disclosure in the specification, it is

my opinion that a person of ordinary skill in the art would have understood that the term “graft covering” claimed in the ’236 patent must be nonporous and must prevent the flow of fluid through the material.

17. The ’236 patent’s use of the term “graft covering” to mean a nonporous material is within the general meaning of the term “graft covering” in the prior art. In the prior art, the term “graft covering” simply referred to a material attached to the stent device. Such materials could be either porous or nonporous. Indeed, as I explain later in this Declaration, the use of porous, compressible covering materials to promote sealing and tissue ingrowth on cardiovascular graft devices was well known for decades prior to 2012. *See infra* ¶¶29, 45. The prior art would sometimes refer to such materials as a “graft” or a “graft cover.” *See infra* ¶¶29, 45. However, both Dr. Brecker and I agree that such a porous material **would not** constitute the “graft covering” as that term is used and claimed in the ’236 patent.

18. During my deposition for several related IPRs, I was asked the following questions with respect to Figure 9 of the patents, and I provided the following answers:

Q: And we can all see clearly that there is no graft covering between the outer frame and the fibers; correct?

A. What do you mean by – I mean, this could be seen as a graft covering, but a loose one. But it could be seen as a graft covering. The fibers of collagen which are there could easily be considered to be a graft covering.

Q. So your expert opinion is that the fibers that we see in Figure 9 can be a graft covering; is that correct?

A. It could be a cover. You could barely refer to it to as a covering of collagen.

Q. You just testified that you – your expert opinion is that the fibers we see in Figure 9 can be a graft covering; correct?

A. Could be fairly said to be a covering.

Q. I didn't – you left out the word "graft." I'm asking – you answer the question that I'm asking. You agree that the fibers we see in Figure 9 can be a graft covering; correct?

A. Yes.

Ex. 2052 (Buller Deposition I) at 154:5-155:1. Patent Owner argues that the above response is somehow inconsistent with other testimony I have provided in the case. POR at 94-95. I do not believe my testimony is inconsistent. I believe that Patent Owner has misunderstood my testimony due to ambiguity in the questions that were asked. To clarify, I understood the questions identified above to focus on whether the collagen fibers in Figure 9 *could* be considered a graft covering in any context. The question did not ask, and I did not understand the question to be asking, whether the collagen fibers in Figure 9 constituted a "graft covering," as that term is used in the claims of the Aortic Innovations patents. Notably, the questioning attorney did not mention or refer to any specific patent claims when asking the questions. As I explained in my answer, the collagen fibers might be considered a "graft covering, but a loose one." *Id.* at 9-10. And as I explained in the preceding paragraph, the term "graft covering" in the prior art could encompass a loose, porous material. *Supra* ¶17. However, to be clear, it is not my opinion

that such a “loose” covering would constitute a “graft covering” as that term is used in the claims of the ’236 patent because that “loose” covering would not be nonporous and would not prevent the flow of fluid through the material.

19. To avoid confusion, when I refer to a “graft covering” in the following sections of this Declaration, I am referring to the meaning of “graft covering” that both Dr. Brecker and I agree applies to the claims of the ’236 patent – a nonporous covering material that prevents fluid from passing through the surface.

B. Walther Does Not Teach An “Outer Graft Covering” Between The Fibers Of The Outer Cloth And The Frame Of The SAPIEN Valve

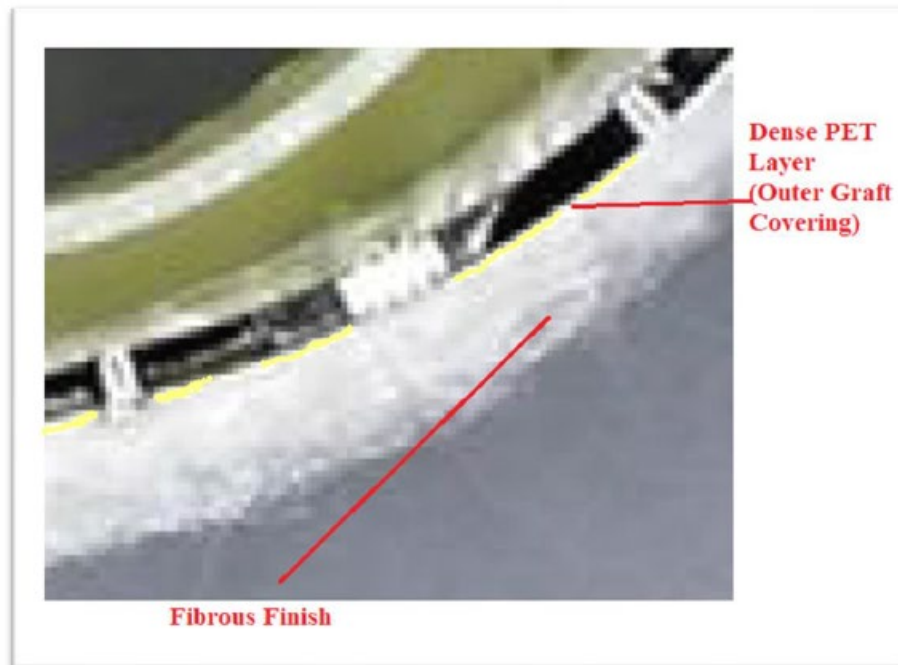
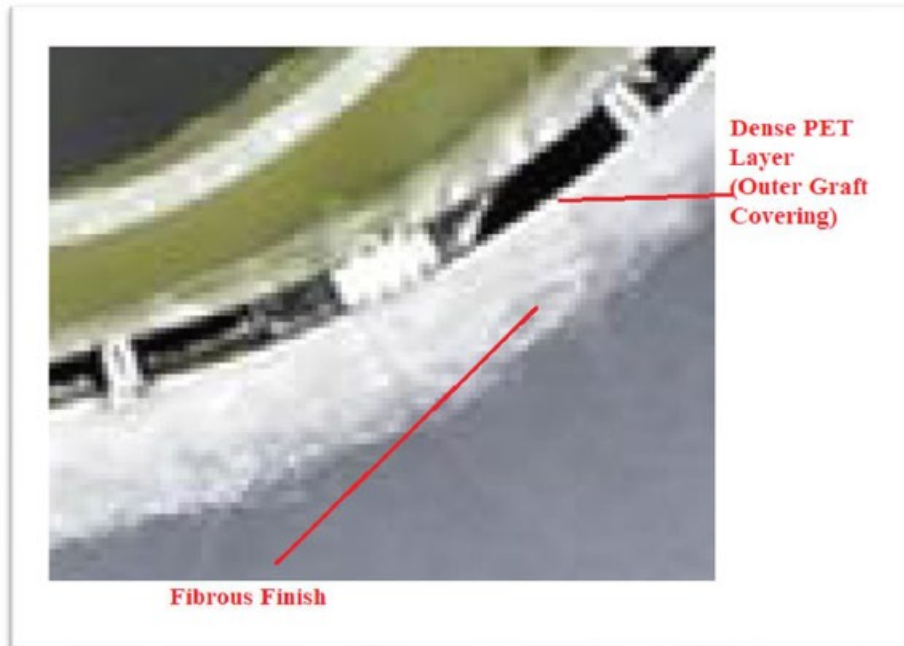
20. I disagree with Dr. Brecker’s position that Walther’s outer cloth includes a “graft covering” as claimed in the ’236 patent, and I further disagree with Dr. Brecker’s position that Walther’s outer cloth includes a tightly woven, dense, nonporous “backing layer.” In my opinion, a person of ordinary skill in the art would have understood that the outer PET cloth disclosed in Walther does not include any such dense, nonporous “backing layer” or a “graft covering” as that term is claimed in the ’236 patent.

21. Additionally, I disagree with Dr. Brecker’s opinion that a person of ordinary skill in the art would have believed that such a dense, nonporous “backing layer” would be desired or required to achieve the stated purposes in Walther of decreasing paravalvular leakage and tissue ingrowth. To the contrary, it is my

opinion that a person of ordinary skill in the art would have understood that Walther's outer cloth ***does not teach*** such a dense, nonporous "backing layer" to achieve the stated purposes of the cloth. Moreover, as I explain below, a person of ordinary skill in the art would have known of many porous cloths that did not include a dense, nonporous "backing layer" prior to 2012.

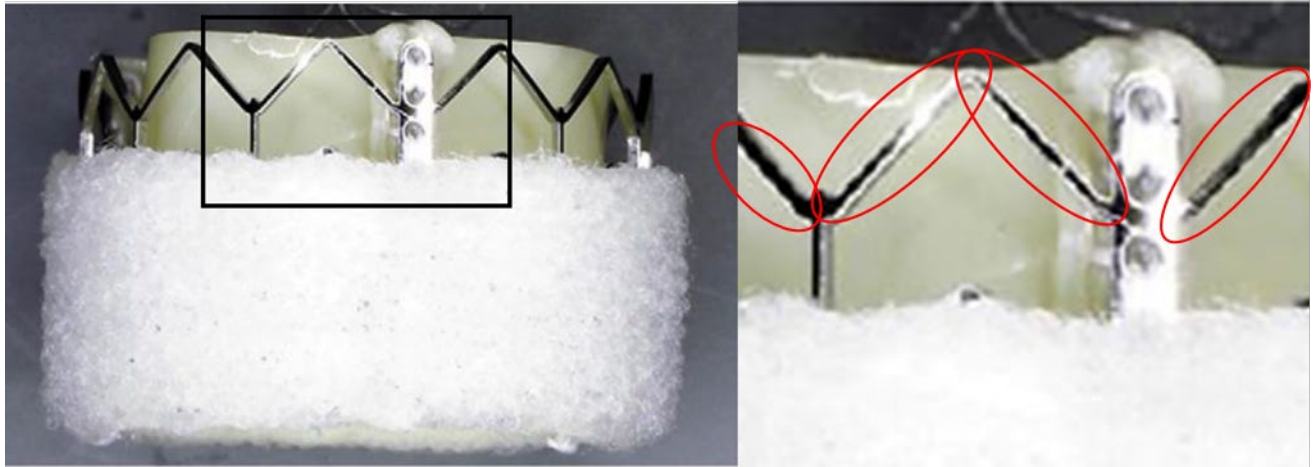
22. Dr. Brecker appears to agree with me that not all PET cloths are "graft coverings" as claimed in the '236 patent. Ex. 1105 (Brecker Dep.) at 97:14-21. Dr. Brecker also appears to agree with me that not all woven PET cloths are "graft coverings" as claimed in the '236 patent. Ex. 2103 at ¶148 n.2. Dr. Brecker also appears to agree that not all woven or knitted "bases" of a cloth or fabric would constitute a "graft covering" as claimed in the '236 patent. *See id.* Accordingly, even assuming Walther's outer cloth includes a "backing layer," Dr. Brecker appears to agree that a "backing layer" ***alone*** is not determinative of whether an outer cloth includes a "graft covering." In my opinion, the relevant question is whether Walther's outer cloth is nonporous and would prevent the flow of blood through the thickness of the material. Based on his deposition testimony, Dr. Brecker does not appear to disagree. Ex. 1105 (Brecker Dep.) at 39:3-4 (Dr. Brecker testifying that "something that is porous with holes wouldn't be a graft cover"); *see also id.*, 37:15-17, 40:4-8, 41:5-11, 42:3-8, 47:3-11, 60:11-20, 172:5-12.

23. I disagree with Dr. Brecker's opinion that a "dense PET layer" is visible in Figure 1 of Walther. In my opinion, the portion of Figure 1 that Dr. Brecker identifies as the "dense PET layer" is not such a layer but rather light reflecting off the metal bars of the frame. I have reproduced the images where Dr. Brecker attempts to identify the "dense PET layer" in Walther's figure 1 below:



Ex. 2103 (Second Brecker Decl.) at ¶38. As shown, Dr. Brecker highlights a thin white line along the outer edge of the metal struts of the frame. Yet, similar white

lines are visible along the edges of additional struts of the frame in Figure 1 of Walther that are *not covered* by the outer cloth:



Ex. 1007 (Walther) at Fig. 1. In my opinion, the presence of similar white lines along the metal struts of the frame that are not covered by the outer cloth confirms that the portion of the image Dr. Brecker identifies as a “dense PET layer” is merely a reflection of light from the metal struts of the frame.

24. My opinion is further confirmed by the yellow highlighting in the above figures from Dr. Brecker’s report. In the lower figure, Dr. Brecker has allegedly highlighted in yellow the “dense PET layer.” Ex. 2103 (Second Brecker Decl.) at ¶38. However, as shown, the alleged “dense PET layer” is not continuous around the circumference of the frame, but instead includes numerous gaps (*see e.g., break in the yellow line*). *See id.* These breaks are inconsistent with a “dense PET layer,” which, if present, a person of ordinary skill in the art would expect to be continuous and uniform around the circumference of the frame, and instead

reflects changes in the reflection of light at different points around the stent frame. Notably, Dr. Brecker does not provide any explanation for why the alleged “dense PET layer” would include breaks in continuity, or how such broken layer would be formed. *See* Ex. 1105 (Brecker Dep.) at 149:5-152:1.

