

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. 11,337,834

**DECLARATION OF NIGEL BULLER, M.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,337,834**

<i>Edwards v. Aortic Innovations</i> U.S. Patent 11,337,834 Edwards Ex. 1003

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Exhibit No.	Description
1001	U.S. Patent No. 11,337,834 B2 (“ ’834 patent ”)
1002	Excerpts from the prosecution history of the ’834 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“Walther”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	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 ”)
1012	Reserved
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

Exhibit No.	Description
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)

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1031-1033	Reserved
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	Reserved
1036	Nietlispach, Fabian, et al., <i>Current Balloon-Expandable Transcatheter Heart Valve and Delivery Systems</i> , Catheterization and Cardiovascular Interventions, 75:295-300 (2010)
1037	U.S. Patent Application Publication No. US 2009/0281619 A1 to Le et al.
1038-1044	Reserved
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al.
1046	Reserved
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.

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1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braidó et al.
1055-1056	Reserved
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall (“Birdsall”)
1058	Reserved
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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”)
1075-1106	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”)

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Exhibit No.	Description
1110	Pourdeyhim, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterial App. 163-204 (1987) (“Pourdeyhim”)
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”)

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1124	<i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 Patent Owner’s Preliminary Response (“’011 POPR”)
1125	U.S. Pat. App. No. 17/469,391, January 4, 2022 Amendment (“’634 patent Jan. 4, 2022 Amendment”)
1126	U.S. Pat. No. 4,739,762
1127	U.S. Pat. No. 5,102,417
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
1131-1138	Reserved
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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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 1-6 and 8-18 of U.S. Patent No. 11,337,834 (“the ’834 patent”). For the reasons discussed herein, I have concluded that claims 1-6 and 8-18 of the ’834 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 ’834 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 ’834 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 8000 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 1980’s I became involved in the research and development of cardiovascular stent implant devices, and I gained hands on experience with some of the first stent devices implanted in patient’s hearts. Subsequently, I also implanted the first coated stents, early stent grafts and drug eluting stents. As such I am very familiar with the concepts used in the design of stent frames and graft coverings including metals, polymers, polyesters, PET and ePTFE. As I discuss later in this Declaration, covering materials had been used on stent devices for decades prior to 2012, and I have personal experience implanting many such devices.

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

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 '834 patent;
- The level of ordinary skill in the art pertaining to the '834 patent;

- The teachings of the prior art; and
- Whether claims 1-6 and 8-18 of the '834 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 '834 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 '834 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 '834 patent cover Petitioner's SAPIEN 3 Ultra valve. *See* Ex. 1122; Ex. 1123 at 2, 24-261. Patent Owner also argued during prosecution that the SAPIEN 3 Ultra valve is covered by the claims of the '834 patent. Ex. 1002 ('834 prosecution history excerpt) at 1152-1153. My interpretation and application of the prior art herein is based on Patent Owner's assertions regarding the scope of the claims of the '834 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 '834 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 '834 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. The references are from the same field as the '834 patent, e.g., cardiovascular implant devices, including endografts and transcatheter heart valves. The references are also pertinent to the problem the inventor was focused on, e.g., treating cardiovascular disease through minimally invasive procedures and providing effective sealing on devices used in such procedures.

41. To assess the differences between 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 1-6 and 8-18 of the '834 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 '834 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 '834 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 '834 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

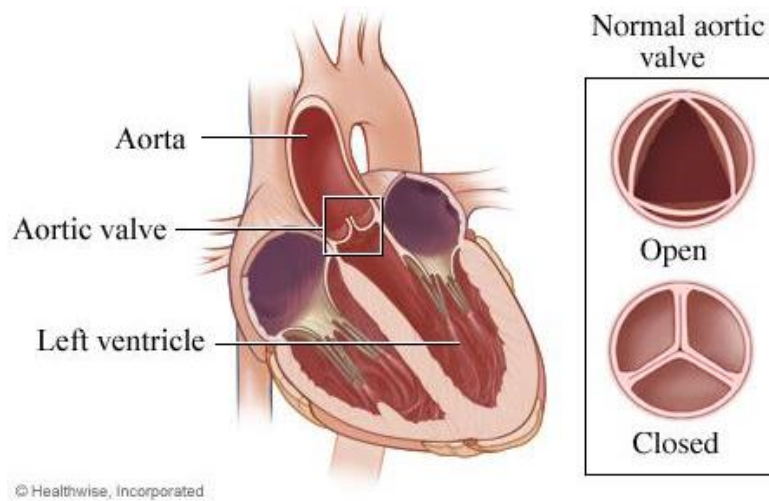
technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

49. Based on my review of the specification and claims of the '834 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

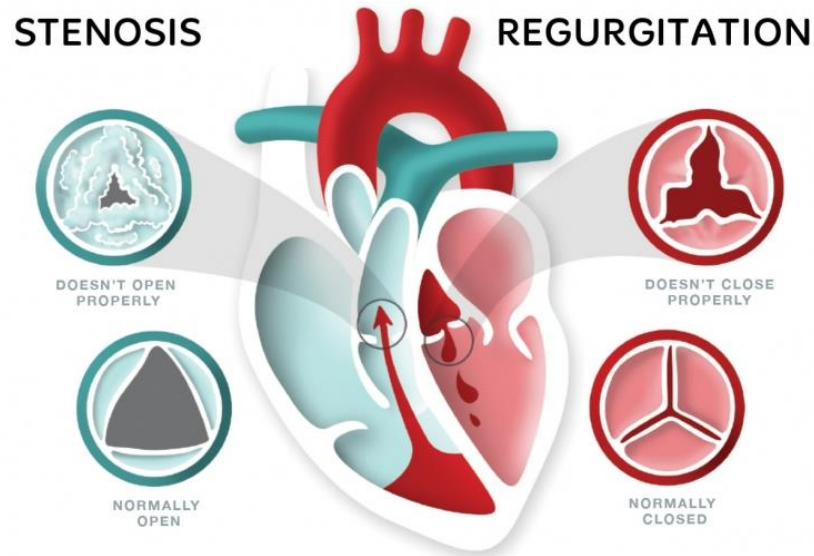
A. Anatomy of the Heart and Background of Aortic Stenosis and Regurgitation

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.



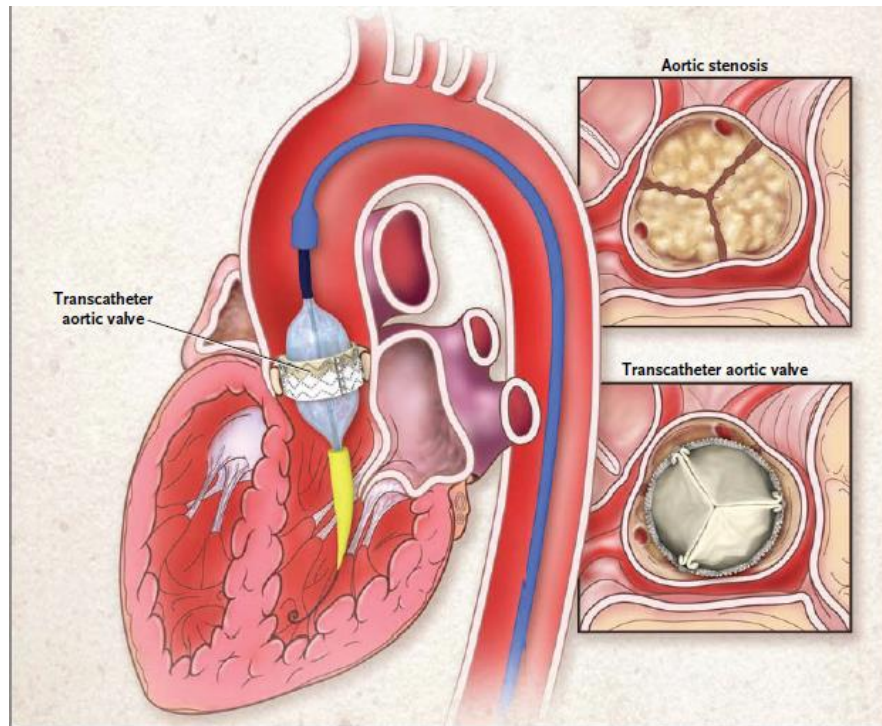
Available at <https://www.heartfoundation.org.nz/your-heart/heart-conditions/heart-valve-disease>. Although the above image illustrates stenosis and regurgitation on different heart valves, persons of ordinary skill in the art would understand that both conditions can occur on the aortic valve.

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 transcatheter heart valves (“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:

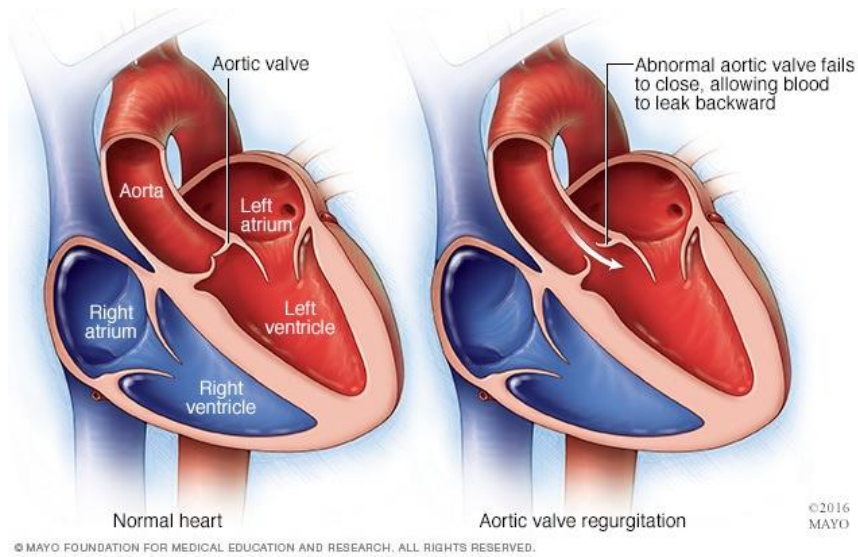
¹ “Paraprosthetic,” “perivalvular,” and “paravalvular” leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



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 '834 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 '834 patent state that “the first plurality of fibers is configured to press some of the fibers against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” See *e.g.*, Ex. 1001 ('834 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 '834 patent identifies the annulus (identified by item #210) as the crown-like structure where the aortic valve leaflets attach to the left ventricle:

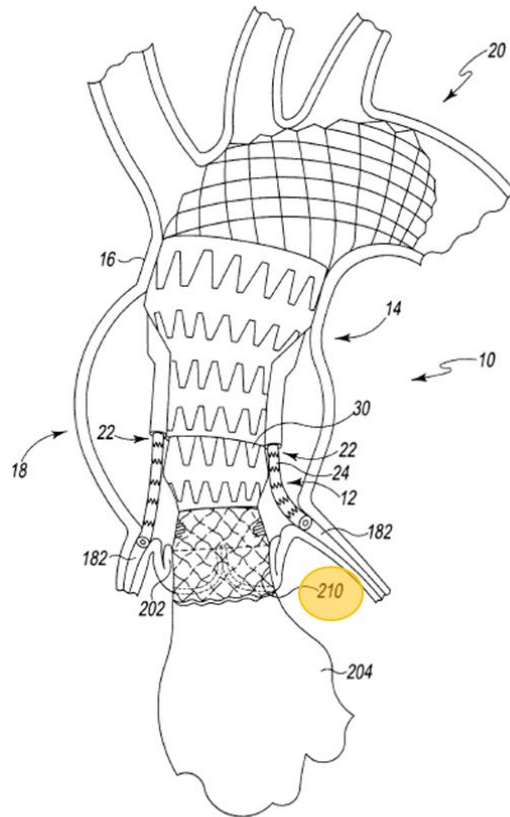
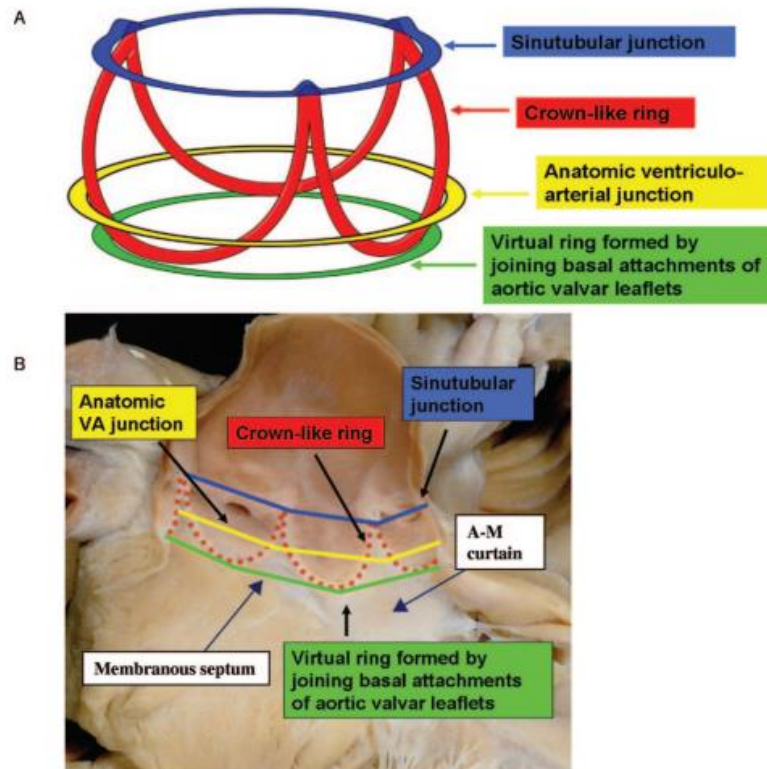


Fig. 2

See *e.g.*, *id.* at Fig. 2.² This is further confirmed by the '834 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 1:62-64. The below image from a prior art journal article reflects the structure of the aortic valve. What the '834 patent identifies as the annulus

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

210 corresponds to a point in the center of the red crown-like ring in the figure below.



Ex. 1047 (Piazza) at Fig. 4. Because the “annulus” referred to in the ’834 patent corresponds to the center of 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 hand-made 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**).

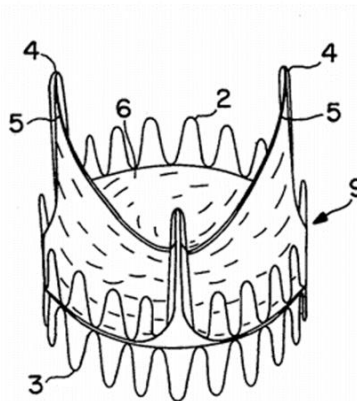


FIG. 2

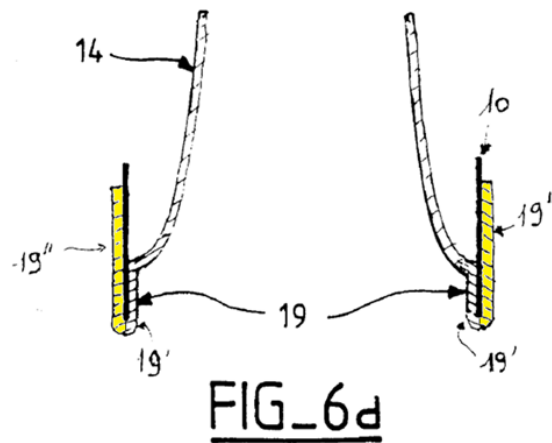
Id. at Fig. 2. The Andersen patent describes multiple THV embodiments that expand upon the inventors' early prototypes, including embodiments having additional tubular graft material that can be used along the surface of the THV. *Id.* at 2:21-27, 2:56-60, 4:3-17, 5:9-28, 7:17-29, Figs. 11-12 (“[T]he 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.

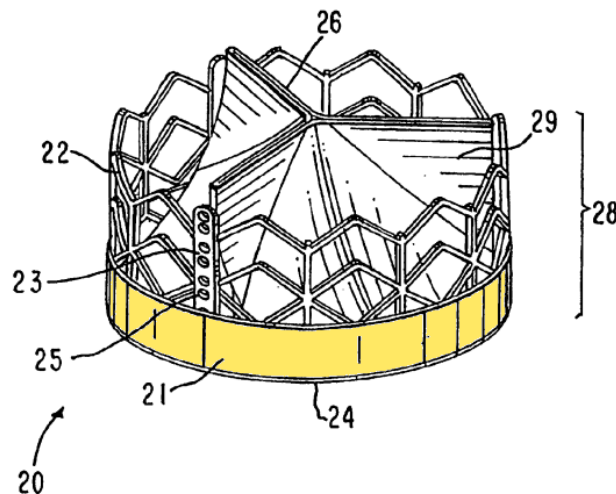
64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then “rolled up to be applied to the external wall of the stent” to form an external cover [19'']:



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

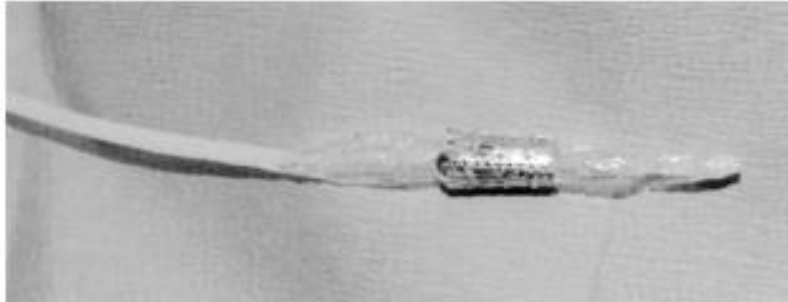
'460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a "sleeve-like" portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* ("To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet 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

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.

mounted within a tubular, slotted stainless steel balloon-expandable stent that was crimped onto a delivery balloon:

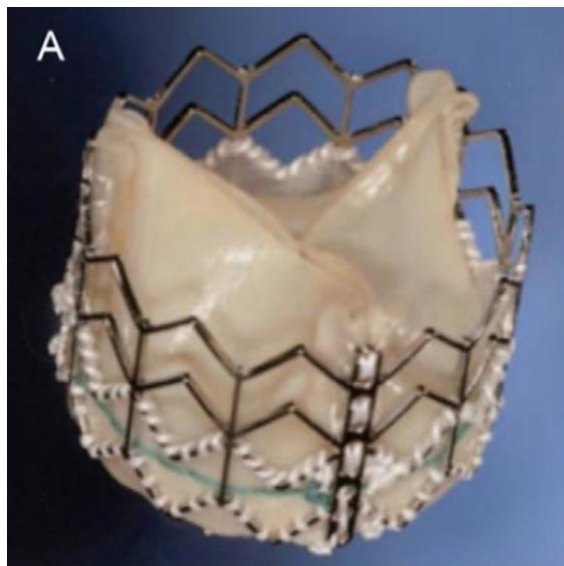


Id. at 3006, Fig. 1. Dr. Cribier implanted the THV using an antegrade approach from the right femoral vein. *Id.* at 3007. Dr. Cribier inserted a 24F sheath into the right femoral vein. The THV was “easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic 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.”

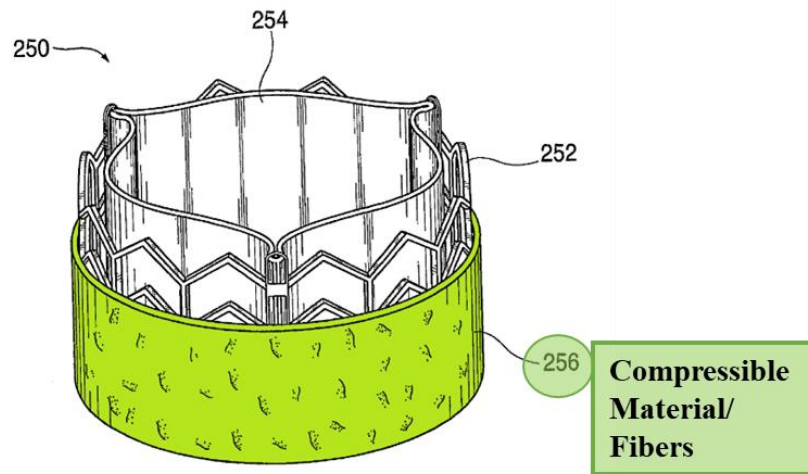
Id.

68. In 2004, Edwards acquired PVT and began developing and testing the Cribier-Edwards THV. **Ex. 1023** (Webb, John G. and Binder, Ronald K., *Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches*, Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)). The Cribier-Edwards THV “was constructed from a laser-cut stainless steel tubular frame within which was sewn valve leaflets constructed from equine pericardium, with the inflow covered with a fabric sealing cuff (Fig. 3A).” *Id.* at 154.



Id. at Fig. 3A.

69. 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].



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.*

70. 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.

71. 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.

72. 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.

