

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC**

Petitioners,

v.

AORTIC INNOVATIONS LLC

Patent Owner

Patent No. 11,497,634

**DECLARATION OF NIGEL BULLER, M.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,497,634**

<p><i>Edwards v. Aortic Innovations</i> U.S. Patent 11,497,634 Edwards Ex. 1003</p>
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1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“ Walther ”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	Reserved
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ Spenser ”)
1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
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1013	U.S. Patent No. 3,365,728 to Edwards et al.
1014	U.S. Patent No. 5,411,552 to Andersen et al.
1015	U.S. Patent Pub. No. 2003/0153974 A1 to Spenser et al.
1016	Reserved

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1017	Cheung, Anson, et al., <i>Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human</i> , Annals of Thoracic Surgery, 87:e 18-20 (2009).
1018	PCT Publication No. WO 98/29057 to Letac et al.
1019	U.S. Patent No. 6,893,460 B2 to Spenser et al.
1020-1021	Reserved
1022	Smith, Craig R., et al., <i>Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients</i> , 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)
1023	Webb, John G. and Binder, Ronald K., <i>Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches</i> , Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)
1024	Reserved
1025	Cribier, Alain, et al., <i>Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis</i> , 1006 Circulation 3006-3008 (December 10, 2002)
1026	U.S. Patent No. 7,393,360 B2 to Spenser et al.
1027-1029	Reserved
1030	Cribier, Alain, et al., <i>Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis</i> , 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031-1033	Reserved

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1034	Andersen, Henning, et al., <i>Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs</i> , European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.
1036	Nietlispach, Fabian, et al., <i>Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems</i> , Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Pub. No. US 2009/0281619 A1 to Le et al.
1038-1044	Reserved
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al.
1046	Preliminary Amendment for Patent Application No. 17/096,253 Submitted November 30, 2020
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	Reserved
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dkt. 1, Complaint (Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braidó et al.

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1072	Deposition Transcript of Stephen Brecker from August 30, 2022
1073	Deposition Transcript of Stephen Brecker from August 31, 2022
1074	U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)
1075-1105	Reserved
1106	Estridge, Trudy & Dale Feldman, <i>Quantification of Vascular Ingrowth into Dacron® Velour</i> , 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”)
1107	Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)
1108	Jonas, Richard A. et al., <i>Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments</i> , 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”)
1109	Ko, Frank K., <i>Fabrics</i> , Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”)
1110	Pourdeyhimi, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyhimi”)

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1111	Scott, Steward M. et al., <i>A Collogen Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)
1112	Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”)
1113-1115	Reserved
1116	U.S. Patent Pub. No. 2002/0151958 to Chuter (“ Chuter ”)
1117	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01527, Final Written Decision (“’172 FWD”)
1118	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584, Final Written Decision (“’011 FWD”)
1119	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00193, Final Written Decision (“’538 FWD”)
1120	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00034, Final Written Decision (“’846 FWD”)
1121	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2022-00549, Institution Decision from (“’735 Institution Decision”)
1122	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Dkt. 13, Second Amended Complaint (Apr. 10, 2023)
1123	Aortic Innovations LLC’s Disclosure of Asserted Claims and Infringement Contentions, C.A. No. 1-23--CV-00158 (JPM) (“PO Infringement Contentions”)
1124	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 PO’s Preliminary Response (“’011 POPR”)
1125	U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment

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1126	U.S. Pat. No. 4,739,762 to Palmaz
1127	U.S. Pat. No. 5,102,417 to Palmaz
1128	Deposition Transcript of Dr. Nigel Buller from November 11, 2022
1129	C. C. Chu, <i>Understanding Implantable Textiles</i> , Advanced Textiles Source (May 21, 2018) (“Chu”)
1130	“Distinct,” Merriam Webster Online Dictionary, <i>available at</i> https://www.merriam-webster.com/dictionary/distinct
1131	H.M. Russell et al., <i>Open Atrial Transcatheter Mitral Valve Replacement in Patients With Mitral Annular Calcification</i> , 72(13) J AMER. COLL. CARDIOL. 1437–48 (2018) (“Russell”)
1132	PTFE Felt, Medline, <i>available at</i> https://punchout.medline.com/product/PTFE-Felt/Surgical-Mesh/Z05-PF31252
1133	Deposition Transcript of Dr. Nigel Buller in IPR2017-00060 (June 15, 2017)
1134	U.S. Pat. No. 4,892,539 (“Koch”)
1135	U.S. Pat. No. 3,878,565 (“Sauvage”)
1136	Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”)
1137	U.S. Pat. Pub. No. 2005/0273155 (“Bahler”)
1138	U.S. Pat. Pub. No. 2012/0143324 (“Rankin”)
1139	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1:21-cv-01377-RGA, Dat. 83, Plaintiff Aortic Innovations’ Opening Claim Construction Brief (Nov. 21, 2021)

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1141	U.S. Pat. Pub. No. 2003/0023300 (“ Bailey ”)
1142	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2023-01151, PO’s Preliminary Response (“’834 POPR”)
1143	<i>Spacing</i> , Merriam Webster, <i>available at</i> https://www.merriam-webster.com/dictionary/spacing
1144	Reserved
1145	Declaration of Dr. Stephen J.D. Brecker Regarding Claim Construction submitted in Case No. 1-23-cv-00158 (D. Del.)
1146	Deposition Transcript of Stephen Brecker from February 8, 2023
1147	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Aortic Innovations LLC’s Identification of Preliminary Claim Constructions and Evidence (Oct. 13, 2023)
1148-1149	Reserved
1150	<i>Aortic Innovations LLC v. Edwards Lifesciences Corp.</i> , Case No. 1-23-CV-00158 (JPM), Aortic Innovations LLC’s LPR4-2(c) Disclosure (Dec. 11, 2023)

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

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, “Edwards” or “Petitioner”) to provide my opinion regarding the patentability of claims 1-7 and 9 of U.S. Patent No. 11,497,634 (“the ’634 patent”). For the reasons discussed herein, I have concluded that claims 1-7 and 9 of the ’634 patent are unpatentable because the prior art references render them obvious.

2. I understand that this Declaration supports Edwards’ Petition for the above-captioned *inter partes* review (“IPR”) of the ’634 patent. I have reviewed the Petition and agree with the unpatentability arguments contained therein.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any expert declaration(s) submitted on behalf of the owner of the ’634 patent, Aortic Innovations, LLC (“Aortic Innovations” or “Patent Owner”).

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation

in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

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

6. I am a retired Consultant Cardiologist. Until January of 2008, I was Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham, and the Lead Clinician for the Cardiac Catheterization Laboratories. The Cardiology Department at the Queen Elizabeth is one of the leading cardiology departments in the UK and one of only five centers in the UK that provides fully comprehensive adult cardiological services including interventional cardiology, electrophysiology, grown-up congenital heart disease, and heart transplantation. I have conducted or directly supervised more than 8,000 diagnostic and therapeutic non-surgical catheterization procedures since I was first appointed to a National Health Service consultant post in 1990.

7. During my medical training, I was awarded The John Mellanby Scholarship to fund an Intercalated Bachelor of Science degree. In 1977, I received a BSc (First Class Honours) in Physiology from the University of London. Modules included muscle physiology and biophysics at University College London (UCL), for which my tutor was the late Professor Andrew Huxley

FRS, and neurophysiology at the Sherrington School of Physiology, for which my tutor was Professor John Stephens.

8. Following my degree, I was awarded an MRC Training Fellowship to continue my research at UCL and submit a PhD thesis. However, I declined the offer and continued my clinical medical training. Nevertheless, during the three years of undergraduate clinical training I continued my research work in my spare time and, before qualifying in medicine, I had published some of the results of my research in both Nature and The Journal of Physiology. In 1980, I was awarded MB BS by St. Thomas's Hospital Medical School, University of London. In 1983, I became a member and, in 1996, I was elected a Fellow of the Royal College of Physicians in London.

9. I have held a number of positions within highly regarded cardiology departments in the UK.

10. From 1995 to 2010, I was Honoree Senior Lecturer in cardiovascular medicine at the University of Birmingham (UK).

11. From 1995 to 2008, I was employed full time at Queen Elizabeth Hospital, Birmingham.

12. From 1991 to 1995, I was Senior Lecturer in the Department of Interventional Cardiology and Cardiac Medicine at the National Heart and Lung

Institute in London, and Honorary Consultant Cardiologist at the Royal Brompton National Heart and Lung Hospital.

13. Before that, I was a Senior Registrar in Cardiology at Harefield Hospital, Middlesex, and the Royal Free Hospital, London and prior to that a Registrar at the National Heart Hospital, London.

14. From 1984 to 1986, I worked for Smith Kline & French Research Ltd, Philadelphia, USA, as a Research Physician and then as a project Chairman in Cardiovascular Drug Development.

15. My first formal postgraduate training in cardiology was at St. Thomas's Hospital and The Middlesex Hospital in 1981 and 1982, respectively.

16. During my years as a junior doctor, I trained in all aspects of cardiology but my interest developed in cardiac catheterization and non-surgical interventional cardiology. My mentor was the late Dr. Anthony Rickards who had performed the first successful coronary artery angioplasty in the UK in 1980. By 1990, I was considered fully trained in catheterization techniques and interventional cardiology including angioplasty and valvuloplasty.

17. In 1990, I was appointed to and, in March 1991, I took up the position of Senior Lecturer in Interventional Cardiology at the National Heart and Lung Institute in London and was the third consultant interventional cardiologist to join

Dr. Anthony Rickards and Dr. Ulrich Sigwart at the Royal Brompton National Heart and Lung Hospital, London.

18. I have routinely assessed and investigated patients suffering from valvular heart disease. Such investigations typically include electrocardiogram (ECG), chest X-ray (CXR), and echocardiography (a sonar examination to obtain detailed anatomical images and functional assessment of the heart and heart valves). These three tests are non-invasive and typically provide confirmation of the clinical diagnosis and allow selection of those patients that require further invasive investigation by means of diagnostic catheterization of the heart (passing flexible tubes through the veins and/or arteries and into the chambers of the heart) for hemodynamic (pressure and flow) measurements and angiography (injection of a radiopaque contrast media into the chambers and blood vessels of the heart so as further to document detailed anatomical and functional information on X-ray imaging). With this information it is then usually possible to determine the cause, the severity, and the options for treatment of a patients' heart valve disease.

19. My research interests have included the prevention, diagnosis, and treatment of heart disease and the development and clinical application of stents and especially coronary artery stents. I have been an investigator for many national and international scientific clinical trials.

20. My earliest “hands on” clinical involvement with stent implantation was in 1987 when working with the late Dr. Anthony Rickards when I assisted him with the first insertions of stents into human coronary arteries in the UK. Stents were difficult to obtain at the time and initially were only for use in situations of acute or threatened closure after balloon angioplasty. This early work was experimental in nature. I have since conducted large numbers of stenting implantation procedures with stents made by many different manufacturers. During 1991 to 1993, I was an investigator for the Benestent Trial (the major international multicenter “proof of concept” trial designed to demonstrate the benefit of elective stent placement over simple balloon angioplasty in the treatment of coronary artery disease), the results of which were subsequently published in the New England Journal of Medicine in 1994.

21. In 1993, Ulrich Sigwart and I were the co-investigators for the “First-in-Man” study of Guidant Corporation’s “Multilink Stent” that subsequently became the long-standing market leader for bare metal stents.

22. In 1994, I implanted the first drug coated stent in a patient in the UK. In the same year I was approved by the U.S. Food and Drug Administration (FDA) to act as a proctor to supervise and oversee the first elective implantations of coronary artery stents in the U.S. (an FDA requirement) following the FDA

approval of the Johnson & Johnson Palmaz-Schatz coronary artery stent. In this latter role I worked at more than fifty of the leading U.S. cardiology departments.

23. In 2013, I received hands-on training on the use and implantation of transcatheter heart valve (“THV”) technology at the New York Presbyterian Hospital.

24. Throughout my career I have had a close working relationship with the research and development departments in the medical device and pharmaceutical industries. I have served on the advisory boards for many of the major medical device manufacturers, including SCIMED, Boston Scientific, Medtronic, Cordis, and Guidant/Abbott.

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

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

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

C. Topics of Opinions

28. I offer opinions in this Declaration on the following general topics:

- The subject matter described and claimed in the '634 patent;
- The level of ordinary skill in the art pertaining to the '634 patent;

- The teachings of the prior art; and
- Whether claims 1-7 and 9 of the '634 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

29. I also provide background information on medical products and devices, including devices for replacing and repairing heart valves.

D. Materials Considered

30. In preparing this Declaration, I have considered the materials referenced in this Declaration and identified in the attached list of exhibits.

31. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '634 patent.

II. APPLICABLE LEGAL STANDARDS

32. I am a medical doctor by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training, and technical knowledge and experience to the evaluation of certain prior art with respect to the '634 patent.

33. Although I have been previously involved as a technical expert in patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of patent law applicable in this matter, which I have used in

arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

34. In determining whether a patent claim is unpatentable in view of the prior art, the Patent Office construes the claim by giving the claim its ordinary and customary (i.e., plain and ordinary) meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification and prosecution history.

35. I understand that Patent Owner has asserted in district court litigation that the claims of the '634 patent cover Petitioner's SAPIEN 3 Ultra valve. *See* Ex. 1122. My interpretation and application of the prior art herein is based on Patent Owner's assertions regarding the scope of the claims of the '634 patent. As I will explain throughout this Declaration, it is my opinion that if Patent Owner's assertion is correct and the claims of the '634 patent cover the SAPIEN 3 Ultra valve, then the claims would have been obvious in view of the prior art. However, none of my opinions herein should be construed as an agreement with Patent Owner's assertions regarding the scope of the claims with respect to the SAPIEN 3 Ultra valve. Additionally, none of my opinions herein should be construed as an agreement that the written description of the '634 patent adequately supports the claims.

B. Anticipation

36. I have been instructed that a claim is “anticipated” if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention.

37. I understand that an element is “inherent in,” and therefore taught by, the prior art, if it necessarily flows from the explicit disclosure of the prior art. The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed.

C. Obviousness

38. I have been instructed that a claim is “obvious” if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. An obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

39. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e., appropriate) prior art if it falls within the

field of the inventor's endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

40. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. Spenser, Spenser II, Birdsall, and Bailey are from the same field as the '634 patent, e.g., repair of heart valve disease, including minimally invasive cardiovascular devices for treating heart valves and methods of providing sealing for such devices. Chuter is from the related field of intravascular stents and is analogous art at least because, like the other references applied in this Declaration, it is pertinent to the problem the inventor was focused on, e.g., treating cardiovascular diseases through minimally invasive procedures and providing effective sealing around the devices used in such procedures.

41. To assess the differences between the prior art and the claimed subject matter, I have been instructed that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems

as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

42. I am also informed that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include:

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

43. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

44. I have also been informed that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

45. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a

teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that claims 1-7 and 9 of the '634 patent would have been non-obvious, as further explained in Section X below.

D. Person of Ordinary Skill in the Art

46. It is my understanding that when interpreting the claims of the '634 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the '634 patent is November 7, 2012. However, my opinions would not change if the relevant priority date were December 6, 2011 (the earliest filing date identified on the face of the '634 patent). I have been informed that all of the references relied upon in this Declaration qualify as prior art under either priority date.

47. I am informed 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. This is a person of ordinary creativity, not an automaton.

48. I am informed that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and

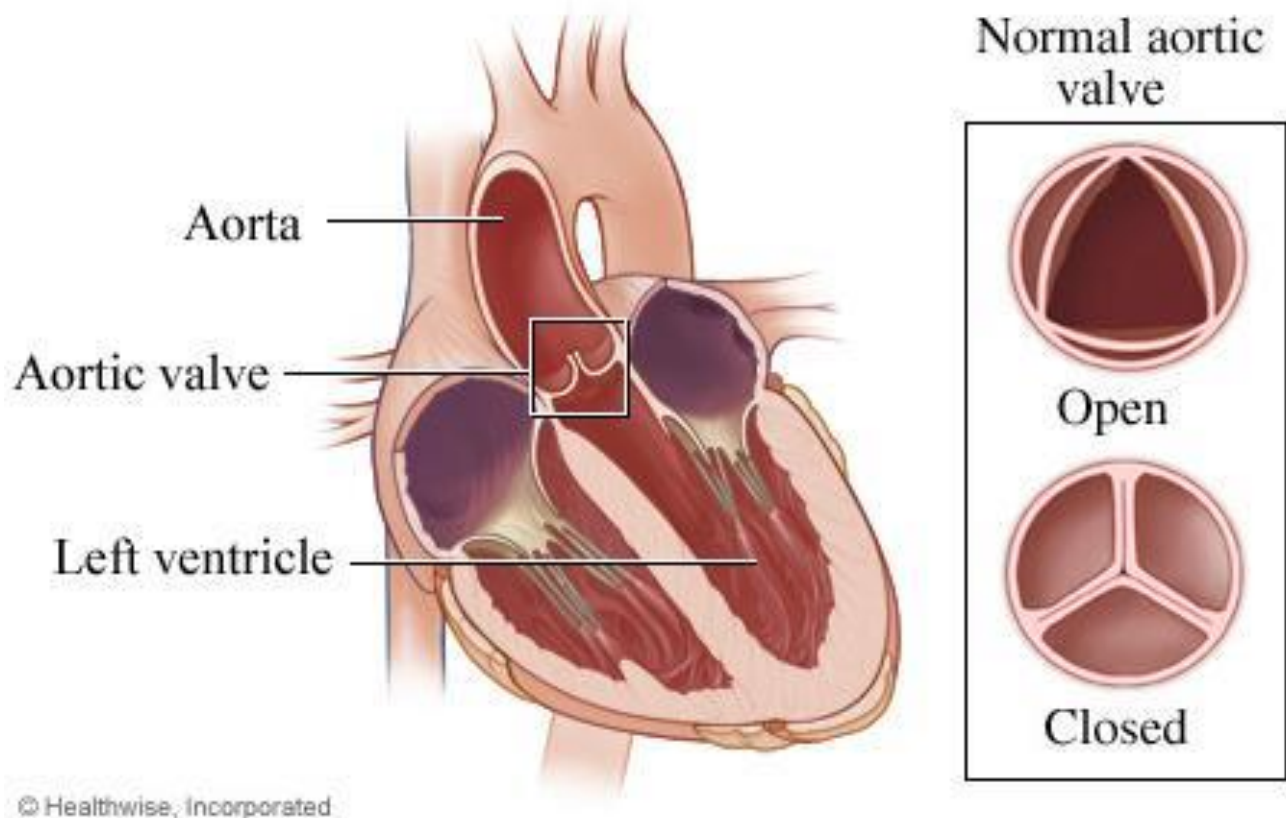
(v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

49. Based on my review of the specification and claims of the '634 patent, it is my opinion that a person of ordinary skill in the art 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.

III. BACKGROUND OF HEART VALVE TECHNOLOGY

A. Anatomy of the Heart and Background of Aortic Stenosis and Regurgitation

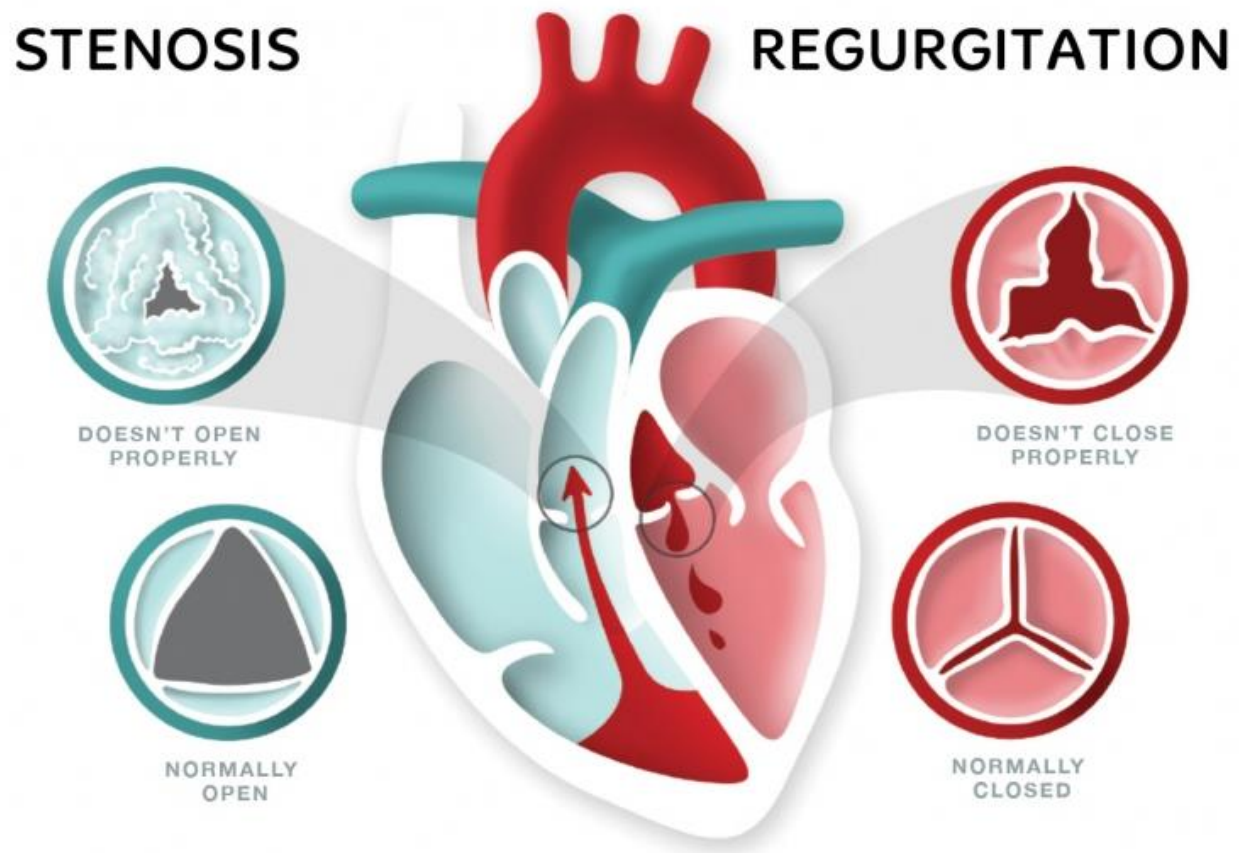
50. The human heart has two upper chambers, known as the left and right atriums, and two lower chambers, known as the left and right ventricles. The aortic valve connects the left ventricle with the aorta, the major artery that carries oxygenated blood from the heart to the rest of the body, on the left side of the heart. The aortic valve includes three leaflets that coapt and expand to operate as a one-way valve which regulates blood flow from the left ventricle into the aorta and prevents backflow of blood from the aorta to the left ventricle.



Available at: <https://www.uofmhealth.org/conditions-treatments/aortic-valve-disease>.

51. Aortic stenosis is a medical condition that occurs when the opening of the aortic valve is narrowed, often by excessive buildup of calcium deposits on the valve. This condition restricts the flow of blood through the aortic valve, which can have severe health consequences for the patient. Aortic regurgitation is another medical condition that occurs when the aortic leaflets fail to coapt properly, allowing blood to flow backward from the aorta into the left ventricle. Both aortic stenosis and regurgitation can cause the left ventricle to work harder to

pump the necessary amount of blood. Untreated, this can lead to cardiomyopathy (thickening of the heart muscle), irregular heartbeat, and even heart failure.



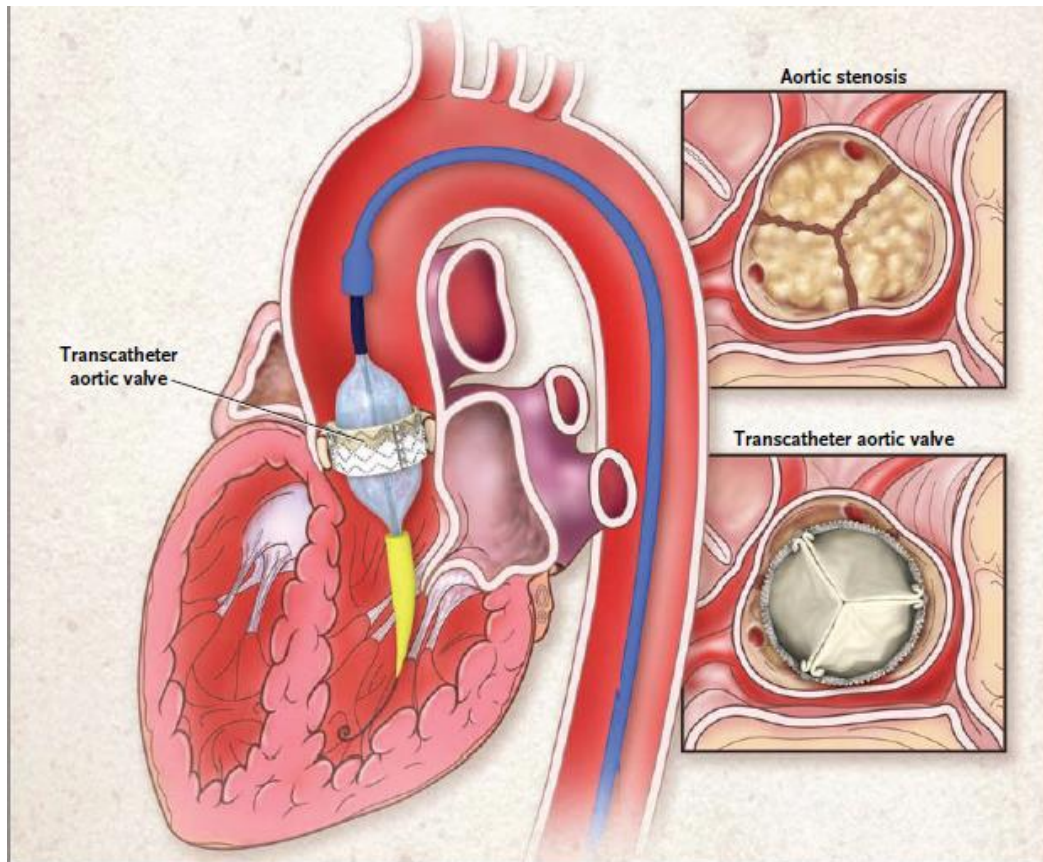
Available at <https://www.heartfoundation.org.nz/your-heart/heart-conditions/heart-valve-disease>. Although the above image illustrates stenosis and regurgitation on different heart valves, persons of ordinary skill in the art would understand that both conditions can occur on the aortic valve.

52. A common treatment for both aortic stenosis and aortic regurgitation is replacement of the diseased native aortic valve with a prosthetic heart valve. The prosthetic valve takes the place of the diseased native leaflets and acts to

regulate blood flow in a similar manner as a healthy native aortic valve. One of the key considerations for prosthetic aortic valves is ensuring an effective seal is created between the valve and the patient's native aortic tissue. Without such a seal, blood can leak between the prosthetic valve and the native tissue, causing potentially harmful paravalvular leakage ("PVL").¹ Untreated PVL can lead to the same undesirable health conditions as aortic stenosis and regurgitation. Early prosthetic valves addressed PVL with sewing rings that were attached to the native tissue by sutures. However, implanting these valves required invasive open-heart surgery, limiting the availability of the valves for severely ill patients. *Infra* §III.C.

53. To avoid the risks of open-heart surgery, minimally invasive THVs were developed that could be implanted through the patient's vasculature via a catheter. *Infra* §III.D. Rather than sewing rings, which required open-heart surgery and suturing the ring to the native tissue, THVs created a seal by pressing the exterior of the THV against the diseased native leaflets and surrounding tissue, as shown in the illustration of Petitioner's SAPIEN THV below:

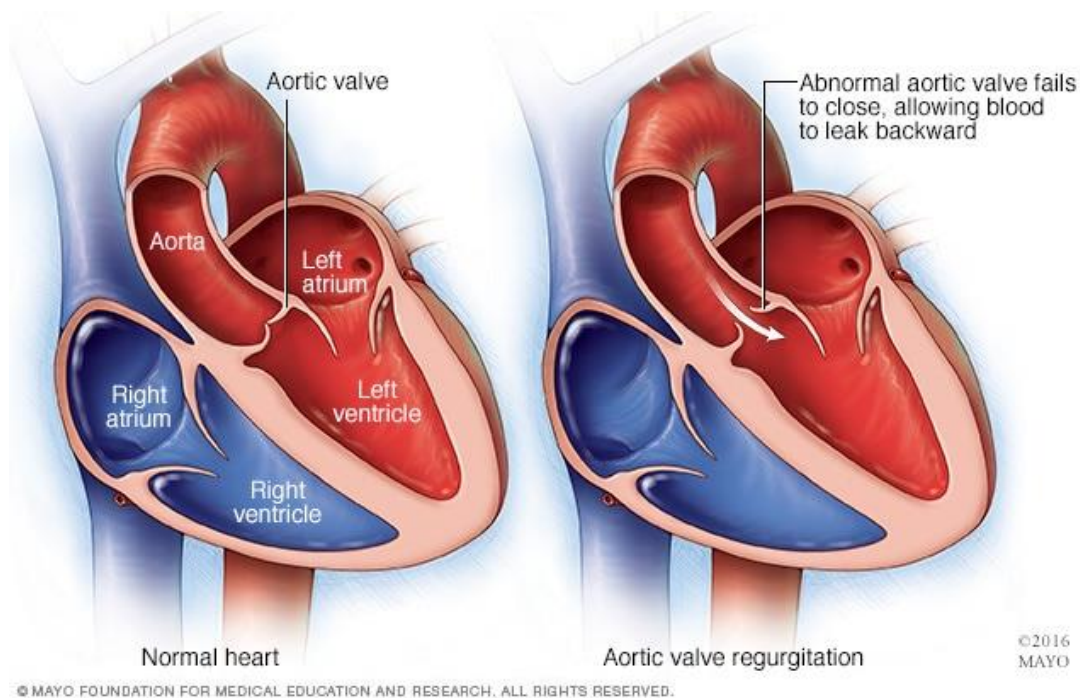
¹ "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



Ex. 1022 (Smith) at 2189, Fig. 1. Due to their minimally invasive implantation, THVs could be implanted in severely ill patients not eligible for open heart surgery, and they quickly became highly successful. Despite their success, however, the potential for PVL remained a major concern with THVs. As I discuss in detail below, this concern motivated those in the art, including Petitioner, to develop methods for minimizing PVL by creating more effective seals.

B. Anatomy of the Aortic Valve

54. As I noted in the prior section, the aortic valve lies between the left ventricle and the aorta. As shown below, the aortic valve leaflets extend distally (to use the terminology in the '634 patent) towards the aorta.



Available at: <https://www.mayoclinic.org/diseases-conditions/aortic-valve-disease/symptoms-causes/syc-20355117#dialogId16413996>.

55. The claims of the '634 patent state that “wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings.” See *e.g.*, Ex. 1001 ('634 patent) at claim 1. As described below, persons of ordinary

skill in the art would have understood that if the fibers press against the annulus of the aortic valve, they must also press against the leaflets.

56. The '634 patent identifies the annulus (identified by item #210) as the crown-like structure where the aortic valve leaflets attach to the left ventricle:

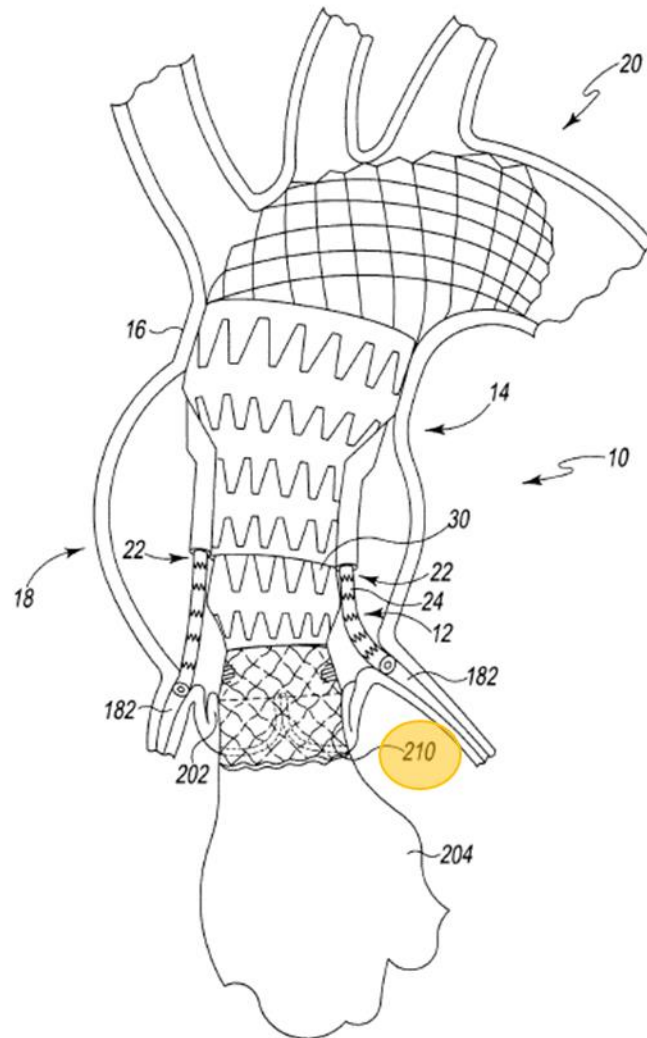
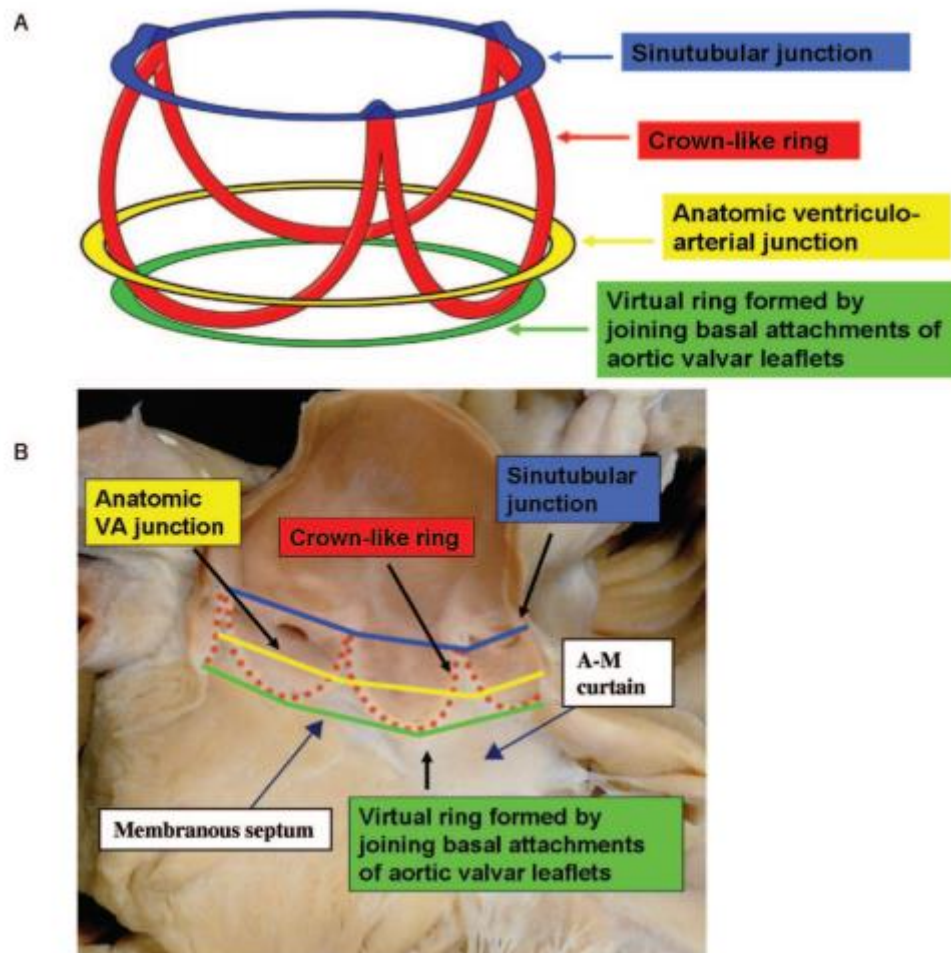


Fig. 2

See e.g., *id.* at Fig. 2.² This is further confirmed by the '634 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valsalva, the sinutubular junction, and the tubular portion." *Id.* at 1:66-2:1. The below image from a prior art journal article reflects the structure of the aortic valve. What the '634 patent identifies as the annulus 210 corresponds to the red crown-like ring illustrated below.



² All colors and annotations to patent figures and other figures/images herein have been added by myself and Petitioner, unless expressly noted otherwise.

Ex. 1047 (Piazza) at Fig. 4. Because the “annulus” referred to in the ’634 patent is the crown-like ring where the leaflets begin, a person of ordinary skill in the art would have recognized that fibers pressing against the annulus must also press against the valve leaflets. *Id.* at 76. The journal article confirms this to be the case.

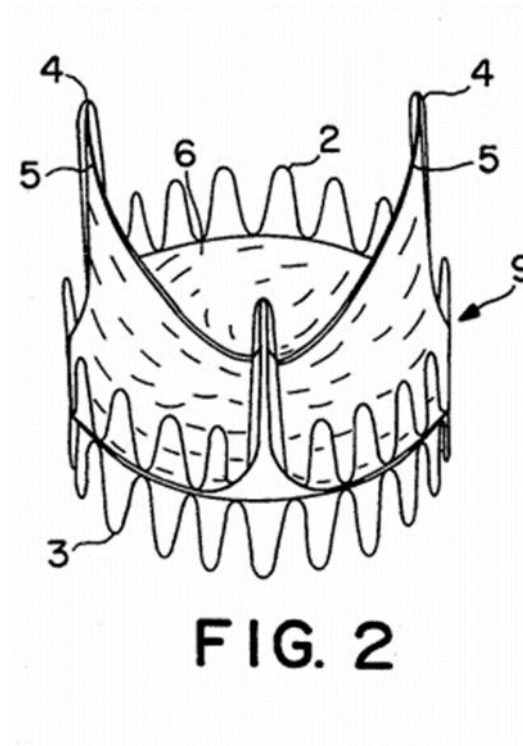
C. Transcatheter Heart Valve (“THV”) Technology

57. THV technology is aimed at providing a patient with a permanently implanted prosthetic heart valve that can be delivered via a catheter.

58. In 1989, Danish doctor Henning Rud Andersen conceived of the seminal invention of a permanently implanted transcatheter bioprosthetic heart valve. That year, Dr. Andersen and his colleagues, Drs. Michael Hasenkam and Lars Knudsen, built the first prototype by hand. The Danish team successfully implanted its prototype in pigs using a catheterization procedure.

59. The Danish team published their results in 1992. **Ex. 1034** (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)). There, Drs. Andersen, Hasenkam, and Knudsen described their handmade THV, which included “a foldable biological cardiac valve inside a balloon expandable metallic stent.” *Id.*

60. The Danish team's work also led to several patents, including U.S. Patent No. 5,411,552 ("Andersen patent"). (**Ex. 1014**).