25. I also note that Walther does not mention any sort of “dense PET layer” as part of the outer cloth. Dr. Brecker has invented the term “dense PET layer” and is reading this unsupported characterization into the Walther article based on his erroneous interpretation of the figures. Therefore, it is my opinion that Dr. Brecker’s contention that Walther’s outer PET cloth includes a “dense PET layer” is not supported by any disclosure in the Walther reference. Nor does Walther state that the outer cloth is “nonporous.” Instead, as I testified in my prior Declaration, Walther describes a single PET cloth that is stitched directly to the perimeter of the SAPIEN frame. Ex. 1003 (First Buller Decl.) at ¶¶126, 140. Walther does not describe or illustrate a separate “graft covering” or a “dense PET layer” that is distinct from the fibers of the outer cloth.

26. In related IPRs, I have previously testified that Walther’s outer cloth appears to show a velour-like woven PET fabric. Ex. 2008 (193 Buller Decl.) at ¶305. Velour-like woven fabrics were well known in the prior art and were commonly used in cardiovascular implant devices prior to November 2012. *See, e.g.,* Ex. 2057 (Chu) at 4; Ex. 1110 (Pourdeyhim) at 170; Ex. 1111 (Scott) at

Summary. Dr. Brecker agrees that Walther's cloth is velour-like woven PET. Ex. 2103 (Second Brecker Decl) at ¶¶41-44. However, I also testified in those related IPRs that Walther's outer cloth could also be formed from a knitted velour-like PET fabric, as opposed to a woven fabric. Ex. 2052 (Buller Dep.) at 93:22-94:4. Velour-like knitted fabrics were also well known in the prior art and were commonly used in cardiovascular implant devices prior to November 2012. *See, e.g.,* Ex. 2057 (Chu) at 4; Ex. 1110 (Pourdeyhimi) at 172; Ex. 1109 (Ko) at 1049.

27. My opinion that Walther's outer cloth does not include an "outer graft covering" does not change regardless of whether Walther's outer cloth is woven or knitted. Whether a cloth is formed by weaving or knitting does not determine whether the fabric is porous or nonporous. Instead, the porosity of the material is determined by how tightly the fibers of the fabric are packed together. Although knitted fabrics are generally more porous than woven fabrics, both woven and knitted fabrics can be manufactured with varying degrees of porosity. *See, e.g.,* Ex. 2057 (Chu) at 4 ("Since the numbers of intersections of both weft and warp yarns are closely related to the mechanical and physical properties of the resulting fabrics, a significant reduction in these numbers would make the fabrics more flexible and porous."); Ex. 1109 (Ko) at 1049 ("By controlling the stitch (loop) density, a wide range of pore geometries can be generated."). Critically, however, persons of ordinary skill in the art would have known that velour and velour-like

fabrics, whether woven or knitted, were designed to be porous in order to improve compressibility, conformability, and tissue ingrowth. *See, e.g.*, Ex. 2057 (Chu) at 4; Ex. 1106 (Estridge) at 158 (“The most commonly used porous soft tissue biomaterial is Dacron¹ velour. This material has been used extensively as an artificial vascular graft material and in percutaneous devices. Tissue vascularity has been cited as the key to long-term ingrowth. Therefore, pores of a size sufficient to allow vascular ingrowth are required.”) The Chu article, cited by Dr. Brecker, teaches exactly this. Ex. 2057 (Chu) at 4.²

28. Chu discloses that “there are three basic textile structures—all different from each other in porosity, mechanical and biological properties—for vascular fabrics: woven, knitted and nonwoven.” *Id.* at 4. Chu discloses that “[w]oven structures provides [sic] strength with high dimensional stability and low permeability to blood, and it is less prone to kinking.” *Id.* Chu further discloses that the “main disadvantages of woven vascular fabrics are their ***very low healing porosity leading to poor healing***, difficulty in suturing, fraying of cut edges, and

¹ Dacron is a brand name for PET. *See* Ex. 1106 (Estridge) at 159.

² I note that Chu was published in 2018 and therefore does not qualify as prior art to the '236 patent. *See* Ex. 2057 (Chu). However, because Dr. Brecker relies on Chu for his opinions, I have addressed the article here despite the fact that it is not prior art to the '236 patent.

poor compliance to the adjacent nature blood vessels.” *Id.* (emphasis added). Chu discloses that “to *improve the healing porosity* and compliance of woven vascular fabrics, *velour woven vascular fabrics were introduced*” which “were made by floating portions of the weft or/and warp yarns so that the numbers of intersections along both warp and weft directions were reduced considerably from the conventional 1 x 1 woven structure.” *Id.* (emphasis added). Chu teaches that “[s]ince the numbers of intersections of both weft and warp yarns are closely related to the mechanical and physical properties of the resulting fabrics, a significant reduction in these numbers would *make the fabrics more flexible and porous*” and the floated portions of a velour “have another advantage: they produce three-dimensional loose surface structures as the framework for tissue attachment and ingrowth that conventional woven fabrics do not have.” *Id.* (emphasis added). Accordingly, Chu reinforces a person of ordinary skill in the art’s understanding that a velour-like woven fabric would be porous and would not include a tightly woven, nonporous “graft covering” or “backing layer” as Patent Owner and Dr. Brecker contend. Indeed, Chu affirmatively teaches that “[t]he inherent *porous nature* of textile materials has provided *the required space* for the fibrous connective tissue to grow into for achieving full-wall healing.” *Id.* (emphasis added).

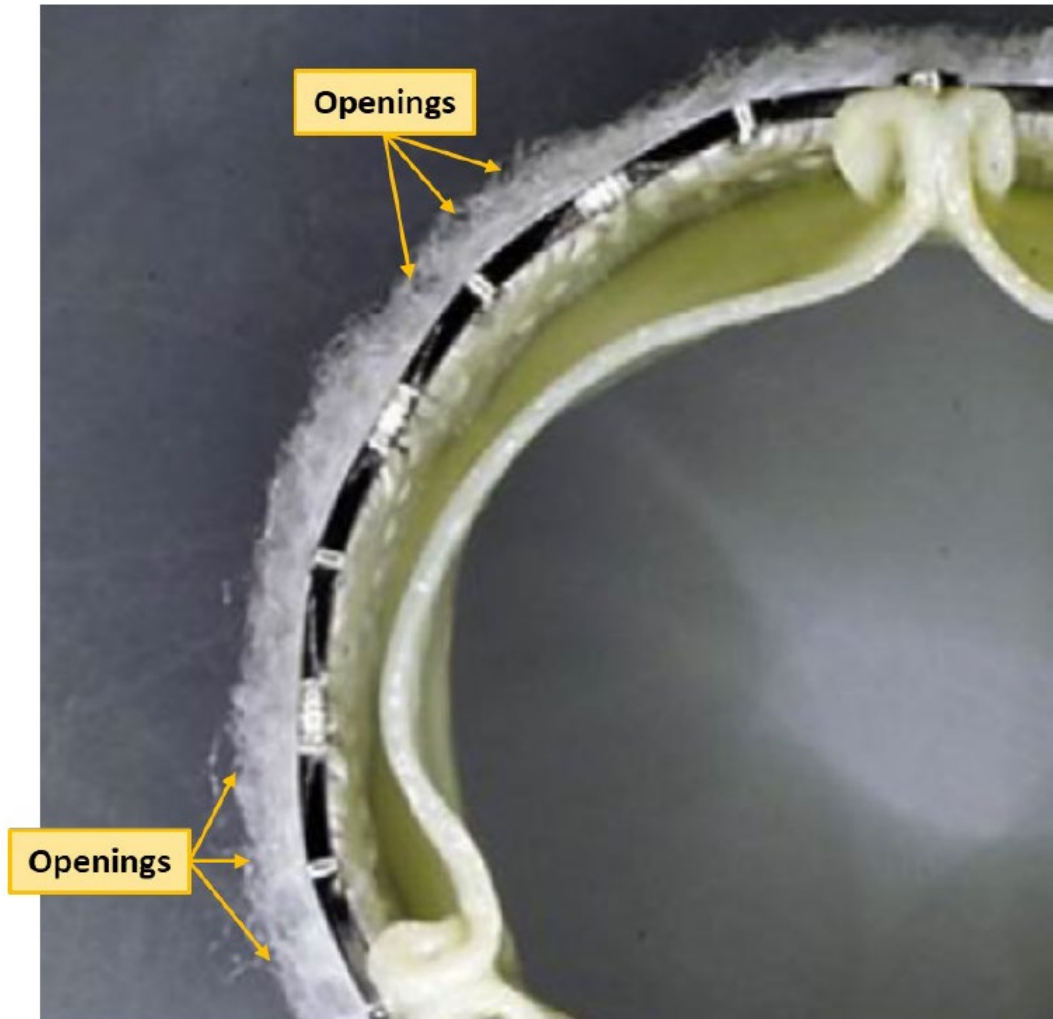
29. Chu is consistent with a person of ordinary skill in the art's understanding of velour-like fabrics used in cardiovascular implants prior to November 2012. Velour-like fabrics had been used in cardiovascular implants, such as vascular grafts, for decades prior to 2012. *See, e.g.*, Ex. 1107 (Hall) (1967 article discussing the use of velour fabrics in cardiovascular implants); Ex. 1106 (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.”); Ex 1110 (Pourdeyhimi) at 172 (“The weft knitted velour grafts such as Sauvage & Filamentous® are superior in performance to the smooth walled weft knitted grafts. They are easier to suture and handle, and show higher degrees of healability.”). The primary reason for the use of velour-like fabrics in such devices was their ability to promote tissue ingrowth, which led to better healing of the device. *See, e.g.*, Ex. 1107 (Hall) at 180-181; Ex. 1106 (Estridge) at 158; Ex. 1110 (Pourdeyhimi) at 172. However, because velour-like fabrics were more porous than tightly woven fabrics, they also had a greater tendency to allow blood to leak through the material. *See, e.g.*, Ex. 1108 (Jonas) at 657; Ex. 1112 (Stegmann) at 54. Because of their permeability, procedures were developed to “preclot” or impregnate both woven and knitted velour fabrics with nonporous materials like collagen to temporarily reduce their permeability when the velour fabrics were used as a vascular or arterial prosthesis, where leakage of

blood through the thickness of the material could be harmful to the patient. *See, e.g.,* Ex. 1108 (Jonas) at 657 (“Pretreatments with biological sealants are available to temporarily reduce the porosity of knitted Dacron at the time of implantation with subsequent resorption of the sealant.”); Ex. 1111 (Scott) at Summary (“[W]oven, double velour Dacron vascular graft was made nonporous by coating it with a layer of collagen prepared from fresh, young calf skin.”); Ex. 1112 (Stegmann) at Summary (“The present study describes the clinical application and results of a new knitted Dacron double-velour prosthesis (primary porosity: 1,400cc/min/cm²), coated with cross-linked bovine collagen; the resulting porosity for implantation is 0cc/min/cm².”).

30. Notably, Walther does not disclose that its outer PET cloth was coated with collagen. If a material such as collagen or silastic (i.e., rubber) had been added to Walther’s outer PET cloth, a scientific article such as Walther would have described it. It does not. Instead, Walther describes the sealing material as a “PET cloth,” telling a person of ordinary skill in the art that there was no coating material added to the cloth.

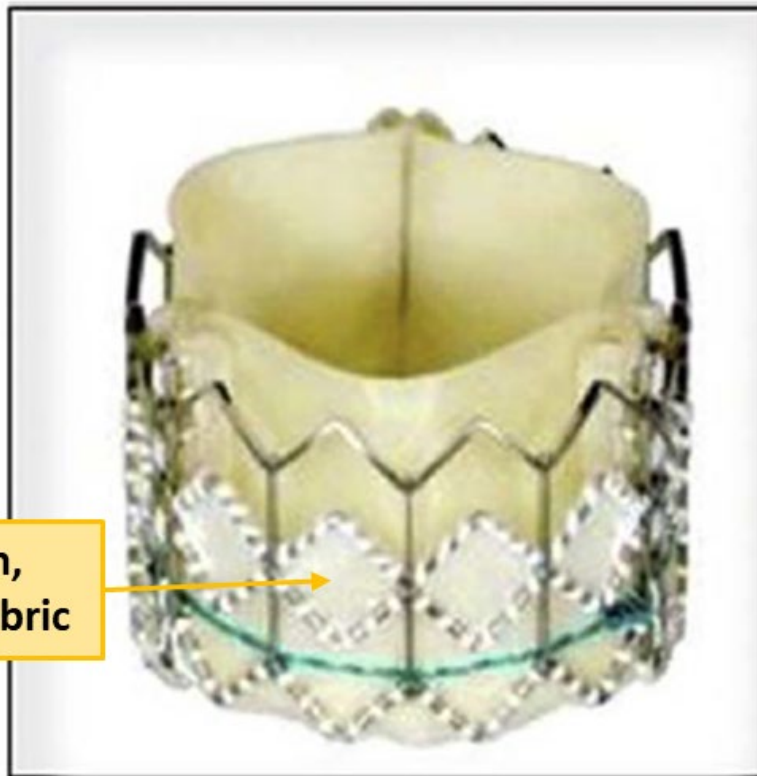
31. Several aspects of Walther’s disclosure further confirm my opinion that Walther’s outer cloth is a porous woven or knitted velour-like PET fabric and does not include a tightly woven, nonporous “dense PET layer” as Dr. Brecker contends.