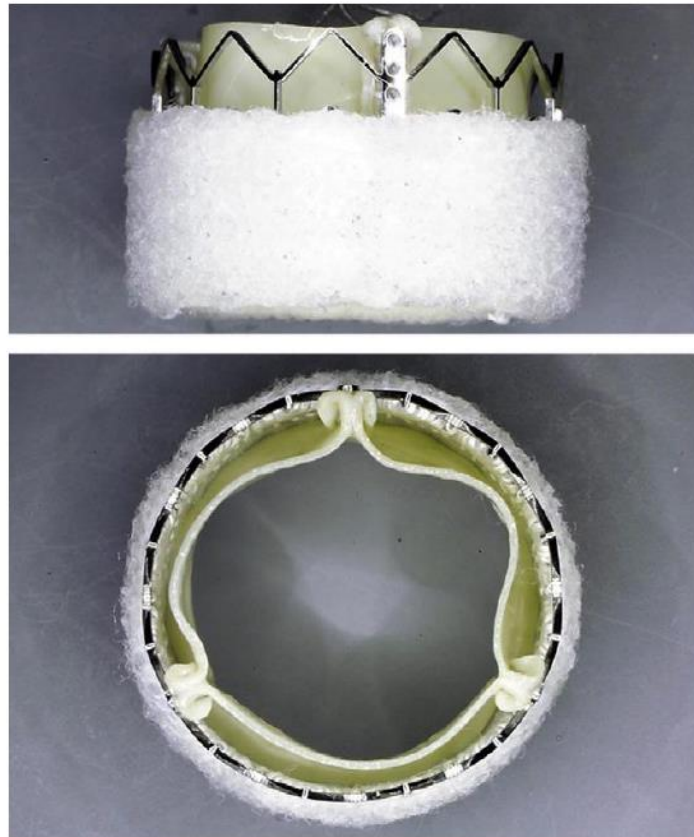
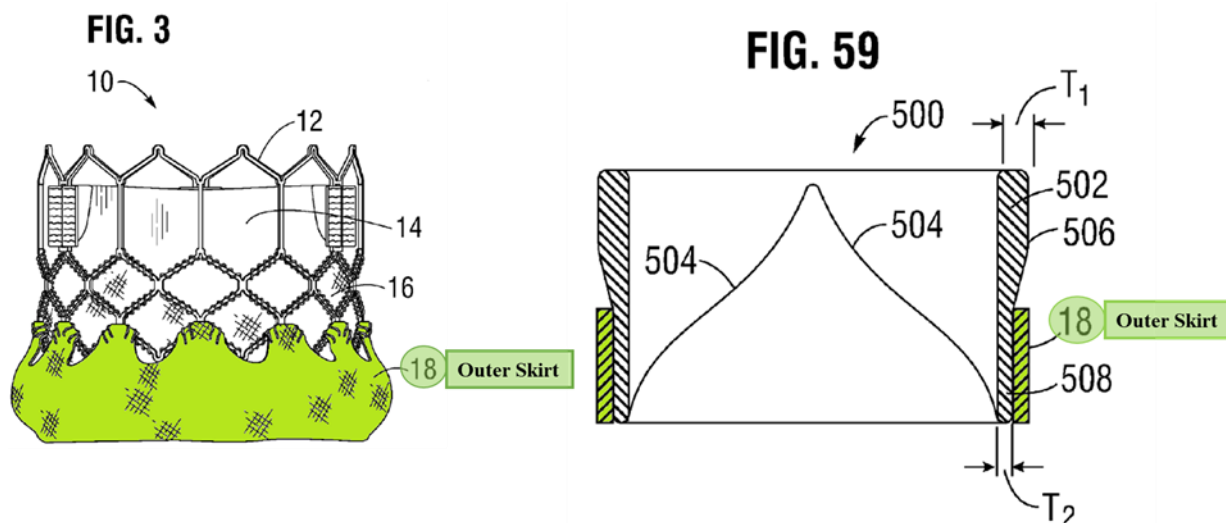


Fig. 1. Cloth valve.

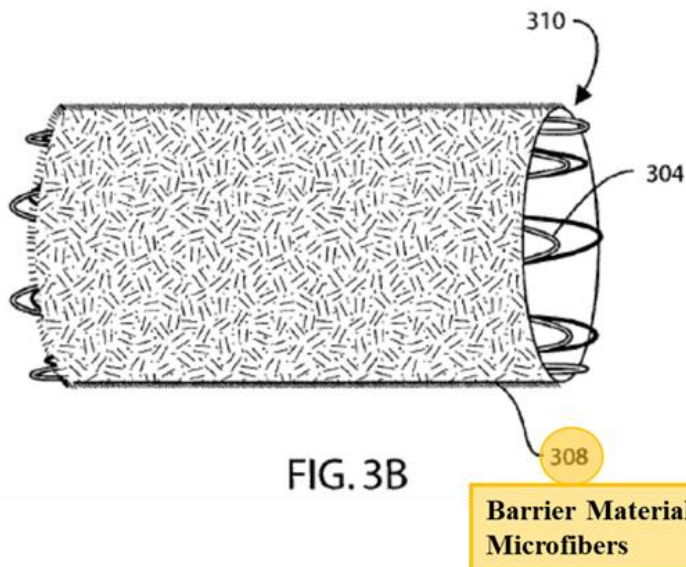
Id. at Fig. 1. Edwards had developed the SAPIEN valve as the follow-up generation to the Cribier-Edwards valve. See **Ex. 1023** (Webb) at 154. The Walther team explained that the “addition of an outer cloth to the SAPIEN cloth valve is designed to reduce paravalvular leak by creating a seal between 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.*

73. 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, 59. “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.

74. 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. Ex. 1057 (Birdsall) at Abstract. 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. While Birdsall teaches that this embodiment is intended to be implanted within a vascular conduit, Birdsall’s teaching of extending fibers to form a seal is broader and is not limited to this context. Therefore, persons of ordinary skill in the art would have understood that a fibrous material like Birdsall’s “barrier material” would perform a similar sealing function when implanted in a native tissue valve. Indeed, like the other THVs discussed above, Birdsall’s valve is also designed for transcatheter, percutaneous implantation. *See id.* at 2:33-39.

75. 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.

76. 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.

77. 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.

78. 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

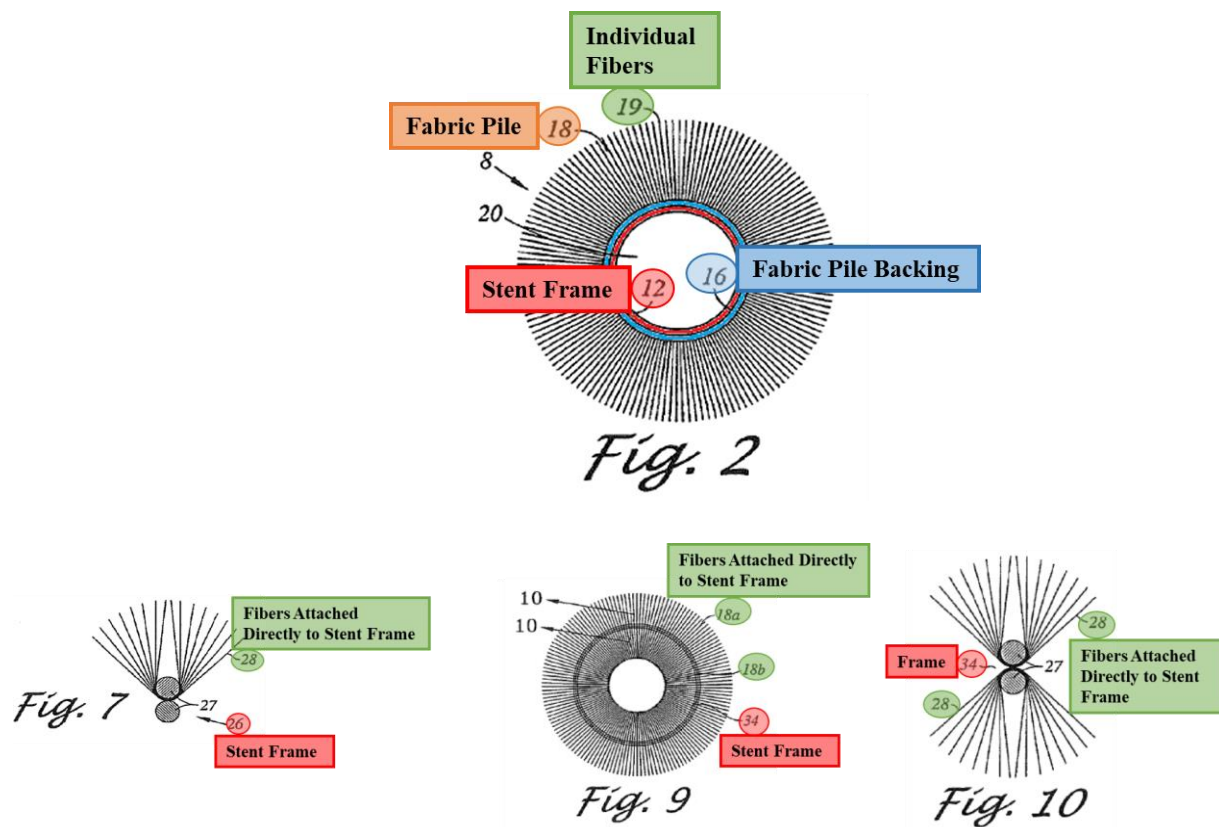
26 mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, the Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23 mm valve and 19 French for the 26mm valve. *Id.* The Novaflex incorporated an innovative 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.

79. 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

80. 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 sealing on other cardiovascular devices. For example, **Chuter**, a patent application published in October 2002, 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” layer (Fig. 2) or they can be attached directly to the stent frame without any backing layer (Figs. 7, 9-10):



Id. at [0017]-[0022], Figs 1-10. Chuter also teaches embodiments with individual fibers extending both outwardly and inwardly from the stent frame, as illustrated

in Figures 9 and 10 above. *Id.* at [0057], Figs. 8-10. Chuter teaches that the “[i]ndividual fibers 19 of the fabric pile backing fill the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel” when the device is implanted, thereby preventing blood from flowing around the outside of the stent frame. *Id.* at [0064].

81. 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 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; *Ex. 1074* (Norris).

82. 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 stent 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 '834 PATENT

A. Summary of the '834 Patent

83. The '834 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.

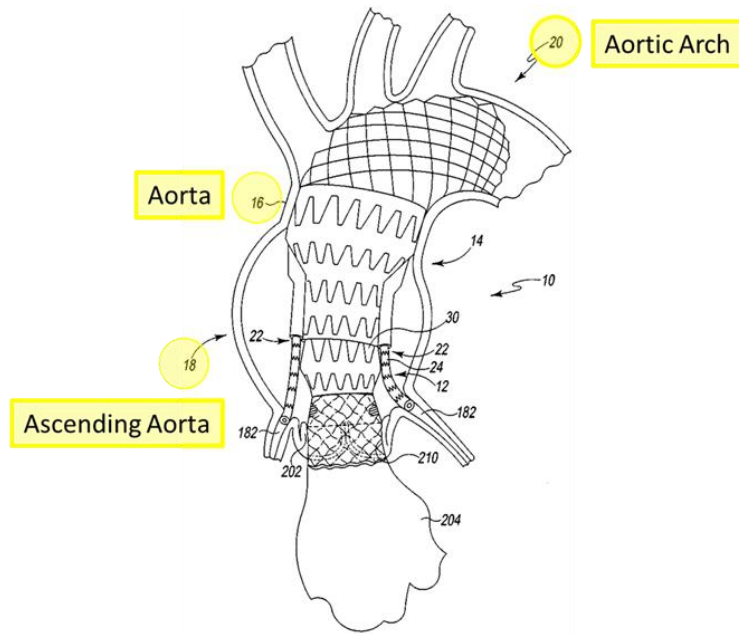


Fig. 2

84. However, the challenged claims of the '834 patent focus on an “endovascular prosthetic heart valve” for replacing an aortic heart valve. The '834 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** ('834 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”:

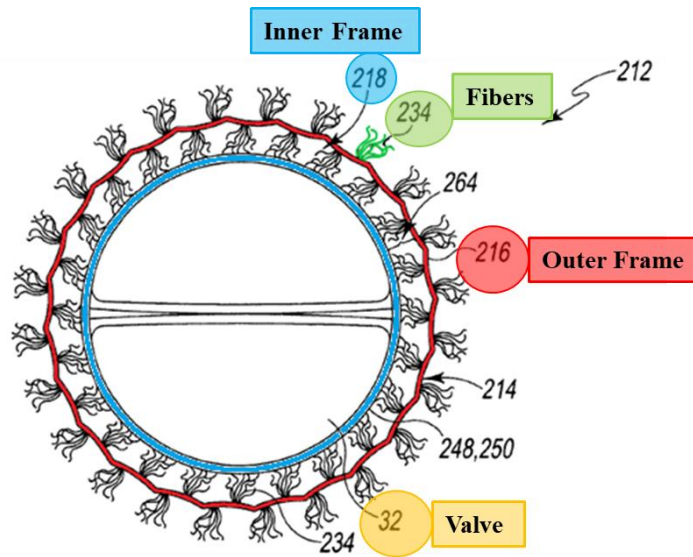


Fig. 13

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

85. The '834 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, 18:4-9, 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 13:50-54. The inner frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:16-18.

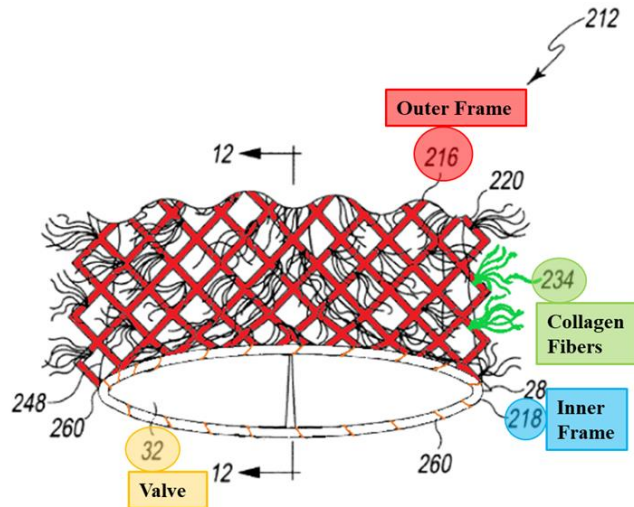


Fig. 11

86. The '834 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

87. The challenged claims include claims 1-6 and 8-18 of the '834 patent. Claims 1, 17, and 18 are independent claims.

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

1. An endovascular prosthetic heart valve for use in a patient, comprising:
 - a frame formed of a plurality of struts that cooperate to form a plurality of cells,
 - wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
 - a leaflet assembly within the frame;

a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

a first plurality of fibers that extend away from the frame,
wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,

wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers,

wherein the second plurality of fibers is in direct contact with the frame.

C. Prosecution History

89. I have reviewed the '834 patent's prosecution history. I see that the Patent Examiner issued a non-final office action and a final office action, neither of which included any prior-art based rejections. Ex. 1002 ('834 patent prosecution history excerpt) at 1030-1035, 1155-1161.

90. While the Patent Examiner did not discuss any of the prior art references included in the grounds of unpatentability discussed in this Declaration, I see that Patent Owner made arguments about the prior art and statements concerning the scope of the claims in Amendments during prosecution.

91. For example, Patent Owner made arguments about Spenser II in an August 14, 2021 Amendment, arguing that Spenser II "appears to teach a thick band with fibers emanating therefrom in FIG. 22." Ex. 1002 ('834 patent prosecution history excerpt) at 1144. Patent Owner argued that the "thick outer

seal of Spenser [II] adds to valve profile size and restricts foreshortening.” *Id.* Patent Owner also argued that Spenser II discloses “a very tightly knitted outer seal made of tightly knitted fibers” and argued “the lack of ‘spacings’ between some fibers would not allow for compression of the outwardly extending fibers.” *Id.* at 1001. Patent Owner’s arguments regarding the thickness, density, tightness of the knitting, and valve profile of Spenser II’s outer seal ignore Spenser II’s teaching that its outer seal is **compressible**. As I explain in detail below, a person of ordinary skill in the art would understand that such compressibility would allow Spenser II’s outer seal to crimp down when the valve is compressed, greatly reducing any increase in the valve’s overall crimped profile. *See infra* §VI.a.7. Additionally, I disagree with Patent Owner’s assertion that Spenser II’s compressible material would restrict foreshortening of the valve for the reasons I explain below. *See infra* VI.A.

V. SUMMARY OF IPR GROUNDS

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

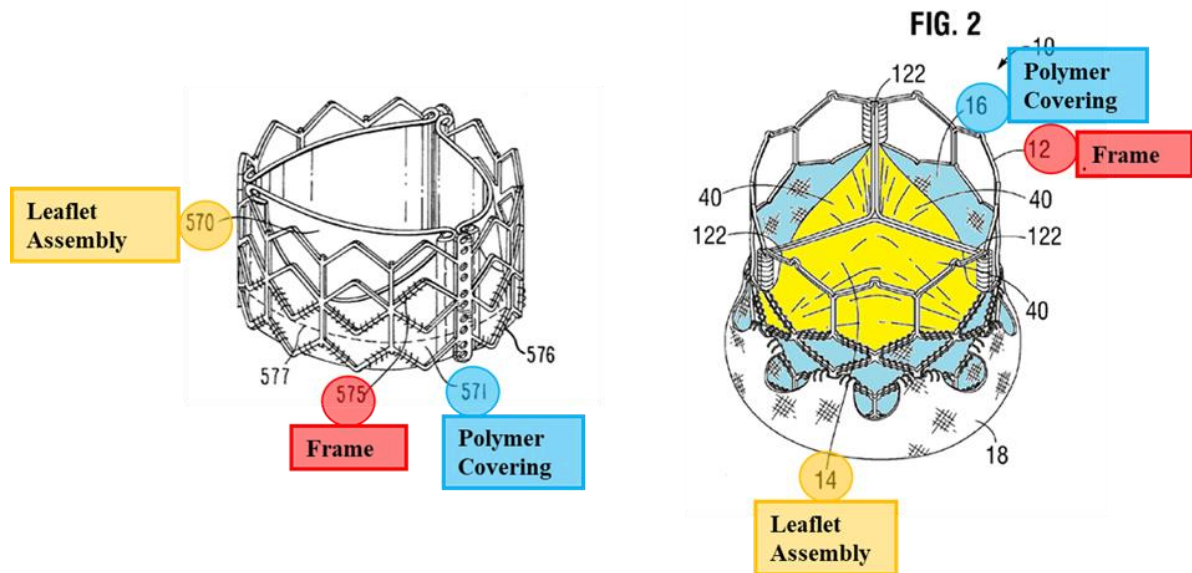
Ground	Claims Challenged	Pre-AIA 35 U.S.C. §	References
1	1-6, 8-18	103	Spenser + Spenser II
2	1-6, 8-18	103	Levi + Spenser II
3	1-6, 8-18	103	Spenser + Chuter

4	1-6, 8-18	103	Levi + Chuter
5	1-6, 8-18	103	Spenser + Chuter + Spenser II
6	1-6, 8-18	103	Levi + Chuter + Spenser II

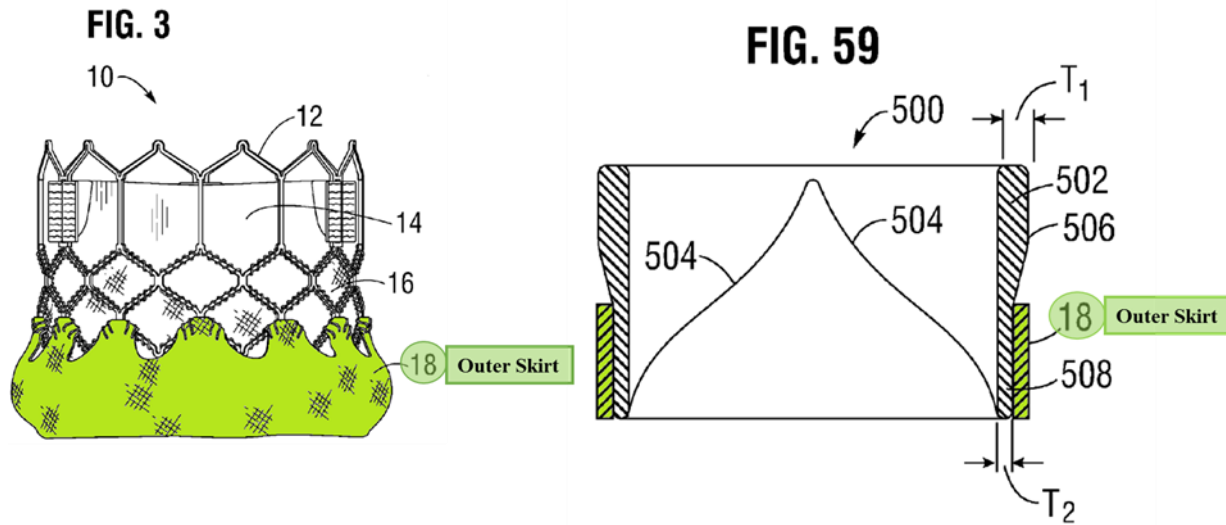
VI. GROUNDS 1-2: CLAIMS 1-6, 8-18 OBVIOUS OVER SPENSER *OR*

LEVI AND SPENSER II

93. Spenser (left) and Levi (right) describes heart valve assemblies having a frame, an inner polymeric covering, and a leaflet assembly, as illustrated below:

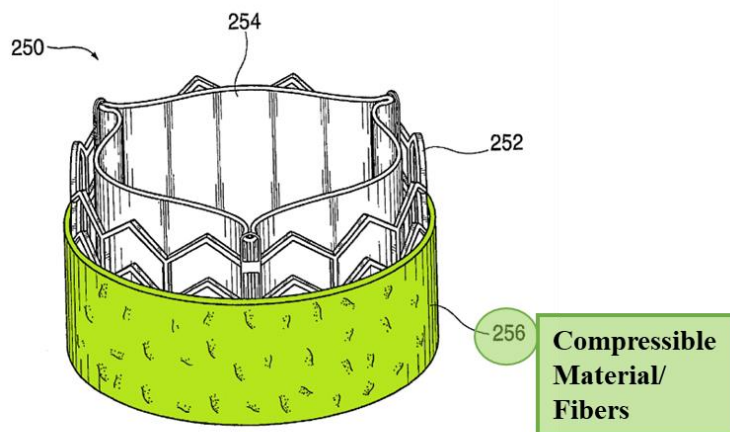


Ex. 1010 (Spenser) at Fig. 44a; Ex. 1008 (Levi) at Fig. 2. Levi's valves also include an outer skirt of woven PET fabric secured to the exterior surface of an outer frame, as shown in Figure 3 below:



Ex. 1008 (Levi) at 13:50-53, 13:62-66, Figs. 3, 59.