Id. at Fig. 2. The Andersen patent describes multiple THV embodiments that expand upon the inventors' early prototypes, including embodiments having additional tubular graft material that can be used along the surface of the THV. *Id.* at 2:21-27, 2:56-60, 4:3-17, 5:9-28, 7:17-29, Figs. 11-12 ("[T]he stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted.").

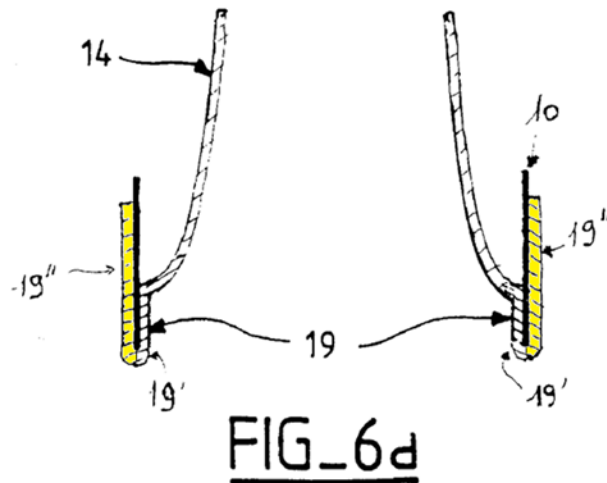
61. In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s. These designs provided the basis for a

December 1996 patent application. A family of patents and patent applications stems from this 1996 application, including WO 98/29057 to Letac et al. (“Cribier patent publication,” **Ex. 1018**).

62. This patent publication aims to improve upon the THV technology described in the Andersen patent discussed above. The Cribier patent publication notes that an “aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular in a stenosed aortic orifice, taking advantage of the strong structure made of the distorted stenosed valve and the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure.” *Id.* at 5:11-16.

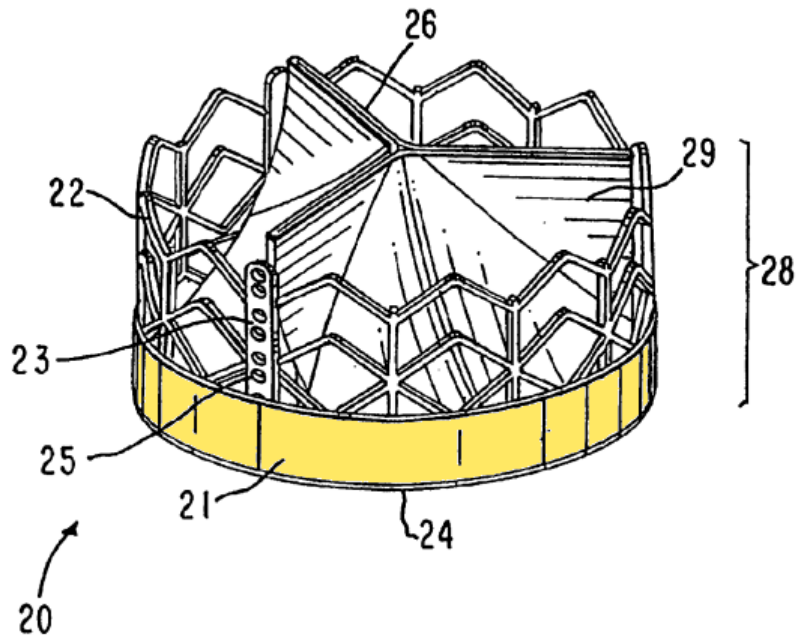
63. Further aims of the Cribier patent publication include providing a THV frame structure capable of withstanding the recoil forces of the native aortic valve in treating aortic stenosis and providing a THV with a frame covering that “prevent[s] any passage of the body fluid through said frame.” *Id.* at 5:6-10, 8:28-9:6; *see also id.* at 5:17-18, 20:26-21:3, 22:11-20.

64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then “rolled up to be applied to the external wall of the stent” to form an external cover [19"]:



Id. at 22:23-26, Fig. 6d. The single-piece cover is a tubular structure that can be made with any of the materials disclosed for making the valve structure, which include fabric (*e.g.*, Dacron), biological material (*e.g.*, pericardium), or other synthetic materials (*e.g.*, polyethylene). *Id.* at 8:16-23, 22:11-20. The Cribier patent publication discloses multiple ways of securing the cover to the frame. Specifically, the cover can be secured to the frame “at various points of attachment on various parts of the internal [and external] surface” by suturing, molding, gluing, or soldering the cover to the bars of the frame and, in its expanded state, would prevent blood from flowing between the cover and heart tissue. *Id.* at 22:23-26, 23:15-16, 24:24-27, Fig. 6d; *see also id.* at 23:12-24:23, Figs. 7, 8a-b.

65. In 2001, a company named Percutaneous Valve Technologies (“PVT”), which was co-founded by Dr. Cribier and three others (Stan Rowe, Stan Rabinovich, and Dr. Martin Leon), filed a patent application on another THV design that included an external cover:

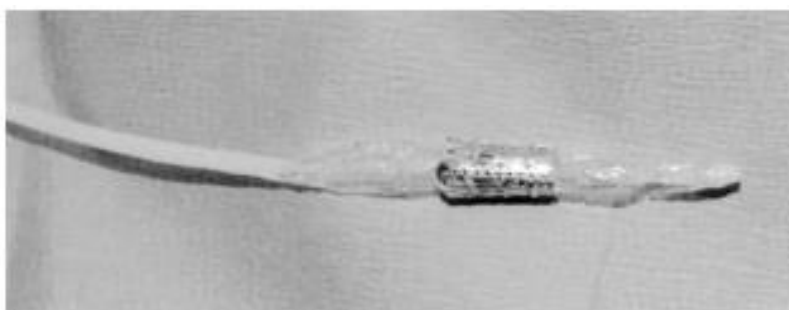


Ex. 1019 (U.S. Patent No. 6,893,460 B2 to Spenser *et al.* (“’460 patent”)) at Fig. 1. The ’460 patent discloses a THV having a tricuspid valve, a support stent including support beams for securing the commissures of the valve, and a cuff portion wrapped around the support stent at its inlet. *Id.* at 9:1-22, Fig. 1. The ’460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a “sleeve-like” portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* (“To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet.”). The cuff portion can be formed with PET (Dacron) fabric. *See id.* at 7:7-10, 10:57-11:10 (“Figs. 8a and 8b demonstrate a method of manufacturing a composite valve, which is based on flexible PU 92 as

the main body of the valve, rigid PU support beams 94 serving for the attachment area, and PET sleeve 96 portions for the valve inlet.”).

66. Edwards’s U.S. Patent No. 7,510,575 (referred to herein as “**Spenser**,” **Ex. 1010**), claims priority to the ’460 patent and includes the THV embodiment having an outer cuff. **Ex. 1010** at 13:4-25, claim 31, Fig. 1.

67. In April 2002, using a THV developed by PVT, Dr. Cribier performed the first-in-human implantation of a THV in the aortic valve position. **Ex. 1025** (Cribier, Alain, et al., *Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis*, 1006 Circulation 3006-3008 (December 10, 2002)).³ The THV consisted of three bovine pericardial leaflets mounted within a tubular, slotted stainless-steel balloon-expandable stent that was crimped onto a delivery balloon:



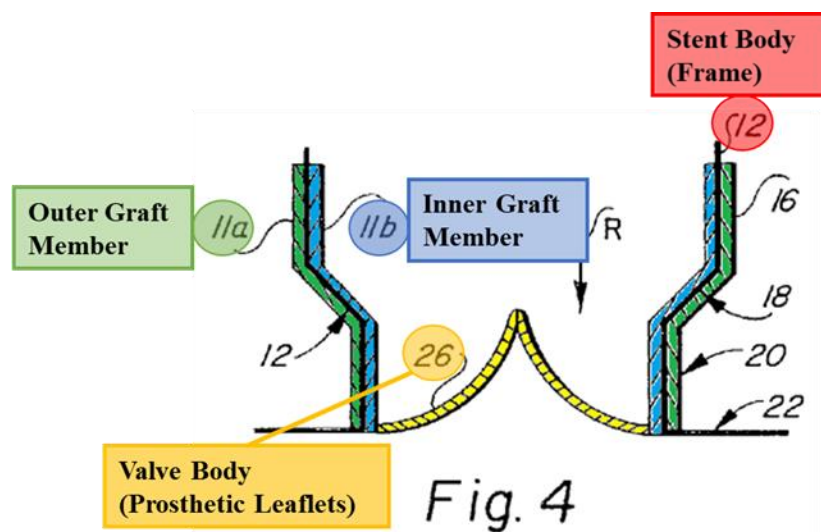
Id. at 3006, Fig. 1. Dr. Cribier implanted the THV using an antegrade approach from the right femoral vein. *Id.* at 3007. Dr. Cribier inserted a 24F sheath into the

³ Dr. Cribier uses the phrase “percutaneous heart valve” or “PHV” to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

right femoral vein. The THV was “easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic valve.” *Id.* The balloon was then inflated to place the THV. *Id.* Dr. Cribier concluded that the implantation was successful and demonstrated “the feasibility of implanting a prosthetic heart valve percutaneously, with the use of standard interventional techniques, within the native diseased valve of a patient with calcific aortic stenosis.” *Id.* at 3008. Dr. Cribier continued to successfully use this implantation procedure in later patients. **Ex. 1030** (Cribier Early Experiences). From April 2002 to August 2003, Dr. Cribier attempted THV implantation in six patients. *Id.* at 699. The THV “was successfully and accurately delivered in the subcoronary position in all but one patient.” *Id.* at 700. Dr. Cribier used the “anterograde trans-septal approach” for all cases. *Id.* at 701. Dr. Cribier’s work confirmed “that a bioprosthetic valve can be implanted percutaneously within the native diseased stenotic aortic valve of patients with end-stage life-threatening calcific aortic stenosis, using standard interventional techniques under local anesthesia.” *Id.*

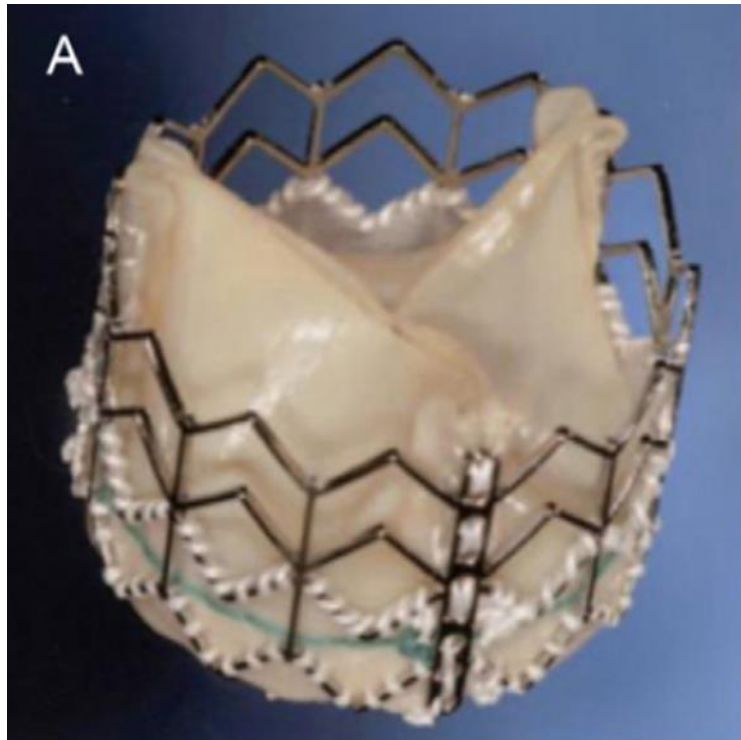
68. In September 2002, Steven Bailey and Christopher Boyle filed U.S. Patent App. No. 10/260,205 which was published on January 30, 2003 as U.S. Pub. No. 2003/0023300 (“**Bailey**”). **Ex. 1142 (Bailey)**. Bailey discloses embodiments of prosthetic heart and venous valves that can be implanted percutaneously, including embodiments of the valve in “a chamber-to-vessel (CV) configuration

which is particularly well-suited as an aortic valve prosthesis to facilitate blood flow from the left ventricle to the aorta.” *Id.* at Abstract, [0002]. Bailey’s chamber-to-vessel THV includes “an expandable stent body member 12 and graft member 11.” *Id.* at [0048]. “The graft member 11 consists of an outer or abluminal graft member 11a and an inner or luminal graft member 11b.”



Id. at [0049], Fig. 4. Bailey’s stent body member “is formed of a plurality of stent struts 13 which define interstices 14 between adjacent stent struts” and “is configured to have three functional sections: a proximal anchor flange 22, an intermediate annular section 20 and a distal anchor section 16.” *Id.* at [0048]. Bailey’s Figures 1 and 4 disclose an embodiment where the inner and outer graft members extend over sections 16, 18, and 20 of the frame, but **not** the proximal apices:

pericardium, with the inflow covered with a fabric sealing cuff (Fig. 3A).” *Id.* at 154.



Id. at Fig. 3A.

70. In 2004, Edwards filed a patent application that formed the basis for PCT Patent Publication WO 2006/005015 A2, referred to herein as **Spenser II (Ex. 1011)**. Spenser II “provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis itself.” *Id.* at [0014]. Figure 22 (below) “illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible

material, such as a cloth material, is provided along an exterior surface of a stented valve.” *Id.* at [0085].

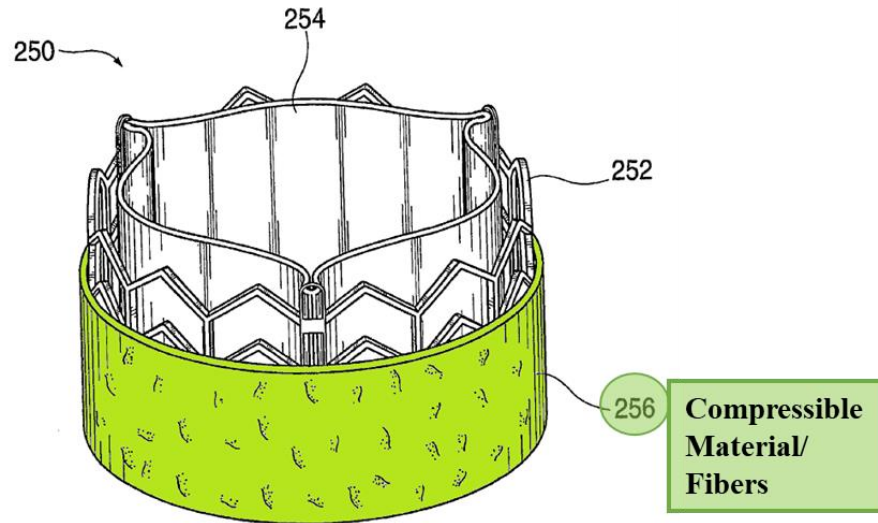


FIG. 22

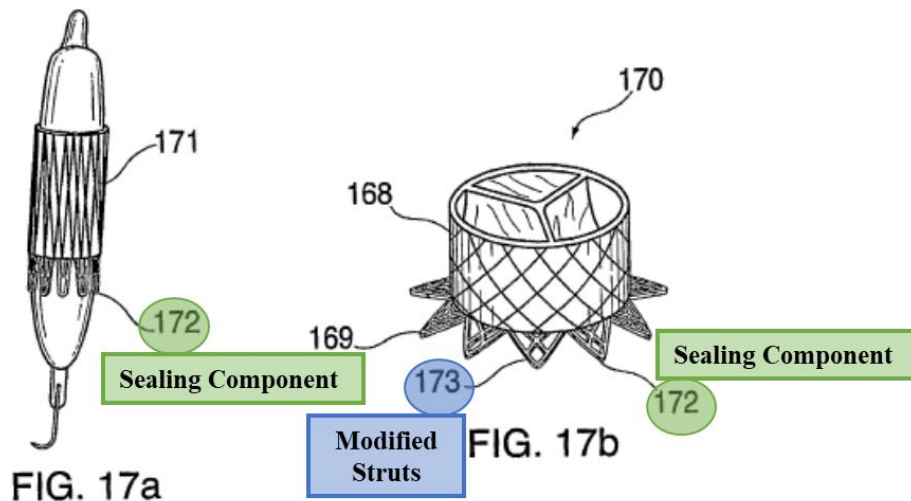
Id. at Fig. 22. As shown, “a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.” *Id.* at [00145]. The material “may extend entirely around the stent structure, such as in the form of a sleeve.” *Id.* “In one preferred embodiment, the compressible material is formed from polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.” *Id.* “In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped” and are illustrated as having different lengths. *Id.*

71. Spenser II explains that the purpose of the compressible material is “to reduce or prevent paravalvular leakage.” *Id.* Spenser II states:

The compressible material expands after deployment at the treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps.”

Id.

72. In addition to the embodiment shown in Figure 22, Spenser II describes several other embodiments and solutions for addressing paravalvular leak, including the embodiment depicted in Figures 17a-e. Figures 17a-e show a “valve adapted to seal paravalvular leaks” by using a “sealing component [that] is built into a ring 172 of the stent struts” at the proximal end of the frame as shown below:



Id. at [00136], Figs. 17a-b. Spenser II explains that the “modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.” *Id.* at [00136]. A person of ordinary skill in the art would have found it obvious to combine the compressible material of Figure 22 with a frame having the ring in Figures 17a-17e. Notably, the embodiments illustrated in both figures have similar frames and are both intended to provide enhanced sealing and prevent paravalvular leak. The similar aspects of each embodiment would have encouraged a person of ordinary skill in the art to combine the features of both embodiments.

73. Edwards did not merely patent THVs having outer sealing materials. Edwards also worked with clinical groups on both sides of the Atlantic to add an

outer cloth to the external surface of a THV frame. In 2008, Edwards collaborated with Dr. Anson Cheung and other physicians to develop and test “a cuffed, 26-mm Cribier Edwards transcatheter valve.” **Ex. 1017** (Cheung, Anson, et al., *Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human*, *Annals of Thoracic Surgery*, 87:e 18-20 (2009)) at e18.



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

Id. at Fig.2. Dr. Cheung implanted the cuffed Cribier-Edwards valve within a patient’s existing mitral bioprosthesis (Carpentier-Edwards PERIMOUNT Plus 6900P valve) using a transapical approach. *Id.* at e18. In the transapical approach,

the valve is inserted through the patient's heart wall. Dr. Cheung and his team "used a cuffed device for the valve-in-valve implant to provide a better seal within the rigid support ring, minimizing paraprosthetic leak." *Id.* at e19.

74. Similarly, in 2010, Dr. Thomas Walther and several Edwards engineers conducted a valve-in-valve study "focused on the use of an Edwards SAPIEN trans-catheter heart valve (THV) cloth valve (see Fig. 1), which is identical to the SAPIEN, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve." **Ex. 1007** (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)) at 1120.

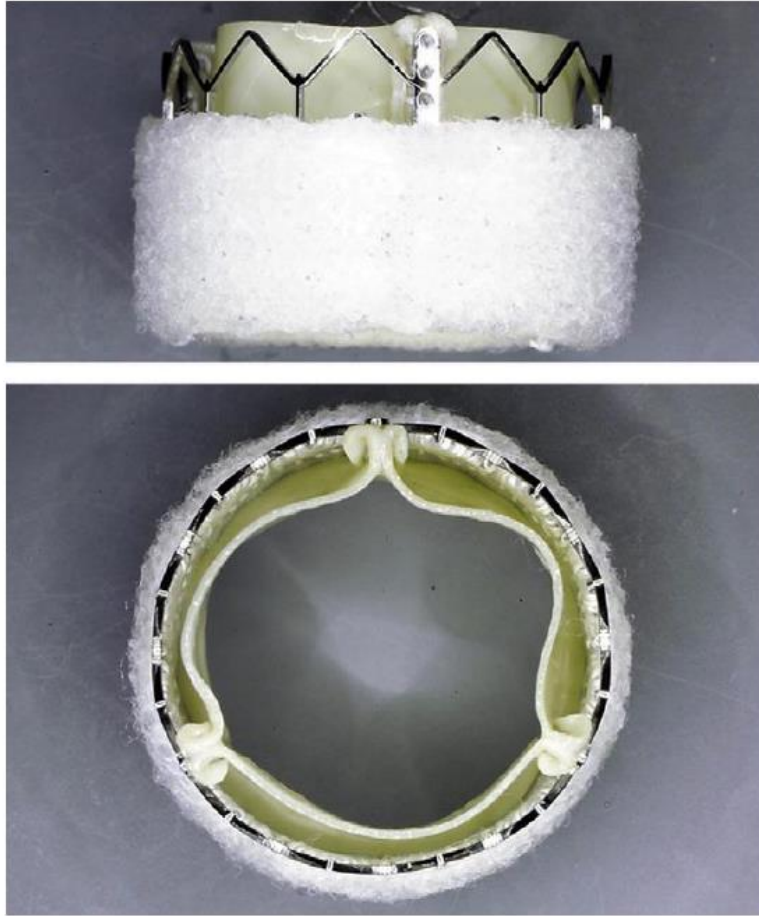
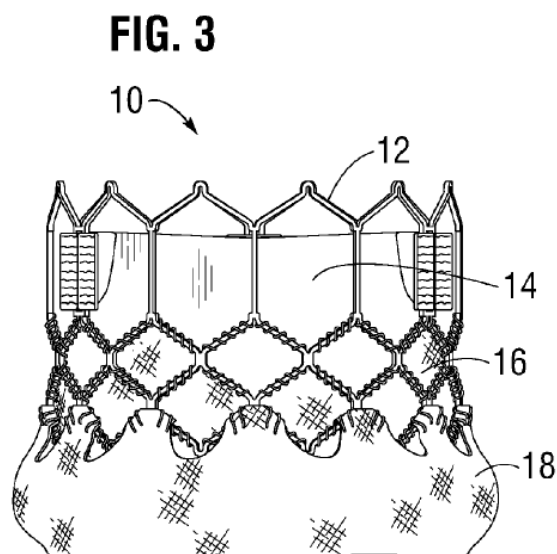


Fig. 1. Cloth valve.

Id. at Fig. 1. Edwards had developed the SAPIEN valve as the follow-up generation to the Cribier-Edwards valve. See **Ex. 1023** (Webb) at 154. The Walther team explained that the “addition of an outer cloth to the SAPIEN cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better ‘fit’ within surgical Perimount valves.” Ex. 1007 (Walther) at 1120. The team concluded that the “SAPIEN + cloth THV implanted valve-in-valve within the CEP valve

demonstrated excellent hydrodynamic performance.” *Id.* at 1125. The team also concluded that an *in vivo* procedure “is feasible.” *Id.*

75. In October 2010, Edwards filed a provisional patent application that matured into U.S. Patent No. 9,393,110 B2, referred to herein as “**Levi**” (**Ex. 1008**). Levi discloses a THV with “four main components: a stent, or frame, 12, a valvular structure 14, an inner skirt 16, and an outer skirt 18”:

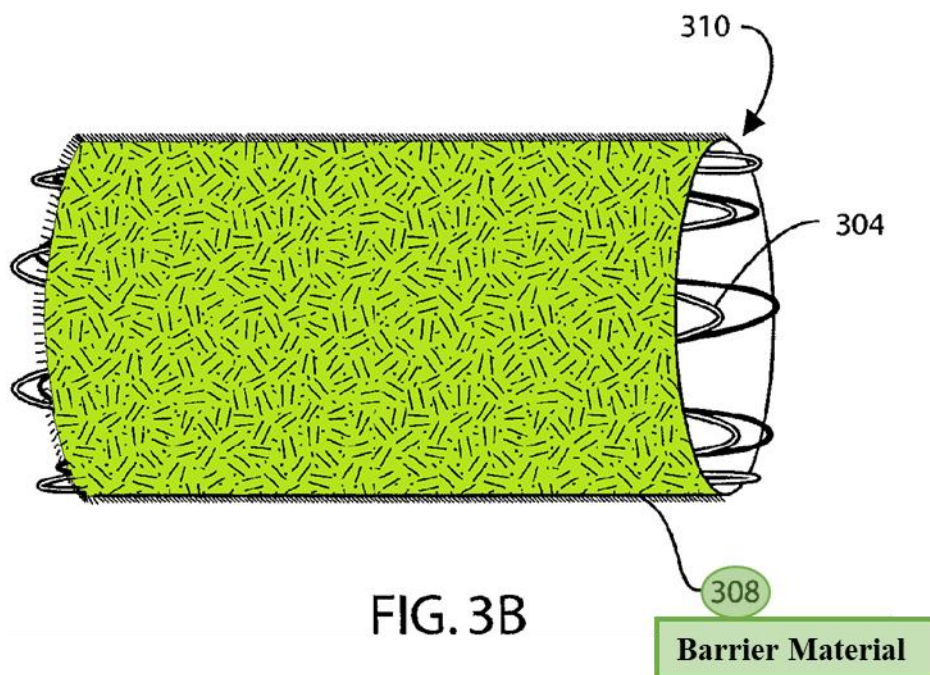


Id. at 5:52-58, 6:12-24, 9:7-35, 13:49-14:14, Figs. 1-3, 41-43. “The outer skirt 18 can be laser cut or otherwise formed from a strong, durable piece of material such as woven PET, although other synthetic or natural materials can be used.” *Id.* at 13:49-53. “[W]hen the valve 10 is deployed within the body, the excess material of the outer skirt 18 can fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” *Id.* at 14:3-7. “The outer skirt 18 therefore cooperates with

the inner skirt 16 to avoid perivalvular leakage after implantation of the valve 10.”

Id. at 14:7-9.

76. Persons of ordinary skill in the art were also aware of fibrous outer sealing materials to prevent paravalvular leakage when replacing valves other than the aortic valve. For example, Birdsall, a patent filed in 2006 discloses the use of a fibrous outer seal in a prosthetic valve implanted within a vascular conduit and for “replacing a pulmonary valve.” Ex. 1057 (Birdsall) at Abstract, 3:6-10. Birdsall teaches that its valve may be covered with a “barrier material 308” that “comprises directionally oriented microfibers . . . extending outward” that “contact the interior wall of the conduit and form a barrier that prevents blood from flowing around stented valve 310, between the outer surface of the stented valve and the inner wall of the conduit”:



Id. at 6:9-33, Fig. 3B. As shown above, Birdsall's barrier material does not cover the apices at either end of the frame. *Id.* While Birdsall discloses implanting this embodiment within a "lumen or conduit," including the pulmonary valve, Birdsall's teaching of extending fibers to form a seal is broader and is not limited to this context. *Id.* at 3:6-10, 6:4-37. For example, Birdsall broadly discloses that its "invention relates generally to medical devices for treating cardiac valve abnormalities." *Id.* at 1:7-10. And Birdsall further discloses that "[o]ne embodiment of a stented valve suitable for use in the present invention is disclosed in U.S. Pat. No. 5,957,949 titled 'Percutaneous Placement Valve Stent' to Leonhardt, et al.," and incorporates the '949 patent by reference. *Id.* at 5:65-6:3. The '949 patent incorporated by Birdsall discloses that its stented valves are suitable for replacing a patient's aortic valve via transfemoral delivery. *See* Ex. 1035 (Leonhardt) at 9:63-10:21, Fig. 3. Persons of ordinary skill in the art would therefore have understood that a fibrous material like Birdsall's "barrier material" would perform a similar sealing function when implanted in other valves, including the aortic valve. *Infra* ¶¶151-153, 200. Indeed, like the other THVs discussed above, Birdsall's valve is also designed for transfemoral implantation into the patient's native aortic valve. *See* Ex. 1057 (Birdsall) at 2:33-39, 5:65-6:3; Ex. 1035 (Leonhardt) at 9:63-10:21, Fig. 3.

77. The Norris patent, which issued in April 2011, discloses another type of outer sealing material suitable for use in a heart valve or a stent graft. **Ex. 1074** (Norris) at 9:18-22. Norris teaches embodiments of:

a compressible resilient fabric 10 can include a ground layer 20 of knitted yarn, and a loop layer 30 comprising a plurality of loops 32 of yarn 31, each loop 32 having a point 33 knit into the ground layer 20. The fabric 10 can be compressible from a non-compressed configuration 40, in which each loop 32 has an apex 34 extending substantially perpendicularly outward 42 from the ground layer 20, into a compressed configuration 41, in which each loop 32 is collapsed onto the ground layer 20.

Id. at 4:22-31. Norris further teaches that:

In the non-compressed configuration 40, some embodiments of the fabric 10 can have a thickness 43 of about 1-5mm. In the compressed configuration 41, some embodiments of the fabric 10 can have a thickness 44 of about 0.004-0.008 inches. Thus, some embodiments of the fabric 10 can be compressed into a very thin profile for insertion to a target site in a location in a body. . . .

Id. at 4:54-60. Norris discloses that one means of achieving this compressibility is by providing a porous ground layer “that can provide some space into which the loops 32 can be compressed.” *Id.* at 8:45-48. Norris discloses that its compressible fabric can be used to seal cardiovascular devices, including heart valves:

As shown in FIGS. 3 and 4, the implantable device 50 and the inner member 51 can be tubular in shape. Such tubular embodiments can be utilized in cardiovascular applications, such as with a heart valve or stent-graft. In such applications, the intraluminal sealing member 52 can be formed, wrapped, or attached about the radially expanding inner member 51. In this manner, when the device 50 is implanted in a

target location, flow of blood between the exterior of the device 50 and the wall of the vessel can be restricted and/or prevented. When the device 50 is radially expanded, there can be gaps and/or voids between the implanted device 50 and the vessel wall because the flexibility of the device 50 may not completely conform to the contours of the vessel. The intraluminal sealing member 52 can fill those gaps and/or voids. Accordingly, the sealing member 51, and/or fabric 10, can function as an in vivo sealant or gasket for the expandable medical device 50. In certain embodiments, the loops 32 can comprise a thrombogenic material. Such as polyester, that can further enhance clotting by the sealing member 52, or fabric 10. In addition, the intraluminal sealing member 52 can serve as a frictional retention mechanism to help secure the implanted device 50 to the target location in the body.

Id. at 9:18-39.

78. The prior-art references identified above demonstrate that Petitioner and others had invented and disclosed prosthetic heart valves, and specifically THVs, having an outer sealing material to reduce paravalvular leakage before November 2012. Moreover, by 2012, Petitioner had advanced THV technology to the point that persons of ordinary skill in the art had a number of options they could balance when adding an outer sealing material to a THV device. For example, the prior art demonstrates that persons of ordinary skill in the art had access to a wide range of suitable cloths and fabrics for use as a sealing material. *See e.g.*, Ex. 1074 (Norris) at 4:22-31; Ex. 1007 (Walther) at 1120-21; Ex. 1008 (Levi) at 13:49-53; Ex. 1010 (Spenser) at 13:4-25; Ex. 1011 (Spenser II) at [0085], [00145]; Ex. 1017 (Cheung) at e18-e19; Ex. 1018 (Cribier patent publication) at 8:16-23, 22:11-20; *infra* §VI.A. The cloths and fabrics had varying densities,

thicknesses, and finishes. *Id.* A person of ordinary skill in the art would have had the option of selecting a cloth or fabric that best suited the specific heart valve assembly and met the necessary size requirements.

79. Additionally, by 2012, Petitioner had developed innovations for the heart valve frame and leaflets to further reduce the size of the heart valve assembly, thereby creating additional space for an outer sealing material. For example, well before November 2012, Edwards had developed SAPIEN XT, which replaced SAPIEN's stainless steel frame with a cobalt chromium alloy. Ex. 1023 (Webb) at 154; Ex. 1036 (Nietlispach, Fabian, et al., *Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems*, Catheterization and Cardiovascular Interventions, 75:295-300 (2010)) at 296. The cobalt chromium frame allowed "for a thinner, stronger, more open and compressible frame." *Id.*; see also Ex. 1008 (Levi) at 6:31-6:49 (explaining that less material is needed with a cobalt chromium alloy frame). Edwards had also developed methods to reduce the diameter of the inlet portion of the heart valve frame to accommodate a sealing material. Ex. 1008 (Levi) at 16:51-17:18. Likewise, Edwards had disclosed innovative leaflet designs to reduce the crimp profile of the valve and offset or minimize any increase in diameter caused by adding additional components, like a sealing material, to the outside of the valve. *Id.* at 16:24-16:50.

80. Additionally, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. For example, the Retroflex 3 allowed the transfemoral introduction of SAPIEN 23- or 26-mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, the Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23-mm valve and 19 French for the 26-mm valve. *Id.* The Novaflex incorporated an innovative feature where the heart valve was crimped on the inner catheter proximal to the inflatable balloon and then moved onto the balloon once the delivery system had been advanced into the aortic arch. *Id.*; *see also* Ex. 1037 (Le Patent Publication) at [0005]-[0006] (describing off balloon delivery). This unique feature enabled a reduction in sheath size.

81. In 2012, persons of ordinary skill in the art would have been familiar with the above innovations and understood that they could use one or more of the above options to optimize a THV having an outer seal. Thus, the challenged claims are not novel or nonobvious, but merely describe the predictable use of prior art elements according to their established functions.

D. Sealing Materials in Intravascular Stents

82. In addition to the prior art discussed above regarding sealing materials on THVs, persons of skill in the art would have also been aware of fibrous materials used to provide similar sealing on other cardiovascular devices, such as vascular stents. For example, **Chuter**, a patent application published in May 2011, discloses embodiments of endovascularly delivered intravascular stents for either maintaining patency or occluding diseased vessels. See **Ex. 1116** (Chuter) at Abstract, [001]. Chuter discloses stents having a “fiber pile” attached to the stent frame that is composed of outwardly extending individual fibers which are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” *Id.* at [0012]. Chuter teaches that the individual fibers of the “fiber pile” can either extend from a “fabric pile backing” (Fig. 2) or they can be attached directly to the frame without any backing (Figs. 7, 9-10):

device is implanted, thereby preventing blood from flowing around the outside of the frame. *Id.* at [0064].

83. Additionally, a person of ordinary skill in the art would have been aware of many types of porous, velour-like fabrics that had been used as outer sealing materials in cardiovascular implant devices, such as stent grafts, for decades prior to November 2012. *See, e.g., Ex. 1107* (Hall) (1967 article discussing the use of velour fabrics in cardiovascular implants); **Ex. 1106** (Estridge) at 158 (“The most commonly used porous soft tissue biomaterial is Dacron velour. This material has been used extensively as an artificial vascular graft material and in percutaneous devices.”). These velour-like fabrics were commonly used in stent grafts and other devices because they were more flexible, compressible, and provided better healing porosity and tissue ingrowth than dense, tightly woven nonporous fabrics. *See Ex 1110* (Pourdeyhimi) at 172 (“The weft knitted velour grafts such as Sauvage & Filamentous® are superior in performance to the smooth walled weft knitted grafts. They are easier to suture and handle, and show higher degrees of healability.”); *see also Ex. 1107* (Hall) at 180-181; *Ex. 1106* (Estridge) at 158.

84. Persons of ordinary skill in the art developing THVs would have looked to references dealing with sealing materials for intravascular stents and stent grafts, such as those discussed above, because those devices presented similar

sealing challenges as THVs. Like the outer seals on THVs, the outer seals on vascular stents were intended to prevent blood from leaking between the outer wall of the stent and the patient's native tissue. One way to achieve this sealing for both types of devices, as demonstrated by the prior art, was the use of fibrous materials added to the frame, which could fill in gaps between the device and the patient's tissue and promote tissue ingrowth and blood coagulation, further sealing off any blood flow around the outside of the device.

IV. THE '634 PATENT

A. Summary of the '634 Patent

85. The '634 patent describes endograft devices for repairing ascending aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments combine multiple components to form a structure that extends into the patient's ascending aorta and aortic arch.

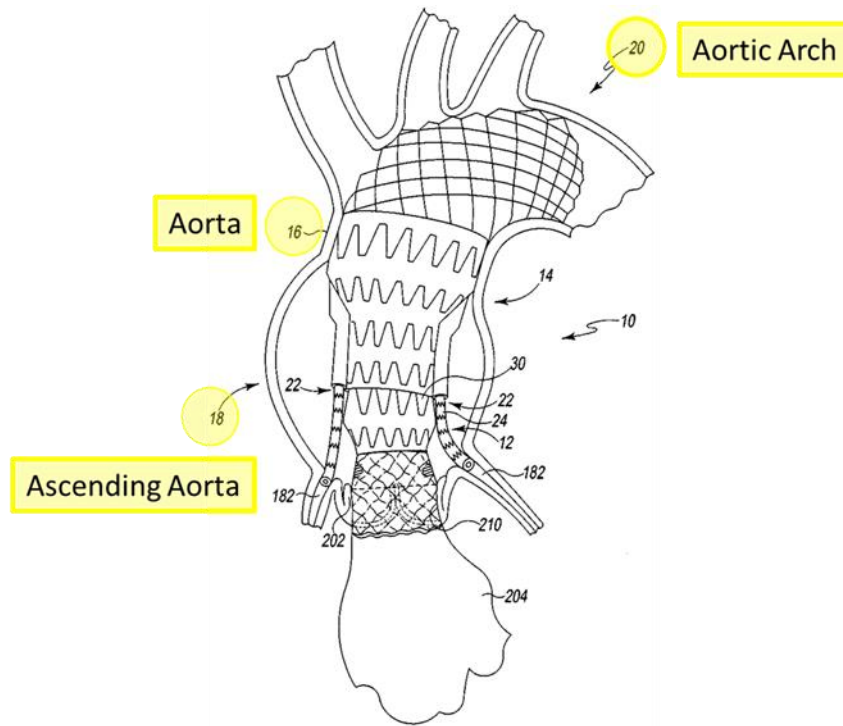


Fig. 2

86. However, the challenged claims of the '634 patent focus on an endovascular prosthetic heart valve for replacing an aortic heart valve. The '634 patent's specification describes a heart valve assembly that includes a "dual-frame" extending from a proximal end (i.e., nearest the left ventricle) to a distal end (i.e., furthest from the left ventricle). **Ex. 1001** ('634 patent) 12:4-6; 17:57-59. The "dual-frame" includes a "self-expanding outer frame 216" [red] and a "balloon-expandable inner frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32":

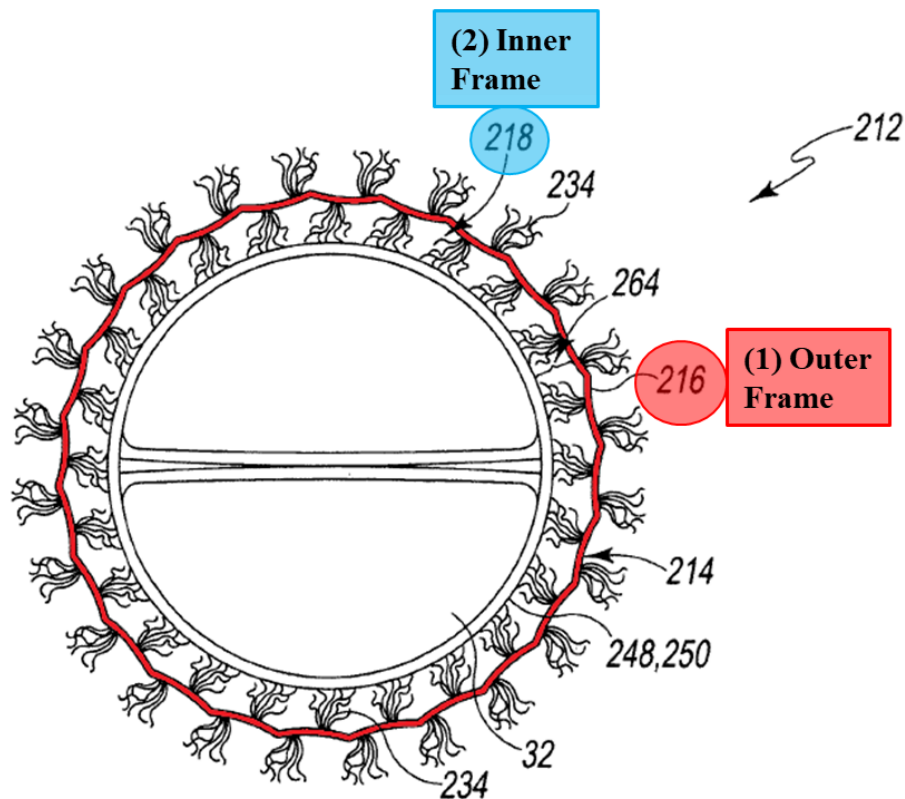
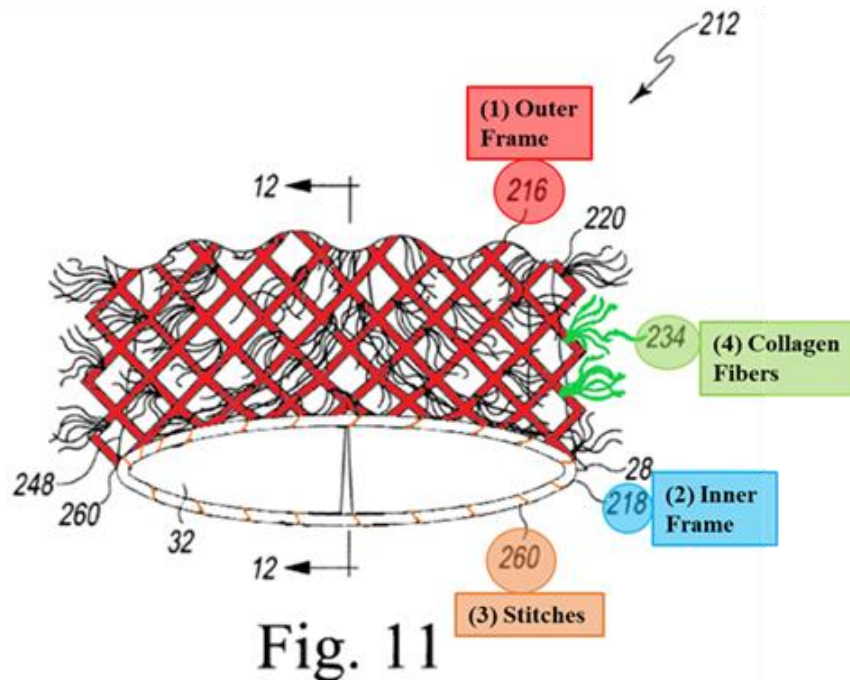


Fig. 13

Id. at 12:19-22; 18:1-4, Fig. 13.