32. First, as I explained in my deposition, the images of the cloth-covered SAPIEN device in Walther show that the fibers of the cloth are relatively loosely arranged with openings between the fibers that are readily visible:



Ex. 2104 (Buller Dep. II) at 72:5-19, 73:16-22, 137:4-8; Ex. 1007 (Walther) at Fig. 1. The fibers of the outer cloth appear much less densely configured than a tightly woven, dense, nonporous PET material, like the inner skirt on the SAPIEN valve:

**Tightly Woven,
Nonporous Fabric**

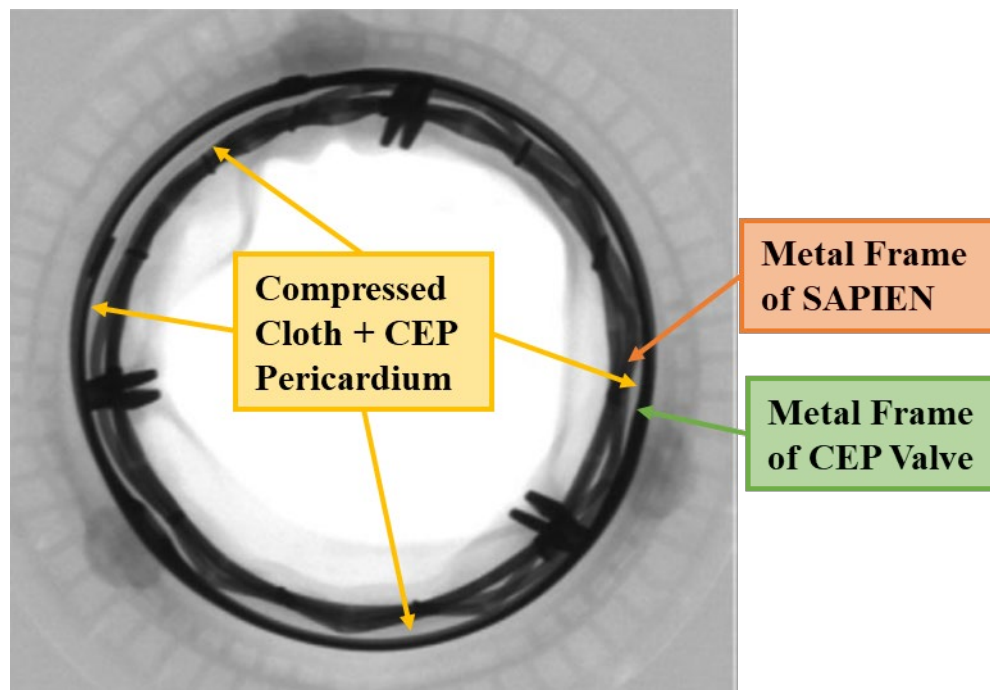


**Edwards SAPIEN® THV
23 mm, 26 mm**

Ex. 1012 (Cribier) at Fig. 1. As I explained during my deposition, the appearance of the loosely arranged fibers in Walther's outer cloth suggests to a person of ordinary skill in the art that the outer cloth is porous. Ex. 2104 (Buller Dep. II) at 72:5-19, 73:16-22, 137:4-8.

33. Second, as I've testified for several related IPRs, Walther's outer cloth is highly compressible. Ex. 2052 (Buller Dep. I) at 102:22-103:5; Ex. 2104 (Buller Dep. II) at 73:21-22. This is evident from Figure 3 of Walther, which shows an x-ray image of the cloth-covered SAPIEN valve expanded within the surgical valve. *See* Ex. 1007 (Walther) at 1121. As shown in Figure 3, when the cloth-covered

SAPIEN valve was expanded within the surgical valve, the outer PET cloth became highly compressed, resulting in little space between the metal frame of the SAPIEN valve and the metal frame of the CEP valve:



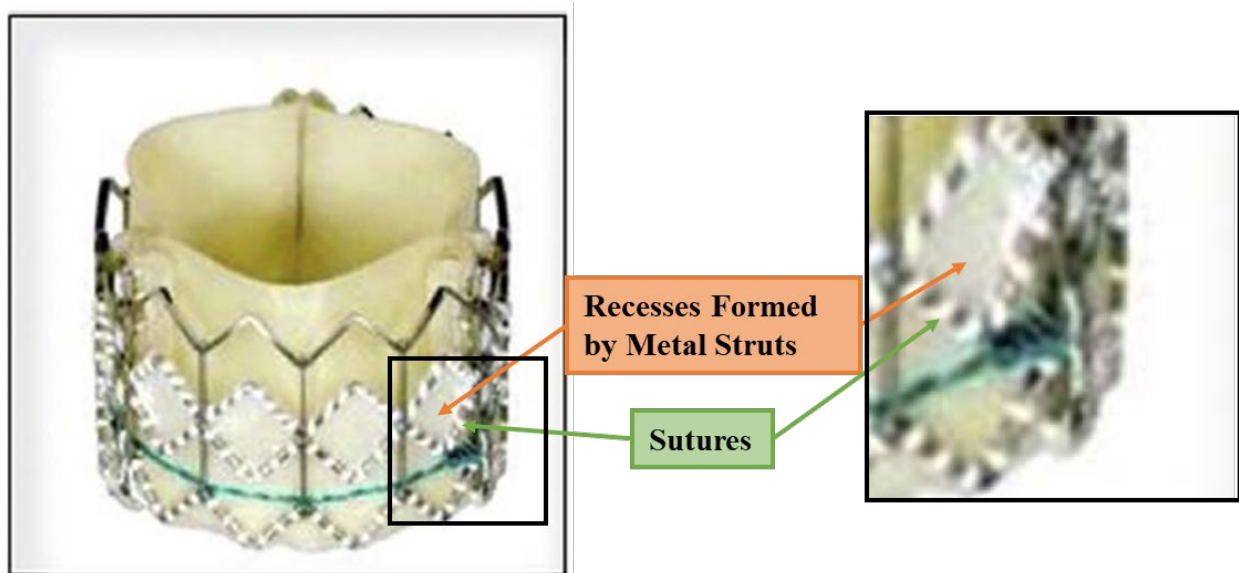
Id. at Fig. 3. The high compressibility of Walther’s outer cloth would convey to a person of ordinary skill in the art that it was formed from a porous fabric, rather than tightly woven/knitted nonporous material, because porous fabrics form a more open, and therefore more compressible, structure than dense nonporous fabrics. *See, e.g.*, Ex. 1109 (Ko) at 1048 (“[W]eft knits have high extensibility and are extremely comfortable and compressible.”); Ex. 1110 (Pourdeyhimi) at 172 (“Single jersey [knitted] grafts are inherently more porous than wovens. The increased porosity (see Figure 5) in this class of grafts results in a greater degree of yarn mobility. In consequence, these grafts are more compliant, easier to handle

and suture.”); Ex. 2057 (Chu) at 4. As I explain in the following paragraph, porous cloths are also more flexible than tightly woven, nonporous fabrics, which also contributes to the enhanced compressibility of porous fabrics. *See*, Ex. 1109 (Ko) at 1048; Ex. 1110 (Pourdeyhimi) at 172; Ex. 2057 (Chu) at 4.

34. Third, Walther states that one of the purposes of its outer PET cloth is to improve the fit between the SAPIEN valve and the surgical CEP valve. Ex. 1007 (Walther) at 1120. A person of ordinary skill in the art would have understood that a soft, compressible porous cloth would be required to achieve that purpose. Porous fabrics, such as velour-like woven or knitted PET fabrics, were known in the prior art to be more compliant and flexible than tightly woven nonporous fabrics. Ex. 2057 (Chu) at 4 (“In order to improve the healing porosity and compliance of woven vascular fabrics, velour woven vascular fabrics were introduced. . . . Knitted vascular fabrics have a much higher porosity than woven grafts and hence show better full-wall healing. . . . Knitted vascular fabrics are also softer and more flexible than woven grafts and show better compliance.”); Ex. 1109 (Ko) at 1049 (“The high level of conformability and porosity of weft-knitted fabrics makes them ideal candidates for vascular implants.”); Ex. 1110 (Pourdeyhimi) at 172.

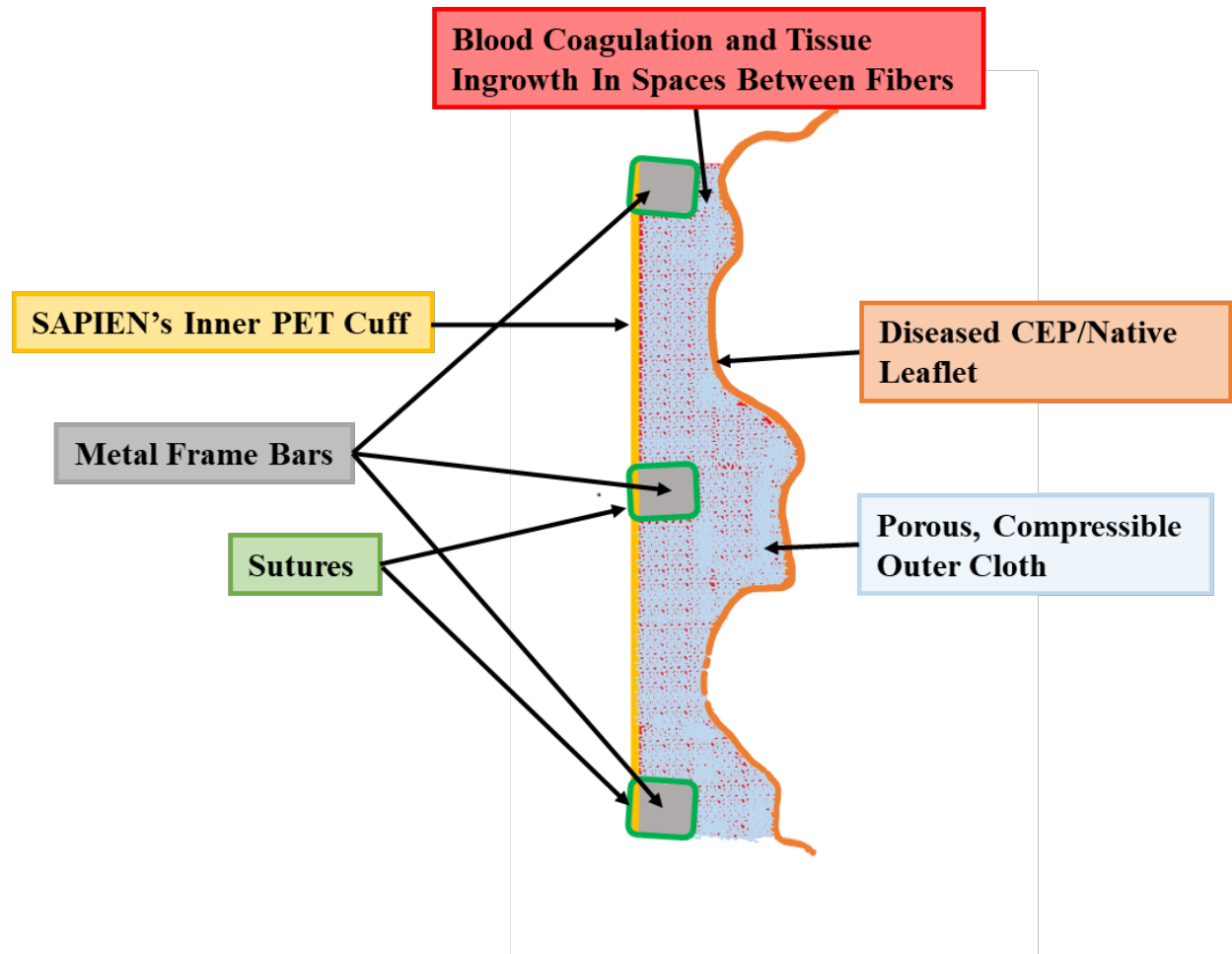
35. Additionally, a person of ordinary skill in the art would understand that both the inwardly facing surface and the outwardly facing surface of the cloth

must be porous, compressible, and compliant to increase the fit between the two valves. A person of ordinary skill in the art would have understood that the outer surface of the SAPIEN valve, to which Walther's outer PET cloth is sutured, forms an irregular surface with many recessed gaps formed by the deformed metal struts, the sutures wrapping around the metal struts, and the recessed inner PET cuff:



Ex. 1012 (Cribier) at Fig. 1. A person of ordinary skill in the art would also understand that the leaflets of a degenerated CEP valve, or a diseased native aortic valve, would also present a highly irregular surface, with many bumps and gaps created by calcium deposits on the leaflets. *See* Ex. 1007 (Walther) at 1120. As a result, a person of ordinary skill in the art would have understood that both the inwardly facing surface and the outwardly facing surface of Walther's outer PET cloth must be able to compress in order to "fit" with the irregularly shaped surfaces

against which it is pressed. This requires the entirety of Walther's outer PET cloth to be formed from a porous, compressible/expandable PET fabric. The illustration below, which is intended to represent a longitudinal cross-sectional view of one side of the cloth-covered SAPIEN valve, demonstrates this point:



If Walther's outer PET cloth included a dense, tightly woven nonporous "backing layer," as Dr. Brecker asserts, the inwardly facing surface of the cloth would not be able to compress and conform to the irregularly shaped surface of the SAPIEN valve, which could leave gaps between the cloth and the SAPIEN valve,

potentially leading to paravalvular leakage. Such a dense, tightly woven nonporous “backing layer” would not “increase the ‘fit’” between the two valves as Walther expressly teaches.

36. Accordingly, a person of ordinary skill in the art would understand that a porous PET cloth would be required to achieve Walther’s stated purposes of preventing paravalvular leak and increasing the “fit” between the SAPIEN valve and the surgical CEP valve. In contrast, a person of ordinary skill in the art would have understood that a dense, nonporous tightly woven cloth would not accomplish Walther’s stated objectives. *See, e.g.* Ex. 2057 (Chu) at 4 (“The main disadvantages of woven vascular fabrics are their very low healing porosity leading to poor healing.”).