94. 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:



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 fibers extending away from the frame). *Id.* at [00145].

95. For the reasons I provide in detail below, I believe that a person of ordinary skill would have been motivated to combine Spenser II’s compressible material with the heart valve assemblies in Spenser and Levi. Based on my review of these references, I believe that the combination of Spenser *or* Levi and Spenser II renders claims 1-6 and 8-18 obvious.

A. Claim 1

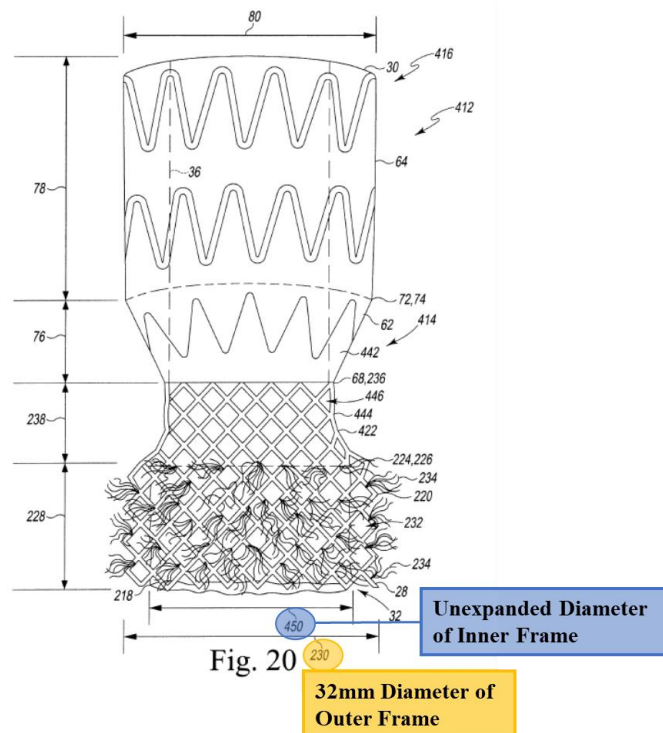
96. Based on my review of the prior art, it is my opinion that Spenser *or* Levi in combination with Spenser II renders claim 1 obvious.

1. Preamble

97. The preamble of claim 1 recites: “An endovascular prosthetic heart valve for use in a patient.” If this preamble is limiting Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

98. I note that despite claiming an endovascular prosthetic heart valve, the ’834 patent does not contain any disclosure regarding how to size the disclosed valves for endovascular delivery. For example, the ’834 patent never discloses the length, thickness, or width of the sealing material and fibers, the density of the fibers, or the crimp profile of the valve assembly, other than the

teaching that the unexpanded inner frame is 20mm due to the gap 264 between the unexpanded inner frame the expanded outer frame.



See Ex. 1001 ('834 patent) at 12:40-43, 14:16-28, 18:21-24, 19:29-34, Fig. 20. In my opinion, the dual-frame concept must rely on the prior art and the knowledge of a person of ordinary skill in the art for all of the dimensional teaching.

99. Spenser discloses that “[a]n aspect of the present invention deals with the possibility of *implanting the valve percutaneously... via a large blood vessel such as the femoral artery*[.]” Ex. 1010 (Spenser) at 2:6-12 (emphases added).

100. Levi discloses “collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or

stent.” Ex. 1008 (Levi) at 1:57-2:7; *see also id.* at 5:53-56, 6:46-49, 7:10-12, 14:60-64; Ex. 1051, 5:14-67, 28:37-48, Fig. 4.

101. 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]. Persons of ordinary skill in the art would have understood the description of endovascular delivery to apply to the cloth-covered 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).

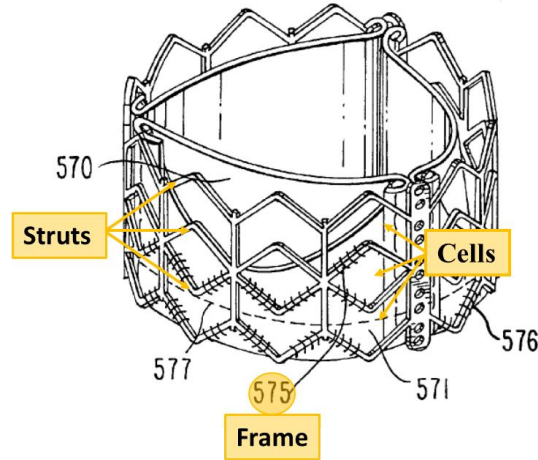
2. Frame

102. Claim 1 next recites: “a frame formed of plurality of struts that cooperate to form a plurality of cells.” Spenser and Levi disclose this limitation.

a. Spenser

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

FIG. 44a

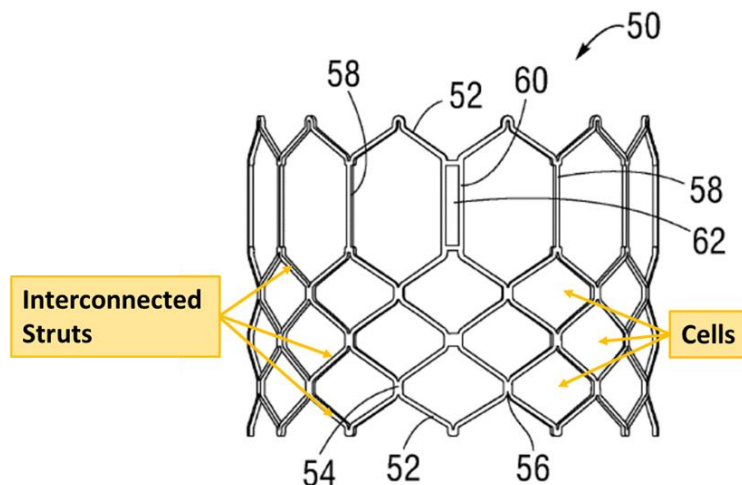


Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame). As shown, the frame is formed of a plurality of struts that form a plurality of cells.

b. Levi

104. Levi discloses an expandable metal frame formed from a plurality of interconnected struts that form a plurality of cells, as shown in Figure 11 of Levi below:

FIG. 11



Ex. 1008 (Levi) at 6:17-7:3, Fig. 11.

3. **Radially Expandable**

105. Claim 1 next recites: “wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser and Levi disclose this limitation.

106. Spenser’s valve “has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation].” Ex. 1010 (Spenser) at 27:67-28:2. Levi teaches that “[w]hen constructed of a plastically-expandable material, the frame 12 (and thus the valve 10) *can be crimped to a radially compressed* state on a delivery catheter and then *expanded* inside a patient by an inflatable balloon or equivalent expansion mechanism.” Ex. 1008 (Levi) at 6:20-24 (emphases added).

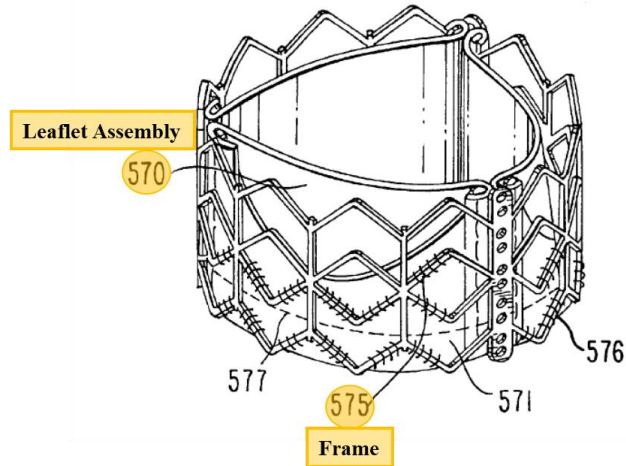
4. **Leaflet Assembly**

107. Claim 1 next recites: “a leaflet assembly within the frame.” Spenser and Levi disclose this limitation.

a. **Spenser**

108. Spenser’s Figure 44a includes “pericardial leaflets 570” which are a “leaflet assembly” that is within frame 575:

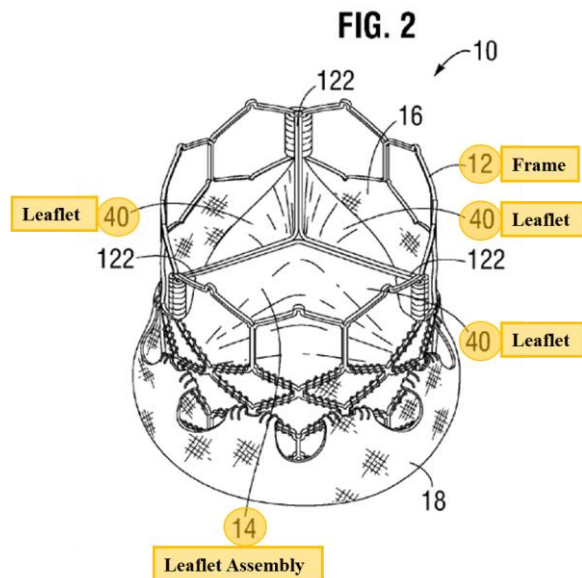
FIG. 44a



Ex. 1010 (Spenser) at 26:34-37, Figs. 44a-44c.

b. Levi

109. Levi's valve includes a "valvular structure 14 [that] can comprise three leaflets 40, collectively forming a leaflet structure" that is within the frame 12, as shown in Figure 2 of Levi below:



Ex. 1008 (Levi) at 5:59-60, Fig. 2.

5. Polymer Covering

110. Claim 1 next recites: “a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.” Spenser and Levi also disclose this limitation.

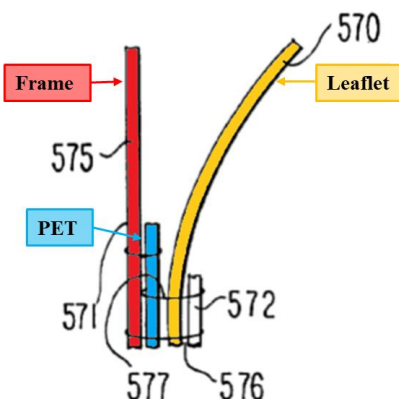
a. Spenser

111. 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”). PET stands for polyethylene terephthalate, which is a polymer. *Id.* at 3:2. 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 “polymer covering.”

112. As shown in Figure 44b of Spenser below, the PET 571⁴ [blue] is positioned “between the leaflets [570 yellow] and the frame [575 red]”:

⁴ 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.

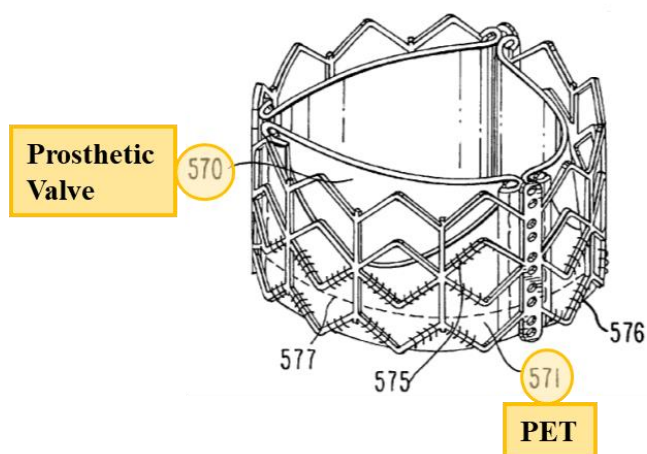
FIG. 44b



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

113. As shown in Figure 44b above and Figure 44a below, the PET 571 is positioned radially outwardly of the prosthetic heart valve 570 and radially inwardly of the frame 575:

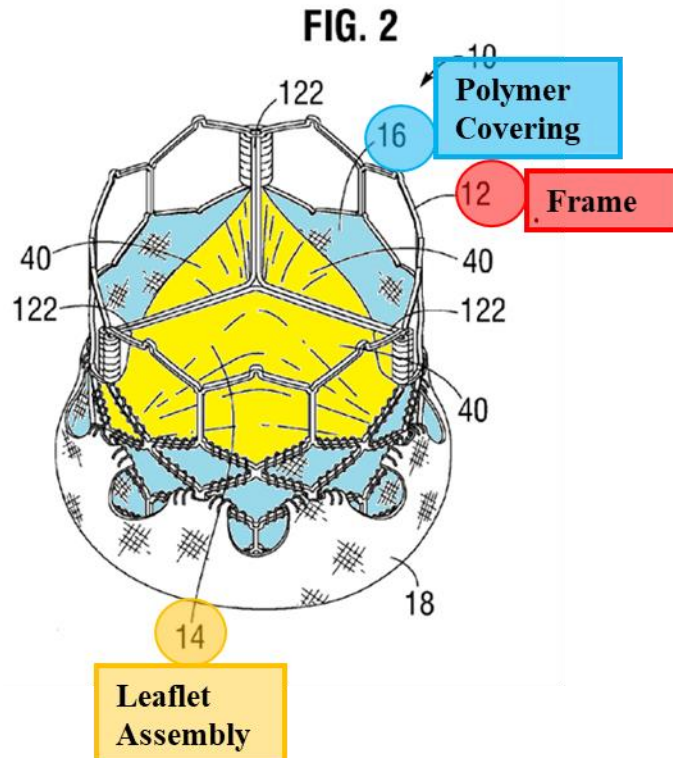
FIG. 44a



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

b. Levi

114. Levi discloses an “inner skirt 16 ... to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through the open cells of frame 12 below the lower edge of the leaflets.” Ex. 1008 (Levi) at 9:7-11. The inner skirt is constructed of “a tough, tear resistant material such as polyethylene terephthalate (PET).” *Id.* at 9:11-16. PET is a synthetic polymer and is therefore a “polymer covering.” The inner skirt is attached to the valvular structure “via one or more thin PET reinforcing strips.” *Id.* at 9:25-29. Levi’s inner skirt 16 [blue] is positioned radially outwardly of the leaflet assembly [yellow] and radially inwardly of the frame 12 [red]:



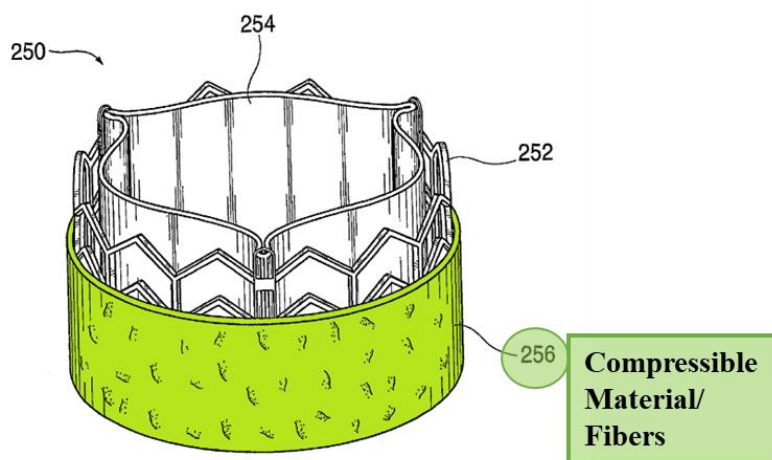
Ex. 1008 (Levi) at Fig. 2.

6. First Plurality of Fibers

115. Claim 1 next recites: “a first plurality of fibers that extend away from the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

116. I am aware that the Board has previously concluded that Spenser II’s compressible material discloses a plurality of radially extending fibers. Ex. 1117 (’172 FWD) at 21, 55-57, 70. I agree with the Board’s conclusion.

117. 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 outer 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.* (emphasis added).

Spenser II further discloses that the compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.*

a. Spenser and Spenser II

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 ('172 FWD), 64; *see also* Ex. 1118 ('011 FWD), 68; Ex. 1119 ('538 FWD), 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 paravalvular leakage.

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.2-5. 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].

b. Levi and Spenser II

122. In my opinion, a person of ordinary skill in the art would have found it obvious to replace Levi's outer PET skirt with Spenser II's compressible material. A person of ordinary skill would have been motivated by Spenser II's teachings that its radially extending fibers reduce or prevent paravalvular leakage and "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." Ex. 1011 (Spenser II) at [00145]. In addition, the combination of Spenser II's compressible material and Levi would merely entail substitution of one known element (Levi's PET skirt) for another (Spenser II's compressible material) to yield the predictable results of reducing paravalvular leakage.

123. Moreover, the field of heart valves had a finite number of options to address paravalvular leakage in November 2012. Spenser II and Levi disclose two such options. A person of ordinary skill would have found it obvious to

select either of these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in doing so. Spenser II's compressible material may "encourage coagulation of blood," which would have motivated a person of ordinary skill in the art to try replacing Levi's PET skirt with Spenser II's compressible material. Ex. 1011 (Spenser II) at [0055].

124. A person of ordinary skill would have had a reasonable expectation of success in substituting Spenser II's compressible material for Levi's outer skirt. The stent frames in Levi and Spenser II have many similar features, including being metallic and balloon-expandable. *Supra* §VI.A.2; Ex. 1011 (Spenser II) at [00144]. Moreover, Levi and Spenser II are from the same field of endeavor and share the same objective of providing a prosthetic valve suitable for minimally invasive procedures. *See, e.g.*, Ex. 1008 (Levi) at Abstract, 2:1-7; Ex. 1011 (Spenser II) at Abstract. Further, the references specifically relate to prosthetic heart valves developed by Edwards. Levi and Spenser II also share a common inventor (Benichou). *See* Ex. 1008 (Levi) at 1; Ex. 1011 (Spenser II) at 1. A person of ordinary skill in the art would therefore have found it obvious to combine the features among these closely tied references.

125. Moreover, Levi suggests mounting "***additional components***" to Levi's valve. Ex. 1008 (Levi) at 16:41-45 (emphasis added.) A person of ordinary skill in the art would have understood that Spenser II's compressible

material would be a potential “additional component.” Moreover, as I discuss below, Levi discloses several features of its valve that enable the addition of an additional fibrous component on the exterior of the valve without disadvantageously increasing the valve’s minimum crimped diameter. *Infra* §VI.A.7. For all of these reasons, a person of ordinary skill in the art would have reasonably expected success in using Spenser II’s compressible material on Levi’s valve.

7. Endovascularly Deployed

126. Claim 1 next recites: “wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

a. Spenser and Spenser II

127. 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.

128. 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.

129. 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.

130. 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.

131. Persons of ordinary skill in the art would have reasonably expected that Spenser’s Figure 44a 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).

132. 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.

133. 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.

134. 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. Levi and Spenser II

135. Levi discloses "collapsible transcatheter heart valves [which] can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent." Ex. 1008 (Levi) at 1:57-67. Persons of ordinary skill in the art would have understood that Levi's percutaneous delivery would be transfemoral delivery in view of Levi's teaching that the "diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve ***through the femoral artery or vein.***" *Id.* at 2:3-5 (emphasis added). Levi also incorporates by reference the percutaneous methods described in U.S. Patent No. 6,730,118 (Spenser's parent), which expressly describes endovascular delivery through the femoral artery. *Id.* at 1:57-67; Ex. 1051, 2:3-13. Indeed, during IPR proceedings involving related patents, Patent Owner has admitted that Levi contemplates transfemoral delivery. *See, e.g.*, Ex. 1124 ('011 POPR), 37.

136. Levi discloses several features to enable endovascular delivery through the femoral artery. See Ex. 1008 (Levi) at 6:46-49. For example, Levi discloses that its frame is preferably constructed of nickel-cobalt-chromium-molybdenum alloy, which allows for less material to be used so that “the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body.” *Id.* at 6:46-49; see also *id.* at 7:10-12. Levi discloses that “[b]y minimizing the diameter of the valve when mounted on the delivery shaft,” “the assembly can [be] contained within a smaller diameter catheter and thus can be passed through smaller vessels in the body and can be less invasive in general.” *Id.* at 14:60-64.

137. Levi additionally discloses several other features that minimize the crimped profile of the valve and would enable endovascular delivery via the femoral artery of a valve with a fibrous outer sealing material. Levi teaches that the configuration of its outer frame enables a “reduction in the frame wall thickness to achieve a smaller crimped diameter of the valve.” *Id.* at 7:10-12. Levi’s outer frame is also formed with relatively larger open cells in the uppermost row, which allow portions of the prosthetic leaflets to protrude from the frame when the valve is crimped, again reducing the minimum crimped profile of the valve. *Id.* at 7:36-42, 15:17-24. The frame may also be formed with a “thickness that varies along its length to optimize strength where needed, yet

minimize material (and therefore crimp profile) at selected regions of the frame,” such as the inflow end that is covered by the outer skirt. *Id.* at 16:54-17:18. The frame may also include window frame portions which are depressed radially inwardly relative to the other portions of the frame, which also minimizes the crimp profile of the valve. *Id.* at 14:40-45. The shape of Levi’s prosthetic leaflets also minimizes the valve’s profile. Levi teaches that the leaflets may be tapered or “V-shaped” instead of the traditional “U-shaped leaflets.” *Id.* at 14:26-30, 16:24-40. The tapered shape of the leaflets results in less leaflet material at the inflow end of the valve, which further minimizes the crimped profile of the inflow end that is covered by the outer skirt or some other “additional component.” *Id.* Even Levi’s inner skirt is designed to help minimize the crimp profile. Levi teaches that its inner skirt is woven with fibers that are non-perpendicular to the upper and lower edges of the skirt, which enables the skirt to undergo greater axial elongation when the valve is crimped, resulting in a more uniform crimping profile and a smaller crimped diameter. *Id.* at 9:36-11:2. Levi also teaches that a leaflet structure with fewer than three leaflets may be used (i.e., a bicuspid valve), which would further narrow the crimped profile. *Id.* at 11:15-17. Levi also teaches that the frame may be self-expanding, which would not require a balloon-catheter in the delivery apparatus, further narrowing the delivery profile. *Id.* at 6:12-30. A person of ordinary skill in the art would have found it obvious to use

any or all of Levi's methods to minimize the crimped profile of the valve, which would enable endovascular delivery of a valve with a fibrous outer seal.

