

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS LLC,
Patent Owner.

Case IPR2022-00556
Patent 10,987,236

EXHIBIT 2103

SECOND DECLARATION OF DR. STEPHEN J.D. BRECKER

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I. INTRODUCTION

1. My name is Stephen J.D. Brecker. I have been retained as an expert witness to provide my independent opinion in regard to the matters at issue in *inter partes* review of U.S. Patent No. 10,987,236 (“the ’236 patent”) in IPR2022-00556. I have been retained by Aortic Innovations LLC (“Aortic Innovations”), the Patent Owner in the above proceedings. Petitioner is Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively “Edwards” or “Petitioner”).

2. I am being compensated GB£625.00 per hour for my time spent working in connection with this case. My compensation is in no way related to the outcome of this litigation. If called as a witness, I would testify as to the statements and opinions contained in this report.

3. I am not a legal expert and offer no opinions on the law. However, I have been informed by counsel of the various legal standards that apply, and I have applied those standards in arriving at my conclusions.

II. QUALIFICATIONS

4. I am an interventional cardiologist with a special interest in adult structural heart disease and valvular intervention. I have over 25 years of medical experience as a practicing interventional cardiologist. I am a Consultant Cardiologist at St. George’s University Hospitals in London, U.K. and Professor of

Cardiology at St. George's University of London. I have recently completed a six-year term as Chief of Cardiology at these institutions. I have performed over thirteen hundred transcatheter aortic valve replacement ("TAVR") procedures.

5. I graduated from St. Thomas' Hospital Medical School, London in 1984. Subsequently, I completed senior house officer posts at the Hammersmith Hospital, St. Thomas' Hospital, the Brompton Hospital, and the National Hospital for Nervous Diseases. I then completed registrar training in cardiology at St. Thomas' Hospital and the London Chest Hospital, before taking up a British Heart Foundation Junior Research Fellowship at the Royal Brompton Hospital. I was also a visiting fellow at Johns Hopkins Hospital, Baltimore, before becoming a Consultant Cardiologist and Honorary Senior Lecturer at St. George's in 1996. I am now Professor of Cardiology and Consultant Cardiologist at St. George's University Hospitals.

6. I have proctored over 600 TAVR procedures in which I assist and teach other physicians how to perform TAVR. I have been and remain a Global proctor for Medtronic since 2010 at approximately 80 centers worldwide, including over 50 medical centers in the USA for the US Pivotal Trial of the Corevalve product. I have also proctored the TAVR procedure in the UK, Denmark, Belgium, Japan, India, Israel, Holland, Austria, Greece, Thailand, Vietnam, Singapore, Sri Lanka and South Korea.

7. I have performed TAVR procedures with Medtronic's Corevalve EvolutR, Evolut PRO and Evolut PRO+products, as well as Boston Scientific's Lotus product and Edwards' Sapien products.

8. I have been active in the field of TAVR as a clinician, researcher, teacher, and innovator, and I have performed over 1,300 percutaneous TAVR procedures since 2007, including more than 200 cases between 2007 and 2012. I have proctored over 600 TAVR procedures and taught other physicians how to perform TAVR in 14 countries. I have performed TAVR operations with numerous devices including Edwards' SAPIEN products.

9. I have been a practising cardiologist since 1996 and I am aware of the technological advances since then.

10. I have experience, since 1996, of looking after cardiology patients with thoracic and abdominal aortic aneurysms and have over more than 20 years, worked closely with our vascular team in their management. St. George's Vascular Surgery are considered international leaders in this field and have carried out many of the pivotal clinical trials in this area. I refer these patients for assessment and treatment and look after them before and after. On a daily basis I have always interacted with our vascular team and discussed cross-over technologies between our subspecialties. I have implanted covered coronary stents

and peripheral stent grafts (probably around 30 procedures for management of iliofemoral perforations following TAVR procedures since 2007).

11. I am a named inventor on one patent, describing a specific TAVR guidewire, acquired by Medtronic.

12. I am a Fellow of the Royal College of Physicians, the European Society of Cardiology, the American College of Cardiology, the British Cardiovascular Society, and the British Cardiovascular Intervention Society.

13. I am the author or co-author of four books, 16 book chapters, and more than 130 peer-reviewed articles.

14. In my professional experience, I have become familiar with many problems faced by cardiologists, surgeons, and medical device engineers, in transcatheter aortic valve replacement and related topics.

15. A detailed record of my professional qualifications is set forth in the attached Exhibit A, which is my *curriculum vitae*, including a list of publications, awards, and professional activities. A list of the depositions, hearings, and trial at which I have testified is set forth in the attached Exhibit B.

III. BASES OF OPINIONS

16. In the course of conducting my analysis and forming my opinions, I have reviewed materials including those listed below:

- i. U.S. Patent No. 10,987,236 (Ex. 1001) (“the ’236 patent” or “’236”);

- ii. The prosecution history of the '236 Patent (Ex. 1002);
- iii. The Declaration signed by Nigel P. Buller, M.D. in IPR2022-00556 (Ex. 1003) (the “Buller Declaration”);
- iv. The Petition by Edwards in IPR2022-00556;
- v. Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves*, 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“Walther”) (Ex. 1007);
- vi. U.S. Patent No. 9,393,110 B2 to Levi et al. (“Levi”) (Ex. 1008);
- vii. Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010*, 2(4) Interventional Cardiology 513-523 (2010) (“Conradi”) (Ex. 1009);
- viii. U.S. Patent No. 7,510,575 to Spenser et al. (“Spenser”) (Ex. 1010);
- ix. WO 2006/005015 A2 to Spenser et al. (“Spenser II”) (Ex. 1011);
- x. Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach*, Herz, 34:347-56 (2009) (“Cribier”) (Ex. 1012);
- xi. U.S. Provisional Application No. 61/567,458 (Ex. 1005);

- xii. U.S. Provisional Application No. 61/723,446 (Ex. 1006);
- xiii. U.S. Patent No. 3,365,728 to Edwards et al. (Ex. 1013);
- xiv. U.S. Patent No. 5,411,552 to Andersen et al. (Ex. 1014);
- xv. U.S. Patent Pub. No. 2003/0153974 to Spenser et al. (Ex. 1015);
- xvi. Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 ((September/October 2010) (Ex. 1016);
- xvii. Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human*, *Annals of Thoracic Surgery*, 87:e 18-20 (2009) (Ex. 1017);
- xviii. PCT Publication No. WO 98/29057 to Letac et al. (Ex. 1018);
- xix. U.S. Patent No. 6,893,460 B2 to Spenser et al. (Ex. 1019);
- xx. Yuksel, Uygur, *Balloon-Expandable Transcatheter Aortic Valve Implantation*, Cardiac Interventions Today (Aug./Sept. 2009) (Ex. 1020);
- xxi. Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation*, 116 [suppl I] *Circulation* I-240—I-245 (September 11, 2007) (Ex. 1021);

- xxii. Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients*, 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011) (Ex. 1022);
- xxiii. Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches*, Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012) (Ex. 1023);
- xxiv. Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement*, 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) (Ex. 1024);
- xxv. Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis*, 106 Circulation 3006-3008 (December 10, 2002) (Ex. 1025);
- xxvi. U.S. Patent No. 7,393,360 to Spenser et al. (Ex. 1026);
- xxvii. Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) (Ex. 1027);
- xxviii. Tyagi, G.K., *Chapter 5: Yarn structure and properties from different spinning techniques*, Advances in Yarn Spinning Technology (Ex. 1028);

- xxix. Kothari, V K, *Hairiness properties of polyester-cotton blended yarns*, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) (Ex. 1029);
- xxx. Cribier, Alain, et al., *Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis*, 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004) (Ex. 1030);
- xxxi. Akin, Jodi and Sharma, Pooja, “Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System,” *Transcatheter Aortic Valve Implantation*, edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114 (Ex. 1031);
- xxxii. Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011) (Ex. 1032);
- xxxiii. Press Release: FDA Approves Expanded Indication for Edwards Lifesciences’ Transcatheter Valve (October 19, 2012) (Ex. 1033);
- xxxiv. Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial*

- results with implantation by catheter technique in closed chest pigs,*
European Heart Journal, 13:704-08 (1992) (Ex. 1034);
- xxxv. U.S. Patent No. 5,957,949 to Leonhardt et al. (Ex. 1035);
- xxxvi. Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems*, Catheterization and Cardiovascular Interventions, 75:295-300 (2010) (Ex. 1036);
- xxxvii. U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al. (Ex. 1037);
- xxxviii. Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007) (Ex. 1038);
- xxxix. Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021 (Ex. 1039);
- xl. SAPIEN Instructions For Use (Ex. 1040);
- xli. Saia, Francesco, et al., *In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry*, EuroIntervention 15:1240-1247 (2020) (Ex. 1041);
- xlii. Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010) (Ex. 1042);

- xliii. Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan*, General Thoracic Cardiovascular Surgery 59:273-276 (2011) (Ex. 1043);
- xliv. Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations*, J. Endovasc. Ther. 14:347-351 (2007) (Ex. 1044);
- xlv. U.S. Patent No. 7,585,321 B2 to Cribier et al. (“Cribier ’321”) (Ex. 1045);
- xlvi. Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020 (Ex. 1046);
- xlvii. Piazza, Nicolo, et al., *Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve*, Cir Cardiovascular Intervention 1:74-81 (2008) (Ex. 1047);
- xlvi. WO 2011/051043 A1 to Essinger et al. (Ex. 1048);
- xlix. Excerpts from the prosecution history of U.S. Patent No. 10,792,172 (Ex. 1049);
- l. Complaint from Aortic Innovations LLC v. Edwards Lifesciences Corp., 1-21-cv-01377, District of Delaware (Filed Sept. 28, 2021) (Ex. 1050);
- li. U.S. Patent No. 6,730,118 B2 to Spenser et al. (Ex. 1051);

- lii. PCT Publication No. WO 2006/124649 A3 to Nguyen et al. (Ex. 1052);
- liii. U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh (Ex. 1053);
- liv. U.S. Patent Pub. No. 2011/0098802 to Braidó et al. (Ex. 1054);
- lv. Excerpts from the prosecution history of U.S. Patent No. 10,857,011 (Ex. 1055);
- lvi. Excerpts from the prosecution history of U.S. Patent No. 10,881,538 (Ex. 1056);
- lvii. U.S. Patent No. 7, 524,331 B2 to Birdsall (Ex. 1057);
- lviii. Declaration of Sylvia D. Hall-Ellis Ph.D. (Ex. 1059);
- lix. Walther, Thomas, et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves*, 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (November 2011), obtained from the University of California Los Angeles Library (Ex. 1060);
- lx. European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database (Ex. 1061);
- lxi. Library of Congress subject heading sh85059711 (Ex. 1062);
- lxii. Library of Congress subject heading sh85099890 (Ex. 1063);
- lxiii. Library of Congress subject heading sh85023143 (Ex. 1064);

- lxiv. Azadani, Ali N., *Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation*, *Cir Cardiovascular Intervention* 4:621-628 (2011) (Ex. 1065);
- lxv. Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach*, *Herz*, 34:347-56 (2009), obtained from the British Library (Ex. 1066);
- lxvi. Herz MARC Record from the British Library (Ex. 1067);
- lxvii. Library of Congress subject heading sh2009118412 (Ex. 1068);
- lxviii. Herz MARC Record from the OCLC Database (Ex. 1069);
- lxix. The exhibits and other documents cited herein. Additionally, my opinions are further informed by the materials and testimony in IPR2021-01527, -01584, 2022-00034, -00193, including my own.

IV. APPLICABLE LEGAL STANDARDS

A. Level Of Ordinary Skill In The Art

17. My opinions in this declaration are based on the understandings of a person of ordinary skill in the art, which I understand is sometimes referred to as an “ordinary artisan” or by the acronyms “POSITA” or “PHOSITA,” as of the time of the invention. I understand that Petitioner has asserted that the time of the

invention is November 7, 2012, the filing date of provisional application 61/723,446. Pet., 26. For the purposes of this declaration I will use this date as the time of the invention of the '236 patent. I understand that the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. By "relevant," I mean relevant to the challenged claims of the '236 patent.

18. I understand that factual indicators of the level of ordinary skill in the art include the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field. I understand that, in assessing the level of skill of a person of ordinary skill in the art, one should consider the type of problems encountered in the art, the prior solutions to those problems found in the prior art references, the rapidity with which innovations are made, the sophistication of the technology, the level of education of active workers in the field, and my own experience working with those of skill in the art at the time of the invention.

19. In this case, Dr. Buller has asserted in his declaration that a person of ordinary skill in the art as of the time of the '236 patent would have:

been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This person of ordinary skill in the art would, where necessary, work as a team in combination

with a medical device engineer to experiment with or manufacture a prosthetic heart valve.

Ex. 1003 [Buller-Decl.] ¶ 45.

20. I do not believe this level of ordinary skill is correct. In view of the types of problems confronting TAVRs with respect to endovascular delivery and paravalvular leakage, I believe the level of ordinary skill would be an interventional cardiologist with experience implanting, researching or designing TAVRs in the 2010-2012 timeframe. Notably, many of Petitioner's references—Levi (filed Oct. 2011), Walther (available online, April 2011)—are from this timeframe. My opinion on the level of ordinary skill is informed by the opinions proffered in Section VI of this declaration.

21. The 2012 timeframe is critical to understanding the operative level of skill. The TAVR landscape in 2012 was extremely active both clinically and from a research and development perspective. Many called TAVR the most exciting innovation in interventional cardiology for decades and perhaps ever. By 2012, large numbers of TAVR procedures had been performed by interventional cardiologists. For an interventional cardiologist to claim skill in the art in 2012, it is my opinion he or she would have to have been involved in clinical implant procedures. Many cardiologists were also involved in clinical research concerning TAVRs—either by being involved in clinical trials (recruitment, trial design,

steering committees), or working with industry in TAVR design (design panels, advisory boards, usability testing). If an individual had none of the above activities, my opinion would be that they could not be considered a POSITA in 2012. Cardiologists involved in the field and professing a level of ordinary skill would have been actively involved in at least one and typically at least two or three of the above domains.

22. As further discussed below, my opinions as stated in this declaration are valid even if the Board adopts a slightly different level of ordinary skill in the art.

B. My Understanding Of Legal Standards

23. When considering the '236 patent and stating my opinions, I rely on the following legal standards as described to me by the attorneys for Aortic Innovations.

24. I understand that a patent claim is unpatentable if the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the purported invention.

25. I understand that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the invention in view of the prior art and in light of the general knowledge in the art as a whole. I also

understand that obviousness is ultimately a legal conclusion based on underlying facts of four general types, all of which must be considered: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of non-obviousness, including any praise of the invention.

26. I also understand that obviousness may be established under certain circumstances by combining or modifying the teachings of the prior art. Specific teachings, suggestions, or motivations to combine any first prior art reference with a second prior art reference can be explicit or implicit, but must have existed before the date of purported invention. I understand that prior art references themselves may be one source of a specific teaching or suggestion to combine features of the prior art, but that such suggestions or motivations to combine art may come from the knowledge that a person of ordinary skill in the art would have had.

27. I understand that a reference may be relied upon for all that it teaches, including uses beyond its primary purpose, but also including teachings that lead away from the invention. I understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, although the mere disclosure of alternative designs does not teach away.

28. I further understand that whether there is a reasonable expectation of success in combining references in a particular way is also relevant to the analysis.

29. I understand that it is improper to use hindsight to combine references or elements of references to reconstruct the invention using the claims as a guide. My analysis of the prior art is made from the perspective of a person of ordinary skill in the art at the time of the invention.

30. I am not offering any legal opinions in this declaration nor am I qualified to do so. I only consider such legal standards in framing my opinions and conclusions as well as placing assertions made by Petitioner in the Petition into the proper context. Additionally, from a subject matter perspective, I understand that the petitioner always has the burden of persuasion regarding a challenge of patentability of an invention under an *inter partes* review.

V. CLAIMS-AT-ISSUE

31. I understand that claims 1-4 of the '236 patent are challenged by Petitioner with the following grounds.

Ground	Claim Challenged	Asserted Pre-AIA 35 U.S.C. §	Asserted References
1	1-4	103	Cribier + Walther
2	1-4	103	Spenser + Walther
3	1-4	103	Spenser + Spenser II
4	1-4	102(e)	Levi
5	1-4	103	Levi
6	1-4	103	Levi + Walther
7	1-4	103	Levi + Spenser II

Pet., 27.

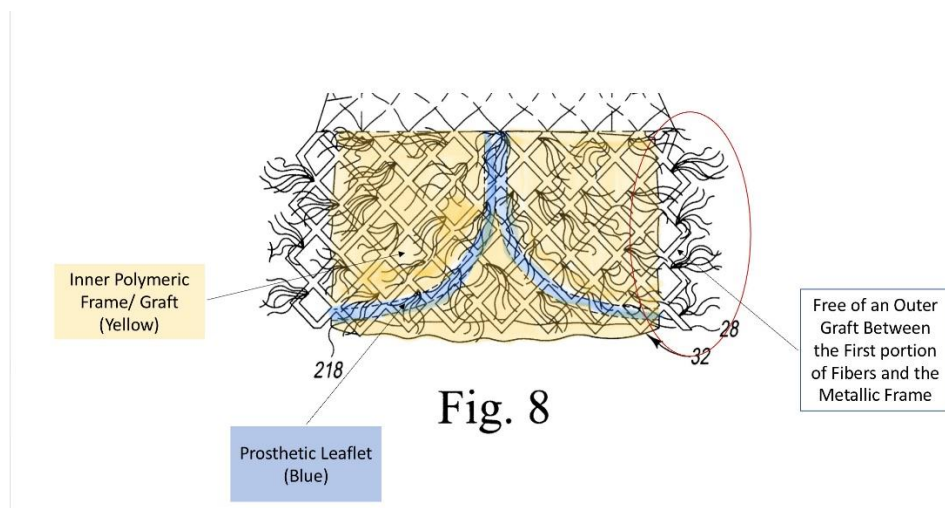
VI. OPINIONS

A. A “Valve Assembly” That Is “Free Of An Outer Graft Covering Between The First Portion Of Fibers And The Outer Frame” (All Grounds, All Claims).

32. The claims require a “transcatheter aortic valve assembly” that “is free of an outer graft covering between the first portion of fibers and the outer frame.”

Ex. 1001 [’236-Patent] cl. 1.

33. To illustrate this limitation, below is an annotated version of Figure 8, showing the absence of an “outer graft covering”:



34. Petitioner and Dr. Buller allege that these limitations are disclosed by Walther’s outer cloth (Grounds 1, 2, and 6), Spenser II’s compressible material (Grounds 3 and 7), and Levi’s outer skirt (Grounds 4-5). For the reasons set forth below, I disagree.

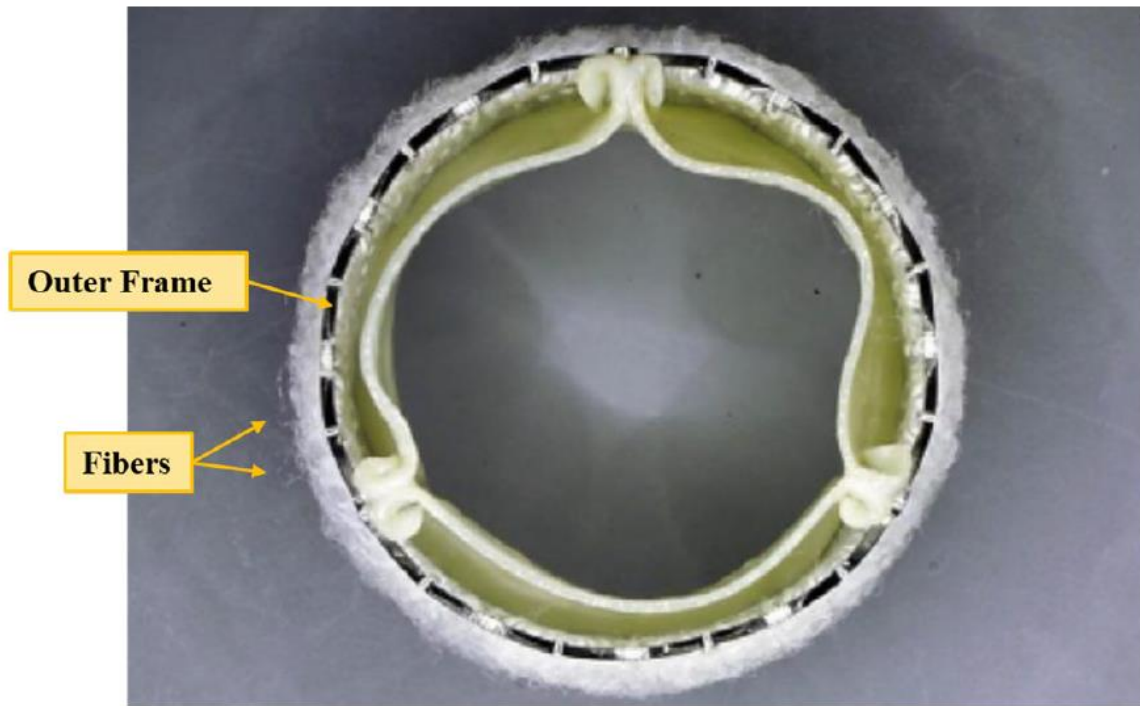
1. Walther's Outer PET Cloth (Grounds 1-2 And 6)

a. *Prior Opinions Offered*

35. I have previously submitted a preliminary declaration in this case. For convenience, I include the testimony from my preliminary declaration with regard to Walther's outer PET cloth, replicated below.

36. Dr. Buller states that "PET ... is a ... graft covering." Ex. 1003 [Buller-Decl.] ¶109 ("Cribier also discloses that SAPIEN includes 'a polyethylene terephthalate (PET) fabric cuff.' ... PET is a type of polyester and also a polymer **and is a 'polymeric graft covering.'**"); ¶ 60 ("**Graft** material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as **polyester** or PTFE.'). I also agree that PET cloth or fabric can be a graft covering.

37. Dr. Buller also asserts that "Cribier in combination with Walther renders this limitation obvious." Ex. 1003 [Buller-Decl.] ¶ 139-141. Citing these same paragraphs, he further argues that Walther in combination with Spenser or Levi also render this limitation obvious. *See id.*, ¶ 203 (Walther in combination with Spenser); ¶ 266 (Walther in combination with Levi). To support his conclusion, Dr. Buller says that "[a]s shown below, the fibers of Walther's outer cloth are directly stitched to the metal bars of the outer frame:"



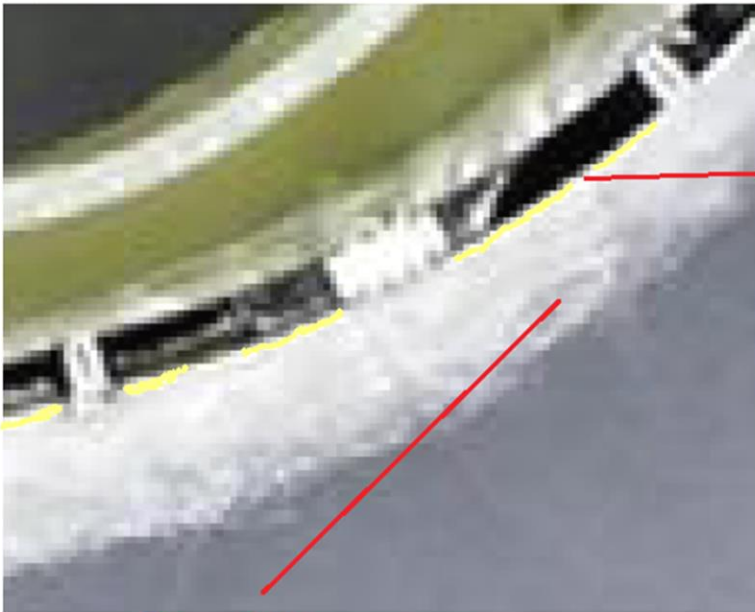
Id., ¶ 140 (citing Ex. 1007 [Walther] Fig. 1). I disagree.

38. If we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the second image) sandwiched beneath a fibrous finish and the black metal frame.



Dense PET
Layer
(Outer Graft
Covering)

Fibrous Finish



Dense PET
Layer
(Outer Graft
Covering)

Fibrous Finish

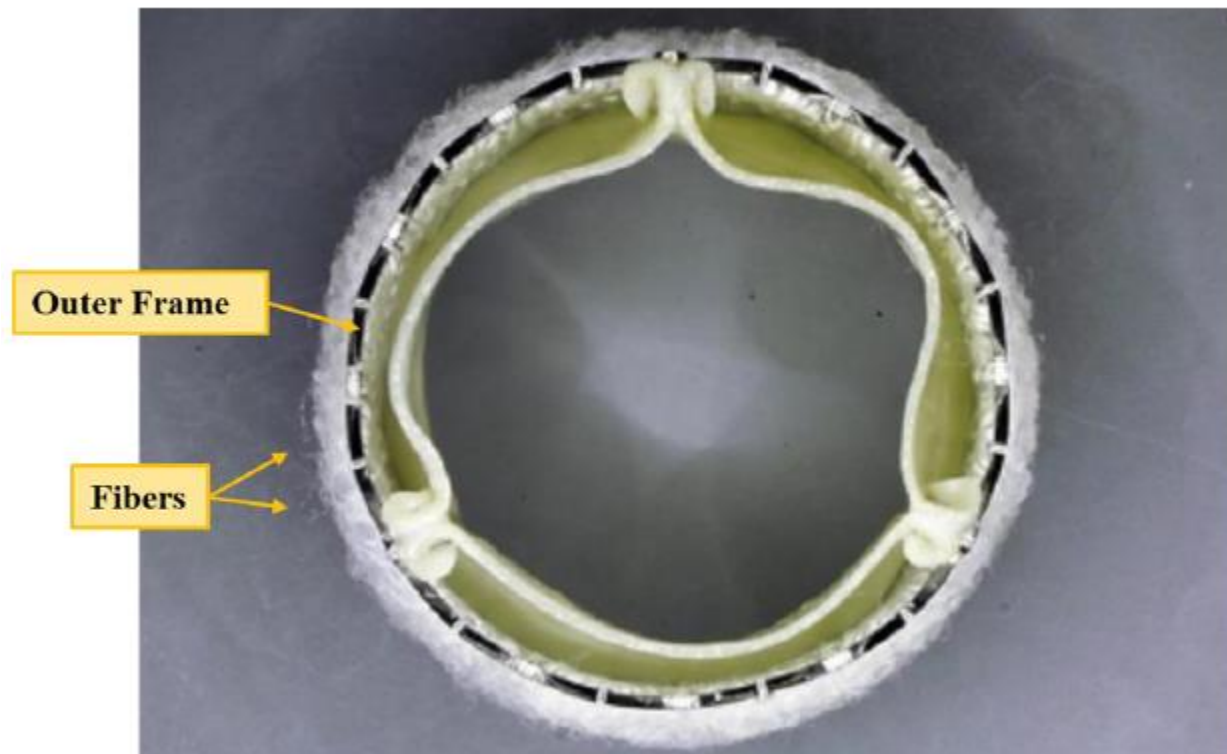
Ex. 1007 [Walther] Fig 1. (excerpted, magnified, annotated) (yellow highlighting added). I note that Dr. Buller acknowledges that graft material can be made of polyesters, which include PET and repeatedly relies on a dense PET layer/cloth/skirt as the claimed “inner graft covering.” Ex. 1003 [Buller-Decl.] ¶¶ 60, 109, 174, 232. This is consistent with my understanding that a conventional densely woven PET cloth constitutes a “graft covering.” I also understand that Dr. Buller relies on the fibrous finish for the claimed “first portion of fibers positioned radially outwardly of the outer frame.” *Id.*, ¶¶115-117. Accordingly, a POSITA would understand that the dense PET layer underneath the outer PET cloth’s fibrous finish would be an “outer graft covering between the first portion of the fibers and the outer frame.”