37. Fourth, a person of ordinary skill in the art would understand that a porous PET fabric would better serve the stated purposes for Walther’s outer PET cloth—to prevent paravalvular leak and promote tissue ingrowth—but it would not significantly restrict the crimping or expansion of the valve like a tightly woven/knitted nonporous fabric might. Porous fabrics, such as velour and velour-like woven/knitted fabrics, were known to be more stretchable than tightly woven nonporous fabrics. *See, e.g.,* Ex. 2057 (Chu) at 4; Ex. 1110 (Pourdeyhimi) at 172. Thus, a person of ordinary skill in the art would understand that a porous PET cloth would be better able to conform to the SAPIEN valve as the valve is

expanded without either restricting the expansion of the device or creating excess material if the valve is not expanded to its maximum dimensions.

38. As I explained during my deposition, a person of ordinary skill in the art would have understood that a porous fabric would also be better suited to achieve Walther's stated purpose of reducing paravalvular leak and promoting tissue ingrowth than a dense, tightly woven nonporous material. *See, e.g.*, Ex. 2104 (Buller Dep.) at 119:13-18 ("The reason for having the increased surface area with all the fibers is to get blood clotting through the thickness of the cloth to help prevent paravalvular leakage, so that the increased surface areas with all the fibers matters all the way through to the frame."); Ex. 2057 (Chu) at 4 (The "main disadvantages of [non-velour] woven vascular fabrics are their very low healing porosity leading to poor healing, difficulty in suturing, fraying of cut edges, and poor compliance to the adjacent nature blood vessels."); Ex. 1106 (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. Tissue vascularity has been cited as the key to long-term ingrowth. Therefore, pores of a size sufficient to allow vascular ingrowth are required."); Ex. 1107 (Hall) at 180-181 ("It is generally accepted that arterial grafts should be fashioned of a porous material in order to obtain a well-anchored, healthy inner lining. Such material permits the organization of the internal lining

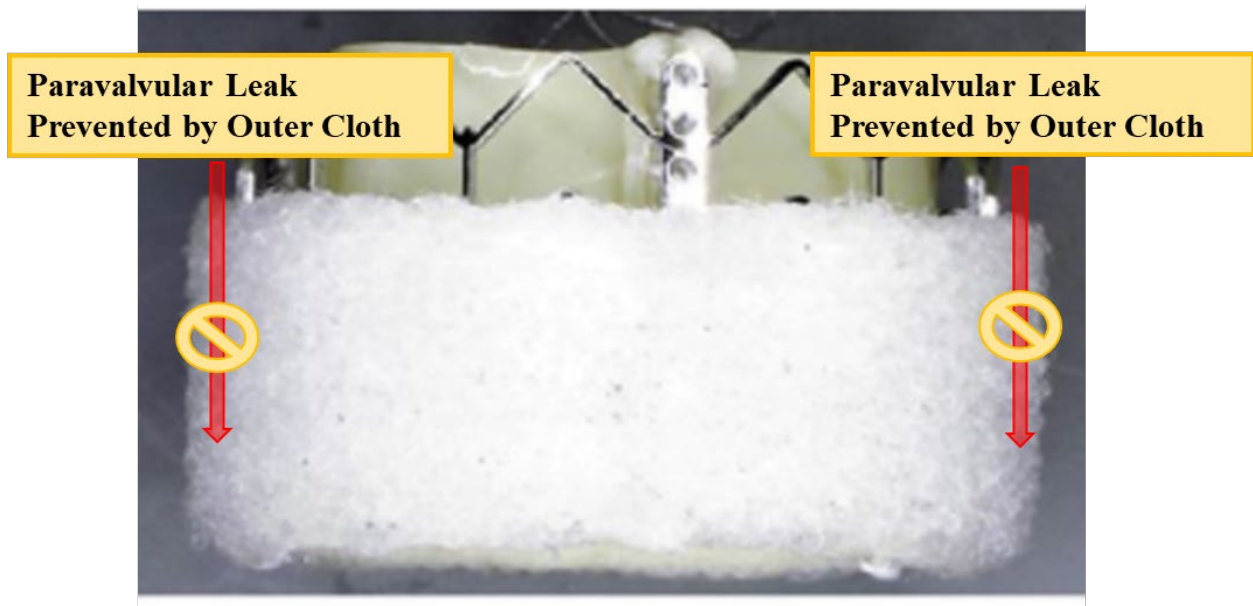
and invasion by surrounding connective tissue with further vascularization.”); Ex. 1108 (Jonas) at 657 (“Knitted high-porosity conduits allow fibrous and vascular ingrowth and more secure anchoring of the pseudointima.”); Ex. 1109 (Ko) at 1049 (“The high level of conformability and porosity of weft-knitted fabrics makes them ideal candidates for vascular implants.”).

39. In contrast, a person of ordinary skill would have understood that a dense, nonporous, tightly woven material would not promote tissue ingrowth and would result in less effective anchoring and sealing as compared to a porous, loosely knitted or woven material. *See, e.g.,* Ex. 1107 (Hall) at 181 (“An impervious material used as an arterial substitute has no means to anchor the fibrin deposit and as a consequence embolization occurs.”); Ex. 1108 (Jonas) at 657 (“Woven Dacron used in extracardiac conduits tends to form a poorly adherent, obstructing layer of pseudointima.”); Ex. 2057 (Chu) at 4 (The “main disadvantages of woven vascular fabrics are their very low healing porosity leading to poor healing, difficulty in suturing, fraying of cut edges, and poor compliance to the adjacent native blood vessels.”).

40. I am aware that Dr. Brecker testified during his deposition that a porous cloth would not reduce paravalvular leak. Ex. 1105 (Brecker Dep.) at 128:7-17. I disagree with Dr. Brecker’s testimony, as it is directly contradicted by numerous prior art references and Dr. Brecker’s own reference, the Chu article.

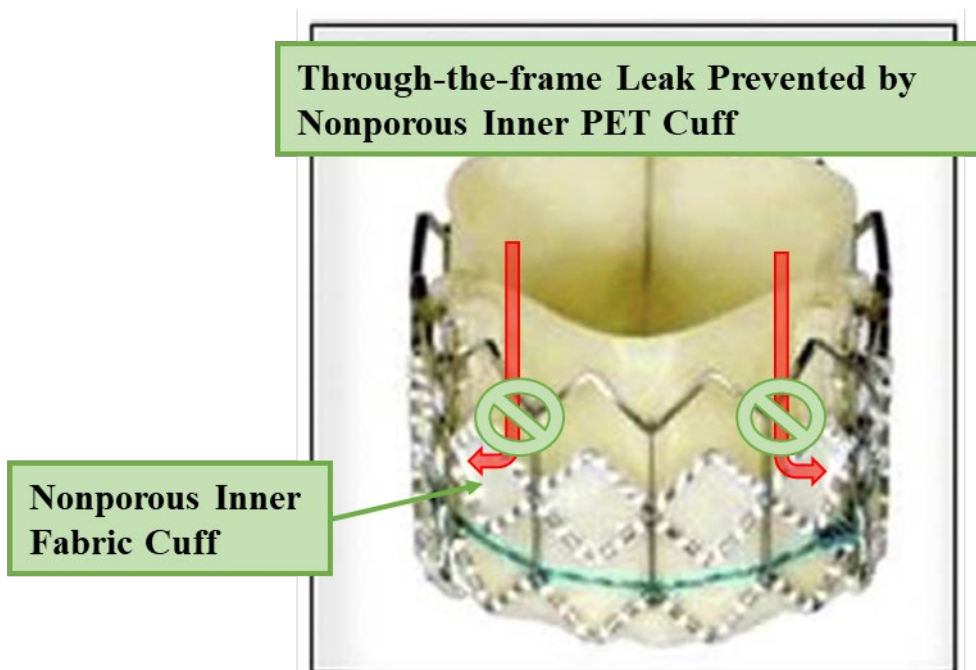
Dr. Brecker's testimony is also inconsistent with the common understanding of a person of ordinary skill in the art in November 2012.

41. I agree with Dr. Brecker that the purpose of Walther's outer PET cloth is to prevent blood from leaking down the outside of the frame, between the SAPIEN's frame and the native tissue, as I've illustrated below:



See Ex. 1007 (Walther) at Fig. 1; Ex. 1105 (Brecker Dep.) at 129:12-130:1. As I explained during my deposition, a person of ordinary skill in the art would understand that a porous cloth, like that pictured in Walther, would achieve this purpose by promoting coagulation of blood, tissue ingrowth, and vascularization into the spaces formed within the fabric. See, e.g., Ex. 2104 (Buller Dep.) at 119:13-18; Ex. 1106 (Estridge) at 158; Ex. 1107 (Hall) at 180-181; Ex. 1108 (Jonas) at 657; Ex. 2057 (Chu) at 4.

42. Importantly, however, a person of ordinary skill in the art would also understand that the outer PET cloth **does not** need to be nonporous and impermeable to the flow of fluid through the lateral thickness of the outer cloth. That is because, as Dr. Brecker recognized in his deposition, the SAPIEN valve in Walther includes an inner PET fabric cuff made of a tightly woven, nonporous PET fabric. Ex. 1105 (Brecker Dep.) at 102:12-104:9. SAPIEN's inner fabric cuff prevents fluid from leaking through the frame of the valve, as I've illustrated below:



See Ex. 1012 (Cribier) at Fig. 1. Because the SAPIEN includes the nonporous inner PET cuff, which prevents through-the-frame leaks, a person of ordinary skill in the art would understand that Walther's outer cloth **does not** need to prevent this

type of leakage, and therefore *does not* need to be made of a tightly woven nonporous material.

43. Thus, the use of a porous PET fabric for Walther's outer cloth would provide all the stated benefits noted in the Walther article. In contrast, a tightly woven, nonporous cloth would provide a reduced surface areas for tissue ingrowth and may adversely restrict the expansion of the device. This further reinforces my opinion that Walther's outer cloth is most likely a loosely knitted or woven PET velour-like fabric. I note that Walther discloses that its cloth-covered SAPIEN devices achieved "excellent hydrodynamic performance," and it does not mention any issues relating to the expansion of the devices. *See* Ex. 1007 (Walther) at 1124-25.

44. For similar reasons, a person of ordinary skill in the art would have understood that even if Walther's outer PET cloth were to include a "backing layer," as Dr. Brecker and Patent Owner assert, the "backing layer" would be loosely knitted or woven and would be porous because such porosity is necessary for promoting tissue ingrowth, promoting flexibility and compressibility of the cloth, and promoting the "fit" between the cloth and both valves. *Supra* ¶¶34-43. Accordingly, it is my opinion that even if Walther's outer PET cloth were to include a "backing layer," the "backing layer" would not constitute an "outer graft covering" as that term is claimed in the '236 patent.

45. The Norris prior art reference further confirms my opinion that a highly compressible fabric, such as Walther's outer PET cloth, would be porous. Norris discloses a "compressible resilient fabric" that can be used "in vascular and endovascular implants such as stents, stent-grafts, and heart valves." Ex. 1074 (Norris) at 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. Norris also teaches that the "compressed thickness 44 of the fabric 10 can be affected by various factors, including, for example, the type of yarn, ***the porosity of the ground layer 20***, and the density and height 43 of the loop layer 30." *Id.* at 8:3-7 (emphasis added). Norris further teaches that "in some embodiments, the ground layer 20 ***can have a porosity that can provide some space into which the loops 32 can be compressed.***" *Id.* at 8:45-48; *see also id.* at claim 10 ("The fabric of claim 1, wherein the ground layer comprises a porosity sufficient to allow collapse of each loop onto the ground layer."). Thus, even in a fabric material with a "ground layer" and "loop layer," such as that disclosed in Norris, a person of ordinary skill in the art would have understood that such a fabric may be porous, particularly when the material is designed to be maximally compressible. In my opinion, such

a porous “ground layer” would not constitute an “outer graft covering” as claimed in the ’236 patent for the reasons I’ve explained above.

46. Patent Owner and Dr. Brecker rely on the Hartley prior art reference to assert that a velour-like woven PET cloth would include a nonporous “backing layer” or graft covering. *See, e.g.*, Ex. 2104 (Second Brecker Decl.) at ¶¶46-49. Patent Owner and Dr. Brecker misinterpret the Hartley reference. Hartley discloses embodiments of endoluminal stent grafts that may include “a continuous band of velour material 20 *fastened to the graft* 1 by stitching 22 at the proximal end and 21 at the distal end of the velour band 20,” as shown in Figure 2:

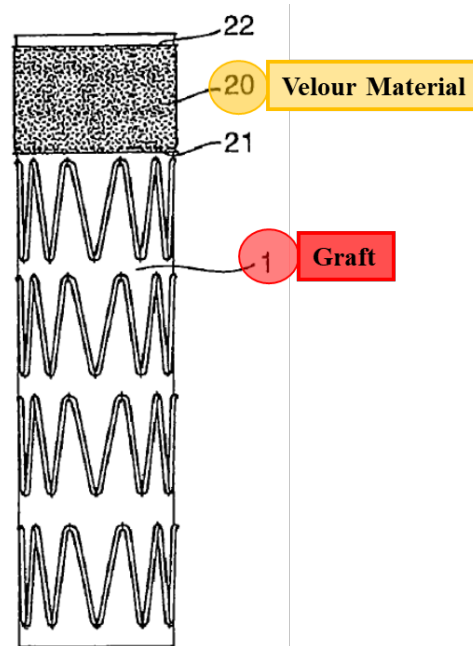


Fig 2

See Ex. 2056 (Hartley) at [0035], Fig 2. Thus, Hartley teaches that the “velour material 20” is secured on top of a separate “graft” material. *See id.* Hartley does

not teach that the “velour material 20” is itself a “graft” or a “graft covering,” and it does not teach that the “velour material” includes a “graft covering,” particularly as the term “graft covering” is used in the claims of the ’236 patent. Indeed, the fact that Hartley separately describes the “velour material” as being “fastened to the graft” teaches that the “velour material” and the “graft” are distinct.