138. Persons of ordinary skill in the art would have understood that after replacing Levi's outer skirt with Spenser II's compressible material, the resulting device would remain suitable for endovascular delivery through the femoral artery.

139. Levi discloses that "[w]hen crimped, the frame 12 has a reduced diameter region extending along a portion of the frame . . . that generally corresponds to the region of the frame covered by the outer skirt 18" so that the outer skirt "does not increase the overall crimp profile of the valve." Ex. 1008 (Levi) at 8:46-54; *see also id.* at 2:22-35, 14:22-35, 16:38-45, 17:14-18. Spenser II's compressible material could also be prepared to cover the reduced diameter region, which would ensure that the compressible material would not disadvantageously increase the crimp profile. *Id.*, 8:46-54. Indeed, persons of ordinary skill in the art would have had a finite number of locations to attach Spenser II's compressible material to Levi's frame and would have found it obvious to try covering the reduced diameter region with the compressible material so that the compressible material would not disadvantageously increase the crimp profile.

140. Additionally, Levi expressly suggests adding other components to the inflow portion of the frame, stating “if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component.” *Id.* at 16:41-45. Persons of ordinary skill in the art would have understood that Spenser II’s compressible material would be a potential “additional component.” For these reasons, persons of ordinary skill in the art would have reasonably expected success in adding Spenser II’s compressible material to Levi’s valve and endovascularly delivering the valve through a patient’s femoral artery.

141. Additionally, persons of ordinary skill in the art would have been aware of many types of fibrous, compressible sealing materials with a range of thicknesses and porosities that could be used consistent with Spenser II’s teaching and would have found it obvious to select an appropriate compressible material that would enable endovascular delivery through a patient’s femoral artery, particularly given the disclosure of such delivery in Levi and Spenser II. *See, e.g.*, Ex. 1074 (Norris); Ex. 1116 (Chuter).

8. First Plurality of Fibers Pressed Against Native Leaflets

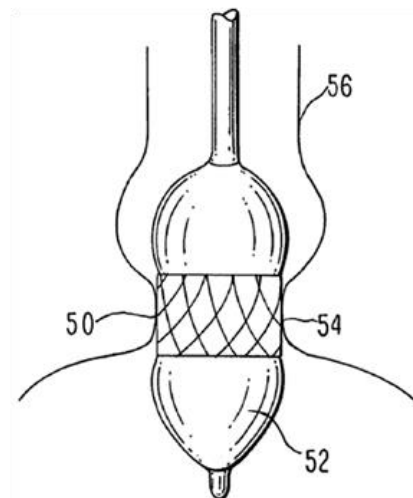
142. Claim next recites: “wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart

valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

a. Spenser and Spenser II

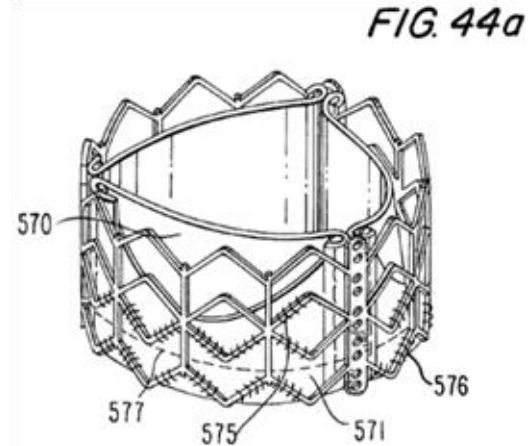
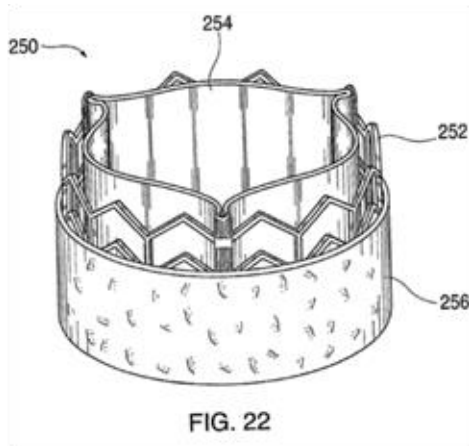
143. I am aware that the Board has previously concluded that the combination of Spenser II’s compressible material with Spenser’s Figure 44a discloses this limitation. Ex. 1119 (’538 FWD), 83-86. The Board found that persons of ordinary skill in the art “reading Spenser II, would understand that, if 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.” *Id.* I agree with the Board’s conclusion.

144. 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.

145. Spenser II's compressible material expands upon implantation in the patient's heart valve and "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]. When added to Spenser's Figure 44a, the compressible material would cover at least the bottom two rows of grids formed by the frame, as shown in the below comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):



146. As I explained above, expanding Spenser’s Figure 44a within a patient’s native aortic valve would cause at least a portion of the proximal two rows of the frame to press against the native annulus and aortic leaflets. *Supra* ¶143.

b. Levi and Spenser II

147. Levi’s outer skirt is constructed with excess material that bulges radially outwardly as the frame expands. Ex. 1008 (Levi) at 13:62-14:2. The excess material allows the outer skirt to “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. When the outer skirt “form[s] a good fluid-tight seal between the valve and the native annulus,” the fibers of the outer skirt would also seal against the native aortic leaflets, which are attached to the native annulus and extend distally therefrom. Indeed, I note that Patent Owner has previously admitted that Levi’s outer skirt would “extend[] into crevices

created by the native leaflets.” Ex. 1046 (Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020) at 21.

148. When Levi’s outer skirt is replaced with Spenser II’s compressible material, the compressible material, rather than the outer skirt, would press against the patient’s native leaflets. A person of ordinary skill in the art would have been motivated and had a reasonable expectation of success in covering the same portion of the valve with Spenser II’s compressible material as is covered with Levi’s outer skirt. Therefore, if the outer skirt presses against the leaflets, as admitted by Patent Owner, then so would the compressible material.

9. Second Plurality of Fibers

149. Claim 1 finally recites: “a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

150. As I explained previously, Spenser II discloses a compressible material disposed along the exterior of an expandable valve stent that “may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that in these embodiments of Spenser II, the PET cloth or fabric would be constructed of a plurality of PET fibers. For example,

Merriam-Webster defines “cloth” as “a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments.” *Available at:* <https://www.merriam-webster.com/dictionary/cloth>. Therefore, a person of ordinary skill would have understood that the entirety of the PET cloth or fabric in these embodiments of Spenser II’s compressible material would be composed of fibers. The fibers extending away from the surface of the material (and away from the frame) are the first plurality of fibers, as I explained above. *Supra* §VI.A.6. The fibers underlying those extending fibers, which would directly abut the frame, are a “second plurality of fibers” as required by claim 1 under Patent Owner’s interpretation of this limitation evidenced by the ’834 patent’s prosecution history and Patent Owner’s infringement contentions.

151. During prosecution of the ’834 patent, Patent Owner asserted that the sealing skirt of Petitioner’s SAPIEN 3 Ultra device meets the “second plurality of fibers” limitation because it includes “a first array of fibers forming a mesh, and a second array of fibers that end [sic] therefrom and into engagement with native leaflets of the patient.” Ex. 1002 (’834 patent prosecution history) at 1152-1153. Patent Owner has made similar allegations in its Infringement Contentions in the litigation. See Ex. 1123 at 75-78. Although I have not analyzed SAPIEN 3 Ultra for purposes of this Declaration, as explained above, Spenser II’s compressible material includes a plurality of fibers on the inward-facing surface of the material

that may “form[] a [compressible] mesh” of fibers, and the compressible material also includes a compressible plurality of fibers extending radially outwardly “that end therefrom and into engagement with native leaflets.” Many compressible materials with such a configuration of fibers were 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.”

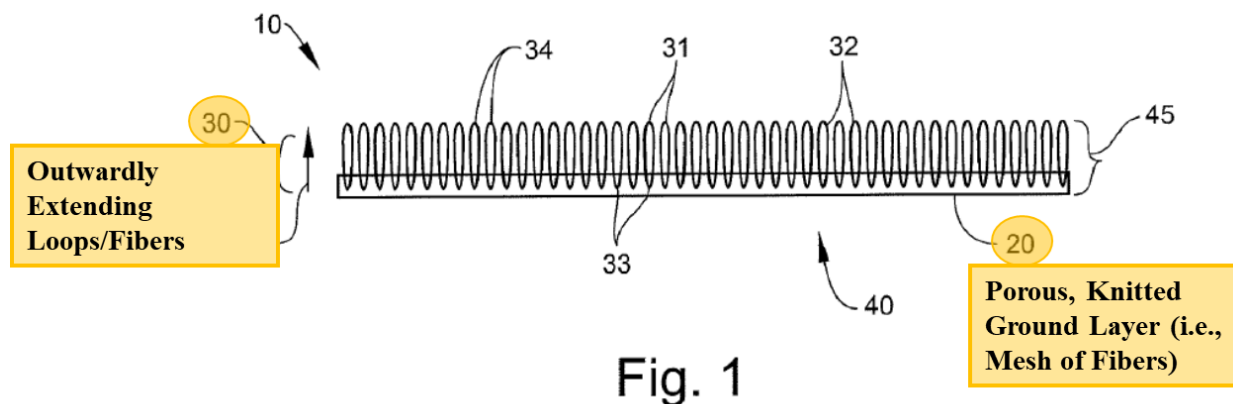


Fig. 1

Ex. 1074, 4:22-26. This configuration is also similar to the compressible velour materials commonly used to seal cardiovascular devices I discuss below. *Infra* ¶¶158-162. Therefore, Spenser II discloses this limitation according to Patent Owner’s own arguments during prosecution of the ’834 patent and Patent Owner’s infringement contentions.

152. My analysis of Spenser II is also consistent with the Board’s Final Written Decision for the IPR of Patent Owner’s ’834 patent, where the Board decided that in Spenser II’s embodiments with a cloth/fabric compressible material, the fibers of the cloth/fabric form a “graft covering” that is radially inward from the outwardly extending fibers, between the extending fibers and the frame. Ex. 1120 (’846 FWD), 46-49. The fibers that make up the inner cloth/fabric layer that the Board concluded was a “graft covering” between the outwardly extending fibers and the frame are a “second plurality of fibers” under Patent Owner’s interpretation of this limitation. As the Board found, the fibers of that layer are positioned radially inwardly from the outwardly extending fibers comprising the first plurality of fibers. *See id.*

153. A person of ordinary skill in the art would have understood that the compressible material’s second plurality of fibers are in “direct contact” with the frame because Spenser II discloses that the compressible material “is disposed along an outer surface of the stent structure 252,” as shown in Figure 22 below:

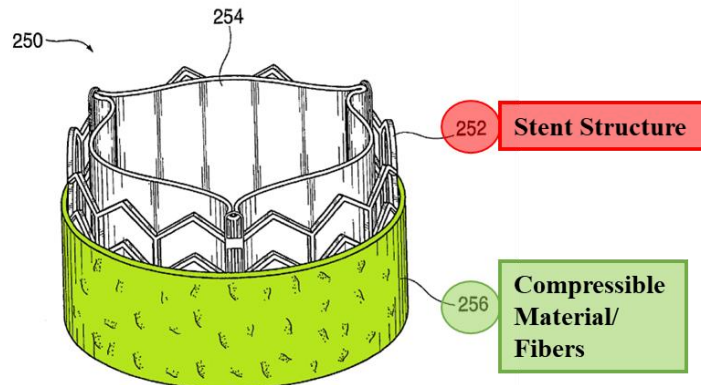
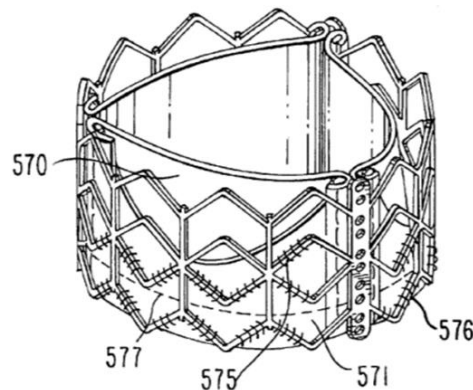


FIG. 22

Id. at [00145], Fig.22.

154. Spenser’s Figure 44a does not have any covering on the exterior of the frame 575:

FIG. 44a

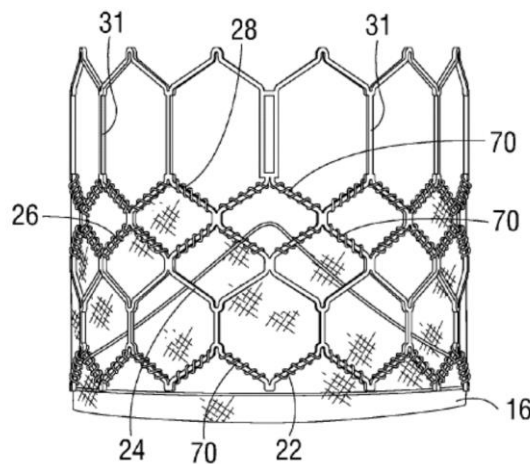


Ex. 1010 (Spenser) at Fig. 44a. Therefore, if Spenser II’s compressible material was added to Figure 44a, the second plurality of fibers would be in “direct contact with the frame.”

155. Levi’s outer skirt is stitched to Levi’s frame. *Supra* §VII.A.6.a. A person of ordinary skill in the art would have been motivated to stitch Spenser II’s compressible material to Levi’s frame because Levi describes this method of

attachment and stitching is simple and would have been known to persons of ordinary skill. When Spenser II's compressible material is stitched to the frame, the second plurality of fibers would be in direct contact with the frame, as Levi does not include any material on the exterior of the frame besides the outer skirt:

FIG. 20



Ex. 1008 (Levi) at Fig. 20. The combination of Spenser II's compressible material with Levi's valve would therefore include a second plurality of fibers in "direct contact" with the frame.

156. I note that in prior decisions, the Board has construed the terms "radially extending" and "outwardly extending" to mean "that the tips of the fibers must extend in a generally outward direction from the frame as shown in the figures of the" Aortic Innovations patents. *See, e.g.*, Ex. 1117 ('172 Institution Decision) at 36-37. I understand that Patent Owner has taken the position in pending district court litigation that loops of fibers, such as those in

Norris, would have “tips” that extending outwardly from the frame. *See* Ex. 1139 (Aortic Innovations’ Claim Construction Brief) at 21-22. Therefore, if the Board construes the first plurality of fibers to require “that the tips of the fibers must extend in a generally outward direction from the frame as shown in the figures of the” ’834 patent, then Norris’s loops of fibers would meet that requirement according to Patent Owner’s own arguments.

B. Claim 2

157. Claim 2 recites: “The prosthetic heart valve of claim 1, wherein the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

158. First, I note that the ’834 patent does not claim or disclose how to size or arrange the fibers to provide “a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.” *See* Ex. 1001. For example, the ’834 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 ’834 patent also does not disclose the size of the “spacing.” I note that the figures of the ’834 patent illustrate relatively large openings between the groups or clusters of collagen

fibers. *See, e.g.*, Ex. 1001 ('834 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 them would not be able to form a sufficient seal against the patient's native tissue to prevent PVL. A person of ordinary skill in the art would have also understood that the size of the cells, width of the struts, and length of the struts would also influence the density of fibers needed to form a seal around the frame and prevent PVL, but again, the '834 patent does not provide any guidance on these aspects. Therefore, persons of ordinary skill in the art would have understood that the '834 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 '834 patent indicates that any of the figures are drawn to-scale.

159. As I explained in claim 1, a person of ordinary skill in the art would have understood that Spenser II's compressible material, which may be a PET cloth or fabric, includes a second plurality of PET fibers that are radially inward of the fibers extending away from the surfaced of the cloth/fabric. *Supra* §VI.A.9. A person of ordinary skill in the art would have understood that Spenser II's compressible material would encompass a cloth/fabric with spacings between the second plurality of fibers for several reasons.

160. First, Spenser II does not describe the compressible material as being dense or nonporous. *See* Ex. 1011 (Spenser II) at [00145]. To the contrary, Spenser II's description is broad, and it would encompass loose, porous cloths, fabrics, and other materials that would have spacings between the fibers making up the cloth/fabric/material. Many such materials were known in the prior art and had been used in cardiovascular implant devices for decades prior to November 2012 because they were more flexible, compressible, and provided better healing, blood coagulation, and tissue ingrowth than dense, tightly woven nonporous fabrics. *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.").

161. My opinion that Spenser II's compressible material would encompass loose, porous cloths, fabrics, and other materials that would have spacings between the fibers making up the cloth/fabric/material does not change regardless of whether the compressible material is formed of knitted or woven

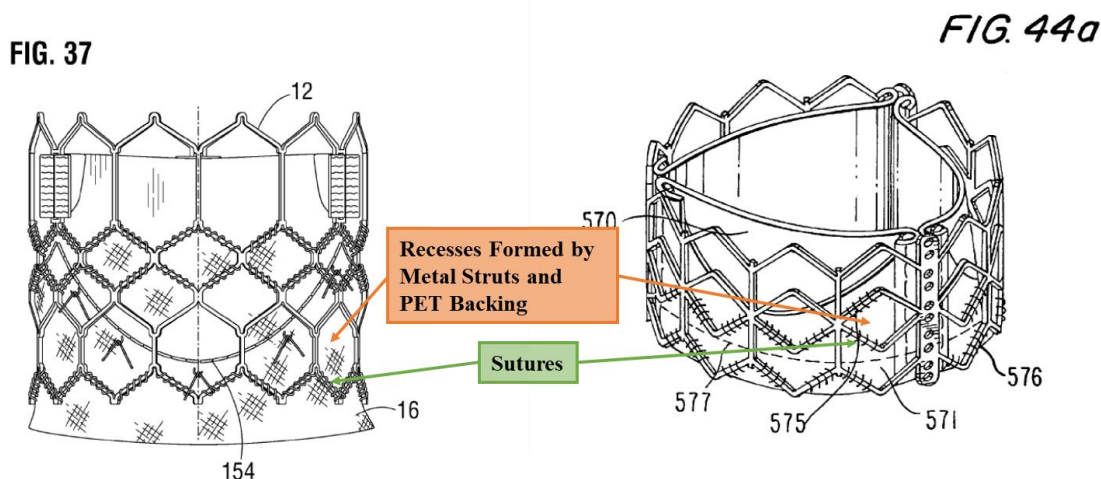
fibers. Whether a cloth is formed by weaving or knitting does not determine whether the fabric is porous or nonporous. Instead, the porosity of the material is determined by how tightly the fibers of the fabric are packed together. Although knitted fabrics are generally more porous than woven fabrics, both woven and knitted fabrics can be manufactured with varying degrees of porosity. *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. 2057 (Chu) at 4; Ex. 1106 (Estridge) at 158 (“The most commonly used porous soft tissue biomaterial is Dacron⁵ velour. This material has been used extensively as an artificial vascular graft material and in percutaneous devices. Tissue vascularity has been cited as the key to long-term ingrowth. Therefore, pores of a size sufficient to allow vascular ingrowth are required.”).

⁵ Dacron is a brand name for PET. *See* Ex. 1106 (Estridge) at 159.

162. Spenser II describes the material 256 as “compressible.” A person of ordinary skill in the art would have understood that cloth, fabric, or other material must have spaces between the fibers making up the material in order 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. 2057 (Chu) at 4. Porous fabrics with spacings between the fibers are also more flexible than tightly woven, nonporous fabrics, which also contributes to their enhanced compressibility. *See*, Ex. 1109 (Ko) at 1048; Ex. 1110 (Pourdeyhimi) at 172; Ex. 2057 (Chu) at 4. Accordingly, a person of ordinary skill in the art would have been motivated to use a porous fabric or material with spacings between the fibers, such as a velour-like knitted or woven PET cloth, for the “compressible material” in Figure 22 of Spenser II. This is particularly the case given that Spenser II is directed to percutaneously delivered valves, which require a relatively smaller crimped profile than non-percutaneously delivered valves. Ex. 1011 (Spenser II) at Abstract. Therefore, Spenser II would have motivated a person of ordinary skill

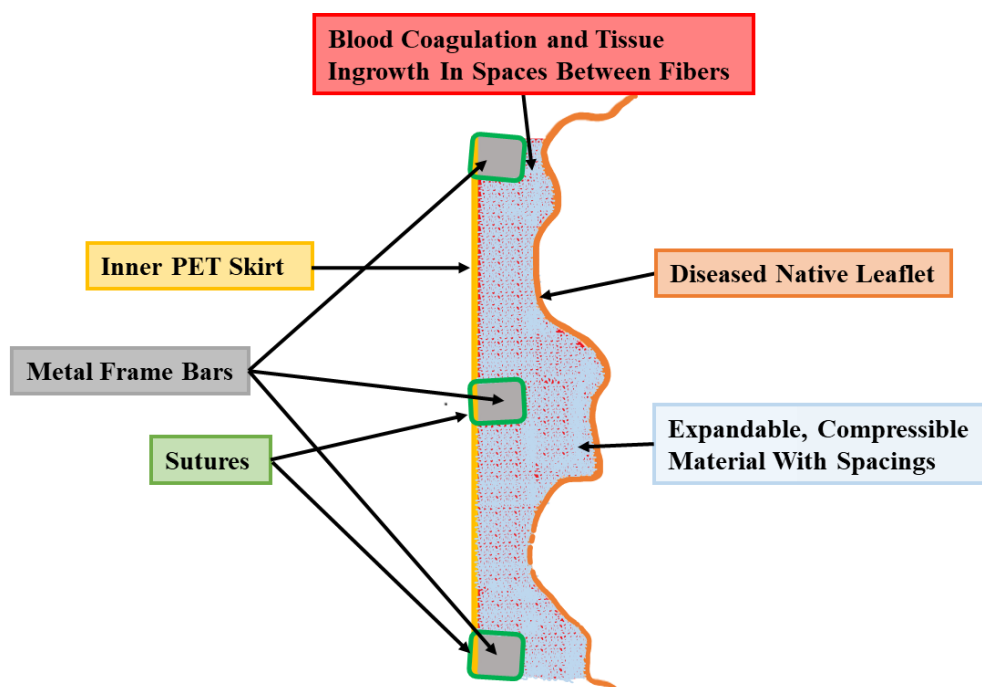
in the art to use a material that is as compressible as possible to minimize the crimped profile of the device, which would require a porous fabric.