87. The '634 patent states that the outer frame [red] is composed of a metallic or polymeric material that defines a gridded or “open-cell stent configuration.” *Id.* at 12:22-26, 13:27-30, 18:4-7, Fig. 9. The outer frame is self-expanding and may include a plurality of radially extending “collagen fibers” [green] attached to the exterior of the frame “to aid in preventing paravalvular leaks and migration of the [heart valve assembly] within the aortic walls.” *Id.* at 12:53-56, 18:34-37. The inner frame [blue] is a “balloon-expandable tubular stent”

constructed of metallic or polymeric material. *Id.* at 13:51-58. The inner frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:16-18.



88. The '634 specification discloses that the outer surfaces of the outer and inner frames may include a covering material, such as polyester, which prevents fluid from passing through the surface of the frame. *Id.* at 13:35-47, 13:61-67, 19:17-20.

B. The Challenged Claims

89. The challenged claims include claims 1-7 and 9 of the '634 patent. Claim 1 is the sole independent claim.

90. Claim 1 is illustrative (but not representative) of some of the limitations in the challenged claims. Claim 1 states:

1. A transcatheter aortic heart valve assembly comprising:
 - a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto;
 - a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration,
 - wherein the frame is secured to the graft covering,
 - wherein the graft covering is made of a polymer; and
 - a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame,
 - wherein the fibers are arcuate, spaced-apart, and outwardly extending,
 - wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state,
 - wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers,
 - wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings,
 - wherein the graft covering is engaged with fibers of the plurality of fibers,
 - wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.

C. Prosecution History

91. I have reviewed the '634 patent's prosecution history. I see that the Patent Examiner issued two office actions, one non-final and one final, which asserted the following combinations of prior art references:

- Spenser in combination with Spenser II⁴ (November 30, 2021 non-final rejection);
- Levi, Spenser II, and U.S. Pat. App. Pub. No. 2012/0143324 ("Rankin") (January 24, 2022 final rejection);

Ex. 1002 ('634 patent prosecution history excerpt) at 247-151, 385-388. Although the Examiner considered the Spenser and Spenser II prior art references I discuss herein, it is my opinion that the Examiner materially erred by allowing the claims of the '634 patent over those prior art references because the references render the allowed claims obvious. I note that the Examiner withdrew its rejection based on Spenser and Spenser II based on Patent Owner's arguments that the combined valve would not be endovascularly deliverable through the femoral artery. I am aware that in related IPRs, the Board has rejected Patent Owner's arguments, and specifically the calculations underpinning those arguments. As discussed below, I disagree with Patent Owner's argument that the combination of Spenser and Spenser II could not be delivered endovascularly through the femoral artery.

⁴ The Examiner referred to Spenser II as "Dehdashtian."

92. I also see that Patent Owner made several arguments that mischaracterize the teachings of the prior art during prosecution. I only address Patent Owner's statements below that are most pertinent to my opinions herein. The fact that I do not address a particular statement or representation by Patent Owner should not be interpreted as an agreement with such statement or representation, and I reserve my rights to address additional representations by Patent Owner in the future.

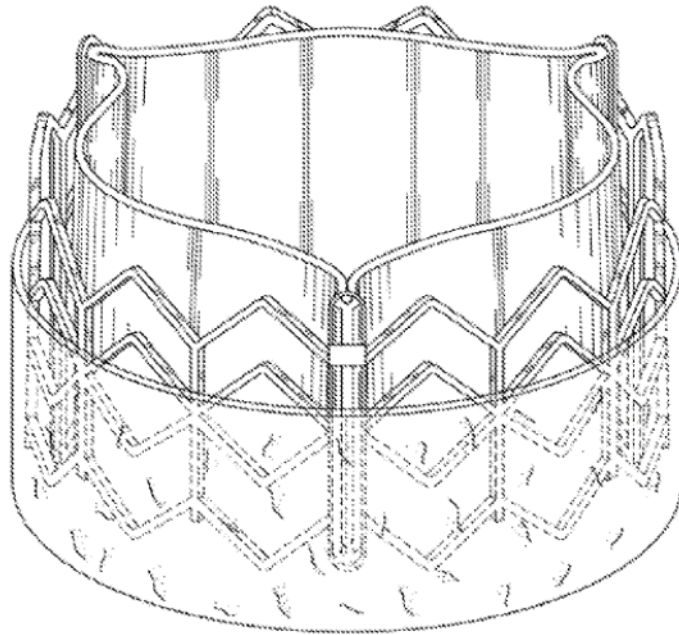
93. For example, in a January 4, 2022 Amendment, Patent Owner described Spenser II's compressible material as a "high density seal" and as "a very tightly knitted outer band made of tightly knitted fibers. . . where the lack of 'spacings' between some fibers would not allow for compression of the outwardly extending fibers." *Id.* at 373, 377. Patent Owner provided no support for this argument, and I see no such support in any of Spenser II's disclosures. Spenser II never describes the compressible material as "high density" or "tightly knitted." *See* Ex. 1011 (Spenser II) at [00145]. To the contrary, Spenser II expressly teaches that the compressible material is "compressible," which directly contradicts Patent Owner's position that the compressible material would lack spacings between the fibers necessary for compression. *See id.* As I explain below, persons of ordinary skill in the art would have understood that Spenser II's compressible material must have such spacings to compress, as Spenser II teaches. *Infra* §VI.A.6.

94. Patent Owner made further mischaracterizations of Spenser II in a May 18, 2022 Amendment, arguing that Spenser II's compressible material "is the direct opposite of Applicant's claimed inventions where the fibers are compressed upon deployment" because Spenser II teaches that the compressible material "expands after deployment at a treatment site." Ex. 1002 ('634 patent prosecution history excerpt) at 221. Again, Spenser II's express disclosure contradicts Patent Owner's characterization. Spenser II teaches that the compressible material is **compressible**, and thus persons of ordinary skill in the art would have understood that the material would be compressed when pressed against the native tissue upon deployment to form a seal to prevent PVL. See Ex. 1011 (Spenser II) at [00145]. Moreover, to the extent that a person of ordinary skill in the art could make a valve with collagen fibers like that disclosed in the '634 patent, the collagen fiber layer would also "expand after deployment at a treatment site" when the valve is released from the catheter sheath. And just like the fibers in Spenser II's compressible material, only after this initial expansion would the fibers be compressed against the patient's native tissue when the valve is expanded.

95. Patent Owner further argued that Spenser II "teaches a surface from which fibers can extend, however, . . . such surface would be a flat, smooth type surface generally associated with a graft covering, and not one formed from fibers with spacings therebetween. To the extent that the seal is PET, it is likely tightly

woven PET as used in cardiovascular applications and not spaced-apart fibers.” Ex. 1002 (’634 patent prosecution history excerpt) at 222. Spenser II’s disclosures do not support Patent Owner’s characterization. Spenser II never describes the compressible material as “tightly woven,” “flat,” or “smooth.” See Ex. 1011 (Spenser II) at [00145]. To the contrary, as I explain in detail below, persons of ordinary skill in the art would have understood from Spenser II’s disclosures that the compressible material would be a porous material with spacings between the fibers to achieve the stated purposes disclosed in Spenser II. *Infra* §VI.A.6.

96. Patent Owner also submitted the following image in the May 18, 2022 Amendment to argue that Spenser II’s compressible material must cover the bottom most surface of Spenser’s frame when attached thereto:



Ex. 1002 ('634 patent prosecution history excerpt) at 235. This image is **not** disclosed in Spenser or Spenser II, and it does not accurately represent a person of ordinary skill in the art's understanding regarding Spenser II's disclosure. A person of ordinary skill would not have interpreted Spenser II to teach that the compressible material should extend far below the struts of the frame as Patent Owner inaccurately suggested, at least because doing so could cause serious harm to the patient. For example, in the configuration illustrated by Patent Owner, the overhanging portion of the compressible material might fold over and obstruct the inflow orifice of the valve. Moreover, Spenser II specifically teaches that the compressible material "is disposed along an outer surface of the stent structure 252" and that the material "fills the gaps between the stented valve and the surrounding tissue." Ex. 1011 at [00145]. The seal in Patent Owner's unjustifiable drawing is not "disposed along an outer surface of the stent structure" and the proximal portion would not fill the gaps between the stented valve and the surrounding tissue. Thus, Patent Owner's drawing is inconsistent with Spenser II. Moreover, as I explain below, persons of ordinary skill in the art would have understood that Spenser II's Figure 22, a patent drawing, is a diagrammatic representation of the placement of the compressible material in one possible embodiment of the compressible material. *Infra* §VI.A.7. Persons of ordinary skill in the art would therefore have not limited Spenser II's broad disclosure to the

single embodiment illustrated in Figure 22, which again, does not include the altered image submitted by Patent Owner during prosecution.

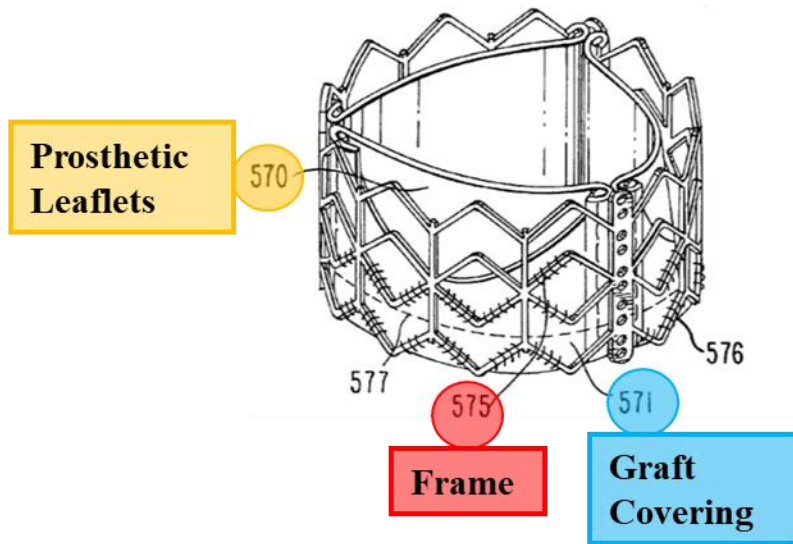
V. SUMMARY OF IPR GROUNDS

97. I have identified the following grounds of unpatentability in this Declaration:

Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1-7, 9	103	Spenser + Spenser II
2	1-7, 9	103	Spenser + Spenser II + Birdsall
3	1-7, 9	103	Spenser + Spenser II + Bailey
4	1-7, 9	103	Spenser + Birdsall
5	1-7, 9	103	Spenser + Chuter + Birdsall
6	1-7, 9	103	Spenser + Chuter + Bailey
7	1-7, 9	103	Bailey + Spenser II
8	1-7, 9	103	Bailey + Birdsall
9	1-7, 9	103	Bailey + Chuter

VI. GROUNDS 1-3: CLAIMS 1-7, 9 OBVIOUS OVER SPENSER AND SPENSER II, AND OPTIONALLY BIRDSALL OR BAILEY

98. Spenser discloses heart valve assemblies having a frame, an inner graft covering, and prosthetic leaflets, as illustrated below:



Ex. 1010 (Spenser) at Fig. 44a.

99. Spenser II discloses a prosthetic stented valve that includes a layer of “compressible material” [i.e., sealing material] disposed along the outer surface of the stent structure” to reduce paravalvular leaks:

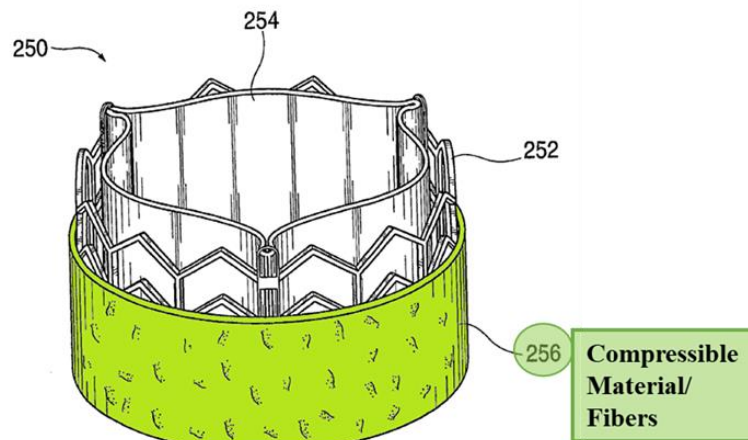
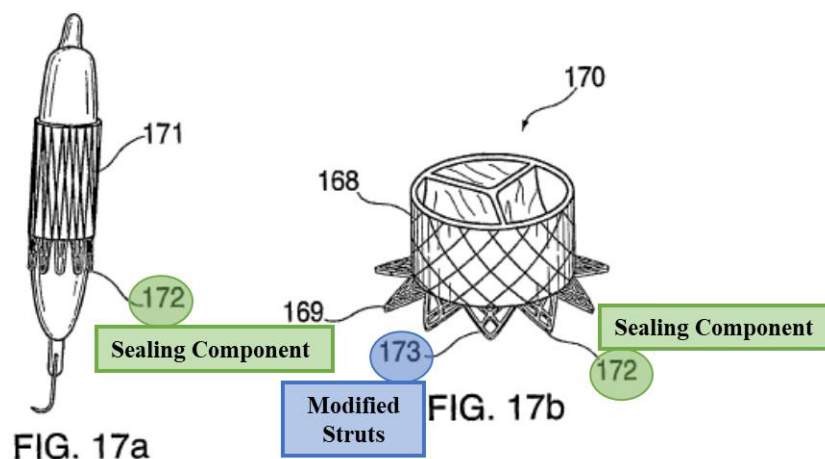


FIG. 22

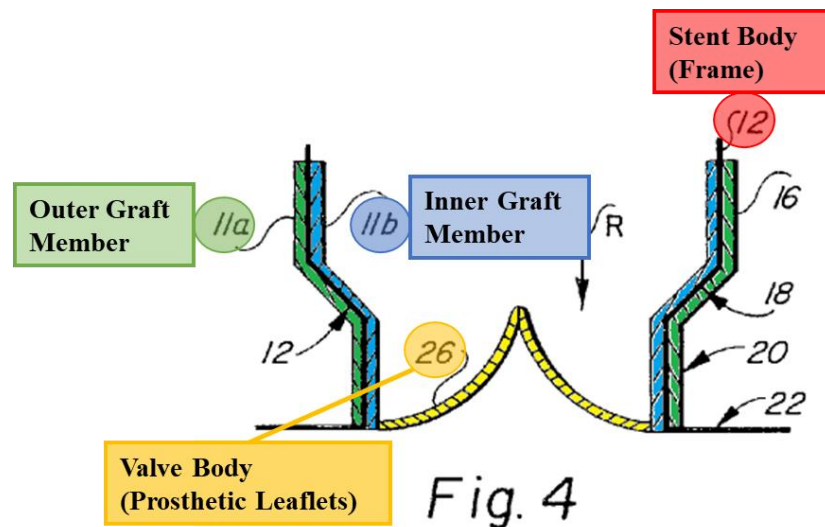
Ex. 1011 (Spenser II) at [00144]-[00145], Fig. 22. Spenser II explains that in certain configurations the compressible material “may resemble a cloth or fabric

having small fibers extending from the surface of the material” (i.e., a plurality of radially extending fibers). *Id.* at [00145]. Spenser II also discloses an embodiment with a sealing component formed from modified struts at the proximal end of the stent frame which “bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent” upon deployment, thereby preventing PVL:

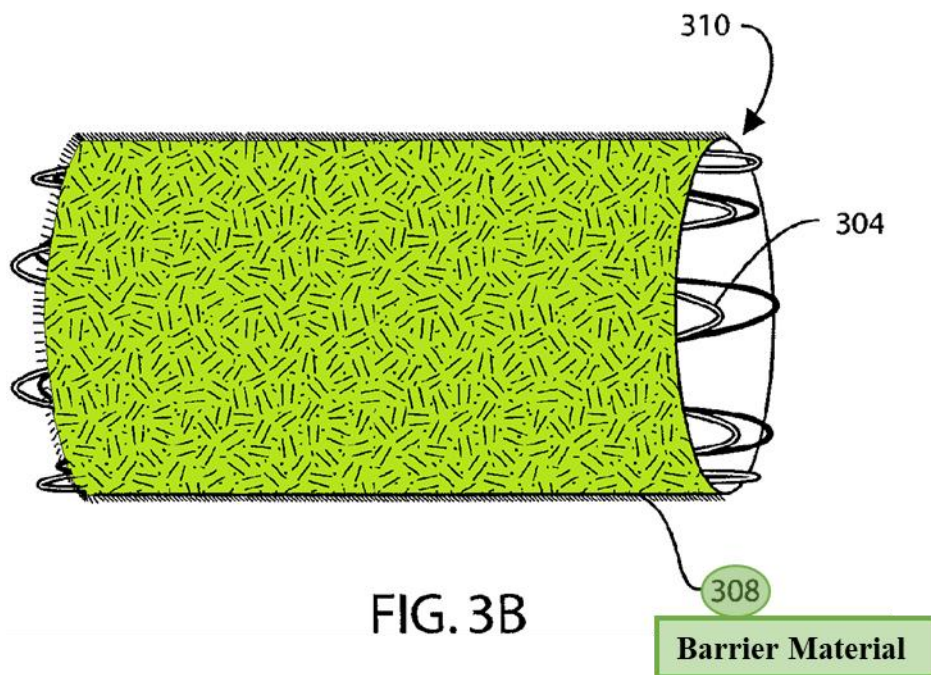


Id. at [00136], Figs. 17a-b. As I explain below, a person of ordinary skill in the art would have been motivated to combine these two embodiments from Spenser II to further reduce PVL, and in doing so they would have been motivated and found it obvious to position the compressible material from Figure 22 such that the proximal apices of the struts 173 would be uncovered by the compressible material.

100. Bailey also describes aortic THVs having a frame, inner and outer graft members, and prosthetic heart valve leaflets:

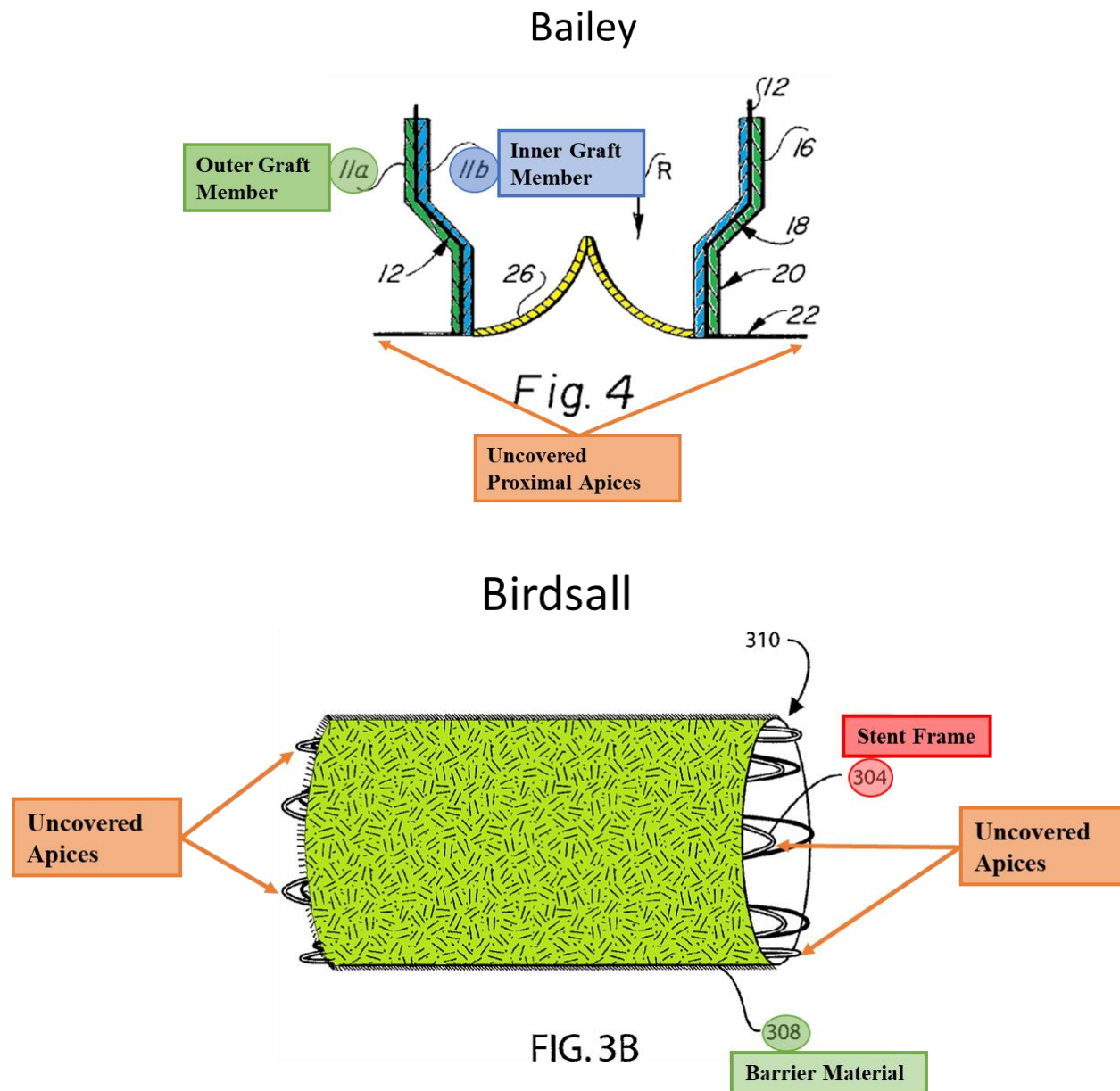


Ex. 1141 (Bailey) at [0048]-[0049]. Birdsall discloses a stented valve “for replacing the pulmonary valve” that includes a “barrier material” comprised of microfibers that helps prevent valve migration and PVL:



Ex. 1057 (Birdsall) at 6:9-25, 6:56-65, Figs. 3B-3C. Both Bailey and Birdsall disclose that the outer coverings (i.e., Bailey’s outer graft member and Birdsall’s

barrier material) do not cover the proximal apices of the frame of their respective THVs:



Ex. 1141 (Bailey) at Fig. 4; Ex. 1057 (Birdsall) at Fig. 3B.

101. For the reasons I provide in detail below, a person of ordinary skill would have been motivated to combine Spenser II's compressible material with the

heart valve assemblies in Spenser, as the Board previously concluded in several IPR proceedings of related patents in which I submitted expert testimony. As I further explain below, a person of ordinary skill in the art would have been motivated to also combine Spenser II's sealing component 172 in Figure 17 with Spenser's valve to further reduce PVL and would have been motivated to position the compressible material such that it would not cover the proximal apices of the sealing component 172. A person of ordinary skill in the art would have also been motivated to position Spenser II's compressible material on Spenser's valve such that the compressible material would not cover the most proximal apices of the frame given the disclosure of such positioning in both Bailey and Birdsall. Thus, based on my review of these references, I believe that the combination of Spenser and Spenser II and optionally Bailey **or** Birdsall renders the challenged claims obvious

A. Claim 1

102. Based on my review of the prior art, it is my opinion that Spenser and Spenser II and optionally Bailey **or** Birdsall renders claim 1 obvious.

1. Preamble

103. The preamble of claim 1 recites: "A transcatheter aortic heart valve assembly." If this preamble is limiting Spenser, Spenser II, and Bailey disclose this limitation.

104. Spenser discloses a transcatheter heart valve prosthesis that may be implanted “at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient.” Ex. 1010 (Spenser) 1:13-15, 5:17-25, 5:65-6:3, 17:19-18:43.

105. Spenser II discloses similar THVs as those in Spenser having fibrous compressible materials secured to the outside of the frame:

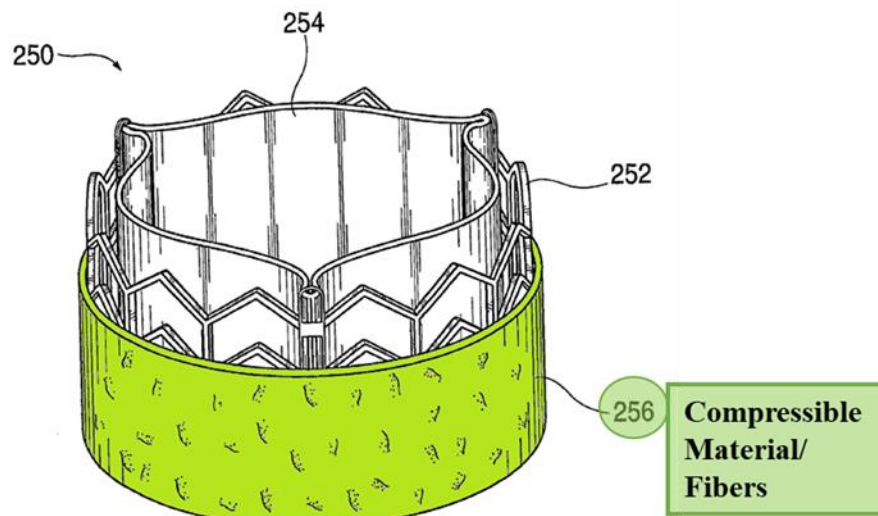
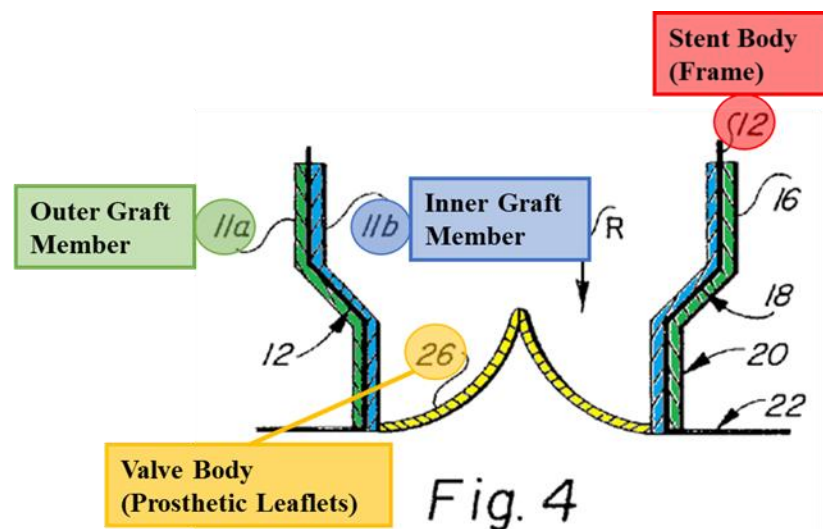


FIG. 22

Ex. 1011 (Spenser II) at [00144]-[00145]. Spenser II explains that the embodiment in Figure 22 is a “stented valve 250 configured to reduce or prevent paravalvular leaks” that includes “an expandable stent structure 252 which supports a valvular structure 254” that “forms three leaflets and is illustrated in the open configuration” in Figure 22. *Id.* at [00144].

106. Bailey is directed to “prosthetic cardiac and venous valve implants which are capable of being delivered using endovascular techniques and being implanted at an intracardiac or intravenous site without the need for anatomic valve removal.” Ex. 1141 (Bailey) at [0002]. Bailey describes embodiments of aortic THVs that include a stent body 12 (i.e., frame), inner and outer graft members 11a and 11b, and a valve body 26:



Ex. 1141 (Bailey) at [0048]-[0049].

2. Graft Covering

107. Claim 1 next recites: “graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto.” Spenser discloses this limitation.

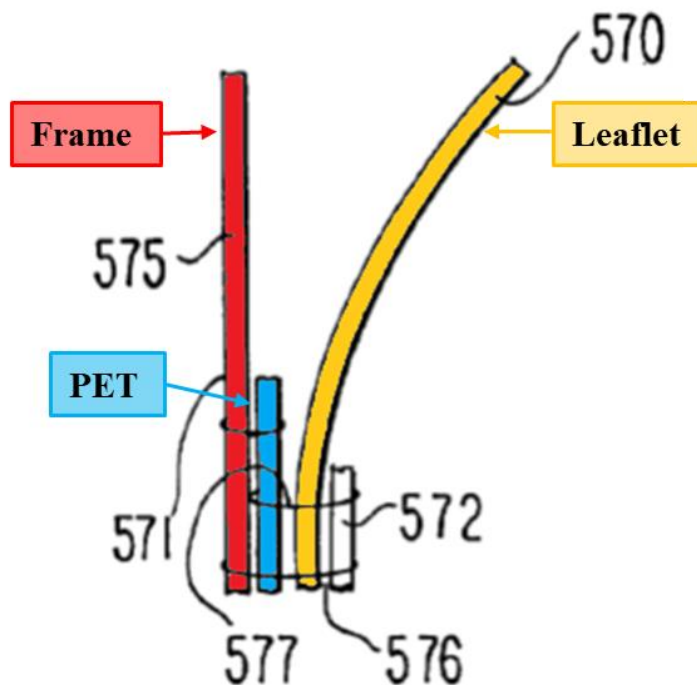
108. The embodiment in Figure 44a of Spenser includes an “additional piece of PET” 571 for “sealing and protecting the pericardium.” Ex. 1010 (Spenser) at 26:30-34, Figs. 44a-44c; *see also id.* claims 10, 30 (“including a fabric

layer interposed between the valve assembly and support stent”). The “pericardium” is the prosthetic pericardial leaflets 570 (see *e.g.*, Figures 44a-b below). *Id.* at 26:30-54. The PET 571 is a “graft covering.”

109. As shown in Figure 44b of Spenser below, the PET 571 [blue] is positioned “between the leaflets [570 yellow] and the frame [575 red]”⁵:

⁵ In Fig. 44b, the lead lines for 571 and 575 both point to the frame [red]. See Ex. 1010 (Spenser) at Fig. 44b. I believe this is a drafter’s error. As explained in Spenser’s written disclosure, the lead line for the outer PET layer 571 should point to the middle layer [blue] because PET 571 is described as being positioned “between the leaflets [570] and the frame [575].” *Id.* at 26:40-42.

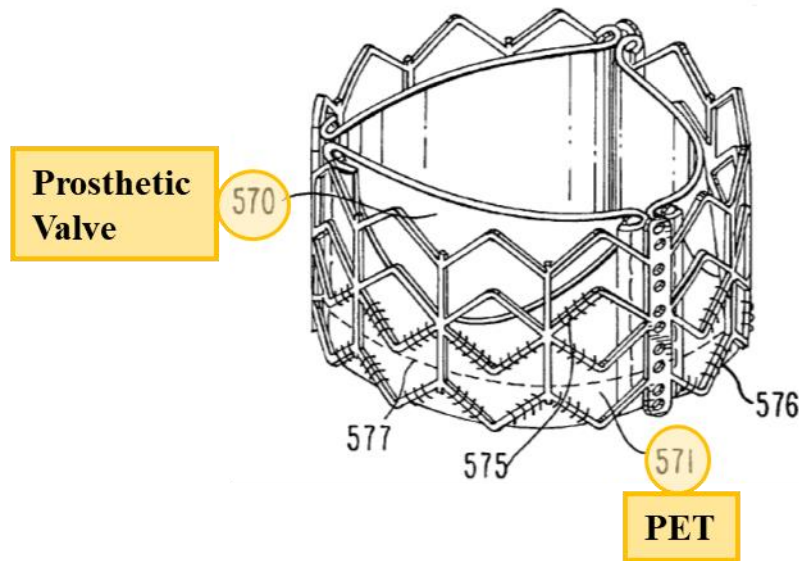
FIG. 44b



Id. at 26:30-54, Fig. 44b. Spenser teaches that the PET 571 is stitched to the prosthetic valve using at least suture 576, and thus PET 571 is “engaged with” the prosthetic leaflets. *Id.* at 26:45-47

110. As shown in Figure 44b above and Figure 44a below, the PET 571 extends about the prosthetic leaflets 570:

FIG. 44a



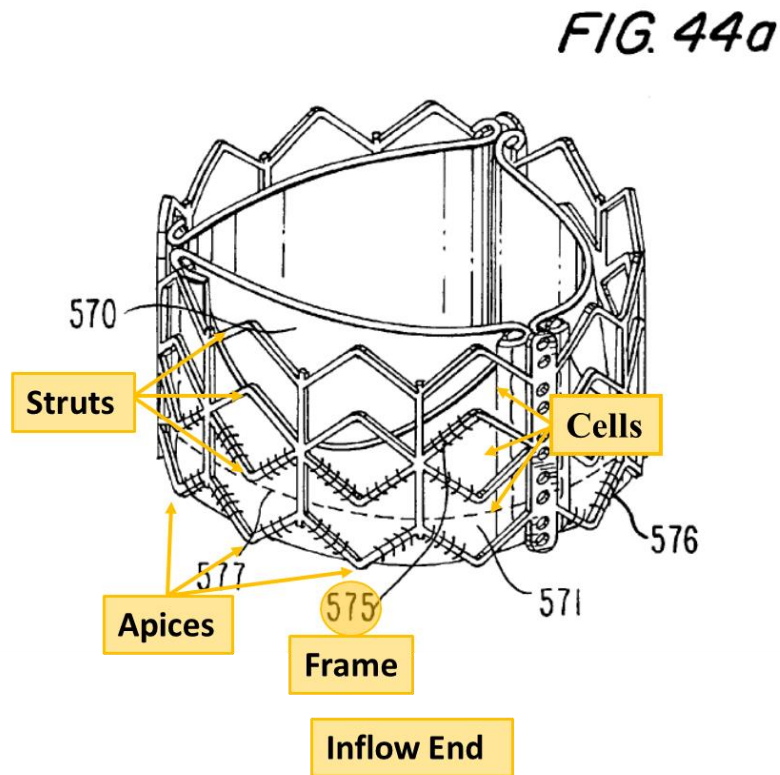
Id. at 26:30-34, Fig. 44a.

3. Frame

111. Claim 1 next recites: “a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration, wherein the frame is secured to the graft covering.” Spenser discloses this limitation.

112. As I explained above, my opinions regarding this limitation are based on Patent Owner’s continued assertion that the “frame” need not be a self-expanding frame. *Supra* §II.A.

113. Figure 44a of Spenser illustrates “an implantable prosthetic valve in accordance with [a] preferred embodiment of the present invention” that includes “frame 575”:



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame). The frame is formed of a plurality of struts that form a plurality of open cells and is made from metal. *Id.* at 12:28-31, Fig. 44a-44b. The frame’s struts join each other at the inflow end of the frame to form apices. *Id.* at 12:28-31, Fig. 44a-44b. The frame is secured to PET 571 via sutures. *Id.* at 26:45-47, Figs. 44a-44c.

4. Polymeric Graft Covering

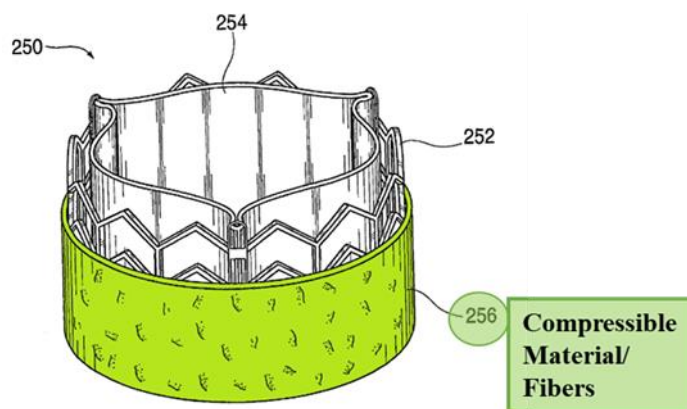
114. Claim 1 next recites: “wherein the graft covering is made of a polymer.” Spenser discloses this limitation.