47. Importantly, unlike Hartley, which expressly discloses a “graft” with an added “velour material,” Walther does not disclose or depict any such “graft.” *Supra* ¶25. In my opinion, if Walther’s outer cloth did include such a “graft” that is distinct from the velour-like outer PET cloth, such a graft would have been detailed or addressed in the article. The fact that no such “graft” is disclosed in Walther reinforces my opinion that Walther’s outer cloth does not include any such graft.

48. Hartley also teaches that it was known, as of at least 2004, that “tufts of fibrous material may be placed on grafts to enhance blood clotting and adhesion.” Ex. 2056 (Hartley) at [0005]. Hartley further teaches that when “such grafts are deployed endoluminally it is desirable that the amount of fibrous material be kept to a minimum to ensure that the graft can be compressed into small enough volume to enable deployment while at the same time ensuring good adhesion of the graft.” *Id.* As I explained above, a porous fabric material will be more compressible and have less density (i.e., less fibrous material) than a dense,

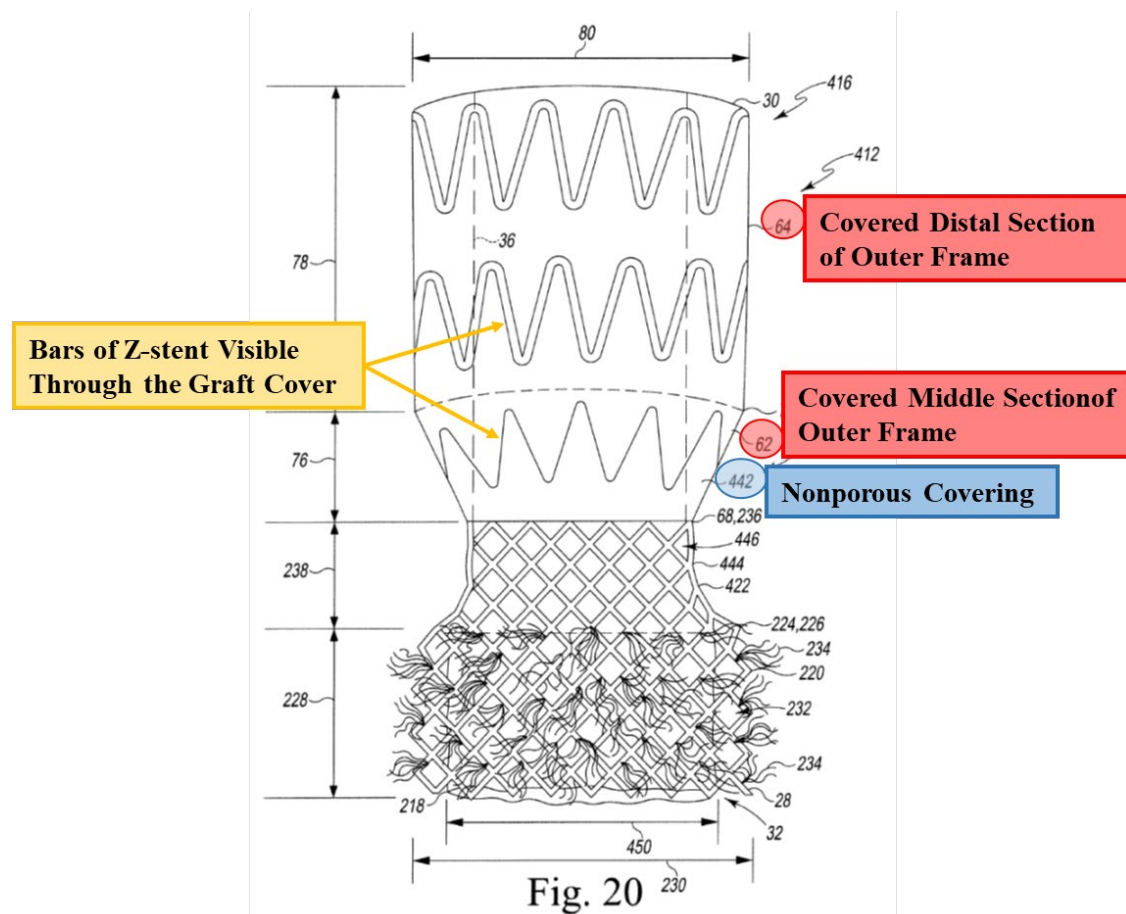
tightly woven, nonporous fabric. *Supra* ¶¶33, 45. Thus, Hartley, like the other prior art references discussed above, would have motivated a person of ordinary skill in the art to use a porous, compressible fabric as a sealing material on a prosthetic heart valve.

1. **The Translucence And/Or Opacity Of A Fabric Is Not Determinative For Whether It Includes A “Graft Covering”**

49. Patent Owner and Dr. Brecker rely on the translucence and/or opacity of an outer sealing material as determinative of whether the sealing materials contain an “outer graft covering.” For example, in his Second Declaration, Dr. Brecker testified that “[w]hereas Ultra’s skirt has clear holes and the frame is visible through it, each of Petitioner’s references include a tightly woven graft covering that is opaque and does not include openings.” Ex. 2103 (Second Brecker Decl.) at ¶152. Dr. Brecker’s reliance on opacity and the alleged “clear holes” in SAPIEN 3 Ultra’s skirt to distinguish SAPIEN 3 Ultra’s outer skirt from Walther’s outer cloth on the basis of an “outer graft covering” is improper for several reasons.

50. First, Dr. Brecker’s position is premised on an incorrect interpretation that the ’236 patent teaches that the collagen fibers attached the outer frame are transparent/translucent and the “graft covering” is opaque. I disagree with Dr. Brecker that the figures of the ’236 patent are limiting on the density and/or opacity of the either the collagen fibers or the graft covering material. However,

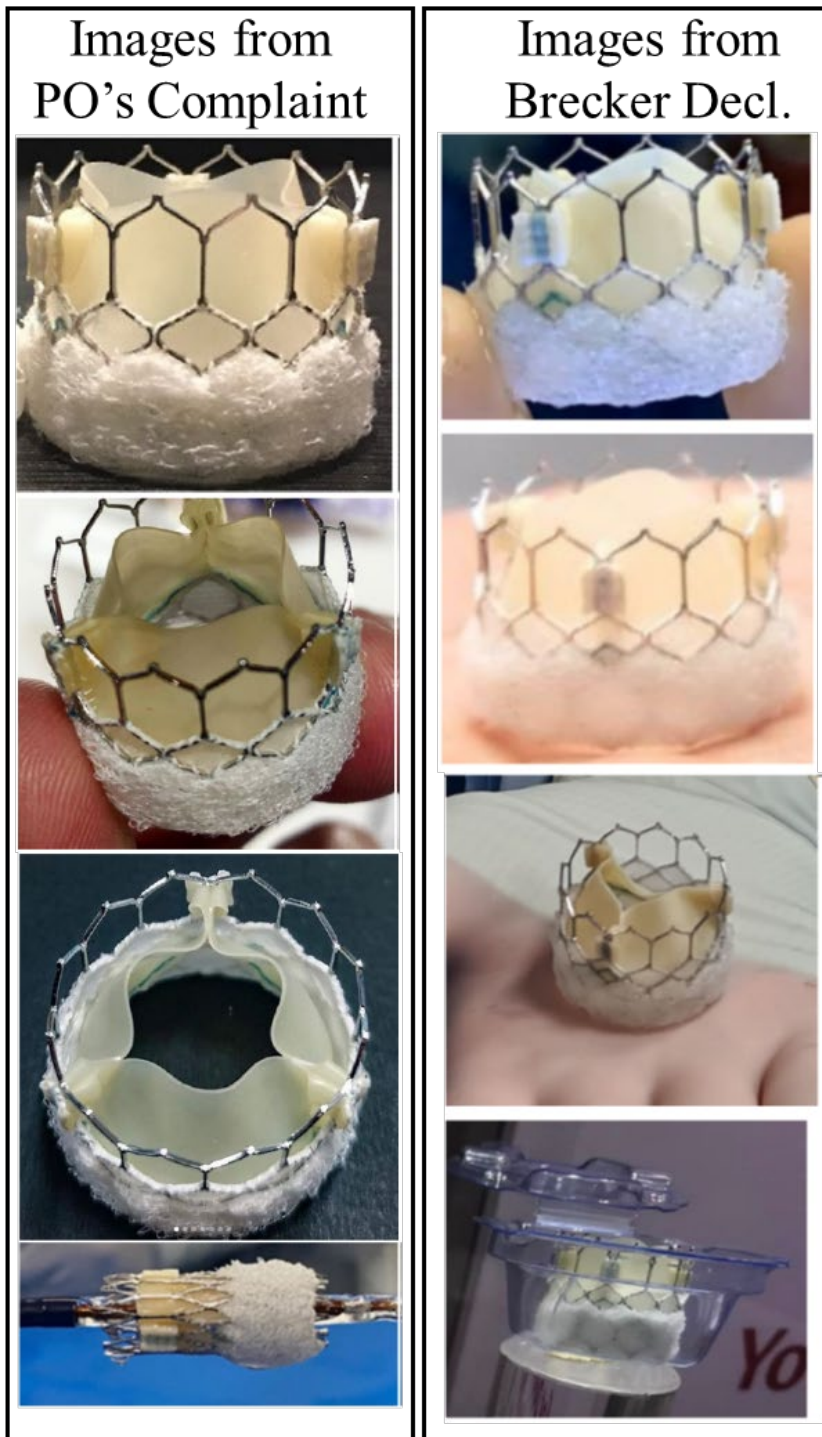
even if they were limiting in that way, the figures of the '236 patent do not support Dr. Brecker's interpretation. For example, Figure 20 of the '236 patent depicts the dual-frame embodiment, and shows the outer surface of middle section 62 and distal section 64 of the outer frame "covered with a low profile polyester, ePTFE, or other nonporous covering material 442 such that fluid is prevented from passing through the surface 440." Ex. 1001 ('236 patent) at 19:5-8. As shown below, the bars of the Z-stent that forms the sections 62 and 64 of the outer frame are clearly visible through the nonporous covering material 442 (i.e., graft covering):



Id. at Fig. 20. Thus, the '236 patent does not support Dr. Brecker's position that a

graft covering must be opaque, while the sealing material must be transparent.

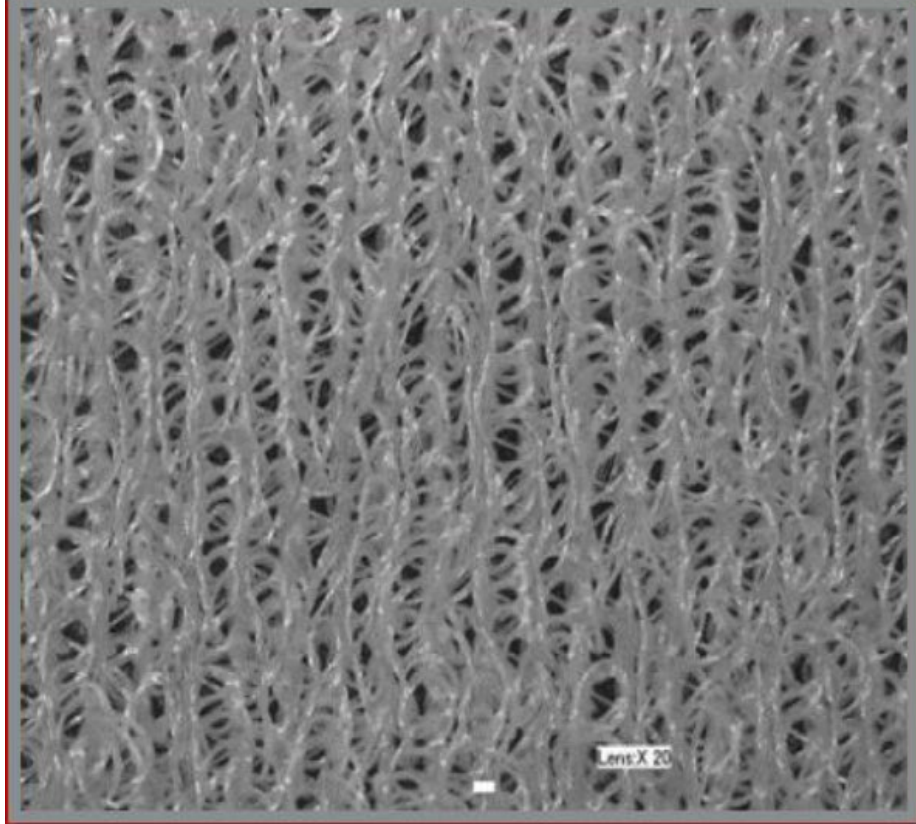
51. Second, Dr. Brecker either ignores or fails to appreciate that the opacity/translucence of a fabric material, such as SAPIEN 3 Ultra's outer skirt or Walther's outer cloth, is impacted by numerous factors, including the lighting of the image, whether the fabric is wet, and the angle from which the image was taken. Ex. 2104 (Buller Dep. II) at 136:21-137:3. For example, a person of ordinary skill in the art would understand from common life experience that a white fabric material will become more translucent when it is wet or when it is lit from behind. *See id.* The error in Dr. Brecker's analysis is clearly illustrated by the comparison of the following images of the SAPIEN 3 Ultra. The images on the left are images of SAPIEN 3 Ultra from Patent Owner's complaint filed in the district court litigation, while the images on the right are the images of SAPIEN 3 Ultra that Dr. Brecker relied upon to show a "translucent" outer skirt:



