

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 IPR2023-01325
Patent 11,491,033

EXHIBIT 2002

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. 11,491,033 (“the ’033 patent”) in IPR2023-01325. 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 \$800 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 Mayo Clinic Healthcare London and at St. George’s University

Hospitals in London, U.K. I am 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 fifteen 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 Mayo Clinic Healthcare London and at St. George's University Hospitals, London.

6. I have proctored over 600 TAVR procedures in which I assist and teach other physicians how to perform TAVR. I have been 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 1,500 percutaneous TAVR procedures since 2007.

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 in the last five years 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. 11,491,033 (Ex. 1001) (“the ’033 patent” or “’033”);
- ii. The prosecution history of the ’033 Patent (Ex. 1002);

- iii. The Declaration signed by Nigel P. Buller, M.D. in IPR2023-01325 (Ex. 1003) (the “Buller Declaration”);
- iv. The Petition by Edwards in IPR2023-01325;
- v. U.S. Patent No. 9,393,110 B2 to Levi et al. (“Levi”) (Ex. 1008);
- vi. U.S. Patent No. 7,510,575 to Spenser et al. (“Spenser”) (Ex. 1010);
- vii. WO 2006/005015 A2 to Spenser et al. (“Spenser II”) (Ex. 1011);
- viii. U.S. Patent Pub. No. 2002/0151958 to Chuter (“Chuter”) (Ex. 1116);
- ix. U.S. Provisional Application No. 61/567,458 (Ex. 1005);
- x. U.S. Provisional Application No. 61/723,446 (Ex. 1006);
- xi. 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);
- xii. U.S. Patent No. 3,365,728 to Edwards et al. (Ex. 1013);
- xiii. U.S. Patent No. 5,411,552 to Andersen et al. (Ex. 1014);
- xiv. U.S. Patent Pub. No. 2003/0153974 to Spenser et al. (Ex. 1015);
- xv. 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);

- xvi. PCT Publication No. WO 98/29057 to Letac et al. (Ex. 1018);
- xvii. U.S. Patent No. 6,893,460 B2 to Spenser et al. (Ex. 1019);
- xviii. 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);
- xix. 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);
- xx. Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis*, 1006 Circulation 3006-3008 (December 10, 2002) (Ex. 1025);
- xxi. U.S. Patent No. 7,393,360 to Spenser et al. (Ex. 1026);
- xxii. 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);
- xxiii. 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);
- xxiv. Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems*, Catheterization and Cardiovascular Interventions, 75:295-300 (2010) (Ex. 1036);
- xxv. U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al. (Ex. 1037);
- xxvi. U.S. Patent No. 7,585,321 B2 to Cribier et al. (“Cribier ’321”) (Ex. 1045);
- xxvii. 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);
- xxviii. Excerpts from the prosecution history of U.S. Patent No. 10,792,172 (Ex. 1049);
- xxix. Complaint from Aortic Innovations LLC v. Edwards Lifesciences Corp., 1-21-cv-01377, District of Delaware (Filed Sept. 28, 2021) (Ex. 1050);
- xxx. U.S. Patent No. 6,730,118 B2 to Spenser et al. (Ex. 1051);
- xxxi. PCT Publication No. WO 2006/124649 A3 to Nguyen et al. (Ex. 1052);

- xxxii. U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh (Ex. 1053);
- xxxiii. U.S. Patent Pub. No. 2011/0098802 to Braidó et al. (Ex. 1054);
- xxxiv. U.S. Patent No. 7, 524,331 B2 to Birdsall (Ex. 1057);
- xxxv. Deposition Transcript of Stephen Brecker from August 30, 2022 (Ex. 1072);
- xxxvi. Deposition Transcript of Stephen Brecker from August 31, 2022 (Ex. 1073)
- xxxvii. U.S. Patent No. 7,921,678 to Norris et al. (“Norris”) (Ex. 1074)
- xxxviii. Estridge, Trudy & Dale Feldman, Quantification of Vascular Ingrowth into Dacron® Velour, 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”) (Ex. 1106)
- xxxix. Hall, William C. et al., Velour Fabrics Applied to Medicine, 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”) (Ex. 1107);
- xl. Jonas, Richard A. et al., Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments, 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”) (Ex. 1108);
- xli. Ko, Frank K., Fabrics, Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”) (Ex. 1109);

- xlii. Pourdeyehimi, B. & Text, C., A Review of Structural and Material Properties of Vascular Grafts, 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyehimi”) (Ex. 1110);
- xliii. Scott, Steward M. et al., A Collogen Coated Vascular Prosthesis, 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”) (Ex. 1111);
- xliv. Stegmann, Th et al., Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis, 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”) (Ex. 1112);
- xlvi. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2021-01527, Final Written Decision (“’172 FWD”) (Ex. 1117);
- xlvi. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2021-01584, Final Written Decision (“’011 FWD”) (Ex. 1118);
- xlvi. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2022-00193, Final Written Decision (“’538 FWD”) (Ex. 1119);
- xlvi. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2022-00034, Final Written Decision (“’846 FWD”) (Ex. 1120);
- xlix. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2022-00549, Institution Decision from (“’735 Institution Decision”) (Ex. 1121);

- l. Aortic Innovations LLC v. Edwards Lifesciences Corp., Case No. 1-23-CV-00158 (JPM), Dkt. 13, Second Amended Complaint (Apr. 10, 2023) (Ex. 1122);
- li. Aortic Innovations LLC’s Disclosure of Asserted Claims and Infringement Contentions, C.A. No. 1-23--CV-00158 (JPM) (“PO Infringement Contentions”) (Ex. 1123);
- lii. Edwards Lifesciences Corp. v. Aortic Innovations, LLC, IPR2021-01584 Patent Owner’s Preliminary Response (“’011 POPR”) (Ex. 1124);
- liii. U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment (Ex. 1125);
- liv. U.S. Pat. No. 4,739,762 (Ex. 1126);
- lv. U.S. Pat. No. 5,102,417 (Ex. 1127);
- lvi. Deposition Transcript of Dr. Nigel Buller from November 11, 2012 (Ex. 1128);
- lvii. C. C. Chu, Understanding Implantable Textiles, Advanced Textiles Source (May 21, 2018) (“Chu”) (Ex. 1129);
- lviii. Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”) (Ex. 1136);

lix. The exhibits and other documents cited herein.

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., 17-18. For the purposes of this declaration I will use this date as the time of the invention of the ’033 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 ’033 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 '033 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.] ¶49.

20. For the purposes of this Declaration only, I accept Dr. Buller's proposed qualifications of a POSITA. I reserve the right to revisit the issue should the Petition be instituted.

21. 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

22. When considering the '033 patent and stating my opinions, I rely on the following legal standards as described to me by the attorneys for Aortic Innovations.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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

30. I understand that claims 1-2 and 4-6 of the '033 patent are challenged by Petitioner with the following grounds:

Ground	Claims Challenged	Asserted Pre-AIA 35 U.S.C. §	Asserted References
1	1-2, 4-6	103	Spenser I + Spenser II
2	1-2, 4-6	103	Spenser I + Levi
3	1-2, 4-6	103	Spenser I + Chuter
4	1-2, 4-6	103	Levi + Chuter
5	1-2, 4-6	103	Spenser I + Chuter + Spenser II
6	1-2, 4-6	103	Levi + Chuter + Spenser II

Pet., 18.

VI. OPINIONS

A. Petitioner Fails To Prove That Its Spenser II Combinations Disclose Or Render Obvious The “Spacings” Limitations (Grounds 1-2, All Claims).

31. The claims require:

Claim 1: “the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state, wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state:

...compresses the plurality of fibers relative to the spacings thereby reducing the spacings; and expands the polymer covering radially outwardly, wherein the compression of the plurality of fibers relative to

the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.”

Ex. 1001 [’033] cl. 1.

32. I understand that Petitioner refers to these limitations as the “spacings,” and “compression creates paravalvular seal” limitations. *See* Pet., 46, 59. For the purposes of this Declaration, I will similarly refer to these limitations as the “spacings” limitations.

1. Prosecution History.

33. I note that Petitioner’s Spenser II grounds (Grounds 1-2) rely upon Spenser II’s compressible material as the claimed “sealing assembly,” and the fibers extending outwardly from what Petitioner describes as the compressible material’s “base layer” as the “plurality of fibers.” *See* Pet., 29-33; Ex. 2136 [-01151-Pet.] 66.

34. I note that the ’033 is a continuation of U.S. Patent No. 11,337,834 (“’834”). *See* Ex. 1001 [’033]. The ’033 and the ’834 share the same specification and drawings, and both require “spacings.” *Compare id.*, cl. 1 with Ex. 2143 [’834] cls. 2, 17-18. I further observe that, in prosecution of the ’834, the Applicant expressly distinguished Spenser II’s compressible material as lacking “spacings.” Ex. 2140 [’834-FH] 1001. In my opinion, the Applicant’s statements

distinguishing Spenser II as lacking “spacings” in the ’834’s prosecution apply equally to the ’033’s “spacings” for the reasons discussed below.

35. I observe that, in prosecution of the ’834, the Applicant distinguished both Spenser II’s Fig. 22 and Walther (per Dr. Buller, a “real-world embodiment” of Fig. 22), as not disclosing “spacings”:

Compare [the claimed spacings] to a very ***tightly knitted outer seal*** made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, ***or WIPO Publication 2006005015 A2 to Spenser [i.e., Spenser II], with reference to Figure 22, of record in the IDS dated July 11, 2021), there the lack of “spacings” between some fibers*** would not allow for the compression of the outwardly extending fibers.

Ex. 2140 [’834-FH] 1001.

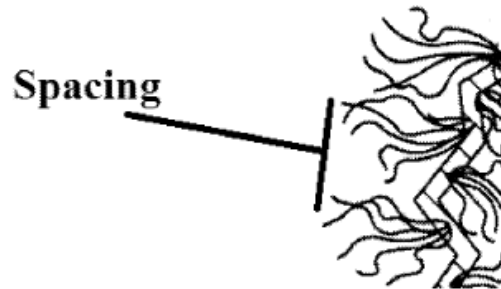
36. Notably, I understand that Petitioner’s district court expert, Dr. Brookstein, testified that the Applicant “argued that the collagen fibers in the Asserted Patents ***were distinguishable from the prior art because the prior art (including Walther and Spenser II)***” due to the “lack of ‘spacings.’” Ex. 2141 [Brookstein-Decl.] ¶35 (quoting Ex. 2140 [’834-FH] 1001). I further note that Dr. Brookstein testified that the Applicant “argued during prosecution” that the ’033’s claims “do not include cloths like those described in Walther and Spenser II.” ¶33; *id.*, ¶40 (’033’s claims do not “cover” outer coverings “described in Walther and Spenser II.”). I agree that the Applicant distinguished the outer coverings

disclosed by Spenser II and Walther as lacking “spacings,” and that neither of these coverings are covered by the ’033’s claims.¹

37. The Applicant’s statements distinguishing Spenser II’s compressible material as lacking “spacings” were, in my opinion, correct. The Applicant cited Figs. 11 and 12 as exemplifying the claimed “spacings,” and explained that “spacings” are “not shown in the prior art” of record:

Applicant submits that FIG. 12 of the Application as filed illustrates this spacing. An annotated version is shown below:

¹ I disagree, however, the Applicant disclaimed **all** “spacings between fibers that are present in a ‘cloth,’ ‘sleeve,’ ‘graft,’ or ‘graft covering’” (Ex. 2140 [Brookstein-Decl.] ¶33), and that the claims do not cover **any** “distance” between fibers “form[ing] a sleeve, graft covering, or cloth” (*id.*, ¶41). The Applicant clearly disclaimed tightly constructed outer seals, such as Spenser II’s dense, non-porous graft. Ex. 2140 [’834-FH] 1001; Ex. 1002 [Pros.-Hist.] 29-30. The Applicant did not, however, disclaim all sleeves, grafts, or cloths in my opinion. A loosely woven/knitted cloth with spacings extending through its thickness allowing fluid to pass therethrough in an undeployed state, for example, would satisfy the claims in my opinion.



And with further reference to annotated FIG. 11:

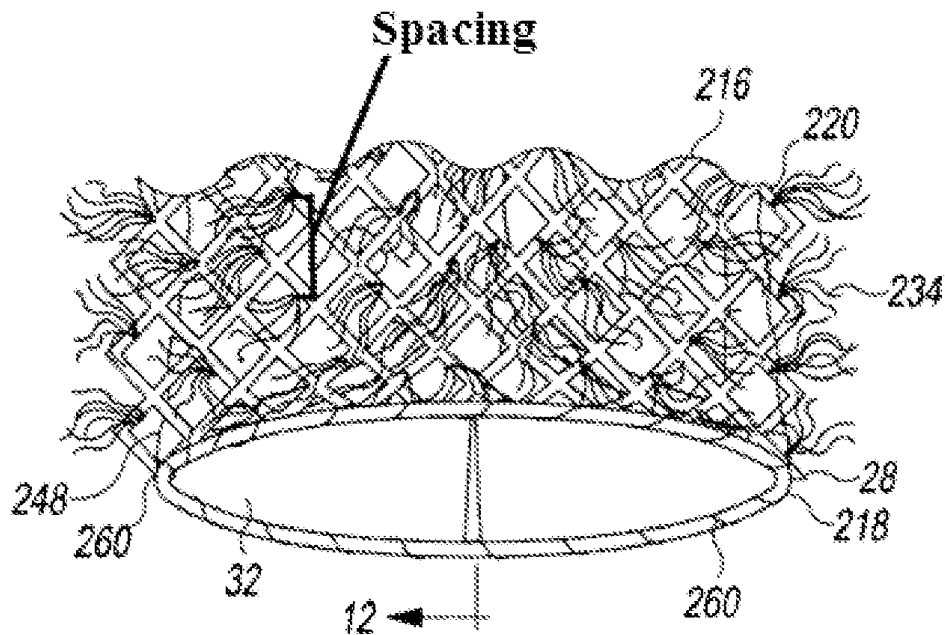


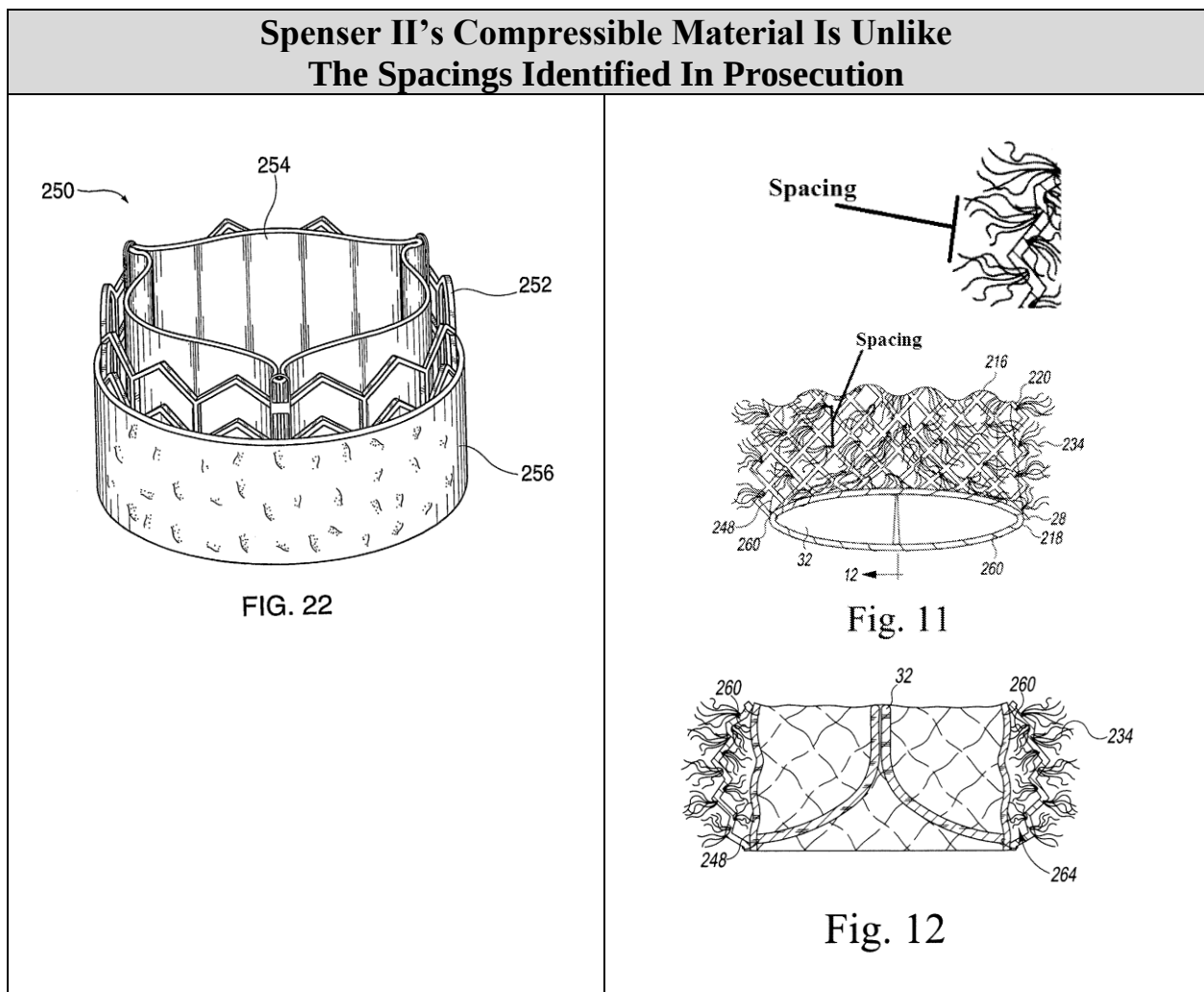
Fig. 11

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

Ex. 2140 [’834-FH] 1001-2.