163. Spenser II also discloses that the compressible material “expands after deployment at a treatment site” and that “[a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.” *Id.* at [00145]. A person of ordinary skill in the art would understand that the compressible material must have spacings between the fibers in order to expand and “fill[] the gaps between the stented valve and the surrounding tissue” as described. The outer surface of a stented valve, such the valve in Figure 44a of Spenser or Levi, creates an irregularly shaped surface, with gaps between the bars of the stent frame and sutures on the outside of the frame:



Ex. 1008 (Levi) at Fig. 37; 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 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 have spacings between the fibers making up the material.

164. 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. 2057 (Chu) at 4; Ex. 1106 (Estridge) at 158; Ex. 1107 (Hall) at 180-181; Ex. 1108 (Jonas) at 657; Ex. 1109 (Ko) at 1049. Accordingly, Spenser II’s description of the fibers of the compressible material encouraging coagulation of blood would further confirm to a person of ordinary skill in the art that the compressible material must have spacings between the fibers of the material.

165. A person of ordinary skill in the art would have understood that Spenser II’s compressible material would also include spacings that are “created

by distance between adjacent fibers,” as claimed in claim 2 of the ’834 patent, in order to promote tissue ingrowth. *See, e.g.,* Ex. 1106 (Estridge) at 158 (“Most researchers suggest that 40 μ m diameter pores or more are needed for soft tissue ingrowth, while others argue that pores of at least 100 μ m are needed.”). A person of ordinary skill in the art would have understood that such spacings must exist between the fibers extending away from the surface of the material (i.e., the first plurality) and the second plurality of fibers that are radially inward from the first plurality. As I explained previously, such openings are necessary to allow tissue ingrowth into the material and to allow the material to be compressible and conform to the stent frame as the valve is crimped and expanded. *Supra* ¶¶158-161. If fibers lacked such spacings, the compressible material would not serve the stated purposes disclosed in Spenser II.

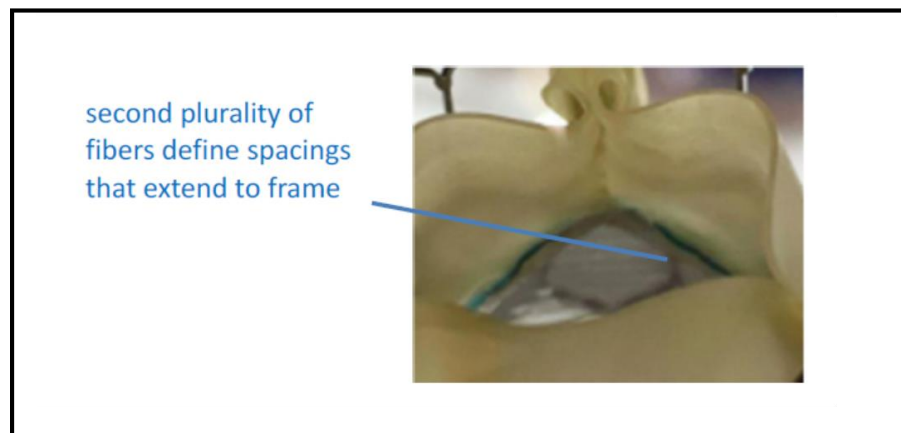
166. A person of ordinary skill in the art would have understood that in the embodiments wherein the compressible material is a cloth/fabric, the spaces between the fibers must exist and extend through a thickness of both the fibers extending outwardly from the cloth (first plurality) and the base layer/surface of the cloth (second plurality) 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* ¶¶159-164. In fact, 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].

167. A person of ordinary skill in the art would have further understood that at least some of these spacings in the second plurality of fibers would extend to the outer frame because the compressible material is disposed along the exterior of the outer frame, and the fibers of the second plurality directly abut and are compressed against the outer frame. Indeed, in the litigation, Patent Owner has alleged that a similar configuration in the outer skirt of the SAPIEN 3 Ultra valve meets this limitation, stating that “the Sapien 3 Ultra sealing skirt includes fibers

carried by the frame facing the frame” and the “fibers are knitted together to form spacings between adjacent fibers that extend at least to the frame” and providing the following annotated image:

Patent Owner’s Infringement Contentions



Ex. 1123 (Aortic Innovation’s Infringement Contentions) at 75-78.⁶ Thus, Spenser II discloses this limitation under Patent Owner’s own reading of the term.

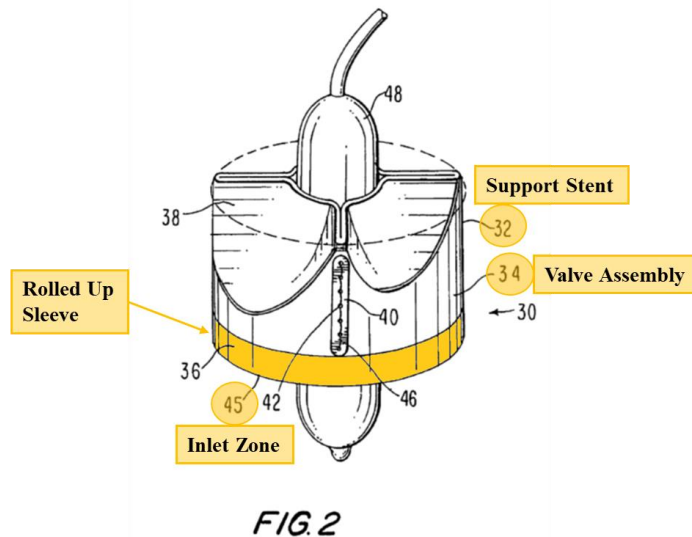
C. Claim 3

168. Claim 3 recites: “The prosthetic heart valve of claim 1, wherein the polymer covering extends further than a proximal end of the leaflet assembly.” Spenser *or* Levi in combination with Spenser II renders this claim obvious.

⁶ I have not analyzed the SAPIEN 3 Ultra valve for purposes of this Declaration, and none of my opinions herein should be interpreted as an agreement with any of Patent Owner’s positions taken in its Invalidity Contentions (Ex. 1123).

1. Spenser

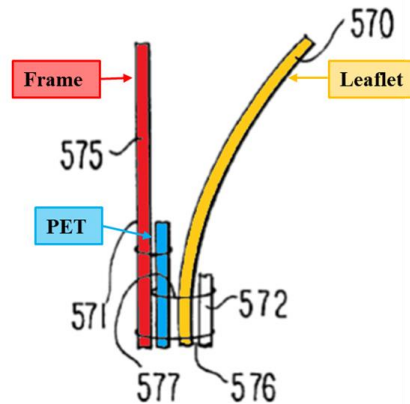
169. Spenser discloses an embodiment of its valve, shown in Figure 2, in which a “portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve [yellow], which enhances the sealing of the device at the valve inlet.” Ex. 1010 (Spenser) at 14:6-9. I note that in Figure 2 below, the dashed lines indicate the support stent, which is not shown in full in the figure. *Id.* at 13:63-66.



Id. at Fig. 2.

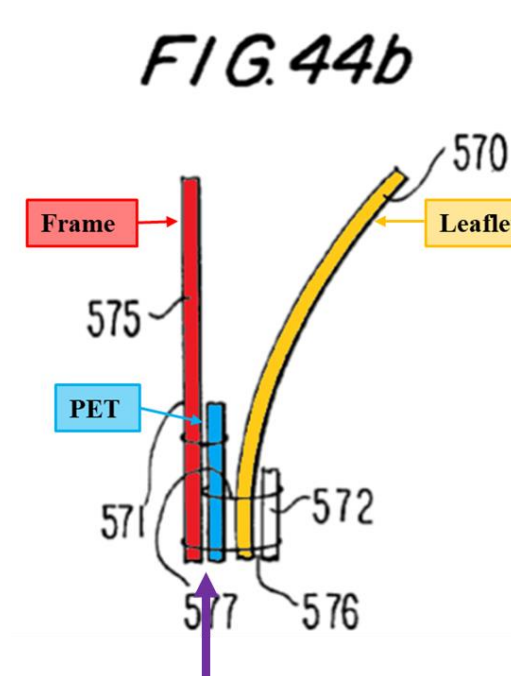
170. As I explained above, Spenser’s Figure 44a includes a piece of PET fabric (polymer covering) positioned between the outer frame and the valve leaflets, as shown in Figure 44b below:

FIG. 44b



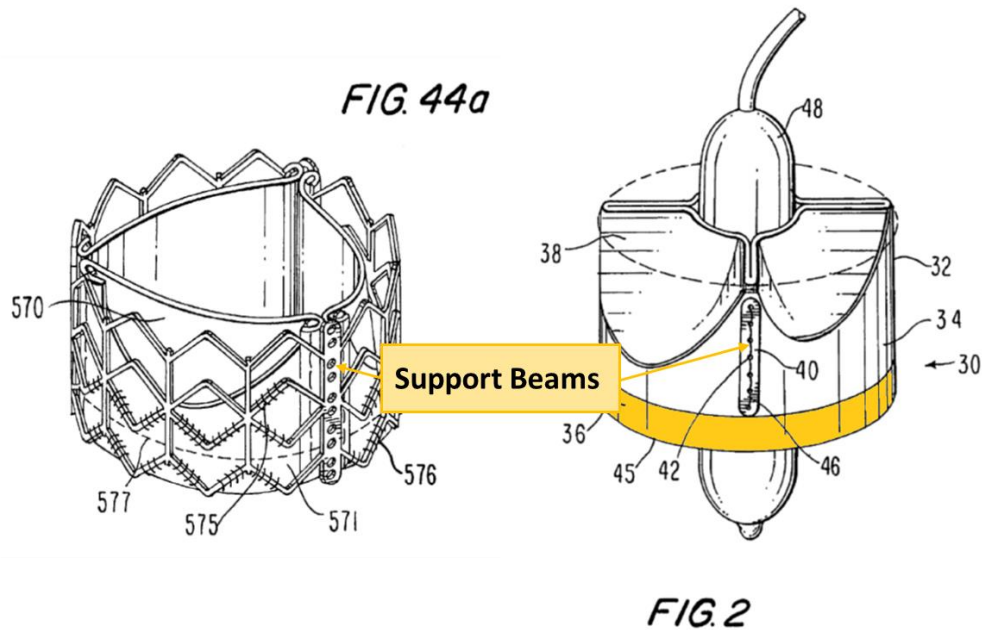
Ex. 1010 (Spenser) at Fig. 44b.

171. A person of ordinary skill in the art would have found it obvious to apply Spenser’s teachings regarding the embodiment in Figure 2 to the inner PET fabric in Figure 44a and extend the inner PET fabric 571 over the proximal end of the outer frame 575. A person of ordinary skill in the art would have been motivated to do so to further “enhance[] the sealing of the device [in Figure 44a] at the valve inlet.” *Id.* at 14:6-9. A person of ordinary skill would have understood that extending the inner PET fabric beyond and over the proximal end of the outer frame would provide an additional seal between the inner PET and the outer frame at the valve inlet. This additional seal would ensure that blood does not leak through any gaps between the PET fabric and the outer frame, indicated by the purple arrow in Figure 44b below:



Id. at Fig. 44b.

172. A person of ordinary skill in the art would have reasonably expected success in extending the inner PET fabric beyond and over the proximal end of the outer frame due to similarities between the valve assemblies in Figures 2 and 44a. *See id.* at 14:41-44, 26:30-54. For example, the valves in Figures 2 and 44a include a balloon-expandable, gridded, metallic support stent secured to the prosthetic heart valve via three parallel support beams, which are part of the support stent:

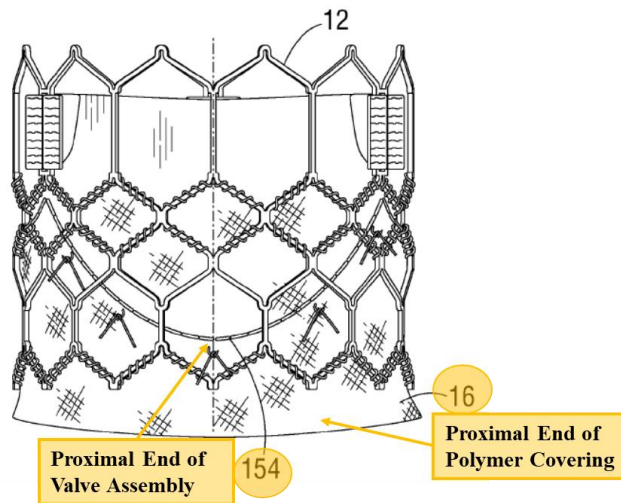


Id. at 13:62-14:3; 26:30-54, Figs. 2, 44a. Moreover, both valve assemblies include an inner PET graft covering attached to the prosthetic leaflets. *Id.* Given these similarities between the valves in Spenser's Figures 2 and 44a, a person of ordinary skill in the art would have reasonably expected that the inner PET fabric of Figure 44a may be rolled over the proximal end of the stent frame as illustrated in Figure 2.

2. Levi

173. Levi discloses an inner PET skirt sutured to the interior surface of the frame. *Supra* §VI.A.5. Levi also discloses that the lower (i.e., proximal) edges of the valve leaflets are sutured to the inner skirt along suture line 154. Ex. 1008 (Levi) at 11:10-14. Levi's inner skirt extends proximally further than suture line 154 and the proximal end of the leaflet assembly:

FIG. 37



Id. at Fig. 37.

D. Claim 4

174. Claim 4 recites: “The prosthetic valve of claim 1, wherein a distance that the first plurality of fibers extends from a centerline longitudinally through the frame varies along a length of the center line.” Spenser *or* Levi in combination with Spenser II renders this claim obvious.

175. Spenser II teaches that the fibers of the compressible material “may be straight, curved, or hook shaped.” Ex. 1011 (Spenser II) at [00145]. As illustrated by the speckled markings below, some fibers extend further out from the frame than others:

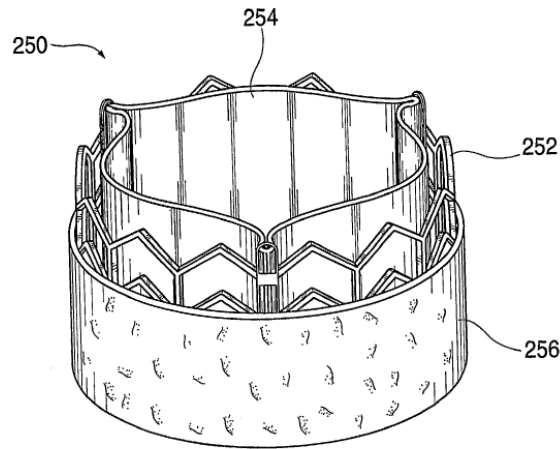


FIG. 22

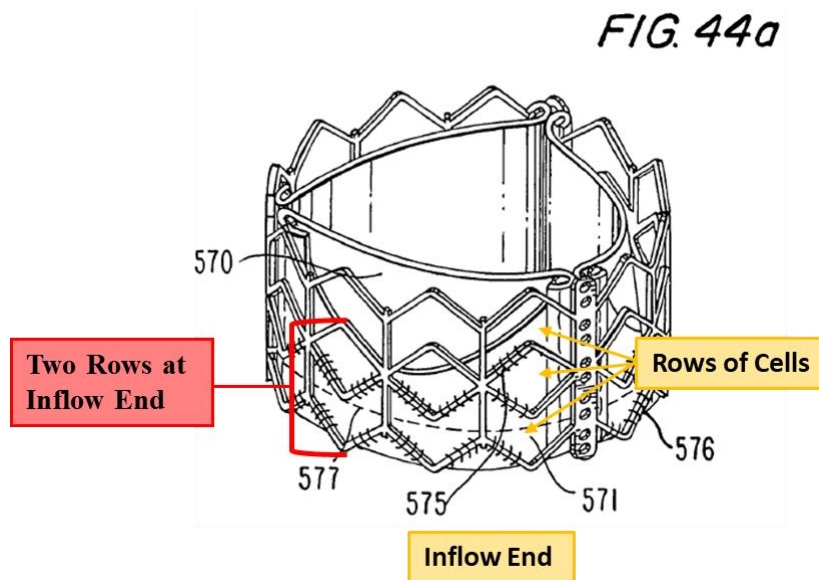
Id. at Fig. 22. Thus, the outwardly extending fibers of the compressible material extend to different distances relative to a centerline extending longitudinally through the frame along a length of the centerline.

E. Claim 5

176. Claim 5 recites: “The prosthetic heart valve of claim 1, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first plurality of fibers extends over each of the at least two rows of cells.” Spenser *or* Levi in combination with Walther *or* Spenser II renders this claim obvious.

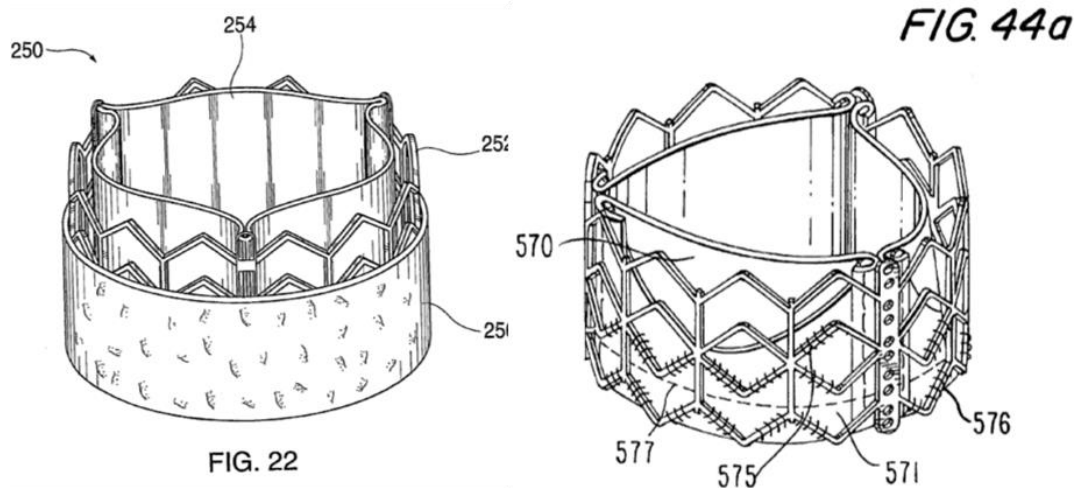
1. Spenser and Spenser II

177. Spenser’s Figure 44a includes a frame that defines three rows of open cells, including two rows of cells at the inflow end:



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

178. When added to Spenser's Figure 44a, the compressible material would extend over at least the proximal two rows of cells at the inflow end of the frame, as shown in the comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right):

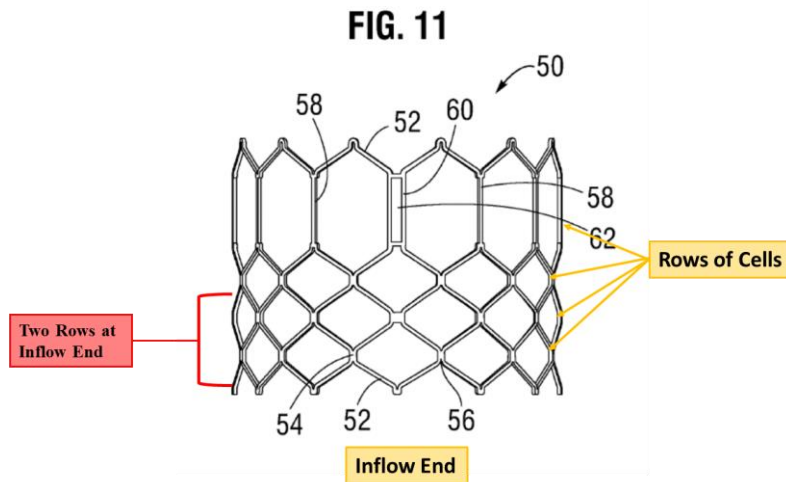


Ex. 1010 (Spenser) at Fig. 44a; Ex. 1011 (Spenser II) at Fig. 22.