39. In sum, Dr. Buller has not shown that Walther, in combination with Cribier, Spenser, or Levi, render obvious a “transcatheter aortic valve assembly” that “is free of an outer graft covering between the first portion of fibers and the outer frame.”

b. *Additional Opinions*

40. I note that Petitioner contends that Walther discloses the “free of an outer graft covering” limitation because “***Walther does not state that the outer cloth includes a ‘graft covering’ ...***” Pet., 47, 74. Petitioner also points to a

bird's eye view of Walther, arguing that “the cloth does not include any visible graft covering,” with reference to this annotated image:



Pet., 47-48. For the reasons set forth below, I disagree.

1) Walther's Cloth Is Consistent With A "Velour-Like Woven PET" Cloth

41. I am aware that Walther depicts an Edwards' 9000MIS model number valve. While I do not see a clear image of the inner surface of the outer cloth present in Walther, I note that such images are present in other references (Cheung and Apogee) that also depict 9000MIS valves, as I further explain below in Section VI.A.1(b)(2).

42. In Petitioner’s discussion of the “free of an outer graft covering” limitation, I do not see any description of Walther’s cloth or explanation for how its fibers are attached, relying instead upon what Walther allegedly does not show or say. Pet., 47-49. I am aware, however, that in a co-pending case before the Board, Dr. Buller testified that Walther’s outer cloth was a “velour-like **woven PET cloth**...” Ex. 2008 [-193-Buller-Decl.] ¶ 305. Relatedly, here, Dr. Buller testifies that Walther’s PET cloth is made of “woven fibers.” Ex. 1003 [Buller-Decl.] ¶ 115.

43. Dr. Buller and I agree that Walther’s and Spenser II’s outer coverings are not just a “mass of fibers.” Dr. Buller testified that Walther and Spenser II are “velour-like **woven PET**” cloths. This is consistent with the evidence I have seen (and discussed herein) regarding the outer cloths. Dr. Buller also repeatedly refers to Walther as being made of “woven” fibers—**not** as “masses of fibers.” Ex. 2008 [-00193-Buller-Decl.] ¶305; Ex. 1003 [Buller-Decl.] ¶115 (“cloths are known to be made of **woven** fibers”), ¶157 (“any **woven** fabric, including Walther’s outer cloth”), ¶195 (Spenser II: a POSITA “would have understood that a PET cloth or fabric **would be constructed of a plurality of woven PET fibers**.”), ¶213 (similar), ¶222 (“any **woven** fabric, including Spenser II’s PET cloth/fabric ...”). Dr. Buller further correctly recognizes that a “graft material ... could be made with low-porosity woven fabrics.” *Id.*, ¶60. A “velour-like woven PET” or a “woven PET”

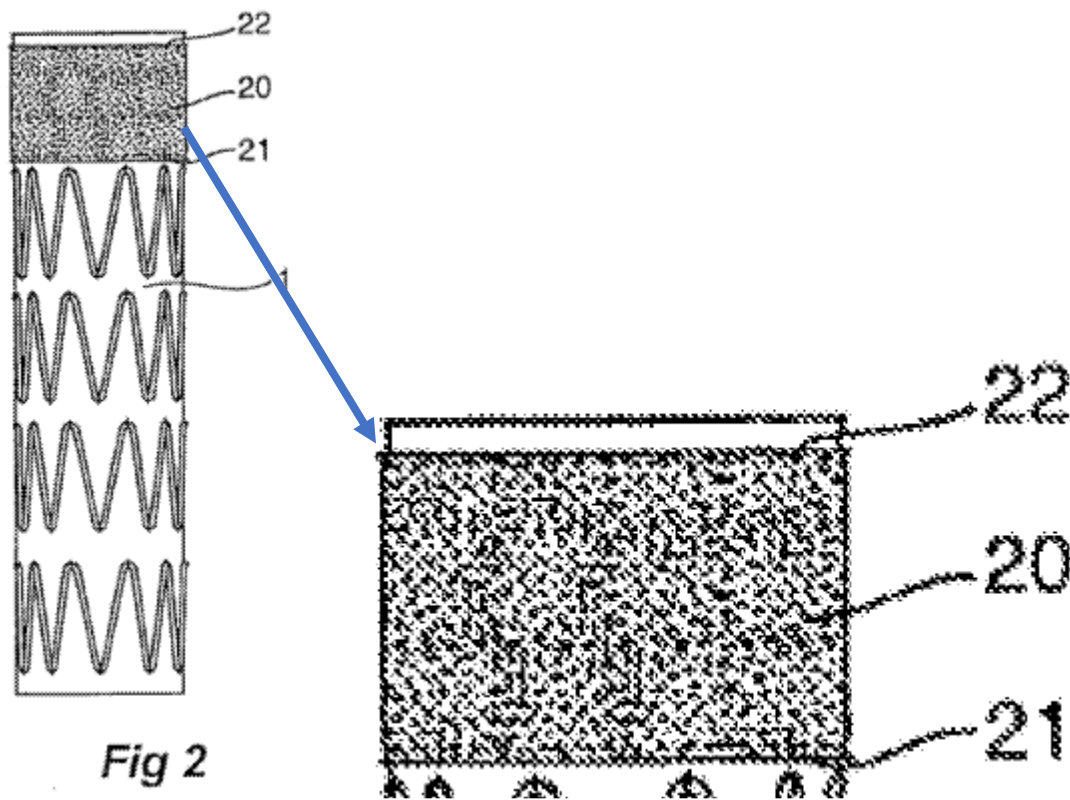
cloth is not a “mass of fibers.” I have not seen any evidence suggesting that either Walther or Spenser II are a “cloth” comprised of “mass of fibers.” That is not a structure or term I am familiar with in my practice and Dr. Buller has not claimed that Walther or Spenser II is such a thing.

44. Dr. Buller’s description of Walther as a “velour-like woven PET cloth” seems entirely consistent with Walther’s images, its description as a cloth from which extending fibers are visible, and the images of the back of the 9000MIS cloth shown in Cheung and Apogee. Dr. Buller does not explain, however, why Walther’s “velour-like woven PET cloth” would not include a graft covering between the frame and the first set of fibers.

45. This contention is inconsistent with Petitioner’s position elsewhere. For instance, Petitioner relies on PET fabrics to satisfy the “**inner graft covering**” limitation, including Cribier’s and Levi’s woven PET inner skirt. Pet., 34 (“Cribier discloses ... an inner ‘(**PET**) **fabric** cuff,’ which **is a ... graft covering.**”), 85-86, 101; Ex. 1008 [Levi] 9:53-54. Petitioner states that: “PET **is** a ‘... graft covering.’” Pet., 60; 85-86 (same). Dr. Buller agrees. Ex. 1003 [Buller-Decl.] ¶109; Ex. 2104 [Buller-2nd-Depo] 72:20-22; Ex. 2052 [Buller-1st-Depo.] 40:24-41:3, 60:11-16; Ex. 2042 [Buller-34-Decl.] ¶¶107-108, 142, 214, 58. If a “woven PET” covering is a graft covering in the case of Cribier and Levi’s inner skirts, the

same would seem to presumptively follow with respect to Walther's "velour-like **woven PET**" cloth.

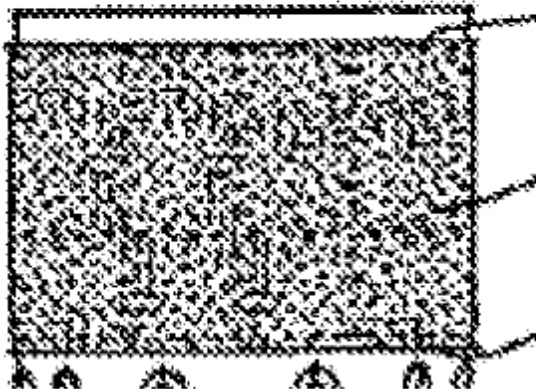
46. In prosecution, the "free of an outer graft covering" limitation was used to distinguish Hartley's (US 2004/0256759) Fig. 2, which "teaches a **velour band ...**" Ex. 1002 [Pros.-Hist.] 191, 197.



Ex. 1002 [Pros.-Hist.] 191. The Applicant explained that "stent grafts" like Hartley "**teach a graft covering** on the outside of the metal stent frame, **and the fibers extend from the graft covering**" whereas the "claimed invention recites that the outer seal is free of an outer graft covering." Ex. 1002, 197.

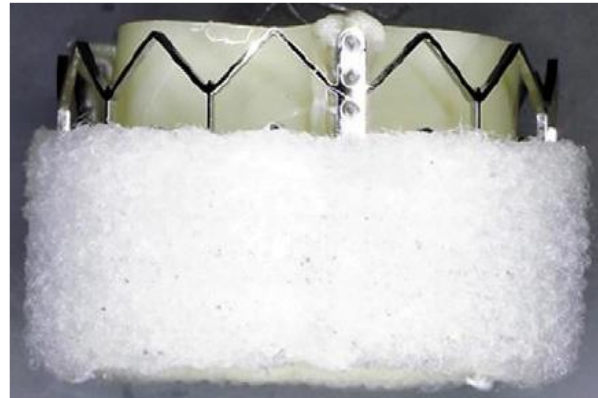
47. Hartley's velour band closely resembles Walther's cloth:

Hartley



Ex. 2056 [Hartley] Fig. 2.

Walther



Ex. 1007 [Walther] Fig. 1.

48. Thus, Dr. Buller previously identified Walther's cloth as being a "velour-like woven PET" cloth and this opinion seems reasonable given, *inter alia*, Walther's appearance and how it resembles Hartley. But, as the Applicant explained, such a velour band would not be "free of an outer graft covering," as further explained in both Hartley and Chu. Ex. 2056 [Hartley] [0035] ("Around the proximal end 19 of the graft 1 is a continuous band of velour material 20 fastened to the graft 1 by stitching 22 ... The velour provides loops of fibrous material which can be incorporated into the wall of the lumen into which the graft is placed by fibrous ingrowth."); Ex. 2057 [Chu] 4 (velour fabric adds "floating portions" of yarn on the surface of a woven graft to produce "three-dimensional loose surface structures" that serve as "the framework for tissue attachment").

49. Thus, the prosecution history confirms Walther would not be “free of an outer graft covering” between the frame and the fibers.

50. Furthermore, I note that Dr. Buller’s position that Walther lacks an outer graft covering contradicts his testimony that even Figure 9’s “fibers” “could easily be considered to be a graft covering”:

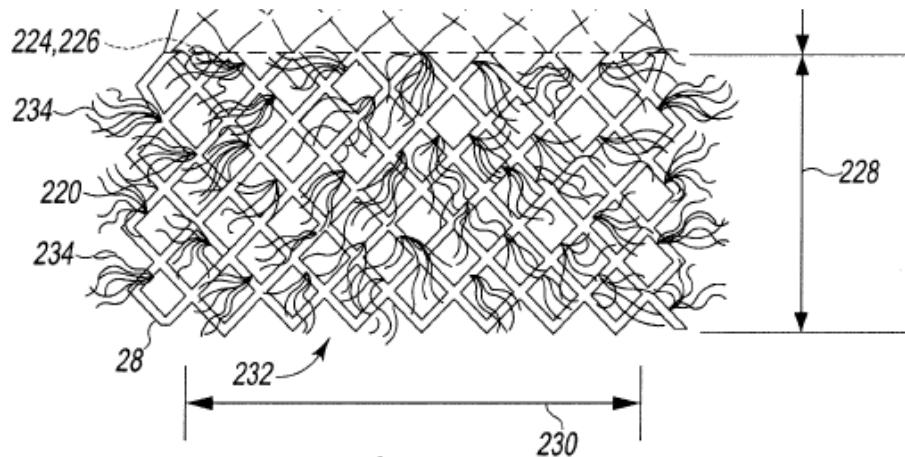
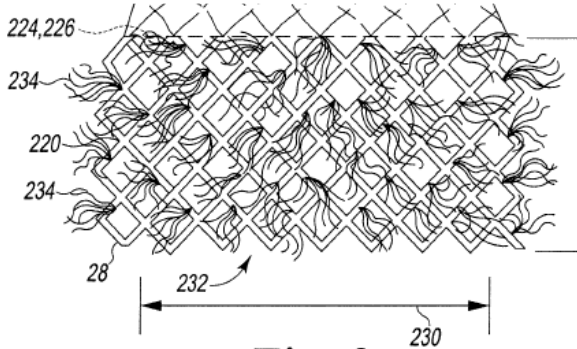
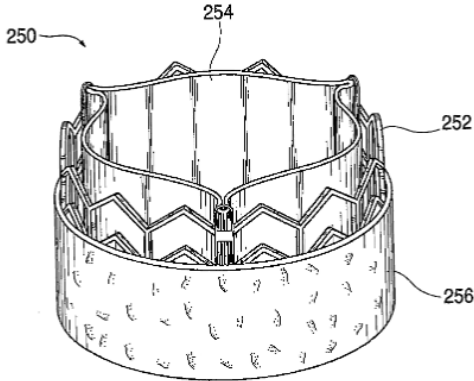
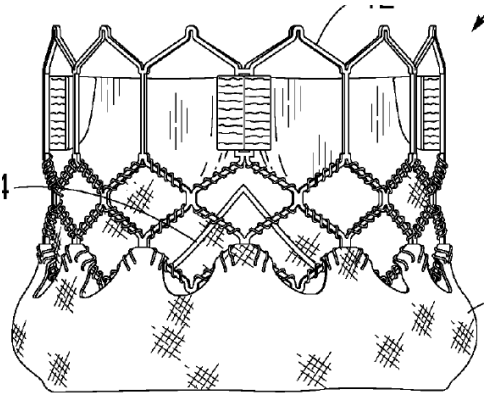


Fig. 9

Ex. 1001 [’236] Fig. 9; Ex. 2052 [34-Buller-Depo.] 154:5-12. Inconsistently, Dr. Buller simultaneously contends that Figure 9 “could easily be considered to be a graft covering” while maintaining that Walther (or Spenser II or Levi, for that matter) lack an “outer graft covering,” as this side-by-side comparison confirms:

Dr. Buller's Inconsistent Testimony	
"could easily be considered to be a graft covering"	No graft covering
 <p>Fig. 9</p>	  <p>FIG. 22</p> 

2) *A Woven, Graft Backing Layer Is Visible In Images Of The 9000MIS Valve*

51. In my review of Petitioner’s district court invalidity contentions, I note that Petitioner explains that the “Cribier-Edwards MIS Aortic Bioprosthesis Model 9000MIS (“9000MIS”) was implanted within the diseased aortic valve of patients at least as early as 2006 ...” Ex. 2083 [Petitioner’s-Preliminary-Invalidity-Contentions] 43. The document further explains that the 9000MIS is disclosed in both Cheung and Walther:

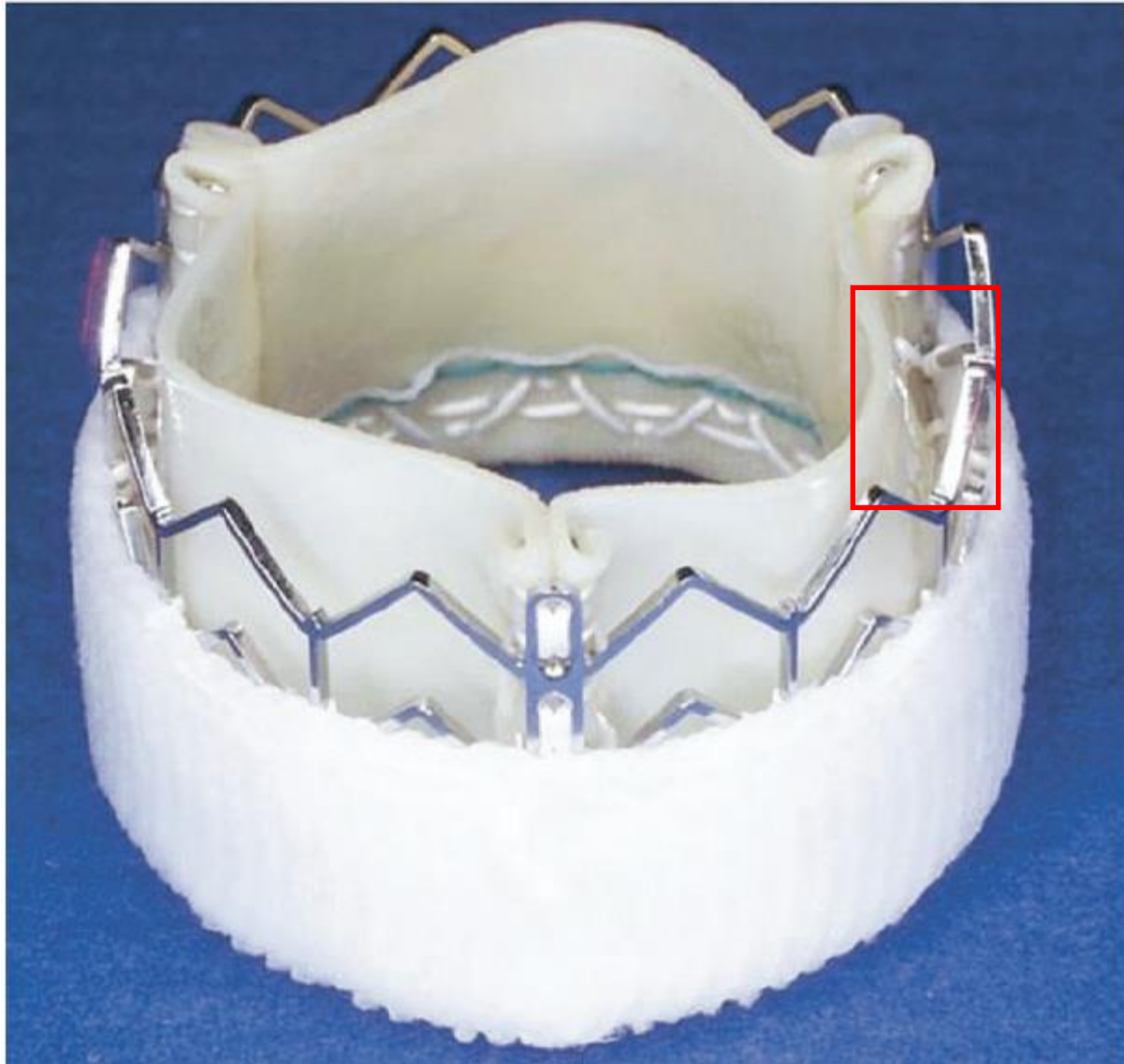
The 9000MIS was publicly known in the United States at least as early as 2009, the publication date of an article by Dr. Anson Cheung published in the Annals of Thoracic Surgery entitled “Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,” which discloses and describes the 9000MIS. The 9000MIS was also disclosed and describe in an article published in April 2011 by Dr. Thomas Walther and colleagues in the European Journal of Cardio-thoracic Surgery entitled, “Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves.”

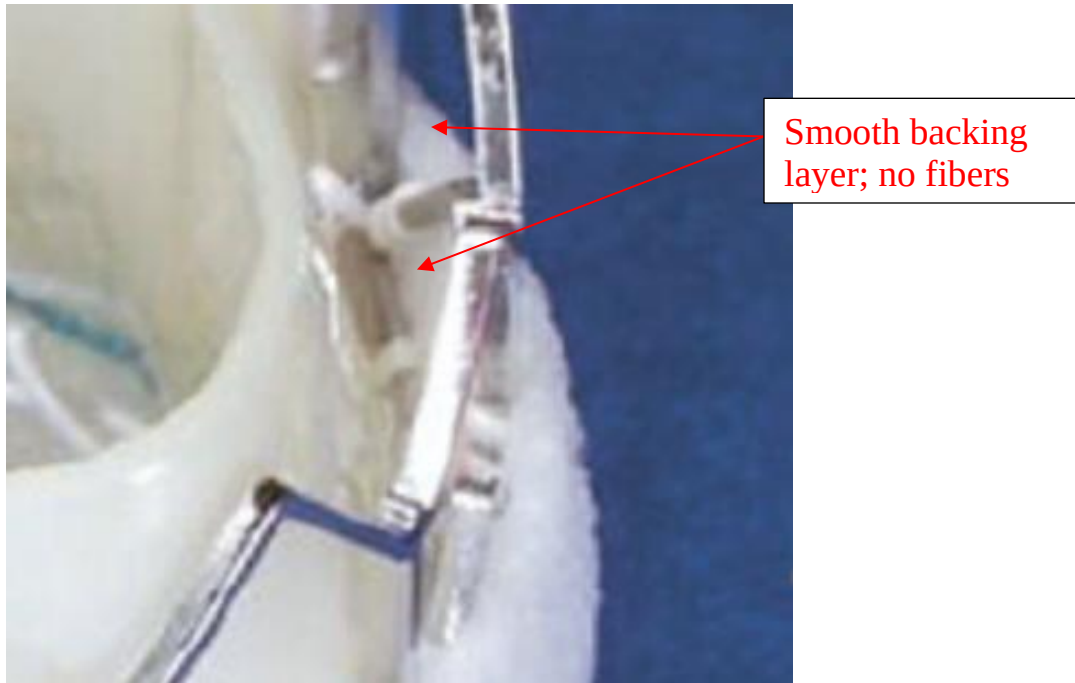
Id.

52. Thus, per Petitioner’s Preliminary Invalidity Contentions (“PICs”) and the documents themselves, Walther and Cheung were both 9000MIS valves. The PICs identify a third 9000MIS valve, apparently called “Apogee.” See Ex. 2087,

6-7. Each of these valves have a similar cloth cover. That said, there are at least some differences between the three 9000MIS valves. Whereas Walther is a cloth-covered SAPIEN valve, Cheung and Apogee are cloth-covered Cribier-Edwards valves. The Cribier-Edwards valve was a pre-cursor to the SAPIEN and had a shorter skirt as discussed later. This is consequential because the inner surface of the outer cloth can be seen with relative clarity in Apogee and Cheung but not in Walther. I also note that the cloth in Apogee appears like it may extend further below the inner skirt such that its inner surface is visible at the bottom as well. Despite these and potentially other differences, the three 9000MIS valves are very similar and appear to have very similar outer cloths.

53. Cheung, like Walther, is identified as a 9000MIS valve and Dr. Buller testified that Cheung is “very similar” to Walther. Ex. 2052 [Buller-Depo.] 200:11-14, 198:15-19. Unlike Walther, however, Cheung provides an unencumbered view of the inner surface of its outer cloth. The inner surface appears to be smooth, with no inwardly-extending fibers, which would be consistent with a woven graft backing layer:





Ex. 1017 [Cheung] Fig. 2. Dr. Buller testified, and I agree, that the portion outlined by the red-box at about 3:00 o'clock, if we were to view Cheung's figure as a clock-face, shows the outer cloth's inner surface. Ex. 2104 [Buller-2nd-Depo.] 8:6-16.

54. We know that this is the outer cloth we are looking at because Cheung utilizes a Cribier-Edwards valve, a precursor to the SAPIEN:

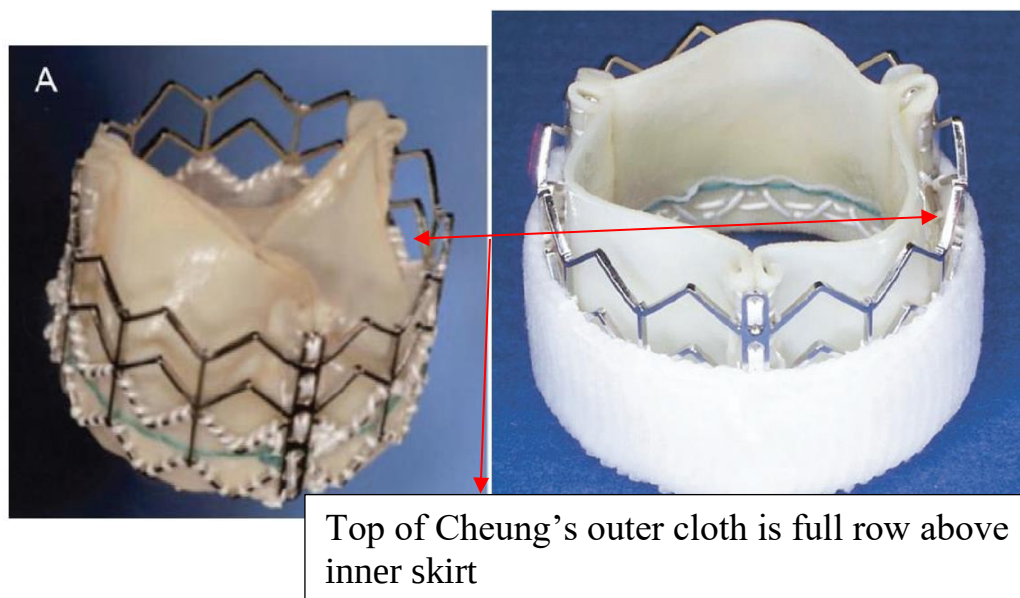
Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

Ex. 1017 [Cheung]; Ex. 2052 [Buller-Depo.] 198:11-21. We can tell that this portion is the inside of the outer cloth because the inner skirt in Cribier-Edwards covered only one row of cells versus the two covered in SAPIEN:



Figure 3. Balloon-expandable valves. The Cribier-Edwards (A), SAPIEN (B) and SAPIEN-Reprinted with permission.

Ex. 1023 [Webb] Fig. 3. Thus, when we look at the aforementioned diamond at 3:00 o'clock, we are seeing the inner surface of the outer cloth:



55. As the inner surface of its outer cloth confirms, Cheung's outer cloth is not just a "mass of fibers." Dr. Buller recognized, and I agree, that there are no

visible “stray, outwardly extending fibers on the inner surface of Cheung’s outer cloth.” Ex. 2104 [Buller-2nd-Depo.] 9:1-4.