38. I note that after the claims were amended to require “spacings” and the Applicant’s above arguments, the Examiner allowed the ’834’s claims and expressly identified the “spacings” limitations as **“not [being] disclose[d] or render[ed] obvious”** by the prior art of record (including Spenser II, Spenser I, and Levi) in the Examiner’s Reasons for Allowance. Ex. 2140 [’834-FH] 850, 995-1002. I agree with the Examiner’s analysis.

39. In my opinion, Spenser II’s compressible material looks nothing like the “spacings” identified in prosecution:



40. And, as Petitioner’s litigation expert recognized, the Applicant “**repeatedly** distinguished the claimed ‘spacing(s)’ from spacings between fibers that are present in ... [the] materials disclosed in Walther and Spenser II.” Ex. 2141 [Brookstein-Decl.] ¶33, ¶35 (“Aortic Innovations argued that the collagen fibers in the Asserted Patents **were distinguishable from the prior art ... (including Walther and Spenser II)**” due to the “lack of ‘spacings’”) (quoting Ex. 2140 [’834-FH] 1001) (quoting Ex. 2140 [’834-FH] 1001). In accord, the Board has found that Spenser II’s compressible material “corresponds to an outer graft covering.” Ex. 2124 [-00556FWD] 38; Ex. 1120 [-00034FWD] 48 (same). I further note that the Board credited my testimony distinguishing “the gaps and spaces between the fibers” shown in the ’033’s Fig. 13 with a “solid, non-porous, graft material” as “seen in ... Spenser II.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Breckner-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar).

41. Thus, in my opinion, the Applicant rightly distinguished Spenser II’s compressible material as not disclosing or rendering obvious “spacings.”

42. The Applicant’s statements distinguishing Spenser II, and particularly Figure 22, as lacking “spacings” in the ’834’s prosecution also apply to the ’033 in my opinion.

43. The ’033’s claims require “spacings” which “extend[] through a thickness” of a “sealing assembly,” that includes a “plurality of [] fibers that

extend away from the frame for providing sealing against paravalvular leakage.” Ex. 1001 [’033] cl. 1. These “spacings” “allow fluid to pass” through the “sealing assembly” when the valve is in “an undeployed state.” *Id.* When the valve is deployed and expanded, the extending fibers are “compresse[d] ... relative to the spacings.” *Id.* This compression “relative to the spacings” works “cooperatively” with the expansion of the “polymer covering” to “create a paravalvular seal ... by reducing the spaces in the sealing assembly.” *Id.*

44. The ’834 similarly requires a “spacing” that extends through one or two pluralities of fibers and either “to the frame” or “through the ... frame.” Ex. 2143 [’834] cls. 2, 17-18. Also similar to the ’033, the ’834’s claims further require that when the valve expands, the extending fibers are “compresse[d] ... relative to the spacing to create a seal thereabout.” *Id.*, cls. 17-18. Notably, the ’033 and its parent share the same specification and figures. *Compare* Ex. 1001 [’033] *with* Ex. 2143 [’834]. Accordingly, POSITAs reviewing the ’033 and the ’834 would regard their respective “spacings” limitations, requiring spacings into which extending fibers are compressed when the valve is expanded on deployment to facilitate the formation of a paravalvular seal, as pertaining to this same subject matter.

45. I note that Petitioner’s litigation expert, Dr. Brookstein declared that “particularly in view of Aortic Innovations’ arguments during prosecution,” the

'033's "spacings" which "allow fluid to pass" through the "sealing assembly" "would not have led a POSA to understand that the claims cover" the graft coverings "described in Walther and Spenser II." Ex. 2141 [Brookstein-Decl.] ¶40. And, notably, the Board credited my testimony describing Spenser II's outer covering as a "solid, non-porous graft material." Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). Thus, there does not seem to be any dispute that the statements in the prosecution of the '834 apply equally to the '033.

46. The Applicant's parallel statements distinguishing Spenser II's "real-world embodiment" Walther in the '033's prosecution as lacking "spacings" further confirms, in my opinion, that these statements also apply to the '033.

47. As in the '834's prosecution, the Applicant identified "spacings" as illustrated in the '033's Fig. 11, as annotated below:

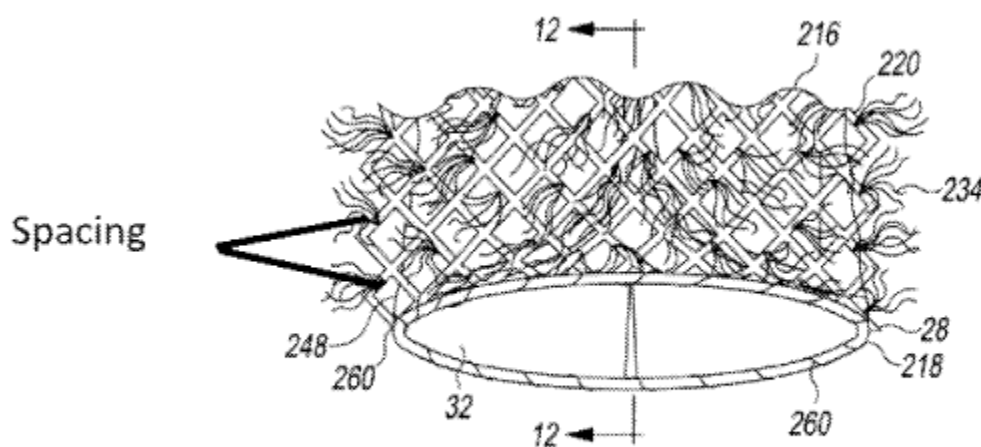


Fig. 11

Ex. 1002 [Pros.-Hist.] 29; Ex. 2140 ['834-FH] 1001-2.

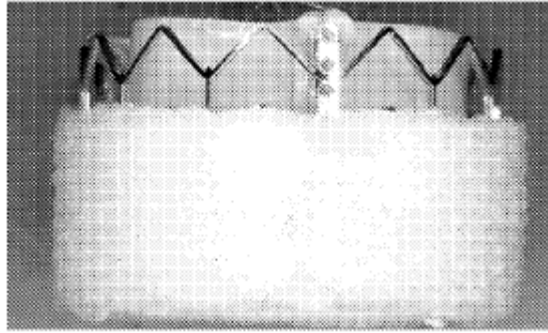
48. I note that, as with the '834, the '033's claims were allowed once they were amended to require "spacings." Ex. 1002 [Pros.-Hist.] 84-85, 96, 46; Ex. 2140 ['834-FH] 850, 995-1002. Notably, after the Examiner asked the Applicant to identify the most relevant prior art, the Applicant specifically pointed to each of Walther, Spenser II, Spenser I and Levi. Ex. 1002 [Pros.-Hist.] 93, 86.

49. I observe that after the claims were allowed, the Applicant submitted an IDS including the Institution Decision from IPR2022-00556 ("-00556") concerning the related '236 patent (Ex. 1002 [Pros.-Hist.] 34, 40) with remarks, addressing Petitioner's argument in the -00556 that the same Spenser II combinations relied upon here would satisfy the '236's "openings" limitations (which the Applicant identified as "parallel" to the '033's "spacings"). Ex. 1002 [Pros.-Hist.] 28-30; IPR2022-00556, Paper 1 (Petition), 52-55, 80-82, 102-104.

50. The Applicant's remarks in the '033's prosecution distinguished Spenser II's "real-world embodiment" Walther as lacking "spacings," paralleling the statements made in the '834's prosecution:

The specification illustrates spacing between fibers that are an intentionally placed spacing, *i.e.*, not just the spacing that may be inherent between radially extending fibers such as those that appear to be found in the Walther reference. Applicant notes that the claims recite spacings extending through a thickness of the sealing assembly

that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state ... ***These claim limitations are clearly not shown in the Walther reference***, an image of which is reproduced below:



[It] does not appear that any such spacings are visible or disclosed in the Walther reference.

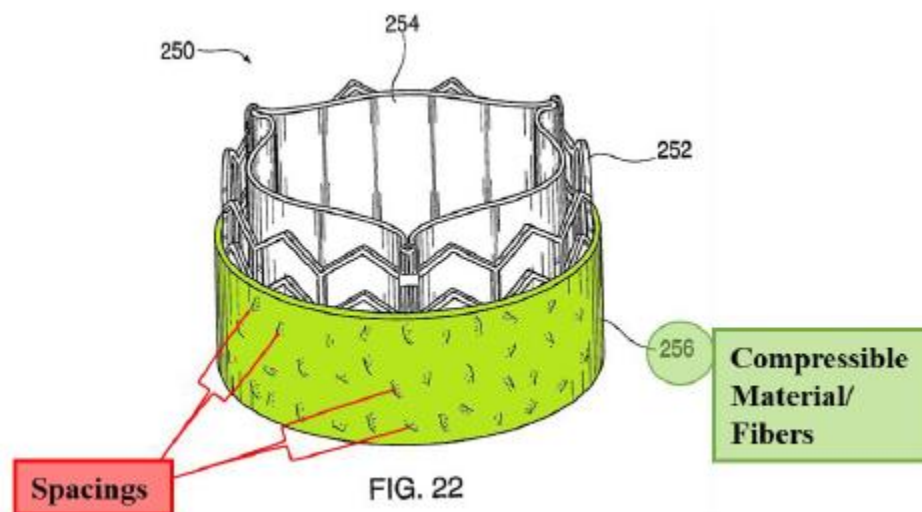
Ex. 1002 [Pros.-Hist.] 29-30; Ex. 1007 [Walther] Fig. 1; Ex. 2052 [Buller-00034-Depo.] 104:17-105:7 (Walther is a “real-world embodiment” of Spenser II); see also Ex. 2140 [’834-FH] 1001-2. I further note that the Applicant’s remarks further distinguished the ’033’s “spacings” as not those which are “inherent between radially extending fibers.” Ex. 1002 [Pros.-Hist.] 29. I observe that the Applicant further explained that the claimed “spacings” were “not shown in the references of record,” which notably included Walther, Spenser II, and Levi. See Ex. 1002 [Pros.-Hist.] 30, 135-138. Indeed, the Examiner’s finding was “confirmed” in a Corrected Notice of Allowability issued in response to the Applicant’s remarks distinguishing Walther and “the references of record” as not showing “spacings.” Ex. 1002 [Pros.-Hist.] 28-30, 15. This confirmation further

followed the Applicant identifying, per the Examiner's request, Walther, Spenser II, and Levi as among the most relevant references of record. Ex. 1002 [Pros.-Hist.] 86, 93. Therefore, the Examiner appears to have agreed with the Applicant that, as with the '834, the "references of record," including Walther and Spenser II, did not disclose or render obvious the '033's "spacings."

51. Thus, the prosecution history confirms that Petitioner's Spenser II combinations fail to satisfy the "spacings" limitations in my opinion.

2. Petitioner Fails To Show That Spenser II Expressly Discloses "Spacings Extending Through A Thickness Of The Sealing Assembly."

52. I understand that Petitioner contends that Spenser II's FIG. 22 "illustrates 'spacings' between the [extending] fibers" which "extend 'through a thickness of the sealing assembly,' where the 'thickness' is at least the length of the fibers":



Pet., 46 (Petitioner's annotation). I disagree that Spenser II's Fig. 22 "illustrates"

the claimed “spacings extending through a thickness of the sealing assembly.”

53. As discussed, the Applicant distinguished Spenser II’s Fig. 22 as lacking “spacings” in the prosecution of the ’033’s parent, the ’834. See Section VI.A.1, *supra*. Again, these statements also apply to the ’033’s “spacings.” While Petitioner here contends that Spenser II’s Fig. 22 illustrates “spacings,” this is, in my opinion, inconsistent with the testimony of its district court expert, Dr. Brookstein. As discussed, Dr. Brookstein declared that “Aortic Innovations argued that the collagen fibers in the Asserted Patents *were distinguishable from the prior art ... (including Walther and Spenser II)*” due to the “lack of ‘spacings.’” Ex. 2141 [Brookstein-Decl.] ¶35 (quoting Ex. 2140 [’834-FH] 1001). Dr. Brookstein further declared that the “*Aortic Innovations clearly argued during prosecution*” that the “cloths ... *described in Walther and Spenser II ... were not covered*” by the ’033’s claims. *Id.*, ¶40, ¶33 (similar). Thus, while Petitioner here contends that Spenser II’s Fig. 22 “illustrates” the claimed “spacings,” its district court expert does not dispute that the Applicant distinguished Spenser II and Fig. 22 as lacking “spacings.” I agree with Dr. Brookstein that Spenser II was distinguished as not disclosing or rendering obvious the ’033’s “spacings.”

54. Moreover, to the extent that Petitioner is arguing that the required “spacings,” as allegedly illustrated in Spenser II’s FIG. 22, may extend only the distance between the tips of Spenser II’s extending fibers and the outer surface of

Spenser II's compressible material's base layer, this appears, in my opinion, inconsistent with its position in IPR2023-01232. There, Petitioner contended that Spenser II "discloses" that its extending fibers are "in contact with the frame" when the valve is in either the "radially compressed" or "radially expanded" orientation. Ex. 2144 [-01232-Pet.] 44, 47.

55. Petitioner's position in IPR2023-01232, in my opinion, indicates an understanding that the spacings would extend "the length" of Spenser II's fibers, through the compressible material's base layer to the frame. But, no such "spacings" are disclosed by Spenser II in my opinion. Rather, as the Board found, Spenser II's compressible material "corresponds to an outer graft covering," which "covers" both the frame's struts and the interstices therebetween. Ex. 2124 [-556-FWD] 29-30; Ex. 1120 [-00034-FWD] 48. Indeed, the Board further credited my testimony describing Spenser II's compressible material as a "***solid, non-porous, graft material.***" Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar); *see also* Ex. 2128 [Buller-556-Decl.] ¶60 (exemplary graft covering is a "low-porosity woven fabric.") (citing Ex. 2144 [Leonhardt] 3:53-55). Nothing about such a non-porous graft, however, suggests "spacings extending through a thickness of the sealing assembly" in my opinion.