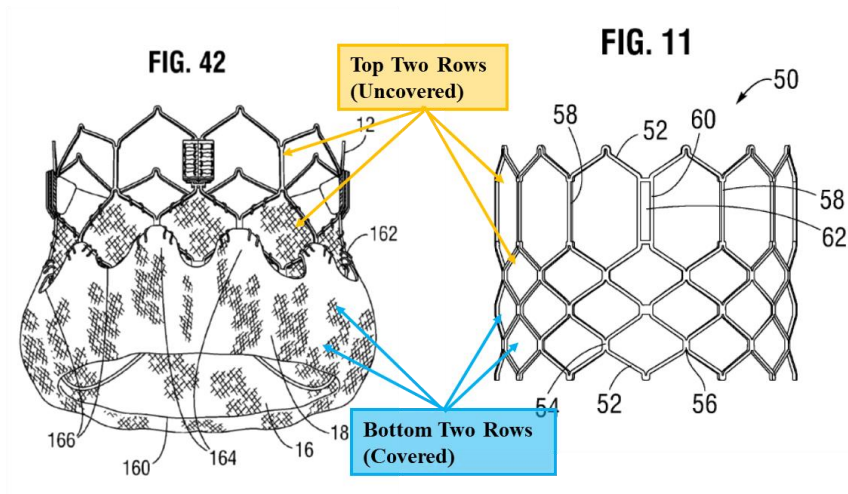
179. If the Board concludes that this claim requires the fibers to *entirely* extend over two rows of cells, a person of ordinary skill in the art would have found it obvious to slightly increase the height of Spenser II's compressible material from the height depicted in Figure 22 to entirely cover the proximal two rows of cells, as taught by Levi's Figure 42, for example. Moreover, there was a finite number of options for the height of the compressible material along the exterior of the valve, and therefore, persons of ordinary skill in the art would have found it obvious to try a height that extends slightly further toward the distal end of the valve than the illustrative embodiment depicted in Figure 22. As I've explained previously, persons of ordinary skill in the art would have understood that Figure 22 is a diagrammatic illustration of one embodiment of Spenser II and is not limiting on Spenser II's broad disclosure. Moreover, a person of ordinary skill in the art would have had access to many different cloths having different dimensions and sizes. *Supra* §VI.A. A person of ordinary skill in the art would not have expected the minimal increase in height that would be necessary to entirely cover the second row of grids to affect the performance or deliverability of the valve.

2. Levi and Spenser II

180. Levi's frame defines four rows of cells and includes two rows of cells at the inflow end of the frame, as shown in Figure 11 of Levi below:



Ex. 1008 (Levi) at Fig. 11. A comparison of Figures 11 and 42 show that Levi's outer skirt extends over the bottom two rows at the inflow end:



Id. at Figs. 11, 42. Persons of ordinary skill in the art would have been motivated to attach Spenser II's outer compressible material to Levi's outer frame at the same location, and expected success in doing so, because the references demonstrate that extending over the bottom two rows creates an effective seal.

F. Claim 6

181. Claim 6 recites: “The prosthetic heart valve of claim 1, wherein the first plurality of fibers and the second plurality of fibers are non-metallic.” Spenser *or* Levi in combination with Spenser II renders this claim obvious.

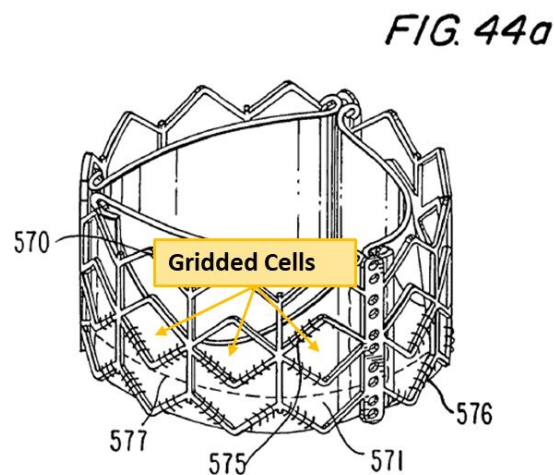
182. Spenser II’s compressible material is comprised of PET fibers. Ex. 1011 (Spenser II) at [00145]. PET fibers are made from a synthetic polymer and are non-metallic.

G. Claim 8

183. Claim 8 recites: “The prosthetic heart valve of claim 1, wherein the cells formed in the frame are gridded.” Spenser and Levi disclose this limitation.

1. Spenser

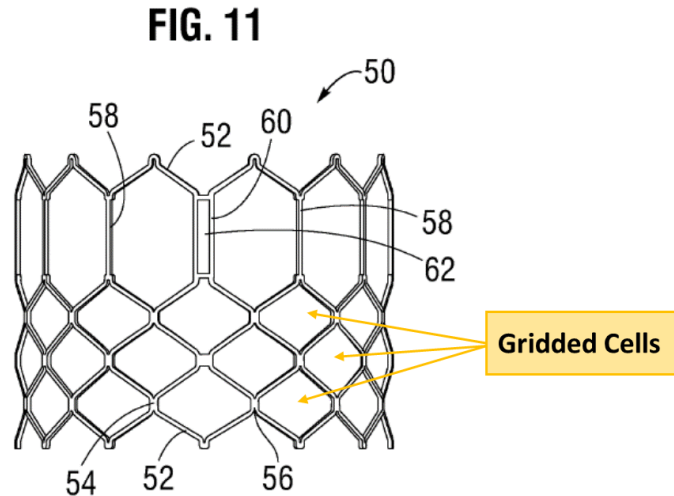
184. Spenser’s Figure 44a’s includes grided cells:



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

2. Levi

185. Levi's frame is formed of three rows of gridded cells:



Ex. 1008 (Levi) at Fig. 11.

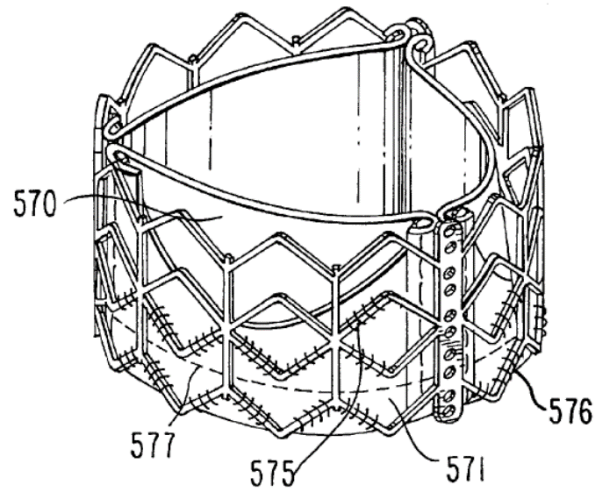
H. Claim 9

186. Claim 9 recites: “The prosthetic heart valve of claim 1, wherein the prosthetic heart valve is free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame.”

Spenser **or** Levi in combination with Spenser II renders this claim obvious.

187. Spenser's Fig. 44a does not include any “non-porous” graft covering on the exterior of the frame:

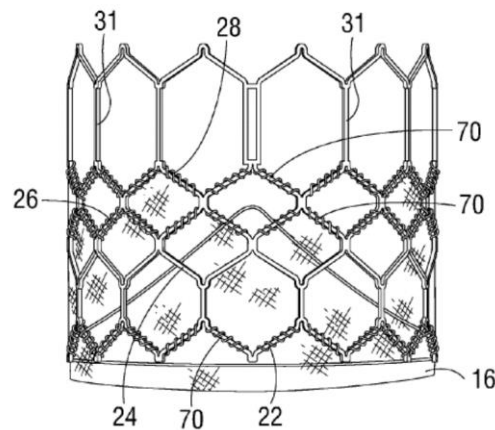
FIG. 44a



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

188. Similarly, Levi's valve does not include any "non-porous graft covering" on the outside of the frame once the outer skirt is removed:

FIG. 20



Id. at Fig. 20.

189. As I explained previously, persons of ordinary skill in the art would have understood that Spenser II's compressible material would have preferably been a porous, compressible material. *Supra* §VI.B. Therefore, if Spenser II's

compressible material were added to Spenser's Figure 44a's frame or Levi's frame there would be no "***non-porous*** graft covering" between the fibers of the compressible material and the frame.

I. Claim 10

190. Claim 10 recites: "The prosthetic heart valve of claim 1, wherein the polymer covering is stitched to the frame." Spenser **or** Levi in combination with Spenser II renders this claim obvious.

1. Spenser

191. Spenser discloses that a "[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame[.]" Ex. 1010 (Spenser) at 26:45-47, Figs. 44a-44c.

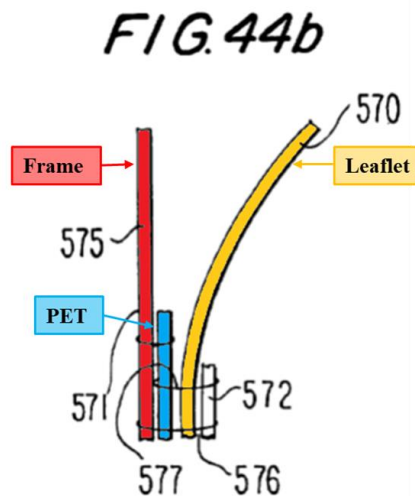
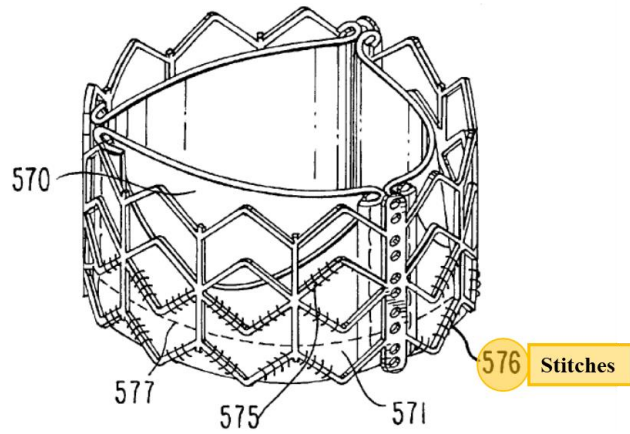


Figure 44a shows that sutures 576 secure PET 571 to frame 575:

FIG. 44a

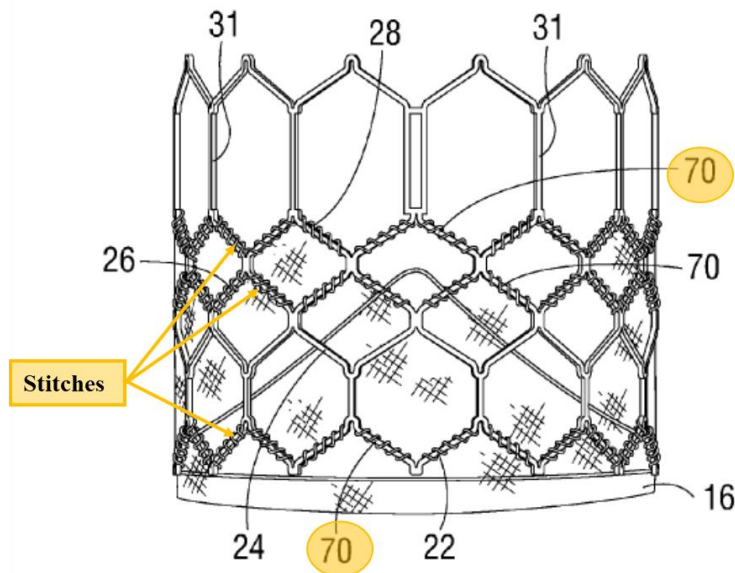


Id. at Fig. 44a-b.

2. Levi

192. Levi's inner skirt 16 is secured to the frame 12 via a plurality of sutures 70:

FIG. 20



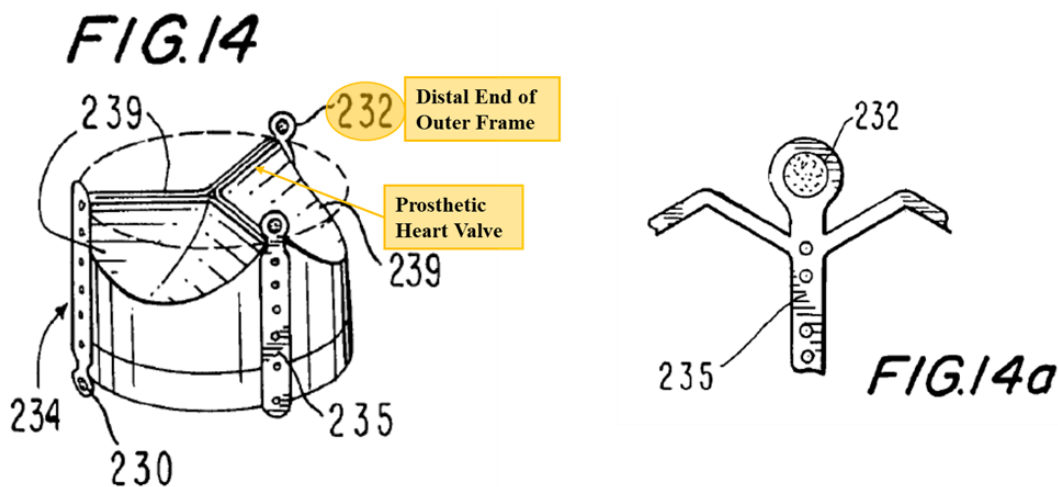
Ex. 1008 (Levi) at 9:24-25, 10:11-30, Figs. 20, 39.

J. Claim 11

193. Claim 11 recites: “The prosthetic heart valve of claim 1, wherein the frame extends distally further than the leaflet assembly.” Spenser *or* Levi in combination with Spenser II renders this claim obvious.

1. Spenser

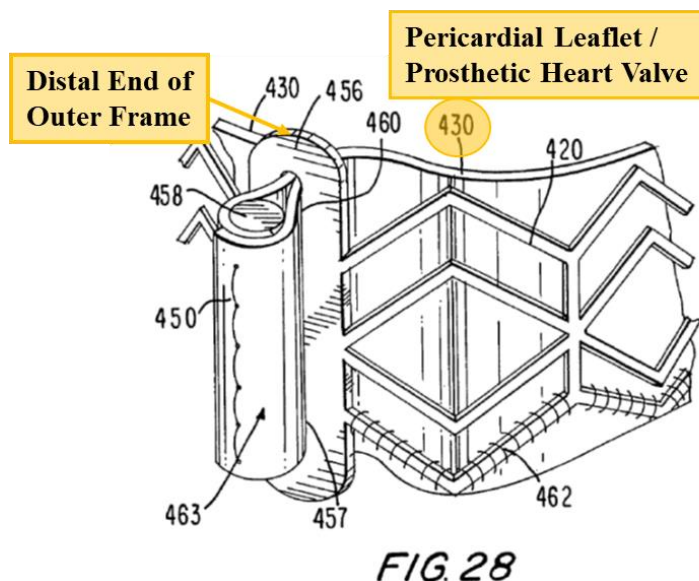
194. Spenser discloses several embodiments satisfying this limitation. In Figure 14-14c, Spenser illustrates heart valves having “heavy metal markers [232] on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location”:



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.

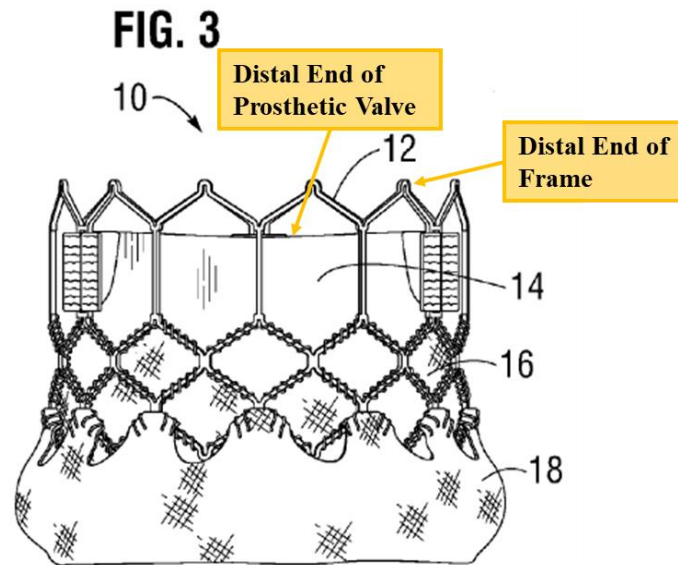
195. In Figure 28, Spenser illustrates a method of attaching the leaflets 430 to a metallic frame 420:



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, and Levi discloses similar configurations.

2. Levi

196. Levi discloses a prosthetic heart valve having a radially compressible and expandable stent frame. Ex. 1008 (Levi) at 6:17-20, 6:31-40. Levi discloses that “the inflow and outflow ends of a frame generally tend to over-expand more so than the middle portion of the frame due to the ‘dog boning’ effect of the balloon used to expand the valve.” *Id.* at 8:8-11. “To protect against over-expansion of the leaflet structure 14,” Levi teaches that the “***leaflet structure desirably is secured to the frame 12 below the upper row of struts 32.***” *Id.* at 8:11-13 (emphasis added). Levi teaches that this configuration helps ensure that the leaflets do not “protrude outwardly beyond the outflow end of the frame when the valve is crimped,” protecting the leaflets from damage that may be caused by a “pushing mechanism or stop member [of the balloon catheter] that pushes against or abuts the outflow end of the valve.” *Id.* at 8:21-39. When the leaflet structure is secured to the frame below the upper row of struts, as in Figure 3 below, the frame 12 extends distally further than the prosthetic valve leaflets 14:



Id. at Fig. 3.

K. Claim 12

197. Claim 12 recites: “The prosthetic heart valve of claim 1, wherein the polymer covering and the first plurality of fibers and the second plurality of fibers are distinct elements.” Spenser **or** Levi in combination with Spenser II renders this claim obvious.

198. As I explained in claim 1, Spenser and Levi each discloses a layer of PET fabric (inner polymeric covering) stitched to the interior surface of the outer frame. *Supra* §VI.A.5. A person of ordinary skill in the art would have understood that when Spenser II’s compressible material is added to the outside of Spenser’s or Levi’s valve, the compressible material and the inner polymer covering of Spenser/Levi would be positioned on opposite sides of the frame and would be separately attached to the frame. For example, the inner PET layer

would be positioned on the inner surface of the frame and stitched thereto. The compressible material, however, would be positioned on the exterior surface of the outer frame and secured thereto. The inner PET covering and the compressible material would therefore be “distinct elements.” See Ex. 1030 (Merriam-Webster) (defining “distinct” to mean “distinguishable to the eye or mind as being discrete or not the same”).

199. As I explained in claim 1, Spenser II’s compressible material, in one configuration, may be a cloth or fabric that includes fibers extending away from the outward-facing surface of the cloth/fabric (first plurality of fibers) and a second plurality of fibers making up a “graft covering” that are radially inward of the outwardly extending fibers. *Supra* §§VI.A.6, 9. Because the first plurality of fibers and the second plurality of fibers are on opposite sides of the cloth and make up distinguishable portions of the cloth, the first and second pluralities are “distinct elements.”

200. Patent Owner’s arguments during prosecution of Patent Owner’s related ’634 patent confirm my opinions. During prosecution of the ’634 patent, Patent Owner argued that Spenser II’s compressible material has “two distinct elements: the cloth base material, plus fibers extending from the cloth base material.” Ex. 1125 (’634 patent Jan. 4, 2022 Amendment) at 13. Although Patent Owner was improperly limiting the scope of Spenser II’s disclosure to a

single preferred embodiment, Patent Owner's arguments confirm that in Spenser II's embodiments wherein the compressible material is a cloth having fibers extending from the surface, the compressible material comprises two "distinct elements."

L. Claim 13

201. Claim 13 recites: "The prosthetic heart valve of claim 1, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient." Spenser *or* Levi in combination with Spenser II renders this claim obvious.

202. Spenser discloses that the valve shown in Figure 44a "resembles the valve shown in Fig. 43." Ex. 1010 (Spenser) at 26:34-35. The valve shown in Figure 43 may be "inflated by a balloon[.]" *Id.* at 26:19-22. Therefore, a person of ordinary skill in the art would understand that Figure 44a is balloon expandable. Expansion of Figure 44a with Spenser II's compressible material would be "configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient" for the reasons I explained in claim 1. *Supra* §VI.A.8.

203. Levi discloses that "the frame 12 (and thus the valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded

inside a patient by an inflatable balloon[.]” Ex. 1008 (Levi) at 6:17-28. Levi in combination with Spenser II, discloses a valve “configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient” for the reasons I explained in claim 1. *Supra* §VI.A.8.

M. Claim 14

204. Claim 14 recites: “The prosthetic heart valve of claim 1, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.” Spenser ***or*** Levi in combination with Spenser II renders this claim obvious.