56. Dr. Buller testified that he thought the inner surface of Cheung is “far from smooth” and has “toughs [sic], fibers, and [is] undulating” like the outer surface. *Id.*, 26:18-27:9. I do not see this; the inner surface of Cheung’s outer cloth appears smooth, and I do not see roughness, tufts, fibers, or an undulating surface:

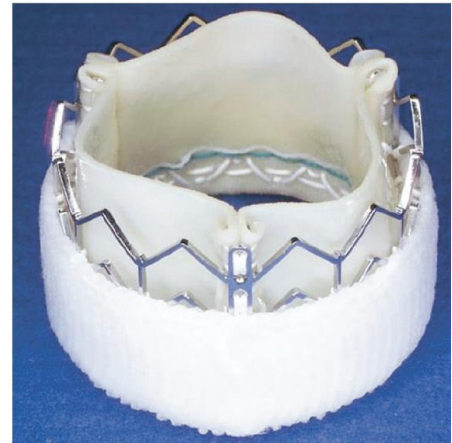


57. I believe that Cheung is informative as to Walther’s outer cloth because it shares the same model number and the two cloths resemble one another:

Walther



Cheung



Ex. 2052 [Buller-1st-Depo.] 200:11-14 (“They look[]...to be very similar...”),
198:15-19, 197:20-198:5, 199:24-25, 266:20, 207:15-18, 216:15-19.

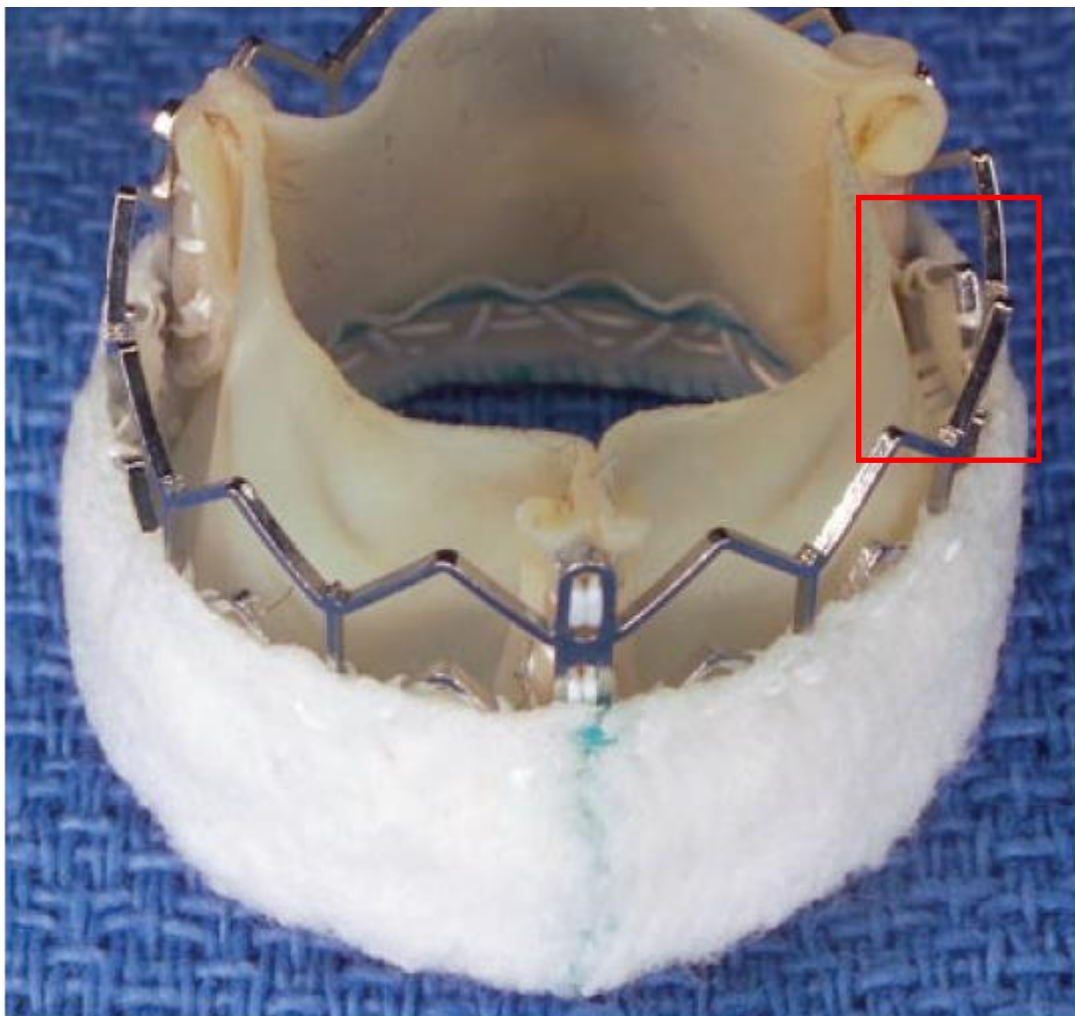
58. I do not believe that Walther provides a clear image of the inner surface of its outer cloth. In deposition, Dr. Buller testified that the inner surface of Walther’s outer cloth is visible in this image:



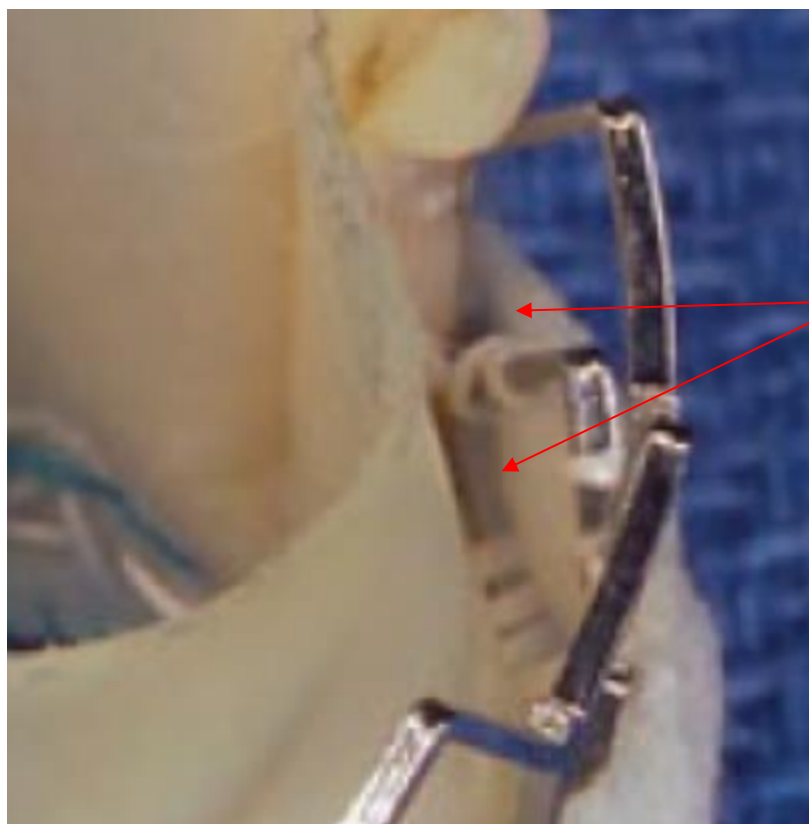
Per Dr. Buller, the inner side of Walther’s outer cloth

Ex. 1007 [Walther] 1121, Fig. 2 (excerpt); Ex. 2104 [Buller-2nd-Depo.] 61:21-63:13. It is difficult to discern what this is given the low resolution and the beige coloration. Even if it were, *arguendo*, the inner surface of the outer cloth, I do not see anything that would be inconsistent with a woven backing layer or suggestive of inward fibers. This portion, if anything, seems smooth.

59. Petitioner's PICs contain yet another image of a 9000MIS valve which Petitioner appears to refer to as "Apogee." A photograph of Apogee, taken from roughly the same angle as Cheung shows another image of the inner surface of the 9000MIS outer cloth. Like Cheung, Apogee is described as a "Cribier-Edwards Model 9000 MIS" valve (Ex. 2087, 6-7) and, thus, as in Cheung, the red box below provides a fairly clear view of the inner surface of the outer cloth. The photograph suggests that the inner surface is a smooth, woven graft covering without inwardly-extending fibers.



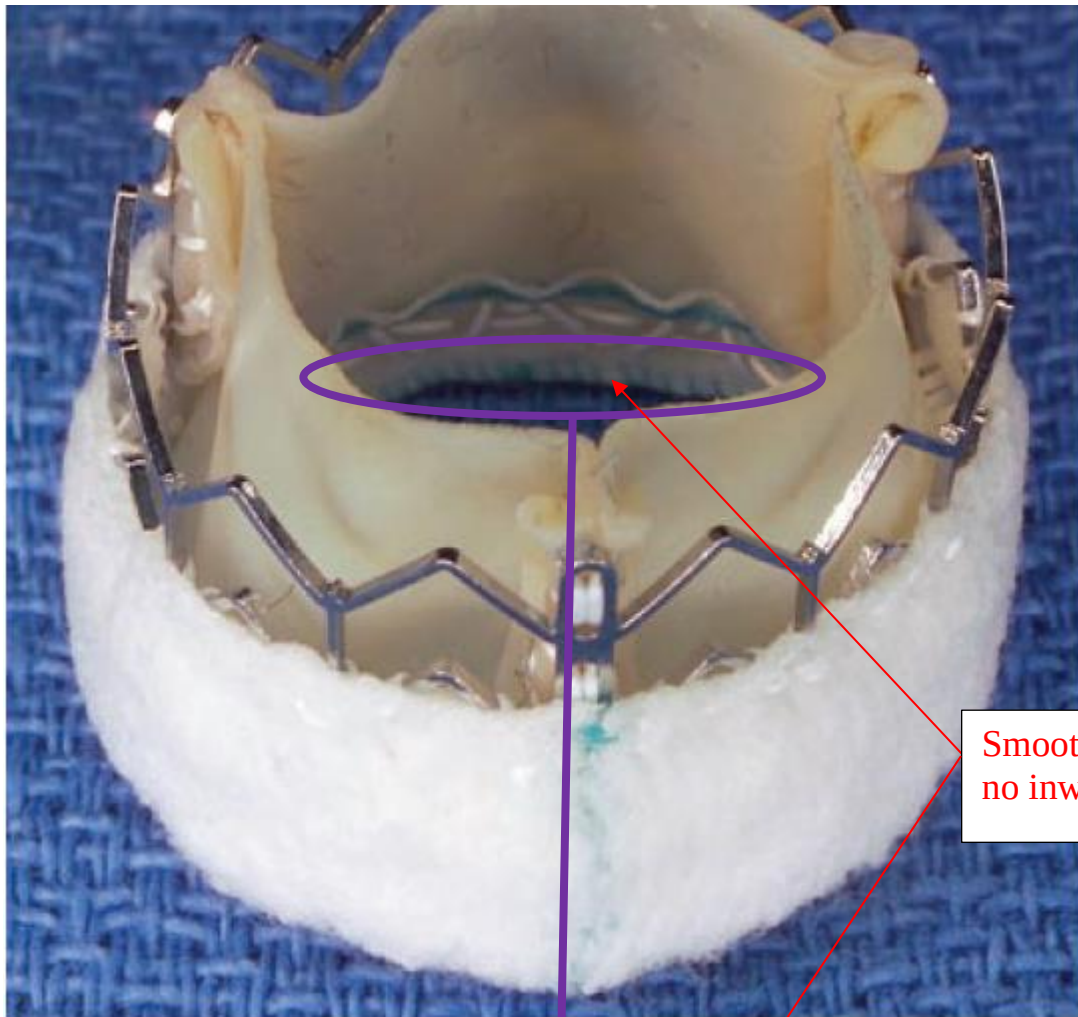
Apogee Gen 1b Greinecker 041305 at EDWARD



Smooth backing
layer; no inward
fibers

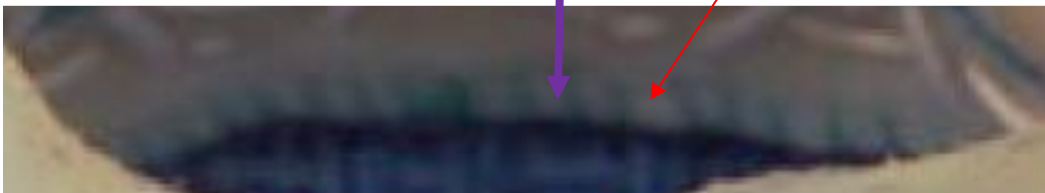
Ex. 2087, 7; Ex. 2104, 36:2-7 (agreeing this is inner surface of outer cloth).

Additionally, the outer cloth can also be seen at the bottom of Apogee in the purple oval below. There too, the surface appears smooth and no inward fibers are visible:

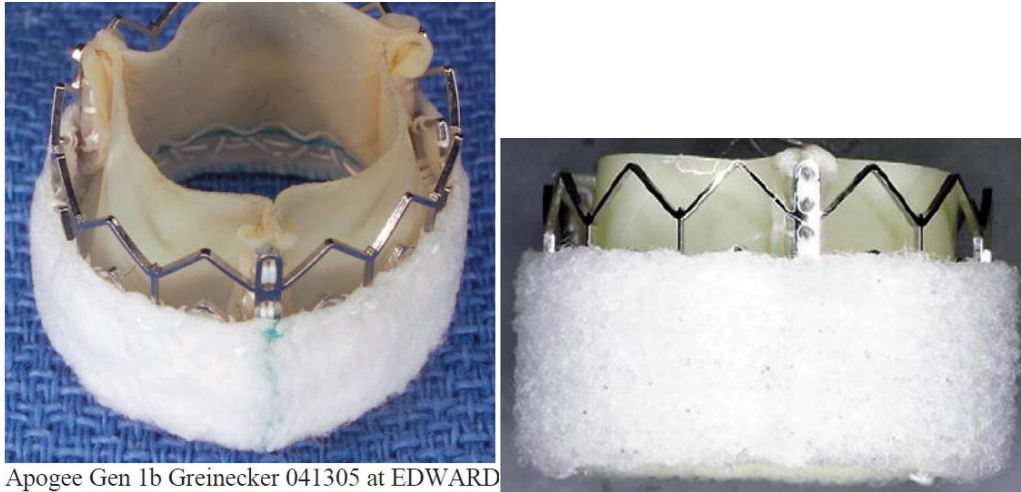


Smooth surface,
no inward fibers

Apogee Gen 1b Greinecker 041305 at EDWARD



60. Dr. Buller agreed that no inward fibers are shown on the proximal end of the cloth. Ex. 2104 [Buller-2nd-Depo.] 40:12-41:16. Like Cheung, Apogee's cloth resembles Walther's cloth.



61. Thus, while Walther does not provide a clear, unimpeded view of the inner surface of its outer cloth, the same is not true of Cheung and Apogee, two other 9000MIS valves, albeit ones that employ a Cribier-Edwards valve rather than a SAPIEN. Cheung and Apogee reveal the inner side of the outer cloth to include a smooth backing layer with no inwardly-facing fibers. I find this to be significant evidence that Walther, a SAPIEN 9000MIS similarly has a woven graft covering that is a solid “backing layer” between the outer frame and its outwardly extending fibers.

3) The Dehdashtian Patent

62. I have been informed and am aware that Mark Dehdashtian, the second author of Walther’s paper and the inventor of Spenser II apparently responsible for Figure 22 is the lead inventor of a patent assigned to Petitioner concerning just such a cloth. See Ex. 2101 [US6,663,667] (“Dehdashtian”). I have been informed that Spenser II claims priority to Application No. 10/883,575 (“’575

Application”). The ’575 Application was published in patent application U.S. 2006/0004442 (“’442 Application,” Ex. 2102). I observe that the ’442 Application does not contain Spenser II’s Figure 22 and also does not identify Mark Dehdashtian as an inventor. See Ex. 2102 (listing Spenser, Benichou, and Bash as inventors). Mr. Dehdashtian’s addition as an inventor to Spenser II suggests to me that his contribution included the compressible material that is the subject of Figure 22. I have confirmed with counsel for Aortic that this is a reasonable inference.

63. I note that Dehdashtian, titled “Towel Graft Means For Enhancing Tissue Ingrowth In Vascular Grafts,” concerns a woven graft covering with floating fibers extending from the weave on the **exterior** of the graft to promote tissue ingrowth. The “summary of the invention” provides:

*The present invention uses floaters, or specifically tailored threads integrated with the graft, which extend outside of the weave of the graft material. Such threads may be viewed as forming loops. These floaters may be formed from material similar to that used to form the graft, or may be formed from a material otherwise specifically tailored to promote tissue ingrowth. The floaters promote tissue ingrowth where they are placed along the **exterior** of the **graft** body. As such, they may be used to promote tissue ingrowth along the entire length, or at specific locations of grafts ...*

Ex. 2101 [Dehdashtian] 3:7-16; 1:14-19 (Field of the Invention: “The present invention relates ... to a vascular ***graft having an exterior texture*** ...”); 3:42-46 (describing “a ***woven vascular graft ... the graft having a texturized exterior surface*** designed to increase tissue in growth”); 3:55-64, 3:65-4:6, 4:31-33, 9:24-26, 10:23-25, 10:46-52.

64. Similarly, Dehdashtian’s “Detailed Description” begins:

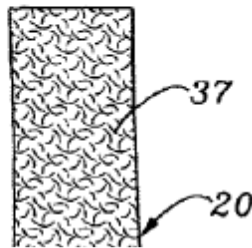
The present invention provides a ***woven, tubular graft*** having a selected, ***texturized exterior surface***. ***The exterior surface of the graft is ‘texturized’ by the presence of floaters***. The floaters are formed during the weaving process ***by adding fibers lying along the warp of the weave***. ***These additional fibers are partially integrated into the weave of the graft material***. That is, each additional fiber skips one or more of the perpendicular fibers by not alternatively extending over, and under, adjacent perpendicular fibers. In this manner, sections of the floater fibers are woven into, and integrated with, the graft material, and ***sections of the floater fibers lie along the exterior of the graft surface***. ***The floater fibers may be positioned over the entire exterior surface of the graft or at selected locations on the graft***.

Ex. 2101 [Dehdashtian] 5:12-26.

65. Consistent with its title, Dehdashtian refers to its fibers extending from the graft as “towel-like.” Concerning Figure 10, I note that Dehdashtian describes:

The graft as shown in Fig. 10 has an exterior surface that is covered in short, looped, ‘towel-like’ floaters 37 extending from the surface of the graft 20. These towel-like floaters 37, which do not significantly impact the porosity of the graft material, serve the dual purpose of preventing endoleak and encouraging tissue ingrowth into the woven graft from which they extend. As discussed in greater detail above, the towel-like floaters are incorporated with the woven graft during the weaving process.

Fig. 10



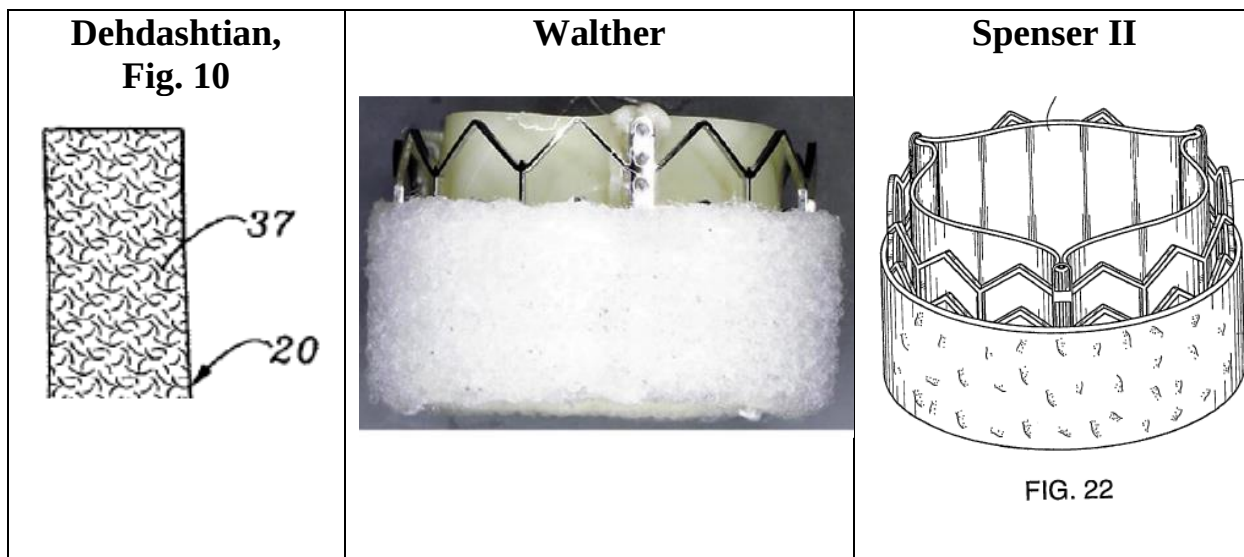
Id., 13:13-24; Fig 10 (excerpt); Abstract, 3:55-59, 4:14-19. While the “exterior” or “outer” surface of the graft has fibers that extend therefrom, the inner surface is “smooth.” *Id.*, 3:37-41 (describing a “graft having vertical, horizontal and/or angled strands to promote tissue ingrowth along the length of an **outer face of the graft member** while providing a **smooth inner surface** for the reconstructed vessel lumen.”). I note that the Dehdashtian Patent further teaches that some portions of the outer surface may be smooth while others are textured. *Id.*, 4:19-21.

66. I further note that such cloths were well-known prior to Dehdashtian as well. In describing the related art, Dehdashtian describes grafts with “a plurality

of loops *extending from the exterior surface of the graft*” (*id.*, 2:50-52) and a “texturized graft [] equipped with a plurality of loosely associated fibers, which may be affixed or sewn to the exterior surface of the graft” (2:57-59), noting that the known “texturized grafts” insufficiently encouraged tissue ingrowth (2:61-65). Dehdashtian’s “towel-like” cloth is also similar to the “velour woven fabric” described in Chu, which is made by “floating portions of the weft or/and warp yarns,” producing “three-dimensional loose surface structures as the framework for tissue attachment and ingrowth that conventional woven fabrics do not have.” Ex. 2057 [Chu] 4; Ex. 2105 [Woven Textiles] 454 (“velour woven fabrics ... produce loose surface structures which promote tissue attachment and ingrowth that conventional woven fabrics do not have.”).

67. Dehdashtian’s towel-like cloth would not meet the claim requirements owing to the presence of an “outer graft covering” between the frame and the outwardly extending fibers and the absence of a “second portion of fibers” “configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst.”

68. By description and appearance, Dehdashtian, moreover, is similar to Walther and Spenser II:



69. Dehdashtian also corresponds to Walther’s and Spenser II’s descriptions of their outer coverings. Dehdashtian refers to the fibers extending from its graft material as “towel-like.” “Towel-like” is a fitting description for Walther’s “cloth,” in view of Walther’s photographs. Walther further describes that its cloth is designed to “promote tissue ingrowth” (Ex. 1007, 1), a principal goal of Dehdashtian. *See, e.g.*, Ex. 2101 [Dehdashtian] Abstract (“A woven vascular graft having a texturized outer surface **to promote tissue ingrowth.**”).

70. Spenser II states that “compressible material 256 may resemble a cloth or fabric having small fibers **extending from the surface of the material.**” Ex. 1011 [Spenser II] ¶ 145, cl. 29 (“the compressible material includes a plurality of fibers extending outward from the outer surface”). This matches Dehdashtian’s description of having fibers extend from the outer surface of a woven graft.

71. That Dehdashtian, the apparent inventor of Figure 22 and Walther's second author, designed a "towel-like" woven graft cloth with extending fibers and with significant similarities to Walther and Spenser II is circumstantial evidence that a similar such cloth was used. At the very least, a key person behind Walther and Spenser II invented such a cloth shortly prior to Spenser II's priority date and Walther's publication.

72. This is particularly so as what is described in Dehdashtian seems to reflect what we see in both Cheung and Apogee; a cloth with outwardly extending fibers on the outer surface but with a smooth, woven backing layer without inwardly-facing fibers.

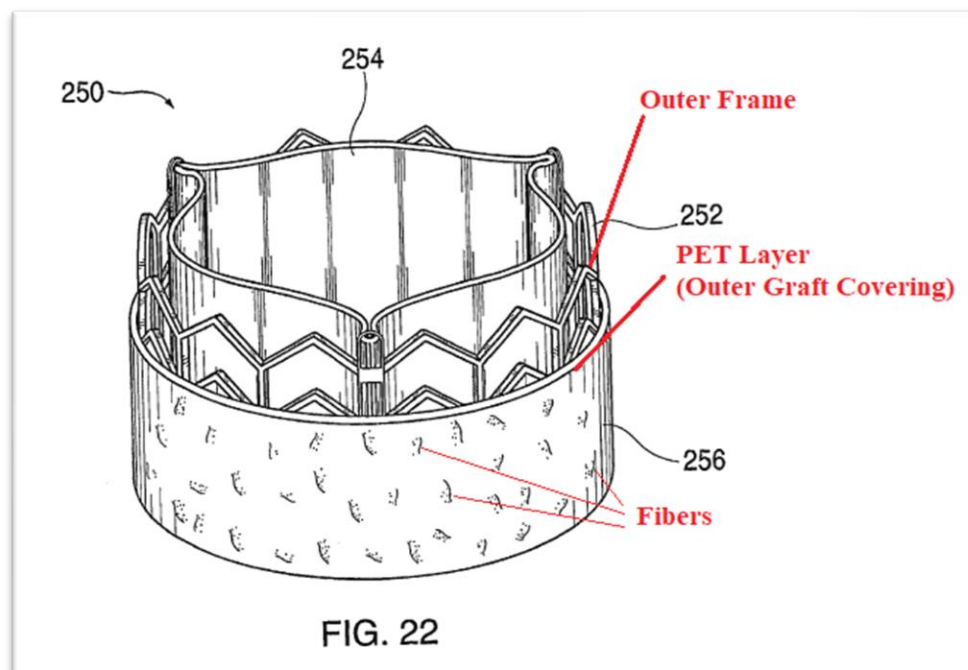
2. Spenser II's Compressible Material Sleeve (Grounds 3 And 7).

a. *Prior Opinions Offered*

73. I have previously submitted a preliminary declaration in this case. For convenience, I include the testimony from my preliminary declaration with regard to Spenser II's compressible material sleeve, replicated below.