56. Thus, Petitioner fails to show that Spenser II expressly discloses “spacings extending through a thickness of the sealing assembly” in my opinion.

3. Petitioner Fails To Show That Spenser II Discloses Or Renders Obvious “Spacings ... That Allow Fluid To Pass []Through” The “Sealing Assembly.”

57. Even if we assumed that “spacings extending through a thickness” of Spenser II’s compressible material were present, Petitioner further fails to show, in my opinion, that those “spacings” would “**allow fluid to pass []through**” the “sealing assembly” when the “prosthetic heart valve assembly is in an undeployed state.” Ex. 1001 [’033] cl. 1.

a. *Petitioner’s Inherency Arguments Fail.*

I note that Petitioner and Dr. Buller do not argue that there is any express disclosure of “spacings ... that allow fluid to pass []through” the “sealing assembly” when the valve is “undeployed.” Pet., 47-49. Instead, they contend that POSITAs allegedly “**would have understood**” that Spenser II discloses this limitation because the compressible material allegedly “**must have spacings** extending through a thickness of the material” which “also mean[s] that the material is porous and would permit the flow of fluid therethrough.” Pet., 47-49 (“**POSITAs would have understood** that fluid can pass through Spenser II’s compressible material when the prosthetic heart valve assembly is in an undeployed state.”). I note that Petitioner further contends that “POSITAs **would**

have understood that fluid can pass through Spenser II’s compressible material when the prosthetic heart valve assembly is in an undeployed state” to “compress,” “fill[] the gaps” between the frame and native tissue, “encourage the coagulation of blood” and “promote tissue ingrowth.” Pet., 47-49 (“**POSITAs would have understood** that promoting blood coagulation and tissue ingrowth into the compressible material would have only been possible, and necessary, if the material were porous and did not, on its own, prevent the flow of fluid therethrough”). I further note that Petitioner also contends that “**POSITAs would have understood** that the spacings necessary to promote tissue ingrowth into a fibrous material were in the range of 40-100 μ m, far larger than the size of a spacing necessary to allow passage of fluid therethrough.” *Id.*, 48-49 (citing Ex. 1003 [Buller-Decl.] ¶156; Ex. 1106 [Estridge] 158).

58. I have been informed by counsel and understand that inherency analysis applies to arguments about what a POSITA supposedly “would have understood” are not about what Spenser II expressly discloses. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1066 (Fed. Cir. 2017). I have also been informed and understand that demonstrating obviousness by inherency is a “high standard” and requires a showing that the limitation “**necessarily** must be present.” *Par Pharm., Inc. v. Twi Pharms., Inc.*, 773 F.3d 1186, 1195-6 (Fed. Cir. 2014). In my opinion, Petitioner and Dr. Buller have not shown that “spacings ... that allow fluid to pass

[]through” Spenser II’s compressible material “in an unexpanded state” are “necessarily present.”

59. Compressible material 256 is described as a “layer,” “sleeve,” “cloth,” or “fabric.” Again, no mention is made of any “spacings” therein, much less ones “that allow fluid to pass” through the compressible material in “an unexpanded state.” Nor are such “spacings” suggested by Spenser II’s FIG. 22, which depicts a thick, opaque, seal without any spacings extending through the compressible material/graft:

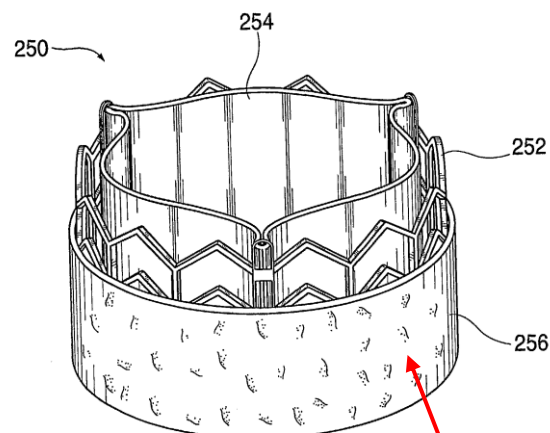
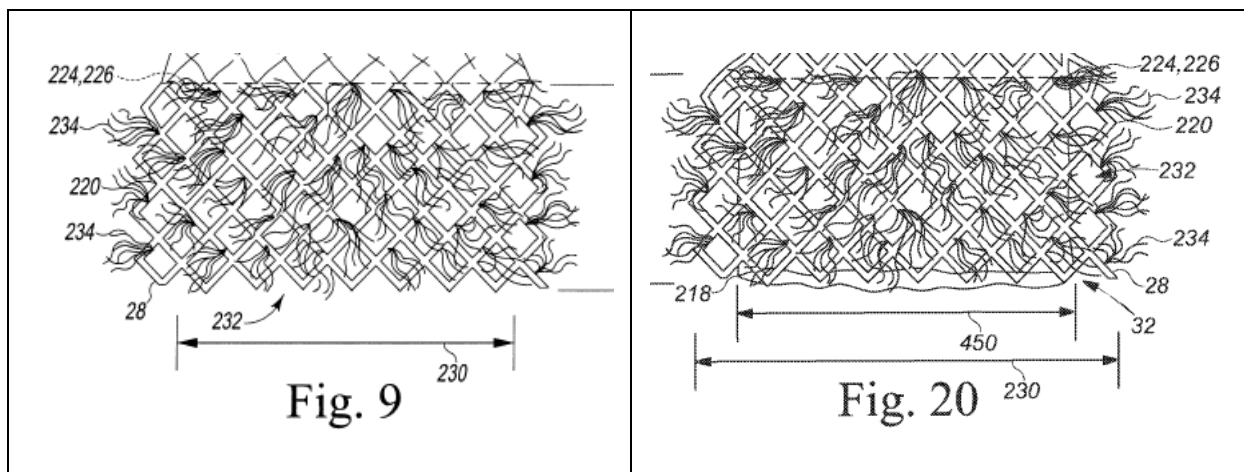


FIG. 22

No Spacings

In this regard, Spenser II’s FIG. 22 stands in stark contrast with the fibers with spaces therebetween illustrated in the ’033’s figures, which would allow blood to pass through in an undeployed state:



Ex. 1001 [’033] Figs. 9, 20; *see also id.*, Figs. 8, 11-16, 21-22.

60. Moreover, even if some “spacings” were imagined, there is nothing in FIG. 22 or its corresponding description indicating that any unmentioned, hypothetical “spacings” would further “extend” through the material’s thickness “that allow fluid to pass” through Spenser II’s graft in “an undeployed state.”

61. Indeed, as the Board (rightly, in my opinion) found, Spenser II’s compressible material “corresponds to an outer graft covering.” Ex. 2124 [-00556FWD] 38; Ex. 1120 [-00034FWD] 48 (same). The Board also credited my testimony describing Spenser II’s compressible material as a “solid, **non-porous**, graft material.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). A “non-porous graft covering,” however, would not allow, much less necessarily permit, “fluid to pass therethrough” in “an undeployed state.” *See* Ex. 2122 [Buller-556-Reply-Depo.] 20:2-21:3 (“nonporous” means “impermeable to fluid.”). In the TAVR context,

blood is the relevant fluid which TAVRs must form a seal against to prevent paravalvular leaks.

62. In accord, Dr. Buller similarly testified that Spenser II's compressible material would be "**sufficiently dense** to prevent blood from leaking through the cloth/fabric." Ex. 2128 [Buller-556-Decl.] ¶222. I agree that POSITAs would understand that the compressible material would be "sufficiently dense" to prevent blood from leaking because that is its principal purpose. This indicates a "non-porous graft covering," a favored solution to prevent PVL.

63. Nor do the materials used in the compressible material suggest that is porous. Spenser II teaches that the compressible material is "prefer[ably] ... formed of polyethylene terephthalate (PET)," a type of polyester. But a thick, sleeve-like PET layer as depicted in FIG. 22 would not suggest, much less necessarily indicate, a "porous" covering. Indeed, the '033 repeatedly describes standard polyester, low-profile polyester, and ePTFE as "covering materials" that "prevent[] blood from passing through the [] surface." Ex. 1001 ['834] 7:30-36, 8:51-55, 9:35-38; 13:35-38, 13:61-67, 15:60-65, 17:6-10, 19:17-20.

64. Petitioner, moreover, proposed claims in Spenser II's European prosecution requiring that "the compressible material is a **fluid impermeable membrane**." Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093. A "fluid

impermeable membrane” would not “allow fluid to pass therethrough,” much necessarily do so.

65. Quite simply, Spenser II’s FIG. 22 and description thereto provide no basis to conclude that “spacings” that would “allow fluid to pass” through the compressible material in “an undeployed state” are “necessarily” present.

66. Nor, in my opinion, do Petitioner’s real-world products suggest that that “spacings” extending through Spenser II’s compressible material which “allow fluid to pass therethrough” are **required** for Spenser II’s material to be compressible, “fill[] the gaps,” encourage blood coagulation or promote tissue ingrowth. Walther’s outer cloth “promotes tissue ingrowth,” “fill[] little gaps,” and, per Petitioner, is “highly compressible” and “clots” blood. See Ex. 1007 [Walther] 1, 7; IPR2022-00556, Paper 22 (Reply) 8 (“Walther’s outer cloth is highly compressible”); Ex. 1128 [Buller-556-Depo.] 72:8-9 (“blood clots” in Walther’s outer cloth). Yet, Walther does not reveal any “spacings” extending through its outer cloth, much less ones further allowing “fluid to pass therethrough.”

67. Additionally, Spenser II’s compressible material (and Walther’s outer cloth) are designed to prevent paravalvular **leakage**. Ex. 1011 [Spenser-II] ¶145; Ex. 1007 [Walther] 1. To that end, per Dr. Buller, POSITAs would understand the material would be “sufficiently dense” to prevent blood from leaking through the

cloth. Ex. 2128 [Buller-556-Decl.] ¶222. Accordingly, Spenser II addresses PVL via a “solid, non-porous, graft material.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Breckner-556-Decl.] ¶160); *see also* Ex. 1120 [-00034FWD] 44 (similar); Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093 (proposing claims indicating the compressible material is “a fluid impermeable membrane.”). Again, this would not indicate that “fluid could pass []through” Spenser II’s compressible material “in an undeployed state” in my opinion.

68. Petitioner’s and Dr. Buller’s contentions, moreover, are directed towards functions which are addressed not by Spenser II’s graft/compressible material, but by the fibers extending outwardly therefrom.

69. Petitioner’s and Dr. Buller’s posited goals—filling gaps, encouraging blood coagulation, and promoting tissue ingrowth—are each addressed via the fibers extending from Spenser II’s compressible material, and do not require any “spacings” which “allow fluid to pass” through the “thickness” of the compressible material/graft. The extending fibers “fill the gaps between the stented valve and the surrounding tissue” and, “[a]ccordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.” Ex. 1011 [Spenser-II] ¶145. Spenser II tells us directly that it is “the fibers” that “encourage coagulation of blood to further fill the gaps and prevent leakage.” *Id.* These teachings refer to the filling of gaps between the outer surface of the compressible material’s base layer

and the “surrounding tissue,” and do not indicate that fluid could pass through the thickness of the compressible material/graft in “an undeployed state.” In accord, Spenser II further teaches that a growth factor may be applied “along the outer surface of the compressible material,” *i.e.*, where the extending fibers are, and may promote tissue ingrowth on the outer side of the valve where the cloth attaches to the vessel wall. *Id.*, ¶¶145, 55. This is consistent with Dehdashtian’s teaching that extending fibers facilitate tissue ingrowth. Ex. 2101 [Dehdashtian] 3:7-16, 3:37-41 (describing a graft with floaters that “promote tissue ingrowth where they are placed along the exterior of the graft body”)². None of this suggests the compressible material must allow fluid to pass through in an undeployed state.

² I have been informed that Spenser II claims priority to Application No. 10/883,575 (“’575 Application”). I observe that the ’575 Application was published in patent application U.S. 2006/0004442 (“’442 Application,” Ex. 2102), does not identify Mark Dehdashtian as an inventor. *See* Ex. 2102 (listing Spenser, Benichou, and Bash as inventors), and does not contain Spenser II’s Fig. 22. Mr. Dehdashtian’s addition as an inventor to Spenser II suggests to me his contribution included the compressible material that is the subject of Fig. 22. I have confirmed with counsel for Aortic that this is a reasonable inference.

70. I further disagree with Petitioner’s additional contentions that that promoting tissue ingrowth and blood coagulation requires “spacings ... that allow fluid to pass []through” the compressible material. Even if “spacings” between the extending fibers (which address tissue ingrowth and blood coagulation) were assumed, this would not, in my opinion, suggest that fluid could pass through the “sealing assembly” in an undeployed state, particularly given the presence of a non-porous graft covering/“fluid impermeable membrane.” Thus, regardless of whether any spaces exist between extending fibers, this would not indicate that fluid may pass through the undeployed sealing assembly in my opinion.

71. I note that Petitioner also contends that “spacings” allegedly “far larger than the size of a spacing necessary to allow passage of fluid” are required for promoting tissue ingrowth. *Id.*, 48-49 (citing Ex. 1003 [Buller-Decl.] ¶156; Ex. 1106 [Estridge] 158). I disagree.

72. The relied-upon Estridge article does not mention fluid permeability. *See* Ex. 1106 [Estridge] 157-158. Instead, Estridge appears to be referring to “healing porosity” (pertaining to tissue ingrowth), not “bleeding porosity” (pertaining to fluid permeability). *See* Ex. 1106 [Estridge] 157 (“there is little information about the design criteria that could lead to optimal tissue ingrowth into [] porous materials.”); Ex. 2122 [Buller-556-Reply-Depo.] 43:8-45:12 (healing porosity refers to “the ability of tissue to ... grow through the fabric,” not “the

passage of fluids” therethrough). Yet, Petitioner’s own evidence confirms that sufficient healing porosity need not come at the expense of bleeding porosity. See Ex. 1110 [Pourdeyhimi] 172 (“the use of bulk texturized yarns has led to a reduction in porosity (increasing healing porosity) without adversely affecting permeability (bleeding porosity).”); Ex. 1129 [Chu] 7. Thus, Petitioner fails to substantiate its position that spacings allowing for tissue ingrowth would be “far larger than ... necessary to allow passage of fluid therethrough.”

73. I understand that Petitioner further contends that the claimed “spacings” may be the “inherent spacings between fibers.” Pet., 51. I disagree.

74. The Applicant clearly distinguished the claimed “spacings” from the “inherent” spaces between fibers as shown in Walther (Spenser II’s real-world embodiment):

The specification illustrates spacing[s] between fibers that are an intentionally placed spacing, *i.e.*, ***not just the spacing that may be inherent between radially extending fibers*** such as those that appear to be found in the Walther reference.

Ex. 1002 [Pros.-Hist.] 29. Indeed, Petitioner’s district court expert, Dr. Brookstein, agreed that the claimed spacings are not the “inherent” spacings between fibers .

Ex. 2141 [Brookstein-Decl.] ¶.] ¶36 (recognizing Applicant’s statement distinguishing the claimed “spacings” from “the spacing that may be inherent between radially extending fibers ...”) (quoting Ex. 1002, 29).

75. I observe that Petitioner nevertheless contends that the Applicant’s statement distinguishing inherent spacings is “unsupported by the intrinsic record,” “improperly attempts to inject an intent element into the construction,” and is “vague,” leaving POSITAs “no meaningful definition to apply.” Pet., 50-52. I disagree. The Applicant did not “inject” any “intent element” into the meaning of “spacings.” Rather, the Applicant made clear what it was not claiming, “*i.e.*, the ***spacing that may be inherent between radially extending fibers.***” Ex. 1002 [Pros.-Hist.] 29. Indeed, if, as Petitioner contends, the claims were satisfied by inherent spacings, this would render “spacings” meaningless, in my opinion. I note that the claims already require a “plurality of fibers” that “extend away from the frame.” Ex. 1001 [’033] cl. 1. I do not see how a requirement of “spacings” inherent to an already-claimed feature would impart any significance to the term “spacings.”