115. The graft coverings in Spenser may be made of PET. *Supra* §VI.A.2. PET is a polymer.

5. Plurality of Fibers

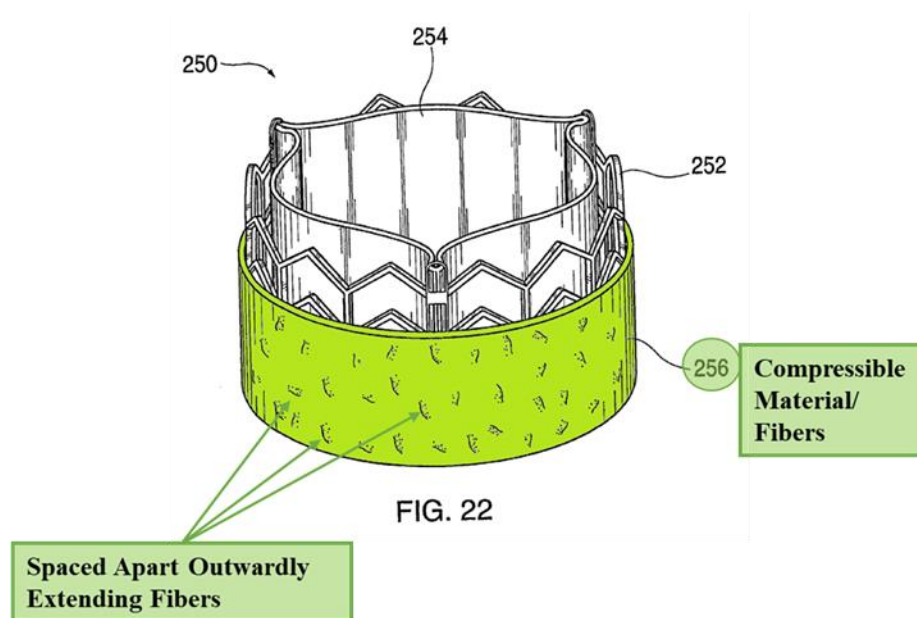
116. Claim 1 next recites: “a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame, wherein the fibers are arcuate, spaced-apart, and outwardly extending.” Spenser in combination with Spenser II renders these limitations obvious.

117. Spenser II discloses this limitation. Spenser II discloses that “[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252”:



Ex. 1011 (Spenser II) at [00145], Fig. 22. As shown, the compressible material is positioned externally to the frame. Spenser II explains that “[i]n certain

configurations the compressible material may resemble a cloth or fabric having small fibers extending from the surface of the material.” *Id.* The fibers of the compressible material “may be straight, curved or hook-shaped.” *Id.* A “curved” or “hook-shaped” fiber would be arcuate. Spenser II’s outwardly extending fibers are also illustrated as being “spaced-apart”:



Id. at Fig. 22. As discussed more in the next section, Spenser II’s fibers are spaced apart so the material can compress for delivery and encourages tissue and ingrowth and promotes blood coagulation after delivery. Moreover, I see that during prosecution of the ’634 patent, Patent Owner admitted that the fibers in all cloths are spaced apart, stating that “all fibers have some degree of being spaced-apart.” Ex. 1002 (’634 prosecution history excerpt) at 222. I agree with Patent Owner’s statement that the fibers in all cloths, including the PET cloths disclosed by

Spenser II, would have “some degree of being spaced apart.” Any woven or knitted cloth has spacings between the fibers where the fibers overlap and those spacings extend through the fibrous and base layers.

118. I am aware that the Board has previously concluded that a person of ordinary skill in the art would have been motivated to add Spenser II’s compressible material to Spenser’s Figure 44a with a reasonable expectation of success. (Ex. 1117, 64; *see also* Ex. 1118, 68; Ex. 1119, 80-81.) I agree with the Board’s conclusion.

119. A person of ordinary skill in the art would have been motivated to combine Spenser II’s compressible material with Spenser’s Figure 44a for a number of reasons. First, Spenser and Spenser II describe similar valves, share three common inventors, and Spenser II explicitly references Spenser’s parent application: U.S. Publication No. 2003/0153974 (Ex. 1015). *See, e.g.*, Ex. 1010 (Spenser) at Abstract, 2:5-15; Ex. 1011 (Spenser II) at [0001], [0009]-[0014]. Indeed, Spenser II explicitly proposes improvements to the valves described in Spenser U.S. Publication No. 2003/0153974 (Ex. 1015). *See* Ex. 1011 (Spenser II) at [0009-00010] (explaining that Spenser’s parent application describes similar heart valves but does not address “leaks that can occur around the implanted valve”).

120. A person of ordinary skill in the art would have also been motivated to combine Spenser II's compressible material with Spenser's Figure 44a to "address leaks that can occur around the implanted valve" and "to encourage coagulation of blood to further fill the gaps and prevent leakage." Ex. 1011 (Spenser II) at [0010], [0145]. Moreover, adding the compressible material to Spenser would have merely entailed the combination of known elements (Figure 44a and compressible material) according to known methods (stitching or otherwise attaching) to yield the predictable result of reducing PVL.

121. A person of ordinary skill would have had a reasonable expectation of success in combining Spenser II's compressible material with Spenser's Figure 44a because the valve assemblies share many common features, including a balloon-expandable metallic stent having a gridded configuration that supports prosthetic leaflets, and being radially compressible for endovascular delivery. *See supra* §§ VI.A.1-3. Moreover, Spenser already discloses valves having a sealing material positioned around the inlet, for example in Figure 1. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. A person of ordinary skill in the art would thus have been confident that other sealing structures with superior sealing capabilities, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. Also, a person of ordinary skill in the art would not have had any concerns about stent foreshortening because the valve in Spenser II, which is

very similar to Spenser's Figure 44a, is a balloon expandable valve and Spenser II does not describe any problems with foreshortening. Ex. 1011 (Spenser II) at [00144]-[00145].

122. Spenser II's compressible material 256 covers two rows of cells at the inflow end of the stent structure 252:

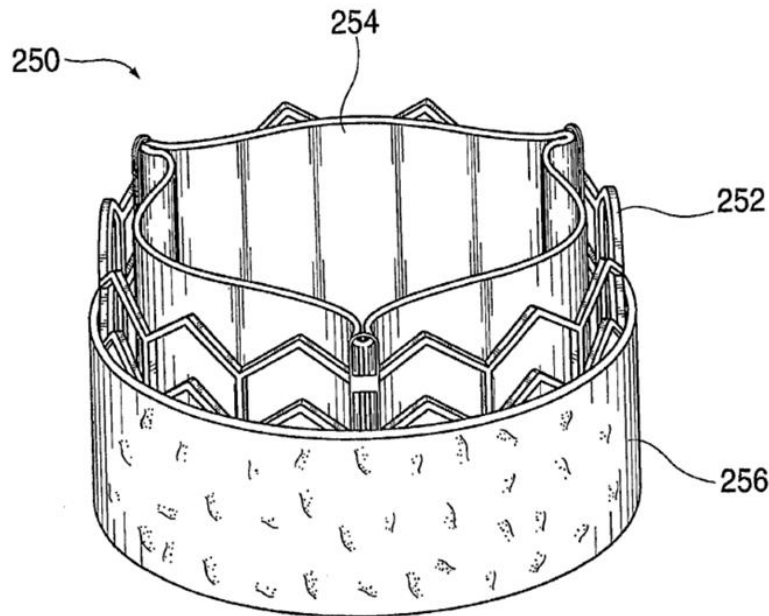


FIG. 22

Id. at Fig. 22. If Spenser II's compressible material were added to Spenser's Figure 44a valve in the same way, the material would cover at least two rows of cells. A comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right) confirms that the stent structures are similar, and that the compressible material would cover at least two rows of cells in the frame of Figure 44a:

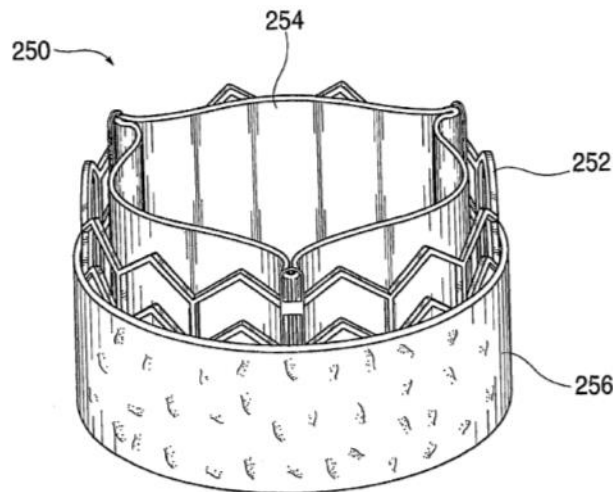
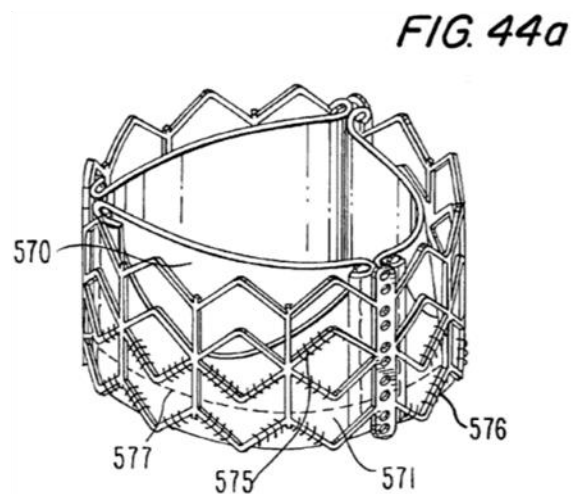
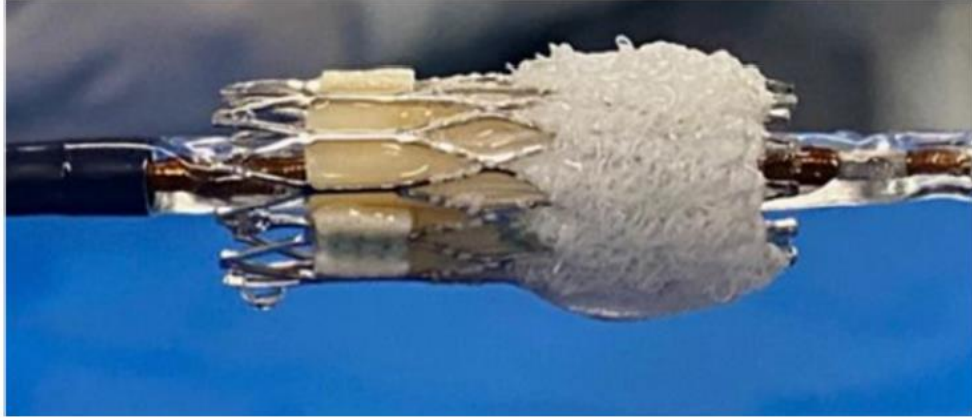
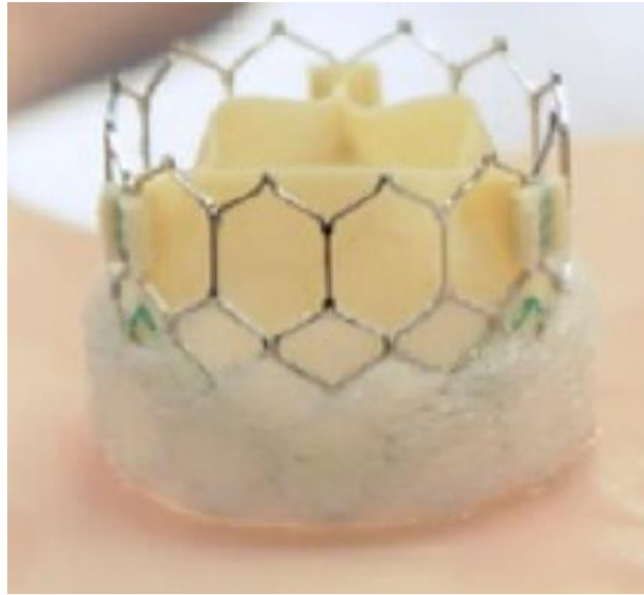


FIG. 22



Id. at Fig. 1011, Fig. 22; Ex. 1010 (Spenser) at Fig. 44a.

123. Additionally, Spenser II's compressible material would be "in contact" with at least two rows of open cells at the inflow end of Spenser's frame. I see that during prosecution of the '634 patent, Patent Owner suggested that this limitation is met if the "sealing material" is in contact with the frame. See Ex. 1002 ('634 prosecution history excerpt) at 223. Patent Owner's interpretation during prosecution appears consistent with Patent Owner's contentions for the SAPIEN 3 Ultra valve, which rely on the photos below.



See Ex. 1123 (Patent Owner's Infringement Contentions) at 329-330. Spenser II discloses this limitation as applied by Patent Owner. Spenser II's compressible material is "disposed along an outer surface of the stent structure 252," and therefore, the compressible material (i.e., sealing material) is in contact with the stent structure along the height of the sealing material, as illustrated in Fig. 22. As such, where the compressible material is made of a fibrous velour cloth, the radially extending fibers are also in contact with the frame:

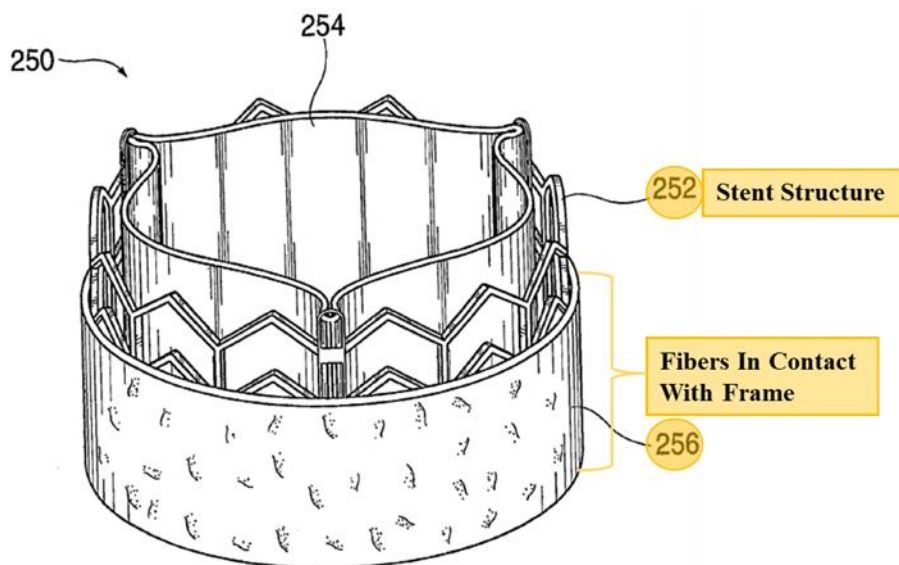
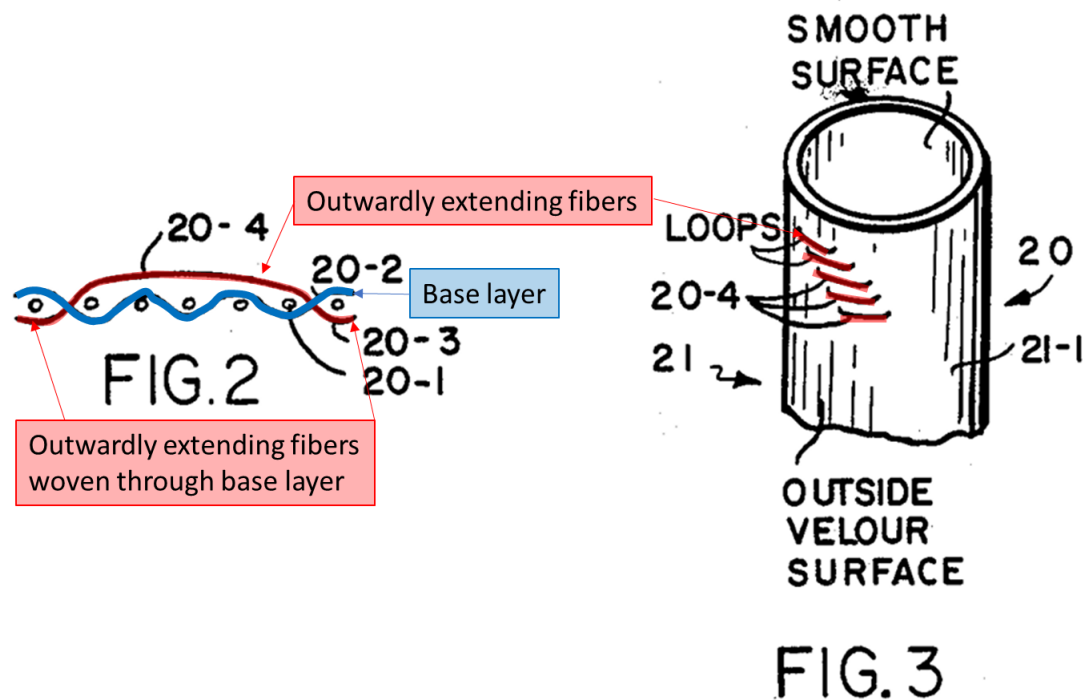


FIG. 22

Ex. 1011 (Spenser II) at [00145].

124. If the Board concludes that this limitation requires that the radially extending fibers of the sealing material are in direct contact with the outer frame, then Spenser II still discloses and renders this limitation obvious in two ways.

125. First, in the embodiments of Spenser II wherein the compressible material is a “cloth or fabric having small fibers extending from the surface of the material,” persons of ordinary skill in the art would have understood that at least some of these fibers extending from the surface would be in contact with the frame. *Id.* at [00145]. Persons of ordinary skill in the art would have found it obvious to weave or knit the outwardly extending fibers through the base layer so that the fibers are in contact with the frame along a height of the sealing material, as illustrated in Koch (weaving) and Sauvage (knitting):



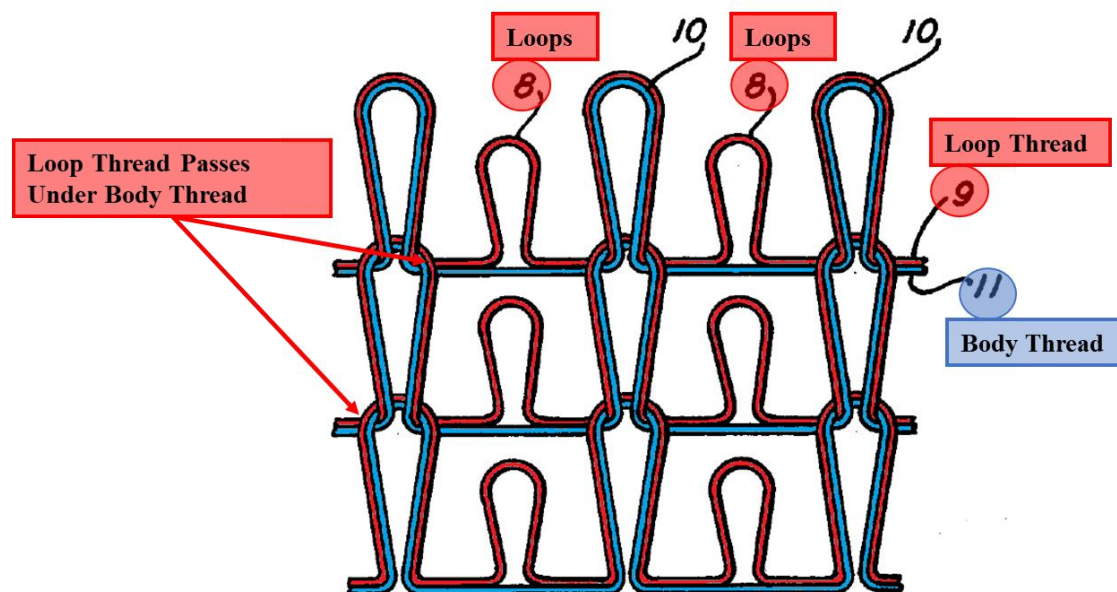
Ex. 1134 (Koch) at 2:55-3:9, Figs. 2-3. Koch explains that the “velour in the fabric is formed by interlacing of the fill yarn portion 20-3 which forms a velour pattern having outside loops 20-4 which float (extend) over five warp yarn ends 20-1 as shown.” *Id.*, 2:62-64. As shown, Koch’s radially extending fibers (loops 20-4) extend through the base layer and would therefore be in contact with the frame when disposed along the exterior of a THV, as Spenser II teaches. Many such fabrics, such as woven and knitted velours, were known in the prior art for use in cardiovascular devices before November 2012 and reflect the state of the prior art.

126. Notably, Norris specifically describes making a “compressible resilient fabric 10” using the method described in Koch. Ex. 1074 (Norris) at

13:31-41. Norris states, “the fabric 10 can also be made by weaving.” *Id.* Norris explains that in “woven embodiments of the fabric 10, the loops 32 can comprise floated yarns.” *Id.* Norris concludes that the “woven embodiments of the present invention may provide the advantages of increased stability, while including thinner fabric 10.” *Id.* It is also worth noting that Koch is listed on the face of Norris under the “References Cited.”

127. As another example, Sauvage, a patent issued in 1975, discloses a “tubular prosthesis [that] is knitted with pile loops on the inside, as is customary with available knitting machines, and is then turned inside out” to provide a “velour exterior surface to enhance the retention of clotted blood and improve the rate of growth of tissue within the confines of the length thereof.” Ex. 1135 (Sauvage) at 1:44-60. Sauvage discloses that the fabric is formed by knitting a loop thread 9 (red) that forms a plurality of loops 8 with a body thread 11 (blue). *Id.* at 2:35-55, Fig. 3. The body thread 11 forms the base layer of the fabric and the loops 8 extend from the base layer. As illustrated in Sauvage’s Figure 3 below, the loop thread 9 repeatedly passes underneath the body thread as the fabric is knitted:

FIG. 3



Id. at Fig. 3. As a result, the threads/fibers that make up the outwardly extending loops extend all the way to the inside surface of the fabric once it is turned inside-out after knitting. *See id.* at 2:56-57. Persons of ordinary skill in the art would have therefore understood that the fibers making up the outwardly extending loops would be in contact with the frame when the fabric is disposed along the exterior of a THV, as taught by Spenser II.

128. Once again, Norris specifically describes making a “compressible resilient fabric 10” using knitting methods like those described in Sauvage. Ex. 1074 (Norris) at 11:51-12:18. Norris discloses one method of making the fabric “can include knitting the ground layer 20 of yarn and the loop layer 30 comprising a plurality of loops 32 of yarn 31, each loop 32 having point 33 knit into the ground layer 20.” *Id.* at 11:54-57. Norris further discloses that the “compressible

resilient fabric 10” “can be made utilizing warp knitting techniques.” *Id.* at 12:3-6. In warp knitting, the “yarns are fed through on or more guide bars to knitting needles that form the yarns into interlaced loops 32.” *Id.* at 12:8-10. “A ‘warp knit fabric’ is a knit fabric in which the yarns generally run lengthwise but in a zigzag pattern, which forms loops 32 in two or more wales.” *Id.* at 12:16-18.

129. Koch, Sauvage, and Norris are representative of the state of the art of velour fabrics for vascular prostheses prior to November 2012. Persons of ordinary skill in the art would have been motivated, and found it obvious, to make Spenser II’s “compressible material” out of velour fabrics like those disclosed in Koch, Sauvage, and Norris due to the benefits of velour fabrics. Koch explains that the woven velour construction “provides a staggered design outer looped surface extending around the circumference thereof to allow for the body tissue which grows thereabout after implantation to firmly support it in the body.” Ex. 1134 (Koch) at 1:26-30. Similarly, Sauvage explains that the knitted velour construction provides “a synthetic graft having a velour exterior surface formed to enhance the retention of clotted blood and improve the rate of growth of tissue within the confines of the length thereof.” Ex. 1135 (Sauvage) at 1:56-60. Finally, Norris discloses that such velour fabrics can be highly compressible and, therefore, appropriate for heart valves delivered through the femoral artery. *See e.g.*, Ex. 1074 (Norris) 4:54-60, 9:18-39 (describing use of fabric on heart valve and high

compressibility). A person of ordinary skill in the art would have reasonably expected success in using a woven compressible material (as described in Koch/Norris) or a knitted compressible material (as described in Sauvage/Norris) due to the ubiquity and predictability of these fabrics.

130. Second, persons of ordinary skill in the art would have understood that Spenser II is not limited to the embodiments where the compressible material is a cloth or fabric but would also encompass embodiments where the compressible material comprises outwardly extending fibers secured directly to the frame. Spenser II teaches that the compressible material is a cloth only “[i]n certain configurations,” and it further teaches that the compressible material “may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve.” Ex. 1011 (Spenser II) at [00145]. These disclosures are exemplary and inform a person of ordinary skill in the art that the compressible material is not limited solely to embodiments comprising a cloth or sleeve. Persons of ordinary skill in the art would have understood Spenser II’s disclosures regarding the compressible materials more broadly and to encompass other embodiments of compressible materials, such as extending fibers attached directly to the frame, as disclosed in Birdsall and Chuter (discussed below). In such embodiments, the fibers of the compressible material would be “in contact” with the frame because they would be attached directly thereto.

131. The above references exemplify the types of fabrics with outwardly extending fibers that were known in the art for use in cardiovascular devices prior to November 2012 that are encompassed by Spenser II's disclosure regarding the compressible material. As demonstrated, there were numerous types of fabrics with outwardly extending fibers known in the art, and it would have been within the skill of a person of ordinary skill in the art to select a suitable fabric for the compressible material consistent with Spenser II's disclosure.

6. Spaced-Apart Fibers

132. Claim 1 next recites "wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state." Spenser in combination with Spenser II renders this limitation obvious.

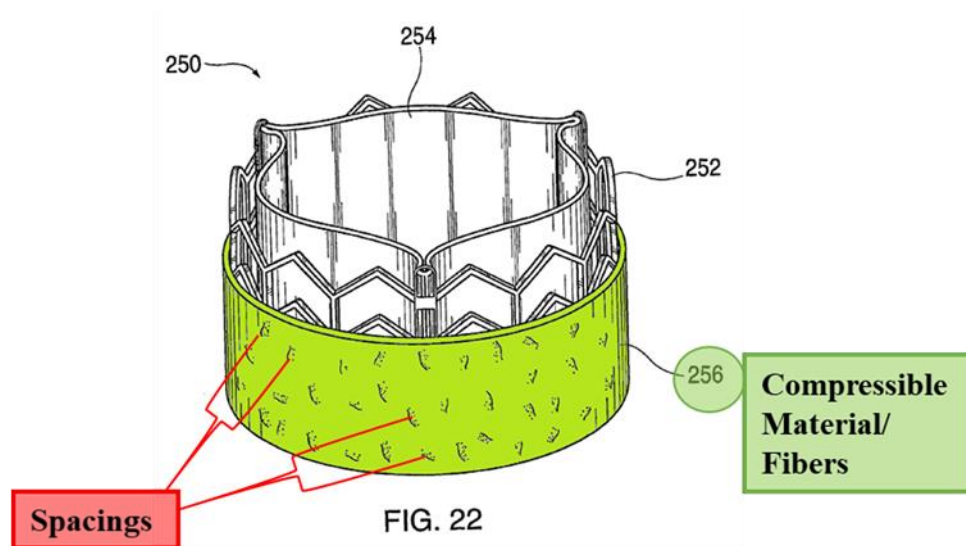
133. First, I note that the '634 patent does not claim or disclose how to size or arrange the fibers. *See* Ex. 1001. For example, the '634 patent never discloses the length or width of the fibers, the number or density of the fibers, or any particular arrangement of the fibers. *Id.* The '634 patent also does not disclose the size of the "spacings." I understand that during prosecution Patent Owner relied on the figures to support the "spacings," but the patent figures depict a random distribution of fibers around the frame that fail to define the size of the "spacings."

For example, some cells of the frame have fiber-free struts on one side, some on two sides, and some on three sides. Thus, the distances between the bundles of fibers differ significantly depending on which cell I am examining. Also, the illustrated bundles of fibers contain variously between 2 to 7 fibers, and in some instances there are single fibers. Moreover, the spacings in the figures are specific to the stents shown in the figures. The patents do not give any description of “spacings” on frames with other strut configurations like, for example, the SAPIEN 3 Ultra valve. I also note that the figures of the ’634 patent illustrate relatively large openings between the groups or clusters of collagen fibers. *See, e.g.*, Ex. 1001 (’634 Patent) at Figs. 8-9, 11-14. A person of ordinary skill in the art would have understood that fibers with such large openings between groups would be unlikely to form a sufficient seal against the patient’s native tissue to prevent PVL. Therefore, persons of ordinary skill in the art would have understood that the ’634 patent’s figures are merely schematic or conceptual, and do not accurately reflect the dimensions, number, density, or placement of the collagen fibers on the frame. Additionally, nothing in the ’634 patent indicates that any of the figures are drawn to-scale.

134. I am aware that Patent Owner has argued in an IPR of related Patent No. 11,337,834 (the “’834 patent”) that Patent Owner disclaimed a “sleeve,” “layer,” or “cloth” such as Spenser II’s compressible material from the scope of the

term “spacings” in the claims of the ’834 patent. *See* Ex. 1142 (’834 POPR) at 10-12. However, I am also aware that in litigation involving the ’834 patent and the ’634 patent, both Patent Owner and its expert, Dr. Brecker, have asserted an inconsistent position, arguing that the term “spacings” should receive its plain and ordinary meaning and that Patent Owner made no disclaimer. *See* Ex. 1147 (PO Preliminary Claim Constructions) at 44-45; Ex. 1145 (Brecker Claim Construction Decl.) at ¶¶83-92. As I explained above, my interpretation and application of the prior art herein is based on Patent Owner’s assertions regarding the scope of the claims of the ’634 patent, including its assertions in the litigation that the term “spacings” should receive its plain and ordinary meaning. The plain meaning of “spacings” does not require a specific size of “spacings” between the fibers, and as I noted above, Patent Owner admitted during prosecution that the fibers in all cloths have some degree of spacings between them. *Supra* ¶117. Merriam-Webster identifies two definitions for “spacing,” neither of which requires specific sizes or dimensions: (1) the act of providing with spaces or placing at intervals; an arrangement in space (2) a limited extent; the distance between any two objects in a usually regular arranged series.” Ex. 1143. Accordingly, under Patent Owner’s own interpretation of this term in the litigation, Spenser II’s compressible material discloses the “spacings” limitations for the reasons I explain further below.

135. Spenser II's Figure 22 illustrates one embodiment of the compressible material having small fibers extending from the surface of the compressible material and shows "spacings" between the extending fibers:



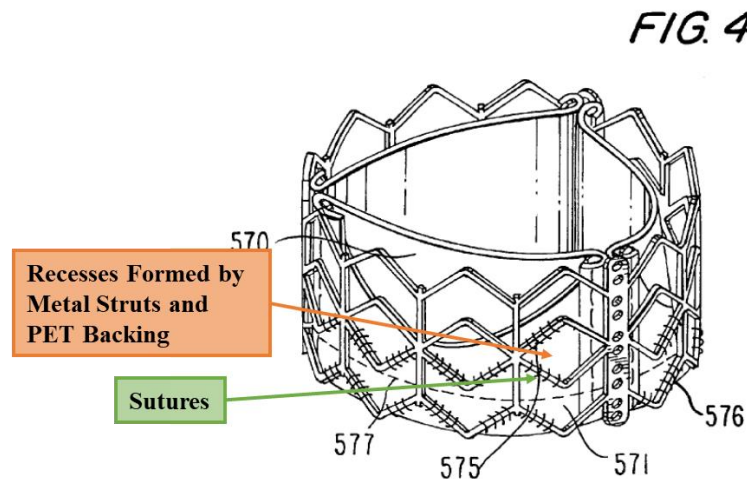
Ex. 1011 (Spenser II) at [00145], Fig. 22.

136. Based on the above illustration, the description of the compressible material in Spenser II, and a person of ordinary skill's general experience with fibrous cloths, a person of ordinary skill in the art would have been motivated, and found it obvious, to use a cloth for Spenser II's valve with spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame for several reasons. Spenser II describes the material 256 as "compressible." *Id.* A person of ordinary skill in the art would have understood that a material must and should have spaces between the fibers making up the material to be compressible. *See, e.g.,* Ex. 1109 (Ko) at 1048 ("[W]eft knits have

high extensibility and are extremely comfortable and compressible.”); Ex. 1110 (Pourdeyhimi) at 172 (“Single jersey [knitted] grafts are inherently more porous than wovens. The increased porosity (see Figure 5) in this class of grafts results in a greater degree of yarn mobility. In consequence, these grafts are more compliant, easier to handle and suture.”); Ex. 1129 (Chu) at 4. A material without spacings is not compressible. Porous materials with spacings between the fibers are also more flexible than tightly woven, nonporous materials, which also contributes to their enhanced compressibility. See, Ex. 1109 (Ko) at 1048; Ex. 1110 (Pourdeyhimi) at 172; Ex. 1129 (Chu) at 4. A person of ordinary skill in the art would have been motivated to use a flexible material for the cloth because these valves must be delivered to the heart through the patient’s tortuous vasculature, making flexibility an important consideration for the valve.

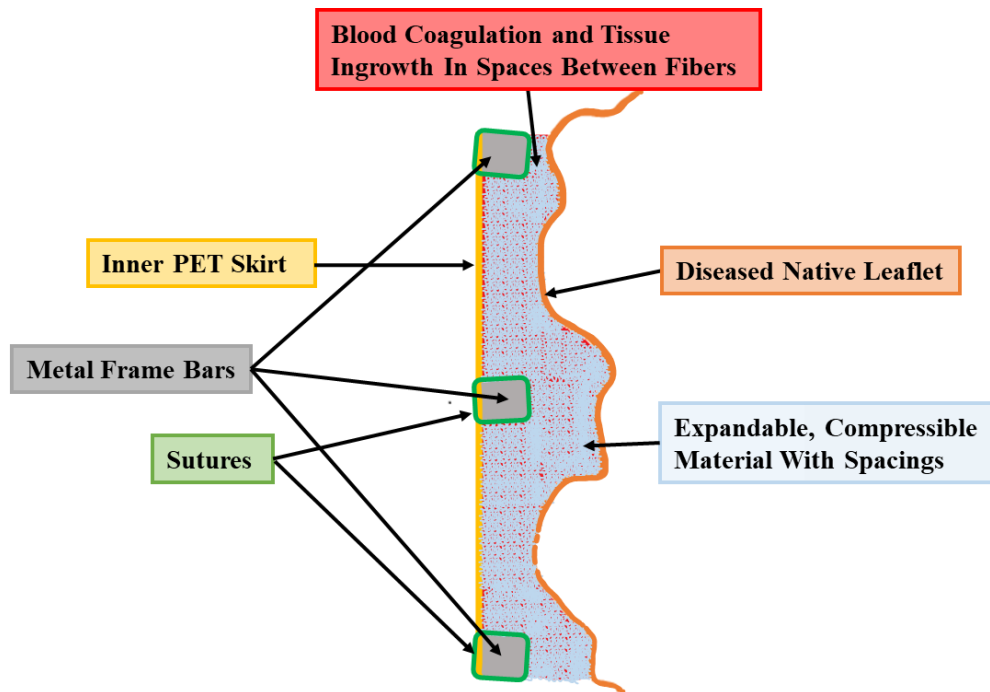
137. Spenser II also discloses that the compressible material “expands after deployment at a treatment site” and that “[a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that the compressible material must and should have spacings between all layers of the fibers in order to expand and “fill[] the gaps between the stented valve and the surrounding tissue” as described. If, for example, the base layer did not have spacings, then it could not expand with the valve during deployment and

would negatively impact the functionality. Also, the outer surface of a stented valve, such the valve in Figure 44a of Spenser, creates an irregularly shaped surface, with gaps between the bars of the stent frame and sutures on the outside of the frame:



Ex. 1010 (Spenser) at Fig. 44a. Similarly, a person of ordinary skill in the art would have understood that the patient’s diseased native valve leaflets would also present an irregularly shaped surface due to calcium deposits on the leaflets, which can form gaps and spaces on the surface of the native leaflets. A person of ordinary skill in the art would have understood that the compressible material must and should be compressible and have spacings between the fibers of the fabric in order to “expand” and “fill[] the gaps” presented on the outer surface of the stented valve and the patient’s diseased native leaflets. This is illustrated in the diagram below, which is intended to represent a longitudinal cross-sectional view of one side of the valve in Spenser/Levi with the addition of Spenser II’s compressible

material:



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

138. Spenser II also discloses that the fibers of the compressible material “may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in

the art would have understood that a fabric, cloth, or other material with spacings between the fibers would be better suited to encourage the coagulation of blood in this manner because it would provide a much greater surface area. *See, e.g.*, Ex. 1128 (Buller Dep.) at 119:13-18 (“The reason for having the increased surface area with all the fibers is to get blood clotting through the thickness of the cloth to help prevent paravalvular leakage, so that the increased surface areas with all the fibers matters all the way through to the frame.”); *see also* Ex. 1129 (Chu) at 4; Ex. 1106 (Estridge) at 158; Ex. 1107 (Hall) at 180-181; Ex. 1108 (Jonas) at 657; Ex. 1109 (Ko) at 1049. Accordingly, Spenser II’s description of the fibers of the compressible material encouraging coagulation of blood would further confirm to a person of ordinary skill in the art that the compressible material must and should have spacings between the fibers of the material.

139. A person of ordinary skill in the art would have understood that in the embodiments wherein the compressible material is a cloth/fabric having fibers extending from the surface of the cloth, the spaces between the fibers must and should exist and extend through both the fibers extending outwardly from the cloth and the base layer/surface of the cloth to achieve all of the purposes I explained above. If the base layer/surface of the cloth did not include spaces between the fibers, it would not be able to compress, promote coagulation of blood, or promote tissue ingrowth, as I explained above. *Supra* ¶¶136-138. Additionally, a lack of

spacings between the fibers could cause the material to disadvantageously bunch during crimping, which would negatively impact the crimped profile and deliverability of the valve. Cloths, like those disclosed in Spenser II, were so well known to be porous that the prior art disclosed methods of coating cloths/fabrics with nonporous substances, such as a collagen or rubber coatings, to reduce the permeability of cloths. *See, e.g.*, Ex. 1108 (Jonas) at 657 (“Pretreatments with biological sealants are available to temporarily reduce the porosity of knitted Dacron at the time of implantation with subsequent resorption of the sealant.”); Ex. 1111 (Scott) at Summary (“[W]oven, double velour Dacron vascular graft was made nonporous by coating it with a layer of collagen prepared from fresh, young calf skin.”); Ex. 1112 (Stegmann) at Summary (“The present study describes the clinical application and results of a new knitted Dacron double-velour prosthesis (primary porosity: 1,400cc/min/cm²), coated with cross-linked bovine collagen; the resulting porosity for implantation is 0cc/min/cm².”). Notably, Spenser II does not teach or suggest coating the compressible material with collagen, rubber, or any other nonporous material. *See* Ex. 1011, [00145]. This informs a person of ordinary skill in the art that the compressible material is porous.