74. Dr. Buller also asserts that "Spenser II's compressible material is also 'free of an outer graft covering between the first portion of fibers and the outer frame.'" Ex. 1003 [Buller-Decl.] ¶¶ 205-206. He also argues that Levi in combination with Spenser II renders this limitation obvious. *Id.*, ¶ 266. I disagree.

75. Similar to Walther, a POSITA would understand Spenser II's compressible material sleeve as illustrated to be a PET cloth with fibers on top of the denser PET layer. See Ex. 1011 [Spenser II] ¶ 145 (“the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.”). This dense PET layer forms an “outer graft covering.” It is located between the alleged “first portion of fibers,” located on the outer surface of the PET sleeve, and the outer frame. Thus, Spenser II is not “free of an outer graft covering between the first portion of fibers and the outer frame.”



Ex. 1011 [Spenser II] Fig. 22 (annotated in **red**). It is also notable that Dr. Buller, in his declaration in IPR2022-00034, repeatedly stated that “Spenser II does not disclose any **additional** ‘outer graft covering’ between the fibrous fabric of the

compressible material and the stent frame.” Ex. 2042 [IPR2022-00034 Buller-Decl.] ¶¶ 92, 193. Dr. Buller does not state that Spenser II’s sleeve is not itself an “outer graft covering.”

76. In sum, Dr. Buller has not shown that Spenser II, in combination with Spenser, or Levi, render obvious a “transcatheter aortic valve assembly” that “is free of an outer graft covering between the first portion of fibers and the outer frame.”

b. *Additional Opinions*

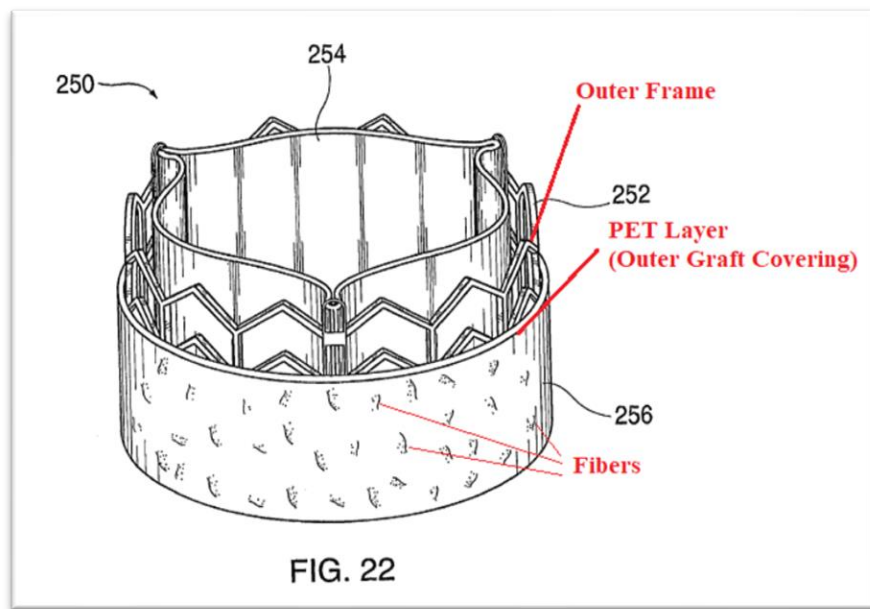
77. In my review of the Institution Decision (“ID”), I note that the Board found that Spenser II’s “compressible material” suggests a graft covering:

However, the “cloth or fabric” from which the fibers extend could also be reasonably interpreted as constituting the “outer graft covering between the first portion of fibers and the outer frame” that is precluded by claim 1. We have previously found, in a related inter partes review, that the densely woven outer PET skirt of Levi constitutes an outer graft covering. See IPR2022-00034 Paper 14, at 27. Spenser II’s description of a fabric or cloth compressible material ***suggests a similar outer graft covering.***

ID, 47.

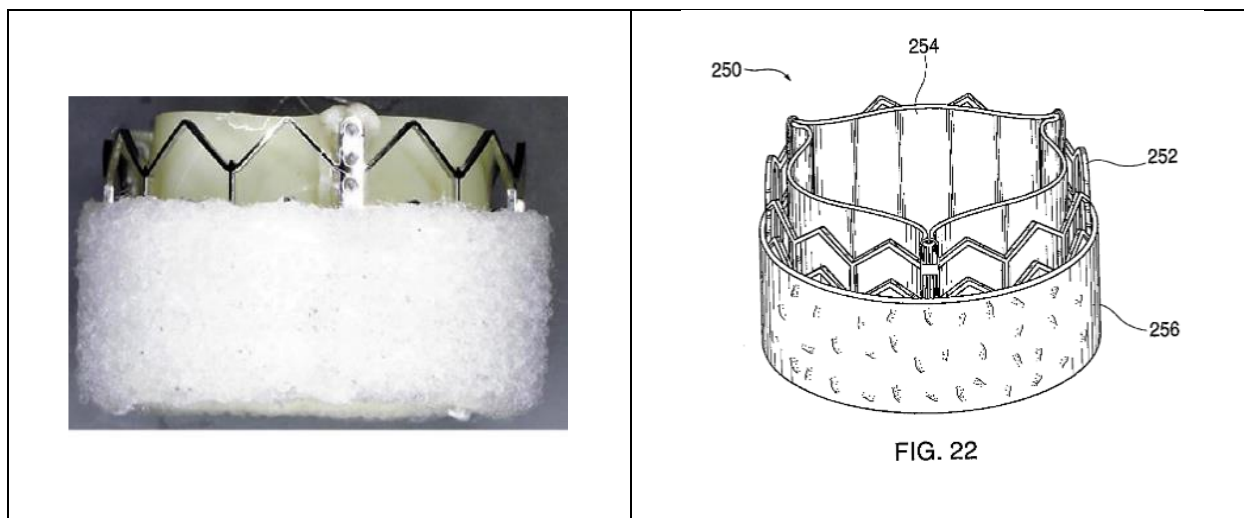
78. I agree with the Board’s finding that Spenser II’s outer cloth contains an outer graft covering between the frame and the outward fibers. Like Walther, a POSITA would understand Spenser II’s “outer seal” to be a PET cloth with fibers

on top of the denser PET layer. Indeed, Spenser II describes its cloth as “extend[ing] entirely around the stent structure, such as in the form of a *sleeve*,” and shows the dense PET layer/sleeve as being distinct from the fibers on top of it. The “fibers extend[] from *the surface of the material*.” Ex. 1011 [Spenser-II] ¶145. The compressible material is meant to “reduce or prevent paravalvular leakage.” *Id.*



79. Thus, the compressible material is described as a “sleeve,” meant to address PVL, and from which fibers outwardly extend. It is not a “mass of fibers.” This does not satisfy the limitation.

80. Dr. Buller has testified that Walther is a “real-world” embodiment of Spenser II’s Figure 22. Ex. 2052 [Buller-1st-Depo.] 104:17-105:7. Spenser II and Walther’s cloths also resemble one another:



81. Dr. Buller has also testified that, like Walther, Spenser II’s compressible material is a “velour-like, woven PET.” Ex. 2008 [193-Buller-Decl.] ¶305 (“velour-like **woven PET cloth** or fabric, **such as... Spenser-II’s compressible material.**”); *id.*, ¶¶195, 222 (describing compressible material as “woven”). As discussed, a “velour-like woven PET cloth” would not be “free of an outer graft covering” and it was the type of cloth described in Hartley and distinguished in prosecution. *See* ¶¶43-47, *supra*.

82. As Walther is a “real-world” embodiment of Figure 22, I also believe the images of Cheung and Apogee, too, are informative. As previously described, those images reveal a smooth, woven backing layer, further suggesting that Figure 22’s compressible material (from which fibers extend) is a graft covering disposed between the frames and the outwardly-extending fibers. *See* ¶¶51-61, *supra*.

83. Lastly, Figure 22, again, appears to be the contribution of Mark Dehdashtian, Dehdashtian’s inventor. Dehdashtian again, discloses a woven

“towel-like” graft with fibers extending on the exterior surface. See ¶¶62-72, *supra*. This is consistent with Spenser II’s disclosure that the “fibers extend from the surface of the compressible material.”

84. I also note that Spenser-II was correctly, in my opinion, distinguished in prosecution as it was not “free of an outer graft covering”:

the seal of Spenser [II] appears to be relatively thick in construction, including *a graft covering* or sleeve *with fibers extending from the sleeve*.

...

Spenser [II] appears to include *an outer graft covering between the fibers and the outer frame*... Finally, Spenser [II] is *not modifiable to be free of an outer graft covering*, as such modification would have no structure for the fibers to attach to since the fibers emanate from compressible material 256.

Ex. 1002 [Pros.-Hist.] 196.

3. Levi’s Woven PET Outer Skirt (Grounds 4-7).

a. *Prior Opinions Offered*

85. I have previously submitted a preliminary declaration in this case. For convenience, I include the testimony from my preliminary declaration with regard to Levi’s woven PET outer skirt, replicated below.

86. Dr. Buller states that Levi discloses the limitation “wherein the valve assembly is free of an outer graft covering between the first portion of fibers and

the outer frame” or render it obvious in combination with Walther or Spenser II. Ex. 1003 [Buller-Decl.] ¶ 264. I understand that the Board has previously found that, “Petitioner has failed to recognize that Levi’s outer skirt is an ‘outer graft covering’” Ex. 2043 [IPR2022-00034 Inst.-Dec.] 27. I disagree with Dr. Buller and agree with the Board that Levi’s outer skirt is an “outer graft covering.” Moreover, Dr. Buller has admitted that, “Levi discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame.” Ex. 1003 [Buller-Decl.] ¶ 237. Thus, Dr. Buller has not shown that Levi, renders obvious a “transcatheter aortic valve assembly” that “is free of an outer graft covering between the first portion of fibers and the outer frame.”

b. *Additional Opinions*

87. I note that the Board has consistently found that “***Levi’s outer skirt is an ‘outer graft covering.’***” ID, 51-52 (quoting Ex. 2043 [IPR2022-00034-DI] 27). In my opinion, the Board is correct. Levi describes an outer skirt made of woven PET fabric. Ex. 1008 [Levi] 13:50-53 (“The outer skirt 18 can be laser cut or otherwise formed from a strong, durable piece of material, such as ***woven PET*** ...”). Both Petitioner and Dr. Buller have argued that Levi’s woven PET inner skirt forms an “inner ***graft covering.***” Pet., 34, 60, 85-86; Ex. 1003 [Buller-Decl.] ¶¶ 60, 109. I do not see any explanation, however, of why woven PET when inside

the frame is an “inner graft covering” while the same material outside the frame is not an “outer graft covering.”

88. As recognized by the Board, and I agree, there is no evidence that Levi even has a “first portion of fibers” that meet the claim limitations. ID, 51. There is, however, no question that this “outer graft covering” is “between” what Petitioner claims to be “the first portion of fibers” and the “outer frame.” See Pet., 88-89 (Ppetitioner relying upon Levi’s fibers allegedly found on outer skirt for the claimed “first portion of fibers”). Thus, Levi’s woven PET skirt is an outer graft covering and it is positioned between the outer frame and what Petitioner contends are the first fibers.

B. “A Second Portion Of Fibers” That “Form[s] A Second Sealing Interface” And Is “In Overlapping Radial Alignment” (All Grounds, All Claims).

89. The claims require “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,” and further requires “the first portion of fibers and the second portion of fibers are in overlapping radial alignment.” Ex. 1001 [’236-Patent] cl. 1.

90. An embodiment of the “first” and “second” portions of fibers are visible in Figure 13 and Figure 14 which shows how a seal is formed via compression:

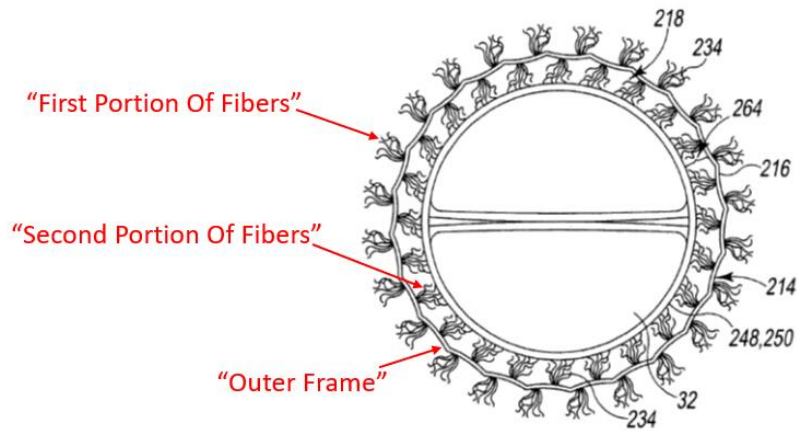


Fig. 13

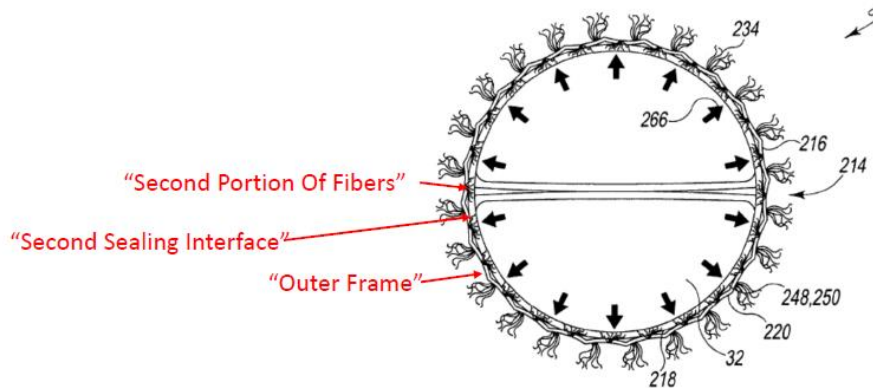


Fig. 14

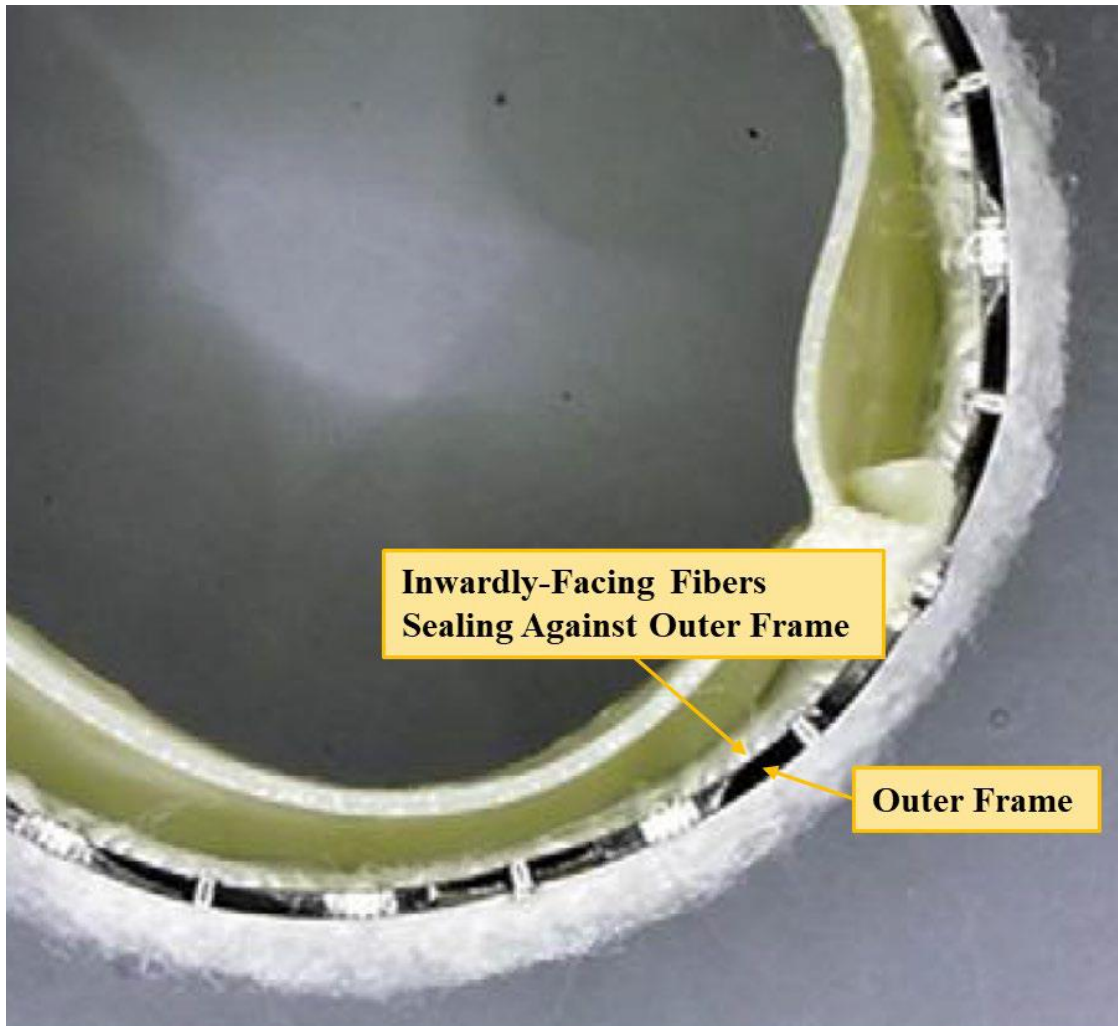
Ex. 1001 ['236] Figs. 13-14.

1. Prior Opinions Offered

91. For convenience to the Board, I include the testimony from my preliminary declaration with regard to “a second portion of fibers,” replicated below.

92. Dr. Buller asserts that Walther, in combination with Cribier, Spenser, or Levi render this limitation obvious. Ex. 1003 [Buller-Decl.] ¶¶ 131-137

(discussing Cribier and Walther); ¶¶ 193-194 (discussing Spenser and Walther); ¶ 256-257 (discussing Levi and Walther). In support of his conclusion, Dr. Buller states that “[F]ibers pressing the outer frame are visible in Walther’s Figure 1 below:” *Id.*, ¶ 132.



Id. (citing Ex. 1007 [Walther] Fig. 1).

93. It is unclear what Dr. Buller is pointing to with the arrow that he added Walther’s Figure 1. The image is very blurry and difficult to discern. To the extent this blurry image shows any fibers that appear on the inside of the frame,

the fibers may just as well be stray fibers from the stitching on top of the frame or may emanate from the outer surface of the PET cloth and wrapped over the top of the outer frame when the cloth was cut. If they do originate from the stitching or the outer surface of the outer cloth they cannot “form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst.” Even if the fibers did originate on the inner surface of the PET cloth a few fibers, whether they pass through the open cells of the outer frame or not, would not create such a “second sealing interface.”¹

94. I see no evidence of a “second portion of fibers” on the interior side of Walther’s outer cloth that are, moreover, “configured” to form a “second sealing interface.” Walther makes clear that its valve assembly is “identical to the SAPIEN model, but has an **added outer cloth** ...” Ex. 1007 [Walther] 1120. Walther is directed towards a valve-in-valve procedure wherein Walther is implanted inside an existing but degenerating valve. *Id.* “The addition of an outer

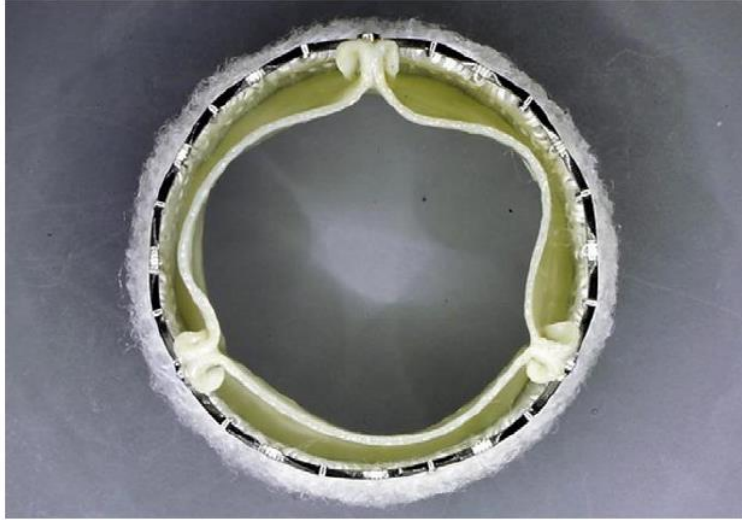
¹ As discussed in ¶¶109-122, *infra*, based upon further review and analysis of Walther’s photographs, a comparison with the SAPIEN valve, further study of the Cheung and Apogee valves, the Dehdashtian patent, Dr. Buller’s deposition testimony and more, I believe what Petitioner is pointing to is, in fact, the sutures that attach the inner skirt to the frame.

cloth ... is designed to reduce paravalvular leak by creating a seal ***between the two valves*** ...” *Id.* Thus, Walther only discloses an ***outer*** cloth to create a seal with the valve Walther’s assembly is implanted within. There is no disclosure of Walther’s outer cloth having a “second” portion of fibers or creating an interior second sealing interface. Given Walther’s focus on reducing paravalvular leakage, if PVL were reduced on the inner side of Walther’s outer frame, Walther presumably would have mentioned it.

95. Moreover, when we examine the outer cloth that Walther adds, we can see that the outer side of that cloth has a thick, fibrous finish meant to promote sealing:



96. It is this thick fibrous outer cloth that Walther believes is necessary to address PVL. By contrast, when we look at the top down view of Walther’s valve, we see no such fibrous finish on the other side of the outer cloth.



97. If Walther intended to have a second portion of fibers on the inside of Walther's outer cloth intended to address PVL, it presumably would have added a similar fibrous finish on the inside of the outer cloth. But we do not see it and it is not mentioned. Instead, we see a thick, fibrous cloth on the outer side and the absence of a fibrous finish on the inside of the outer cloth. Consequently, Walther's disclosure does not reveal a "second portion of fibers," much less one that is "configured" to form a "second sealing interface" upon compression.

98. In sum, Dr. Buller has not shown that Walther, in combination with Cribier, Spenser, or Levi, render obvious "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 ... wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment."

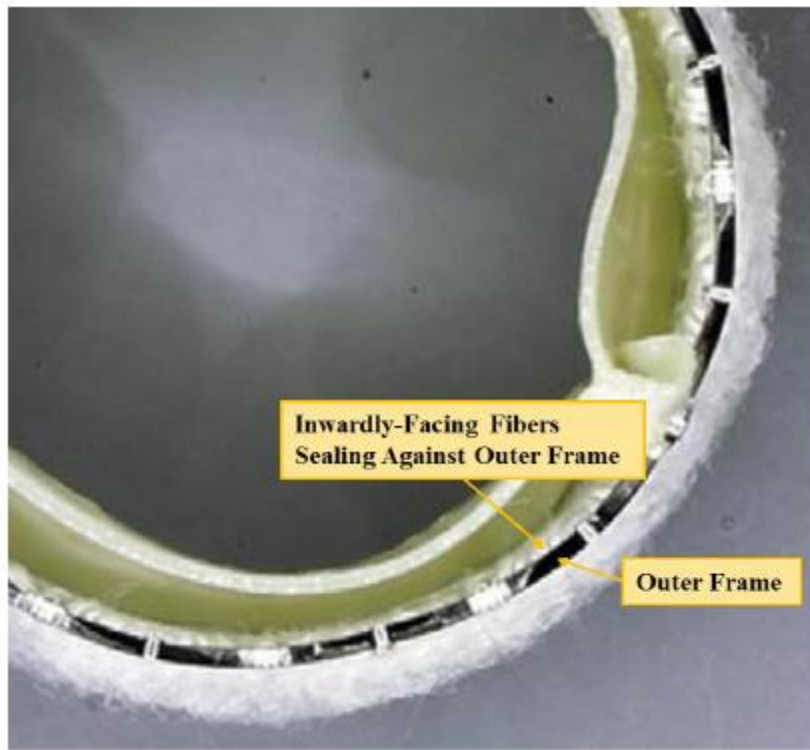
2. Additional Opinions

a. *Walther's Cloth (Grounds 1-2, 6)*

99. As an initial matter, I note that Dr. Buller, for the first time in deposition, pointed to this portion of Walther's Figure 2 as showing the inner surface of Walther's outer cloth. However, even if this were the inner side of the outer cloth, it does not show any inward fibers in my opinion:



100. I note that in Grounds 1-2, and 6, Petitioner and Dr. Buller contend that Walther's outer cloth satisfies the "second set of fibers" limitations. Petitioner states that, "Walther's outer cloth includes ... inwardly facing fibers on the inward-facing surface of the cloth that form a sealing interface against the outer frame ..." relying upon the following annotated image:

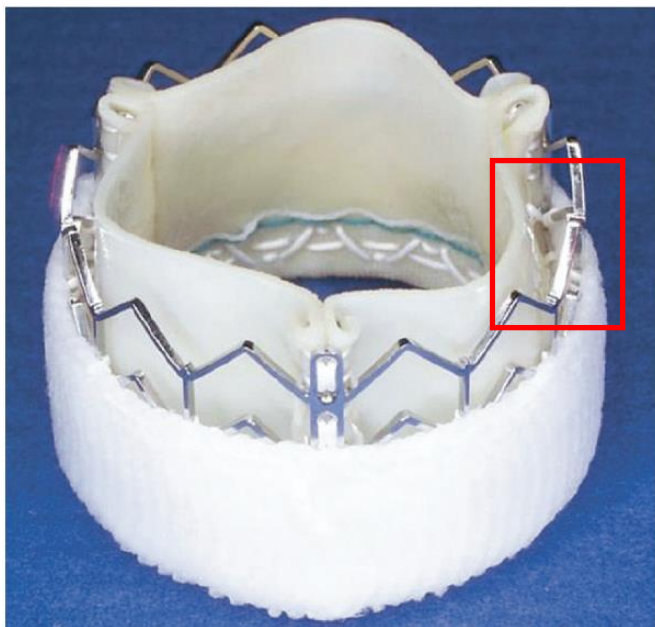
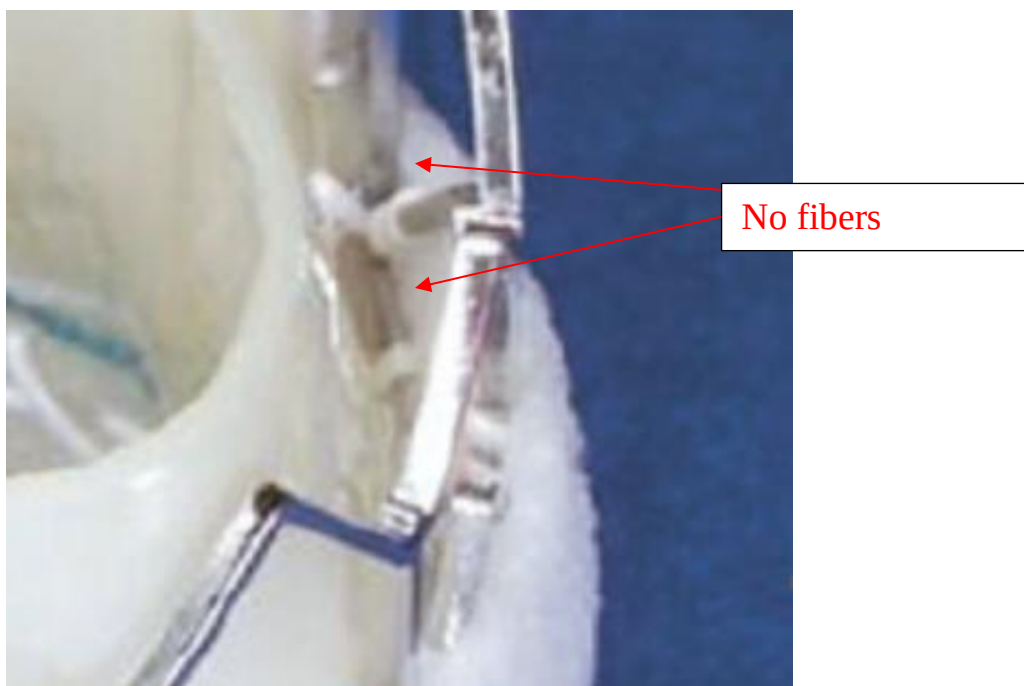


Pet., 43-44; Ex. 1003 [Buller-Decl.] ¶¶ 131-134. Petitioner and Dr. Buller further contend that “some of the inwardly-facing fibers are pressed through the open cells of the outer frame and extend radially inwardly of the outer frame,” and that the “inwardly-facing fibers that do not pass through the open cells of the outer frame instead press against and form a sealing interface with the outer frame.” Pet., 44; Ex. 1003 [Buller-Decl.] ¶ 132. For the reasons set forth below, I disagree.