76. Thus, in my opinion, Petitioner fails to show that Spenser II inherently discloses “spacings ... that allow fluid to pass [t]hrough” the “sealing assembly” when the valve is undeployed.

b. *Petitioner Fails To Show A POSITA Would Be Motivated To Modify Spenser II’s Outer Covering.*

77. I understand that Petitioner alternatively argues that “POSITAs would have been motivated to use, and expected success in using, a porous fabric or cloth, such as a knitted or woven velour-like fabric, as the compressible material

taught by Spenser II ... because they were known to be compressible, stretchable, and provide enhanced tissue ingrowth.” Pet., 49 (citing Ex. 1003 [Buller-Decl.] ¶157). I disagree.

78. The benefits Petitioner alleges would motivate POSITAs to modify Spenser II’s compressible material are, in my opinion, already disclosed by Spenser II (compressibility and promoting tissue ingrowth) and/or are not shown to either enhance the compressible material’s performance or to even result from Petitioner’s proposed modifications (stretchability).

79. Petitioner contends that POSITAs would modify the compressible material to provide compressibility and enhance tissue ingrowth. Pet., 49. But Spenser II’s **compressible** material is already compressible, as Petitioner has repeatedly recognized. *See, e.g.*, Pet., 47 (“Spenser II describes a ‘**compressible** material’”) (emphasis in Petition); Ex. 2136 [-01151-Pet.] 49 (“Spenser II expressly describes the material as ‘compressible.’”). Spenser II’s compressible material, moreover, may already promote tissue ingrowth. *See* Ex. 1011 [Spenser-II] ¶145 (“a tissue growth factor may be applied ... for promoting the growth of tissue into the material.”). It is unclear why a POSITA would be motivated to modify Spenser II to provide benefits that Spenser II already expressly discloses.

80. Petitioner further contends that POSITAs would be motivated to modify Spenser II to provide “stretchability.” Pet., 49 (citing Ex. 1003 [Buller-

Decl.] ¶157). But I do not see any explanation as to why a POSITA would be motivated to make Spenser II's compressible material "stretchable" or demonstrate that the compressible material is insufficiently stretchable to achieve an unidentified purpose. Therefore, Petitioner fails, in my opinion, to show that POSITAs would have found it obvious to modify Spenser II's compressible material to "allow fluid to pass therethrough" when the valve is undeployed.

81. Even if we assumed that POSITAs were motivated to make Spenser II's compressible material "stretchable," Petitioner's relied-upon evidence does not, in my opinion, substantiate its contention that this aim would be achieved by making Spenser II's compressible material porous. Petitioner relies upon Dr. Buller's testimony which in turn relies upon Hall (Ex. 1007), Estridge (Ex. 1006) and Pourdeyhimi (Ex. 1110). See Pet., 49 (citing Ex. 1003 [Buller-Decl.] ¶157). neither mention "stretchability" nor any benefits thereof, much less establish that a porous velour fabric is desirably more stretchable than a nonporous velour. See Ex. 1006 [Estridge]; Ex. 1007 [Hall]; Ex. 1110 [Pourdeyhimi]. Thus, in my opinion, Petitioner further not only fails to prove that a POSITA would be motivated to make Spenser II's compressible material more stretchable, it also fails to prove its proffered modification would achieve that end.

82. I further disagree with Petitioner that a POSITA would be motivated to make Spenser II's compressible material porous. Spenser II's compressible

material is intended to address paravalvular leakage and uses a non-porous graft covering, or, per Petitioner, a “fluid impermeable membrane” to do so. Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093. Making this “fluid impermeable membrane” “porous,” such that fluid could “pass therethrough” when the valve is “undeployed” would further be inconsistent with Dr. Buller’s previous testimony that the compressible material would be “**sufficiently dense** to prevent blood from leaking through the cloth/fabric.” Ex. 2128 [Buller-556-Decl.] ¶222. Thus, a POSITA would not be motivated to make Spenser II’s compressible material porous. Petitioner’s contrary contention appears to be hindsight.

83. Thus, in my opinion, Petitioner fails to show that a POSITA would be motivated to modify Spenser II’s compressible material to have “spacings...that allow fluid to pass therethrough” in “an undeployed state.”

4. Petitioner Fails To Show How The “Polymer Covering” Assists In “Reducing The Spaces In The Sealing Assembly.”

84. The claims require that the “plurality of fibers” and “polymer covering” “cooperatively create a paravalvular seal **by reducing the spaces in the sealing assembly.**” Ex. 1001 [’033] cl. 1. Thus, it is not enough that the plurality of fibers create a “paravalvular seal” in my opinion. Instead, the fibers must work “cooperatively” with the “polymer covering” to create that seal “by reducing the spaces in the sealing assembly.”

85. Petitioner, however, does not argue that the inner skirts of Levi or Spenser I (the alleged “polymer covering”) assist in “reducing the spaces in the sealing assembly.” Rather, Petitioner merely states that these elements are present, and that POSITAs “would have understood” the limitation is met. Pet., 60. I do not see any explanation how or why the mere presence of these elements would lead POSITAs to understand that the “polymer covering” assists in “reducing the spaces in the sealing assembly.”

86. Dr. Buller (but not Petitioner) further contends that “the polymer covering would prevent blood from leaking through the open cells of the frame and the compressible material would prevent blood from leaking around the outside of the THV, between the frame and the patient’s native tissue.” Ex. 1003 [Buller-Decl.] ¶171. But, even were this so, Dr. Buller does not even contend that the polymer covering would “cooperatively ... reduc[e] the spaces in the sealing assembly.”

87. Nor, in my opinion, does Petitioner provide any basis upon which to assume that the polymer covering would “cooperatively” reduce spaces in Spenser II’s compressible material.

88. It is unclear how Petitioner’s Spenser II combinations would satisfy the claims’ requirement that the expansion of the “polymer covering” works “*cooperatively*” with the extending fibers’ compression “to create a paravalvular

seal ... *by reducing the spaces in the sealing assembly.*” Ex. 1001 [’033] cl. 1.

The inner skirts of Spenser I/Levi (relied-upon “polymer covering”) are positioned inside the frame. Pet., 27-28 (citing Ex. 1010 [Spenser-I] Fig. 44b; Ex. 1007 [Levi] Fig. 2). Spenser II’s compressible material 256 (relied-upon “sealing assembly”) including its base layer, is outside the frame. Therefore, at least the bars of the metal frame and the compressible material’s base layer would be between the extending fibers and the “polymer covering.” While the struts of the frame would not preclude the polymer covering from assisting in “reducing the spaces in the sealing assembly” through the frame’s open cells, the dense base layer of the “fluid impermeable membrane” (Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093) compressible material would span across those open cells. Petitioner, however, does not explain how the polymer covering nevertheless assists in reducing the spaces in view of these intervening elements. Moreover, per Dr. Buller, the compressible material must “be sufficiently dense” to prevent leakage therethrough. Ex. 2128 [Buller-556-Decl.] ¶222. The solid, dense, graft covering of the outer seal, particularly when coupled with the struts of the metal frame³, may hinder the polymer covering from assisting in “reducing the spaces

³ This is not to say that a metal frame alone, in the absence of dense graft covering, would prevent the reduction of spaces.

in the sealing assembly.” How this limitation could nevertheless be met by Petitioner’s Spenser II combinations is unexplained.

89. Consequently, in my opinion, Petitioner fails to show that the “polymer covering” assists in “reducing the spaces in the sealing assembly” in its Spenser II combinations.

90. Thus, Petitioner fails to show that its Spenser II combinations disclose or render obvious the “spacings” limitations.

B. Petitioner’s Chuter Combinations (Grounds 3-6)

91. I understand that Petitioner and Dr. Buller propose combining Chuter’s fiber pile with the frame of Spenser I or Levi (the Chuter grounds/combinations). Pet., 67-68. More specifically, I note that Petitioner and Dr. Buller rely on either of two distinct embodiments. The first concerns Chuter’s graft embodiment featuring a fabric pile backing. *Id.*, 68. The second concerns Chuter’s occluder embodiment without a backing layer, wherein fibers are secured between twisted wire strands forming a helically wound stent. *Id.*, 67-68. In my opinion, Petitioner fails to show that any of its proposed Chuter combinations disclose or render obvious any of the claims.

1. Prosecution History.

92. I note that, as Petitioner recognizes, the Applicant disclosed each of Chuter, Levi, Spenser I, and Spenser II to the Examiner in prosecution. Ex. 1002

[Pros.-Hist.] 93, 135; Pet., 81. I further observe that Examiner confirmed these documents were “considered by the Examiner.” *Id.*, 93, 135-138, 46, 84-85, 96. I further note that the Applicant submitted remarks specifically distinguishing Walther and “the references of record” as not showing “spacings,” the Examiner issued a Corrected Notice of Allowability. *Id.*, 28-30, 15. Thus, each of the references in Petitioner’s Chuter combinations were presented in prosecution.

2. Petitioner Fails To Show That The Chuter Backing Layer Combinations Disclose Or Render Obvious The “Spacings” Limitations.

93. The claims require:

Claim 1: “the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state, wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state:

...compresses the plurality of fibers relative to the spacings thereby reducing the spacings; and expands the polymer covering radially outwardly, wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.”

Ex. 1001 [’033] cl. 1.

94. I understand that Petitioner refers to these limitations as the “spacings” limitation. See Pet., 44, 77. For the purposes of this Declaration, I will similarly refer to these limitations as the “spacings” limitations.

95. For the reasons discussed below, I do not believe that Petitioner has shown that its Chuter backing layer combinations disclose or render obvious the “spacings” limitations.

a. *The Prosecution History Confirms That The Chuter Backing Layer Combinations Do Not Disclose Or Render Obvious “Spacings.”*

96. As discussed, each of Chuter, Levi, Spenser I, and Spenser II were disclosed to, and considered by, the Examiner in prosecution. Ex. 1002 [Pros.-Hist.] 93, 135-138, 46, 84-85, 96. Even if this were ignored, Chuter’s backing layer embodiments, which Chuter describes as a “graft” or “sleeve,” are similar to Spenser II’s solid, nonporous, “sleeve”-like compressible material that the Board found “corresponds to an outer graft covering.” Ex. 2124 [-00556FWD] 38; Ex. 1120 [-00034FWD] 48 (same); *compare* Ex. 1116 [Chuter] ¶25 (“[t]he stents of the present invention that employ a **graft** ... The **graft** pouch, sock, or **sleeve** can extend beyond one end or both ends of the stent.”) *with* Ex. 1011 [Spenser-II] ¶145 (describing compressible material as a “sleeve.”). Notably, as discussed, Spenser II was distinguished in prosecution as not disclosing or rendering obvious

“spacings.” See Section VI.A.1, *supra*. These statements, in my opinion, apply to Chuter’s similar backing layer embodiments.

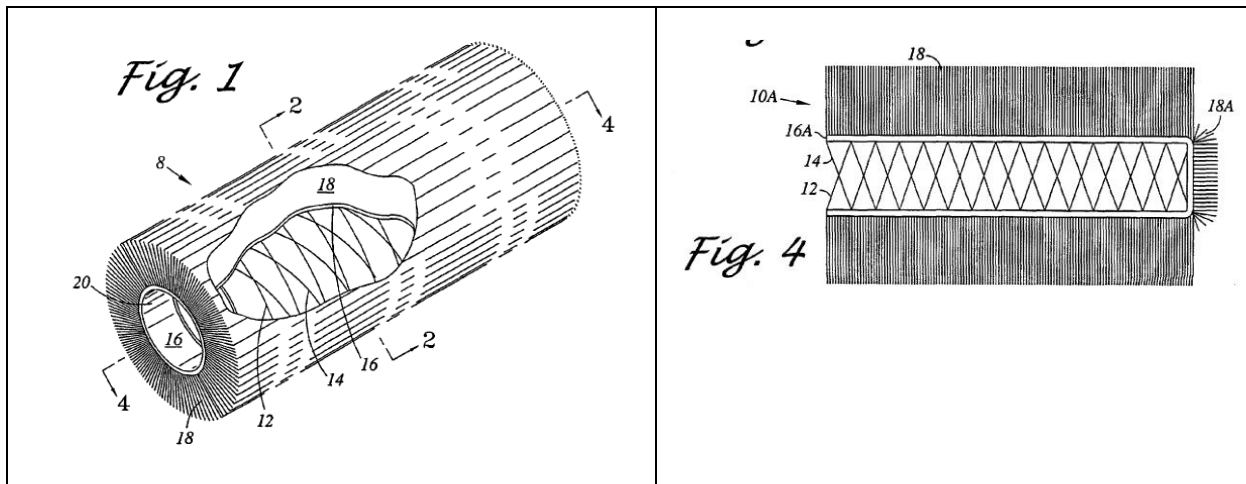
97. As discussed, the Applicant distinguished both Spenser II (and particularly Figure 22) and Walther (FIG. 22’s “real world embodiment”) as not disclosing “spacings” in prosecution of the ’033’s parent, the ’834. See Section VI.A.1, *supra*; Ex. 2140 [’834-FH] 1001 (distinguishing Walther and Spenser II as disclosing “tightly knitted outer seal[s]” that “lack [] ‘spacings.’”). And, again, Petitioner’s district court expert, Dr. Brookstein, agrees that the Applicant’s arguments apply to the ’033. Dr. Brookstein testified that the Applicant “argued during prosecution” that the ’033’s claims “do not include cloths like those described in Walther and Spenser II” (Ex. 2141 [Brookstein-Decl.] ¶33), and that “Aortic Innovations argued that the collagen fibers in the Asserted Patents **were distinguishable from the prior art because the prior art (including Walther and Spenser II)** due to the “lack of ‘spacings’” (*id.*, ¶35 (quoting Ex. 2140 [’834-FH] 1001)). See also *id.*, ¶40 (the ’033’s claims do not “cover” the outer coverings “described in Walther and Spenser II.”). I agree that Spenser II and Walther were distinguished as not satisfying the “Spacings” limitations.

98. Like Spenser II’s compressible material, which the Board found “corresponds to an outer graft covering” (Ex. 2124 [-556-FWD] 29-30; Ex. 1120 [-00034-FWD] 48) and is described as a “sleeve” (Ex. 1011 [Spenser-II] ¶145),

Chuter's backing layer is similarly described as a "graft" and "sleeve." Ex. 1116 [Chuter] ¶25 ("[t]he **graft** pouch, sock, or **sleeve** can extend beyond one end or both ends of the stent."). Chuter, moreover, relies upon a nonporous backing layer extending over at least one open end of the stent to form an occluder blocking all blood flow. Ex. 1116 [Chuter] ¶¶5, 12, 25, 55, Figs. 4, 11. Chuter thus, in my opinion, describes a dense, nonporous sleeve/graft just like Spenser II's compressible material which, per Dr. Brookstein, cannot satisfy the "spacings" limitations.