140. A person of ordinary skill in the art would have further understood that at least some of the spacings between the fibers would extend in a radially extending direction from the outermost aspect of the fibers to the outer surface of

the frame because the compressible material is disposed along the exterior of the outer frame, and the fibers of the that form the base layer/surface of the cloth directly abut and are compressed against the outer frame. Therefore, at least some of the spacings between the outwardly extending fibers would overlap with the spacings between the fibers of the base layer/surface of the cloth and would extend in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame. As I mentioned above, both the fibrous and base layers must have spacings to permit compression, among other functionalities. A person of ordinary skill in the art would have understood, and found it obvious, to use cloths having spacings in the base layer that the fibers in the fibrous layer can compress into. Norris, for example, teaches this exact configuration. Ex. 1074 (Norris) at 12:45-48. In a cloth like Norris, the spacings in the fibrous layer and base layer are aligned, at least in many instances, and extend through the entire cloth. A person of ordinary skill in the art would have been motivated and reasonably expected success in using a cloth like Norris for the Spenser II compressible material for all of the reasons discussed above.

141. Persons of ordinary skill in the art would have understood that the spacings between the fibers in Spenser II's compressible material should be sufficiently large to allow fluid to pass through the spacings when the material was not compressed for several reasons. First, Spenser II discloses several different

embodiments and solutions for addressing PVL, and in multiple of the embodiments Spenser II expressly discloses the use of an “impermeable sealing material” that “prevents the passage of fluids through the stent,” such as an impermeable membrane or impermeable PET mesh. *See* Ex. 1011 (Spenser II) at [0017], [0033]-[0037], [00105], [00111], [00118]-[00120], Figs. 4b, 5a-d, 13a-d, 16a-c. Thus, a person of ordinary skill would have recognized that the inventors of Spenser II clearly knew how to specify that a sealing material was impermeable to the passage of fluids and expressly did so when the material had such a property. Notably, however, Spenser II does **not** describe the compressible material in Figure 22 as “impermeable.” This tells a person of ordinary skill in the art that the compressible material is not impermeable to fluids because if it were, the inventors would have described it as having such a property, as they expressly did for several different embodiments. This is consistent with the descriptions of the compressible material as “compressible.” As I explained above, the compressible material must have spacings in its undeployed state to accommodate the compression of the material, and persons of ordinary skill in the art would have understood that the spacings that permit compression also mean that the material is porous and would permit the flow of fluid therethrough. Spenser II also explains that the “compressible material expands after deployment at the treatment site” and “fills gaps between the stented valve and the surrounding tissue” and the

compression against the native tissue “creates a mechanical seal that prevents paravalvular leakage.” Ex. 1011 (Spenser II) at [00145]. Persons of ordinary skill in the art would have understood that when the valve is in the uncompressed state, the compression has not yet occurred, and therefore, no seal has been formed and fluid could pass through the material. Spenser II further discloses that “the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.” *Id.* Spenser II also discloses, “a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps.” *Id.* Persons of ordinary skill in the art 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. Moreover, persons of ordinary skill in the art would have understood that the spacings necessary to promote tissue ingrowth into a fibrous material were in the range of 40-100 μm , which is far larger than the size of a spacing necessary to allow passage of fluid therethrough. See Ex. 1106 (Estridge) at 158 (“Most researchers suggest that 40 μm diameter pores or more are needed for soft tissue ingrowth, while others argue that pores of at least 100 μm are needed.”). Finally, Spenser II does not contain

any suggestion that the compressible material must prevent the flow of fluid thereof in its undeployed state.

142. Even if Spenser II does not disclose the “spacings” limitation, persons of ordinary skill in the art would have been motivated to use a porous fabric or cloth, such as a knitted or woven velour, as the compressible material taught by Spenser II and would have reasonably expected success in doing so. Porous velour fabrics were well known and successfully used in the art as sealing materials for cardiovascular devices for years before November 2012. *See, e.g.*, Ex. 1107 (Hall) (1967 article discussing the use of velour fabrics in cardiovascular implants); Ex. 1106 (Estridge) at 158 (“The most commonly used porous soft tissue biomaterial is Dacron velour. This material has been used extensively as an artificial vascular graft material and in percutaneous devices.”); Ex 1110 (Pourdeyhimi) at 172 (“The weft knitted velour grafts such as Sauvage & Filamentous® are superior in performance to the smooth walled weft knitted grafts. They are easier to suture and handle, and show higher degrees of healability.”). Persons of ordinary skill in the art would have been motivated to use a porous velour or velour-like material as the compressible material because they were known to be compressible, stretchable, and provide enhanced tissue ingrowth when used on cardiovascular devices. *See id.*

143. Persons of ordinary skill in the art would have understood that porous velour and velour-like fabrics and cloths would have spacings between the fibers making up the material that extend through a thickness of the fabric and would allow fluid to pass therethrough when the fabric is uncompressed (i.e., in an “undeployed” state). Indeed, because of their permeability, procedures were developed to “preclot” or impregnate the porous velour-like materials used in the prior art with nonporous materials like collagen to temporarily reduce their permeability when the velour materials were used as a vascular or arterial prosthesis, where leakage of blood through the thickness of the material could be harmful to the patient. *See, e.g.*, Ex. 1108 (Jonas) at 657 (“Pretreatments with biological sealants are available to temporarily reduce the porosity of knitted Dacron at the time of implantation with subsequent resorption of the sealant.”); Ex. 1111 (Scott) at Summary (“[W]oven, double velour Dacron vascular graft was made nonporous by coating it with a layer of collagen prepared from fresh, young calf skin.”); Ex. 1112 (Stegmann) at Summary (“The present study describes the clinical application and results of a new knitted Dacron double-velour prosthesis (primary porosity: 1,400cc/min/cm²), coated with cross-linked bovine collagen; the resulting porosity for implantation is 0cc/min/cm².”).

144. My opinion that persons of ordinary skill in the art would have been motivated to use a porous material, such as a velour or velour-like fabric or cloth,

as Spenser II's compressible material would not change regardless of whether the fabric/cloth is formed of knitted or woven fibers. Whether a cloth is formed by weaving or knitting does not determine whether the fabric is porous or nonporous. Instead, the porosity of the material is determined by how tightly the fibers of the fabric are packed together. Although knitted fabrics are generally more porous than woven fabrics, both woven and knitted fabrics can be manufactured with varying degrees of porosity and both can have porosities that allow fluid to pass therethrough when uncompressed. *See, e.g.,* Ex. 1129 (Chu) at 4 ("Since the numbers of intersections of both weft and warp yarns are closely related to the mechanical and physical properties of the resulting fabrics, a significant reduction in these numbers would make the fabrics more flexible and porous."); Ex. 1109 (Ko) at 1049 ("By controlling the stitch (loop) density, a wide range of pore geometries can be generated."). Critically, however, persons of ordinary skill in the art would have known that the velour and velour-like fabrics commonly used in the prior art for sealing cardiovascular devices, whether woven or knitted, were designed to be porous to improve compressibility, conformability, and tissue ingrowth. *See, e.g.,* Ex. 1129 (Chu) at 4; Ex. 1106 (Estridge) at 158 ("The most commonly used porous soft tissue biomaterial is Dacron⁶ velour. This material has been used extensively as an artificial vascular graft material and in percutaneous

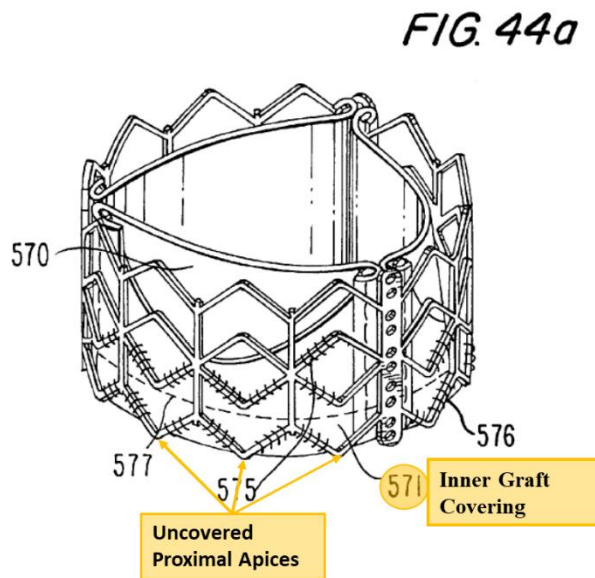
⁶ Dacron is a brand name for PET. *See* Ex. 1106 (Estridge) at 159.

devices. Tissue vascularity has been cited as the key to long-term ingrowth. Therefore, pores of a size sufficient to allow vascular ingrowth are required.”).

7. Uncovered Apices

145. Claim 1 next recites “wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers.” Spenser in combination with Spenser II and optionally Birdsall *or* Bailey renders this limitation obvious.

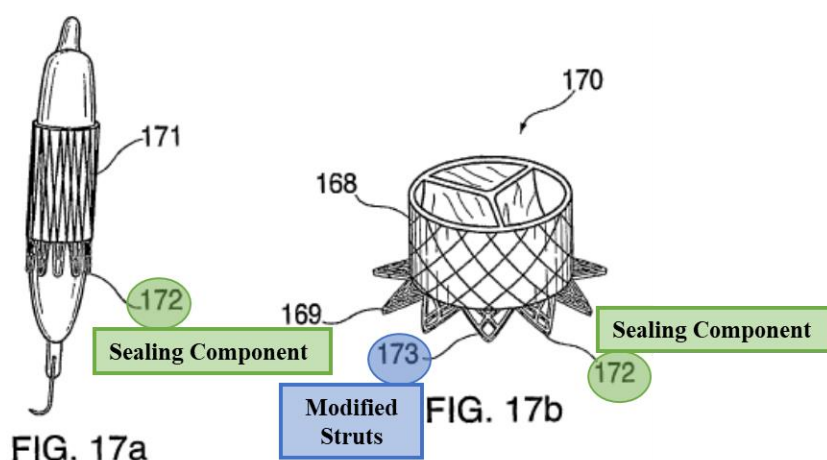
146. Spenser’s PET layer 571 (graft covering) does not cover the ends of the most proximal apices:



Ex. 1010 (Spenser) at Fig. 44a.

a. **Spenser and Spenser II**

147. Spenser II discloses several different embodiments and solutions for preventing PVL. One such embodiment is depicted in Figures 17a-e, which shows a “valve adapted to seal paravalvular leaks” by using a “sealing component [that] is built into a ring 172 of the stent struts” at the proximal end of the frame as shown below:



Id. at [00136], Figs. 17a-b. Spenser II explains that the “modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.” *Id.* at [00136].

148. A person of ordinary skill in the art would have been motivated to combine Spenser’s valves with both the sealing struts 172 of Spenser II’s Figure 17

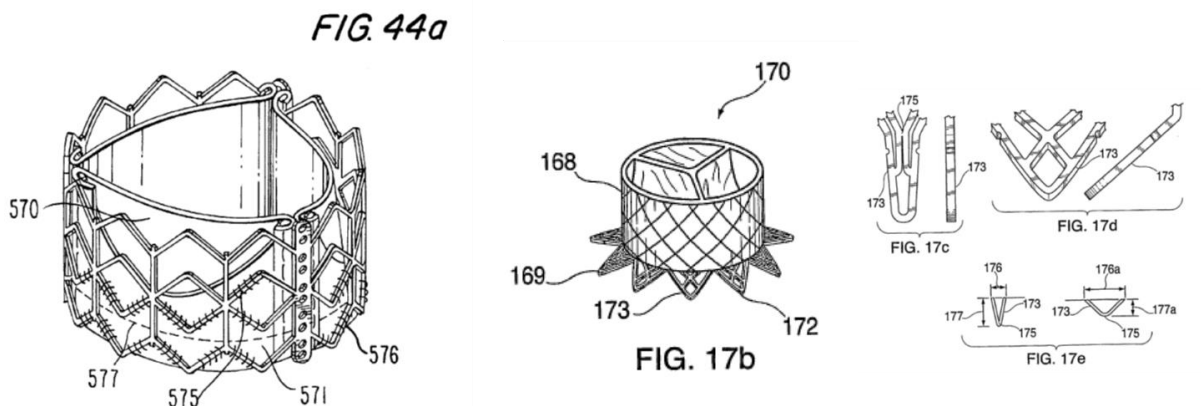
and the compressible material from Figure 22 to further reduce PVL. Notably, Spenser II describes improvements to Spenser's valves and, thus, a person of ordinary skill in the art would have looked to utilize Spenser II's features to improve Spenser's valves. Ex. 1011 (Spenser II) at [0009]-[0010]. A person of ordinary skill in the art would have recognized that the compressible material in Figure 22 and the sealing struts in Figure 17 are distinct and complimentary sealing solutions. The solutions are distinct at least because they are directed to different areas of the valve and help prevent PVL through different mechanisms. They are complimentary at least because they work independently and provide additive benefits that achieve better results than either one alone. For example, the compressible material may cover the cylindrical portion of the valve frame and prevents PVL by promoting tissue ingrowth and blood coagulation through the compressible fibers, while the sealing struts are located at the frame's inlet and help prevent PVL by creating a tight fit within the native aortic valve by having a larger expanded diameter than the rest of the frame, filling gaps and locking the valve in place. See Ex. 1011 (Spenser II) at [00136], [00145]. A person of ordinary skill in the art would have thus sought to use both solutions to reduce PVL as much as possible. Moreover, persons of ordinary skill in the art would have found that combining Spenser II's compressible material and sealing struts with Spenser's Figure 44a, would have merely entailed applying Spenser II's

known techniques for reducing PVL (adding an outer compressible material and ring of modified sealing struts) to Spenser's known valves, which were ready for improvement and would yield predictable results.

149. The sealing struts of Figure 17 would be uncovered by the compressible material of Figure 22 when combining the two embodiments for several reasons. First, Spenser II does not disclose or suggest any covering on the sealing struts in Figure 17. *See id.* at [00136]. Therefore, a person of ordinary skill in the art would have understood that a covering material is not necessary for the sealing struts to perform their sealing function. Second, Figure 22 of Spenser II discloses that the compressible material extends over the cylindrical portion of the valve frame. *Id.* at Fig. 22. Thus, when adding the compressible material to a valve that includes the sealing struts from Figure 17, a person of ordinary skill in the art would place the compressible material above the sealing struts over the cylindrical portion of the frame as disclosed in Figure 22, leaving the sealing struts, and thus the proximal apices of the frame, uncovered. Such positioning would not impact the effectiveness of the compressible material, which would still be able to fill gaps between the frame and the native tissue above the sealing struts, creating an additional seal against PVL. This positioning would also not impact the effectiveness of the proximal sealing struts because Spenser II teaches that the sealing struts do not require a covering material to perform their sealing function,

which is achieved by having the uncovered sealing struts press against the patient's native tissue, filling gaps and locking the valve in place.

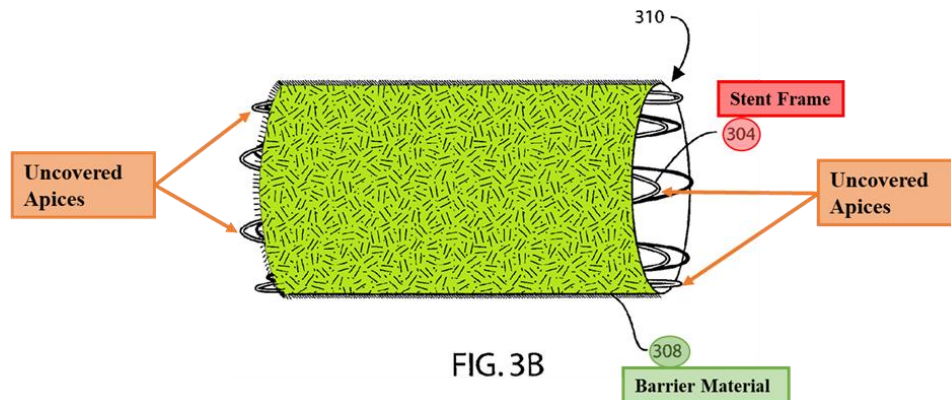
150. A person of ordinary skill in the art would have reasonably expected success in combining Spenser II's compressible material and sealing struts with Spenser's valves for the same reasons I discussed above. *Supra* §VI.A.5. Additionally, a person of ordinary skill in the art would have recognized that the sealing struts in Spenser II's Figure 17 are generally similar in shape to the struts of Spenser's Figure 44a, and could therefore be added to the proximal end of the frame in Figure 44a:



Compare Ex. 1010 (Spenser) at Fig. 44a (left) *with* Ex. 1011 (Spenser II) at Figs. 17b-e (right). The sealing struts are also “geometrically constrained” when the valve is crimped, so they would not negatively impact the crimped profile of the valve. Ex. 1011 (Spenser II) at [00136].

b. Spenser, Spenser II, and Birdsall

151. Birdsall discloses “medical devices for treating cardiac valve abnormalities,” including a stented valve “for replacing the pulmonary valve,” which is the valve that controls the flow of blood from the right ventricle to the pulmonary artery. Ex. 1057 (Birdsall) at 1:7-10, 3:6-10. Birdsall’s valve comprises “a valve connected to a support structure and a barrier material contacting at least a portion of the outer surface of the support structure of the valve device.” *Id.* at 3:14-17. The barrier material prevents blood from flowing between the outer surface of the stented valve and the vessel wall and also prevents the valve from migrating after deployment. *See id.* at 3:17-20, 6:4-65. Birdsall discloses that the “barrier material” may be comprised of “directionally oriented microfibers attached to the surface of stented valve 310 and extending outward,” microfibers “attached to a thin, pliable film or fabric,” or a polyester batting comprised of a “disordered array of polyester microfibers that forms a soft, compressible mass.” *Id.* at 6:10-65. Birdsall’s barrier material does not cover the apices of the frame at either end of the valve:



Id. at Fig. 3B.

152. Persons of ordinary skill in the art would have been motivated by Birdsall's disclosure of a valve with a sealing material that does not extend as far as the proximal apices of the frame to similarly size and position Spenser II's compressible material on Spenser's valves. Birdsall and Spenser disclose similar THVs comprised of a metallic stent surrounding prosthetic leaflets. In both cases, the valves are endovascularly deliverable and can be crimped and expanded by, for example, a balloon. These similarities would have motivated a person of ordinary skill in the art to use features from one invention for the other with a reasonable expectation of success. Additionally, persons of ordinary skill in the art would have been motivated to apply Birdsall's arrangement of the sealing material to Spenser's valves given the similarities between the aortic and pulmonic valves. For example, both the aortic and pulmonic valves regulate the flow of blood from a chamber of the heart to a major artery. *See, e.g., id.* at 1:22-24, 4:29-50, Fig. 1.

And persons of ordinary skill in the art would have known that both valves can suffer from stenosis and regurgitation. *Id.* at 1:14-21. Persons of ordinary skill in the art would have also known that PVL was an issue when implanting prosthetic valves to replace either the aortic or pulmonary valves. *See, e.g., id.* at 6:4-9; Ex. 1011 (Spenser II) at [00144]. Given these similarities, Birdsall's PVL solution for a pulmonary THV would have provided an attractive option for addressing PVL on Spenser's aortic THV.

153. Moreover, while much of Birdsall's disclosure focuses on the pulmonic valve, Birdsall broadly discloses that its "invention relates generally to medical devices for treating cardiac valve abnormalities." *Id.* at 1:7-10. And Birdsall further discloses that "[o]ne embodiment of a stented valve suitable for use in the present invention is disclosed in U.S. Pat. No. 5,957,949 titled 'Percutaneous Placement Valve Stent' to Leonhardt, et al.," and Birdsall incorporates the '949 patent by reference. *Id.* at 5:65-6:3. The Leonhardt '949 patent incorporated by Birdsall discloses stented valves that are suitable for replacing a patient's aortic valve via transfemoral delivery. *See* Ex. 1035 (Leonhardt) at 9:63-10:21, Fig. 3. Persons of ordinary skill in the art would therefore have understood that a fibrous material like Birdsall's "barrier material" would perform a similar sealing function when implanted in other valves,

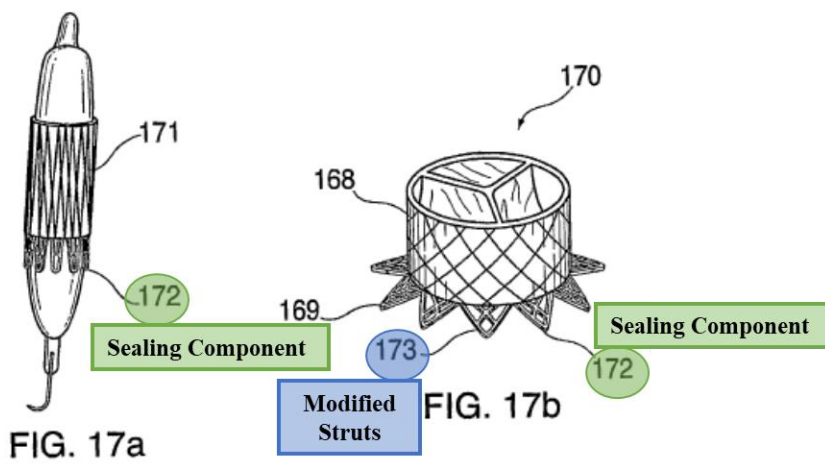
including the aortic valve, providing further motivation to combine Birdsall's teachings with Spenser and Spenser II.

154. Persons of ordinary skill in the art would have found that adapting Spenser II's compressible material so that the proximal apices extend further than the material, as taught in Birdsall, would have merely entailed applying Spenser II's known technique for reducing PVL (adding an outer compressible material) and Birdsall's known positioning and sizing of the seal (leaving the apices uncovered) to Spenser's known valves, which were ready for improvement and would yield predictable results. Additionally, the positioning of Spenser II's compressible material with respect to the proximal apices presented the person of ordinary skill a binary choice – either the material extends as far proximally as the apices, or it does not. A person of ordinary skill in the art would have found it obvious to try both of these finite solutions, which would have yielded the predictable result of reducing PVL based on the teachings of both Spenser II and Birdsall.

155. Persons of ordinary skill in the art would have also been motivated to try and adopt shorter compressible materials to reduce the overall amount of material and reduce the profile. Persons of ordinary skill in the art were always motivated to use less or thinner materials in THVs to reduce the valve profile. See *supra* ¶¶79-81 (describing the many adjustments Petitioner made to valves to

decrease the profile). The height of the skirt would have been an obvious parameter for adjustment.

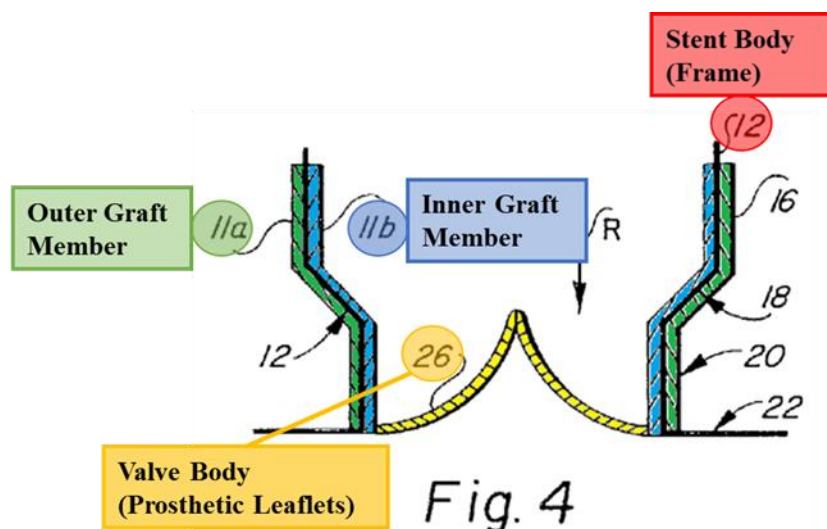
156. Further, Spenser II does not require the compressible material to extend to the frame's proximal apices or cover the proximal apices. Although Figure 22 of Spenser II illustrates the compressible material extending to the proximal end of the frame, a person of ordinary skill in the art would have recognized that Figure 22 merely illustrates one embodiment of the stented valve and that Spenser II is not limited to just that single embodiment. There is no teaching or disclosure in Spenser II suggesting that having the compressible material extend to the proximal end of the frame is critical or necessary for preventing PVL. Indeed, as I explained above, Spenser II discloses embodiments of its stented valve wherein the frame extends proximally beyond where the compressible material is added in Figure 22, such as the embodiment depicted in Figure 17:



Id. at [00136], Figs. 17a-b. Thus, nothing in Spenser II teaches away from Birdsall's disclosure of a sealing material that does not cover the proximal apices of the frame.

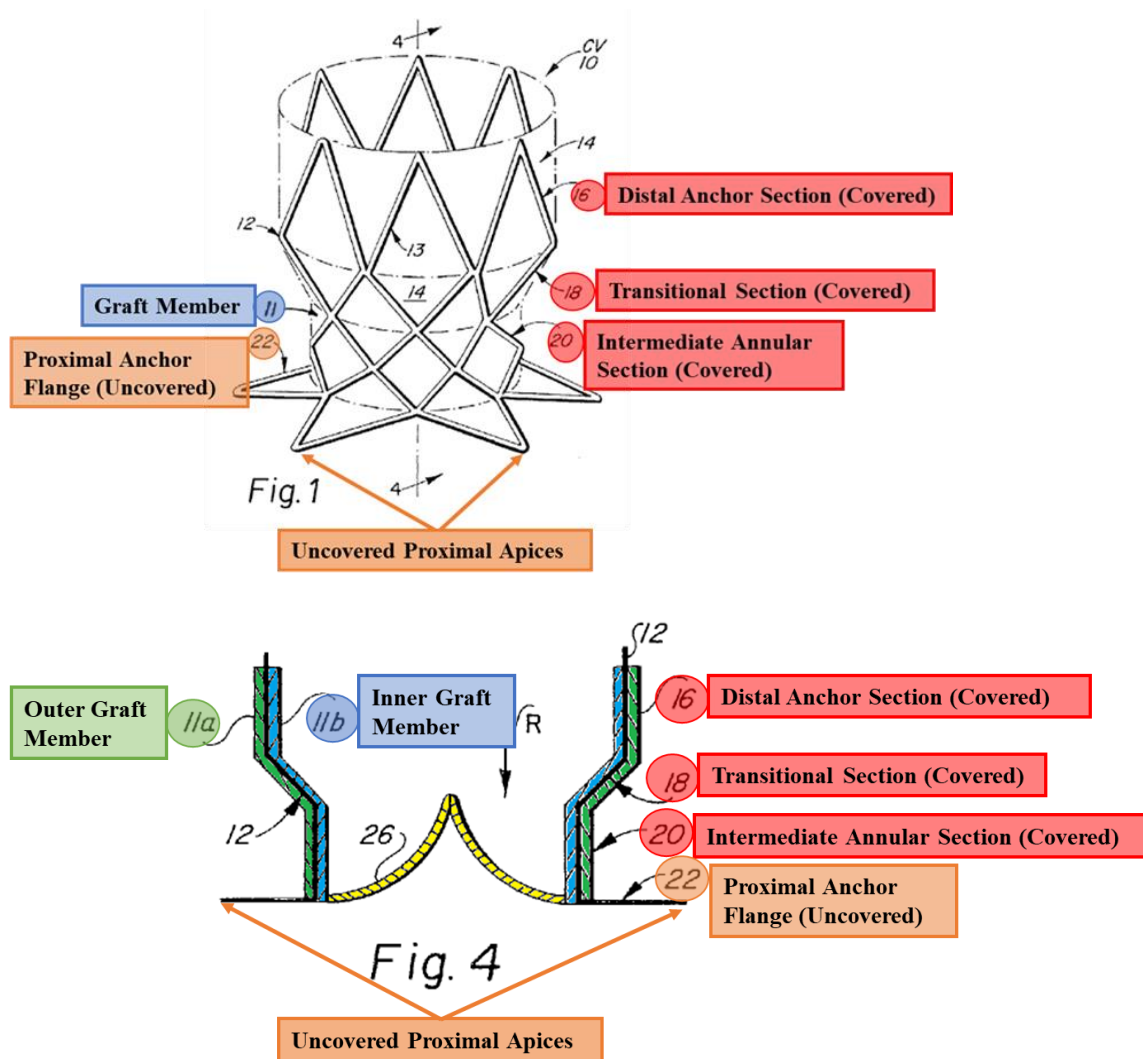
c. Spenser, Spenser II, and Bailey

157. Bailey discloses embodiments of prosthetic heart and venous valves that can be implanted percutaneously, including embodiments of the valve in “a chamber-to-vessel (CV) configuration which is particularly well-suited as an aortic valve prosthesis to facilitate blood flow from the left ventricle to the aorta.” Ex. 1141 (Bailey) at Abstract, [0002]. Bailey's chamber-to-vessel THV includes “an expandable stent body member 12 and graft member 11.”



Id. at [0048], Fig. 4. The stent body can be formed from either self-expanding or balloon-expandable materials and “is configured to have three functional sections: a proximal anchor flange 22, an intermediate annular section 20 and a distal anchor

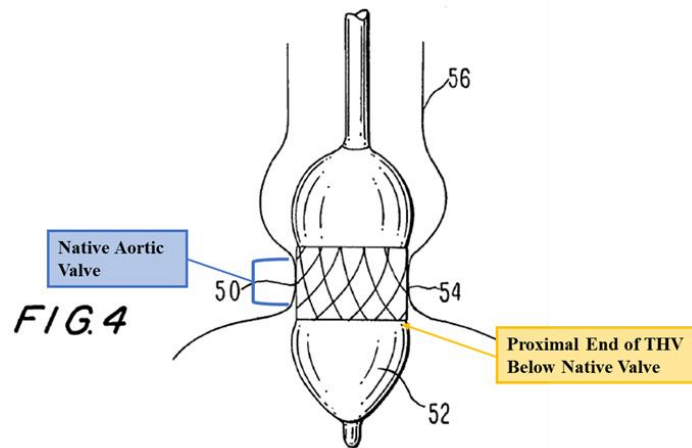
section 16.” *Id.* The stent body member “is formed of a plurality of stent struts 13 which define interstices 14 between adjacent stent struts.” *Id.* “The graft member 11 consists of an outer or abluminal graft member 11a and an inner or luminal graft member 11b.” *Id.* at [0049]. “The outer graft member 11a encloses at least a portion of the abluminal surface of the intermediate annular section 20 of the stent body member, while the inner graft member 11b is coupled, on the luminal surface of the intermediate annular section 20 of the stent body member 12, to the outer graft member 11a through the interstices 14 of the stent body member.” *Id.* Bailey discloses that the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member 12, including the distal anchor section 16, the intermediate annular section 20, the transition section 18 and/or the proximal anchor flange 22, on either or both of the luminal and abluminal surfaces of the stent body member.” *Id.* at [0052]. Bailey’s Figures 1 and 4 disclose an embodiment where the inner and outer graft members extend over sections 16, 18, and 20 of the frame, but **not** the proximal apices:



Id. at Figs. 1, 4.

158. Bailey’s teaching that “the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves” would have motivated a person of ordinary skill in the art to position Spenser II’s compressible material over the portion of Spenser’s valve that overlaps with the native leaflets “in order to exclude the anatomic valves.” *Id.* at [0052]. As shown in Figure 4 of Spenser below, the proximal end of Spenser’s

frame extends into the left ventricle when implanted in the patient's native aortic valve and does not overlap with the patient's native leaflets:



Ex. 1010 (Spenser) at 14:15-20, Fig. 4. Therefore, a person of ordinary skill in the art would have recognized that based on Bailey's teachings, Spenser II's compressible material would not need to extend to the proximal ends of the apices of Spenser's frame to create an effective seal since the proximal apices extend into the left ventricle and do not overlap with the native aortic valve, obviating the need for the sealing material at those points.

159. Accordingly, Bailey would have motivated a person of ordinary skill in the art to position Spenser II's compressible material on Spenser's valve such that the compressible material would not extend to or over the proximal apices of the frame. Further, the person of ordinary skill in the art would have found the combination of Spenser's valve with Spenser II's compressible material and Bailey's positioning of the material to leave the proximal apices exposed to merely

entail applying Spenser II's known technique for reducing PVL (adding an outer compressible material) and Bailey's known technique for positioning the sealing material (overlapping the native leaflets and leaving the proximal apices uncovered) to Spenser's known valves, which were ready for improvement and would yield predictable results. Bailey also confirms that a person of ordinary skill in the art would have found it obvious to try either finite, predictable solution for placement of an outer seal relative to the proximal apices for the same reasons I explained above with respect to Birdsall. *Supra* §VI.A.7.b.

160. For the same reasons I explained above, nothing in Spenser II teaches away from Bailey's design of a sealing material that does not extend to or cover the frame's proximal apices. *Supra* ¶156.

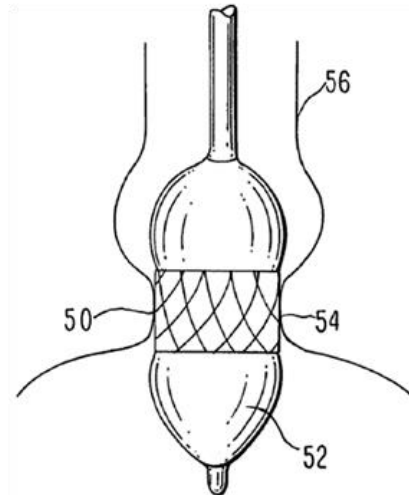
8. Fibers Compressed To Form Seal

161. Claim 1 next recites "wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings." Spenser in combination with Spenser II renders this limitation obvious.

162. I am aware that in a prior IPR of a related patent, the Board concluded that the combination of Spenser and Spenser II would press fibers against the patient's native leaflets because persons of skill in the art "reading Spenser II,

would understand that, if the compressible material that is disposed along the outer surface of the stent extends entirely around the stent, then it would, necessarily, be in radial alignment with the native leaflets around the circumference of where the outer frame presses the native leaflets laterally.” Ex. 1119, 83-86. I agree with the Board’s conclusion.

163. Spenser’s Figure 4 (below) “depicts deployable valve deployment in a natural aortic valve position in accordance with the present invention”:



Ex. 1010 (Spenser) at 8:66-67, 14:15-20, Fig. 4; *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b. As shown above, the valve presses against the patient’s aortic annulus. *Id.* at Fig. 4. Although not pictured in Fig. 4, a person of ordinary skill in the art would understand that the valve also presses against the patient’s native aortic leaflets, which are attached to the annulus and extend distally therefrom. *Supra* §III.B. A person of ordinary skill in the art would have understood Figure 4 to illustrate the placement of Spenser’s Figure 44a because

Figure 4 describes “the present invention” and Figure 44a is described as a “preferred embodiment of the present invention.” Ex. 1010 (Spenser) at 8:66-67, 26:30-34. Thus, Spenser II’s compressible material would extend over at least two rows of grids formed by Spenser’s frame and would press against and form a seal with the native valve leaflets when implanted.

164. Spenser II discloses a compressible material disposed along the frame of a THV “[t]o reduce or prevent paravalvular leakage.” Ex. 1011 (Spenser II) at [00145]. As I explained above, persons of ordinary skill in the art would have understood that Spenser II’s compressible material encompasses porous materials with spacings between the fibers of the material. *Supra* §VI.A.6. Spenser II teaches that “[t]he compressible material expands after deployment at a treatment site [and a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue” which “creates a mechanical seal that prevents paravalvular leakage.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have known that because THVs like those in Spenser are not sutured to the patient’s native tissue, the THV must fit tightly into a patient’s native valve to avoid PVL and/or migration or dislodgment of the THV after delivery. Accordingly, the person of ordinary skill in the art would have understood that while some of the fibers of Spenser II’s compressible material would expand into the “gaps between the stented valve and the surrounding

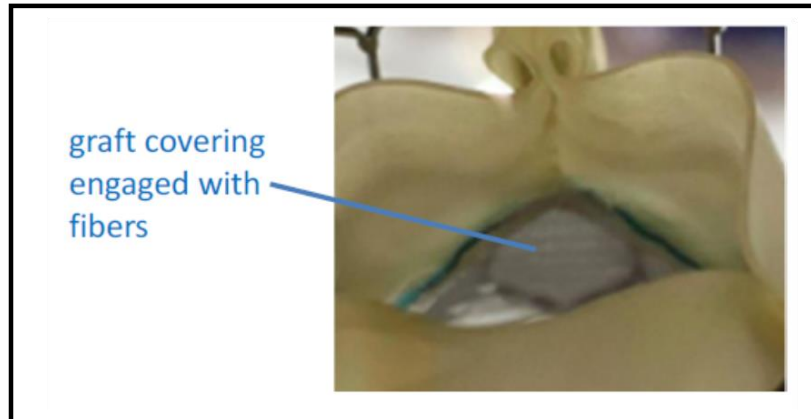
tissue,” the fibers would also be compressed due to the tight fit between the native valve and the THV, creating the “mechanical seal that prevents paravalvular leakage.” *Id.* The compression of Spenser II’s fibers would cause the fibers to be compressed into the spacings between the fibers of the material, reducing the spacings between the fibers and creating the paravalvular seal around the valve.

9. Graft Covering Engaged With Fibers

165. Claim 1 next recites: “wherein the graft covering is engaged with fibers of the plurality of fibers.”

166. As I explained previously, Spenser discloses a graft covering secured to the inner surface of a frame having a plurality of open cells. *Supra* §§VI.A.2-3. Persons of ordinary skill in the art would therefore have understood that when Spenser II’s compressible material is added to Spenser’s valve, the fibers of the compressible material would press against and “engage” the graft covering through the open cells of the frame when the compressible material is pressed against the patient’s native tissue. Indeed, I am aware that Patent Owner’s infringement contentions for the ’634 patent in the district court litigation assert that such a configuration meets this limitation:

Patent Owner's Infringement Contentions



Ex. 1123 (PO Infringement Contentions) at 618-620.

10. Endovascularly Deployed

167. Claim 1 finally recites: “wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.” Spenser **or** Levi in combination with Spenser II renders this limitation obvious.

168. I am aware that the Board has previously concluded that a person of ordinary skill in the art would have expected that the combination of Spenser II’s compressible material with Spenser’s Figure 44a would have been capable of endovascular delivery. Ex. 1117 (’172 FWD), 53-64; Ex. 1118 (’011 FWD), 57-68; Ex. 1119 (’538 FWD), 69-80.) I agree with the Board’s conclusion.

169. Spenser discloses that “[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously***, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the

desired location *via a large blood vessel such as the femoral artery*, in a procedure similar to other known interventional cardiovascular procedures.” Ex. 1010 (Spenser) at 2:6-12 (emphases added). Spenser’s valve may be crimped to a small diameter that is “suitable for percutaneous catheterization and deployment.” *Id.* at 14:12-14; *see also id.* at 12:8-17, 12:28-36, 13:26-54. Spenser also discloses endovascularly implanting the prosthetic valve in a patient’s native aortic valve using a balloon catheter that is guided through the patient’s vasculature to the patient’s native aortic valve. *Id.* at 5:17-6:36, 17:19-18:43.

170. Spenser’s Figure 44a illustrates a “preferred embodiment of the *present invention*[.]” *Id.* at 26:30-34 (emphasis added). Based on at least this description, persons of ordinary skill in the art would have understood that Spenser’s disclosure of endovascular delivery through the femoral artery applies to Figure 44a. *See id.* at 2:6-12, 26:30-34.