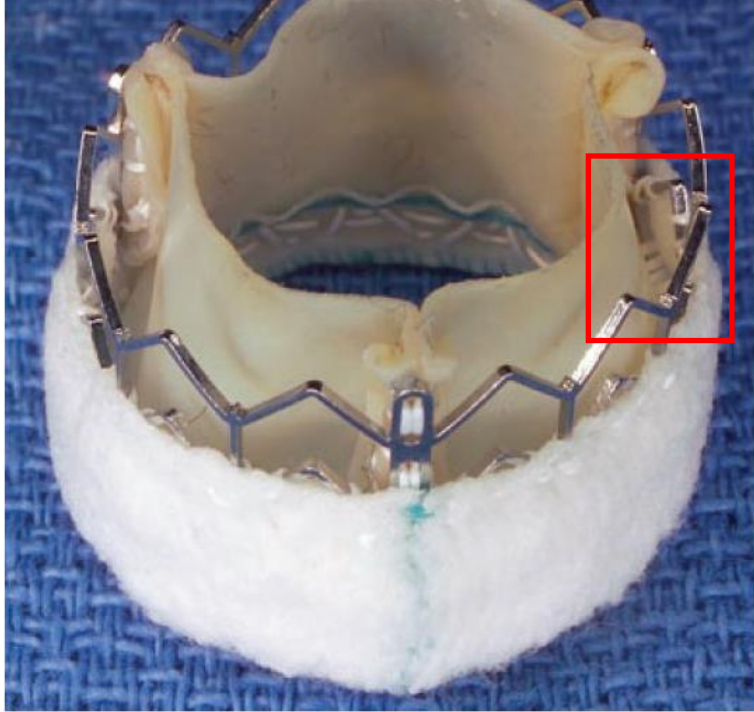
1) *Cheung’s And Apogee’s Images*

101. Cheung’s and Apogee’s photographs, discussed previously, confirm that the 9000MIS’s outer cloth did not include inwardly-facing fibers. As can

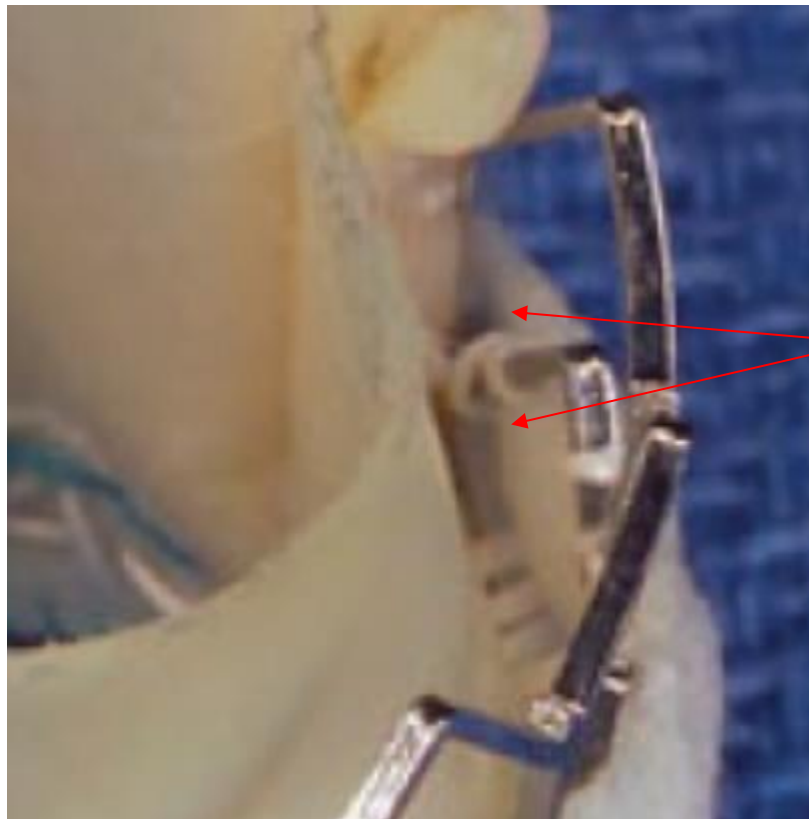
readily be seen, the backside of the cloth in both Cheung and Apogee is smooth, with no inwardly-extending fibers:



Ex. 1017 [Cheung] Fig. 2.

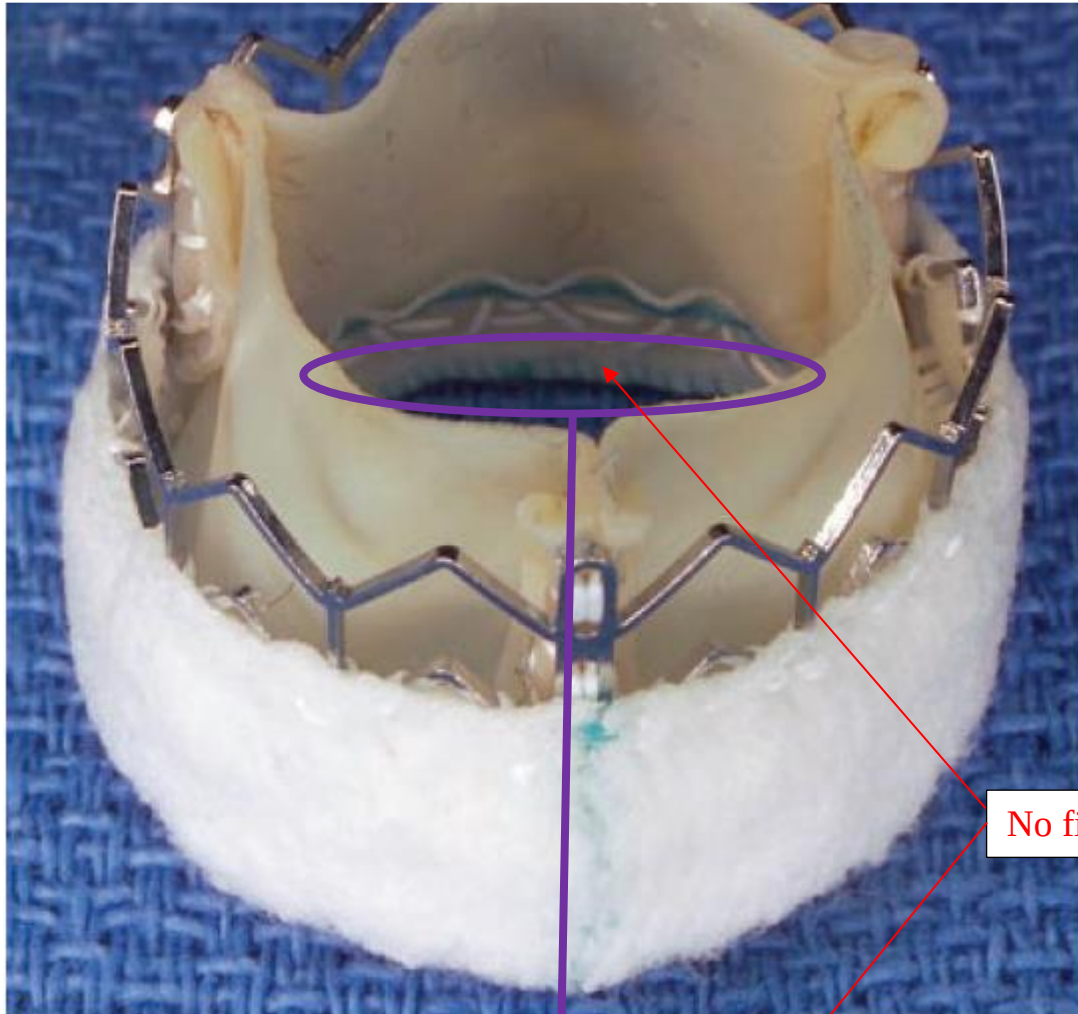


Apogee Gen 1b Greinecker 041305 at EDWARD

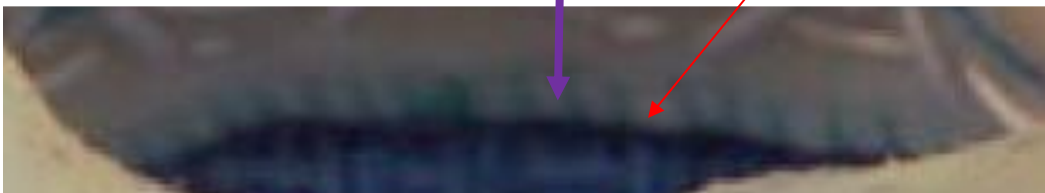


No fibers

Ex. 2087, 7. And, as discussed, Dr. Buller and I agree that no fibers are present at the bottom of Apogee either:



Apogee Gen 1b Greinecker 041305 at EDWARD



Dr. Buller agreed that no inward-facing fibers are present. Ex. 2104 [Buller-2nd-Depo.] 40:12-41:16. Like Cheung, Apogee's cloth closely resembles Walther's cloth.

102. In deposition, Dr. Buller recognized, and I agree, that there are no visible "stray, outwardly extending fibers on the inner surface of Cheung's outer cloth." Ex. 2104 [Buller-2nd-Depo.] 9:1-4. Of note, in the images above, the bars of the frame are clearly visible without any obscuring fibers. If the inner surface looked like the outer surface, one would see fibers sticking out.

103. Dr. Buller later testified that Cheung's inner surface is "far from smooth" and has "toughs [sic], fibers, and [is] undulating" like the outer surface. *Id.*, 26:18-27:9. I do not see anything of the sort; the inner surface of Cheung's outer cloth appears smooth, and I do not see any roughness, tufts, fibers, or an undulating surface. Dr. Buller appears to have reached this conclusion in part by looking at the top of Cheung's cloth rather than the inner surface. *Id.*, 25:15-27:9. But the best way to determine what the inside of Cheung's cloth looks like is by looking at the inside of Cheung's cloth, not its top. It is difficult to discern why the top looks as it does. It may well be frayed. Ex. 2105 [Woven Textiles] 441 ("Woven fabrics ... suffer from the tendency of fraying when cut into shapes ..."), 454 ("The main disadvantages of plain and associated woven structures for use as vascular fabrics are that they fray at cut edges ..."); Ex. 2104 [Buller-2nd-Depo.]

31:15-24 (agreeing fibers may stick up where a fabric is cut), 32:6-11 (agreeing cut woven PET might result in frayed edges). Thus, a frayed top is consistent with a woven PET backing layer.

104. Dr. Buller similarly testified that he could not see “any” visible inwardly-facing fibers on the inner surface of Apogee’s outer cloth, mirroring his Cheung testimony. *Id.*, 36:8-12, 38:12 (“I can’t see them”), 39:5 (“I cannot see individual fibers.”). Here too, the bars of the frame are clearly visible and not obscured at all by inwardly-extending fibers.

105. As with Cheung, Dr. Buller further testified that Apogee’s outer cloth’s inner surface “looks [bobbly] and is not smooth.” *Id.*, 39:5-6; 36:12-13, 42:1-3. I do not agree with Dr. Buller’s visual assessment. Like Cheung, Apogee’s inner surface appears smooth, without any discernible bobbles or fibers.

106. Thus, Cheung and Apogee confirm that the outer cloth in 9000MIS valves (like Walther), includes a smooth backing layer with no inwardly-facing fibers. This is significant evidence that Walther’s outer cloth similarly lacks inwardly-facing fibers.

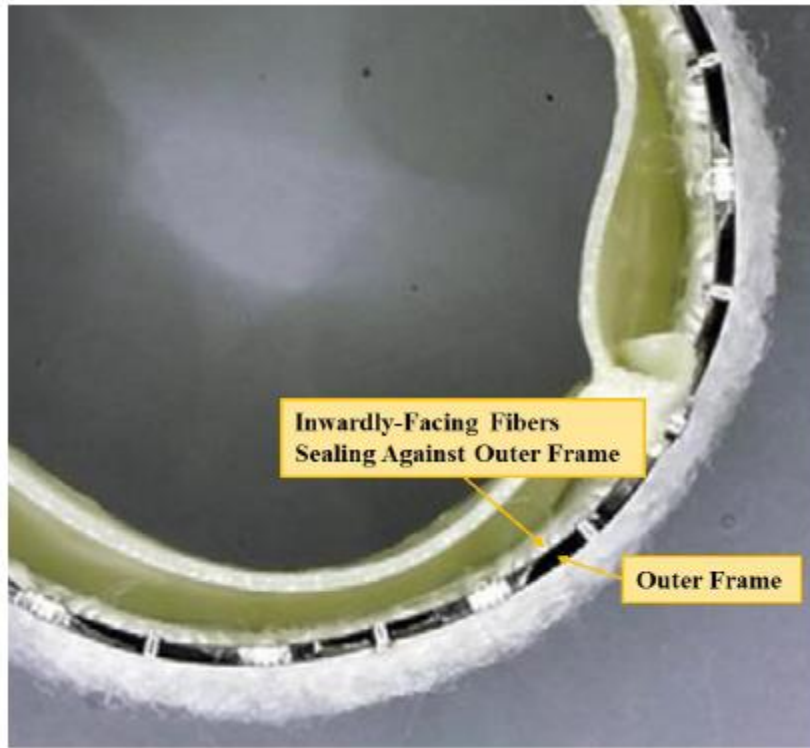
2) *A Graft With Woven Surfaces Only On The Exterior Surface Was Well-Known*

107. In my opinion, Dehdashtian and other references confirm a graft with woven surfaces only on the exterior surface was well-known, including by Walther’s authors.

108. Dehdashtian teaches that a POSITA would attach fibers on the exterior surface to “promote tissue ingrowth” to help anchor the valve in place. *See, e.g.*, Ex. 2101, 3:31-34, 4:2-6, 13:13-23; *see also* Ex. 2104 [Buller-2nd-Depo.] 117:21-118:2 (“outwardly extending fibers may facilitate attachment to native leaflets” and “encourage...blood coagulation and tissue ingrowth, which help to attach things.”). Consequently, a POSITA may be motivated to add fibers to the outer surface. In fact, Walther discusses that a goal of its outer cloth is to “promote tissue ingrowth,” and Spenser II is similarly interested in the same. Ex. 1007, 1; Ex. 1011, ¶ 145. In contrast, the interior surface is not in direct contact with the native valve tissue (or a previously inserted valve) and, thus, would not facilitate attachment or prevent migration.

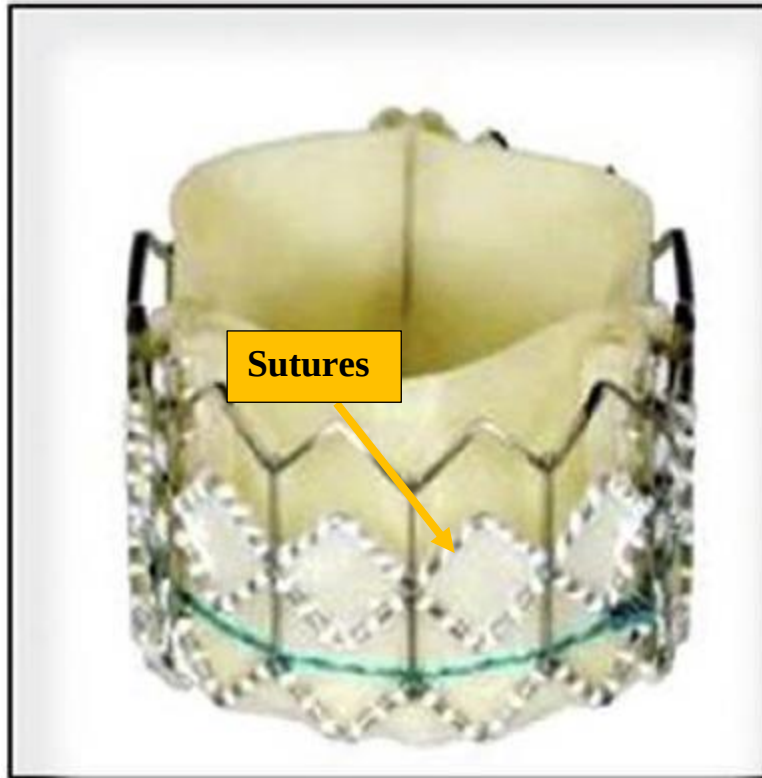
3) *Dr. Buller Mistakes Walther’s Sutures For Fibers On The Inside Of Walther’s Cloth*

109. Petitioner and Dr. Buller also allege that the annotated image below shows that Walther’s outer cloth discloses the claimed “second portion of fibers”:



Pet., 43-44; Ex. 1003 [Buller-Decl.] ¶132. I disagree. What Petitioner and Dr. Buller are pointing to are not inwardly-facing fibers from the inner surface of the outer skirt, but rather sutures for the inner skirt.

110. Walther discloses a SAPIEN valve with an added outer cloth. Ex. 1007 [Walther] 1120-1121. SAPIEN has an inner skirt that is sutured to the inner surface of the outer frame with “three or four stitches along each strut”:

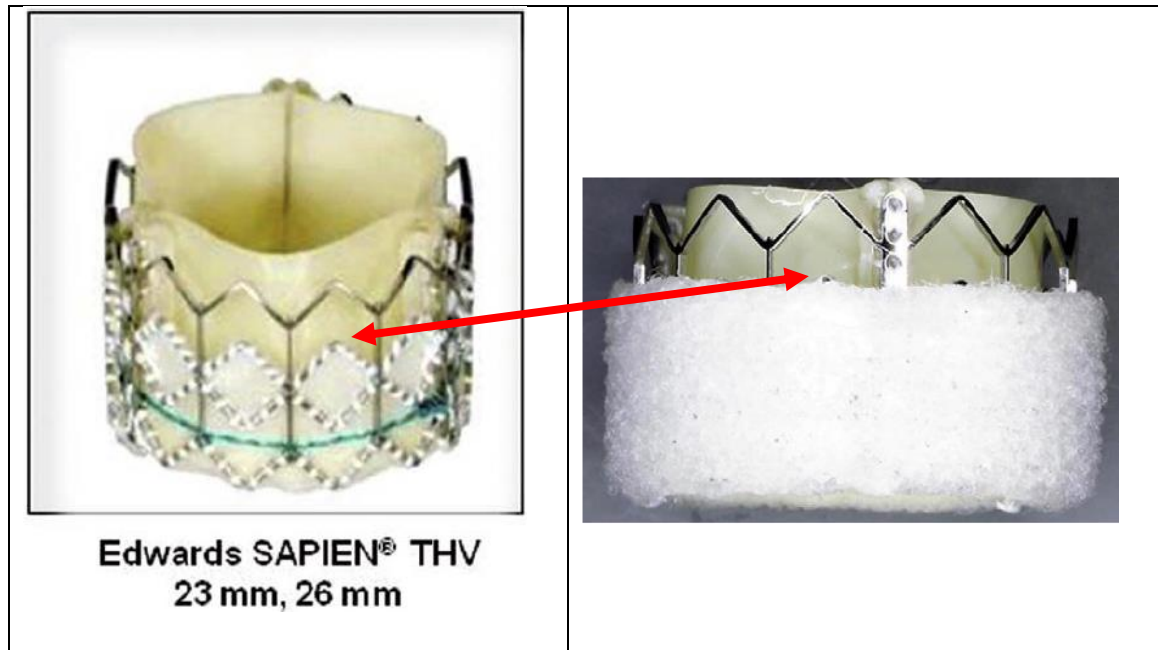


**Edwards SAPIEN® THV
23 mm, 26 mm**

Ex. 1012 [Cribier] Fig. 1; Ex. 2104 [Buller-2nd-Depo.] 44:24-45:3.

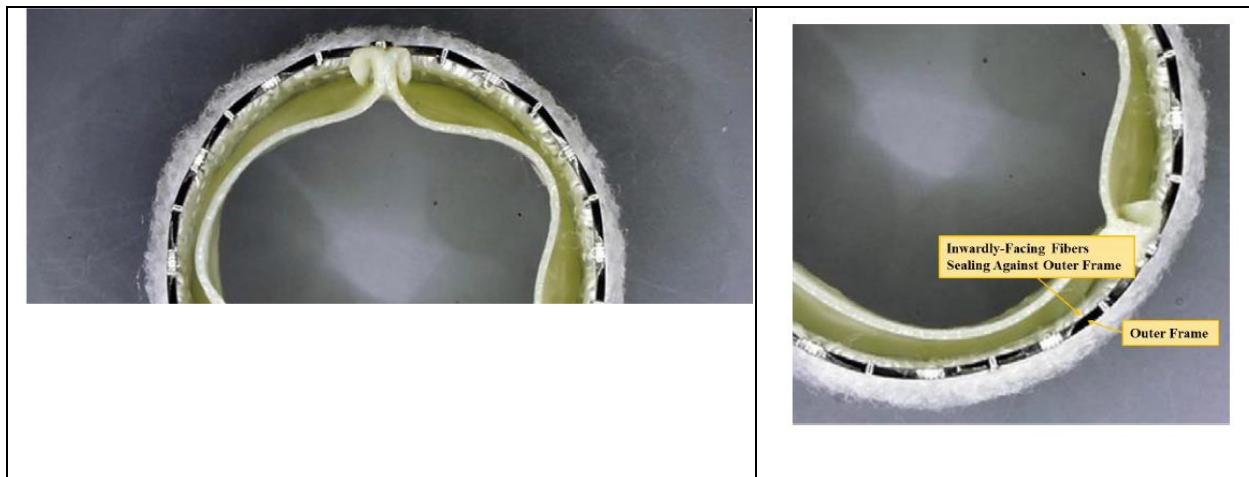
111. Dr. Buller testified, and I agree, that Walther’s outer cloth is “higher” than the inner skirt in certain areas. Ex. 2104 [Buller-2nd-Depo.] 46:1-14 (agreeing that Walther’s cloth is higher than inner skirt and that stitches from the inner skirt can be seen). This is because the top of Walther’s outer cloth is relatively flat and even but its inner skirt has peaks and valleys as it follows the outer frame so where the inner skirt has a valley, the outer cloth is taller. In the comparison below, the double-sided red arrow shows the tips of the cell where the inner skirt is attached.

Note that the SAPIEN inner skirt is one row higher than the Cribier-Edwards predecessor discussed in connection with Cheung and Apogee.



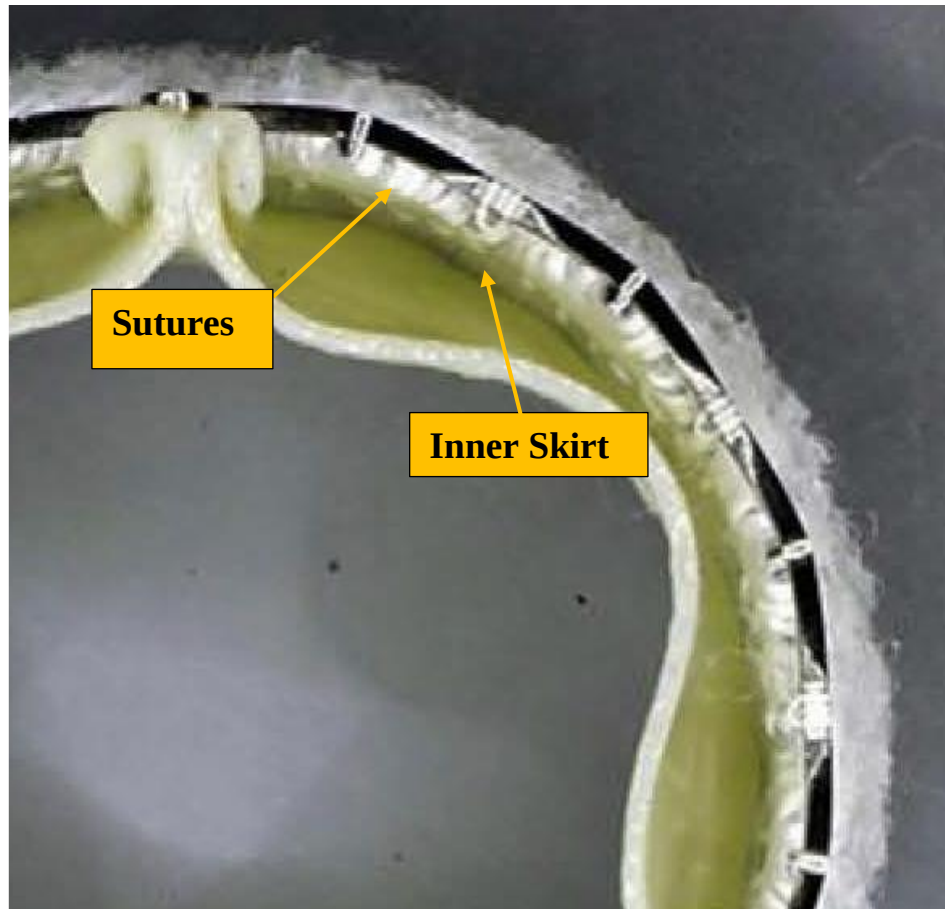
112. Dr. Buller admits that he can “discretely see three or four per strut sutures...attaching the inner skirt to the frame” in Walther’s Figure 1. Ex. 2104 [Buller-2nd-Depo.] 46:25-47:3, 46:6-7. Dr. Buller recognized that “parts” of the white material on the interior of the outer frame in the relied-upon lower right-hand quadrant of Walther’s birds eye image may be “associated ... with the inner skirt or the sutures” thereto. *Id.*, 56:17-21; *see also id.*, 56:7-9. (“I don’t know for a certainty that it doesn’t contain the sutures”).