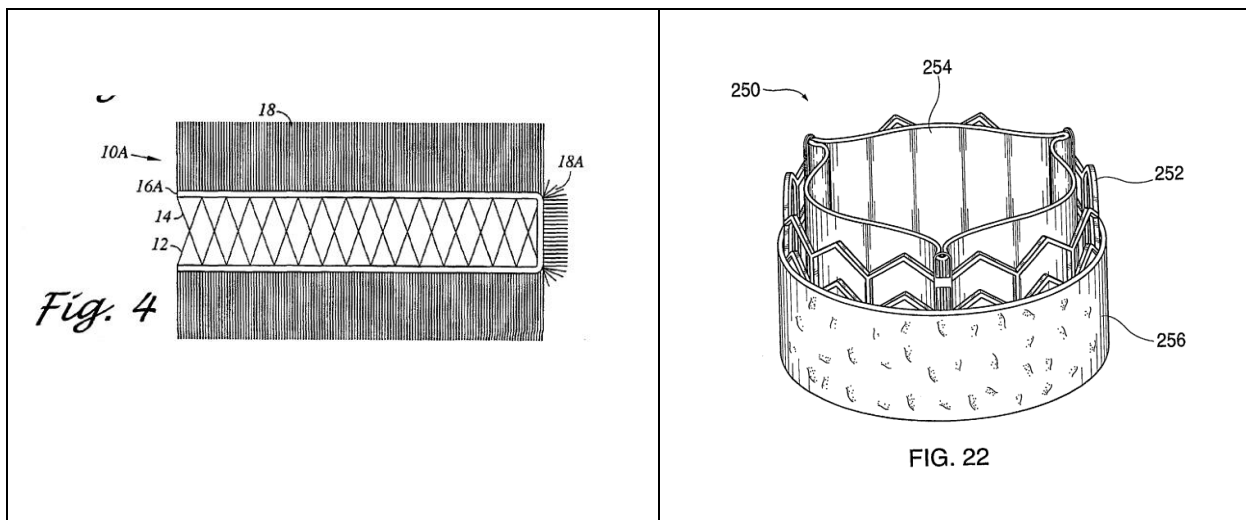
99. Indeed, the manifest similarities between Chuter's backing layer embodiments and Spenser II's FIG. 22 confirm, in my opinion, that the Applicant's statements distinguishing Spenser II's compressible material apply to Chuter's graft.

100. Chuter discloses embodiments comprising individual fibers extending outwardly from fabric pile backing 16 ("backing layer"). Chuter's backing layer embodiments are clearly depicted as lacking any "spacings extending through a thickness" of Chuter's fiber pile (alleged "sealing assembly"), including the fiber pile's backing layer, much less "spacings" "that allow fluid to pass []through" the graft's thickness in an undeployed state:

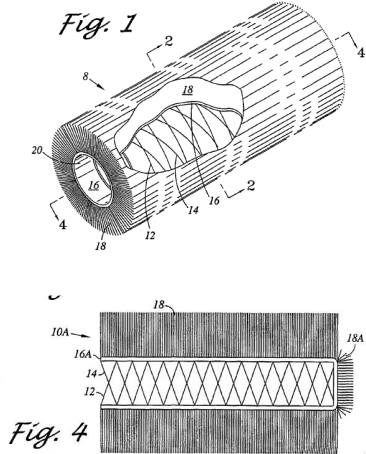
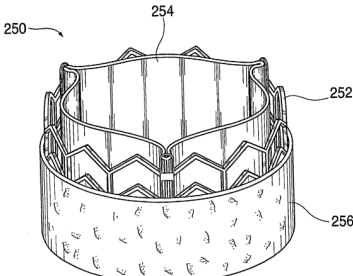
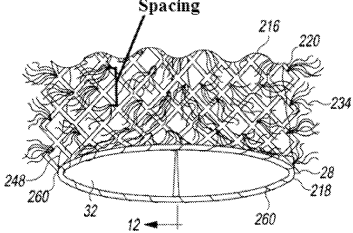


Ex. 1116 [Chuter] Figs. 1, 4, ¶¶54-55; see also Fig. 2.

101. Chuter does not disclose or suggest any “spacings” extending through this backing layer. Rather, like Spenser II’s FIG. 22, Chuter’s figures depict a tight outer seal without such “spacings”:



Certainly, neither Chuter’s fabric pile backing layer nor Spenser II’s compressible material resemble the ’033’s figures identified as showing “spacings” in prosecution:

Chuter	Spenser II	'834
 Fig. 1 Fig. 4	 FIG. 22	 Fig. 11

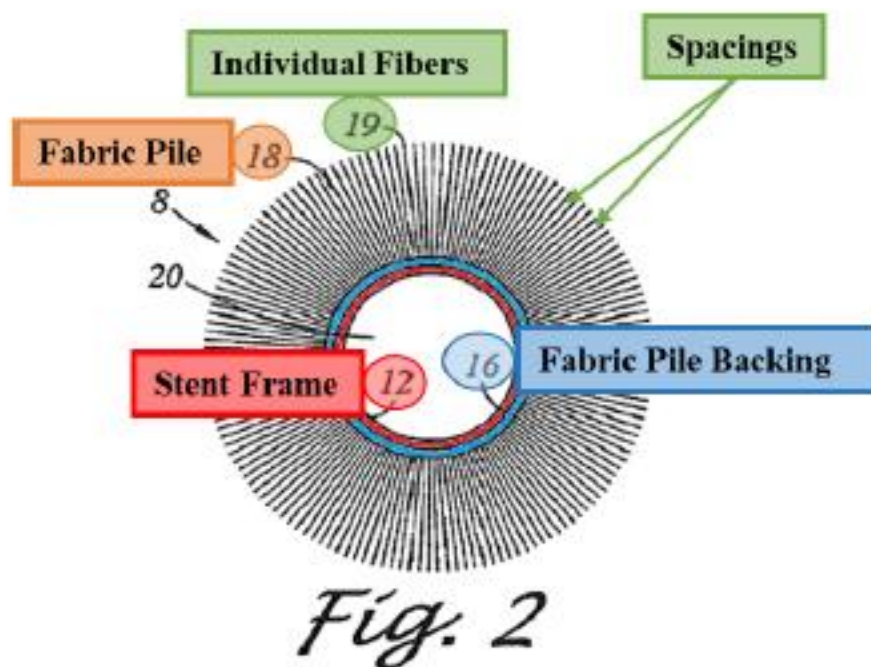
Nor are any “spacings” in the backing layer described. To the contrary, Chuter describes these embodiments as a “graft pouch, sock or sleeve,” mirroring Spenser II’s description of its compressible material as a “sleeve.” Ex. 1116 [Chuter] ¶25; Ex. 1011 [Spenser-II] ¶145. Thus, Chuter’s description of its backing layer embodiments mirrors that of Spenser II’s compressible material, which the Applicant expressly distinguished as lacking “spacings.” See Ex. 2140 [’834-FH] 1001; Ex. 2141 [Brookstein-Decl.] ¶35 (“Aortic Innovations argued that the collagen fibers in the Asserted Patents **were distinguishable from the prior art ... (including Walther and Spenser II)**” due to the lack of “spacings”); *id.*, ¶¶33, 40..

102. Thus, in my opinion, the Applicant’s statements distinguishing Spenser II as not disclosing “spacings” applies to Chuter’s backing layer embodiments. Consequently, in my view, Petitioner does not show that the Chuter backing layer combinations disclose or render obvious the “spacings” limitations.

- b. *Petitioner Fails To Show That Chuter’s Backing Layer Embodiments Disclose Or Render Obvious “Spacings” That Would “Allow Fluid To Pass Therethrough” “In An Undeployed State.”*

103. Notwithstanding the prosecution history, Petitioner further fails to show, in my opinion, that the Chuter backing layer embodiments disclose or render obvious “spacings ... that allow fluid to pass []through” the “sealing assembly” when the valve is in “an undeployed state.”

104. I note that Petitioner argues that Chuter’s backing layer embodiments disclose “spacings” that “‘extend through a thickness of the fiber pile’ (i.e., sealing assembly) and would ‘allow fluid to pass therethrough when the prosthetic heart valve is in an undeployed state.’” Pet., 76-77. I further observe that Petitioner contends these “spacings” are shown in Chuter’s Fig. 2:

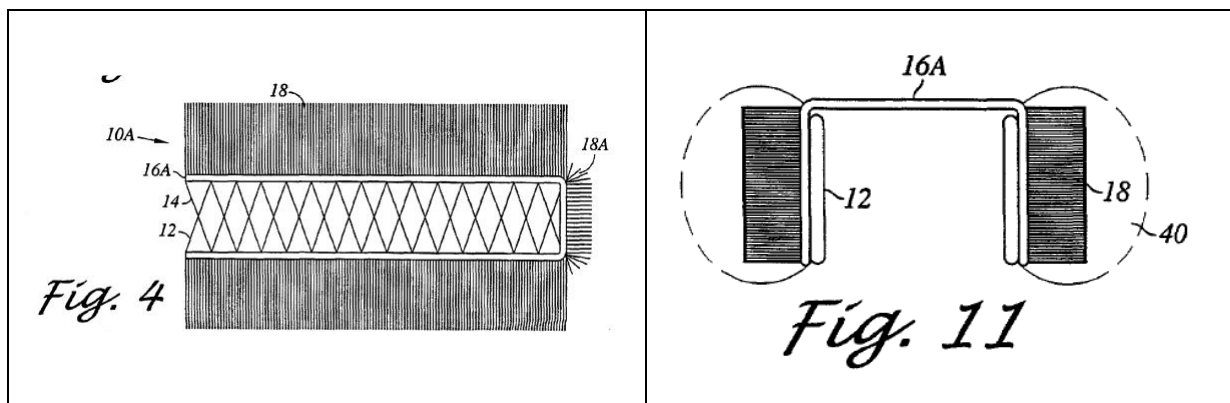


Id., 76 (Petitioner’s annotations). I disagree. Rather, in my opinion, Chuter neither suggests nor discloses “spacings ... that allow fluid to pass [through]” its backing layer/graft.

105. There is no reason to conclude, from Chuter’s disclosure, that its backing layer embodiments disclose “spacings ... that allow fluid to pass [through]” the “sealing assembly.” Chuter does not describe these embodiments as “allow[ing] fluid to pass therethrough” when undeployed. Rather, Chuter discloses that its fabric pile backing is used as either a stent graft or an occluder. Ex. 1116 [Chuter] ¶¶12-16, 25, 54-55, 64. Similar to TAVRs, which are designed to allow blood flow exclusively through the valve, stent grafts are designed to allow blood to flow only inside the channel formed by the inner surface of the stent. *Id.*, ¶54. Chuter teaches that stent grafts had the known requirement of “damming off or wall[ing] off” any “gap between the exterior surface of the stent-graft and the interior arterial wall” to prevent blood leaking therebetween. Ex. 1116 [Chuter] ¶9. Such leaking “frequently leads to complications resulting either from clot formation in the gap which escape ... and enter the lungs or delamination of the interior arterial wall surface.” *Id.*, *see also id.*, ¶4 (similar). Were there “spacings ... allowing fluid to pass [through]” the backing layer, blood may leak through the graft into such “gap[s].” Ex. 1116 [Chuter] ¶9. Accordingly, Chuter operates from the premise that stent grafts must prevent leaks through the wall of the graft

(backing layer) when implanted, which does not suggest that the graft would not also prevent fluid from passing therethrough when undeployed. Nowhere does Chuter suggest that the stent graft allows fluid to pass therethrough in a free air or undeployed state, much less that “spacings” allowing fluid to pass through its graft’s thickness are reduced upon deployment to create a paravalvular seal.

106. Chuter also teaches its backing layer being used in an occluder as a “pouch” or “sock” graft extending over at least one end of the stent to occlude—i.e., prevent blood from passing through—the vessel:



Id., Figs. 4, 11, ¶¶12, 25, 55. Because the fabric pile backing is utilized to occlude the blood vessel, this further indicates that fluid may not pass therethrough. See *id.*, ¶5 (“it is extremely important to cut off and occlude the damaged portion of the vessel to prevent all blood flow into it and through it to prevent future complications.”). Notably, in these embodiments where a portion of the backing covers an open end of the stent, that portion is not compressed against any solid surface. But, even in the absence of compression, blood is prevented from passing

therethrough. This suggests that, similarly, when the backing layer is in an undeployed state, it too would prevent blood/fluid from “passing therethrough.”

107. Additionally, Chuter teaches that its backing layer may be polyester. Ex. 1116 [Chuter] ¶22. The ’033, again, identifies “polyester” as a material that “prevents blood from passing through the [] surface.” Ex. 1001 [’033] 7:30-36, 8:51-55, 13:35-38, 13:61-67, 15:60-65, 17:6-10, 19:17-20.

108. In accord, Dr. Buller recognizes that Chuter’s backing layer may prevent fluid from passing in an undeployed state, arguing in connection with Chuter’s occluder embodiments that the **absence** of a backing layer “traversing the openings between the struts” would “necessarily” indicate “spacings” that “would allow fluid to pass” through the “sealing assembly.” Ex. 1003 [Buller-Decl.] ¶216. But, assuming the absence of a backing layer would allow fluid to pass, the backing layer’s presence would indicate the opposite.

109. Accordingly, nothing in Chuter teaches or suggests “spacings” that “allow fluid to pass []through” its graft in an “undeployed state.” If anything, Chuter suggests the opposite.

c. *Petitioner Fails To Show How The “Polymer Covering” Assists In “Reducing The Spaces In The Sealing Assembly.”*

110. The claims require that the “plurality of fibers” and “polymer covering” “cooperatively create a paravalvular seal by reducing the spaces in the

sealing assembly.” Ex. 1001 [’033] cl. 1. As with its Spenser II grounds, however, Petitioner makes no attempt to prove that the “polymer covering” assists in “reducing the spaces in the sealing assembly.” Indeed, Petitioner’s argument fails for much the same reasons stated in Section IV.A.4., *supra*.

111. As with Spenser II, Petitioner again does not argue that the inner skirts of Levi or Spenser I (alleged “polymer covering”) assist in “reducing the spaces in the sealing assembly.” Rather, Petitioner merely states that these elements are present, and that POSITAs “would have understood” the limitation is met. Pet., 78. Dr. Buller (but, again, not Petitioner), further contends that “the polymer covering would prevent blood from leaking through the open cells of the frame and the fiber pile would prevent blood from leaking around the outside of the THV, between the frame and the patient’s native tissue.” Ex. 1003 [Buller-Decl.] ¶223. But, as discussed regarding Spenser II, neither Petitioner nor Dr. Buller contend that the “polymer covering” assists in “reducing the spaces” in the fiber pile.

112. Nor do Petitioner and Dr. Buller provide any reason to assume that the “polymer covering” would assist in “reducing” the alleged “spaces” in Chuter’s backing layer.

113. It is unclear how Petitioner’s Chuter backing layer/graft combinations would satisfy the claims’ requirement that the expansion of the “polymer covering”

works “**cooperatively**” with the extending fibers’ compression “to create a paravalvular seal ... **by reducing the spaces in the sealing assembly.**” Ex. 1001 [’033] cl. 1. The inner skirts of Spenser I/Levi (relied-upon “polymer covering”) are positioned inside the bars of the frame. Pet., 27-28 (citing Ex. 1010 [Spenser-I] Fig. 44b; Ex. 1007 [Levi] Fig. 2). Chuter’s graft (relied-upon “sealing assembly”), including its dense backing layer that prevents fluid from passing therethrough, is outside the frame (See, e.g., Ex. 1116 [Chuter] ¶¶12, 25, 55; Figs. 1-2, 4).

114. As with Spenser II, at least the struts of the metal frame and Chuter’s dense backing layer would be between the extending fibers and the “polymer covering.” As discussed, while the struts of the frame would not preclude the polymer covering from assisting in “reducing the spaces in the sealing assembly” through the frame’s open cells, Chuter’s dense backing layer would “travers[e] the openings between the struts,” as Dr. Buller recognizes. Ex. 1003 [Buller-Decl.]

¶216. Indeed, as with Spenser II, Chuter’s solid, dense, graft covering, particularly when coupled with the struts of the metal frame⁴, may hinder the polymer covering from assisting in “reducing the spaces in the sealing assembly.”

⁴ As discussed, this is not to say that a metal frame alone, in the absence of dense graft covering, would prevent the reduction of spaces.