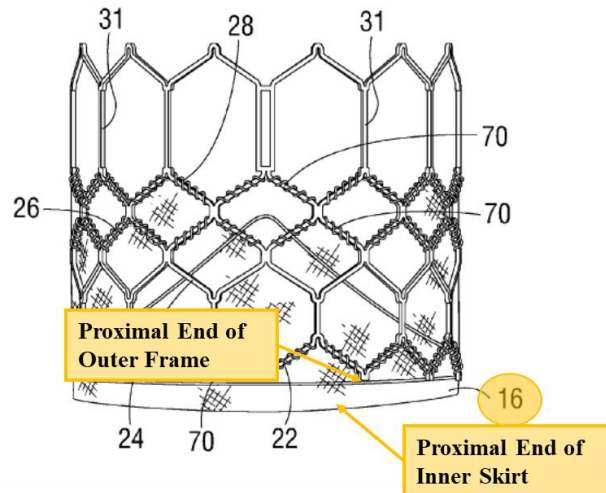
1. Spenser

205. Spenser discloses this limitation for the reasons I explained in claim 3. *Supra* §VI.C.

2. Levi

206. Levi discloses an inner PET skirt (polymer covering) sutured to the interior surface of the stent frame. *Supra* §VI.A.5. As shown in Figure 20 below, the lower edge of Levi’s inner skirt extends beyond the proximal end of the outer frame:

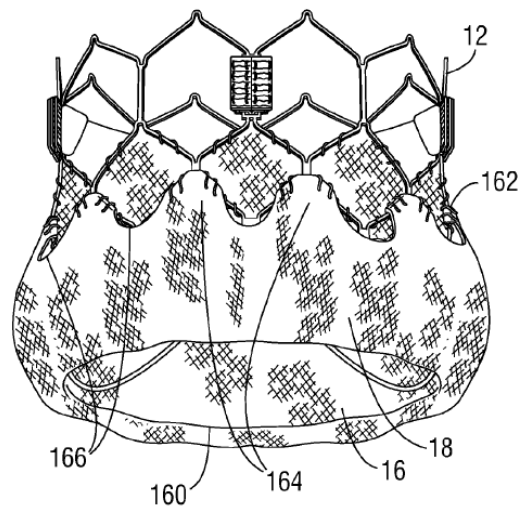
FIG. 20



Ex. 1008 (Levi) at Fig. 20.

207. Additionally, in one embodiment, Levi discloses “the lower edge 160 of the skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.” *Id.* at 13:55-58. This embodiment is illustrated in Figure 42 below:

FIG. 42



Id. at Fig. 42. Because the inner skirt extends beyond the proximal end of the outer frame, a person of ordinary skill in the art would understand that the attachment of the skirts necessarily causes the lower edge of the inner skirt 16 to extend over the proximal end of the outer frame to cover the proximal end of the outer frame.

208. Alternatively, persons of ordinary skill in the art would have found it obvious to extend Levi's inner skirt over the proximal end of the frame to cover the proximal end. Levi discloses that the "upper edge portion [distal] of the [inner] skirt is wrapped around the upper surfaces of struts 28 and secured in place with sutures 70." *Id.* at 10:12-26, Fig. 20. Levi teaches that this wrapping "provides for a stronger and more durable attachment of the skirt to the frame." *Id.*, 10:26-28. A person of ordinary skill in the art would have been motivated to apply this same technique to the lower (proximal) edge of the inner skirt to create a stronger attachment between the inner skirt and frame. Indeed, because the inner skirt extends beyond the proximal end of the frame, persons of ordinary skill in the art would have found it obvious to wrap Levi's inner skirt over the proximal end and secure the inner skirt to the outside of the frame using this wrapping technique. Persons of ordinary skill in the art would have expected success in attaching the inner skirt in this way because Levi already discloses that it was successful for the distal end of the skirt. In this configuration, persons of ordinary

skill in the art would have recognized that the outer skirt could still be stitched to the inner skirt. Thus wrapping the proximal end of Levi's inner skirt around the outer frame would not compromise Levi's outer skirt and, because the inner skirt is made of a thin material, would not have significantly affected the valve's crimped profile.

N. Claim 15

209. Claim 15 recites: "The prosthetic heart valve of claim 1, wherein the first plurality of fibers defines a spacing that extends through a thickness thereof that is created by a distance between adjacent fibers thereof." Spenser *or* Levi in combination with Spenser II renders this claim obvious.

210. First, I note that the '834 patent does not claim or disclose how to size or arrange the fibers to provide "an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." *See* Ex. 1001. For example, the '834 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 '834 patent also does not disclose the size of the "opening." I note that the figures of the '834 patent illustrate relatively large openings between the groups or clusters of collagen fibers. *See, e.g.,* Ex. 1001 ('834 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 them would not be able 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 '834 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 '834 patent indicates that the figures are drawn to-scale.

211. Spenser II discloses that the compressible material, in certain configurations “may resemble a cloth or fabric having small fibers extending from the surface of the material.” Ex. 1011 (Spenser II) [00145]. A person of ordinary skill in the art would have understood that the radially extending fibers would extend away from various different locations along the material and would thus have understood that the compressible material would include openings between the radially extending fibers formed by spacing between the adjacent fibers. Indeed, a person of ordinary skill in the art would have understood that such “spacings” would exist in any cloth or fabric material with radially extending fibers such as Spenser II's compressible material. A person of ordinary skill in the art would have further understood that the spacings define a plurality of “spacings[s] extending through a thickness” of the radially extending fibers for the same reasons I explained in claim 2. *Supra* §VI.B.

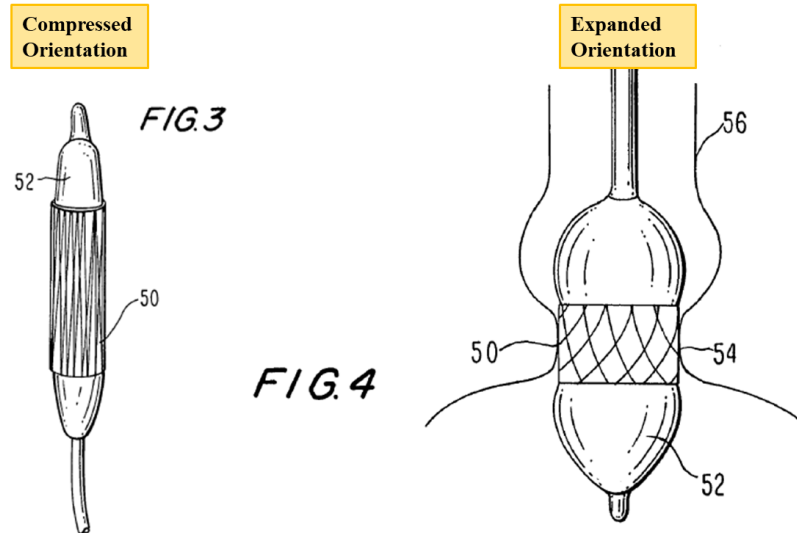
212. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable materials having varying thicknesses and

densities and could have selected a material with a lower density of outwardly extending fibers such that even larger openings existed between the fibers. *Supra* §III.D. The exchange of Spenser II's compressible material for less dense material would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, materials of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known material for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that materials such as cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

O. Claim 16

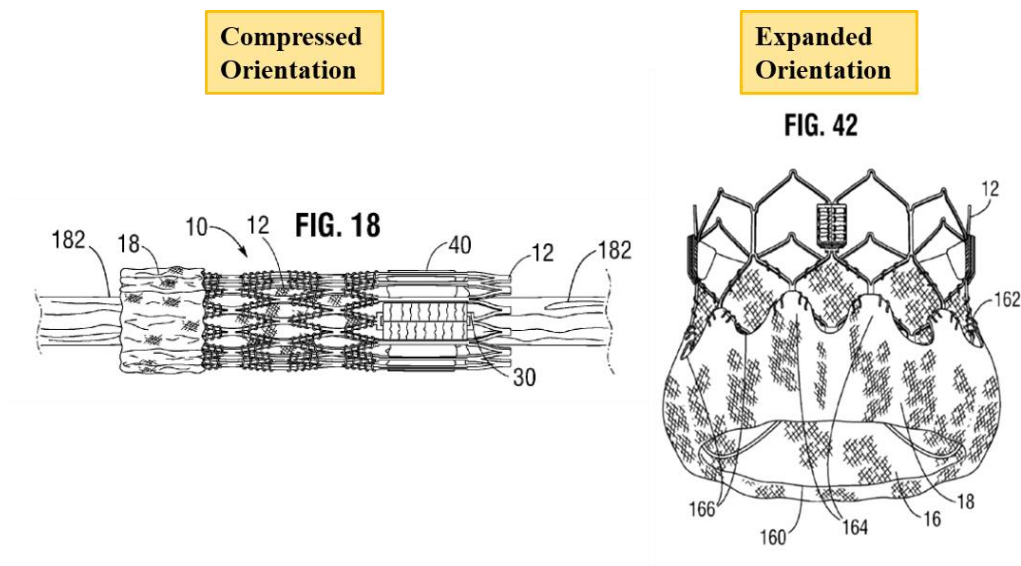
213. Claim 16 recites: "The prosthetic heart valve of claim 1, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof." Spenser *or* Levi in combination with Spenser II renders this claim obvious.

214. Spenser's Figures 3 and 4 show the valve in the compressed and expanded orientations respectively:



Ex. 1010 (Spenser) at Figs. 3-4.

215. Levi's valve is "radially collapsible and expandable." Ex. 1008 (Levi) at Abstract. Levi's Figure 18 shows the valve compressed on a balloon catheter, while Figure 42 shows the valve in its expanded orientation:



Id. at Figs. 18, 42. As shown in the figures above, Levi's frame is radially expandable along a length of the frame extending from a proximal end to a distal end thereof.

P. Claim 17

216. Claim 17 is the next independent claim of the '834 patent. Based on my review of the prior art, it is my opinion that Spenser ***or*** Levi in combination with Spenser II renders claim 17 obvious.

1. Preamble

217. The preamble of claim 17 recites: "An endovascular prosthetic heart valve for use in a patient." If this preamble is limiting Spenser ***or*** Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.1.

2. Frame

218. Claim 17 next recites: "a frame formed of plurality of struts that cooperate to form a plurality of cells." Spenser and Levi disclose this limitation as I explained in claim 1. *Supra* § VI.A.2.

3. Radially Expandable

219. Claim 17 next recites: "wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation."

Spenser, Levi, and Spenser II all disclose this limitation as I explained in claim 1.

Supra § VI.A.3.

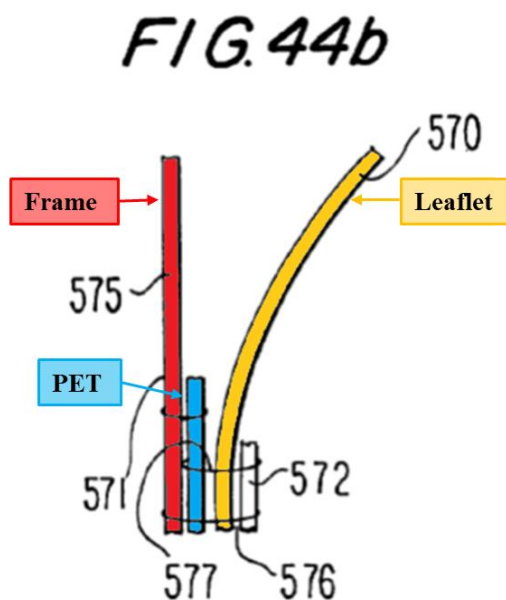
4. Leaflet Assembly

220. Claim 17 next recites: “a leaflet assembly within the frame.” Spenser and Cribier ’321 disclose this limitation as I explained in claim 1. *Supra* § VI.A.4.

5. Polymer Covering

221. Claim 17 next recites: “a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.” Spenser and Levi also disclose this limitation.

222. Spenser’s PET 571 [blue] is positioned “between the leaflets [570 yellow] and frame [575 red]” and is attached to the leaflets via suture 577:



Ex. 1010 (Spenser) at 26:30-54, Fig. 44b. PET 571 therefore “carr[ies]” the leaflet assembly.

223. Levi’s inner skirt is attached to the valvular structure “via one or more thin PET reinforcing strips” and therefore is a “polymer covering carrying the leaflet assembly.” Ex. 1008, 9:25-29.

6. First Plurality of Fibers

224. Claim 17 next recites: “a first plurality of fibers that extend away from the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.6.

7. First Plurality of Fibers Pressed Against Native Leaflets

225. Claim 17 next recites: “wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.8.

8. Second Plurality of Fibers

226. Claim 17 next recites: “a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame.” Spenser *or* Levi in combination with

Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.9.

9. Endovascularly Deployed

227. Claim 17 next recites: “wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.7.

10. Spacing

228. Claim 17 next recites: “wherein the prosthetic heart valve defines a spacing extending through a thickness of the first plurality of fibers that is created by a distance between adjacent fibers thereof, through a thickness of the second plurality of fibers created by a distance between adjacent fibers thereof, and through the plurality of cells of the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

229. First, I note that as I explained previously in claims 2 and 15, the ’834 patent does not include any teaching or disclosure regarding how to size or arrange the collagen fibers to provide spacings between the fibers. *Supra* §§ VI.B, VI.N.

230. Spenser II’s compressible material defines spacings extending through a thickness of the first plurality of fibers and spacings extending through a

thickness of the second plurality of fibers that extend to the frame for the reasons I explained in claims 2 and 15. *Supra* §§ VI.B, VI.N. Because both Spenser's and Levi's frames define a plurality of open cells, the spacings that extend to the frame will also extend through the open cells of the frame. Additionally, because the first plurality and second plurality of fibers radially overlap along the compressible material, the spacings between the adjacent fibers would also radially overlap. Therefore, a person of ordinary skill in the art would have understood that at least some of the overlapping spacings would extend through a thickness of the first plurality, the second plurality, and the open cells of the frame.

231. If Spenser II does not disclose this limitation, persons of ordinary skill in the art would have found it obvious to select different materials having less density and larger gaps between the fibers that would extend through a thickness of the first and second pluralities of fibers and the open cells of the frame. Persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of radially extending fibers such that even larger spacings existed between the fibers. I discuss many of these examples above, such as the sealing material in Norris or the velour-like fabrics used as sealing materials in cardiovascular devices for decades prior to November 2012. *Supra* §VI.A-B.

Persons of ordinary skill in the art would have been motivated to select such a cloth to reduce the crimped profile of the device while still achieving the reduction in PVL provided by the fibers.

11. Seal About Spacing

232. Claim 17 concludes by reciting: “wherein, compression of the first plurality of fibers and the second plurality of fibers in response to expansion of the prosthetic heart valve compresses the first plurality of fibers relative to the spacing to create a seal thereabout.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

233. Spenser II discloses that when compressed against the patient’s native tissue, the compressible material “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 the PET fibers that make up the compressible material are flexible and would be deformed when the material is compressed against the patient’s native tissue. Persons of ordinary skill in the art would have understood that the compressible material “creates a mechanical seal” by compressing the fibers of the material relative to one another, including the fibers extending from the outward-facing surface (the first plurality). Persons of ordinary skill in the art would have understood that such compression would cause

the fibers to deform and be compressed relative to the spacings between the adjacent fibers, creating a seal thereabout.

Q. Claim 18

234. Claim 18 is the third independent claim and the last claim of the '834 patent. Based on my review of the prior art, it is my opinion that Spenser **or** Levi in combination with Spenser II renders claim 18 obvious.

1. Preamble

235. The preamble of claim 18 recites: “An endovascular prosthetic heart valve for use in a patient.” If this preamble is limiting Spenser **or** Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.1.

2. Frame

236. Claim 18 next recites: “a frame formed of plurality of struts that cooperate to form a plurality of cells.” Spenser and Levi disclose this limitation as I explained in claim 1. *Supra* § VI.A.2.

3. Two Rows of Cells

237. Claim 18 next recites: “wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame.” Spenser and Levi disclose this limitation as I explained in claim 5. *Supra* § VI.E.

4. Radially Expandable

238. Claim 18 next recites: “wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser, Levi, and Spenser II disclose this limitation as I explained in claim 1. *Supra* § VI.A.3.

5. Leaflet Assembly

239. Claim 18 next recites: “a leaflet assembly within the frame.” Spenser and Levi disclose this limitation as I explained in claim 1. *Supra* § VI.A.4.

6. Polymer Covering

240. Claim 18 next recites: “a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.” Spenser and Levi disclose this limitation as I explained in claim 17. *Supra* § VI.P.5.

7. Plurality of Fibers

241. Claim 18 next recites: “a plurality of fibers that extend away from the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.6.

8. Endovascularly Deployed

242. Claim 18 next recites: “wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient.” Spenser *or* Levi

in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.7.

9. Plurality of Fibers Pressed Against Native Leaflets

243. Claim 18 next recites: “wherein the plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious as I explained in claim 1. *Supra* § VI.A.8.

10. Spacing

244. Claim 18 next recites: “wherein the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious for the reasons I explained in claim 17. *Supra* § VI.P.10.

11. Seal About Spacing

245. Claim 18 next recites: “wherein, compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacing to create a seal thereabout.” Spenser *or*

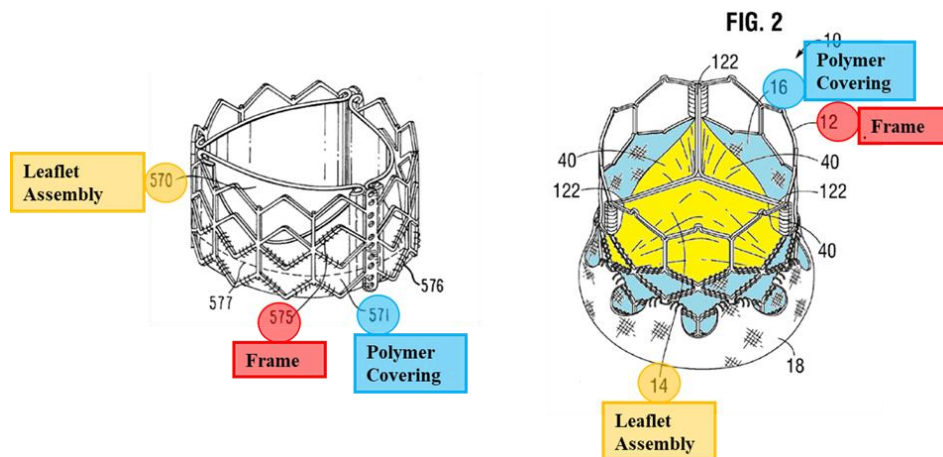
Levi in combination with Spenser II renders this limitation obvious for the reasons I explained in claim 17. *Supra* § VI.P.11.

12. Fibers Extend Over Two Rows of Cells

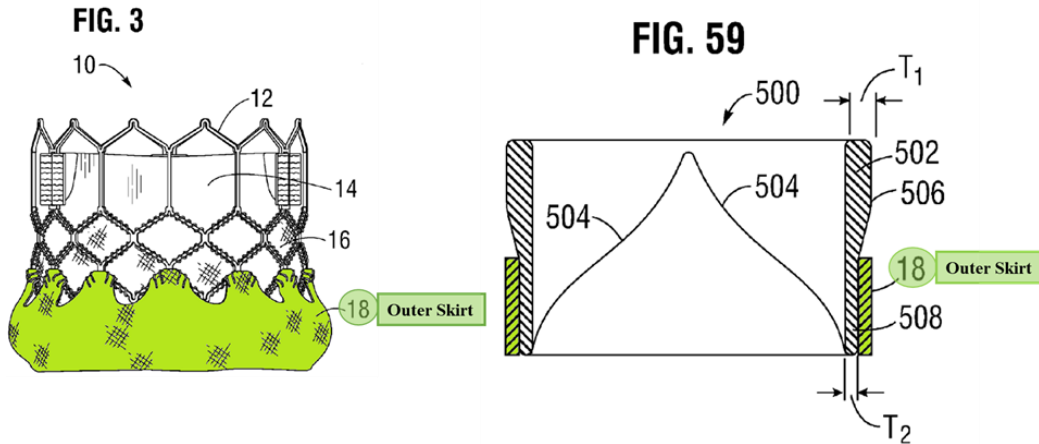
246. Claim 18 concludes by reciting: “wherein the plurality of fibers extends over each of the at least two rows of cells.” Spenser **or** Levi in combination with Spenser II renders this limitation obvious for the reasons I explained in claim 5. *Supra* § VI.E.

VII. GROUNDS 3-4: CLAIMS 1-6, 8-18 OBVIOUS OVER SPENSER OR LEVI IN COMBINATION WITH CHUTER

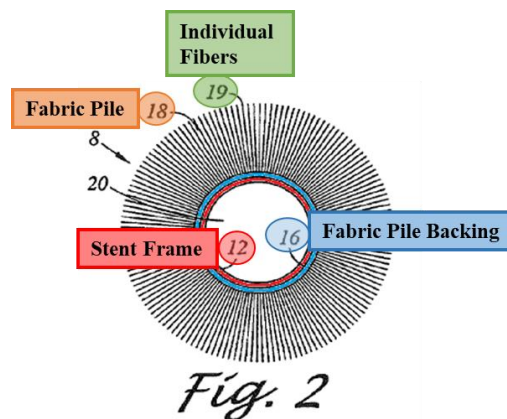
247. As I explained above, Spenser (left) and Levi (right) describe heart valves having a frame, an inner polymeric covering, and a leaflet assembly:

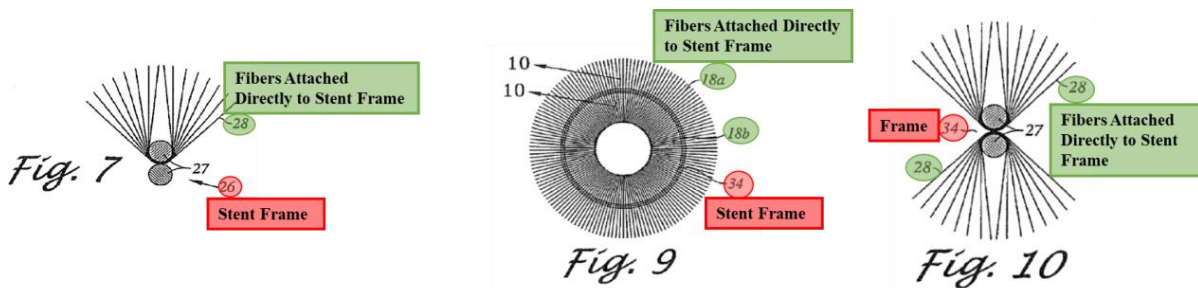


Ex. 1010 (Spenser) at 11:66-12:17, Fig. 44a; Ex. 1008 (Levi) at Fig. 2. Levi also discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame for preventing PVL. Ex. 1008 (Levi) at 13:50-66.