113. Moreover, Dr. Buller testified that the “upper half of the device,” not the relied-upon lower region, is where “more of the inside wall,” including “these discrete three or four stitches” to the inner skirt, are “best” shown. *Id.*, 47:4-17.



Ex. 1007 [Walther] Fig. 1 (excerpt); Pet., 44.

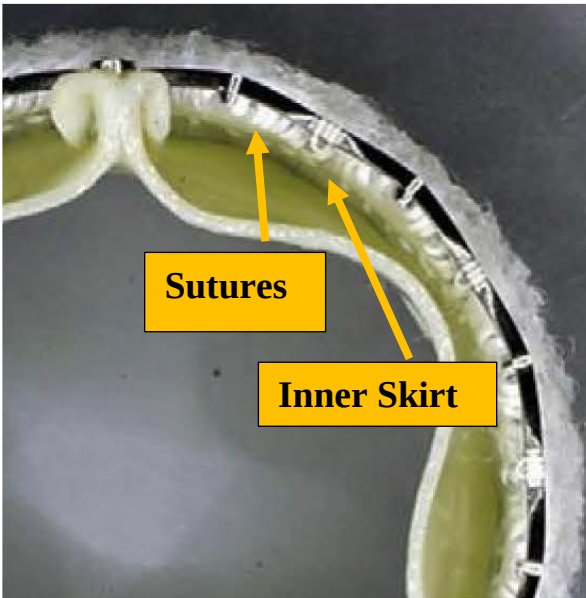
114. When looking at the upper half, however, Dr. Buller conceded—and was “certain”—that he could see “three very uniform” stitches attaching the inner skirt to the outer frame. Ex. 2104 [Buller-2nd-Depo.] 89:11-22, 90:11-91:3. Dr. Buller is also “certain” that he can see “part of the inner skirt” below the sutures. *Id.*, 91:18-20, 91:7 (same), 93:15-94:1 (confirming he can see the inner skirt and sutures thereto).



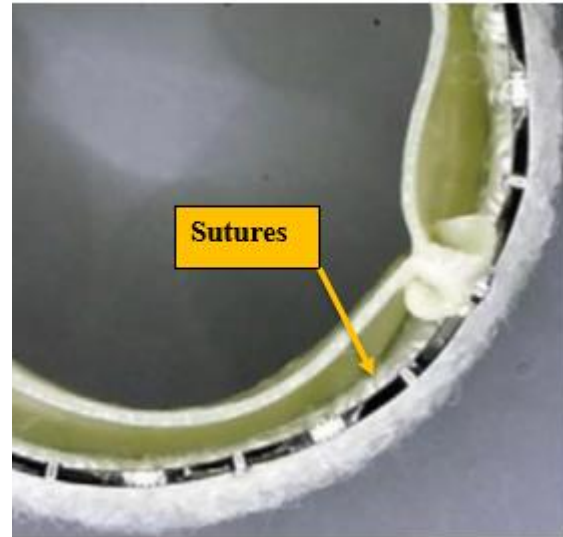
Ex. 1007 [Walther] Fig. 1 (excerpt).

115. The upper portion where Dr. Buller confirms that he can see the sutures of the inner skirt reveals that what he and Petitioner had pointed to as inwardly-facing fibers were, instead, just the sutures attaching the inner skirt to the outer frame, as this comparison reveals:

What Dr. Buller agrees are sutures:

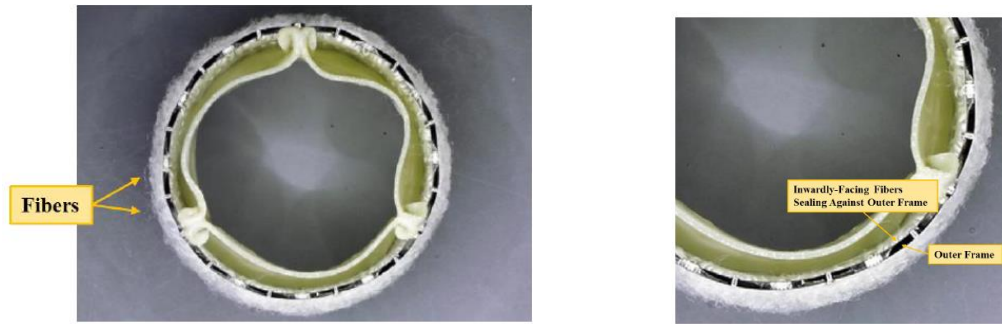


What Dr. Buller contends are inwardly-facing fiber are also sutures:



116. Dr. Buller also recognizes, and I agree, that the upper portion “between 9:00 o’clock and 3:00 o’clock ... the upper half of the device” shows “more of the inside wall” relative to, e.g., “6:00 o’clock” where “you’re seeing less of the inside.” Ex. 2104 [Buller-2nd-Depo.] 46:17-47:17. Thus, Dr. Buller seems to recognize that the above image to the left is more probative and clearly shows sutures, not fibers from the inner surface of the outer cloth.

117. I disagree with Dr. Buller and believe that he has mistaken the sutures for inwardly-facing fibers from the outer cloth. These fibers look very different from the fibers extending from the outer cloth:



Pet., 37, 44 (excerpting Ex. 1007 [Walther] Fig. 1).

118. Notably, despite his testimony that the purported “second portion of fibers” are visibly poking through the open cells in the outer frame above the inner skirt, Dr. Buller admits he can see these sutures “clear as day...without being obscured by fibers from the outer cloth.” Ex. 2104 [Buller-2nd-Depo.] 95:8-13, 94:9-11 (can see sutures “fairly clearly”).

119. This is not consistent with inwardly-facing fibers. Walther’s outer cloth has a thick fibrous exterior surface and extends higher than its inner skirt because the top of the cloth is a straight line whereas the inner skirt has peaks and valleys. The cloth is aligned with the peak and, thus, is taller than the inner skirt elsewhere:



Edwards SAPIEN® THV
23 mm, 26 mm

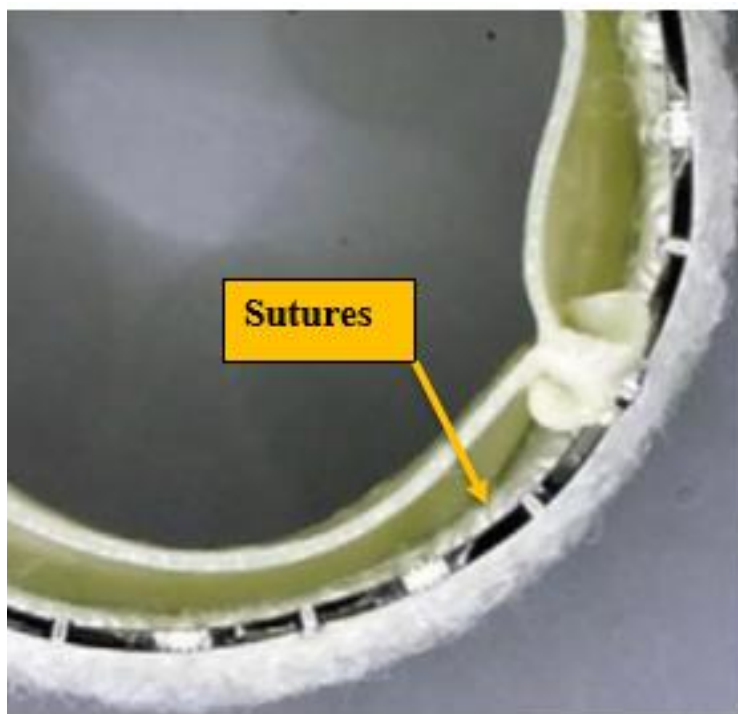
Ex. 1012 [Cribier] Fig. 1



Ex. 1007 [Walther] Fig. 1

120. Therefore, if the inner surface was of a similar composition to the cloth's outer surface, there would be many inward-facing fibers poking through the interstices of the outer frame, such that the sutures attaching the inner skirt to the outer frame would be obscured. However, I agree with Dr. Buller that the sutures can be clearly seen. Ex. 2104 [Buller-2nd-Depo.] 95:8-13 (sutures between 1-2 o'clock "clear as day" "without being obscured by fibers from the outer cloth"). This suggests that there are no inwardly-facing fibers.

121. Here too, in the lower portion Dr. Buller relies upon, the inner skirt and its sutures are unobscured by any protruding fibers from the outer cloth:



b. *Spenser II's Cloth (Grounds 1-2, 6)*

122. I note that Petitioner and Dr. Buller point to Spencer II's compressible material 256 as satisfying the "second portion of fibers" and "free of an outer graft covering" limitations. As to the former, Petitioner and Dr. Buller contend that the "compressible material 'may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material,'" further arguing that the material has both an "outward-facing surface" and an "inward-facing surface," allegedly the "second portion of fibers" required by claim 1. Pet., 71-72; Ex. 1003 [Buller-Decl.] ¶195. I disagree.

123. Spenser-II, like its admitted "real-world" embodiment, Walther, does not discuss the nature of the inner surface of its woven PET compressible material.

Ex. 2052 [Buller-1st-Depo.] 104:18-105:7. I disagree with Dr. Buller’s assertion that Spenser II’s description of “small fibers extending from the surface,” refers to both surfaces (outer and inner). Pet., 71-72; Ex. 1003 [Buller-Decl.] ¶195; Ex. 2104 [Buller-2nd-Depo.] 123:14-20; Ex. 1011 [Spenser-II] ¶145. Figure 22 does not provide any insight as to the interior surface of its outer cloth. Indeed, the inner surface is not visible, much less any inwardly-facing fibers thereon:

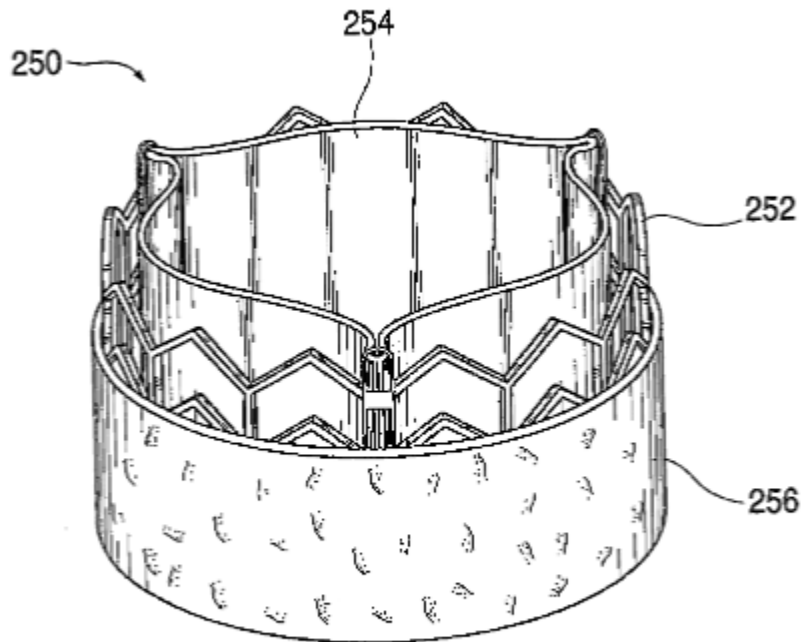


FIG. 22

Ex. 1011 [Spenser-II] Fig. 22. Importantly, Spenser II **does** expressly claim the compressible material including “fibers extending outward ***from the outer surface.***” *Id.*, cl. 29. No corresponding claim exists suggesting inward-facing fibers from the inner surface of the compressible material.

124. In accord, Dehdashtian discloses a woven “towel-like” graft with fibers extending on the “outer” or “exterior” surface but not the inner surface. This is further circumstantial evidence that fibers similarly extend outwardly only from the compressible material’s outer surface. See ¶¶62-72, *supra*. Mr. Dehdashtian was, again, apparently responsible for Figure 22 and is Walther’s second author. *Id.* Dehdashtian is consistent with Spenser II’s disclosure that the “fibers extend[] from the surface of the [compressible] material.” Ex. 1011 [Spenser-II] ¶145. Moreover, as with Walther, a POSITA would appreciate that the fibers on the outer surface would promote tissue ingrowth, which would not be desirable on the inner surface particularly as the added fibers could increase the crimp profile. See ¶108, *supra*.

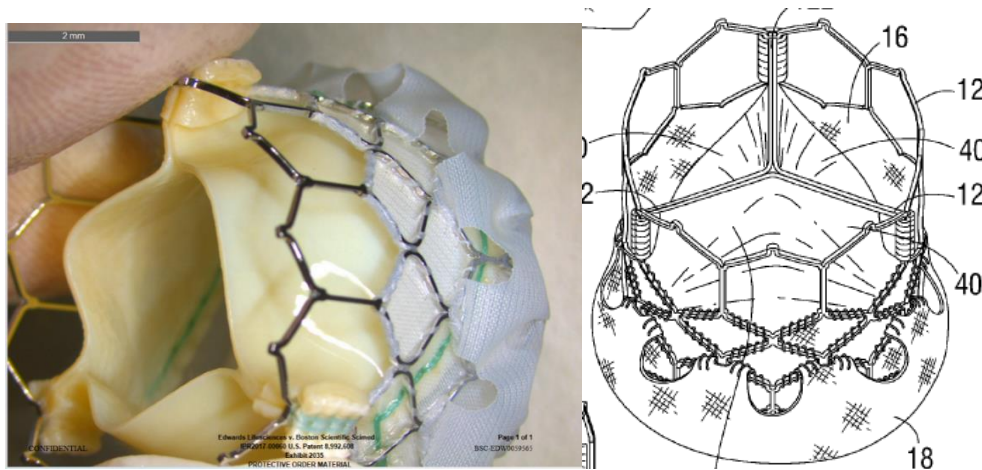
125. Spenser II, like Walther, is also described by Dr. Buller as being made of “velour-like woven PET.” But, as Dr. Buller recognized, velour-like woven PET may have fibers only extending from the outer surface. Ex. 2104 [Buller-2nd-Depo.] 33:4-17, 33:25-34:4. When a graft has fibers extending from both sides, it may be referred to as “double-velour.” Ex. 2064 [Leibig-657] 2:1-5 (describing “double velours” as “having velour loops on both the inner and outer surfaces of the fabric”). Petitioner has not presented evidence that Spenser II (or Walther) deploys “double-velour.”

126. Based upon this evidence, I conclude that Spenser II is silent as to the inner surface of its compressible material. I understand that Dr. Buller has testified that this opinion could not be held by any “objective” or “reasonable” interventional cardiologist. Ex. 2104 [Buller-2nd-Depo.] 125:7-127:1. I respectfully disagree. The evidence quite simply does not suggest that Spenser II’s outer cloth includes inwardly-facing fibers. It suggests the opposite.

c. *Levi’s Cloth (Grounds 4-5)*

127. I do not see any “portion” of fibers visible in any of Levi’s many figures. I note that Levi’s skirt is described as being made of “woven PET” and that no extending fibers are mentioned.

128. In my opinion, Sapien 3 (Levi’s commercial embodiment) further confirms no fibers extend from either surface:



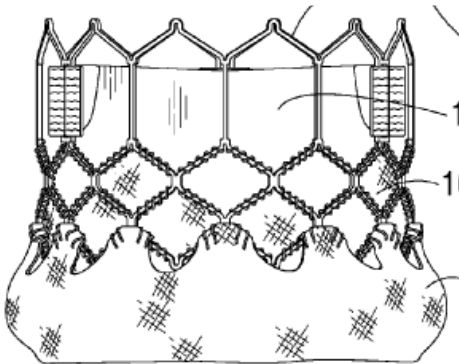
Compare Ex. 2106 [Boston-Ex.-2035] with Ex. 1008 [Levi] Fig. 2.

C. “A First Portion Of Fibers” That “Extend Radially Outwardly” (Grounds 4 And 5, All Claims).

129. The claims require that “the first portion of fibers extend radially outwardly of the outer frame.” Ex. 1001 [’236-Patent] cl. 1. Dr. Buller asserts that Levi discloses this limitation or renders it obvious. Ex. 1003 [Buller-Decl.] ¶¶ 236-239.

130. I have previously submitted a preliminary declaration in this case. For convenience, I include the testimony from my preliminary declaration with regard to “the first portion of fibers extend radially outwardly of the outer frame,” replicated below.

131. For Levi’s outer skirt, the alleged “sealing material”, appears to be very similar to the outer skirt on the SAPIEN 3 valve.



Levi



SAPIEN 3 valve

Ex. 1008 [Levi] Fig. 3; Ex. 2026 [Thomas] 3.

132. I have significant experience handling and implanting the SAPIEN 3 valve. I could not see anything on the outer skirt of SAPIEN 3 that a POSITA would consider to be “radially extending fibers.”

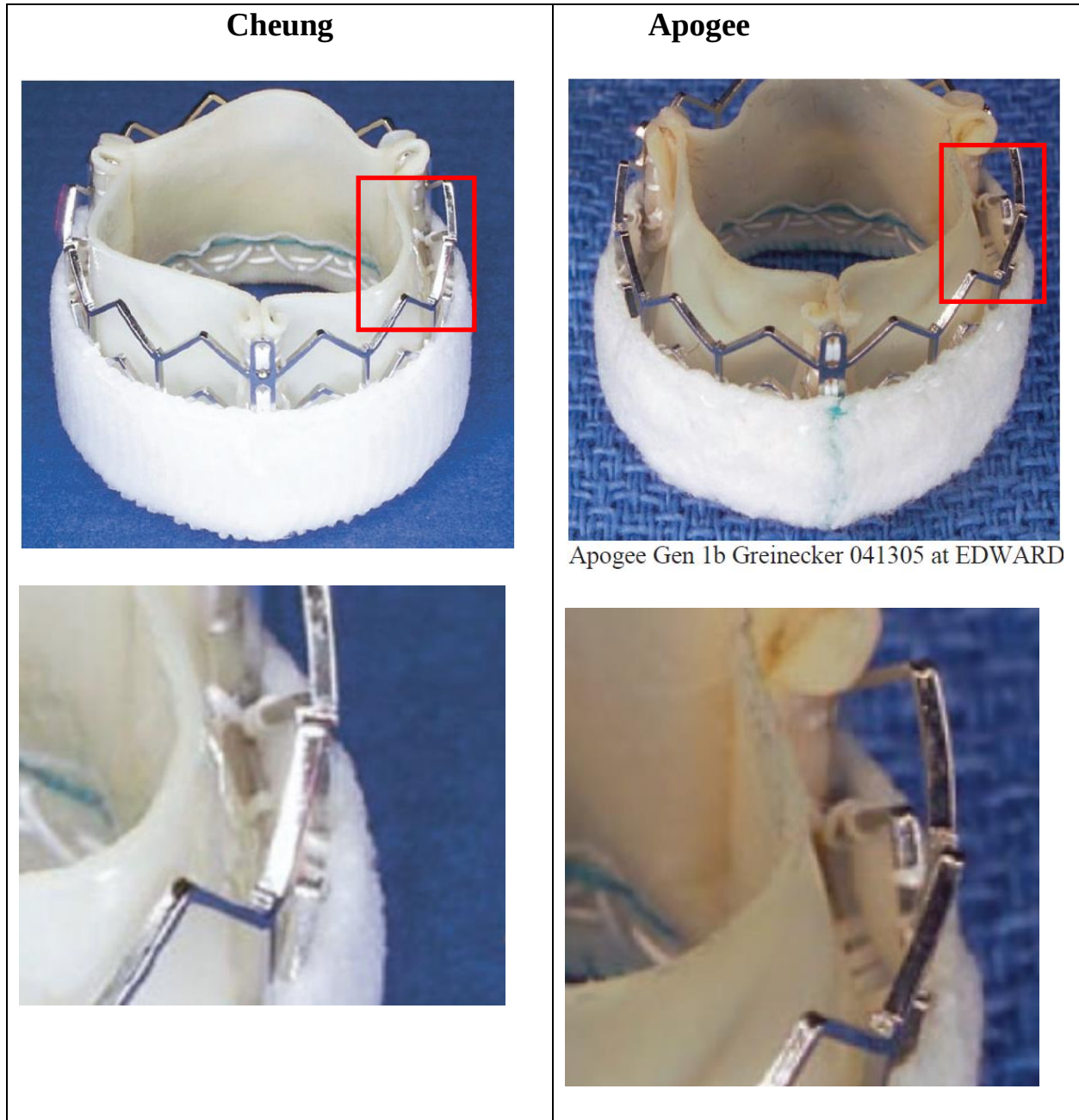
D. “Opening[s]” “Define[d]” By The “Spacing Formed Between Adjacent Fibers” That “Extend Through A Thickness” Of The First And Second Portions Of “Fibers,” And That “Extend[] To The Outer Frame” (Claim 4).

133. Claim 4 requires that the “second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” I do not believe Petitioner or Dr. Buller have demonstrated that this limitation is disclosed or obvious under any of its grounds.

134. As previously explained, none of Petitioner’s references even disclose a “second portion of fibers.” See Section VI.B, *supra*. I further note that neither the Petition nor Dr. Buller rely on any image or disclosure from any reference to show claim 4’s openings. Pet., 55, 82, 103-104; Ex. 1003 [Buller-Decl.] ¶¶155-158, 220-223, 282-285. Nor is there any description of these imagined fibers. Without the “second portion of fibers,” there can be no “opening...through a thickness thereof” much less one that “extends to the outer frame.”

135. As for Spenser II, I do not see the inner surface of the outer frame and find that there is no reason to believe there are inwardly-facing fibers, much less ones with openings extending through to the outer frame. Walther does not present

a clear image of the outer surface of its cloth, and I agree with Dr. Buller there are no discernible fibers on the inner surface of other “very similar” 9000MIS valves (Cheung and Apogee):



See Ex. 2104 [Buller-2nd-Depo.] 9:1-4 (“Q. Do you see any stray, outwardly extending fibers on the inner surface of Cheung’s outer cloth? A. In that little part, no. I can’t.”); *id.*, 36:8-12; (“I can’t see any” inwardly-facing fibers on the inner surface of Apogee’s outer cloth), 38:12 (same), 39:5 (same). Furthermore, as I discussed, if there were inwardly-facing fibers, they would obscure the bar where the inner skirts are attached. Instead, however, the bars are clearly visible. See, e.g., ¶¶102, 104, *supra*. Similarly, in Walther, we can clearly see the sutures for the inner frame without them being obscured by inward-fibers from the outer cloth. See, e.g., ¶¶120-121, *supra*.

136. I am aware that in deposition, Dr. Buller claimed that the back of Walther’s outer cloth is visible in Figure 2. Ex. 2104 [Buller-2nd-Depo.] 11:19-12:5, 16:6-13, 17:13-16. Even assuming this is so, I note that Dr. Buller could not identify “opening[s]” and no inward-facing fibers are visible:

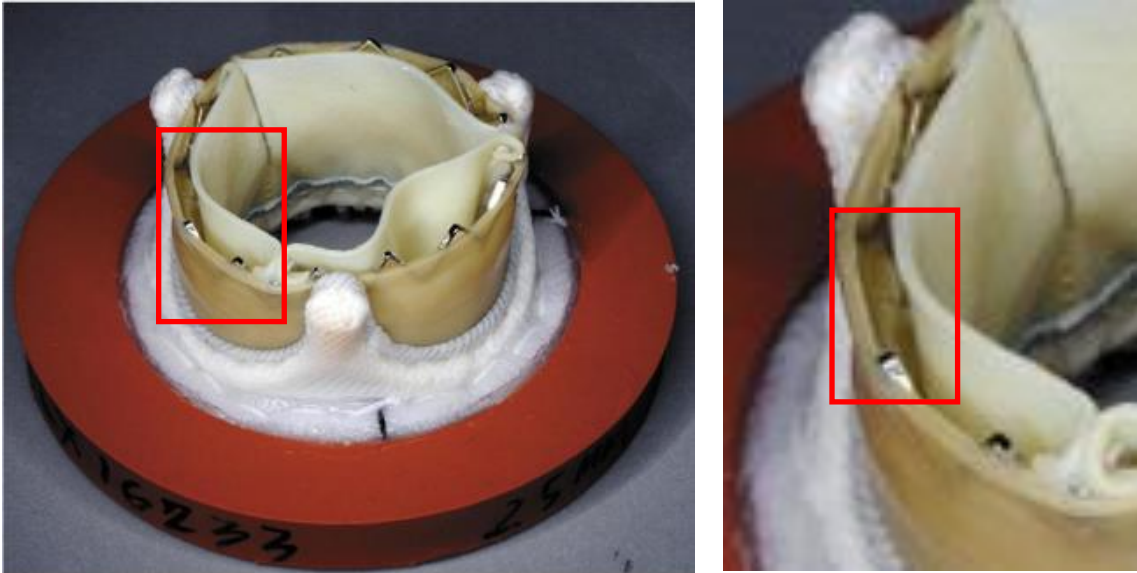


Fig. 2. Cloth THV valve deployed in surgical valve.

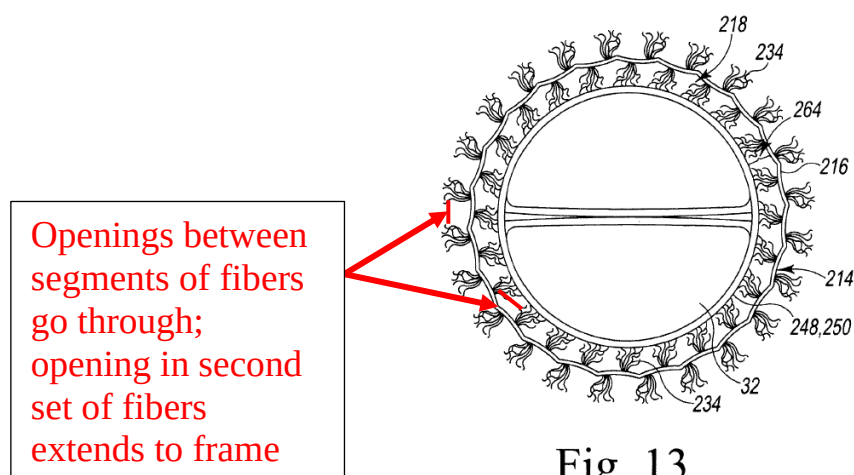
Ex. 1007 [Walther] 1121, Fig. 2 (excerpt) ; Ex. 2104 [Buller-Depo.] 69:22-23 (“I’m certain that that is part of [sic] Walther’s cloth.”); *id.*, 70:22-71:5 (Dr. Buller, unable to identify any openings in Figure 2). I do not see any openings either.