171. Spenser II describes using catheters to endovascularly deliver heart valves “through a body duct to a target location.” Ex. 1011 (Spenser II) at [0009], [0014], [0017], [00144]-[00145]. Spenser II states, “[p]ercutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient’s skin (usually in the groin or armpit area) under local anesthetic sedation.” *Id.* at [0012]. Persons of ordinary skill in the art would have understood the description of endovascular delivery to apply to the

stented valve with the compressible material in Figure 22 because Spenser II discloses that the “present invention provides a series of new **percutaneous** concepts of paravalvular repairs including identifying the leak location, several repair techniques and finally built-in means for leak prevention, **built on percutaneous valves.**” *Id.* at Abstract (emphases added). The methods of percutaneous introduction described in Spenser II are types of endovascular delivery. A person of ordinary skill in the art would have understood that introduction of the valve through a small perforation in the groin area refers to, at least, endovascular delivery through the femoral artery, as that is the most common access point for the femoral artery.

172. Persons of ordinary skill in the art would have reasonably expected that Spenser’s Figure 44a valve would remain suitable for endovascular delivery after the addition of Spenser II’s compressible material. Spenser teaches that the “maximal size of a catheter inserted into the femoral artery should be **no more than 8 mm in diameter.**” Ex. 1010 (Spenser) at 27:65-67 (emphasis added). Spenser’s prosthetic valve “has the ability to change its diameter from about **4 mm** to about 25 mm.” *Id.* at 27:67-28:2 (emphasis added).

173. Spenser II discloses that “in one preferred embodiment” the compressible material “has a thickness ranging from about 1 to 5 mm,” which a person of ordinary skill in the art would have understood to refer the material’s

non-compressed dimensions. Ex. 1011 (Spenser II) at [00145]. Persons of ordinary skill in the art would have reasonably expected that adding a compressible material 1 mm thick to Spenser’s 4-mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery. Additionally, persons of ordinary skill in the art would have recognized the availability of compressible materials having a range of thicknesses, densities, and compressibility that could be used to further reduce the profile, and Spenser II does not limit the compressible material to any particular dimensions.

174. For example, Norris teaches a compressible fabric, suitable for providing sealing to a heart valve, which is highly compressible to enable “a small enough delivery catheter to reach a target implant site.” Ex. 1074 (Norris) at 8:23-39. Norris teaches that “[i]n the non-compressed configuration 40, some embodiments of the sealing member 52 can have a thickness of about 1-5 mm,” the same thickness as Spenser II’s non-compressed compressible material. *Id.* at 10:9-11. Norris further teaches that “[i]n the compressed configuration 41, some embodiments of the sealing member 52 can have a thickness of about 0.004-0.008 inches [0.102–0.203 mm].” *Id.*, 10:11-13. Thus, Norris discloses a sealing material suitable for prosthetic heart valves that may be compressed by rough 10 to 25 times. *See id.* Persons of skill in the art would have been aware of this teaching, and it would have reinforced their expectation that Spenser’s valve with

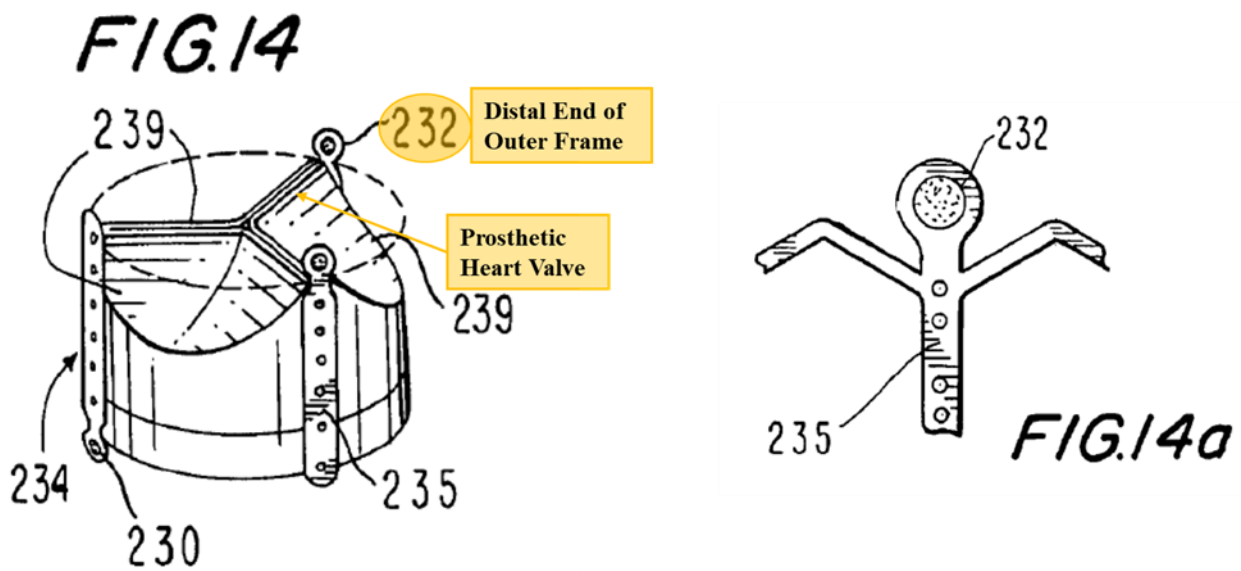
Spenser II's compressible material would be suitable for endovascular delivery through a patient's femoral artery.

175. Thus, persons of ordinary skill in the art would have reasonably expected the combination of Spenser's Fig. 44a valve with Spenser II's compressible material, or a similar but thinner material, would be suitable for endovascular delivery through the femoral artery.

B. Claim 2

176. Claim 2 recites: "The valve assembly of claim 1, wherein the frame extends distally further than the prosthetic heart valve leaflets." Spenser discloses this limitation. Thus, Spenser in combination with Spenser II and optionally Birdsall *or* Bailey renders this claim obvious.

177. Spenser discloses several embodiments satisfying this limitation. In Figure 14-14c, Spenser illustrates heart valves having "heavy metal markers [232] on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location":



Ex. 1010 (Spenser) at 16:27-51, Figs. 14-14a. As shown in Figure 14 (above), the portion of the outer frame having the marker extends distally further than the prosthetic heart valve. A person of ordinary skill in the art would have been motivated to add the markers to the frame in Spenser’s Figure 44a to better visualize the frame during deployment. A person of ordinary skill in the art would have reasonably expected success in adding the marker because Spenser describes using the marker with a frame similar to Figure 44a and metal markers were commonly used in the field by 2012.

178. In Figure 28, Spenser illustrates a method of attaching the leaflets 430 to a metallic frame 420:

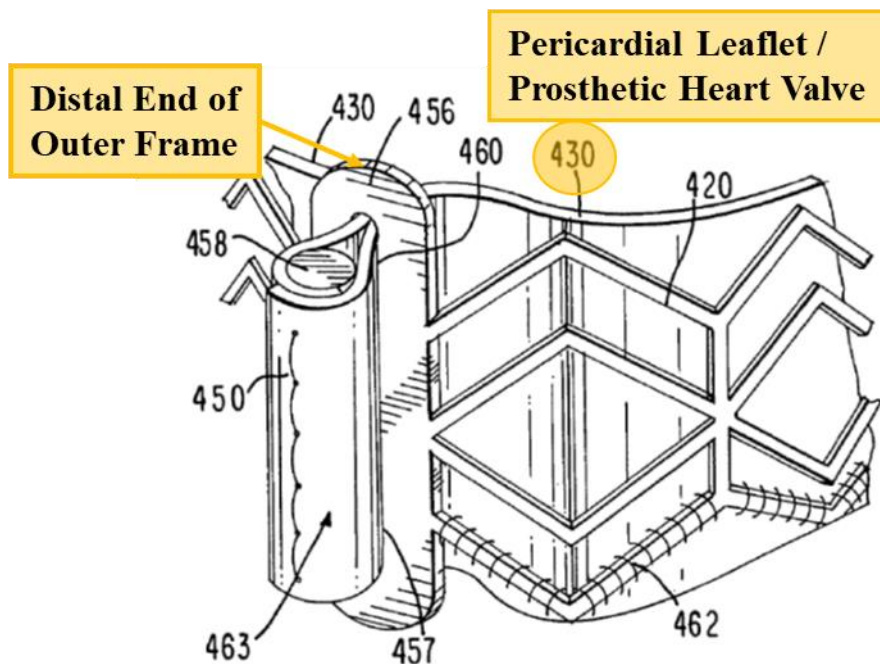


FIG. 28

Id. at 21:46-67, Fig. 28. As shown, the outer frame portion 456 extends distally further than the prosthetic heart valve leaflets 430. A person of ordinary skill in the art would have been motivated to use this method of attachment in Spenser's Figure 44a to reduce stress points and abrasion on the leaflets. *Id.* at 20:60-67. A person of ordinary skill in the art would have reasonably expected success in using this method with Figure 44a because Spenser already discloses using the method in conjunction with a frame like Figure 44a.

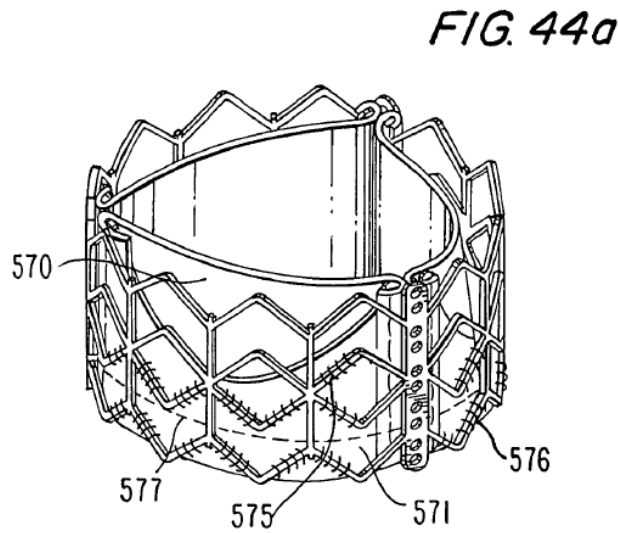
C. Claim 3

179. Claim 3 recites: "The valve assembly of claim 1, wherein the frame is a singular, integral component." Spenser discloses this limitation. Thus, Spenser

in combination with Spenser II and optionally Birdsall *or* Bailey renders this claim obvious.

180. I am aware that the Board has already decided that Spenser discloses a frame that is a singular, integral component in a prior IPR. Ex. 1119 ('538 FWD), 37, 90. I agree with the Board's decision.

181. Spenser's Figure 44a includes "frame 575," which is a singular, integral component:

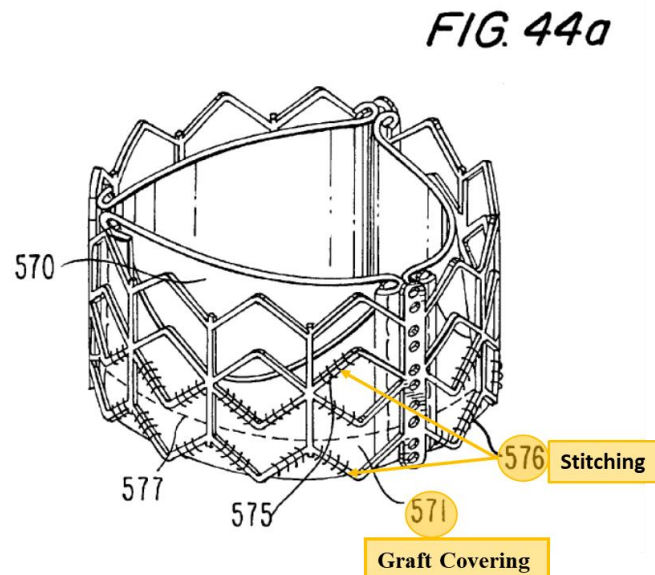


Ex. 1010, 26:30-34, 19:5-13, Figs. 44a-44b. As shown in figure 44a above, the vertically straight bars of the frame are each connected by four rows of interconnected, angular struts that form the gridded shape of the frame. *See id.* Because each of the bars of the frame are interconnected, frame 575 is a singular, integral component. *Id.* at Fig. 44a-44b.

D. Claim 4

182. Claim 4 recites: “The valve assembly of claim 1, wherein the frame and the graft covering are attached by stitching at a top and bottom portion of the graft covering.” Spenser discloses this limitation. Thus, Spenser in combination with Spenser II and optionally Birdsall *or* Bailey renders this claim obvious.

183. Spenser’s PET 571 (graft covering) is attached to the frame with stitches at the top and bottom of PET 571:



Ex. 1010 (Spenser) at 16:45-48, Fig. 44a-b.

E. Claim 5

184. Claim 5 recites: “wherein the valve assembly is balloon expandable.” Spenser discloses this limitation. Thus, Spenser in combination with Spenser II and optionally Birdsall *or* Bailey renders this claim obvious.

185. Spenser discloses that the valve depicted in Figure 44a “resembles the valve shown in Fig. 43.” Ex. 1010 (Spenser) at 26:34-35. The valve in Figure 43 may be “inflated by a balloon[.]” *Id.* at 1010, 26:19-28. Thus, persons of ordinary skill in the art would have understood that Figure 44a is also balloon expandable.

186. Persons of ordinary skill in the art would have understood that Spenser’s valves would remain balloon expandable after adding Spenser II’s compressible material because both Spenser II discloses that the compressible material is combinable with balloon-expandable valves. Ex. 1011 (Spenser II) at [00144] (“The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter.”). Additionally, as discussed above, Spenser II’s compressible material has spacings that allow it to expand, or a person of ordinary skill in the art would have been motivated to use a material with such spacings. *Supra* §VI.A.6.

F. Claim 6

187. Claim 6 recites: “The valve assembly of claim 1, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.” Spenser discloses this limitation. Thus, Spenser in combination with Spenser II and optionally Birdsall *or* Bailey renders this claim obvious.

188. As I explained previously, Spenser discloses a PET graft covering that extends around and are attached to the prosthetic heart valve leaflets. *Supra*

§VI.A.2. Therefore, if a graft covering can be an “inner frame,” as asserted by Patent Owner in litigation, Spenser’s PET 571 forms an inner frame for supporting the prosthetic heart valve.⁷

G. Claim 7

189. Claim 7 recites: “The valve assembly of claim 1, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.” Spenser in combination with Spenser II and optionally Birdsall **or** Bailey renders this claim obvious for the reasons I explained in claim 1. *Supra* §VI.A.10.

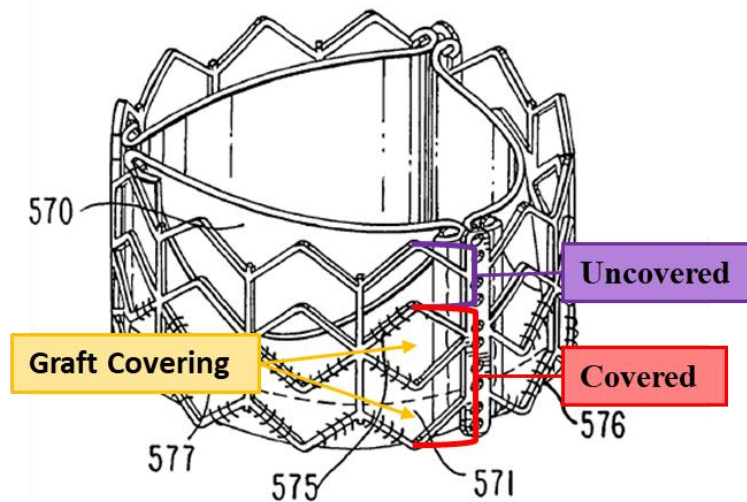
H. Claim 9

190. Claim 9 recites: “The valve assembly of claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.” Spenser in combination with Spenser II and optionally Birdsall **or** Bailey renders this claim obvious.

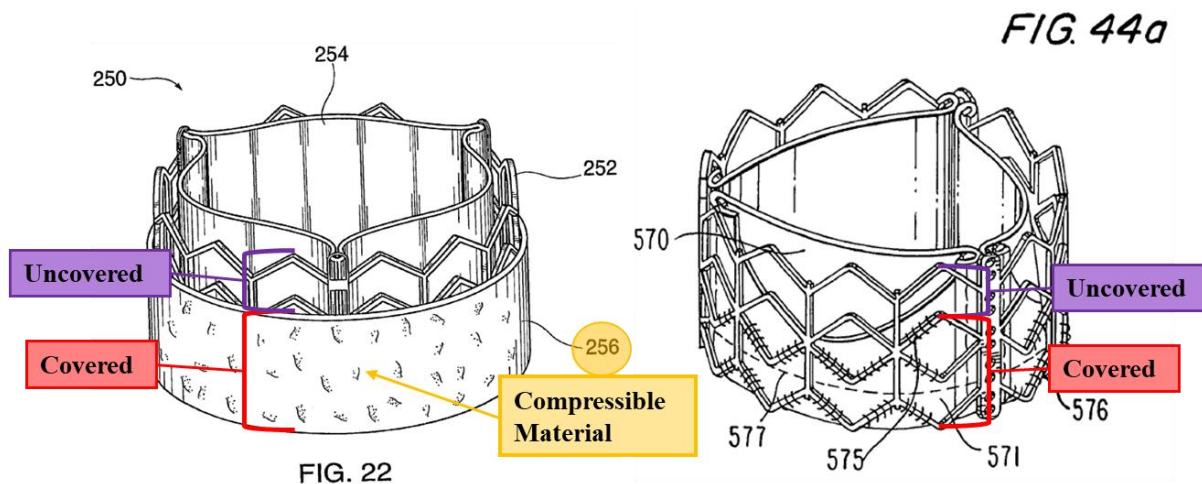
191. PET 571 in Spenser’s Figure 44a does not cover the most distal row of cells:

⁷ As I explained previously, my opinions regarding this claim limitation are based on Patent Owner’s assertions that the claims of the ’634 patent cover Petitioner’s SAPIEN 3 Ultra valve. *Supra* §II.A.

FIG. 44a



Ex. 1010 (Spenser) at Fig. 44a. Spenser II's compressible material also does not extend over the most distal row of cells of stent structure 252. Ex. 1011 (Spenser II) at [00145]. When added to the exterior of the stent in Spenser's Figure 44a, the compressible material would **not** extend over the most distal row of cells, as illustrated by Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



Ex. 1011 (Spenser II) at Fig. 22; Ex. 1010 (Spenser) at Fig. 44a. Accordingly, the combination of Spenser and Spenser II would result in a valve wherein the most

distal row of cells is uncovered by both the graft covering and the fibers attached to the outer surface of the frame.

**VII. GROUND 4: CLAIMS 1-7 AND 9 ARE OBVIOUS OVER SPENSER
AND BIRDSALL**

A. Claim 1

192. Based on my review of the prior art, it is my opinion that Spenser combined with Birdsall renders claim 1 obvious.

1. Preamble

193. The preamble of claim 1 recites: “A transcatheter aortic heart valve assembly.” If this preamble is limiting Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.1.

2. Graft Covering

194. Claim 1 next recites: “graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto.” Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.2.

3. Frame

195. Claim 1 next recites: “a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the

frame to form apices, and the struts cooperatively forming an open cell configuration, wherein the frame is secured to the graft covering.” Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.3.

4. Polymeric Graft Covering

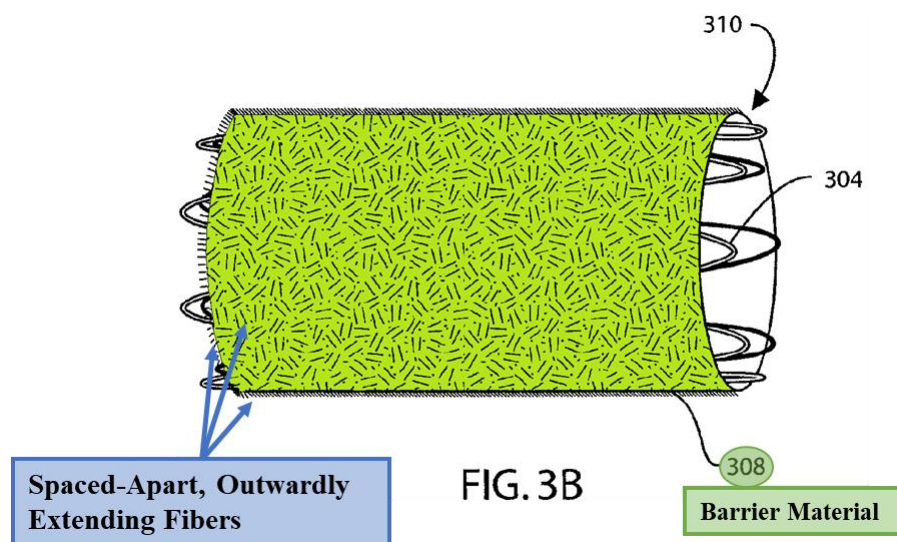
196. Claim 1 next recites: “wherein the graft covering is made of a polymer.” Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.4.

5. Plurality of Fibers

197. Claim 1 next recites: “a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame, wherein the fibers are arcuate, spaced-apart, and outwardly extending.” Spenser in combination with Birdsall renders these limitations obvious.

198. Birdsall discloses a stented valve “for replacing the pulmonary valve,” which is the valve that controls the flow of blood from the right ventricle to the pulmonary artery. Ex. 1057 (Birdsall) at 3:6-10. Birdsall’s valve comprises “a valve connected to a support structure and a barrier material contacting at least a portion of the outer surface of the support structure of the valve device.” *Id.* at 3:14-17. The barrier material prevents blood from flowing between the outer surface of the valve and the vessel wall and also prevents the valve from migrating

after deployment. *See id.* at 3:17-20, 6:4-65. Birdsall discloses that the “barrier material” may be comprised of “directionally oriented microfibers attached to the surface of stented valve 310 and extending outward,” microfibers “attached to a thin, pliable film or fabric,” or a polyester batting comprised of a “disordered array of polyester microfibers that forms a soft, compressible mass.” *Id.* at 6:10-65. As shown below in Figure 3B of Birdsall, the fibers of the barrier material are “spaced apart” and “outwardly extending:



Id. at Fig. 3B.

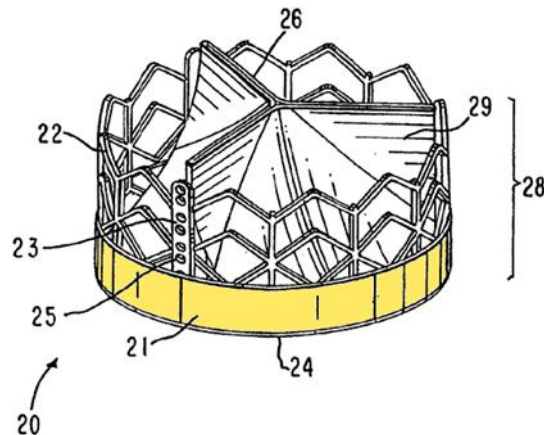
199. Birdsall discloses that the barrier material is “flexible,” and that the microfibers making up the barrier material may be made of flexible materials including polyester and nylon. *Id.* at 6:15-17. Moreover, the flexible fibers of the barrier material would be compressed against the native tissue upon implantation when added to Spenser’s valve. Accordingly, a person of ordinary skill in the art

would have understood that that the flexible fibers would be “arcuate,” especially when implanted. Birdsall also discloses that the polyester microfibers may form a “soft, compressible mass” of “batting” material formed from a “disordered array of polyester microfibers.” *Id.* at 6:56-65. Persons of ordinary skill in the art would have understood many of Birdsall’s flexible polyester fibers in the batting would have an arcuate shape, especially when compressed against the patient’s native tissue upon implantation.

200. Persons of ordinary skill in the art would have been motivated to add Birdsall’s barrier material to Spenser’s valves to prevent PVL and migration of the valve after delivery. I am aware that the Board previously concluded that a person of ordinary skill in the art would have been motivated to add a compressible sealing material to Spenser’s valves to reduce PVL. Ex. 1117 (’172 FWD) at 64; *see also* Ex. 1118 (’011 FWD) at 68; Ex. 1119 (’538 FWD) at 80-81. I agree with the Board’s conclusion, and that same motivation would have applied to Birdsall’s barrier material. Birdsall’s barrier material helps prevent valve migration and PVL by filling gaps between the valve and the irregular, asymmetrical surface of a calcified conduit or vessel. Ex. 1057 (Birdsall) at 6:4-65, 7:29-44. Persons of ordinary skill in the art would have recognized that Birdsall’s member would similarly benefit Spenser’s valves. As I explained above, there are many similarities between the pulmonic and aortic valves, which would have given a

person of ordinary skill in the art a reasonable expectation of success that Birdsall's barrier material would work for Spenser's valves. *Supra* §VI.A.7.b. As I also explained above, Birdsall teaches that its invention is suitable for use with valves disclosed in the Leonhardt patent which may be transfemorally implanted in a patient's native aortic valve. *Id.*

201. Moreover, Spenser already discloses embodiments having a sealing cuff at the proximal end of the valve:



Ex. 1010 (Spenser) at 13:22-25, Fig. 1. However, Spenser II taught that Spenser's valves could still benefit from further PVL prevention. Ex. 1011 (Spenser II) at [0009]-[0010]. A person of ordinary skill in the art would have been motivated to add, and reasonably expected success in adding, Birdsall's barrier material to the exterior of Spenser's valves based on these teachings to achieve Birdsall's stated benefits of reducing PVL and preventing migration. Further, a person of ordinary skill in the art would have found that adding Birdsall's compressible material to Spenser's valves would have merely entailed applying Birdsall's known technique

for reducing PVL (a barrier material) to Spenser's known valves, which were ready for improvement and would yield predictable results.

202. When adding Birdsall's barrier material to Spenser's valve, a person of ordinary skill in the art would have been motivated to position the barrier material such that it extends over at least two rows of open cells at the inflow end of Spenser's frame to ensure that the barrier material could fill the gaps between the valve and the calcified native leaflets when the valve is deployed in the patient. Moreover, the prior art taught that covering the proximal two rows of cells on similar valves, such as Spenser II's stented valve and Walther's cloth-covered SAPIEN valve, was effective for preventing PVL, which would have provided a person of ordinary skill in the art with further motivation to position Birdsall's barrier material to cover two rows of cells at the inflow end of Spenser's valve. *See* Ex. 1007 (Walther) at Fig. 1; Ex. 1011 (Spenser II) at Fig. 22.

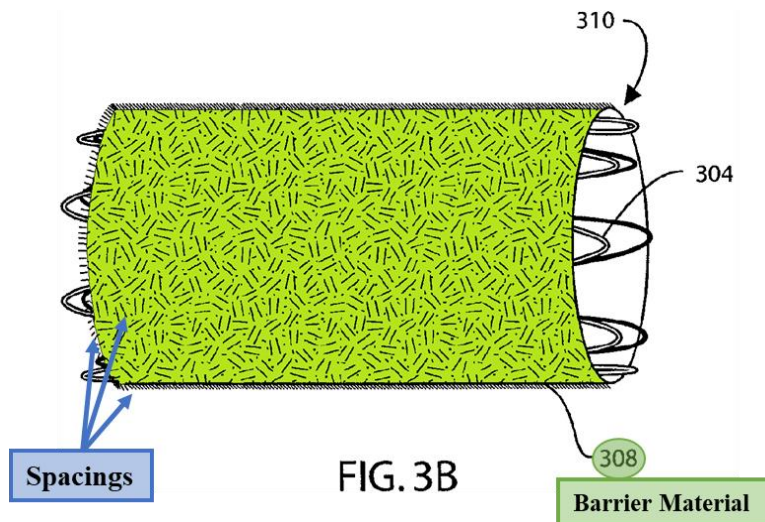
203. The fibers of Birdsall's barrier material would be "in contact" with a plurality of rows of open cells at the inflow end of Spenser's frame. Birdsall describes several types of barrier materials, including materials having "directionally oriented microfibers attached to the surface of stented valve 310 and extending outward." Ex. 1057 (Birdsall) at 6:12-14. These fibers are attached to the frame and "in contact" with the frame. Birdsall also discloses barrier materials formed of "directionally oriented microfibers" attached to the frame, where the

microfibers may be woven into “a fabric of woven polyester fibers such as Dacron® fibers.” *Id.* at 6:12-27. In such embodiments, the outwardly extending microfibers would be woven through the base layer and in direct contact with the frame for the same reasons I explained in Grounds 1-3 for in Spenser II. *Supra* §VI.A.5. Birdsall also discloses barrier materials formed of “polyester batting adhered to the exterior surface” of the valve. Ex. 1057 (Birdsall) at 6:56-65. The outwardly extending fibers comprising the batting are “adhered to the exterior surface of the valve” and are therefore in direct contact with the outer surface of the stent. *Id.*

6. Spaced-Apart Fibers

204. Claim 1 next recites: “wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state.” Spenser in combination with Birdsall renders this limitation obvious.

205. Birdsall’s figures illustrate spacings between the barrier material’s fibers:



Ex. 1057 (Birdsall) at Fig. 3B. A person of ordinary skill in the art would have understood that these visible spacings would and should be sufficiently large to allow fluid to pass therethrough when the barrier material is in an uncompressed state. Moreover, a person of ordinary skill in the art would have been motivated to select a material for the barrier material with spacings large enough for fluid to pass therethrough for the reasons I explained in Grounds 1-3 above. *Supra* §VI.A.6. Like Spenser II's compressible material, Birdsall's barrier material is compressible and formed from a plurality of flexible fibers. *See* Ex. 1057 (Birdsall) at 6:9-37, 6:56-65. Also like Spenser II's compressible material, Birdsall explains that the when the stented valve is implanted in the patient, the barrier material expands to fill the gaps between the stented valve and surface of the vessel wall. *See id.* Accordingly, the same rationales I explained previously in Grounds 1-3 for Spenser II apply equally to Birdsall's barrier material. *Supra* ¶¶136-144.

206. At least some of the spacings between the fibers in Birdsall's barrier material are in a "radially extending direction from the outermost aspect of the fibers to the outer surface of the frame." Birdsall describes that in one embodiment of the barrier material, "directionally oriented microfibers attached to the surface of stented valve 310 and extending outward." Ex. 1057 (Birdsall) at 6:12-14. In other words, in these embodiments the outwardly extending fibers of the barrier material are attached directly to the surface of the frame without any intervening material between the fibers and the frame. *See id.* In such embodiments, the spacings between the "directionally oriented microfibers" would extend to the outer surface of the frame because the fibers are attached directly to the frame. Birdsall also discloses embodiments where the directionally oriented microfibers of the barrier material are attached to a woven polyester cloth. *Id.* at 6:17-27. As I explained above and as Patent Owner acknowledged during prosecution, spacings would exist between the fibers in all cloths, including the woven polyester cloth in Birdsall's barrier material. *Supra* ¶117. Accordingly, even in embodiments of the barrier material having fibers that extend from a cloth, Birdsall discloses spacings that extend "from the outermost aspect of the fibers to the outer surface of the frame."

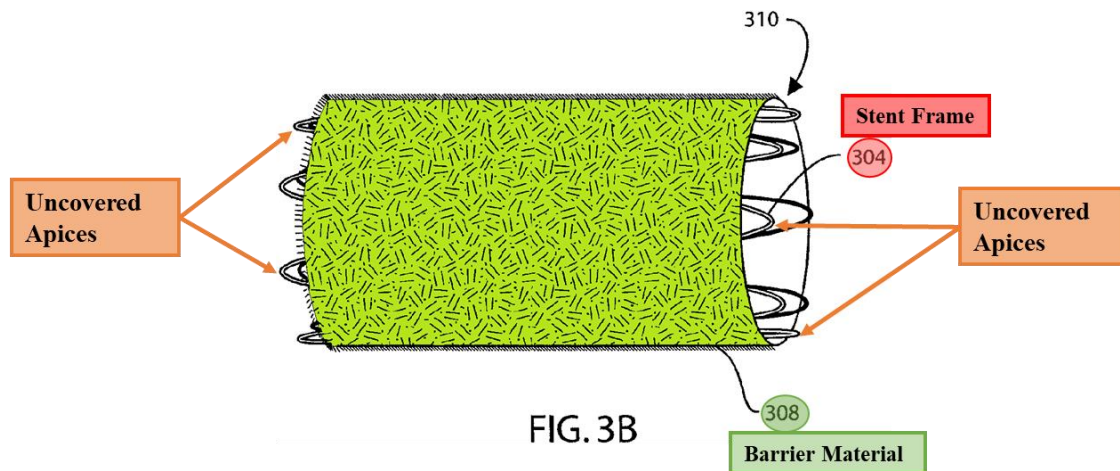
207. Birdsall also discloses barrier materials comprised of polyester batting adhered to the outer surface of the frame that "is a disordered array of polyester

microfibers that forms a soft, compressible mass” that “expands and presses against the wall of the conduit” when implanted to form a seal. *Id.* at 6:56-65. A person of ordinary skill in the art would have been motivated to select polyester batting that included spacings between the fibers so that the batting was “compressible” and could expand when implanted, as I explained in Grounds 1-3 for Spenser II. *Supra* §VI.A.6. At least some of the spacings between the fibers of the batting would extend to the outer surface of the frame because Birdsall discloses that the batting is adhered directly to the exterior surface of the frame. Ex. 1057 (Birdsall) at 6:56-58.

7. Uncovered Apices

208. Claim 1 next recites: “wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers.” Spenser in combination with Birdsall renders this limitation obvious.

209. Birdsall’s barrier material does not cover the apices at either end of the stented valve:



Ex. 1057 (Birdsall) at Fig. 3B. As I explained in Grounds 1-3, Birdsall’s disclosure of a valve having a fibrous sealing material that does not cover the apices of the frame would have motivated a person of ordinary skill in the art to position Birdsall’s barrier material on Spenser’s valve such that the proximal apices of the frame are uncovered by the barrier material and extend proximally further than the barrier material. *Supra* §VI.A.7.

8. Fibers Compressed To Form Seal

210. Claim 1 next recites “wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings.” Spenser in combination with Birdsall renders this limitation obvious.

211. Birdsall discloses that the fibers of the barrier material fill in the gaps between the stented valve and the calcified conduit by pressing against the vessel

wall to form a seal and prevent migration of the valve. Ex. 1057 (Birdsall) at 6:28-37, 6:56-65, 7:36-44. As I explained previously, a person of ordinary skill in the art would have known that a THV must create a tight fit with the native tissue to avoid migration and/or displacement of the valve after deployment. *Supra* ¶164. This tight seal would compress the flexible fibers of the barrier material against the patient's native tissue to form a seal. Therefore, when the barrier material is added to Spenser's valve and the valve is implanted in a patient's native aortic valve, the spaced-apart fibers of the barrier material would be "compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings."

9. Graft Covering Engaged With Fibers

212. Claim 1 next recites: "wherein the graft covering is engaged with fibers of the plurality of fibers." Spenser in combination with Birdsall renders this limitation obvious.

213. As I explained previously, Spenser discloses a graft covering secured to the inner surface of a frame having a plurality of open cells. *Supra* §§VI.A.2-3. When Birdsall's barrier material is added to Spenser's valve, the fibers of the barrier material would press against and "engage" the graft covering through the open cells of the frame when the compressible material is pressed against the

patient's native tissue for the same reasons I explained in Grounds 1-3 with respect to Spenser II. *Supra* §VI.A.9.

10. Endovascularly Deployed

214. Claim 1 finally recites: “wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.” Spenser in combination with Birdsall renders this limitation obvious.

215. Spenser discloses a THV that is endovascularly deployable through a patient's femoral artery for the reasons I explained in Grounds 1-3. *Supra* §VI.A.10. A person of ordinary skill in the art would have reasonably expected Spenser's valve to remain suitable for endovascular delivery via the femoral artery after the addition of Birdsall's barrier material.

216. Birdsall discloses that its stented valve can be percutaneously delivered “through the venous system and into a patient's right ventricle” via the jugular vein, the subclavian vein, the femoral vein, or the common iliac vein. Ex. 1057, 5:37-51, 7:45-67. Also, as I explained above, Birdsall teaches that its invention is suitable for use with valves disclosed in the Leonhardt patent which may be transfemorally implanted in a patient's native aortic valve. *Supra* §VI.A.7.b. Birdsall also discloses that the barrier material is “flexible” and “compressible,” which would facilitate a narrower crimp profile necessary for

transfemoral delivery. Ex. 1057 (Birdsall) at 6:9-12, 6:56-65. Therefore, a person of ordinary skill in the art would have reasonably expected there would be sufficient space on Spenser's 12F compressed valve to accommodate Birdsall's flexible, compressible material and remain suitable for endovascular delivery via the femoral artery.

B. Claims 2-7

217. As I explained in Grounds 1-3, Spenser discloses the additional limitations that are recited by dependent claims 2-7 of the '634 patent. *Supra* §§ VI.B-G. Therefore, it is my opinion that Spenser in combination with Birdsall renders claims 2-7 obvious for the reasons I explained above for the limitations of claim 1 and in Grounds 1-3 for the limitations of claims 2-7. *Supra* §§VII.A, VI.B-G.

C. Claim 9

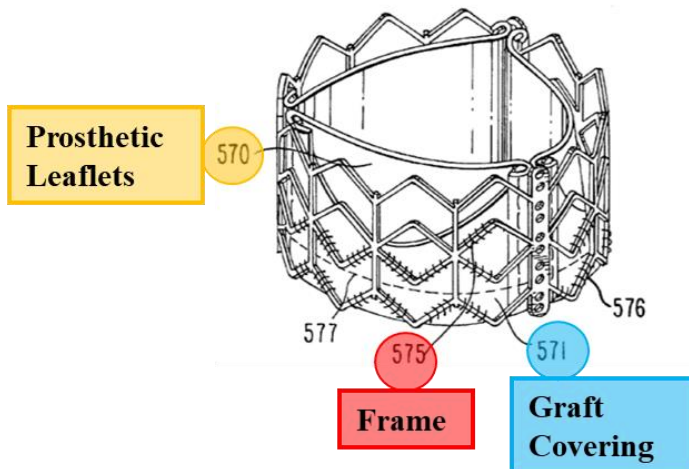
218. Claim 9 recites, "wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers." Spenser in combination with Birdsall renders this claim obvious.

219. As I explained in Grounds 1-3, Spenser discloses embodiments wherein the most distal row of cells are uncovered by the graft covering. *Supra* §VI.H. A person of ordinary skill in the art would have been motivated to position Birdsall's barrier material on Spenser's valves such that the most distal row of cells

is uncovered by the barrier material because the prior art, including Walther and Spenser II, taught such an arrangement created an effective seal on similar THVs. Ex. 1007 (Walther) at Fig. 1; Ex. 1011 (Spenser II) Fig. 22. This configuration would also help to ensure that the barrier material would not obstruct blood flow to the coronary arteries when the valve is implanted and would reduce the volume of material around the valve, which would advantageously benefit the delivery profile. In such a configuration, the most distal row of cells of Spenser's frame would be uncovered by the graft covering and outwardly extending fibers of the barrier material.