Ex. 1050 (Complaint) at ¶¶6, 62, 85; Ex. 2103 (Second Brecker Decl.) at ¶148. As one can see from the images above, while the outline of the metal bars of the frame may be slightly visible in some of the images on the right, the bars of the frame are

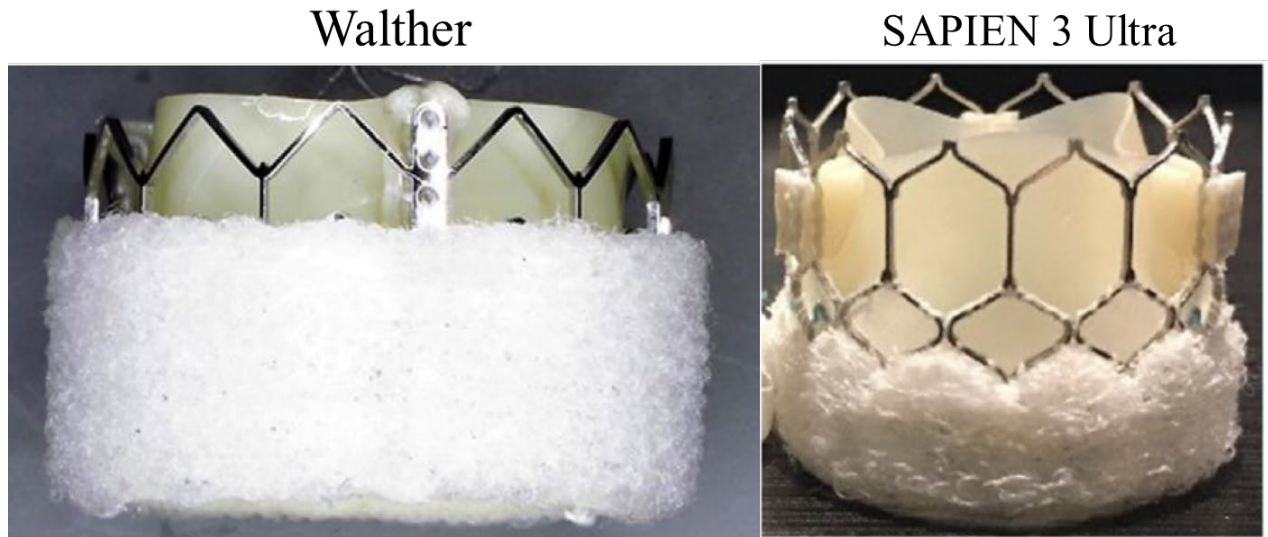
not visible through the outer skirt in the images on the left. In other words, SAPIEN 3 Ultra's outer skirt can appear completely opaque, depending on the circumstances of the image, which highlights the error in Dr. Brecker's reliance on his selected photographs of the device. For these reasons, it is my opinion that a person of ordinary skill in the art would not rely on the opacity or translucence of a material in a photograph to determine whether the material contains a "graft covering" as claimed in the '236 patent.

52. I also disagree with Dr. Brecker's statement that there are "clear holes" visible in SAPIEN 3 Ultra's outer skirt, whereas there are no such holes in Walther's outer cloth. Notably, Dr. Brecker bases this statement on the following image of SAPEIN 3 Ultra's outer skirt, *which has been magnified by 20 times*:



See Ex. 2103 (Brecker Second Decl.) at ¶152. Dr. Brecker then compares this highly magnified image of SAPIEN 3 Ultra’s outer skirt to a *non-magnified* image of Walther’s outer cloth. See *id.* In my opinion, that is an irrelevant and misleading comparison. As I explained above, a person of ordinary skill in the art would have understood that Walther’s outer cloth was a porous PET cloth and would include openings, spaces, and “clear holes” between the fibers like SAPIEN 3 Ultra’s outer skirt, particularly when viewed under significant magnification like the image Dr. Brecker relies upon.

53. A comparison of more-comparable images of SAPIEN 3 Ultra's outer skirt and Walther's outer cloth further illustrates the error in Dr. Brecker's analysis:



Compare Ex. 1007 (Walther) at Fig. 1 with Ex. 1050 (Complaint) at ¶6. In my opinion, Walther's outer PET cloth appears similar to SAPIEN 3 Ultra's outer skirt when viewed at the same level of magnification, and Dr. Brecker's opinion that Walther's outer cloth includes a nonporous, tightly woven PET "graft covering" is inconsistent with his opinion that SAPIEN 3 Ultra's outer skirt does not include such an "outer graft covering."

C. Spenser II's Compressible Material Does Not Include A "Graft Covering" Between The Fibers Of The Compressible Material And The Frame

54. As I testified in my previous Declaration submitted in this IPR, Spenser II discloses a percutaneous prosthetic heart valve with a "compressible

material” disposed along an outer surface of the heart valve’s frame for preventing paravalvular leaks. Ex. 1003 (First Buller Decl.) at ¶187. Spenser II explains that the compressible material “may resemble a cloth or fabric having small fibers extending from the surface of the material.” *Id.* In my opinion, Spenser II does not disclose or suggest to a person of ordinary skill in the art that the “compressible material” includes an “outer graft covering” between the outwardly extending fibers of the material and the frame of percutaneous valve. To the contrary, Spenser II teaches away from the use of a dense, tightly woven nonporous “graft covering” as part of the compressible material, and I disagree with Dr. Brecker’s opinions to the contrary.

55. Dr. Brecker has admitted that not every PET cloth or fabric constitutes a “graft covering” as that term is used in the ’236 patent claims. Ex. 1105 (Brecker Dep.) at 97:14-21. I agree. Accordingly, the fact that Spenser II describes the compressible material as a “a cloth or fabric having small fibers extending from the surface of the material” does not mean that the compressible material is a “graft covering” as that term is claimed in the ’236 patent, and it does not mean that the compressible material includes a “graft covering” as that term is claimed in the ’236 patent. Dr. Brecker appears to agree. Ex. 1105 (Brecker Dep.) at 39:3-4 (Dr. Brecker testifying that “something that is porous with holes wouldn’t be a graft

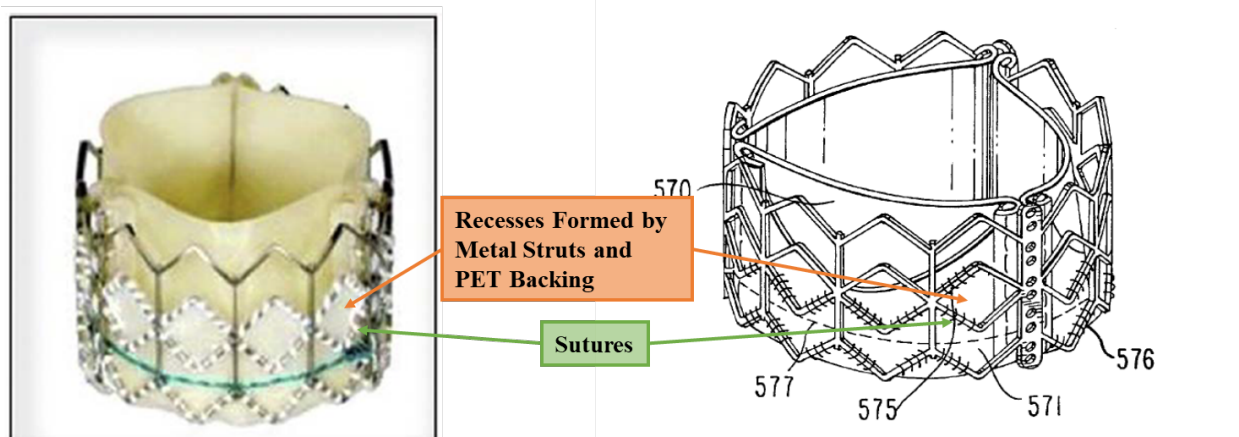
cover”); *see also id.*, 37:15-17, 40:4-8, 41:5-11, 42:3-8, 47:3-11, 60:11-20, 172:5-12.

56. In my opinion, a person of ordinary skill in the art would not conclude that Spenser II’s compressible material is limited to a cloth or fabric having a dense, tightly woven, nonporous “graft covering” as Dr. Brecker contends. To the contrary, it is my opinion that Spenser II teaches away from the use of such a dense, tightly woven, nonporous fabric as part of the compressible material. Instead, Spenser II teaches a person of ordinary skill in the art that porous, compressible fabrics, such as velour-like knitted or woven PET fabrics that were well known in November 2012 and were commonly used in cardiovascular implants for decades before 2012, should be used for the compressible material.

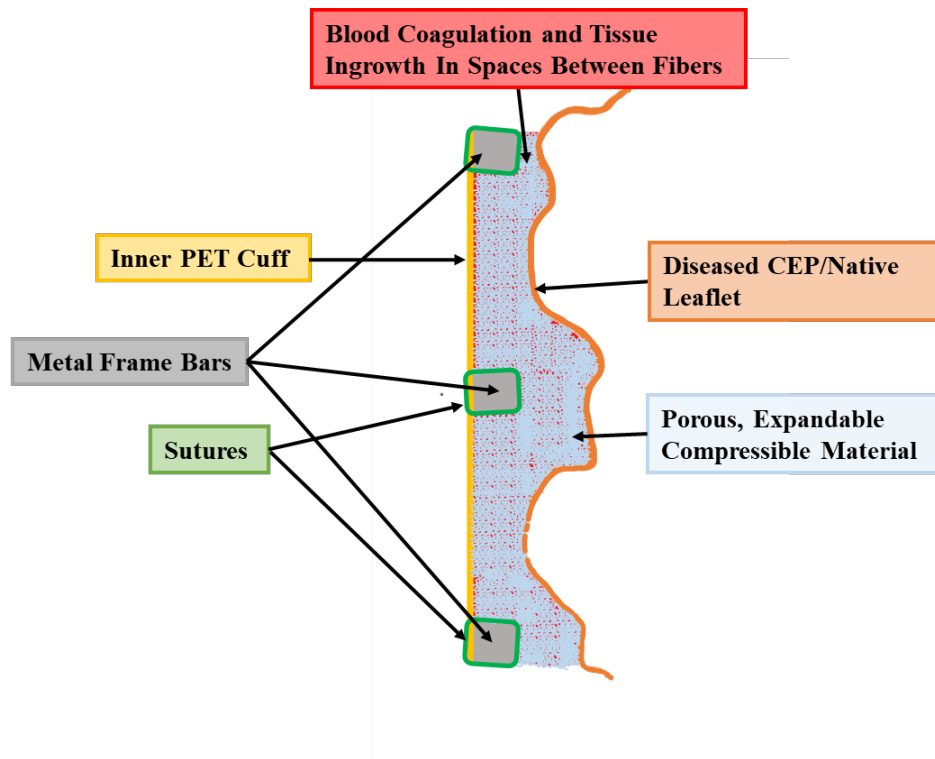
57. Spenser II describes the material 256 as “compressible.” As I explained above, a person of ordinary skill in the art would have understood that a porous cloth or fabric would be more compressible than a tightly woven, nonporous material. *Supra* ¶¶33, 45. Moreover, as I explained previously, a person of ordinary skill in the art would have been aware of many types of porous, velour-like fabrics that had been used in cardiovascular implant devices for decades prior to November 2012 because they were more flexible, compressible, and provided better healing porosity and tissue ingrowth than dense, tightly woven nonporous fabrics. *Supra* ¶¶28-29, 33-43, 45. Accordingly, a person of ordinary

skill in the art would have been motivated to use a porous fabric, such as a velour-like knitted or woven PET cloth, for the “compressible material” in Figure 22 of Spenser II. This is particularly the case given that Spenser II is directed to percutaneously delivered valves, which require a relatively smaller crimped profile than non-percutaneously delivered valves. Ex. 1011 (Spenser II) at Abstract. Therefore, Spenser II would have motivated a person of ordinary skill in the art to use a fabric that is as compressible as possible to minimize the crimped profile of the device, which would require a porous fabric.