137. I note that Petitioner and Dr. Buller appear to rely upon an implicit interpretation of “opening” to include the “small gaps or spacing between the interwoven fibers” that *inherently* exist in “woven PET fabric.” Pet., 102; *see also id.*, 52-55, 81-82, 103-104; Ex. 1003 [Buller-Decl.] ¶¶151-153, 157, 218, 222, 278. I further note that alternatively, Petitioner and Dr. Buller argue that a POSITA would have found it obvious to substitute the cloths in its references for “lower density” alternatives with “even larger openings.” *Id.*, 54-55, 81-82. I disagree with both arguments.

1. Petitioner And Dr. Buller’s Implicit Construction

138. Claim 4 requires that “the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” The claim language and the intrinsic record is inconsistent with Petitioner’s interpretation. Claim 4 requires not just an opening but, rather, one that extends through a thickness thereof and further “extends to the outer frame.”

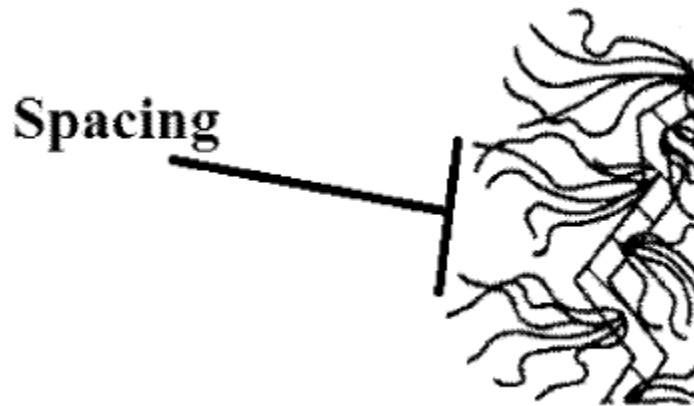
139. The embodiment that best corresponds to claim 4 is Figure 13 which shows clear openings in both the first and second set of fibers:



140. In prosecution, the Applicant explained that Figure 13 teaches the “opening[s]” of claim 3 (then claim 15). Ex. 1002 [’236-PH] 96-97. As can be seen, Figure 13 depicts both a first and second set of fibers where in each set “opening[s]” are clearly defined, based upon spaces between adjacent fibers, with the “opening[s]” extending through the thickness thereof and to the frame. Ex.

1003 [Buller-Decl.] ¶151 (figures “illustrate *relatively large openings between the groups of...fibers.*”).

141. In prosecution of related patent 11,337,834, the Applicant clarified that the “[w]hat the Applicant is claiming is the spacing between segments of some fibers” as shown in an annotated Fig. 10:



Ex. 2114 [’834-FH] 140-142. This makes clear that openings between “segments of some fibers” are contemplated and are intentionally created.

142. Thus, both the specification and the prosecution history indicate that the “openings” claimed are relatively larger and created by design, rather than the mere inherent spaces between fibers. I see nothing in the intrinsic record that is susceptible to Dr. Buller’s interpretation. No evidence or explanation is given to show why a POSITA would understand the inherent gaps between two adjacent fibers in any woven cloth to constitute an “opening” much less one that “extends through a thickness” of the fibers and “to the outer frame.”

143. I disagree with Dr. Buller’s testimony concerning alleged “openings” in the back of Cheung’s and Apogee’s outer cloths. In Cheung, Dr. Buller claimed to see “triangular shadows” that look “like a little cave,” “light variation,” and “dark spots” all of which he characterized as openings. Ex. 2104 [Buller-2nd-Depo.] 11:19-12:5, 16:6-13, 17:13-16. But the backside of Cheung’s outer cloth appears smooth and flat with no openings or “caves”:

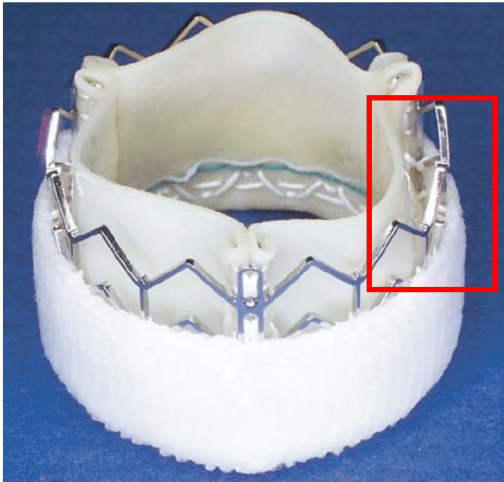


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter



Ex. 1017 [Cheung] e19, Fig. 2. Further, any slight shadow would not connote an “opening,” much less an “opening” “between adjacent fibers” that “extend through a thickness thereof” and extend to the frame.

144. I note that Dr. Buller would argue “openings” in a “big, puffy piece of cotton candy” that’s “20 inches in diameter,” claiming “[i]t’s covered in openings

...” Ex. 2104 [Buller-2nd-Depo.] 22:6-19. In my opinion, neither ordinary usage nor the intrinsic record suggests this is what is contemplated by “openings”:

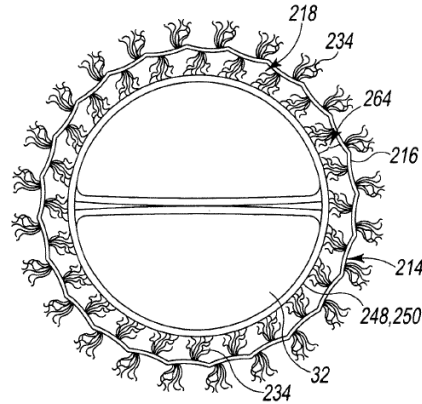


Fig. 13

2. Motivation To Modify The References

145. Alternatively, Petitioner and Dr. Buller argue that a POSITA would have found it obvious to substitute the cloths in its references for “lower density” alternatives with “even larger openings.” Pet., 54-55, 81-82. I disagree.

146. As an initial matter, the proposed modifications are insufficiently specified. Petitioner identifies no such cloth, nor any indication of how much larger these “opening[s]” would be. I do not see an explanation for why, even if such a cloth were available, a POSITA would be motivated to make this unspecified modification. Contrary to this modification, Dr. Buller notes that “the openings...*must be small*” otherwise, “blood may disadvantageously leak through

the openings.” Ex. 1003 [Buller-Decl.] ¶153. I agree that would have been the accepted wisdom at the time.

E. Ultra’s Skirt, Unlike Walther, Spenser II, And Levi, Lacks A Graft Covering, Is Filled With Holes, And Is Highly Porous.

147. I have been informed that in a hearing on December 15, 2022, involving the same parties, Petitioner suggested that Patent Owner’s infringement arguments may in certain respects be inconsistent with Patent Owner’s arguments before the Board. I am not aware of an inconsistency. As discussed below, the Sapien 3 Ultra’s outer skirt is very different from Walther’s, Spenser II’s, and Levi’s outer coverings. I am very familiar with Ultra which, as discussed below, lacks an outer graft covering, is filled with openings, and is highly porous.

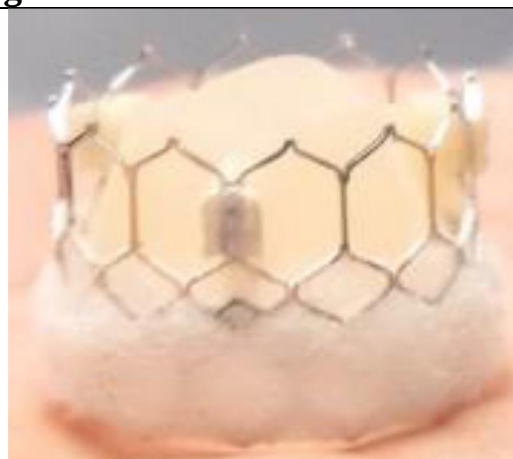
148. Images of the Sapien 3 Ultra (“Ultra”) are below. Ultra includes a translucent outer skirt through which the bars of the frame are visible. This is because there is not a tightly-woven graft layer. Instead, magnified images of Ultra’s outer cover reveal clear “openings,” defined by adjacent fibers. My understanding is Ultra is very loosely knitted² (Ex. 2026, 8) and does not include a tightly-woven base.

² This is not to say either that all “woven” bases would necessarily constitute a graft nor would a knit base necessarily preclude a graft. Among other things, a

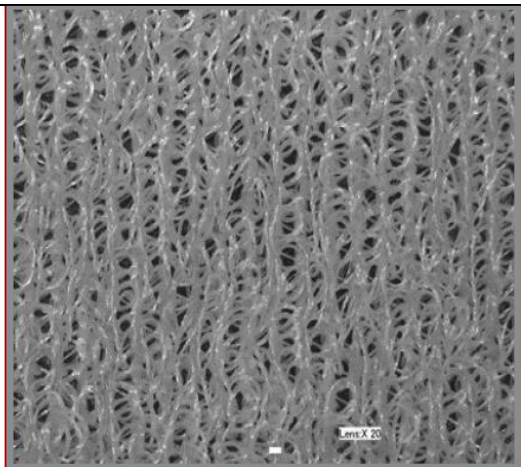
Ultra Images



Ex. 2100, 1



Ex. 2100, 2



Ex. 2026, 8



tightly-woven, tightly-knitted, or non-porous, dense felt layer may well constitute a graft. As discussed herein, however, Ultra's highly porous skirt does not constitute a graft covering.



Transcatheter SAPIEN 3 Ultra | C: X +

<https://www.edwards.com/healthcare-professionals/products-services/transcatheter-heart/transcatheter-sapien-3-ultra>

Product features Paravalvular leak Coronary access Videos

Paravalvular Leak

Designed to deliver excellent PVL outcomes

87.7%
None/Trace
PVL at
30 days

● Mod/Severe
● Mild
● None/Trace

Discharge (N=1,115) 30 days (N=763)
Real-world outcomes* Real-world outcomes*

~40% taller*

Excellent PVL performance

In a study of real-world patients, the SAPIEN 3 Ultra valve demonstrated¹

Edwards SAPIEN 3 Ultra valve

Now featuring a taller, textured polyethylene terephthalate (PET) outer skirt*

*Compared to the Edwards SAPIEN 3 valve

Important safety information

~40% taller*

Edwards SAPIEN 3 Ultra valve

Now featuring a taller, textured polyethylene terephthalate (PET) outer skirt*

*Compared to the Edwards SAPIEN 3 valve

<https://www.edwards.com/healthcare-professionals/products-services/transcatheter-heart/transcatheter-sapien-3-ultra>

149. I also note that the image of Ultra in Dr. Buller's declaration at ¶107 does not accurately depict what Ultra's skirt looks like:

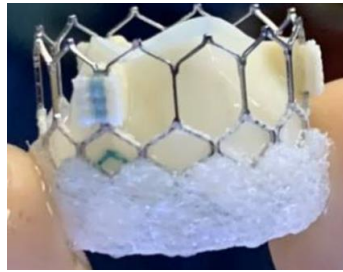
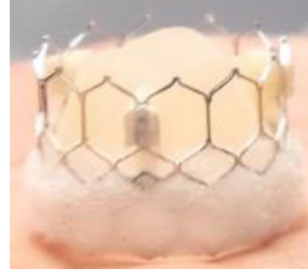
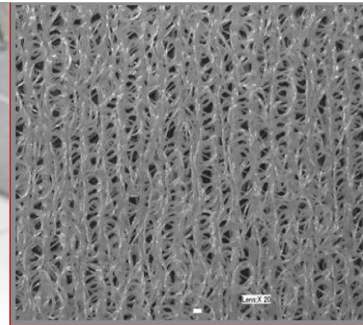
The Ultra Image In Dr. Buller's Declaration Is Imprecise

Buller Decl.

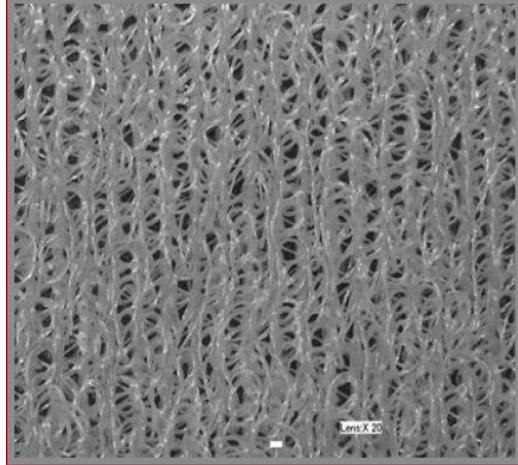


Ex. 1003, ¶107

Actual Ultra Images

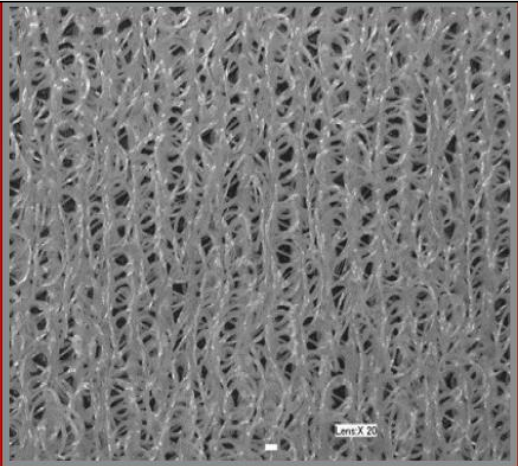
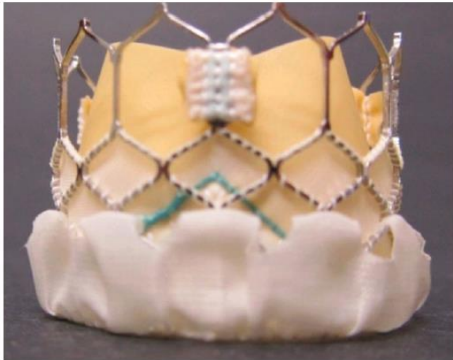
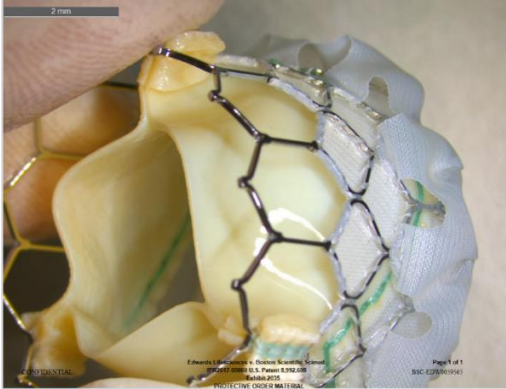
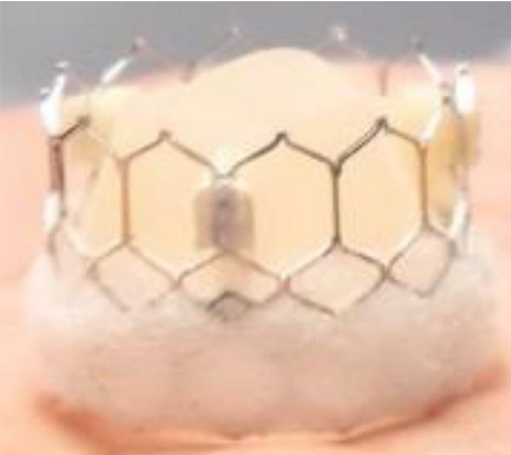


150. In deposition, Dr. Buller was shown the following image of Ultra's outer skirt:



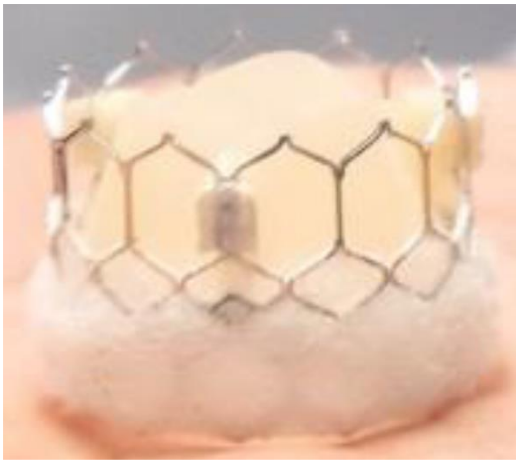
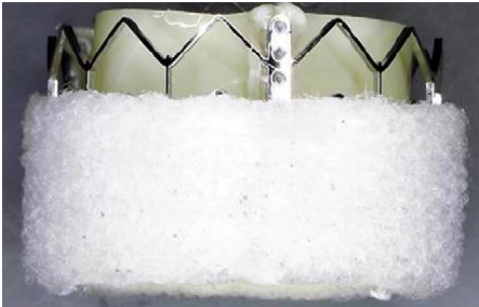
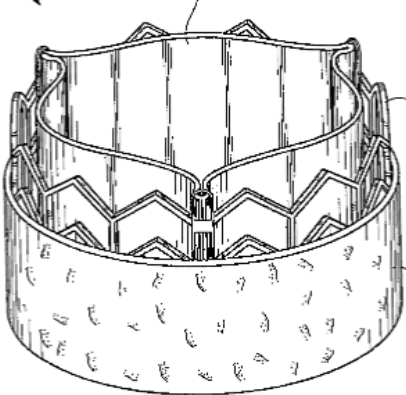
Ex. 2026, 8. Regarding that image, Dr. Buller testified to a “certainty” that Ultra’s skirt has a “porous fabric” and further that it is “clearly a loose fabric,” that “there are clearly holes between the fibers,” and that the “holes are going all the way through it.” Ex. 2104, 132:2-19, *see also* 129:10-132:1 (context). When asked “[d]o you see a graft covering in the Sapien 3 Ultra image?” he answered “I don’t think that would constitute a graft covering, because it would be porous.” *Id.*, 133:4-11.

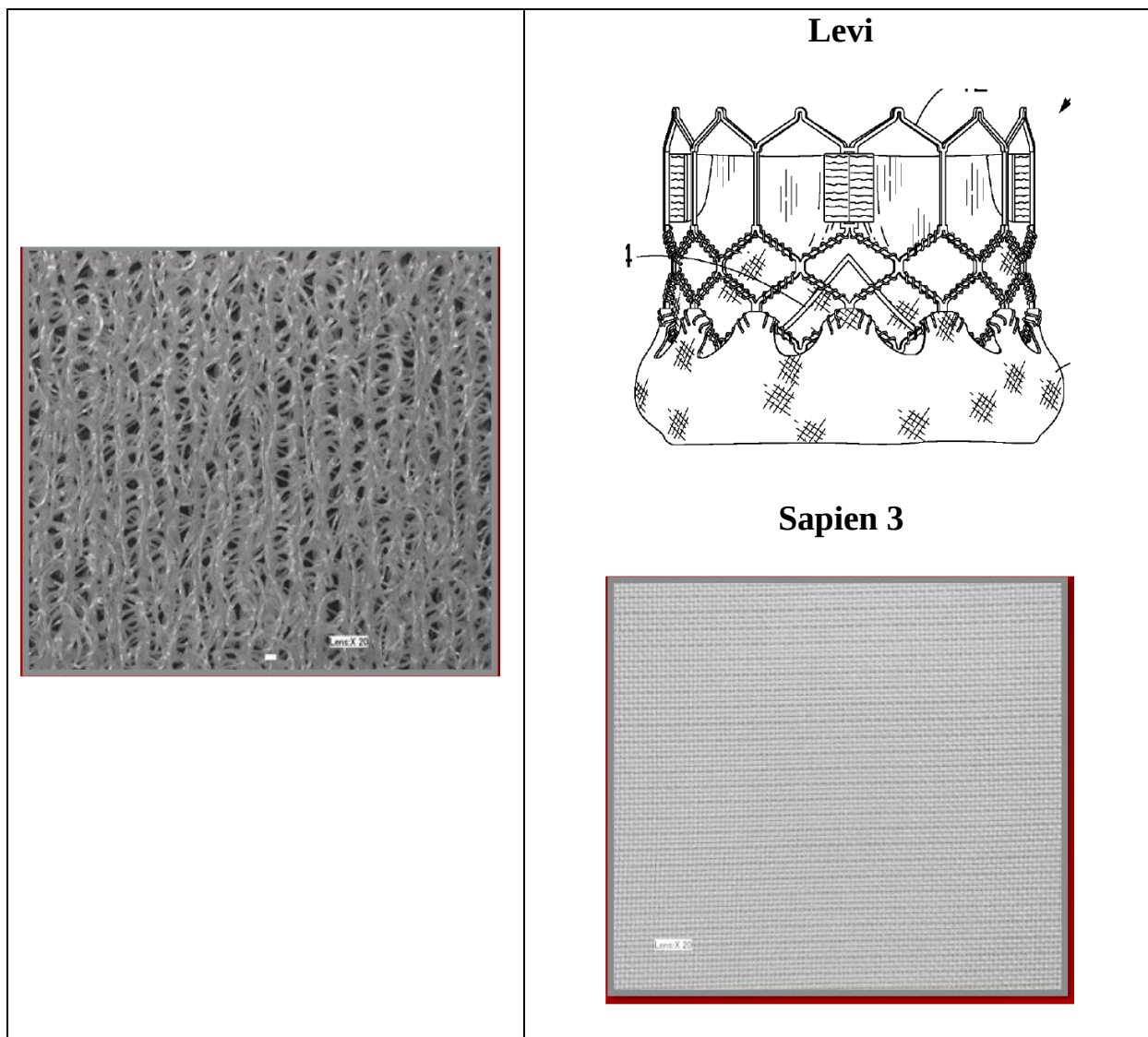
151. I agree with this aspect of Dr. Buller’s testimony. Ultra has a “loose” “porous” fabric with “clear holes between the fibers,” with the “holes [] going all the way through it.” I, like Dr. Buller, fully agree that Ultra is “free of an outer graft covering.” Ultra’s skirt is far more porous relative to Sapien 3/Levi:

Ultra Is Far More Porous Than Sapien 3/Levi	
Ultra	Sapien 3/Levi
	 <p>Sapien 3</p>  <p>Ex. 2106</p>
	
	



152. Similarly, I believe Ultra is distinct from the references Dr. Buller contends is “free of an outer graft covering.” Whereas 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.

Unlike The Prior Art, Ultra's Skirt Has Clear Holes And The Frame Is Visible Through It	
Ultra	Prior Art
  	<p>Walther</p>  <p>Spenser II</p>  <p>FIG. 22</p>



F. Secondary Considerations Of Nonobviousness

1. Prior Opinions Offered

153. For convenience to the Board, I include the testimony from my preliminary declaration with regard to secondary considerations of nonobviousness, replicated below.

154. The claims of the '236 Patent include limitations that together improved upon existing transcatheter aortic valve replacement (“TAVR”) technology, addressed two significant problems. As the Applicant explained:

TAVR devices have competing design forces at all times. The TAVR must maximize valve leaflet size, provide sealing characteristics to reduce PVL and PVR, yet, must maintain a small overall crimped profile as the compressed TAVR must be delivered endovascularly through an access artery and cross the native heart valve of the patient...

Ex. 1002 [Pros.-Hist.] 183. PVL refers to paravalvular leakage, which was a significant problem with early TAVR devices.

155. Prior TAVR solutions such as Walther used a thick outer cloth. As a result, Walther had to use an 11 mm (33 French) delivery catheter for its cloth valve, 3 mm (9 French sizes), which is over the 8 mm maximum for endovascular delivery through the femoral artery. Ex. 1007 [Walther] 1121 (“The SAPIEN valves were deployed ... via the 33F Ascendra system”), 1125 (Table 4) (“Cloth valve (33F delivery)”). This 8 mm maximum is for people with healthy femoral arteries, not the diseased, narrowed arteries often present in patients requiring a TAVR. If a TAVR device has too large a profile, it is not possible to deliver it via a transfemoral route and this would make the device of little or no value..

156. A POSITA would appreciate that the '236's approach of using a valve assembly that was "free of an outer graft covering between the first portion of fibers and the outer frame," would allow for a narrow delivery profile, and avoid the problematic bunching that would occur when tightly crimping a valve with the Walther or Spenser II outer cloths. This was not considered to be an issue in Walther because it sought to take a "trans-apical approach, where tight crimping is not an issue." Ex. 1007 [Walther] 1126.

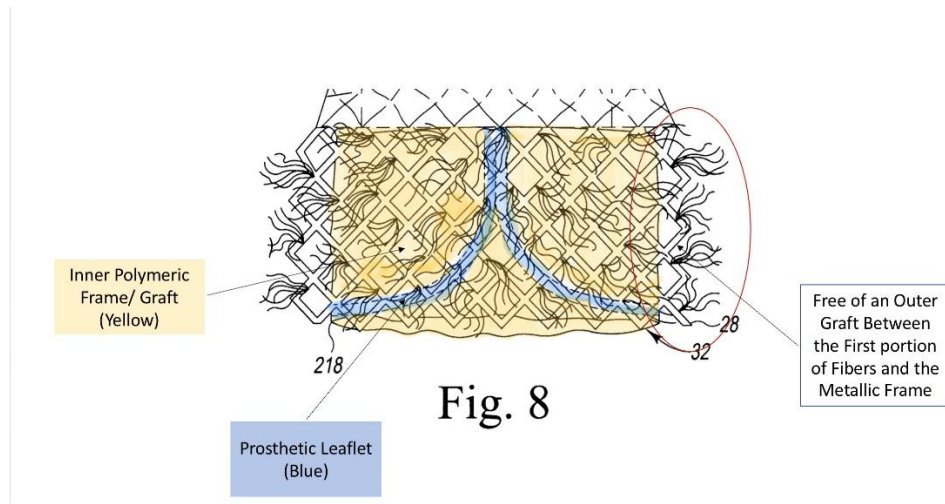
2. Additional Opinions

157. I have been informed that secondary considerations, such as unexpected results, are an important factor in determining obviousness. I have reviewed the specification of the '236 patent, and it describes many innovative concepts, which are in turn reflected in the claims.

158. While the claims of the '236 patent do not require "endovascular" delivery per se, the preamble recites a "transcatheter aortic valve assembly" which is limiting because it provides the prior antecedent basis for a subsequent limitation. The claimed limitations correspond to features that allow for a small crimp profile while addressing PVL.