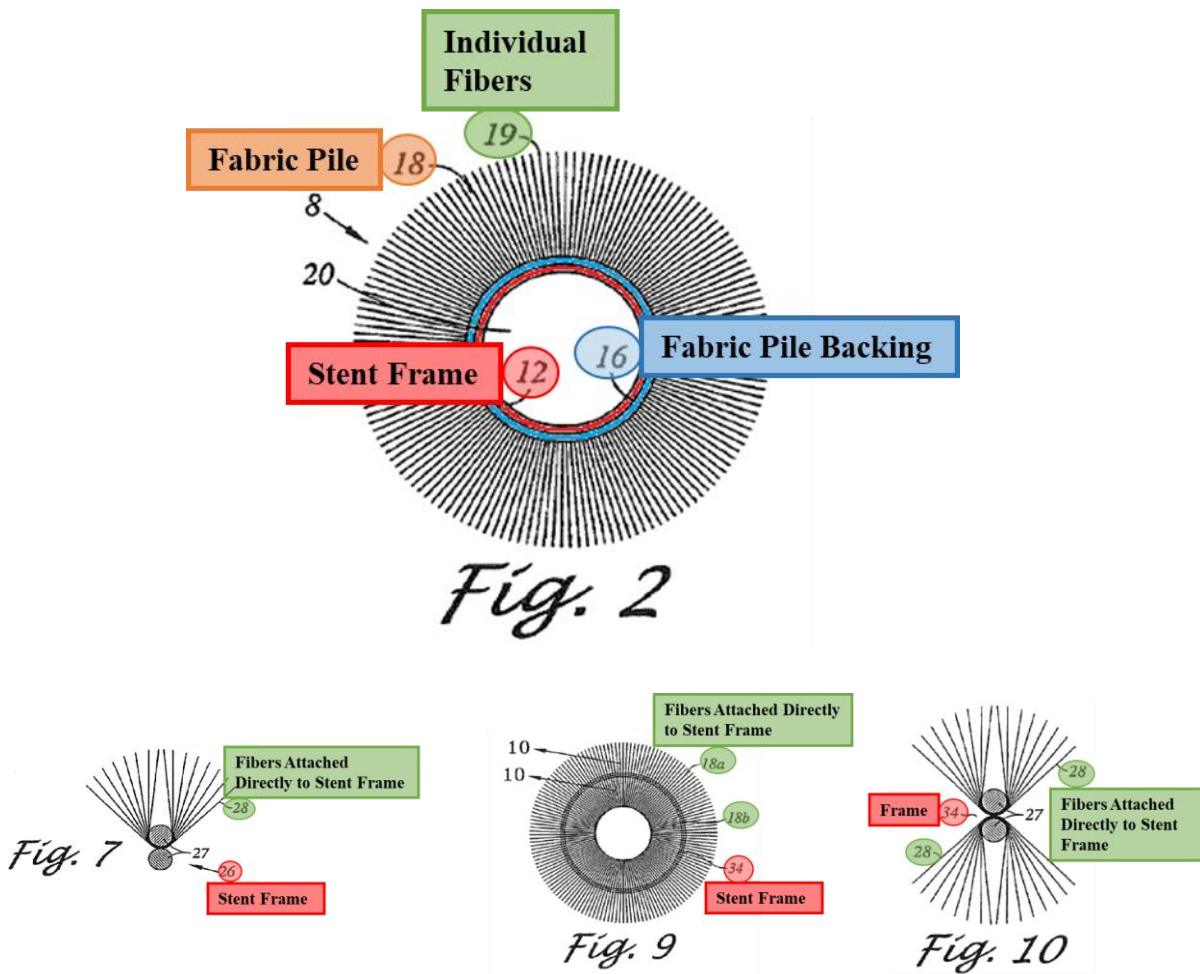
VIII. GROUNDS 5-6: CLAIMS 1-7 AND 9 ARE OBVIOUS OVER
SPENSER AND CHUTER IN COMBINATION WITH BIRDSALL OR
BAILEY

220. As I explained above, Spenser describes heart valve assemblies having a frame, an inner graft covering, and prosthetic leaflets, as illustrated below:



Ex. 1010 (Spenser) at 11:66-12:17, Fig. 44a.

221. Chuter discloses embodiments of endovascularly delivered intravascular stents for either maintaining patency or occluding diseased vessels. *See* Ex. 1116 (Chuter) at Abstract, [001]. Chuter discloses stents having a “fiber pile” attached to the stent frame that is composed of outwardly extending individual fibers which are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” Chuter teaches that the individual fibers of the “fiber pile” can either extend from a “fabric pile backing” (Fig. 2) or they can be attached directly to the stent frame without any backing (Figs. 7, 9-10), as shown in Figures 2, 7, and 9-10 below:



Id. at [0017]-[0022], Figs 1-10.

222. Persons of ordinary skill in the art would have found it obvious to add Chuter’s “fiber pile” to the valves disclosed in to prevent PVL given Chuter’s teachings that the fiber pile is adapted to encourage tissue ingrowth and prevent blood from leaking between the stent graft and the patient’s diseased vessel. And persons of ordinary skill in the art would have been motivated by Birdsall and Bailey to position Chuter’s fiber pile on Spenser’s valve such that the most proximal apices of the frame are uncovered by the fibers of the fiber pile.

Therefore, Spenser in combination with Chuter and Birdsall *or* Bailey renders the challenged claims obvious.

A. Claim 1

223. Based on my review of the prior art, it is my opinion that Spenser and Chuter in combination with Birdsall *or* Bailey render claim 1 obvious.

1. Preamble

224. The preamble of claim 1 recites: “A transcatheter aortic heart valve assembly.” If this preamble is limiting Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* §VI.A.1.

2. Graft Covering

225. Claim 1 next recites: “graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto.” Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.2.

3. Frame

226. Claim 1 next recites: “a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration, wherein the frame is secured to the graft covering.” Spenser

discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.3.

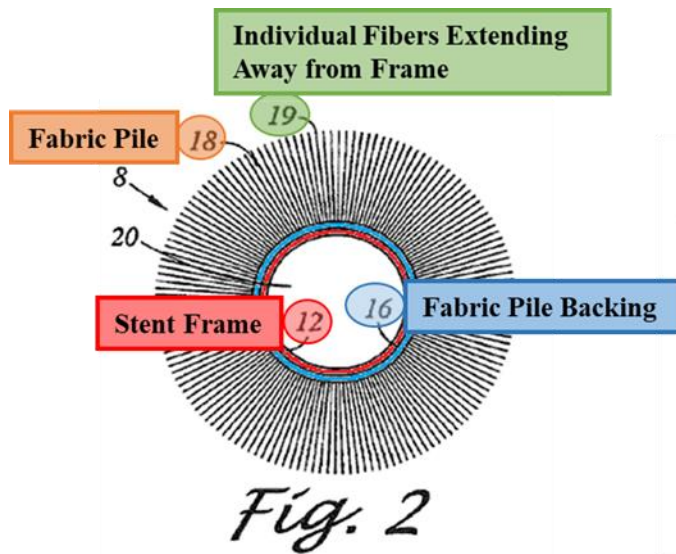
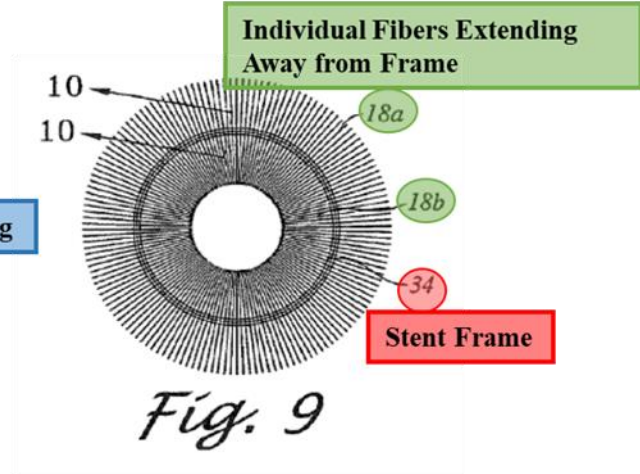
4. Polymeric Graft Covering

227. Claim 1 next recites: “wherein the graft covering is made of a polymer.” Spenser discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.4.

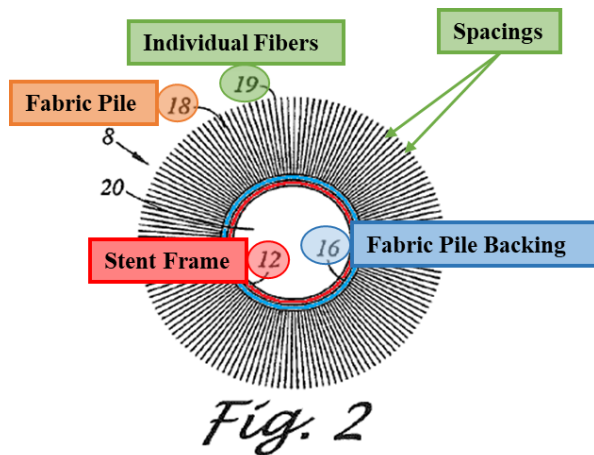
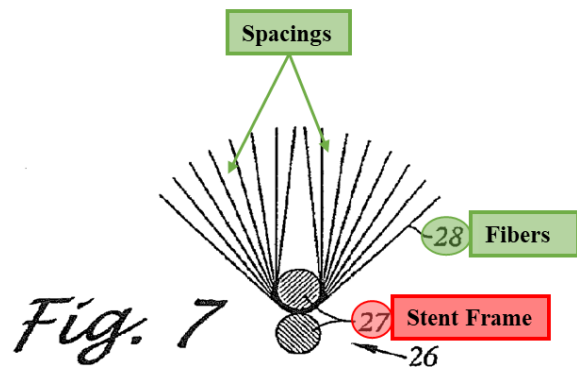
5. Plurality of Fibers

228. Claim 1 next recites: “a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame, wherein the fibers are arcuate, spaced-apart, and outwardly extending.” Spenser in combination with Chuter renders these limitations obvious.

229. Chuter discloses embodiments of “endovascular stent[s] for vascular vessels which can be used to occlude the vessel or bridge damaged areas in the vessel.” Ex. 1116 (Chuter) at Abstract. Chuter discloses stents having a “fiber pile” attached to the stent frame that is composed of outwardly extending individual fibers which are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” *Id.* at [0017]-[0022], [0054]-[0057].) The fiber pile is composed of individual fibers that extend away from the stent frame, as illustrated in Figures 2 and 9:

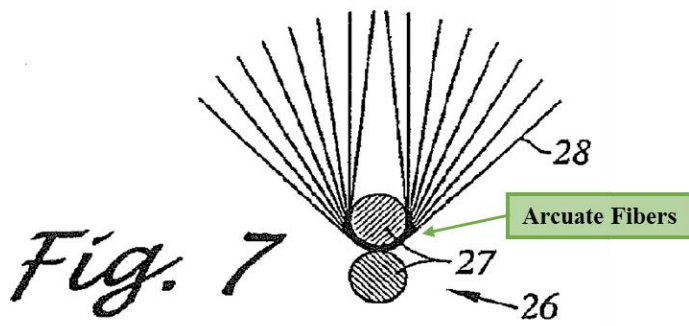
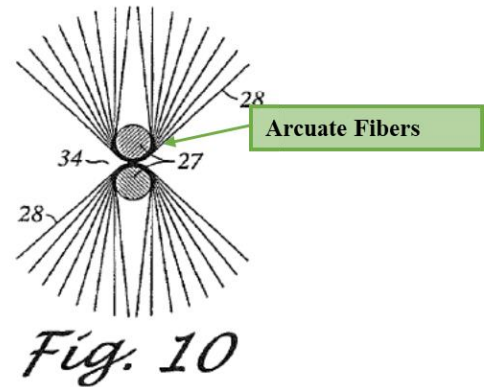


Id. at [0017]-[0022], Figs 1-10. Chuter's fibers are spaced-apart:



Id. at Figs. 2, 7.

230. In Chuter's embodiments lacking the fabric pile backing, Chuter's figures depict the fibers curving and wrapping around the stent frame, as shown in Figures 7 and 10 below:



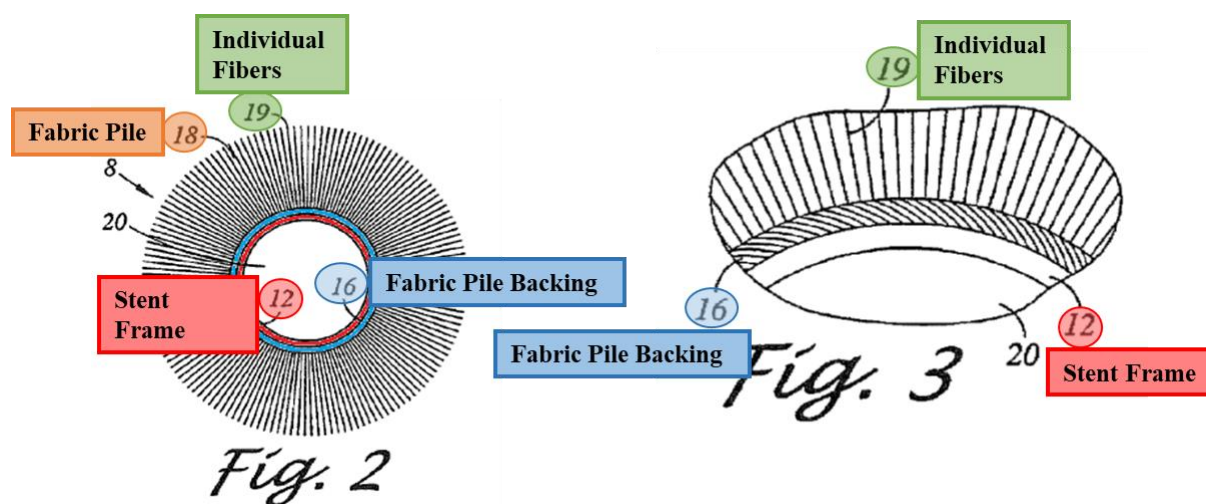
Id., Figs. 7, 10. The illustrated fibers are therefore arcuate.

231. In Chuter’s embodiments having individual outwardly extending fibers that extend from a backing, persons of ordinary skill in the art would have understood that the individual outwardly extending fibers would be curved (i.e., arcuate) at least where they are secured to the backing, likely by weaving or knitting the fibers into and around the backing.

232. Chuter also discloses that the “fibers of the fiber pile are biocompatible fibers which are known to the art” and may “include nylon fibers, polyester fibers, Mylar brand fibers and the like” and further teaches that the fibers are flexible and get “push[ed] down” when the device is crimped. *Id.* at [0022], [0062]. Persons of ordinary skill in the art would therefore have understood that while Chuter’s figures illustrate portions of the fibers as straight, not all (and likely none) of the fibers would have been perfectly straight, and at least some of the flexible fibers would be arcuate, particularly when compressed in the patient.

233. Chuter discloses that the fibers are in contact with the frame in two ways.

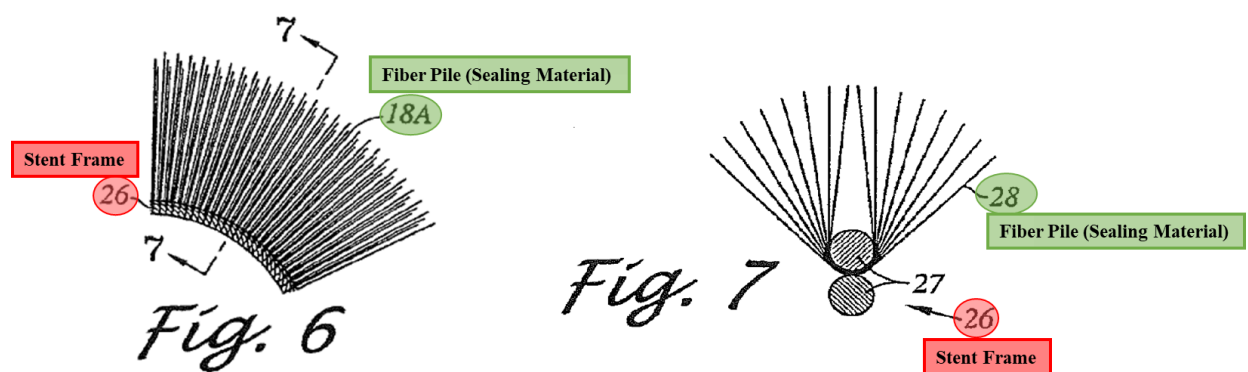
234. First, Chuter teaches embodiments having a “fabric pile backing” that includes “a fabric pile 18 made up of individually extending fibers 19” that “[e]xtend[s] circumferentially outwardly from the backing.”



Ex. 1116 (Chuter) at [0054]-[0055], Figs. 2-3. Persons of ordinary skill in the art would have understood that the “fabric pile backing” would be composed of fibers, which are illustrated in Chuter’s Figure 3. *Id.* at Fig. 3. Such a configuration was well known in the prior art. For example, the Norris reference discloses a compressible fabric for use in stent and heart valves comprising a ground layer of knitted fibers with loops of fibers extending therefrom. *See* Ex. 1074 (Norris) at 4:22-26. As illustrated in Chuter’s Figures 2 and 3 above, the fibers of Chuter’s fabric pile backing are in contact with the stent frame. Ex. 1116 (Chuter) at Figs. 2-3.

235. Moreover, as I explained previously for Spenser II, persons of ordinary skill in the art would have understood that the individual fibers extending from Chuter’s fabric pile backing layer would have been woven or knitted all the way through the thickness of the backing layer, consistent with the numerous examples in the prior art. *Supra* §VI.A.5. Accordingly, persons of ordinary skill in the art would have understood that the individual fibers extending from Chuter’s backing layer would be “in contact” with the frame for the same reasons I explained with respect to Spenser II’s compressible material. *Id.*

236. Second, Chuter also discloses embodiments lacking the backing, with individual fibers attached directly to the stent frame:



Ex. 1116 (Chuter) at [0056]-[0057], Figs. 5-10. As illustrated in Figures 6 and 7, the fibers in these embodiments are in contact with the stent frame. *Id.* at [0057], Figs. 6-7. Persons of ordinary skill in the art would have been motivated to use such an arrangement when adding Chuter’s fiber pile to Spenser’s valve because it

would minimize the amount of material that is added to the exterior of the valve, reducing the overall impact on the crimped profile of the valve.

237. Persons of ordinary skill in the art would have been motivated to add Chuter's fiber pile to Spenser's THVs to prevent PVL. Chuter's teachings suggest to a person of skill that the fiber pile would be very useful in preventing PVL in a THV. For example, Chuter teaches that the fiber pile is "adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel" and also "fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel." Ex. 1116 (Chuter) at [0012]-[0013], [0017]-[0020], [0064]. Persons of ordinary skill in the art would have recognized that both of those features would be useful in preventing PVL for the THVs disclosed in Spenser, and would have therefore been motivated to add Chuter's fiber pile to Spenser's valves. PVL was a well-known issue in the field of TAVR prior to November 2012, and persons of ordinary skill in the art would have recognized the need for improvement of Spenser's valves to address PVL. For example, Spenser II discloses that Spenser's parent application did not address PVL. Ex. 1011 (Spenser II) at [0009]-[0010]. This knowledge would have further motivated a person of skill in the art add Chuter's fiber pile to Spenser's valve prevent PVL. Moreover, a person of ordinary skill in the art in 2012 had a finite number of

predictable ways to arrange fibers on the outside of a frame to prevent PVL. Chuter describes two of the finite ways: a cloth with a backing or fibers attached directly to the frame. Birdsall identifies the third option: a batting material. Ex. 1057 (Birdsall) at 6:56-65. The person of ordinary skill in the art would have found it obvious to try these finite, predictable solutions on Spenser's frame. Thus, adding Chuter's fiber pile to Spenser's valves would have merely entailed applying Chuter's known technique for reducing leaks around a frame (adding a fabric pile) to Spenser's known valves, which were ready for improvement and, as discussed below, would yield predictable results.

238. Persons of ordinary skill in the art would have reasonably expected success in adding Chuter's fiber pile to Spenser's valve, including the valve in Figure 44a, for several reasons.

239. First, Chuter teaches that its invention can be employed on a variety of stents, including both self-expanding and balloon-expandable stents. Ex. 1116, [0003]. Indeed, Chuter discloses that its fiber pile may be used on the same balloon-expandable stent frames described in the '634 patent. Specifically, Chuter incorporates U.S. Pat. No. 4,739,762 by reference as providing examples of stents that may be used with its invention. *Id.* The '634 patent similarly incorporates by reference U.S. Patent No. 5,102,417 for "[e]xamples of balloon-expandable stents." Ex. 1001 ('634 patent) at 7:46-53. The '417 patent, which is incorporated

into the '634 patent, is a continuation-in-part of the '762 patent incorporated in Chuter, and those two patents disclose the same balloon-expandable stent frames. *See* Ex. 1127 ('417 patent); Ex. 1126 ('762 patent).

240. Second, Chuter teaches that “[v]irtually any expanding stent can be used in” its embodiment “having a fiber pile on its external surface about the tubular side wall of the stent, the graft made of fiber adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel.” Ex. 1116 (Chuter) at [0012]. As I explained above, persons of ordinary skill in the art would have understood that the frame in Spenser’s Figure 44a is an expanding stent frame. *Supra* §VI.E. While the preferred embodiment in Chuter includes a double-wire frame, Chuter’s invention is not limited to such frames and encompasses many frames. Accordingly, persons of ordinary skill in the art would have understood that Chuter’s teaching of individual outwardly extending fibers secured directly to a stent frame would broadly apply to “[v]irtually any expanding stent,” including the expanding stent frame taught by Spenser.

241. Additionally, the '634 patent never discloses how the collagen fibers, or any other fibers, are attached to the frame of the described valves, and thus the patent presumes that persons of ordinary skill in the art would have known how to attach individual fibers to the frame of a THV. *See* Ex. 1001 ('634 patent) 12:53-

56. Consistent with this lack of disclosure in the patent, I am aware that Patent Owner's expert in related IPR proceedings, Dr. Brecker, admitted that the specification of the patent-at-issue there, which shares an identical specification with the '634 patent, does not provide "an explicit description of how [the collagen fibers] are attached or secured other than stating that they are attached and secured, and the assumption is that that would be by known biomedical engineering methods." Ex. 1073 (Brecker Tr. Vol. II), 313:18-314:1. This same "assumption" would also need to apply to Chuter's fiber pile.

242. Spenser discloses two rows of cells at the inflow end of the frame as I explained in Grounds 1-3. *Supra* §VI.A.6. Persons of ordinary skill in the art would have found it obvious to position Chuter's fabric pile to extend over at least the proximal two rows of cells on Spenser's valves and would have been motivated to do so to ensure that the extending fibers of the fiber pile would overlap with, and press against, the patient's diseased native aortic leaflets when the valve was implanted, which is necessary for the fibers to form a seal and fill gaps between the native leaflets and the THV. Moreover, multiple references, including Spenser II and Walther, disclosed that having fibers that extend over at least the proximal two rows of cells provided effective sealing. *See* Ex. 1011 (Spenser II) at [00145], Fig. 22; Ex. 1007 (Walther) at Fig. 1.

243. I am aware that in a related IPR, Patent Owner has argued that a person of ordinary skill in the art would not have been motivated to combine Chuter's fibers lacking a backing because Chuter describes those embodiments in the context of an occluder. *See* Ex. 1142 ('834 POPR). I believe that Patent Owner fails to consider or give appropriate weight to the knowledge, skills, and ordinary creativity of a person of ordinary skill in the art. A person of ordinary skill in the art would have recognized that Chuter's stated benefits of promoting tissue ingrowth and preventing blood from flowing between the frame and patient's tissue would have helped prevent PVL on a THV, and a person of ordinary skill in the art would have possessed the skills and ordinary creativity to adapt the fiber pile when adding it to Spenser's valve so that the fibers would not completely occlude the opening in the THV. Patent Owner also ignores that Chuter's occluder embodiments seal off the artery completely by including inwardly extending fibers that extend across nearly the entire diameter of the occluder. *See* Ex. 1116 (Chuter) at Fig. 8. Spenser's figure 44a includes the inner PET 571 sutured to the inner surface of the frame, however, which would prevent any inwardly-extending fibers from spanning the entire diameter of the THV and occluding the opening of the valve. A person of ordinary skill in the art would have also possessed the skills and ordinary creativity to adjust the size, length, and positioning of any inwardly-extending fibers so that they would not occlude the

opening of Spenser's THV. Moreover, Chuter does not restrict the fiber pile embodiments to occluders and persons of ordinary skill in the art would have recognized the broader applications of the fibers, particularly given the use of similar sealing materials to seal THVs in the prior art, such as those in Spenser II and Birdsall. Ex. 1011 (Spenser II) at [00145]; Ex. 1057 (Birdsall) 6:56-65.

244. I am also aware that in the related IPR, Patent Owner argued that a person of ordinary skill in the art would not have reasonably expected success in adding Chuter's fiber pile without a "backing" to Spenser's valves because Spenser's frame is not formed from helically wound double-wire strands. *See* Ex. 1142 ('834 POPR) at 63-67. However, Patent Owner does not appear to address that Chuter expressly discloses that a wide range of frames can be used with its "present invention," including the very same frames that are incorporated by reference in the '634 patent. *See* Ex. 1116 at [0003]; *supra* ¶239. A person of ordinary skill in the art would have understood the "present invention" in Chuter to encompass both the embodiments with and without a "backing" in the fabric pile.

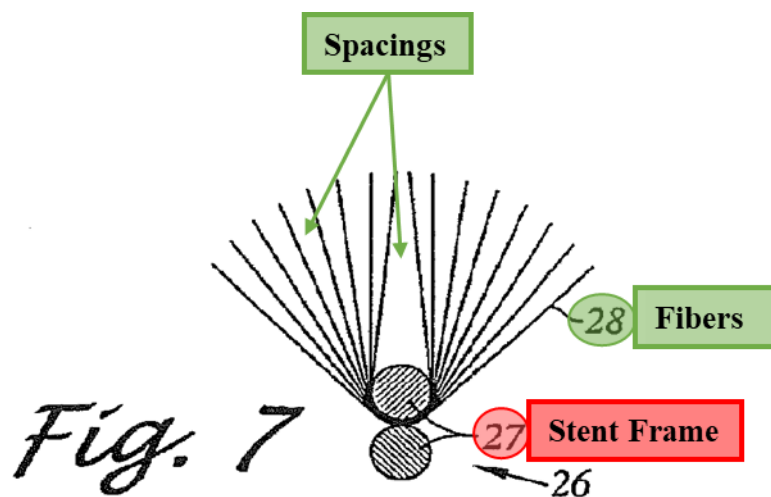
6. Fibers Spaced Apart

245. Claim 1 next recites: "wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough

when the valve assembly is in an uncompressed state.” Spenser in combination with Chuter renders this limitation obvious.

246. As I explained above, Chuter discloses embodiments wherein the fiber pile includes a fabric pile backing and embodiments wherein the individual fibers of the fiber pile are attached directly to the frame. *Supra* §VII.A.5. In both embodiments, there are spacings between the individual fibers in the fiber pile that “in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state.” See Ex. 1116 (Chuter) at Figs. 2, 7.

247. In Chuter’s embodiments lacking a “backing” in the fabric pile, Chuter illustrates spacings “in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame,” as shown in Figure 7:



Id. at Figs. 7. Indeed, persons of ordinary skill in the art would have understood that when the individual fibers of the fiber pile are attached directly to struts of Spenser's frame, consistent with Chuter's teachings regarding the embodiment illustrated in Figure 7, there would necessarily be spacings between adjacent fibers that span at least the width of the open cells between the struts. This is because there would be no fibers, or other material, traversing the openings between the struts, as would be the case when a backing is employed. Persons of ordinary skill in the art would have further understood that spacings spanning the width of the open cells would allow fluid to pass therethrough when the valve is undeployed, meaning that the fibers have not been compressed against the patient's tissue to form a seal.

248. Persons of ordinary skill in the art would have understood that in Chuter's embodiments including the fabric pile backing, the backing would preferably be porous to maximize the compressibility of the fiber pile. Similar covering materials with porous backings was well known in the prior art. For example, Norris discloses a compressible, resilient fabric for providing sealing on medical devices, including prosthetic heart valves, that includes a "ground layer 20 of knitted yarn, and a loop layer 30 comprising a plurality of loops 32 of yarn 31, each loop 32 having a point 33 knit into the ground layer 20." Ex. 1074 (Norris) at 4:22-26. Norris teaches that the "the ground layer 20 can have a porosity that

can provide some space into which the loops 32 can be compressed.” *Id.* at 12:45-48. Persons of ordinary skill in the art would have understood that the porosity taught by Norris would require spacings between adjacent fibers in the backing to “provide some spaces into which the loops 32 can be compressed.” *See id.* Persons of ordinary skill in the art would have understood that Chuter’s backing would have a similar porosity, which would be desirable to maximize the compressibility of the fiber pile. As I explained previously, persons of ordinary skill in the art would have been motivated to use a material with sufficiently large spacings between the fibers to allow fluid to pass therethrough to maximize tissue ingrowth, compressibility, and blood coagulation. *Supra* §VI.A.6. Because Chuter’s fabric pile backing directly abuts the stent frame, at least some of the spacings between the fibers in the backing layer would overlap with the spacings between the outwardly extending fibers and would therefore be in a “in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame.”

249. Adding Chuter’s fiber pile to Spenser’s or Levi’s valve would not change the spacings or porosity of the material when the valve is undeployed, meaning that the fibers have not been compressed against the patient’s native tissue to form a seal. Like the ’634 patent, Chuter illustrates plainly visible spacings between the fibers. Persons of ordinary skill in the art would have

understood that such visible spacings would be large enough to allow fluid to pass therethrough when the fibers are in an uncompressed state.

7. Uncovered Apices

250. Claim 1 next recites: “wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers.” Spenser in combination with Chuter and Birdsall *or* Bailey renders this limitation obvious for the same reasons I explained previously in Grounds 1-3. *Supra* §VI.A.7.

8. Fibers Compressed To Form Seal

251. Claim 1 next recites “wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings.” Spenser in combination with Chuter renders this limitation obvious.

252. As I explained above, Chuter teaches intravascular stents having a fiber pile comprised of outwardly extending polymeric or nylon fibers that “press against the inner luminal wall of the arterial system to form a seal” when the stent is implanted. Ex. 1116 (Chuter) at [0059]. Persons of ordinary skill in the art would have understood that when Chuter’s fiber pile is added to Spenser’s or

valve, the fiber pile would press against the patient's native aortic leaflets when the valves are implanted, compressing the fibers of the fiber pile into the spacings between the fibers and forming a paravalvular seal around the valve. *Supra* §VI.A.8.

9. Graft Covering Engaged With Fibers

253. Claim 1 next recites: “wherein the graft covering is engaged with fibers of the plurality of fibers.”

254. As I explained previously, Spenser discloses a graft covering secured to the inner surface of a frame having a plurality of open cells. *Supra* §§VI.A.2-3. Persons of ordinary skill in the art would therefore have understood that when Chuter's fiber pile is added to Spenser's valve, the fibers of the fiber pile would press against and “engage” the graft covering through the open cells of the frame when the compressible material is pressed against the patient's native tissue for the same reasons I explained previously in Grounds 1-3. *Supra* §VI.A.9.

10. Endovascularly Deployed

255. Claim 1 finally recites: “wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.” Spenser in combination with Chuter renders this limitation obvious.

256. Spenser discloses THVs that are endovascularly deployed through a patient's femoral artery as I explained in Grounds 1-3. *Supra* §VI.A.10. Persons of ordinary skill in the art would have reasonably expected that Spenser's valves would remain capable of such endovascular delivery after Chuter's fiber pile was added to the valve frame.

257. Chuter expressly teaches that its fiber pile is used on endovascularly delivered intravascular stent devices. See Ex. 1116 (Chuter) at e.g., Abstract. Specifically, Chuter teaches that its fiber pile is employed on endovascularly delivered vascular stents which are "delivered through catheters" that are inserted into the patient through "a distal branch of the arterial system" that "will normally be one of the arteries in the legs or in the arms." *Id.* [0062]. Persons of ordinary skill in the art would have understood that the femoral artery is one such distal branch artery in the patient's legs. Chuter further teaches that the stents are compressed when placed in the catheter and that the "compression compresses the stent and pushes down the fabric pile" to allow for endovascular delivery. *Id.* Given these teachings, persons of ordinary skill in the art would have reasonably expected that Chuter's fabric pile would be similarly compressed down when added to Spenser's valve and crimped for delivery via a catheter, allowing for endovascular delivery of the valves. Indeed, as I explained in Grounds 1-3, the

prior art disclosed similar fibrous sealing materials capable of being compressed by up to 10-25 times for delivery. *Supra* §VI.A.10.

258. As I explained previously, Spenser teaches that its valve may be crimped to 4mm, which is half of the maximum crimped profile required for transfemoral delivery. *Supra* ¶172. Persons of ordinary skill in the art would have reasonably expected that Chuter's fiber pile would add significantly less than 4mm to the crimped profile of Spenser's valves, particularly in view of the Norris reference, and would therefore have expected Spenser's valve to remain transfemorally deliverable after the addition of the fiber pile.

B. Claims 2-7

259. As I explained in Grounds 1-3, Spenser discloses the additional limitations that are recited by dependent claims 2-7 of the '634 patent. *Supra* §§VI.B-G. Therefore, it is my opinion that Spenser in combination with Chuter and Birdsall *or* Bailey renders claims 2-7 obvious for the reasons I explained above for the limitations of claim 1 and in Grounds 1-3 for the limitations of claims 2-7. *Supra* §§VIII.A, VI.B-G.

C. Claim 9

260. Claim 9 recites: "The valve assembly of claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers." Spenser *or* Levi in combination with Chuter renders this claim obvious.

261. As I explained in Grounds 1-3, Spenser discloses that the most distal row of cells of the frame are uncovered by the graft covering. *Supra* §VI.H. As I explained in claim 1, persons of ordinary skill in the art would have found it obvious to position Chuter's fiber pile to extend over the proximal two rows of cells of Spenser's frame. *Supra* §VIII.A.5. In such a configuration, the most distal row of cells of the frame would be uncovered by both the graft covering and the outwardly extending fibers.

**IX. GROUNDS 7-9: CLAIMS 1-7 AND 9 OBVIOUS ARE OVER BAILEY
AND SPENSER II, BIRDSALL, OR CHUTER**

A. Claim 1

262. Based on my review of the prior art, it is my opinion that Bailey and Spenser II, Birdsall, or Chuter render claim 1 obvious.

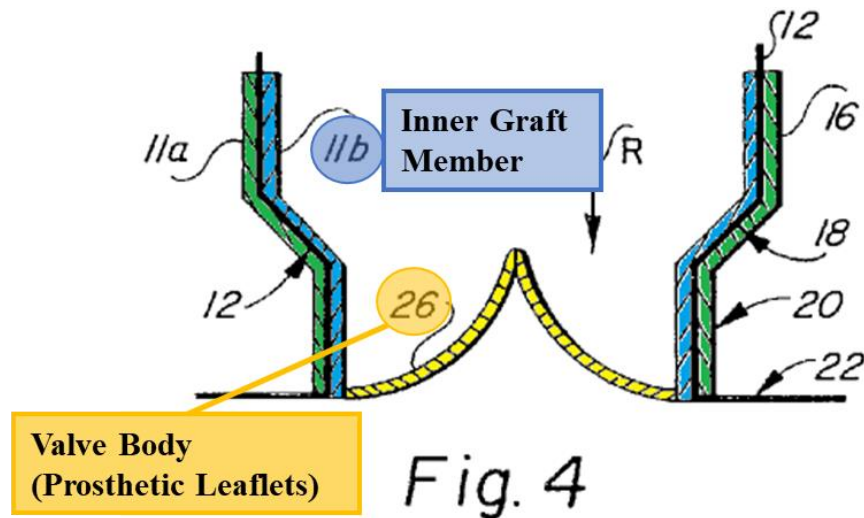
1. Preamble

263. The preamble of claim 1 recites: "A transcatheter aortic heart valve assembly." If this preamble is limiting Bailey discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* § VI.A.1.

2. Graft Covering

264. Claim 1 next recites: "graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto." Bailey discloses this limitation.

265. Bailey discloses embodiments of prosthetic heart and venous valves that can be implanted percutaneously, including embodiments of the valve in “a chamber-to-vessel (CV) configuration which is particularly well-suited as an aortic valve prosthesis to facilitate blood flow from the left ventricle to the aorta.” Ex. 1141 (Bailey) at Abstract, [0002]. Bailey’s chamber-to-vessel THV includes “an expandable stent body member 12 and graft member 11” and a valve body 26. *Id.* at [0048]-[0049]. “The graft member 11 consists of an outer or abluminal graft member 11a and an inner or luminal graft member 11b.” *Id.* at [0049]. “The outer graft member 11a encloses at least a portion of the abluminal surface of the intermediate annular section 20 of the stent body member, while the inner graft member 11b is coupled, on the luminal surface of the intermediate annular section 20 of the stent body member 12, to the outer graft member 11a through the interstices 14 of the stent body member.” *Id.* Bailey’s inner graft member is a “graft covering” that extends about and engages the prosthetic leaflets to provide sealing thereto:



Id. at [0049], Fig. 4.

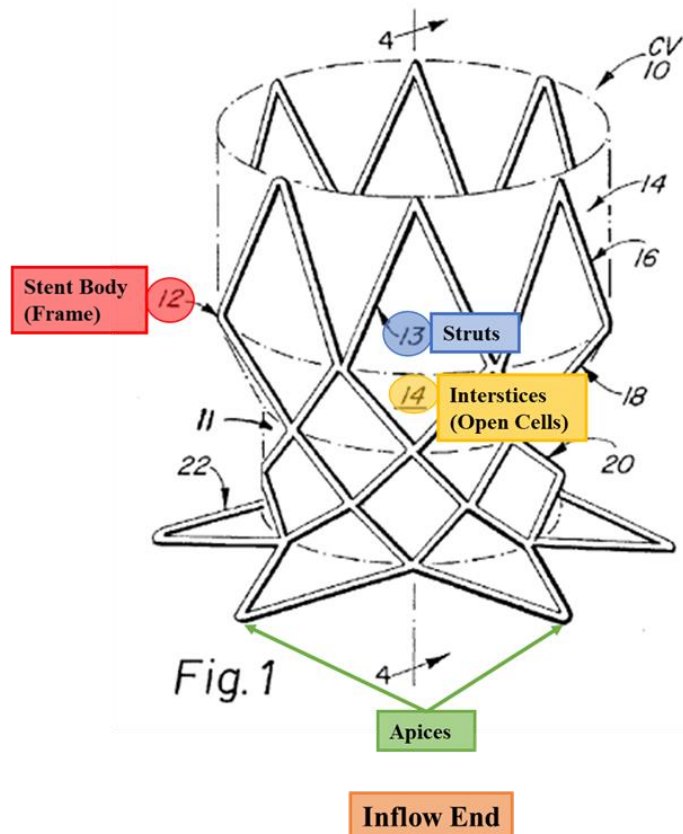
3. Frame

266. Claim 1 next recites: “a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration, wherein the frame is secured to the graft covering.” Bailey discloses this limitation.