58. Spenser II also 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.” *Id.* at [00145]. A person of ordinary skill in the art would understand that the compressible material must be a porous, compressible fabric in order to expand and “fill[] the gaps between the stented valve and the surrounding tissue” as described. Like I explained above with respect to the SAPIEN valve, the outer surface of a stented valve, such as the SAPIEN valve or the valve in Figure 44a of Spenser, in Figure creates an irregularly shaped surface, with gaps between the bars of the stent frame and sutures on the outside of the:



Ex. 1012 (Cribier) at Fig. 1; Ex. 1010 (Spenser) at Fig. 44a. Similarly, a person of ordinary skill in the art would have understood that the patient's diseased native valve leaflets would also present an irregularly shaped surface due to calcium deposits on the leaflets, which can form gaps and spaces on the surface of the native leaflets. As I explained above, a person of ordinary skill in the art would have understood that the compressible material must be a porous, compressible fabric in order to "expand" and "fill[]" the gaps" presented on the outer surface of the stented valve and the patient's diseased native leaflets. *Supra* ¶35. Again, this is illustrated in the diagram below, which is intended to represent a longitudinal cross-sectional view of one side of the SAPIEN valve/Figure 44a of Spenser with the addition of Spenser II's compressible material:



A dense, tightly woven nonporous material would not be able to “expand” and “fill[] the gaps,” and it would not be able to conform to the irregularly shaped surfaces surrounding the compressible material. Accordingly, Spenser II’s description of the compressible material “expand[ing] [to] fill[] the gaps between the stented valve and the surrounding tissue” teaches a person of ordinary skill in the art that the compressible material must be a porous, compressible fabric.

59. Spenser II also discloses that the fibers of the compressible material “may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that a porous fabric or cloth would be better suited to encourage the coagulation of blood in this manner because it would provide a

much greater surface area. *See, e.g.*, Ex. 2104 (Buller Dep.) at 119:13-18 (“The reason for having the increased surface area with all the fibers is to get blood clotting through the thickness of the cloth to help prevent paravalvular leakage, so that the increased surface areas with all the fibers matters all the way through to the frame.”); *see also* Ex. 2057 (Chu) at 4; Ex. 1106 (Estridge) at 158; Ex. 1107 (Hall) at 180-181; Ex. 1108 (Jonas) at 657; Ex. 1109 (Ko) at 1049. Accordingly, Spenser II’s description of the fibers of the compressible material encouraging coagulation of blood would further confirm to a person of ordinary skill in the art that the compressible material must be a porous fabric or cloth.

60. I disagree with Dr. Brecker’s opinion that Spenser II’s compressible material must include a “dense PET layer” that forms an “outer graft covering.” *See* Ex. 2103 (Second Brecker Decl.) at ¶75. I do not see any disclosure in Spenser II that supports Dr. Brecker’s opinion. Spenser II does not describe the compressible material as a “graft” or a “graft covering.” Spenser II does not describe the compressible material as “dense.” Spenser II does not describe the compressible material as including a “dense PET layer.” Spenser II does not describe the compressible material as nonporous. Spenser II does not describe the compressible material as opaque.

61. Dr. Brecker’s only alleged support for his opinion regarding the “dense PET layer” is Figure 22 of Spenser II. *See id.* at ¶78. I disagree with Dr.

Brecker's assessment of Figure 22 of Spenser II. As I testified in my deposition for several related IPRs, it is my opinion that Figure 22 of Spenser II is a diagrammatical representation of the placement of the compressible material along the outer surface of the valve. *See* Ex. 2052 (Buller Dep.) at 158:22-25, 160:17-20, 161:6-12, 167:2-9, 168:9-11. In my opinion, a person of ordinary skill in the art would not interpret the diagrammatic drawing in Spenser II to require a particular density of fibers in the compressible material or to suggest that the compressible material must include a "dense PET layer." *See id.* This is particularly the case given that the description of Figure 22 does not mention any such density. To the contrary, Spenser II describes the material as being "compressible," which would suggest to a person of skill in the art that the material is *not* a dense, tightly woven PET fabric because such a material would be non-compressible. *Supra* ¶¶33, 45.

D. The Dedashtian Reference Is Not Relevant To Or Limiting On The Teachings Of Walther And/Or Spenser II

62. Patent Owner and Dr. Brecker rely on U.S. Patent No. 6,663,667 ("Dedashtian") to argue that both Walther's outer PET cloth and Spenser II's compressible material must include a nonporous outer "graft covering." I disagree with Patent Owner and Dr. Brecker's interpretation and reliance on Dedashtian. In my opinion, Dedashtian has little-to-no relevance to Walther or Spenser II, and a person of ordinary skill in the art would not conclude that Walther and Spenser II are necessarily limited to the specific type of woven graft material disclosed in

Dedashtian. In my opinion, Patent Owner and Dr. Brecker's reliance on Dedashtian appears to be based on speculation and several unsupported inferences.

63. Dedashtian discloses a woven vascular graft that can be used to isolate and treat aneurisms in diseased blood vessels. *See, e.g.*, Ex. 2101 (Dedashtian) at Abstract. Dedashtian discloses that the vascular graft includes a "graft body," and that in certain embodiments, "floaters" can be incorporated into the woven graft material, which are "designed to increase tissue ingrowth." *Id.* at 6:60-64, 13:13-29. Dedashtian describes the floaters as "towel-like," and teaches that they may be "incorporated with the woven graft during the weaving process." *Id.* at 13:13-29. Notably, the vascular graft material disclosed in Dedashtian is not limited to a nonporous graft or fabric, and therefore, even the vascular graft in Dedashtian is not necessarily a "graft covering" as claimed in the '236 patent.

64. The only relationship between Dedashtian and Walther and/or Spenser II that Patent Owner and Dr. Brecker have identified is that Dr. Mark Dedashtian is one of the named inventors on the Dedashtian reference, one of the named inventors on Spenser II, and one of the authors of the Walther paper. From this, Patent Owner and Dr. Brecker conclude that the compressible material in Spenser II and the outer PET cloth in Walther must be identical to the "towel-like" woven vascular graft disclosed in Dedashtian. In my opinion, that conclusion is

speculative and requires several unsupported inferences, and I disagree with that conclusion for several reasons.

65. First, I do not see any reference to the Dedashtian patent in either Walther or Spenser II. This is particularly notable for Spenser II, given that Spenser II expressly references several other patents in paragraphs 3-9, and yet it does not contain any reference to the Dedashtian patent. *See* Ex. 1011 (Spenser II) at [0003]-[0009]. In my opinion, this is strong evidence that the “compressible material” disclosed in Spenser II is not limited to the woven vascular graft disclosed in Dedashtian. If Spenser II’s “compressible material” were limited to the woven vascular graft disclosed in Dedashtian, I believe that Spenser II would have incorporated the Dedashtian patent by reference, or at the very least it would have mentioned the Dedashtian patent in its description of the “compressible material.” Spenser II does neither. As a result, there is simply no disclosure in Spenser II that would suggest to a person of ordinary skill in the art that the “compressible material” must be limited to the woven endoluminal graft material in Dedashtian.

66. Second, in addition to the lack of any reference to the Dedashtian patent, neither Walther or Spenser II use similar language to describe the outer cloth/compressible material as that used in the Dedashtian patent. As I noted above, Dedashtian describes its material as a “woven graft” that includes “towel-

like floaters” incorporated into the woven material. Ex. 2101 (Dedashtian) at 13:13-29. Walther does not refer to the outer PET cloth as a “graft.” Walther also does not mention any “towel-like floaters.” Similarly, Spenser II does not disclose any “graft” as being part of the “compressible material.” Spenser II also does not describe the compressible material as “towel-like” or including “floaters.” In my opinion, this is further strong evidence that the “compressible material” disclosed in Spenser II and the outer PET cloth in Walther are not limited to the woven vascular graft disclosed in Dedashtian. The fact that Dedashtian expressly discloses a “woven graft” material, while neither Spenser II or Walther contain any such description would suggest to a person of ordinary skill in the art that Spenser II and Walther do not include such a “woven graft.” If Spenser II’s “compressible material” were limited to the woven vascular graft disclosed in Dedashtian, I believe that at the very least the inventors of Spenser II would have used similar language to describe the “compressible material” as that used for the “towel-like” woven vascular graft in Dedashtian. They did not.

67. In my opinion, the evidence that Walther and Spenser II are not limited to the woven graft disclosed in Dedashtian is far more compelling than Dr. Brecker’s speculation to the contrary.

68. For the reasons above, it is my opinion that at most, the Dedashtian patent discloses one example of a woven graft material for use in treating

aneurisms. However, a person of skill in the art would not find this one example to be limiting on the teachings of Spenser II or Walther, particularly given the many other types of porous, compressible, velour-like fabrics that were well-known for use in cardiovascular implant devices prior to November 2012. *Supra* ¶¶29, 45. Accordingly, it is my opinion that the Dedashtian patent has very little, if any, relevance to obviousness analysis for the challenged claims of the '236 patent. The Dedashtian patent certainly does not change my opinion that neither Walther's outer PET cloth nor Spenser II's compressible material include an "outer graft covering" as that term is claimed in the '236 patent. As I noted above, even the vascular graft material in Dedashtian is not limited to nonporous fabrics and therefore encompasses materials that lack a "graft covering" as claimed in the '236 patent. *Supra* ¶63.

III. "SECOND PORTION OF FIBERS"

A. Walther's Outer Cloth Includes A "Second Portion Of Fibers"

69. In his Second Declaration, Dr. Brecker repeatedly testifies that Walther's outer PET cloth does not include any "inwardly-facing fibers" and therefore does not teach a "second portion of fibers" as recited in claim 1 of the '236 patent. I disagree with Dr. Brecker's opinion for several reasons.

70. First, Dr. Brecker appears to be requiring an additional limitation for the "second portion of fibers" that is not recited in the claims – that the "second

portion of fibers” must be “inwardly extending fibers.” *See, e.g.*, Ex. 2103 (Second Brecker Decl.) at ¶101 (opining that the Cheung lacks “inwardly-extending fibers”). I disagree with Dr. Brecker importing this extra limitation into the “second portion of fibers” limitation. Claim 1 of the ’236 recites “a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst.” Ex. 1001 (’236 patent) at claim 1. Thus, the claim language requires that the “second portion of fibers” is: (1) carried by the outer frame, and (2) is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst. Nothing in the claim language supports Dr. Brecker’s requirement that the second portion of fibers be “inwardly-extending.”

71. Second, Dr. Brecker’s opinion that Walther’s outer cloth does not include “inwardly-facing fibers” is inconsistent with Walther’s disclosure. As I explained in my previous Declaration submitted in this IPR, Walther’s outer cloth includes two surfaces – one that faces outwardly relative to the SAPIEN valve and one that faces inwardly relative to the SAPIEN valve. Ex. 1003 (Buller Decl.) at ¶132. Walther describes the outer PET cloth as a “PET cloth” that was “stitched onto the perimeter of each SAPIEN valve.” Ex. 1007 (Walther) at 1121. A person of ordinary skill in the art would therefore have understood that the entirety

of Walther's outer PET cloth is composed of PET fibers. I note that Dr. Brecker admitted during his deposition that the alleged "dense PET layer" in Walther's outer cloth would be made of PET fibers. Ex. 1105 (Brecker Dep.) at 133:18-134:7. Accordingly, both the outward facing surface of Walther's PET cloth and the inward facing surface of Walther's PET cloth are made of fibers.

72. As I explained in my previous Declaration, the fibers that form the inwardly facing surface of Walther's outer PET cloth are carried by the frame of the SAPIEN valve because Walther describes the cloth as being "stitched to the perimeter of each SAPIEN valve." Ex. 1003 (Buller Decl.) at ¶133. Dr. Brecker agreed during his deposition that Walther's PET cloth is "attached to" (i.e., carried by) the frame of the SAPIEN valve. Ex. 1105 (Brecker Dep.) at 142:19-148:20.

73. As I also explained in my previous Declaration, the fibers that form the inwardly facing surface of Walther's outer PET cloth press against the outer frame when the valve is expanded, forming a "second sealing interface thereagainst." *Id.* at ¶134. As I further explained during my deposition, Walther discloses that its outer PET cloth creates a "seal between the two valves." Ex. 2104 (Buller Dep.) at 74:9-21, 76:14-79:24; *see also* Ex. 1007 (Walther) at 1120. One of the "two valves" referred to in that statement is the SAPIEN valve, and thus Walther's express disclosure confirms that a seal is formed between the inwardly facing surface of the outer PET cloth and the frame of the SAPIEN valve. Ex.

2104 (Buller Dep.) at 74:9-21, 76:14-79:24; *see also* Ex. 1007 (Walther) at 1120. Dr. Brecker appears to agree. *See* Ex. 1105 (Brecker Dep.) at 142:19-148:20 (Dr. Brecker testifying that Walther's alleged dense PET layer is "attached" to the outer frame and that the aim of Walther's outer cloth "is to seal the space between the two valves").

74. Accordingly, as I explained in my prior Declaration, the fibers that compose the inwardly facing surface of Walther's outer PET cloth satisfy both requirements for the "second portion of fibers" that are recited in claim 1 of the '236 patent. *See* Ex. 1003 (Buller Decl.) at ¶¶131-134.

75. I am aware that in its Institution Decision, the Board provided the following analysis of the "second portion of fibers" limitation with respect to Walther's outer cloth:

Petitioner argues that "the inwardly-facing fibers press[] through the open cells of the outer frame and extending radially inwardly of the outer frame" and that these "inwardly-facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded." Pet. 44–45. We interpret Petitioner's argument to mean that, either due to the elastic nature of the PET cloth or, when expanded in situ into the annulus of the aortic valve, the resulting inward force of the pressure exerted on the outer cloth of the valve by the annulus and native leaflets of the aortic valve would force some of the fibers of the outer cloth inwards through the interstices of the metallic outer frame against the inner frame, thus forming a second portion of inward facing fibers, and forming a second sealing interface between the inner and outer frames. In any event, the figure from Walther above appears to show fibers on the inside and on the outside of the metallic frame.