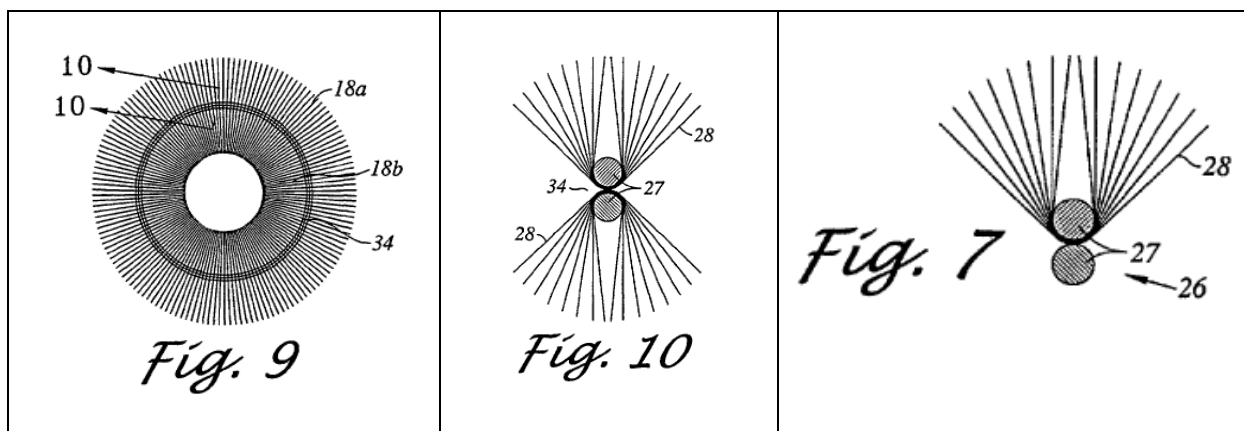
Petitioner, however, again fails to explain how the polymer covering nevertheless assists in reducing the spaces in view of these intervening elements.

115. Consequently, Petitioner fails, in my opinion, to show that the Chuter backing layer combinations disclose or render obvious the limitation requiring that the “polymer covering” assists in “reducing the spaces in the sealing assembly.”

116. Thus, in my opinion, Petitioner fails to show that its Chuter backing layer combinations disclose or render obvious the “spacings” limitations.

3. Chuter Occluder Combinations.

117. I understand that Petitioner alternatively proposes adding the individual extending fibers of Chuter’s occluder embodiments (“Chuter-occluder” combinations) without a backing layer (shown below), to the frame of Spenser I or Levi:



Pet., 67-69, 72-75; Ex. 1116 [Chuter] Figs. 7, 9-10. I further understand that Petitioner alleges that Chuter’s fiber pile represents the “sealing assembly” and that the individual extending fibers correspond to the “plurality of fibers.” Pet., 67-69.

- a. *Petitioner Fails To Demonstrate A POSITA Would Be Motivated To Make Its Chuter-Occluder Combinations Or Could Do So With A Reasonable Expectation Of Success.*

118. In my opinion, a POSITA would not be motivated to combine Chuter's occluder embodiments without a backing layer with the frame of either Spenser I or Levi, and I further do not believe a POSITA would reasonably expect to successfully achieve the combinations as proposed.

119. Chuter is directed toward "Large Vessel Stents And Occluders," and identifies its field of invention as relating to "intravascular stents for occluding vascular members in humans and animals." Ex. 1116 [Chuter] Title, ¶1. The principal function of an occluder, including Chuter's occluder, is to "prevent all blood flow into" a vessel. *See id.*, ¶5 ("it is extremely important to cut off and occlude the damaged portion of the vessel **to prevent all blood flow into it** and through it to prevent future complications"). In contrast, TAVRs **must** leave the aorta (a large vessel) unobstructed to allow blood to flow through the aorta and prosthetic leaflets. It would, accordingly, be counterintuitive for a POSITA to look to a device designed to occlude a blood vessel when designing a TAVR. Indeed, obstructing all blood flow through the aorta and aortic valve would lead to death, and even a partially obstructed aorta or aortic valve would have potentially fatal consequences.

120. Notably, in prosecution of Chuter, Chuter was distinguished from art lacking extending fibers to occlude the stent lumen. In prosecution, Chuter was distinguished from U.S. Patent No. 6,096,052 to Callister (Ex. 2125). Callister, directed towards an occluder for use in the reproductive system, teaches a tubular stent with struts and cells (alternatively described as “braided,” “lattice-like” or having an “open configuration”) and a “permeable mesh member transversely disposed” thereon to “promote tissue ingrowth.” *See, e.g.*, Ex. 2125 [Callister] 1:26-30, 2:1-9, 7:13-16, 7:34-38, 8:4-9. The Examiner issued rejections based, *inter alia*, on the premise that Callister’s permeable mesh, which was not taught to have fibers extending therefrom, disclosed or rendered obvious Chuter’s fiber pile. Ex. 2126 [Chuter-FH] 170-172, 186. In response, Chuter’s applicant explained that:

The fiber pile cannot be a mesh member because the fiber pile cannot expand so that it extends across the expanded lumen of the stent ... ***The fibers of the pile must have sufficient length before the stent lumen is expanded to bridge the expanded lumen of the stent.***

Id., 145, 165 (same); *see also id.*, 141 (“Mesh layer 16 of Callister et al., which comprises woven or bundled strands, is not a fiber pile.”), 161 (same). In accord, Chuter teaches that its inwardly-extending fibers “substantially occlude the inner bore of the stent” and “plug” the blood vessel. *See* Ex. 1116 [Chuter] ¶¶18, 57. Chuter’s occluder embodiments with only outwardly extending fibers must also

perform this function. Otherwise, the device could not “occlude” the stent’s “inner bore.” To accomplish this critical function, as further made clear in prosecution, the fibers must have sufficient length to traverse the stent’s “inner bore” and be densely arranged to immediately form a seal and stop all blood from flowing through the vessel. This teaching regarding the occlusion of the “inner bore,” however, would have no relevance to the spaces and gaps formed between a TAVR frame and the native valve anatomy. Unlike the requirement of a paravalvular leak solution, Chuter’s fibers are designed to form a seal not only across the full width of the vessel, but further without compressing against any solid structure. The dense nature of the occluding fibers secured to Chuter’s twisted wire loops are designed to cause thrombosis and occlusion of the diseased vessel. *Id.*, ¶11 (“the invention is directed to the use of expandable stents and a fabric pile to yield a[n] endovascular occluding stent for sealing off a vascular vessel to induce the thrombosis of large arteries.”). The twisted wire loop stent of Chuter is also uniquely designed for the specific purpose of adapting to the diseased vessels and causing occlusion. No POSITA would look to this design when considering a TAVR valve and a POSITA would further have concerns about the pro-thrombotic potential of the arrangement of fibers in Chuter.

121. A POSITA reading Chuter’s discussion of its occluder embodiments would readily understand these embodiments to be inconsistent with the purpose of

a TAVR. As explained, Chuter's occluders are meant to stop all blood flowing through the vessel, including within the stent. This teaching has no place in a TAVR wherein blood must go through the valve/leaflets within the stent without any risk of surrounding or adjacent thrombosis. Consequently, a POSITA, quite simply, would not be motivated to apply Chuter's occluder teachings in the context of TAVRs and any opposite conclusion seems driven by hindsight.

122. I understand that Petitioner and Dr. Buller contend that Spenser II "would have provided POSITAs additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves," arguing that POSITAs would have "recognized Chuter's fiber pile as a type of compressible material that could be combined with THV's to prevent PVL according to Spenser II's teachings." Pet., 80. I disagree.

123. I do not believe Spenser II would provide additional motivation for a POSITA to add Chuter's occluding fibers to Levi or Spenser I's frames. Chuter's fabric pile in its occluder embodiment is very different from Spenser II's compressible material. Petitioner, here, relies upon occluder embodiments "lacking the fabric pile backing." *See, e.g.*, Pet., 69. While both Spenser II's compressible material and Chuter's backing layer are described as a "**sleeve**," Chuter describes its occluder embodiments without a backing layer as a "**plug**." *Compare* Ex. 1011 [Spenser-II] ¶145; Ex. 1116 [Chuter] ¶25 *with* Ex. 1116 [Chuter] ¶57. Nor are the fibers similar. Whereas Spenser II describes "**small**

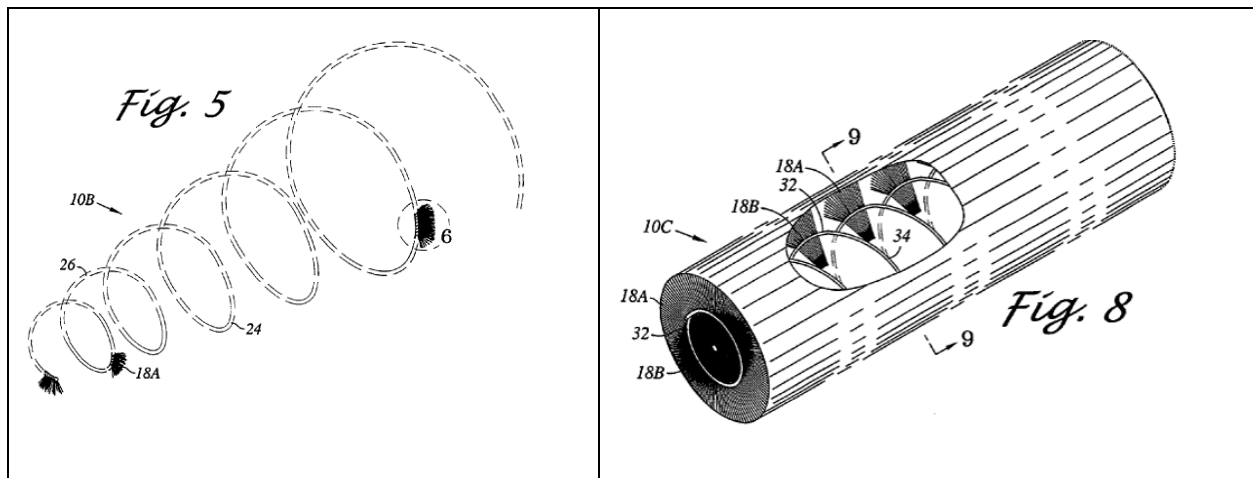
fibers extending from the surface of the [compressible] material,” Chuter’s occluding fibers “***must have sufficient length*** before the stent lumen is expanded to bridge the expanded lumen of the stent.” Ex. 1011 [Spenser-II] ¶145; Ex. 2126 [Chuter-FH] 145, 164-165 (same). Thus, Spenser II and Chuter’s occluder embodiments are quite different and, consequently, the former would not motivate a POSITA to adopt the latter.

124. I note that Petitioner contends that POSITAs “would have been motivated to attach the fiber pile to Spenser’s or Levi’s frames ***in the same way they are attached to Chuter’s frame.***” Pet., 76-77, 74-75 (similar). I disagree.

125. Chuter’s attachment method relies upon placing and securing fibers between the “twisted strands” of “helically wound wire.” Such twisted strands, however, are not present in the frames of Levi and Spenser I. In my opinion, even if we were to assume that a POSITA would be inclined to add an occluder’s fibers to a TAVR, it has not been shown that a POSITA would be motivated to add Chuter’s occluding fibers to the frame of Spenser I or Levi or that such a thing could be done with a reasonable expectation of success, much less “in the same way” as Chuter teaches given the absence of “twisted strands” of “helically wound wire” in the frames of Levi and Spenser I.

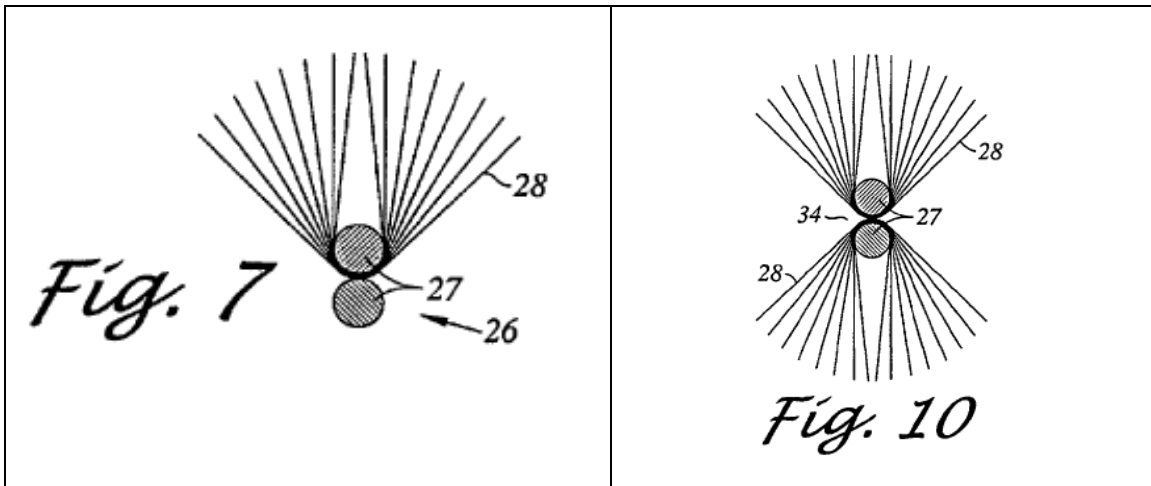
126. Chuter teaches stents “made of at least one helically wound wire ... comprising [] at least two twisted strands ... securing fibers to form a fiber pile.”

Ex. 1116 [Chuter] ¶¶17, 18 (same), 56 (“[r]eferring to FIGS. 5-7, the conical shaped occluder 10B comprises a conical shaped stent 24 comprising at least one helically wound double wire strand 26.”). Chuter’s applicant presented claim amendments requiring the helically wound wire stent further “form[] a plurality of loops,” which Chuter’s applicant identified as shown in Figs. 5-10:



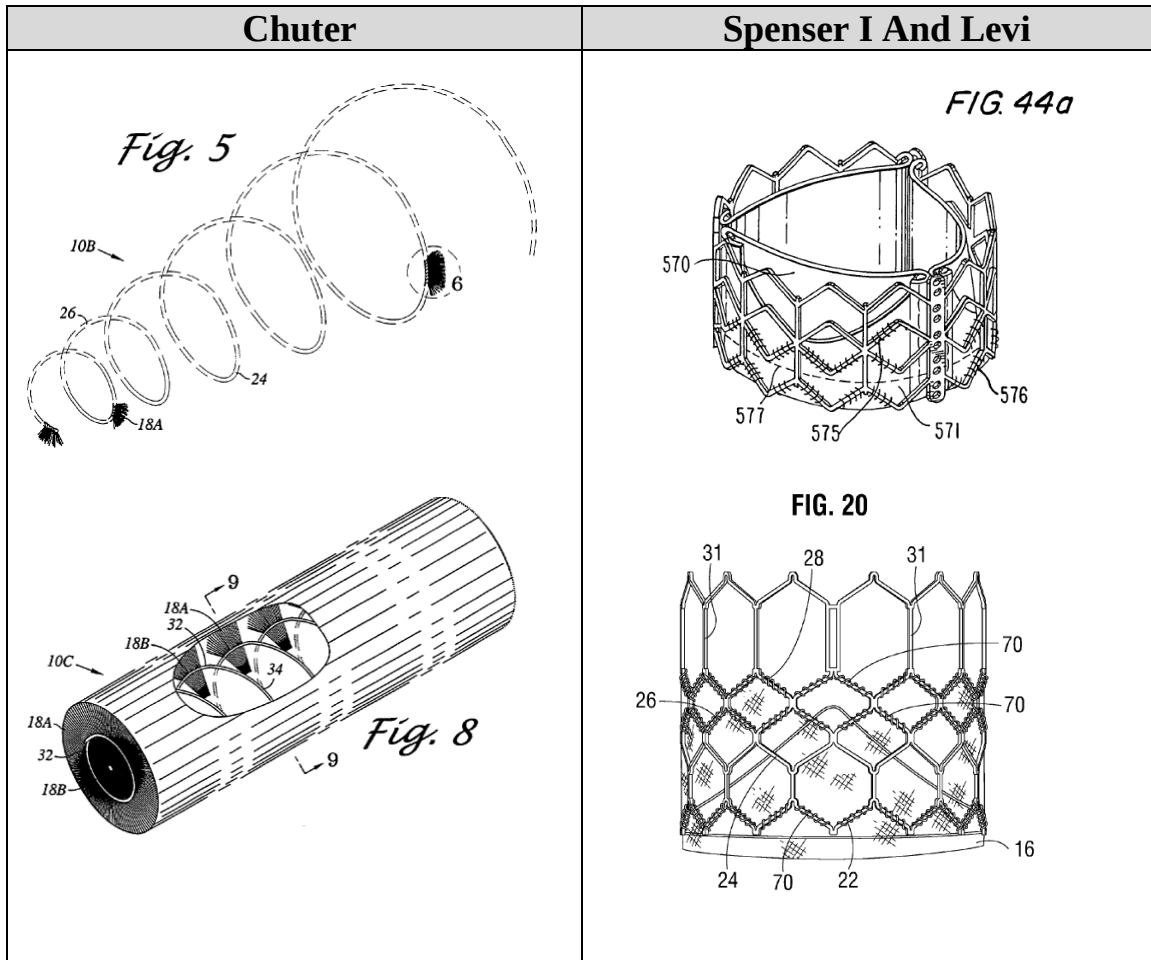
Ex. 1116 [Chuter] Figs. 5, 8; Ex. 2126 [Chuter-FH] 34-40.