267. As I explained above, my opinions regarding this limitation are based on Patent Owner’s continued assertion that an “frame” need not be a self-expanding frame. *Supra* §II.A.

268. Bailey’s chamber-to-vessel THV includes “an expandable stent body member 12 and graft member 11.” Ex. 1141 (Bailey) at [0048]. The stent body can be formed by “laser cutting a hypotube or weaving wires into a tubular

structure. *Id.* at [0021], [0048]. The frame “is configured to have three functional sections: a proximal anchor flange 22, an intermediate annular section 20 and a distal anchor section 16.” *Id.* at [0048]. The stent body member “is formed of a plurality of stent struts 13 which define interstices 14 between adjacent stent struts.” *Id.* “The proximal anchor flange 22, the intermediate annular section 20 and the distal anchor section 16 are each formed during the formation of the stent body member and are formed from the same material as the stent body member and comprise stent struts 13 and intervening interstices 14 between adjacent pairs of stent struts 13.” *Id.* Bailey’s frame includes a plurality of apices at the inflow end of the frame:



Id. at [0048], Fig. 1.

269. Bailey's inner graft member 11*b* (graft covering) is secured to the frame along the "luminal surface of the intermediate annular section 20 of the stent body member 12" as shown in Figure 4 below:

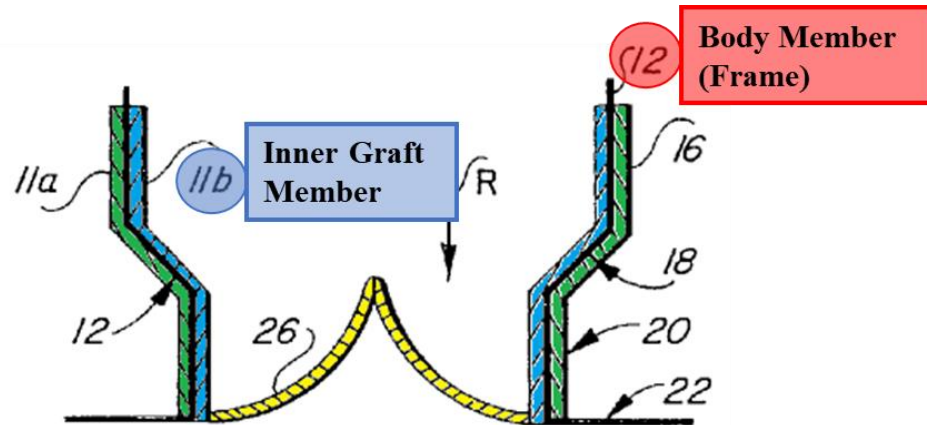


Fig. 4

Id. at [0021], [0049], Fig. 4.

4. Polymeric Graft Covering

270. Claim 1 next recites: "wherein the graft covering is made of a polymer." Bailey discloses this limitation.

271. Bailey's inner graft member (graft covering) may be made of materials "such as DACRON or expanded polytetrafluoroethylene." *Supra* §IX.A.2. Both Dacron and expanded polytetrafluoroethylene are polymers.

5. Plurality of Fibers

272. Claim 1 next recites: “a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame, wherein the fibers are arcuate, spaced-apart, and outwardly extending.” Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

273. Bailey discloses an “outer or abluminal graft member 11a” secured to the frame:

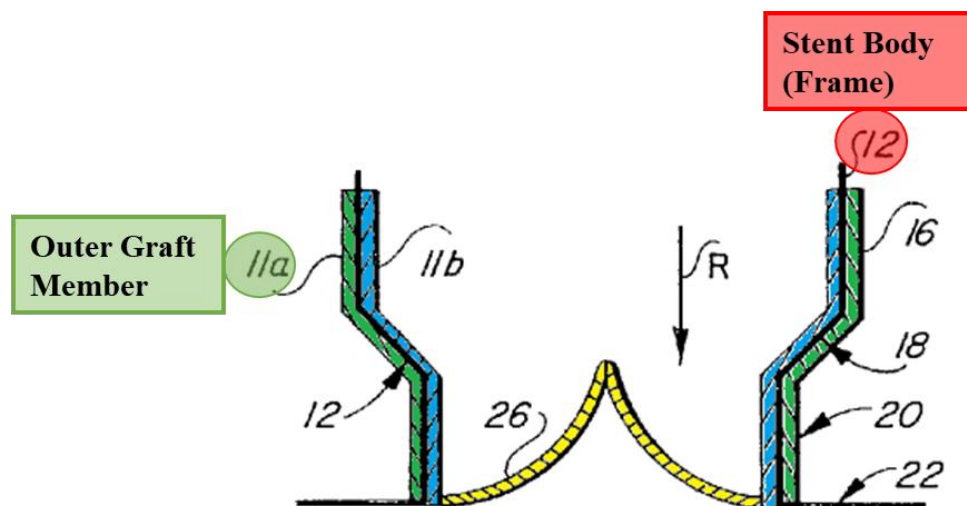


Fig. 4

Ex. 1141 (Bailey) at [0049], Fig. 4. Bailey discloses that the outer graft member “forms a sealing graft which contacts and excludes the immobilized anatomical valve leaflets.” *Id.* at [0023].

a. Bailey and Spenser II

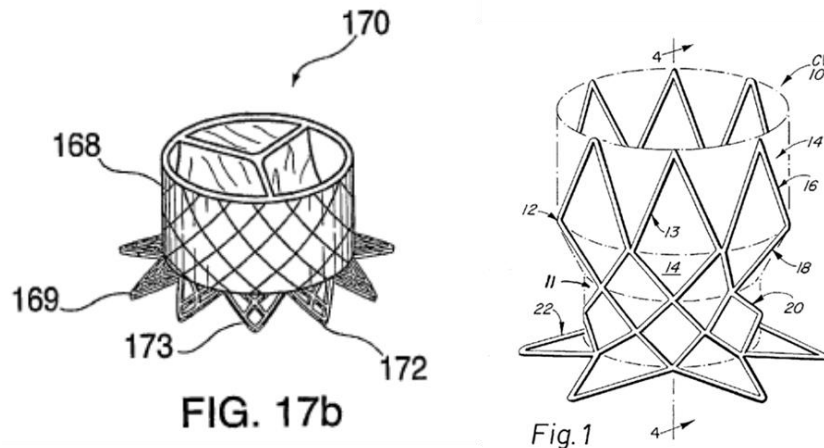
274. Spenser II discloses this limitation for the reasons I explained in Grounds 1-3. *Supra* §VI.A.5.

275. A person of ordinary skill in the art would have been motivated to substitute Spenser II's compressible material for Bailey's outer sealing graft 11a to further prevent PVL. Spenser II's explanation that the compressible material "expands after deployment" and "fills the gaps between the stented valve and the surrounding tissue" would have suggested to the person of ordinary skill that Spenser II's compressible material may provide additional benefits to Bailey's valve and would have motivated them to perform the substitution. Ex. 1011 (Spenser) at [00145]. Spenser II also explains that the fibers of its compressible material "may be adapted to encourage coagulation of blood to further fill gaps and prevent leakage" and that "a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps," providing even more advantages for the compressible material. *Id.* A person of ordinary skill in the art would have understood that a fibrous compressible material such as that in Spenser II would be particularly effective at encouraging blood coagulation and tissue ingrowth due to the increased surface area provided by the fibrous structure. As the Norris reference explains, a fabric or cloth with outwardly extending fibers can facilitate a "clotting cascade" in which blood clots form in the interstices between the fibers and then "progressively outwardly until a clot forms a solid connection between the fabric

10 and/or sealing member 52 and the adjacent anatomical structure, such as a vessel wall.” See, Ex. 1074 (Norris) at 10:14-30; see also *id.* at 5:60-64, 6:4-14.

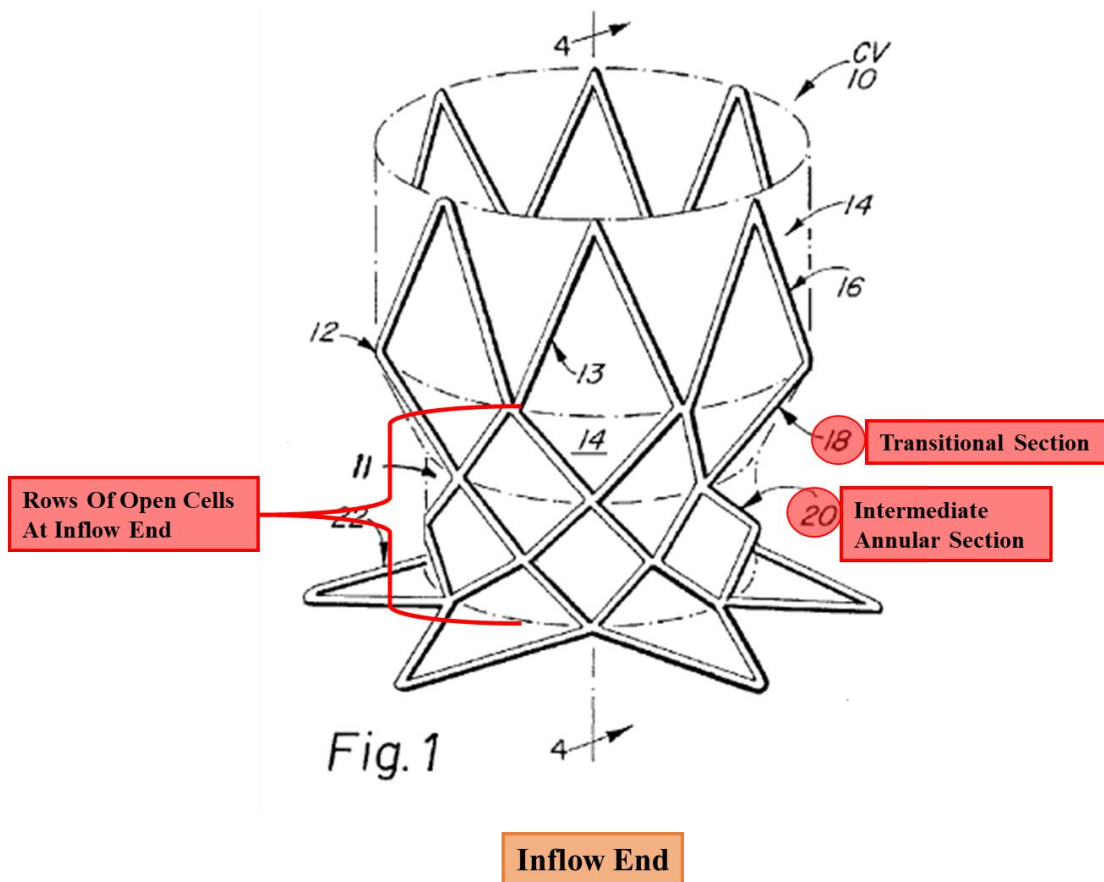
276. A person of ordinary skill in the art would have found the substitution of Spenser II’s compressible material for Bailey’s outer graft member to merely entail substitution of one known element (Spenser II’s compressible material) for another (Bailey’s outer graft member) and would have expected the substitution to yield the predictable results of reducing PVL. Additionally, a person of ordinary skill in the art would have had a finite number of options for sealing the outside of a THV and preventing PVL in 2012. The person of ordinary skill would have recognized Spenser II’s compressible material as one such predictable solution, and would have found it obvious to try the compressible material on Bailey’s THV.

277. A person of ordinary skill in the art would have reasonably expected success in substituting Spenser II’s compressible material for Bailey’s outer graft member given the similarities between the valves in Bailey and Spenser II. The frames in Spenser II and Bailey share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. See Ex. 1011 (Spenser II) at [00144], Fig. 22; Ex. 1141 (Bailey) at [0048]. Moreover, Spenser II discloses an embodiment in Figure 17 having sealing struts at its proximal end that is very similar to Bailey’s valve:

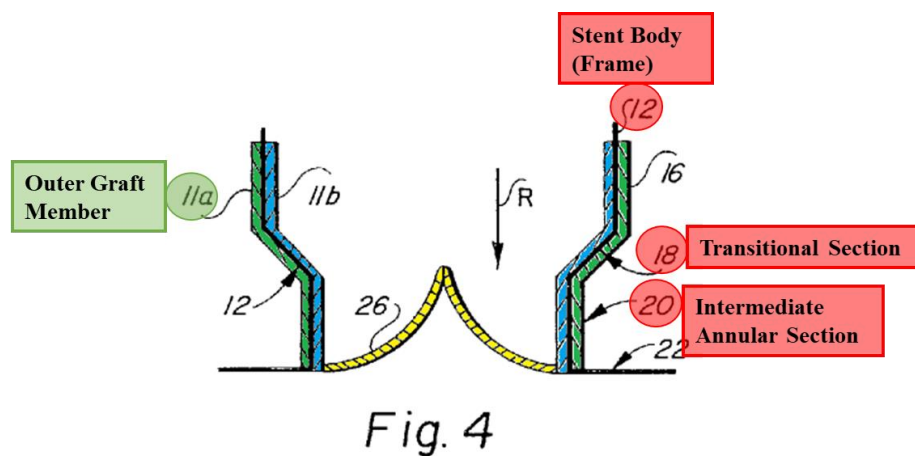


Compare Ex. 1011 (Spenser II) at Fig. 17b (left) with Ex. 1141 (Bailey) at Fig. 1 (right). Further, both Bailey and Spenser II references disclose THVs that are intended for percutaneous (i.e., endovascular) delivery. Ex. 1011 (Spenser II) at [0011]-[0013], [0090]; Ex. 1141 (Bailey) at [0002], [0019], [0073].

278. Bailey explains that the outer graft member “should cover at least a portion of the abluminal surface of the body member 12 in order to exclude the anatomic valves.” Ex. 1141 (Bailey) at [0052]. Thus, when substituting Spenser II’s compressible material for Bailey’s outer graft member, a person of ordinary skill in the art would have been motivated to place Spenser II’s compressible material over sections 18 and 20 of Bailey’s frame so that the compressible material would form a seal with the patient’s native leaflets when the valve is implanted. *Id.*; see also Ex. 1011 (Spenser II) [00145]. Intermediate annular section 20 and transitional section 18 of Bailey’s frame form a plurality of rows of open cells at the inflow end of the frame, as illustrated below:

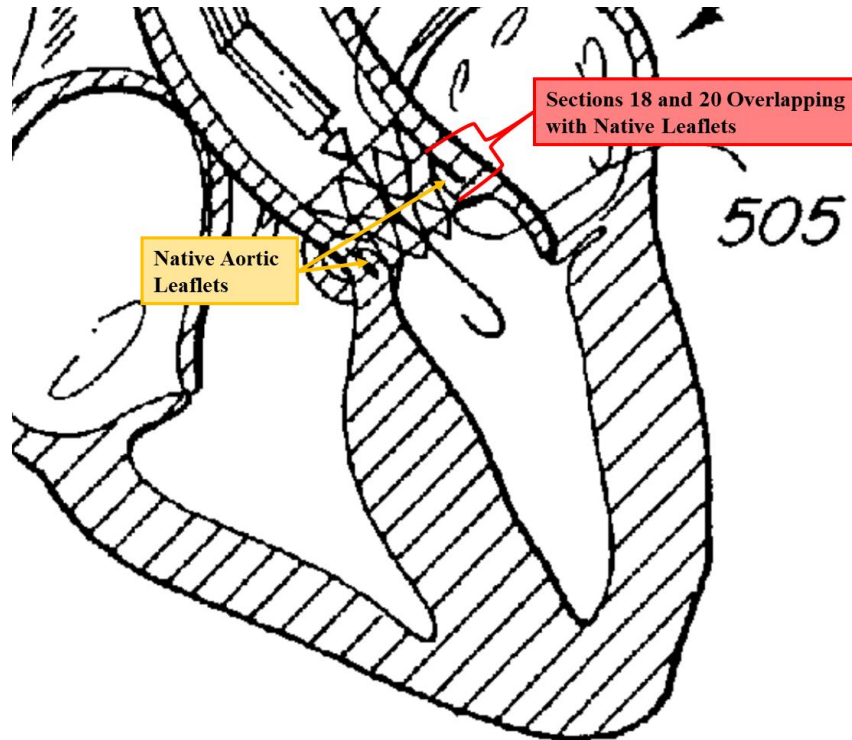


Ex. 1141 (Bailey) at [0048], Fig. 1. As shown in Bailey's Fig. 4, the outer graft member 11a extends over the intermediate annular 20 and transitional 18 sections and is therefore in contact with the rows of open cells formed by those sections:



Id. at [0049], Fig. 4. Figure 4 is consistent with Bailey's teaching that the outer

graft member “should cover at least a portion of the abluminal surface of the body member 12 in order to exclude the anatomic valves” because frame sections 18 and 20 overlap with the native leaflets when Bailey’s valve is implanted. This is demonstrated by Bailey’s Figure 20G:



Id. at [0073], Fig. 20G (excerpt). Accordingly, when Spenser II’s compressible material replaces Bailey’s outer graft member and positioned according to Bailey’s instruction, the compressible material would be “in contact with a plurality of rows of open cells at the inflow end of the frame.” The fibers of the compressible material would be “in contact” with the frame for the same reasons I explained in Grounds 1-3. *Supra* §VI.A.5.

b. Bailey and Birdsall

279. Birdsall discloses these limitations for the reasons I explained in Ground 3. *Supra* §VII.A.5.

280. A person of ordinary skill in the art would have been motivated to substitute Birdsall's barrier material for Bailey's outer sealing graft 11a to further prevent PVL and migration of the valve after deployment. Birdsall discloses that its barrier material includes microfibers that can fill the gaps between the valve frame and the calcified vessel lumen to help prevent PVL and prevent the valve from migrating after deployment. Ex. 1057 (Birdsall) at 6:4-65, 7:29-44. A person of ordinary skill in the art would have thus recognized that the microfibers of Birdsall's barrier material may confer additional benefits over Bailey's outer graft member, motivating the person of skill to make the substitution.

281. A person of ordinary skill in the art would have found the substitution of Birdsall's barrier material for Bailey's outer graft member to merely entail substitution of one known element (Birdsall's barrier material) for another (Bailey's outer graft member) and would have expected the substitution to yield the predictable results of reducing PVL and preventing migration of the valve after deployment. Additionally, a person of ordinary skill in the art would have had a finite number of options for sealing the outside of a THV and preventing PVL in 2012. The person of ordinary skill would have recognized Birdsall's barrier

material as one such predictable solution, and would have found it obvious to try the barrier material on Bailey's THV.

282. A person of ordinary skill in the art would have reasonably expected success in substituting Birdsall's barrier material for Bailey's outer graft member given the similarities between the devices in the two references. For example, the valve frames in Birdsall and Bailey share many common features, including being balloon-expandable and forming rows of open cells that are interconnected by metal struts. *See* Ex. 1057 (Birdsall) at 2:33-39, Fig. 3A; Ex. 1141 (Bailey) at [0048]. Both references also disclose THVs designed for percutaneous (i.e., endovascular) delivery. Ex. 1057 (Birdsall) at 5:37-51, 7:45-67; Ex. 1141 (Bailey) at [0002], [0019], [0073].

283. A person of ordinary skill in the art would have understood that the fibers of Birdsall's barrier material would be "in contact with a plurality of rows of open cells at the inflow end of the frame" when added to Bailey's THV for the same reasons I explained above for Bailey and Spenser II and in Ground 3 for Birdsall and Spenser. *Supra* §§IX.A.5, VII.A.5.

c. Bailey and Chuter

284. Chuter discloses these limitations for the reasons I explained in Grounds 4-6. *Supra* §VIII.A.5.

285. A person of ordinary skill in the art would have been motivated to substitute Chuter's fiber pile for Bailey's outer graft member 11a to further prevent PVL and promote tissue ingrowth. Chuter explains that its fiber pile is "adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel" and "fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel." Ex. 1116 (Chuter) at [0012]-[0013], [0017]-[0020], [0064]. A person of ordinary skill in the art would have been motivated to replace Bailey's outer graft member with Chuter's fiber pile to achieve these advantages.

286. A person of ordinary skill in the art would have found the substitution of Chuter's fiber pile for Bailey's outer graft member to merely entail substitution of one known element (Chuter's fiber pile) for another (Bailey's outer graft member) and would have expected the substitution to yield the predictable results of reducing PVL and promoting tissue ingrowth. Additionally, a person of ordinary skill in the art would have had a finite number of options for sealing the outside of a THV and preventing PVL in 2012. The person of ordinary skill would have recognized Chuter's fiber pile as one such predictable solution, and would have found it obvious to try the fiber pile on Bailey's THV.

287. A person of ordinary skill in the art would have reasonably expected success in adding Chuter's fiber pile to Bailey's valve for the same reasons I explained previously in Grounds 4-5. *Supra* §VIII.A.5. A person of ordinary skill in the art would have understood that the fibers of Chuter's fiber pile would be "in contact with a plurality of rows of open cells at the inflow end of the frame" when added to Bailey's THV for the same reasons I discussed above for Bailey and Spenser II and for the reasons I explained in Grounds 4-5. *Supra* §§IX.A.5, VIII.A.5.

6. Spaced-Apart Fibers

288. Claim 1 next recites "wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state." Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

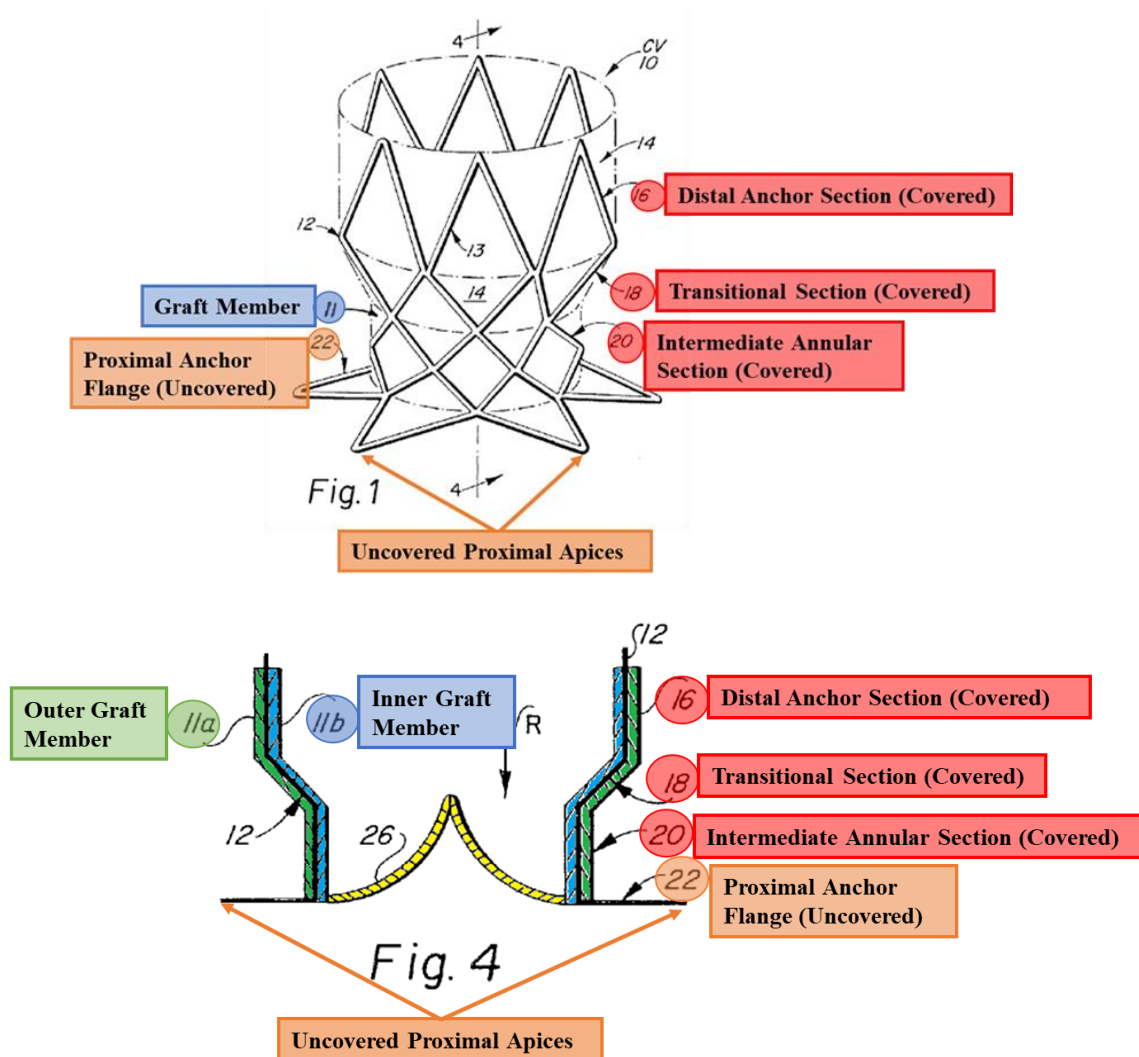
289. Spenser II, Chuter, and Birdsall each disclose this limitation for the reasons I explained previously in Grounds 1-3 (Spenser II), Ground 3 (Birdsall), and Grounds 4-5 (Chuter). *Supra* §§VI.A.6, VII.A.6, VIII.A.6.

7. Uncovered Apices

290. Claim 1 next recites "wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an

end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers.” Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

291. As I explained in Grounds 1-3, Bailey’s Figures 1 and 4 disclose an embodiment where the inner and outer graft members extend over sections 16, 18, and 20 of the frame, but **not** the proximal apices:



Ex. 1141 (Bailey) at Figs. 1, 4. Accordingly, when Bailey's outer graft member is replaced with Spenser II's compressible material, Birdsall's barrier material, or Chuter's fiber pile, the proximal apices would be uncovered by the graft covering and the outwardly extending fibers, and the uncovered proximal apices of the proximal anchor flange would extend proximally further than the compressible material's fibers.

8. Fibers Compressed To Form Seal

292. Claim 1 next recites "wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings." Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

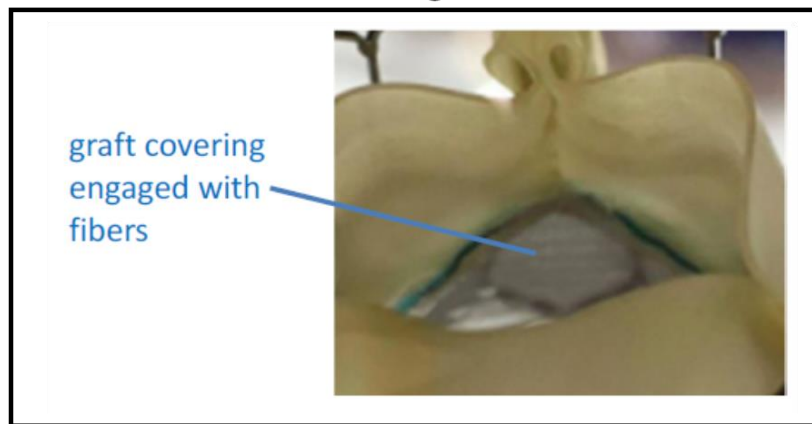
293. Spenser II, Chuter, and Birdsall each disclose this limitation for the reasons I explained previously in Grounds 1-3 (Spenser II), Ground 3 (Birdsall), and Grounds 4-5 (Chuter). *Supra* §§VI.A.8, VII.A.8, VIII.A.8.

9. Graft Covering Engaged With Fibers

294. Claim 1 next recites: "wherein the graft covering is engaged with fibers of the plurality of fibers." Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

295. As I explained previously, Bailey discloses an inner graft member (graft covering) secured to the inner surface of the frame and an outer graft member secured to the outer surface of the frame. *Supra* §IX.2. Bailey discloses that the outer and inner graft members are “coupled” (i.e., engaged) “through the interstices 14 of the stent body member.” Ex. 1141 (Bailey) at [0049]. Thus, when Bailey’s outer graft member is replaced with Spenser II’s compressible material, Birdsall’s barrier material, or Chuter’s fiber pile, the fibers of the compressible material/barrier material/fiber pile would be similarly “coupled” (i.e., engaged) with the graft covering through the interstices of the frame. Indeed, I am aware that Patent Owner’s infringement contentions for the ’634 patent in the district court litigation assert that such a configuration meets this limitation:

Patent Owner’s Infringement Contentions



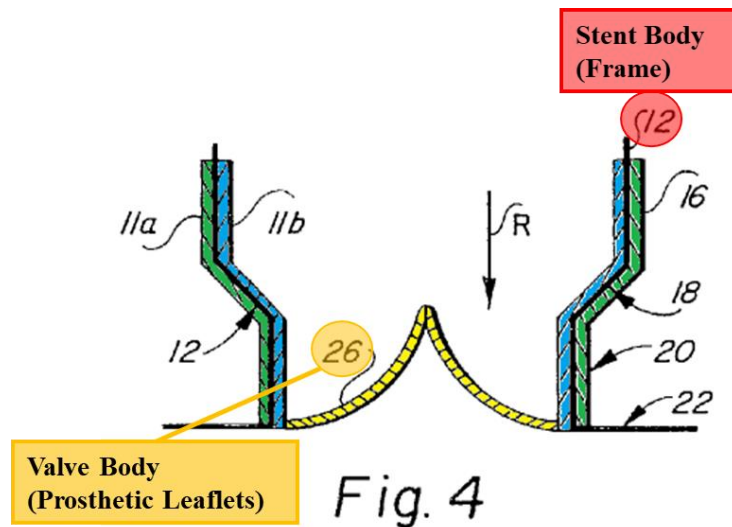
Ex. 1123 (PO Infringement Contentions) at 618-620.

10. Endovascularly Deployed

296. Claim 1 finally recites: “wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.” Bailey in combination with Spenser II, Chuter, or Birdsall renders these limitations obvious.

297. Bailey discloses that its THV is suitable for endovascular delivery through the patient’s femoral artery and expressly discloses that the valve has “a delivery profile which does not exceed the 12 French size suitable for peripheral vascular endoluminal delivery.” Ex. 1141 (Bailey) at [0002], [0019], [0073]. As I explained previously Spenser II, Birdsall, and Chuter similarly disclose that their sealing materials are suitable for use with percutaneously delivered devices. *Supra* §§VI.A.10, VII.A.10, VIII.A.10.

298. A person of ordinary skill in the art would have reasonably expected that Bailey’s THV would remain suitable for endovascular delivery through the femoral artery after replacing the outer graft member with Spenser II’s compressible material, Birdsall’s barrier material, or Chuter’s fiber pile. I am aware that the Board previously found that a 12F (4.0 mm) diameter valve, like Bailey’s valve, “is well within the maximum allowable diameter of 24F [for transfemoral delivery] argued by PO, such that [a person of ordinary skill] could reasonabl[y] understand that there would be sufficient additional space to



Ex. 1141 (Bailey) at Figs. 2, 4

C. Claim 3

301. Claim 3 recites: “The valve assembly of claim 1, wherein the frame is a singular, integral component.” Bailey discloses this limitation.

302. Bailey discloses that its frame can be formed by “laser cutting a hypotube or weaving wires into a tubular structure.” Ex. 1141 (Bailey) at [0021], [0048]. Bailey further explains that the frame is “is formed of a plurality of stent struts 13 which define interstices 14 between adjacent stent struts 13. *Id.* at [0048]. The interconnected struts of Bailey’s frame form a singular, integral component:

that the graft member is securely attached to the frame. A person of ordinary skill in the art would have reasonably expected success in doing so given that such a configuration was well known in the prior art. *See, e.g.*, Ex. 1010 (Spenser) at 16:45-48, Fig. 44a-b; Ex. 1023 (Webb) at Fig. 3A.

E. Claim 5

305. Claim 5 recites: “wherein the valve assembly is balloon expandable.” Bailey discloses this limitation.

306. Bailey discloses that its stent body member (frame) “may be made of balloon expandable stainless steel or other plastically deformable stent materials as are known in the art.” Ex. 1141 (Bailey) at [0021], [0048]. A person of ordinary skill in the art would have understood that a THV with a balloon-expandable frame is a “balloon-expandable.” A person of ordinary skill in the art would have expected that Bailey’s THV would remain balloon expandable after adding Spenser II’s compressible material, Chuter’s fiber pile, or Birdsall’s barrier material because each reference discloses its sealing material can be used with balloon-expandable devices. Ex. 1011 (Spenser II) at [00144]; Ex. 1116 (Chuter) at [0003], [0021]; Ex. 1057 (Birdsall) at 2:33-36.

F. Claim 6

307. Claim 6 recites: “The valve assembly of claim 1, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.” Bailey discloses this limitation.

308. As I explained previously, Bailey discloses an inner graft member (graft covering) that extends around and are attached to the prosthetic heart valve leaflets. *Supra* §IX.A.2. Therefore, if a graft covering can be an “inner frame,” as asserted by Patent Owner in litigation, Bailey’s inner graft member forms an inner frame for supporting the prosthetic heart valve.

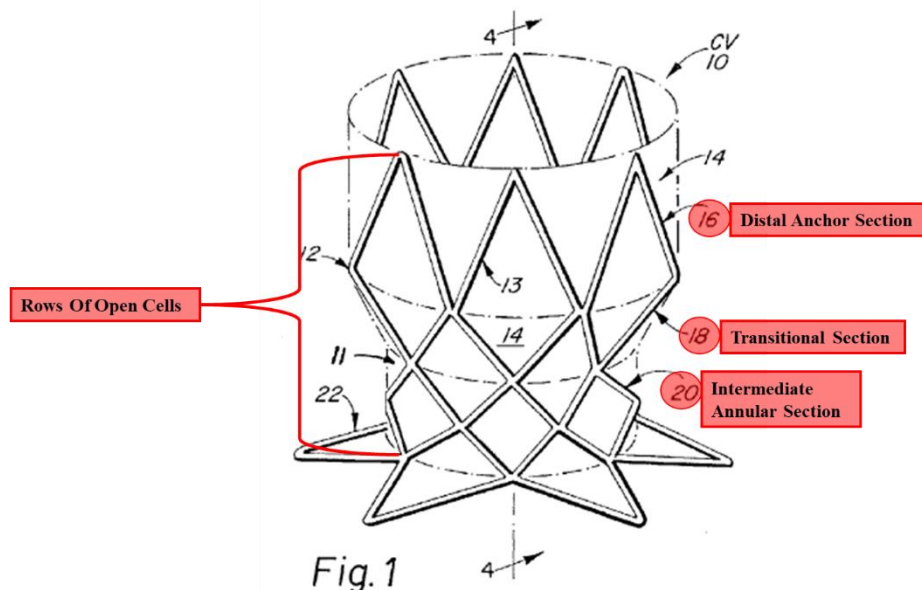
G. Claim 7

309. Claim 7 recites: “The valve assembly of claim 1, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.” Bailey in combination with Spenser II, Chuter, or Birdsall renders this claim obvious for the reasons I explained in claim 1. *Supra* §IX.A.10.

H. Claim 9

310. Claim 9 recites: “The valve assembly of claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.” Bailey in combination with Spenser II and Birdsall **or** Bailey renders this claim obvious.

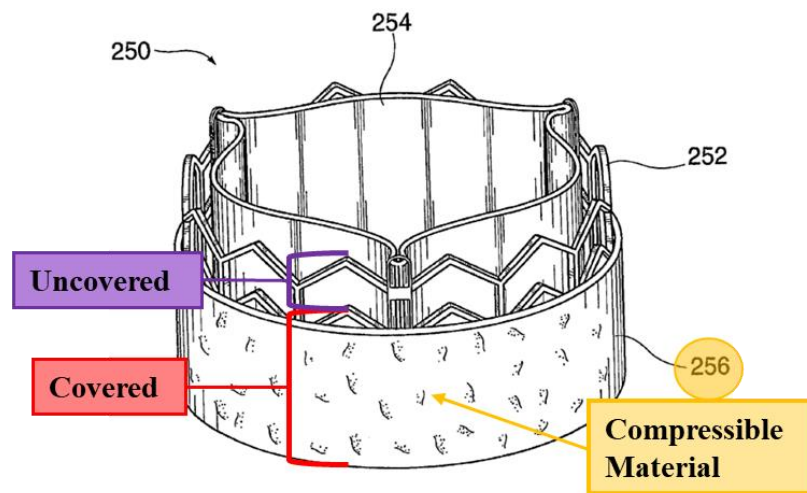
311. As I explained above, Bailey's frame is formed of interconnecting struts that form multiple rows of interstices 14 (open cells):



Ex. 1141 (Bailey) at [0048], Fig. 1. Bailey explains that “the graft member 11 should cover at least a portion of the abluminal surface of the stent body member 12 in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member 12.” *Id.* at [0052]. Bailey’s disclosures therefore encompass embodiments where the most distal row of cells of the frame in section 16 are uncovered by the graft member.

312. A person of ordinary skill in the art would have been motivated to leave the most distal row of open cells in Bailey’s frame uncovered by the graft member to ensure that blood flow to the coronary arteries is not inadvertently obstructed by the graft member. *See id.* at [0054], [0073]. The coronary arteries

are positioned just distally from the aortic valve, and therefore, by leaving the most distal row of cells uncovered by the graft member, a person of ordinary skill in the art could ensure that if Bailey's THV were implanted such that the distal end of the frame extended over the patient's coronary arteries, blood would still be able to flow into the coronary arteries through the uncovered open cells in the frame. A person of ordinary skill in the art would have been further motivated to select such a placement for the sealing material on Bailey's THV by Figure 22 of Spenser II, which illustrates an embodiment of a THV with a sealing material that does not cover the most distal row of cells on the frame:



Ex. 1011 (Spenser II) at Fig. 22.

X. SECONDARY CONSIDERATIONS

313. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '634 patent. For example, I am

not aware of any products sold by Patent Owner that would be covered by the '634 patent and, therefore, I am not aware of any commercial success.

314. Further, given that the devices claimed in the '634 patent are not new, and were invented long before November 2012, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

XI. CONCLUSION

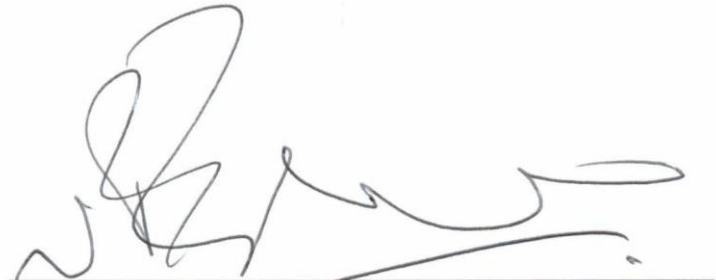
315. For the foregoing reasons, it is my opinion that claims 1-7 and 9 of the '634 patent are rendered obvious by the prior art discussed above in view of the knowledge of one of ordinary skill in the art at the time of the alleged invention.

316. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Patent Owner may raise, as well as new information, including, but not limited to, any claim constructions advanced by Patent Owner or adopted by the Board in the Institution Decision, and respond to any alleged secondary considerations as they become available to me.

317. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements

and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on January 4, 2024.



Dr. Nigel P. Buller