159. **First**, the claimed inventions greatly reduce crimp by requiring that "the valve assembly" be "***free of an outer graft covering*** between the first portion of fibers and the outer frame." Removing the graft covering removed bulky

material and further prevented strut deformation, allowing for more uniform crimping. Ex. 1008 [Levi] 9:36-44. The absence of an outer graft covering is apparent in numerous figures, where the fibers and outer frame are visible without an intervening outer graft between them:



160. **Second**, to still prevent PVL, the claimed inventions require two portions of fibers that create two separate “sealing interface[s]” when “compressed” against the “native valve leaflets” and “the outer frame,” respectively. The patent illustrates these two portions of fibers in Figure 13.

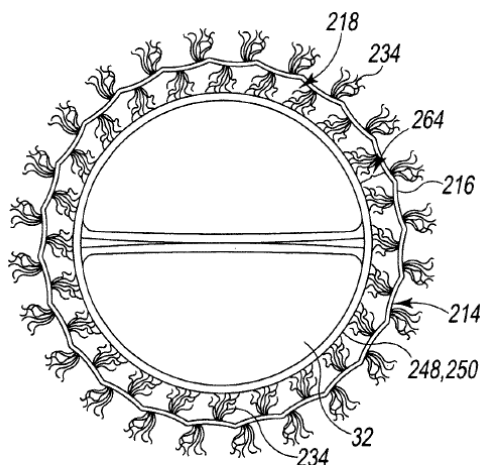
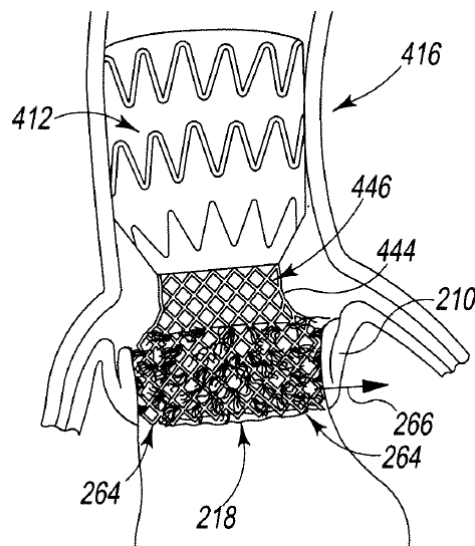


Fig. 13

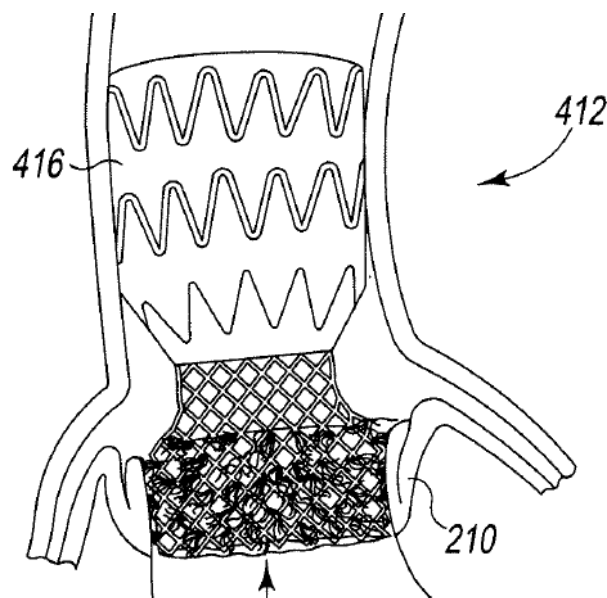
The fibers in the patent’s figures are sparsely distributed. See Figs. 8-9, 11-16, 20-22. Moreover, as is particularly clear in Figure 13 (but also present elsewhere), there are gaps and spaces between the fibers that extend to the frame. These gaps and spaces were, I believe, counterintuitive because a POSITA would have, at the time, favored a solid, non-porous, graft material to address PVL—like the ones seen in Walther, Spenser II, and Levi. See also Ex. 1003 [Buller-Decl.] ¶¶153 (POSITA “would have understood that the openings between the fibers must be small ... to form an effective sealing interface ... If the openings were too wide, blood may disadvantageously leak through the openings.”), 156. That a sparse distribution of fibers with significant gaps and spaces would be porous, at least until compressed within the body would form a seal is an unexpected result.

161. I understand that Petitioner contends Figure 13 reflects a 60F crimp profile because the inner frame is described as “unexpanded.” *Id.*, 14:11-15. This

162. Figure 21 shows how the device is aligned in the patient.



106



Id., Fig. 22. The '236 teaches that Figures 21 and 22 are transfemorally deliverable. *Id.*, 15:16-20, 17:14-18, *see also* Title, Abstract, 1:49-54, 5:44-46, Fig. 8. It also teaches the fibers address PVL when compressed inside the body. *See, e.g., id.*, 18:22-32, 19:41-45, 19:34-39, 14:56-64. I further note that neither Dr. Buller nor I had seen a distribution of fibers in the prior art like that consistently shown in the figures. *See* Ex. 2052, 167:10-12, 169:5-25. Again, it is counter-intuitive that a sparse distribution of fibers as taught could create a seal.

163. Figure 14 shows an axial view of how the valve assembly's expansion compresses the fibers to form "sealing interfaces," depicting the "second sealing interface against the outer frame."

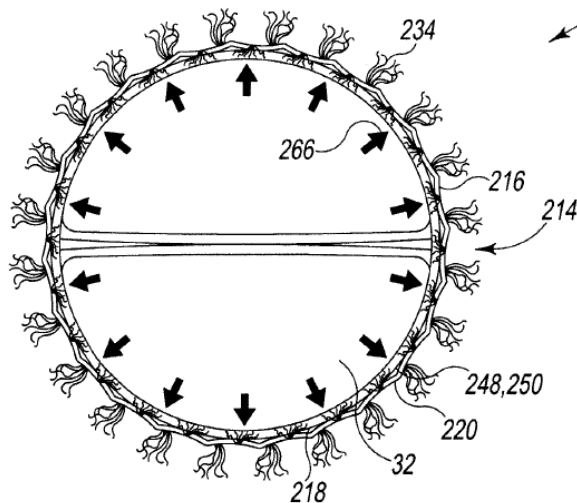


Fig. 14

164. **Third**, for the “first portion of fibers” to adequately “form a first sealing interface,” the fibers must “*extend radially outwardly of the outer frame.*” *Id.*, cl. 1; 12:43-47; 18:22-26. This generally loosely constructed outer seal has an increased surface area, which advantageously allows for increased area for blood thrombosis and tissue ingrowth, both of which address PVL. When deployed, the fibers are compressed to create a seal. These radially extending fibers are shown in numerous figures.

165. **Fourth**, the claims require that “the first portion of fibers and the second portion of fibers are in *overlapping radial alignment*” as shown, *e.g.*, in Figs. 13 and 14. *Id.*, cl. 1. Aligning these fibers aligns the seals and thus prevents blood leakage after the fibers have been compressed.

166. **Fifth**, the claims require “opening[s]” that “extend[] through a thickness” of both the first and second portions of “fibers.” *Id.*, cls. 3-4. These

“opening[s]” allow for the “fibers” to be distributed relatively sparsely, preventing the bunching, bulging, and tight-fitting seal which would otherwise frustrate crimping while still forming an adequate seal when “compressed.” This feature is demonstrated in the above figures, where the spacing between fibers allows the outer frame to be visible therethrough.

167. **Sixth**, the “opening[s]” through the “second portion of fibers” must “extend to the outer frame.” This feature allows for full crimping by removing the need for an “outer graft covering.”

168. This collection of limitations, thus, addresses a long-felt need by allowing for a TAVR with a narrow crimp profile that can be endovascularly delivered while still limiting PVL. It further does so in a novel manner and achieves unexpected results.

VII. CONCLUSION

169. Although my complete opinions are set forth above, for convenience I summarize several points of my opinions in conclusion. For the foregoing reasons, based on my expertise and experience and the record of this case that I have reviewed, it is my opinion that:

- The proposed combinations do not disclose or render obvious a “transcatheter aortic valve assembly” that “is free of an outer graft covering between the first portion of fibers and the outer frame.”

- The proposed combinations do not disclose or render obvious “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 ... wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment.”
- Grounds 4 and 5 do not disclose or render obvious “a first portion of fibers” that “extend radially outwardly.”
- The proposed combinations do not disclose or render obvious “opening[s]” “define[d]” by the “spacing formed between adjacent fibers” that “extend through a thickness” of the first and second portions of “fibers,” and that “extend[] to the outer frame” as required by claim 4.

170. I understand that my opinions discussed above support a legal conclusion that the claims are not obvious.

In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

I hereby declare that all statements made herein of my own knowledge are true and all statements made herein on information and belief were and are believed by me to be true, and that all statements herein were and are 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 and that any such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Dated: December 19, 2022

A handwritten signature in black ink that reads "Stephen Brecker". The signature is written in a cursive style and is positioned above a horizontal line.

Stephen J.D. Brecker, M.D.

EXHIBIT A

CURRICULUM VITAE

STEPHEN JON DAVID BRECKER

ADDRESS : St. George's Hospital, Blackshaw Road, London SW17 0QT
Telephone : +44-(0)20-8725-3556
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NATIONALITY : British
DATE OF BIRTH : 30th April 1960

GENERAL EDUCATION

1973-1978 University College School, London NW3
9 GCE 'O' Levels
3 GCE 'A' Levels & 1 GCE 'S' Level with Distinction

UNDERGRADUATE EDUCATION

1978-1984 St. Thomas' Hospital Medical School
University of London

QUALIFICATIONS

1981 BSc (Hons 2,i) Pharmacology and Basic Medical Sciences
1984 MB, BS with Distinction
1987 MRCP (UK)
1993 MD
1999 FESC
1999 FACC
2000 FRCP

M.D. THESIS Systolic and Diastolic Interactions in Ventricular Disease
University of London : 1993

APPOINTMENTS 1996 - Present
Consultant Cardiologist,
St. George's Hospital, London

2015 - 2021
Chief of Cardiology
St. George's University Hospitals NHS Foundation Trust
St. George's University of London

2016 - Present
Professor of Cardiology
St. George's, University of London

APPOINTMENTS

2005-2006 : Clinical Lead, South West London Cardiac Network
2005-2010 : Director of Cardiac Catheterisation Laboratories
2006-2010 : Care Group Lead - Cardiology
1998-2020 : Recognised Teacher of the University of London
2015-2021 : Chief of Cardiology Clinical Academic Group

HONOURS, AWARDS AND PRIZES

1980	Grainger Testimonial Prize in Pharmacology
1981	Medical Research Council BSc Scholarship
1982	Lord Riddell Surgical Prize - Proxime accessit
1983	Second Charles Box Medical Prize (Clinical Medicine)
1983	Gladstone, Stansfield, Stewart Memorial Bursary
1984	Distinction in Pathology (London Part IV MB,BS)
1990	British Heart Foundation Junior Research Fellowship
1991	E. Merck Travelling Scholarship
1992	1st Runner Up, Rhône-Poulenc Rorer / Junior Cardiac Club Travelling Scholarship - Investigators Awards
2000	South Thames Department of Postgraduate Medical & Dental Education, University of London Certificate in Teaching

PREVIOUS APPOINTMENTS

April 1994 - April 1996	Clinical Lecturer and Honorary Senior Registrar in Cardiology The London Chest Hospital, The Royal Hospitals NHS Trust, London.
April 1993 - April 1994	Waring Lecturer and Honorary Senior Registrar in Cardiology The Royal Brompton National Heart and Lung Hospital & The National Heart and Lung Institute, London.
October 1990 - April 1993	British Heart Foundation Junior Research Fellow, & Honorary Registrar in Cardiology, The Royal Brompton National Heart and Lung Hospital & The National Heart and Lung Institute, London.
May 1989 - October 1990	Registrar in Cardiology, The London Chest Hospital, London.
November 1988 - May 1989	Registrar in General Medicine and Cardiology, St. Thomas' Hospital, London.
November 1987 - October 1988	Registrar in General Medicine, Kingston Hospital, Surrey.
May 1987 - October 1987	Senior House Officer in Neurology, The National Hospital for Nervous Diseases, Queen Square, London.
August 1986 - February 1987	Senior House Officer in Cardiology, Brompton Hospital, London.
February 1986 - July 1986	Senior House Officer, Intensive Therapy Unit, St. Thomas's Hospital, London.
August 1985 - January 1986	Senior House Officer, Department of Renal Medicine and Immunology, Hammersmith Hospital and Royal Postgraduate Medical School, London.
February 1985 - July 1985	House Physician to The Medical Unit, St. Thomas's Hospital, London.
August 1984 - January 1985	House Surgeon, Kingston Hospital, Surrey.

COURSES ORGANISED

Annual Transoesophageal Echocardiography Course

1995 – 1996 **The London Chest Hospital, London**

1997 – 2016 **St. George's Hospital, London**

REVIEWER FOR JOURNALS

Circulation, Journal of the American College of Cardiology, Heart, European Heart Journal, Lancet, Nature Clinical Practice Cardiovascular Medicine, American Journal of Cardiology, EuroIntervention, European Heart Journal Cardiovascular Imaging, Clinical Cardiology, International Journal of Cardiology, Catheterization and Cardiovascular Interventions, Drug & Therapeutics Bulletin, European Journal of Cardiac Pacing and Electrophysiology, Journal of Cardiovascular Risk, Intensive Care Medicine and Thorax.

SCIENTIFIC SESSION ABSTRACT GRADER

European Society of Cardiology, American College of Cardiology, Transcatheter Cardiovascular Therapeutics, British Cardiovascular Society.

FELLOWSHIP & MEMBERSHIP OF SOCIETIES

Fellow of the Royal College of Physicians

Fellow of the European Society of Cardiology

Fellow of the American College of Cardiology

British Cardiovascular Society

British Cardiovascular Intervention Society

PATENT APPLICATIONS

25.09.13	Replacement Heart Valve	GB 2500432
25.09.13	Replacement Heart Valve	EP 2 641 570 A1
26.09.13	Replacement Heart Valve	US 2013/0253642 A1

AWARDED PATENTS

10.02.16	Percutaneous Guidewire	EP 2 396 067 B1
15.05.18	Percutaneous Guidewire	US 9 968 761 B2

GRANTS

01.06.16	MEDTRONIC RESEARCH FELLOW AWARD	£96000
01.06.16	MCS SMALL GRANTS AWARD	£5600
01.06.17	MCS SMALL GRANTS AWARD	£5600
01.06.18	MCS SMALL GRANTS AWARD	£5750

PUBLICATIONS

Books

A Timmis, **S Brecker**. *Diagnosis in Color. Cardiology*. London. Mosby-Wolfe. 1997.

S J Brecker, R H Anderson. *The Adult Heart*. London. Imperial College Press. 2000.

S J D Brecker. *Percutaneous Device Closure of the Atrial Septum*. Abingdon. Informa Healthcare. 2006.

S Brecker, M Rothman. *Clinical Guide to Primary Angioplasty*. London. Informa Healthcare. 2010

Videotape and accompanying book

S J Brecker, R H Anderson. *Echo-morphologic correlates: The adult heart*. London. Imperial College Press. 2000.

Book Chapters

S J D Brecker, P J Oldershaw. Echocardiography. In : A Martin, A J Camm (eds). *Geriatric Cardiology. Principles and Practice*. Chichester. John Wiley & Sons Ltd. 1994, 91-129.

S J D Brecker. Transoesophageal echocardiography. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 17-27.

S J D Brecker. Atrial septal defect. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 103-110.

S J D Brecker. Ventricular septal defect. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 111-117.

S J D Brecker. Atrial septal defect. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 52-53.

S J D Brecker. Eisenmenger complex. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 124-126.

S J D Brecker. Heart block. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 176-178.

S J D Brecker, M T Rothman. Implant complications and management. In : U Sigwart (ed). *Endoluminal Stenting*. London. W. B. Saunders Company Ltd. 1996, 296-305.

S J D Brecker, M T Rothman. 1997. The Cordis coronary stent. In : P W Serruys (ed). *Handbook of Coronary Stents*. London. Martin Dunitz Ltd. 1997, 63-69.

R Sharma, **S J Brecker**. Echocardiography. In : H Purcell, A Kalra (eds). *Cardiology*. Edinburgh. Elsevier Mosby Ltd. 2005, 51-57.

M Hickman, **S Brecker**. Tips and tricks of atrial septal defect closure. In : M Sabate (ed). *Percutaneous Cardiac Interventions. Tips and Tricks of New Techniques Beyond Stenting*. Toulouse. PCR Publishing. 2010, 157-164.

J-C Laborde, **S J D Brecker**. Implantation of the CoreValve aortic valve. In : J D Carroll, J G Webb (eds). *Manual of Adult Structural Heart Disease Interventions*. Philadelphia. Lippincott Williams & Wilkins. 2012, 267-285.

W H Gaasch, **S J D Brecker**, G S Aldea. Transcatheter aortic valve replacement. *UpToDate*. Wolters Kluwer Health 2012-4. www.uptodate.com.

P S Douglas, G S Bloomfield. **S J D Brecker (Ed)**. Imaging for transcatheter aortic valve replacement. *UpToDate*. Wolters Kluwer Health 2014-6. www.uptodate.com.

W H Gaasch, **S J D Brecker**, G S Aldea. Transcatheter aortic valve replacement: Outcomes and complications. *UpToDate*. Wolters Kluwer Health 2015. www.uptodate.com.

S J D Brecker, W H Gaasch, G S Aldea. Transcatheter aortic valve replacement: Indications and periprocedural management. *UpToDate*. Wolters Kluwer Health 2015. www.uptodate.com.

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S J D Brecker. Transcatheter aortic valve replacement: Periprocedural management. *UpToDate*. Wolters Kluwer Health 2016-8. www.uptodate.com.

S J D Brecker, G S Aldea. Choice of therapy for symptomatic severe aortic stenosis. *UpToDate*. Wolters Kluwer Health 2017-8. www.uptodate.com.

D Mohty, P A Pellikka, **S J D Brecker (ed)**. Management and prognosis of low gradient aortic stenosis. *UpToDate*. Wolters Kluwer Health 2017-2020. www.uptodate.com.

M Dalby, V Panoulas. **S J D Brecker (ed)**. Transcatheter aortic valve implantation : Complications. *UpToDate*. Wolters Kluwer Health 2017-2020. www.uptodate.com.

S Messé, **S J D Brecker**. Treatment of patent foramen ovale (PFO) for secondary stroke prevention. *UpToDate*. Wolters Kluwer Health 2018. www.uptodate.com.

J Leipsic, P Blanke, G S Bloomfield, P S Douglas. **S J D Brecker (ed)**. Imaging for transcatheter aortic valve replacement. *UpToDate*. Wolters Kluwer Health 2018-2020. www.uptodate.com.

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Peer Review Editorials and Reviews

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Annals of Medicine 1994; **26**:383-384.

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British Journal of Hospital Medicine 1996; **55**:415-418.

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P M Elliott, **S J D Brecker**, W J McKenna.

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European Heart Journal 1999; **20**:323-324.

S J D Brecker, J R Pepper, S J Eykyn.

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S J D Brecker.

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D Pellerin, **S J D Brecker**.

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European Heart Journal 2002; **23**:768-771.

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D Pellerin, **S Brecker**, C Veyrat.

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R Sharma, **S J Brecker**.

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S J D Brecker.

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N Kakouros, **S J D Brecker**.

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J-C Laborde, **S J D Brecker**, D Roy, M Jahangiri.
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N Moat, **S BreckerB**.
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F Nicholson, K L Clark, **S J D Brecker**, S A Smith.

A pharmacological method for measuring the penetration of topical mydriatic drugs in man.
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S J D Brecker, H H Gray, P J Oldershaw.

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S J D Brecker, C D Pusey.

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Journal of Neurology, Neurosurgery and Psychiatry 1988; **51**:309-311.

S J D Brecker, S J Eykyn.

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S J D Brecker, N J B Trepte.

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S J D Brecker.

Early aspirin in myocardial infarction.
Lancet 1990; **335**:923.

S J D Brecker, P Hurley, C D Johnson.

Painless presentation of ruptured oesophagus.
Gullet 1990; **1**:24-27.

S W Davies, **S J Brecker**, R N Stevenson.

Terodiline for treating detrusor instability in elderly people.
British Medical Journal 1991; **302**:1276.

S J D Brecker, H B Xiao, B B Stojnic, M Mbaissouroum, D G Gibson.

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B B Stojnic, **S J D Brecker**, H B Xiao, S M Helmy, M Mbaissouroum, D G Gibson.

Left ventricular filling characteristics in pulmonary hypertension: a new mode of ventricular interaction.
British Heart Journal 1992; **68**:16-20.

S J D Brecker, H B Xiao, M Mbaissouroum, D G Gibson.

Characteristics of presystolic flow in the superior vena cava: new thoughts on a forgotten sound.
British Heart Journal 1992; **68**:31-37.

B B Stojnic, **S J D Brecker**, H B Xiao, D G Gibson.
Jugular venous 'a' wave in pulmonary hypertension: new insights from a Doppler echocardiographic study.
British Heart Journal 1992; **68**:187-191.

H B Xiao, **S J D Brecker**, D G Gibson.
Effects of abnormal activation on the time course of the left ventricular pressure pulse in dilated cardiomyopathy.
British Heart Journal 1992; **68**:403-407.

S J D Brecker, H B Xiao, J Sparrow, D G Gibson.
Effects of dual-chamber pacing with short atrioventricular delay in dilated cardiomyopathy.
Lancet 1992; **340**:1308-1312.

S J D Brecker, C H Lee, D G Gibson.
Relationship of left ventricular isovolumic relaxation time and incoordination to transmitral Doppler filling patterns.
British Heart Journal 1992; **68**:567-573.

R N Stevenson, R H Roberts, **S J Brecker**, P J Timmins, P D Wilkinson, R Balcon.
Comparison of digital angiograms with conventional cineangiograms for the quantitation of coronary artery stenosis before and after angioplasty.
Coronary Artery Disease 1992; **3**:1183-1188.

S J D Brecker, H B Xiao, M Mbaissouroum, D G Gibson.
Effects of intravenous milrinone on left ventricular function in ischemic and idiopathic dilated cardiomyopathy.
The American Journal of Cardiology 1993; **71**:203-209.

H B Xiao, **S J D Brecker**, D G Gibson.
Differing effects of right ventricular pacing and left bundle branch block on left ventricular function.
British Heart Journal 1993; **69**:166-173.

M Mbaissouroum, C O'Sullivan, **S J Brecker**, H B Xiao, D G Gibson.
Shortened filling time in dilated cardiomyopathy: additional effects on heart rate variability.
British Heart Journal 1993; **69**:327-331.

M Y Henein, H B Xiao, **S J D Brecker**, D G Gibson.
Bernheim 'a' wave: obstructed right ventricular inflow or atrial cross talk ?
British Heart Journal 1993; **69**:409-413.

P Bogaty, **S J Brecker**, S E White, R N Stevenson, H El-Tamimi, R Balcon, A Maseri.
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Circulation 1993; **87**:1938-1946.

A G Heriot, **S J Brecker**, D J Coltart.
Delay in presentation after myocardial infarction.
Journal of the Royal Society of Medicine 1993; **86**:642-644.

S J D Brecker, R N Stevenson, R Roberts, S Uthayakumar, A D Timmis, R Balcon.
Acute myocardial infarction in patients with normal coronary arteries.
British Medical Journal 1993; **307**:1255-1256.

R H Stables, **S J Brecker**.
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New England Journal of Medicine 1994; **330**:1688-1689.

H B Xiao, **S J D Brecker**, D G Gibson.
Relative effects of left ventricular mass and conduction disturbance on activation in patients with pathological left ventricular hypertrophy.
British Heart Journal 1994; **71**:548-553.

S J D Brecker, J S R Gibbs, K M Fox, M H Yacoub, D G Gibson.
Comparison of Doppler derived haemodynamic variables and simultaneous high fidelity pressure measurements in severe pulmonary hypertension.
British Heart Journal 1994; **72**:384-389.

M Petrou, K Wong, M Albertucci, **S J Brecker**, M H Yacoub.
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Circulation 1994; **90**[part 2]:II-198-II-204.

X Y Jin, J R Pepper, **S J Brecker**, J A Carey, D G Gibson.
Early changes in left ventricular function after aortic valve replacement for isolated aortic stenosis.
American Journal of Cardiology 1994; **74**:1142-1146.

C J Garratt, M J Griffith, G Young, N Curzen, **S Brecker**, A F Rickards, A J Camm.
Value of physical signs in the diagnosis of ventricular tachycardia.
Circulation 1994; **90**:3103-3107.

S J D Brecker, X Y Jin, M H Yacoub.
Anatomical definition of aortic root abscesses by transesophageal echocardiography: Planning a surgical strategy using homograft valves.
Clinical Cardiology 1995; **18**:353-359.

D R Holdright, **S Brecker**, M Shepherd.
Ruptured aneurysm of the aortic sinus of Valsalva - difficulties in establishing the diagnosis.
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S P Karwatowski, **S J D Brecker**, G Z Yang, D N Firmin, M St.John Sutton, S R Underwood.
Mitral valve flow measured with cine MR velocity mapping in patients with ischemic heart disease: comparison with Doppler echocardiography.
Journal of Magnetic Resonance Imaging 1995; **5**:89-92.

S P Karwatowski, **S J D Brecker**, G Z Yang, D N Firmin, M St.John Sutton, S R Underwood.
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and left ventricular filling measured by Doppler echocardiography.
European Heart Journal 1996; **17**:795-802.

T W Koh, **S J D Brecker**, C A Layton.
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case report and review of the literature.
International Journal of Cardiology 1996; **55**:193-197.

C G Missouris, D Fluck, **S Brecker**.
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Heart 1999; **81**:270.

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assessment of left ventricular function based on ventricular dimensions and intracardiac pressure
measurements. In : A Murray, R Arzbaechar (eds). *Computers in Cardiology*. 1999;**26**:387-391.

P M Elliott, **S J Brecker**, W J McKenna.
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in patients with hypertrophic cardiomyopathy.
Heart 2000; **83**:e7.

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cardiomyopathy. A comparison of clinical, haemodynamic and exercise outcomes.
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function: A hemodynamic study.
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I F Purcell, **S J Brecker**, D Ward,
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EXHIBIT B

Professor Stephen Brecker : Patent Expert Witness

2009 AGA v Occlutech UK – Trial

2012 Edwards v CoreValve UK – Advice & Statement only

2014 AGA v Occlutech UK - Trial

2018 Boston v Edwards USA – IPR & Trial

2018 Abbott v Edwards UK – Advice & Statement only

2020 Edwards v Meril UK - Trial

2020 Medtronic v Teleflex USA – IPR

2021 Medtronic v Teleflex USA – IPR

2022 Aortic Innovations v Edwards USA IPR & Litigation & Patent Application

2022 White Swell v Abiomed USA - IPR