This analysis depends at least in part upon the nature of Walther's outer cloth. A close inspection of Walther's Figure 1 could lead an individual to conclude that the outer cloth comprises an outer fibrous layer and a solid woven "backing layer" that forms the inner surface of the cloth. This could be interpreted as being the brighter white line forming the inner surface of the outer cloth. Such a backing layer would prevent any of the outer fibers from penetrating inwardly through the interstices of the outer frame and also from forming a second sealing interface between inner and outer frames.

Paper 10 at 27-28. It appears from this discussion that the Board may have misunderstood my analysis of Walther's outer cloth from my prior Declaration, so I provide this additional explanation to clarify any misunderstanding.

76. Claim 1 of the '236 patent requires that the "second portion of fibers" is "configured to form a second sealing interface *against the outer frame.*" Ex. 1001 ('236 patent) at claim 1 (emphasis added). Claim 1 of the '236 patent **does not** require a sealing interface between the "inner and outer frames." Therefore, while it is correct that some of the inwardly facing fibers that form the inward-facing surface of Walther's outer cloth can be seen poking through the struts of the frame, those **are not** the fibers that form the recited "second sealing interface" recited in claim 1. Instead, the fibers on the inward-facing surface of Walther's outer PET cloth that press against the bars of the outer frame are the fibers that form the required "second sealing interface" that is *against the outer frame.* See Ex. 1003 (Buller Decl.) at ¶132. In my opinion, the claims of the '236 patent do not require that any of the "second portion of fibers" extend radially inwardly of

the outer frame to form an additional seal with the inner frame, as suggested in the Board's Institution Decision.

77. I also do not agree that the issue of whether Walther's outer PET cloth includes a "backing layer" is determinative on the "second portion of fibers" limitation. As I noted above, Dr. Brecker admitted that even if Walther's outer PET cloth includes a "backing layer," that "backing layer" would be made up of PET fibers. Ex. 1105 (Brecker Decl.) at 133:18-134:7. And because that fibrous "backing layer" would be sutured to the SAPIEN valve's frame and would seal against the frame when it is expanded in a patient, the fibrous "backing layer" would constitute the "second portion of fibers" recited by claim 1.³

B. Spenser II's Compressible Material Includes A "Second Portion Of Fibers"

78. I disagree with Dr. Brecker's opinion that Spenser II's compressible material does not disclose the "second portion of fibers" recited in claim 1 of the '236 patent for several reasons.

³ As I explained previously, a person of ordinary skill in the art would have understood that even if Walther's outer PET cloth included a "backing layer," the "backing layer" would have been porous and would not constitute an "outer graft covering" as that term is claimed in the '236 patent. *Supra* §II.B.

79. First, Dr. Brecker’s analysis again appears to rely on the addition of an unrecited claim limitation that is not required by claim 1 – that the second portion of fibers be formed of “extending” fibers. *See* Ex. 2103 (Brecker Second Decl.) at ¶¶124-125 (arguing that Spenser II does not include fibers “extending from” its inner surface). As I explained above, claim 1 of the ’236 patent requires that the “second portion of fibers” is (1) carried by the outer frame, and (2) is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst. Claim 1 does not require that the “second portion of fibers” are “extending,” as Dr. Brecker’s implicit construction requires.

80. Second, 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 at [00145]. A person of ordinary skill in the art would have understood that the entirety of the “cloth or fabric” making up the compressible material would be composed of fibers. A person of ordinary skill would have also understood that the compressible material includes two “surfaces,” one surface that faces outwardly from the valve and one surface that faces inwardly toward the valve, which presses against the valve’s frame. A person of ordinary skill in the art would have understood that both surfaces would be composed of fibers, and as I explained in my previous Declaration, the fibers that form the inward-facing

surface of the compressible material, which press against the frame of the prosthetic valve, are the “second portion of fibers” claimed in the ’236 patent. Ex. 1003 (Buller Decl.) at ¶195. Moreover, for the reasons I explained in the previous paragraph, the fibers that make up the inwardly facing surface of Spenser II’s compressible material would form the “second portion of fibers” as claimed in the ’236 patent, regardless of whether those fibers are “extending” from the inwardly facing surface of the material.

81. Although Dr. Brecker opines that the inner surface of Spenser II’s compressible material is not formed of fibers, Dr. Brecker fails to explain what the inner surface of the compressible material is made from, if not PET fibers. Moreover, Dr. Brecker’s own Declaration conflicts with his opinion that the inner surface of the compressible material is not comprised of fibers, as Dr. Brecker refers to Spenser II’s compressible material as being a “woven PET compressible material.” Ex. 2103 (Second Brecker Decl.) at ¶123. Dr. Brecker admitted in his deposition that “woven PET is made of woven PET fibers.” Ex. 1105 (Brecker Dep.) at 133:18-134:7.

82. Third, even if the “second portion of fibers” were required to be “extending,” I disagree with Dr. Brecker’s opinion that Spenser II’s compressible material is limited to a fabric or cloth having fibers that extend only from the outward-facing surface of the material. *See id.* at ¶¶123-126. Spenser II explains

that the compressible material may “resemble a cloth or fabric having small fibers extending from the surface of the material.” Ex. 1011 at [00145]. Notably, the description of the compressible material **does not** state that the fibers extend **only** from the outward-facing surface of the material. *See id.* Moreover, in the same paragraph of Spenser II that describes that the fibers “extend from the surface of the material,” Spenser II also describes that a growth factor may be “applied along the **outer surface** of the compressible material.” *Id.* (emphasis added). This tells a person of ordinary skill in the art that the inventors of Spenser II clearly knew how to specify a disclosure for the outer surface of the compressible material when they so intended. The fact that the inventors did not reference the “outer surface” when describing the “fibers extending from the surface of the material,” like they did for the growth factor, would confirm to a person of ordinary skill in the art that the extending fibers are not limited to just the outward facing surface of the material. *See* Ex. 2104 (Buller Dep.) at 115:9-117:19. Additionally, as I explained during my deposition, a person of ordinary skill in the art would have understood that having extending fibers on both the inner and outer surfaces of the compressible material would be helpful in promoting blood clotting through the thickness of the material to aid in preventing paravalvular leaks. *See* Ex. 2104 (Buller Dep.) at 119:13-18. And as I explained above, a person of ordinary skill in the art would have understood that the inwardly facing surface of the compressible material must

be formed of porous, compressible fibers in order to “fill[] the gaps between the stented valve and the surrounding tissue” as taught in Spenser II. *Supra* ¶¶35, 58.

IV. “OPENINGS” BETWEEN ADJACENT FIBERS

A. Dr. Brecker’s Construction Of “Openings” Is Not Correct

83. In his Second Declaration submitted in this IPR, Dr. Brecker proposed the following claim construction for the term “opening extending through a thickness thereof that is created by spacing formed between adjacent fibers,” in claim 4 of the ’236 patent: “the ‘openings’ claimed are relatively larger and created by design, rather than the mere inherent spaces between fibers.” Ex. 2103 (Second Brecker Decl.) at ¶142. Dr. Brecker also appears to suggest that the “opening” must be created “between ‘segments of some fibers,’” rather than between individual fibers. *Id.* at ¶141. I disagree with Dr. Brecker’s interpretations of the “openings” limitation in claim 4 for several reasons.

84. First, Dr. Brecker states that the “openings” must be “relatively larger,” but he fails to explain what the openings must be “relatively larger” than. I note that Dr. Brecker was unable to provide any such explanation during his deposition. *See* Ex. 1105 (Brecker Dep.) at 179:4-17. This lack of explanation leaves a person of ordinary skill in the art without any workable definition for determining whether the “openings” limitation is satisfied. To the extent that Dr. Brecker was referring to “openings” that are “relatively larger” than “inherent

spaces between fibers,” his interpretation still leaves a person of ordinary skill in the art without a workable definition. It is unclear what Dr. Brecker believes the size of an “inherent space[] between fibers” to be, and such sizes could vary widely depending on the type of fabric. For example, a porous fabric, such as a velour-like fabric, would have larger “inherent spaces between the fibers” than a tightly woven nonporous fabric. Therefore, I do not believe a person of ordinary skill in the art could reasonably apply Dr. Brecker’s definition to either the prior art or an accused device to determine whether it includes the claimed “opening.”

85. Moreover, Dr. Brecker’s requirement for the openings to be “relatively larger” is not supported by the claim language, the specification, or the prosecution history of the ’236 patent. Nothing in the claim language refers to the size of the “opening.” *See* Ex. 1001 (’236 patent) at claim 4. Similarly, the specification of the ’236 patent does not describe or disclose the sizes of any “opening” or “spacing” between the collagen fibers. There is no indication in the ’236 patent’s specification that any of the figures are drawn to scale. I also do not see anything in the prosecution history of the ’236 patent where the Applicant defined the “opening” by its size or distinguished the prior art based on the size of the “opening.” In short, there is nothing in the intrinsic record that supports limiting the claimed “opening” to any particular size. Indeed, the specification teaches that the frame can be “covered” by collagen, further demonstrating that the

patent is not limited to the arrangement of fibers depicted in the drawings. *See id.* at 4:30-32, 19:36-40; *see also* Ex. 1006 ('446 provisional) at 44 (reciting dependent claim “wherein the self-expanding outer frame is covered with collagen or hydrogel”).

86. Second, Dr. Brecker’s requirement that the openings be “created by design” also renders his construction ambiguous. It is not clear what Dr. Brecker means with this language. As I explained above, velour-like fabrics are designed to be porous, which improves their stretchability, compressibility, and ability to promote healing and tissue ingrowth. *Supra* ¶¶28-29, 33-39, 45. It is not clear whether the spaces between fibers in such a porous fabric would be “created by design” under Dr. Brecker’s construction, or whether he would consider them to be “inherent.” Thus, I do not believe a person of ordinary skill in the art could reasonably apply Dr. Brecker’s definition to either the prior art or an accused device to determine whether it includes the claimed “opening.”

87. Third, Dr. Brecker’s requirement that the openings are formed between “some segments of fibers” is not supported by the claim language or the specification of the '236 patent, and it injects significant ambiguity into the claim. The claim language refers to “openings” that are created by “spacing formed between adjacent fibers.” Ex. 1001 ('236 patent) at claim 4. The claim does not recite openings between “segments” of fibers. The specification also does not

describe or refer to any “openings” between “segments” of fibers. Moreover, it is not clear what would constitute a “segment” of fibers under Dr. Brecker’s construction. Dr. Brecker was unable to provide any clarification during his deposition. Ex. 1105 (Brecker Dep.) at 198:11-16.

B. Walther And Spenser II Disclose “Openings” Between Adjacent Fibers

88. As I explained above and in my previous Declaration, a person of ordinary skill in the art would have understood that Walther’s outer PET cloth and Spenser II’s compressible material would be formed of porous, compressible fabrics, like the porous fabrics that had been used in cardiovascular implant devices for decades prior to November 2012. *Supra* §§II.B-C. A person of ordinary skill in the art would have understood that such porous fabrics include openings that are “created by spacing formed between adjacent fibers,” as claimed in claim 4 of the ’236 patent, in order to promote tissue ingrowth. *See, e.g.*, Ex. 1106 (Estridge) at 158 (“Most researchers suggest that 40 μm diameter pores or more are needed for soft tissue ingrowth, while others argue that pores of at least 100 μm are needed.”). A person of ordinary skill in the art would have understood that such openings must exist between the fibers making up both the outward facing surface of the cloth (i.e., the first portion) and the fibers making up the inward facing surface of the cloth (i.e., the second portion). As I explained previously, such openings are necessary to allow tissue ingrowth into the

fabric/cloth and to allow the fabric/cloth to be compressible and conform to the stent frame as the valve is crimped and expanded. *Supra* ¶¶285-29, 33-39, 45, 57-59. If either surface of the cloth/fabric lacked such openings, the cloth would not serve the stated purposes for the outer seal disclosed in Walther and Spenser II.

89. As I explained in my previous Declaration, a person of ordinary skill in the art would have understood that the openings that are formed between the adjacent fibers on the inwardly facing surface of Walther's outer cloth and Spenser II's compressible material (i.e., the second portion) would extend to the outer frame because the inwardly facing surfaces of the fabrics directly abut the outer frame in Walther and Spenser II. *See* Ex. 1003 (Buller Decl.) at ¶¶155-158, 222-223.

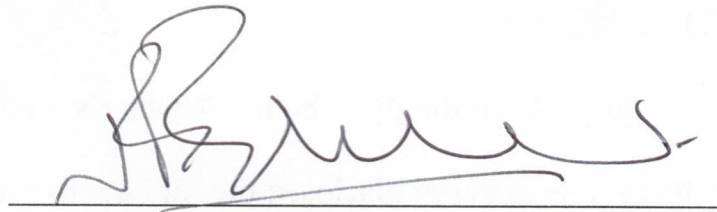
90. Accordingly, both Walther's outer cloth and Spenser II's compressible material disclosed the limitations recited in dependent claim 4 of the '236 patent.

V. CONCLUSION

91. For the foregoing reasons, and the reasons provided in my previous Declaration submitted in this IPR (Ex. 1003), it is my opinion that claims 1-4 of the '236 patent are anticipated and/or rendered obvious by the prior art discussed above in view of the knowledge of one of ordinary skill in the art at the time of the alleged invention.

92. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: March 13, 2023.

A handwritten signature in black ink, appearing to read 'Nigel P. Buller', is written over a horizontal line.

Dr. Nigel P. Buller