127. The only “technique” or “method” Chuter teaches for attaching fibers to this helical loop, is by “inner-dispos[ing]” or “secur[ing]” the fibers between the twisted, helically wound metal wires. Ex. 1116 [Chuter] Abstract, ¶¶17-18, 20, 56-57. Significantly, Chuter’s applicant identified attaching fibers via the “twisted strands of the helical wire” to distinguish Chuter from the prior art, characterizing it as a “key element” of the invention. See Ex. 2126 [Chuter-FH] 144, 164-165, 43. Chuter’s method of attaching fibers via twisted strands is further shown, *e.g.*, Figs. 7 and 10:



Ex. 1116 [Chuter] Figs. 7, 10; Ex. 2126 [Chuter-FH] 39-40, 43, 144, 164-165.

128. In contrast, neither of Petitioner's relied-upon frames (Spenser I/Levi) have helically wound wire stents forming loops, much less double wound or twisted wire strands securing fibers therebetween:



Ex. 1116 [Chuter] Figs. 5, 8; Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20.

129. I do not believe a POSITA would be motivated to add Chuter's fibers, attached via the twisted strands of a helical loop, to stent frames like those present in Spenser I and Levi that lack both a helical loop and twisted strands. There is no suggestion in Chuter, Spenser I, or Levi to support Petitioner's contention that a POSITA could or would attach Chuter's extending fibers to the frame of Spenser I/Levi "in the same way" as in Chuter's occluder embodiments. Pet., 76-77, 74-75 (similar). Moreover, even if we assume a POSITA would be inclined to attach the

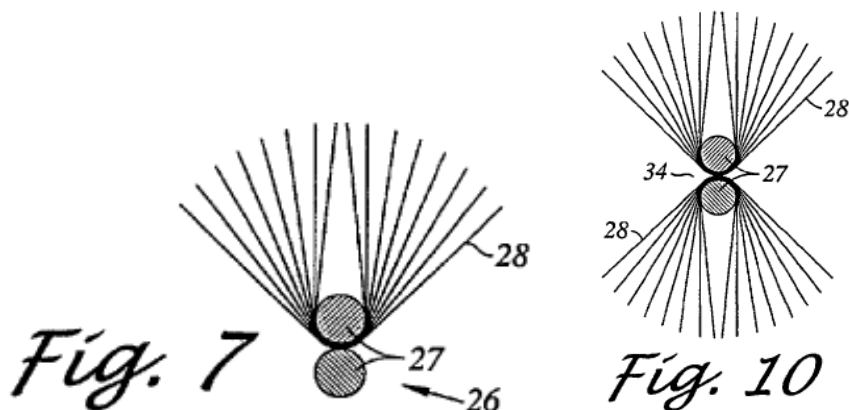
fibers to such a frame by some other method, there is no indication of how this would be done nor is it self-evident how a POSITA would accomplish such a thing with a reasonable expectation of success.

130. I am aware that Petitioner asserts that the relied-upon frames would nevertheless be compatible with Chuter's individual extending fibers, contending that POSITAs "would have possessed the knowledge to attach Chuter's fiber pile to Spenser's frame" by unidentified "known ... engineering methods." Pet., 74. I disagree with this conclusion for several reasons.

131. As discussed, a POSITA would not be motivated to combine Chuter's large vessel stent occluder with a TAVR like Spenser I or Levi in my opinion, at least because their functions are at cross-purposes and producing the combination would involve application of a method Chuter does not teach regarding a "key element" of its invention.

132. Even if we assumed that a POSITA would be motivated to tie or glue Chuter's occluding fibers to the frame of Spenser I or Levi, important remaining issues are not explained.

133. Chuter depicts its occluding fibers wrapped around, and fanning outwardly from, the twisted wire strands of its helically wound wire frame:



Ex. 1116 [Chuter] Figs. 7, 10. Petitioner does not propose any specific alternative attachment method, which renders the proposed combinations difficult to assess. Even if we assumed that these fibers could instead be otherwise attached to the frame of Levi or Spenser I, no explanation is given regarding why these fibers would still fan outwardly from the strut as depicted above, instead of being clumped or clustered together where affixed to the frame. These are critical questions which bear directly on whether a POSITA would be motivated to attach Chuter’s occluding fibers in this (again, unspecified) manner to produce a transfemorally-deliverable TAVR that effectively seals against PVL.

134. Chuter’s applicant noted that the relied-upon occluder embodiments without a backing layer (shown in Figs. 5-10) are directed to a different “species” than its embodiments featuring a backing layer. Ex. 2126 [Chuter-FH] 200 (“Figures 1-4, 11-14, and 26 are directed to one species; [] Figures 5-10 are directed to a second species.”). The “species” of Chuter’s occluder embodiments lacking a fabric pile backing was further distinguished in prosecution from

Callister's tubular stent with struts and cells (alternatively described as "braided," "lattice-like" or having an "open configuration"):

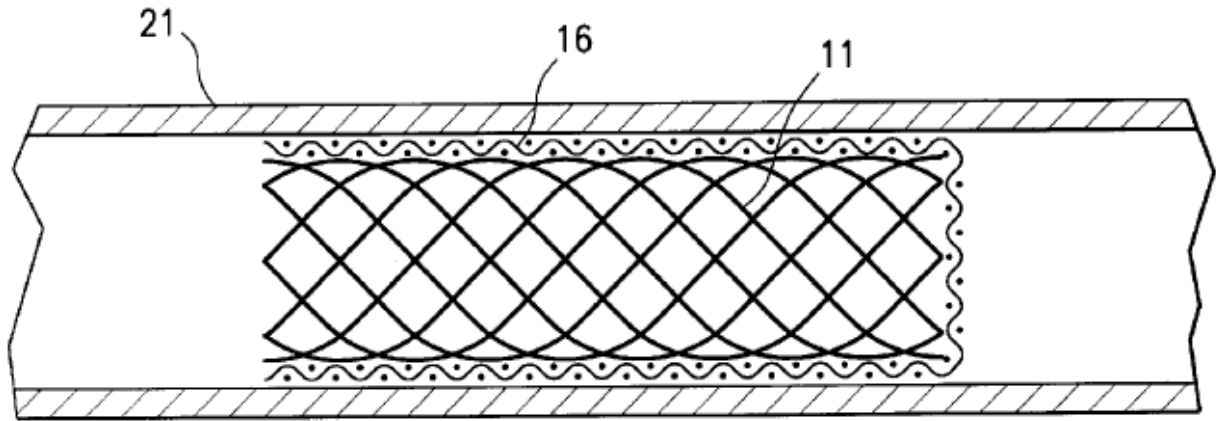
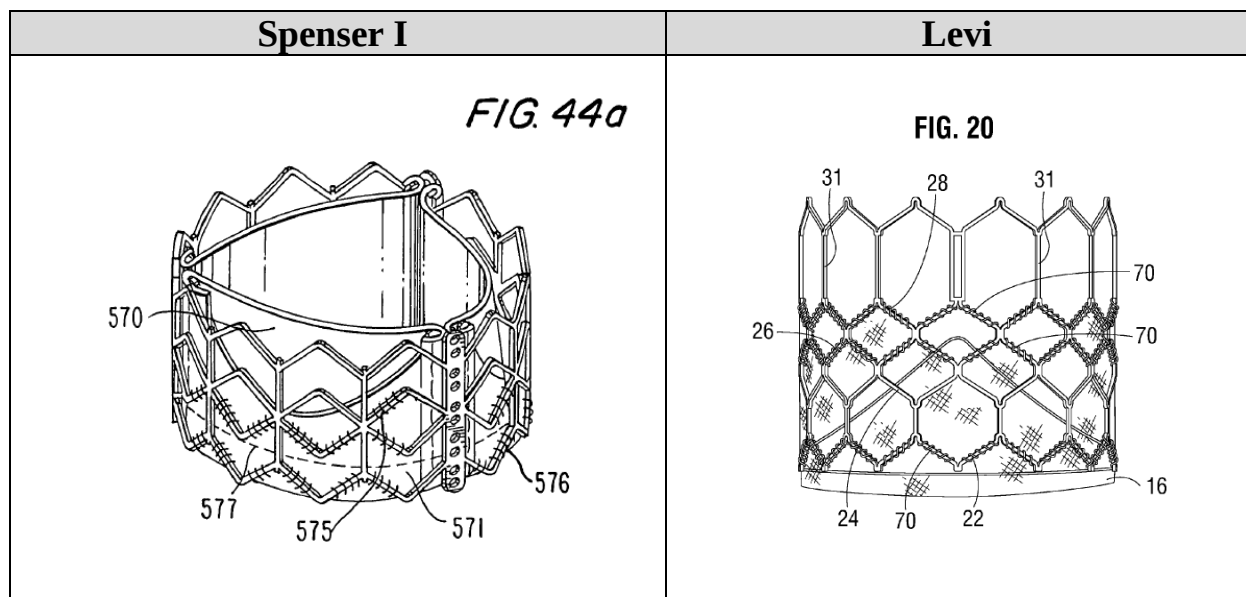


FIG. 11

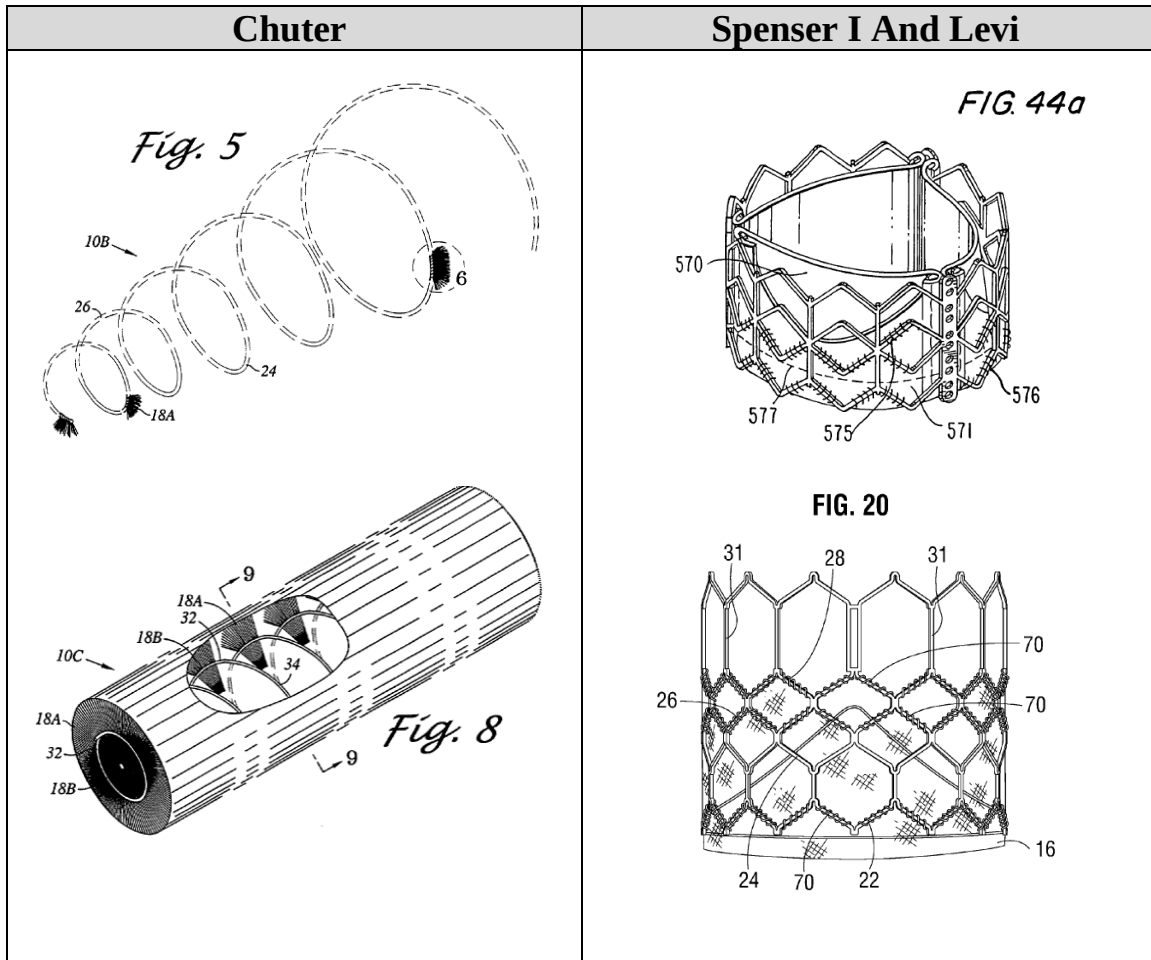
Ex. 2125 [Callister] Fig. 11, 1:26-30, 2:1-9, 7:13-16, 7:34-38, 8:4-9. In response to the Examiner's rejections of Chuter over Callister, Chuter's applicant explained that Callister's "braided tube" stent "is ***not relevant to the patentability of [the] claimed invention***" because "Applicant's stent is not a braided tube." Ex. 2126 [Chuter-FH] 140, 160.

135. Indeed, Chuter criticizes known stent grafts' "constant diameter cylindrical profile[s]" which "usually prevent[] the stent-graft from closing off the artery because of the surface irregularities commonly seen in the recipient artery which is already damaged" causing "gaps" and "leakage."[] Ex. 1116 [Chuter] ¶9. But such "open configuration," "braided"/"woven" or "lattice-like" stent frames

with a “constant diameter cylindrical profile,” are precisely what we see Spenser I’s and Levi’s frames:



Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20; *see also* Pet., 24 (“Spenser and Levi disclose ‘an outer frame formed from a metallic material and defining an open cell configuration.’”). These frames do not resemble Chuter’s helical loop stent of twisted wires:



136. The manifest differences between Chuter’s twisted wire helical loop frame and the relied-upon lattice-like frames distinguished in prosecution and disparaged in the specification would not motivate POSITAs to make the proposed combinations.

137. I further understand that Petitioner and Dr. Buller contend that Chuter teaches its fiber pile “can be adapted” to be compatible with “[v]irtually any expanding stent.” Pet., 70. I note that Petitioner further contends that “Chuter specifically identifies a variety of self-expanding and balloon-expandable frames that can be combined with the fiber pile ... Thus, while the preferred embodiment

in Chuter includes a double-wire frame, Chuter's invention is not limited to such frames and encompasses many frames." *Id.* I disagree.

138. Chuter's disclosure that "[v]irtually any expanding stent" is compatible with Chuter's fabric pile is expressly limited to Chuter's backing layer embodiments. Ex. 1116 [Chuter] ¶¶12-13 ("Virtually any expanding stent can be used ***in this embodiment.***"). Chuter does not suggest that "[v]irtually any expanding stent" is compatible with its embodiments without a backing layer. Indeed, in prosecution, Chuter's applicant clarified that the relied-upon occluder embodiments without a backing layer are a "different species" from Chuter's backing layer embodiments, and that Chuter's individual extending fibers being held between "twisted strands of the helical wire" was a "key element" of Chuter's invention. Ex. 2126 [Chuter-FH] 200, 144, 164-165. Thus, Chuter in no way suggests its occluding fibers without a backing layer could be added to either Spenser I or Levi's frame.

139. I am aware that Petitioner and Dr. Buller further contend "adding Chuter's fiber pile to Spenser's valves would merely entail applying Chuter's known technique for reducing leaks around a frame (adding a fabric pile) to Spenser's known frames" to "yield predictable results." Pet., 69. I am further aware that Petitioner relies on these same "reasons" regarding Levi. *Id.*, 71. But, as discussed, neither Spenser I nor Levi teach a frame comprising the helically

wound twisted wires required for the only attachment “method” taught for Chuter’s fabric pile without a backing layer.

b. *Petitioner’s Unspecified Modifications Are Insufficient To Show Its Combinations Meet Each Of The Claims.*

140. The claims require “[a] transcatheter heart valve assembly” that “is endovascularly deployed through a femoral artery of the patient.” Ex. 1001 [’033] cl. 1.

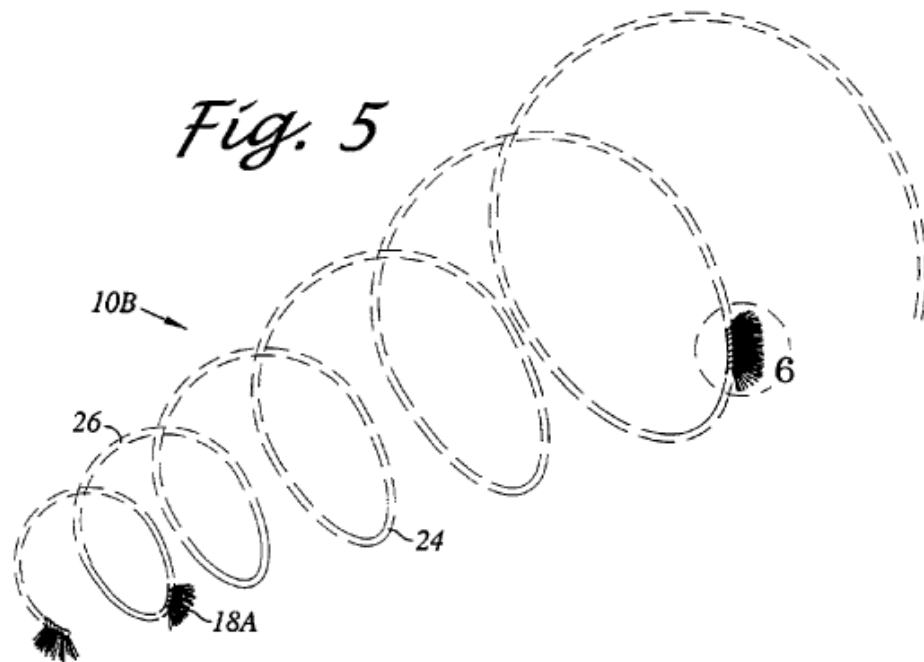
141. In my opinion, even if we assumed that a POSITA would be motivated to combine Chuter’s occluder embodiments with Spenser I or Levi, and even if we still further assumed that a POSITA would have a reasonable expectation of success in attaching Chuter’s individual fibers to the frame of Spenser I or Levi, Petitioner and Dr. Buller have still not shown that the resulting valve would be transfemorally deliverable.

142. I understand that Petitioner contends that a POSITA would be motivated to combine Chuter’s “fiber pile” with the frame of Spenser I or Levi to “prevent PVL.” Pet., 66, 69, 71, 77. I note that Petitioner argues that POSITAs would have reasonably expected Chuter’s fabric pile to [] compress when added to Spenser’s or Levi’s valve, allowing for continued endovascular delivery of the valve through the femoral artery.” Pet., 75-76. its “stents are compressed” when placed in a delivery catheter and “the ‘compression compresses the stent and

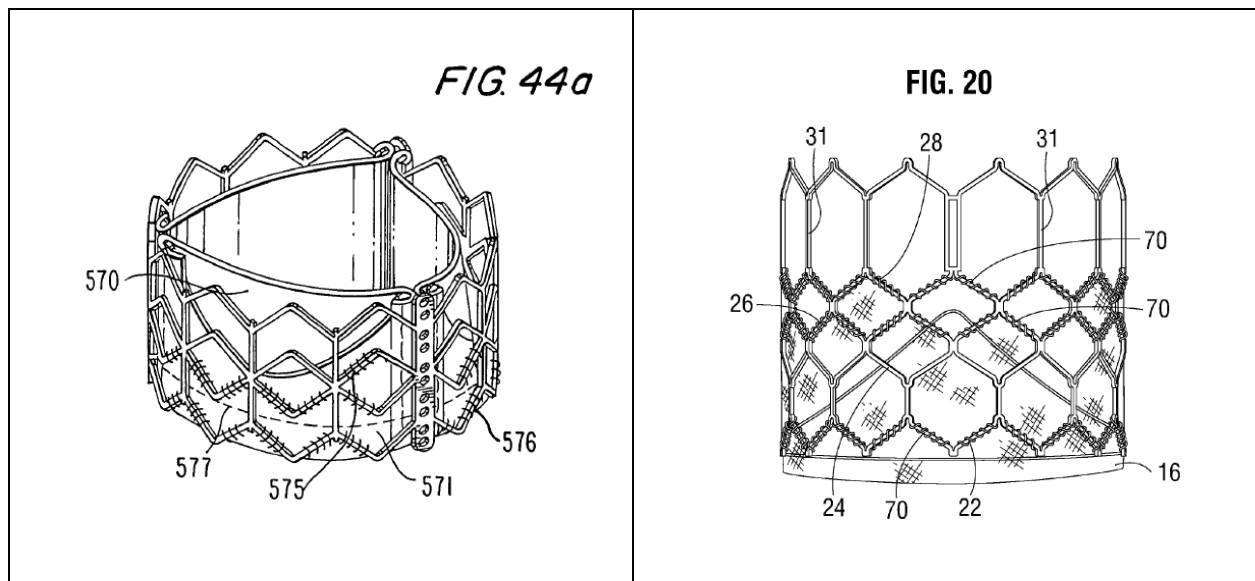
pushes down the fabric pile’ to allow for endovascular delivery.” *Id.*, 75 (citing Ex. 1116 [Chuter] ¶62).

143. Petitioner and Dr. Buller do not argue that Chuter’s occluding fibers could simply be added to the frame of Spenser I or Levi and the resulting combination would, without modification, be transfemorally deliverable. Rather, they contend a POSITA “would have understood that Chuter’s fiber pile could have been optimized for delivery through the femoral artery, such as by adjusting the lengths, densities, and distribution of fibers.” Ex. 1003 [Buller-Decl.] ¶212; Pet., 66, 69, 71, 77.

144. I agree that adding Chuter’s occluding fibers to the frame of Spenser I or Levi would not allow for transfemoral delivery. While Chuter’s occluder embodiments without a backing layer are, themselves, delivered endovascularly, Chuter’s dense fibers are accommodated via Chuter’s helical loop frame because, unlike the frame of Spenser I or Levi, there is no valve structure or graft covering housing the native leaflets within the stent to inhibit crimping:



Ex. 1116 [Chuter] Fig. 5. Spenser I and Levi, by contrast, do not just have a hollow frame but, also, a valve, leaflets, and inner skirt/graft that must be accommodated:



Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20.

145. Dr. Buller contends that the “lengths, densities, and distribution of fibers” could be altered to facilitate transfemoral delivery, (Ex. 1003 [Buller-Decl.] ¶212) but no specifics are proffered for what modifications would be made or how the resulting combination would still be transfemorally deliverable. Additionally, no explanation is given for how the so-modified combination would still be dense enough to prevent PVL.

146. I further note that, while there was a long-felt need for an endovascularly-deliverable TAVR with an effective seal against PVL, Petitioner has not presented any prior art reference disclosing a device comprising a sparse distribution of fibers extending from the frame to form an effective seal against PVL when the valve is expanded. Indeed, Dr. Buller and I were both unaware of any such prior art device with a sparse distribution of fibers like those shown in, *e.g.*, Fig. 9:

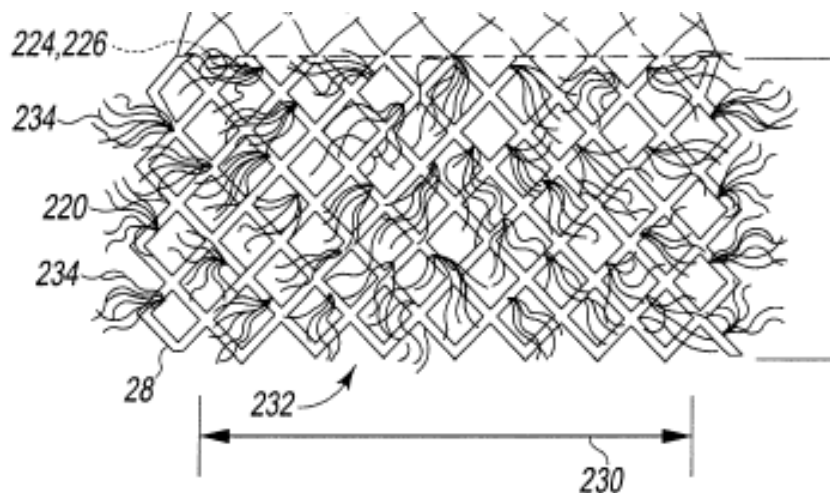


Fig. 9

Ex. 1001 ['033] Fig. 9; Ex. 2052 [Buller-00034-Depo.] 167:10-15, 169:5-25. And, as I have repeatedly testified, that such a sparse distribution of fibers, would form a seal when compressed within the body is an unexpected result. *Accord* Ex. 2103 [Brecker-556-Decl.] ¶160. I note that the Board has credited this testimony. Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar).

147. Nor, in my opinion, does Petitioner show that its Chuter occluder combinations would satisfy the claimed “spacings ... that allow fluid to pass [through]” the “sealing assembly” in “an undeployed state.” Ex. 1001 ['033] cl. 1.

148. I note that Petitioner contends its occluder combinations “disclose” this limitation because “spacings” are allegedly illustrated in Chuter’s Fig. 7. Pet., 76 (citing Ex. 1003 [Buller-Decl.] ¶216). Dr. Buller contends that “POSITAs would have understood” that “there would necessarily be spacings” allowing fluid to pass through the “sealing assembly.” Ex. 1003 [Buller-Decl.] ¶216.

149. As discussed, I have been informed by counsel and understand that inherency analysis applies to arguments about what a POSITA supposedly “would have understood” are not about what Chuter expressly discloses. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1066 (Fed. Cir. 2017); *see* Section VI.A.3(a), *supra*. I have also been informed and understand that demonstrating obviousness by inherency is a “high standard” and requires a showing that the limitation

“**necessarily** must be present.” *Par Pharm., Inc. v. Twi Pharms., Inc.*, 773 F.3d 1186, 1195-6 (Fed. Cir. 2014). Petitioner, however, fails to show this limitation is necessarily met in my opinion

150. I see no basis upon which to conclude that Chuter’s fibers would necessarily “allow fluid to pass therethrough” in “an undeployed state.” As noted, Chuter’s occluding fibers must have high density to plug the blood vessel, indicating Chuter’s fibers would not allow fluid to pass. This is further confirmed by Chuter’s inwardly-extending fibers (made of the same material as the outwardly-extending fibers), which must be densely arranged to “occlude the inner bore of the stent” and “plug” the blood vessel without pressing against any solid surface. See Ex. 1116 [Chuter] ¶¶18, 57. Again, in Chuter’s occluder embodiments without inwardly-extending fibers, the outwardly-extending fibers must be dense enough to achieve the same purpose.

151. Dr. Buller contends that POSITAs “**would have understood**” that, in Petitioner’s occluder combinations, “**there would necessarily be spacings ... that span at least the width of the open cells**” of the frame and “allow fluid to pass therethrough” due to the lack of a backing layer “traversing the openings between the struts.” Ex. 1003 [Buller-Decl.] ¶216. But, this does not account for Chuter’s densely arranged, outwardly-extending occluding fibers, which Petitioner identifies as “arcuate.” Such a dense arrangement of outwardly extending, “arcuate,” fibers

would be unlikely to “allow fluid to pass therethrough,” much less necessarily do so.

152. Thus, in my opinion, Petitioner fails to show that its proposed addition of Chuter’s individual extending fibers without a fabric pile backing to the frame of Spenser I or Levi would meet each of the claims. Rather, Petitioner’s analysis appears to be hindsight.

VII. CONCLUSION

153. 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:

- Petitioner and Dr. Buller’s proposed combinations of Spenser II with Spenser I or Levi do not disclose or render obvious a Petitioner and Dr. Buller’s proposed combinations of Spenser II with Spenser I or Levi do not disclose or render obvious “spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state...wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively

create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.”

- Petitioner and Dr. Buller’s proposed combinations of Chuter’s backing layer embodiments with Spenser I or Levi do not disclose or render obvious a Petitioner and Dr. Buller’s proposed combinations of Spenser II with Spenser I or Levi do not disclose or render obvious “spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state...wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.”
- Petitioner and Dr. Buller fail to show that a POSITA would be motivated to produce, with a reasonable expectation of success, their proposed combinations of Chuter’s occluder embodiments without a backing layer and Spenser I or Levi.
- Petitioner and Dr. Buller fail to show that their Chuter occluder combinations would satisfy each of the claims.

154. 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,

A handwritten signature in black ink that reads "Stephen Brecker". The signature is written in a cursive style and is underlined with a single horizontal stroke.

Dated: November 29, 2023

Stephen J.D. Brecker, M.D.

EXHIBIT A

C U R R I C U L U M V I T A E

STEPHEN JON DAVID BRECKER

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NATIONALITY : British
DATE OF BIRTH : 30th April 1960

GENERAL EDUCATION

1973-1978 University College School, London, UK

UNDERGRADUATE EDUCATION

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

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

CURRENT APPOINTMENTS

Consultant Cardiologist & Professor of Cardiology

St. George's University Hospitals NHS Foundation Trust,
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&

Mayo Clinic Healthcare, London, UK

PREVIOUS APPOINTMENTS

2023	Consultant Cardiologist, Mayo Clinic Healthcare, London
2016	Professor of Cardiology, St George's University of London
2015 – 2021	Chief of Cardiology, Clinical Academic Group St. George's University Hospitals NHS Foundation Trust, London, UK & St. George's University of London, UK
2006-2010	Care Group Lead - Cardiology
2005-2010	Director of Cardiac Catheterisation Laboratories
2005-2006	Clinical Lead, South West London Cardiac Network
1998-2020	Recognised Teacher of the University of London
1996	Consultant Cardiologist St George's University Hospitals NHS Foundation Trust, London, UK

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.

2001

SCIENTIFIC SESSION ABSTRACT GRADER

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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

British Society of Echocardiography

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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
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EXHIBIT B

Professor Stephen Brecker : Patent Expert Witness since 2018

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 & Patent Application

2022 White Swell v Abiomed USA – IPR

2023 Aortic Innovations v Edwards USA IPR & Patent Application & Trial

2023 Speyside v Medtronic - Trial