248. 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” layer (Fig. 2) or they can be attached directly to the frame without any backing layer (Figs. 7, 9-10), as shown in Figures 2, 7, and 9-10 below:





Id. at [0017]-[0022], Figs 1-10. Chuter also teaches embodiments with individual fibers extending both outwardly and inwardly from the stent frame, as illustrated in Figures 9 and 10 above. *Id.* at [0057], Figs. 8-10.

249. Persons of ordinary skill in the art would have found it obvious to add Chuter’s “fiber pile” to the valves disclosed in Spenser and to substitute Levi’s outer skirt for Chuter’s “fiber pile.” Persons of ordinary skill in the art would have been aware of the problem of PVL associated with THVs, and would have been motivated to use Chuter’s fiber pile 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. Therefore, Spenser **or** Levi in combination with Chuter renders obvious claims 1-6 and 8-18.

A. Claim 1

250. Based on my review of the prior art, it is my opinion that Levi **or** Spenser in combination with Chuter renders claim 1 obvious.

1. Preamble

251. The preamble of claim 1 recites: “An endovascular prosthetic heart valve for use in a patient.” If this preamble is limiting Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.1.

2. Frame

252. Claim 1 next recites: “a frame formed of plurality of struts that cooperate to form a plurality of cells.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.2.

3. Radially Expandable

253. Claim 1 next recites: “wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.3.

4. Leaflet Assembly

254. Claim 1 next recites: “a leaflet assembly within the frame.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.4.

5. Polymer Covering

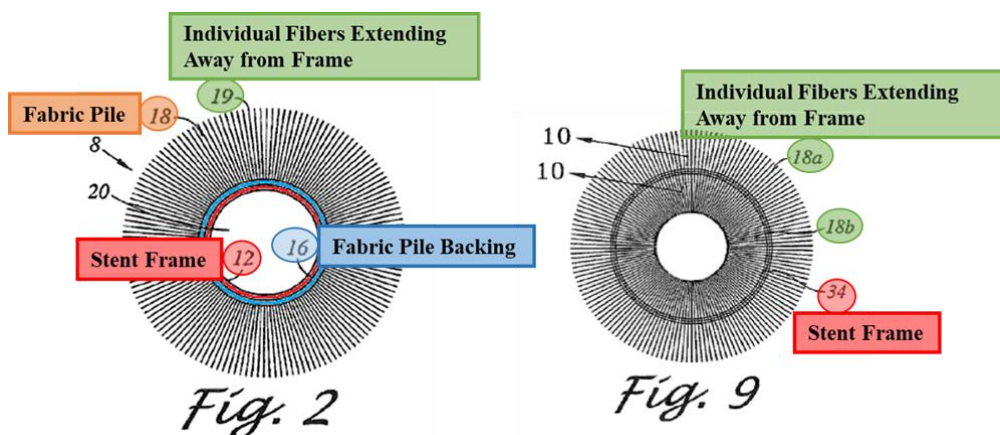
255. Claim 1 next recites: “a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the

frame and radially outwardly of the leaflet assembly.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.5.

6. First Plurality of Fibers

256. Claim 1 next recites: “a first plurality of fibers that extend away from the frame.” Chuter discloses this limitation.

257. 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 outwardly away from the stent frame, as illustrated in Figures 2 and 9:



Id. at [0017]-[0022], Figs 1-10. Chuter’s fiber pile thus discloses a “first plurality of fibers that extend away from the frame.”

a. Spenser and Chuter

258. In my opinion, 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. Thus, adding Chuter's fiber pile to Spenser's valves would merely entail applying Chuter's known technique for reducing PVL (adding a

fabric pile) to Spenser's known valves, which were ready for improvement and, as discussed below, would yield predictable results.

259. 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.

260. First, Chuter teaches that its invention can be employed on a variety of stents, including both self-expanding and balloon-expandable stents. Ex. 1116 (Chuter) at [0003]. Indeed, Chuter discloses that its fiber pile may be used on the same balloon-expandable stent frames described in the '834 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 '834 patent similarly incorporates by reference U.S. Patent No. 5,102,417 for "[e]xamples of balloon-expandable stents." Ex. 1001 ('834 patent) at 7:46-53. The '417 patent incorporated in the '834 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. 1128 ('762 patent).

261. Second, Chuter teaches that "[v]irtually any expanding stent can be used in" its embodiment having "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.A.2-3. Thus, Chuter teaches a person of ordinary skill in the art to use individual outwardly extending fibers attached directly to a stent frame to provide sealing on a cardiovascular implant device. Chuter teaches one method of securing the fibers directly to the frame – via a frame formed of helically wound double wire strands; however, persons of ordinary skill in the art would have known that other methods of securing the individual outwardly extending fibers directly to the frame existed, such as tying or gluing the fibers to the frame. 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.

262. Additionally, the ’834 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 know how to attach individual fibers to the frame of a THV. *See* Ex. 1001 (’834 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 '834 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 analysis from Dr. Brecker would equally apply to Chuter’s fabric pile, and persons of ordinary skill in the art would have understood and expected that the fibers of the fiber pile could be attached to Spenser’s frame by known biomechanical engineering methods, which are within the level of ordinary skill according to the '834 patent.

b. Levi and Chuter

263. Persons of ordinary skill in the art would have been motivated to substitute Levi’s outer skirt with Chuter’s fiber pile with a reasonable expectation of success for the same reasons that I explained in Grounds 1-2 for Spenser II and for the reasons I explained in the previous section. *Supra* §§VI.A.6.ii, VII.A.6.i. Persons of ordinary skill in the art would have been additionally motivated by Chuter’s teaching that its fiber pile is adapted to promote tissue ingrowth, which persons of ordinary skill would have recognized to aid in preventing PVL for Levi’s valve. Ex. 1116 (Chuter) at [0012]-[0013], [0017]-[0020], [0064].

264. Persons of ordinary skill in the art would have reasonably expected success in substituting Levi's outer skirt with Chuter's fiber pile for the same reasons I explained above with respect to Spenser. *Supra* ¶¶255-258.

7. Endovascularly Deployed

265. Claim 1 next recites: "wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient." Spenser *or* Levi in combination with Chuter renders this limitation obvious.

266. Spenser and Levi each disclose THVs that are endovascularly deployed through a patient's femoral artery as I explained in Grounds 1-2. *Supra* §VI.A.7. Persons of ordinary skill in the art would have reasonably expected that Spenser's and Levi's valves would remain capable of such endovascular delivery after Chuter's fiber pile was added to the valve frame.

267. 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 or Levi’s valve and crimped for delivery via a catheter, allowing for endovascular delivery of the valves. Indeed, as I explained in Grounds 1-2, the prior art disclosed similar fibrous sealing materials capable of being compressed by up to 10-25 times for delivery. *Supra* §VI.A.7. Thus, persons of ordinary skill in the art would have understood that Chuter’s fiber pile could have been optimized for delivery through the femoral artery, such as by adjusting the lengths, densities, and distribution of the fibers.

268. 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* §VI.A.7. 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.

269. Further, as I explained in Grounds 1-2, Levi teaches numerous methods for adapting its valves to allow for an external sealing material, such as

Chuter's fiber pile, to be added to the valve without significantly impacting the crimped profile. *Supra* §VI.A.7. These teachings would have further reinforced a person of ordinary skill's expectation that Levi's valve would be capable of transfemoral delivery after the outer skirt was replaced with Chuter's fiber pile.

8. First Plurality of Fibers Pressed Against Native Leaflets

270. Claim 1 next recites: "wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient." Spenser **or** Levi in combination with Chuter renders this limitation obvious.

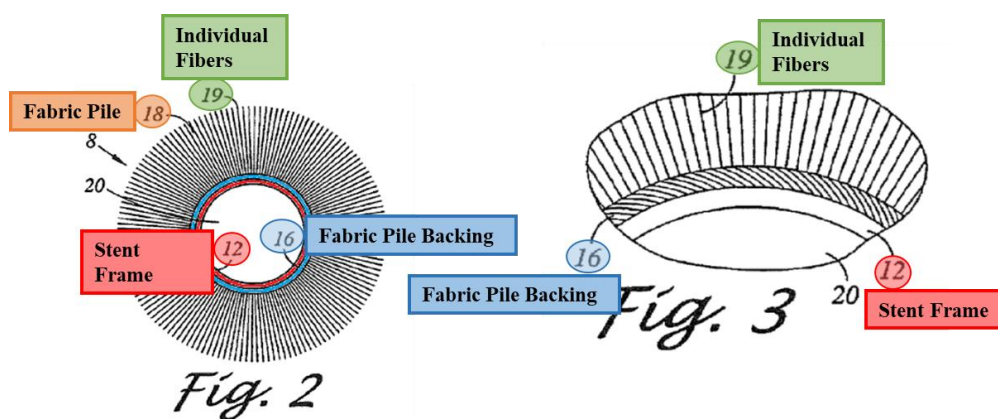
271. In my opinion, Chuter's extending fibers would press against the patient's native leaflets when added to Spenser's or Levi's valve for the same reasons I explained in Grounds 1-2 for Spenser II. In addition, Chuter teaches that its fiber pile "fill[s] the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel" in order to prevent blood from flowing around the outside of the stent device. Ex. 1116 (Chuter) at [0064]. Given this teaching, persons of ordinary skill in the art would have been motivated to position Chuter's fiber pile on Spenser's and Levi's valves in such a way that the fibers could "fill the gaps" between the outer wall of the valve and the patient's

native diseases leaflets in order to prevent blood from flowing around the outside of the THV.

9. Second Plurality of Fibers

272. Claim 1 Finally recites: “a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame.” Chuter discloses this limitation in two ways.

273. 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,” as illustrated in Figures 2 and 3 below:



Ex. 1116 (Chuter) at [0054]-[0055], Figs. 2-3. In such embodiments, persons of ordinary skill in the art would have understood that the “backing” layer would be composed of fibers, which is illustrated in Chuter’s Figure 3 above. *Id.* Fig. 3. This is consistent with similar covering materials that were 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.”

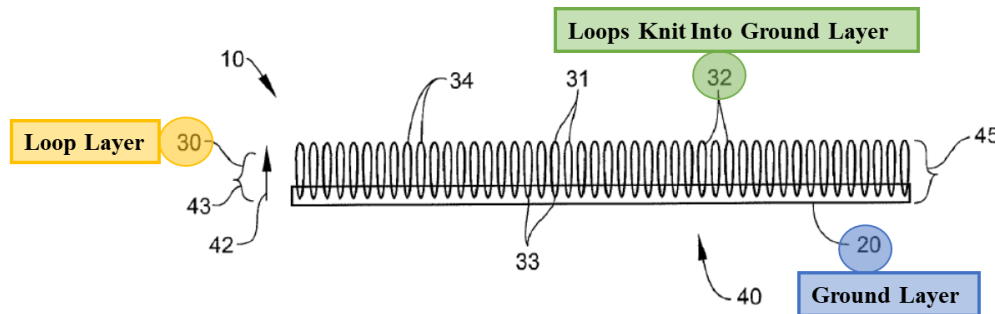
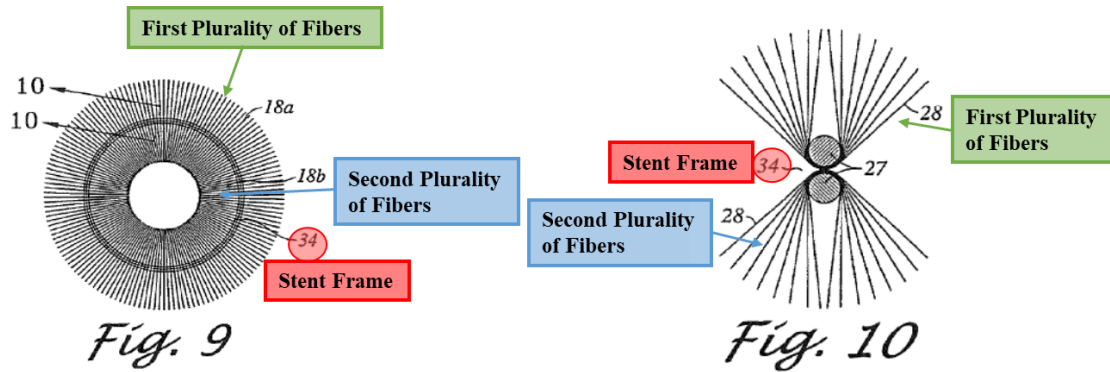


Fig. 1

Ex. 1074 (Norris) at 4:22-26, Fig. 1. The fibers of Chuter’s “fabric pile backing” layer are positioned radially inwardly of the extending individual fibers and therefore constitute the claimed “second plurality of fibers.” Ex. 1116 (Chuter) at Figs. 2-3. As illustrated in Figures 2 and 3 above, the fibers of the backing layer are in direct contact with the stent frame. *Id.* Persons of ordinary skill in the art would have been motivated to add these embodiments of the fiber pile to Spenser’s and Levi’s valves because the use of materials with fibers emanating from a backing layer for sealing cardiovascular devices, including THVs, was done successfully in the art. *See supra* §VI.B; Ex. 1011 (Spenser II) at [00145]; Ex. 1074 (Norris) at 4:22-26, 9:18-21.

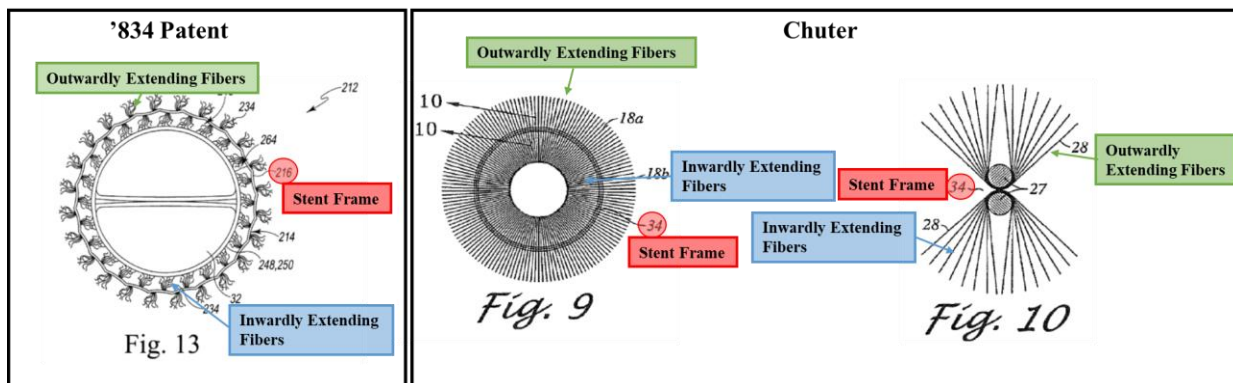
274. Second, Chuter also discloses embodiments lacking the backing layer, with individual fibers attached directly to the stent frame rather than through a backing layer intermediary, as illustrated in Figures 9-10 below:



Ex. 1116 (Chuter) at [0056]-[0057], Figs. 5-10. As illustrated in Figures 9 and 10, those embodiments can include individual fibers extending outwardly away from the frame (i.e., a first plurality) and individual fibers extending inwardly from the frame (i.e., a second plurality). *Id.*, [0057], Figs. 9-10. The inwardly-extending fibers are radially inward of the outwardly-extending fibers and constitute the claimed “second plurality of fibers.” *Id.* As illustrated in Figures 9 and 10 above, the inwardly-extending fibers are in direct contact with the stent frame. *Id.* Persons of ordinary skill in the art would have been motivated to add these embodiments of the fiber pile to Spenser’s and Levi’s valves because the outwardly extending fibers would promote tissue ingrowth, blood coagulation, and seal between both the THV frame and native tissue, and the inwardly extending fibers would similarly promote tissue ingrowth, blood coagulation, and

a seal between the THV frame and the inner polymer covering. In this way, the outwardly and inwardly extending fibers would work together to maximize the tissue ingrowth, blood coagulation, and sealing around the THV, helping to minimize PVL. As I explained previously, persons of ordinary skill in the art would have possessed the skills to optimize the length of the outwardly and inwardly extending fibers to ensure delivery through the femoral artery and optimal sealing. *Supra* §VII.A.7.

275. Chuter’s disclosure of outwardly and inwardly extending fibers attached directly to the stent frame is particularly notable given the disclosure of the ’834 patent. The only feature disclosed in the ’834 patent that may support the claimed “second plurality of fibers” are the collagen fibers extending inwardly from the outer frame. See Ex. 1001 (’834 patent) at 12:56-58, Fig. 13. As I explained above, Chuter discloses this same arrangement of individual extending fibers attached directly to a stent frame, reinforcing the conclusion that Chuter’s discloses the claimed “second plurality of fibers”:



Compare id., Fig. 12 (left) with Ex. 1116 (Chuter) at Figs. 9-10 (right).

276. Chuter teaches that the individual fibers of the fiber pile may be attached directly to the stent frame by being “inner-disposed between” the strands of a “helically wound double wire strand” on the frame. *See* Ex. 1116 (Chuter) at [0056]-[0057]. However, persons of ordinary skill in the art would have understood that the individual fibers could be directly attached to the stent frame by any other known biomechanical engineering methods, as Dr. Brecker asserted with respect to the collagen fibers in the ’834 patent. *See supra* §VII.A.6. This understanding is further confirmed by Chuter’s broad teachings regarding the range of stent frames that may be used with its fiber pile, which include the same balloon-expandable stent frames incorporated in the ’834 patent. *See id.*

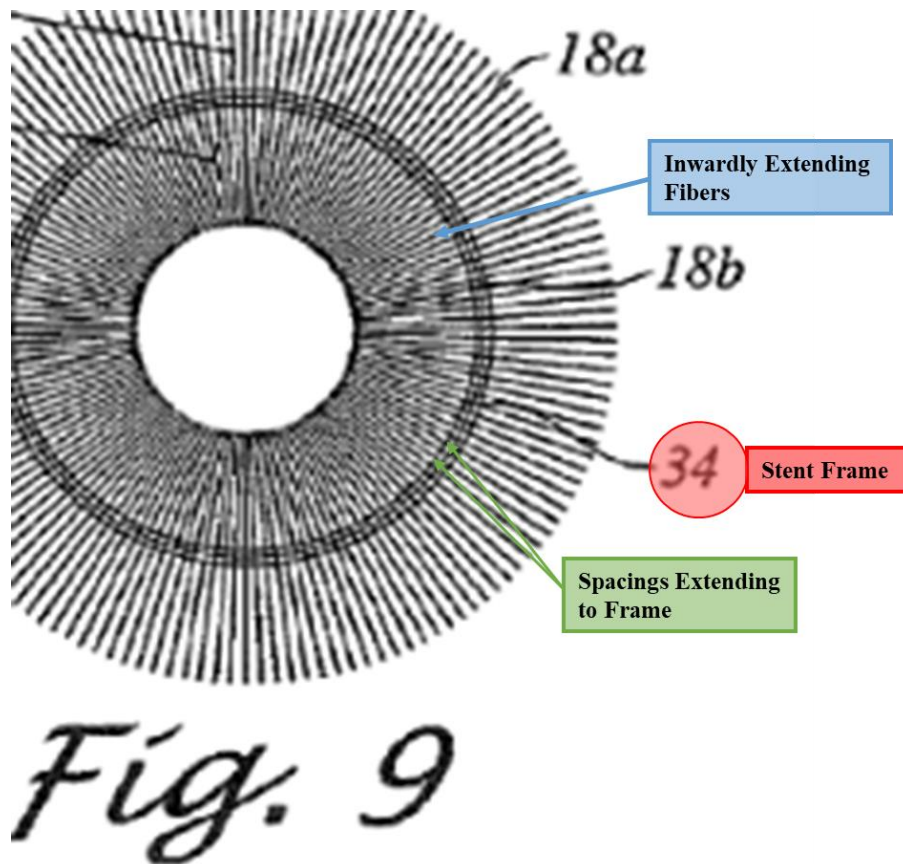
B. Claim 2

277. Claim 2 recites: “The prosthetic heart valve of claim 1, wherein the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.” Chuter discloses the limitations of claim 2 in two ways.

278. First, persons of ordinary skill in the art would have understood that in Chuter’s embodiments including the fabric pile backing layer, the backing layer would preferably be porous to maximize the compressibility of the fiber pile. Similar covering materials with porous backing layers were 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 layer 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 layer would have a similar porosity, which would be desirable to maximize the compressibility of the fiber pile. Because Chuter’s fabric pile backing layer directly abuts the stent frame, at least some of the spacings between the fibers in the backing layer would extend to frame.

279. Second, in Chuter’s embodiments that do not include a fabric pile backing layer, Chuter illustrates that there are spacings between the adjacent inwardly-extending fibers (second plurality), and that those spacings extend to the frame:



Ex. 1116 (Chuter) at [0057], Fig. 9.

280. Moreover, the '834 patent does not claim or disclose how to size or arrange the fibers to provide “a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.” See Ex. 1001. For example, the '834 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 '834 patent also does not disclose the size of the “spacing.” The figures of the '834 patent illustrate relatively large openings between the groups of collagen fibers. See, e.g., Ex. 1001 ('834 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 them would not be able 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 '834 patent's figures are merely schematic or conceptual, and do not accurately reflect the number, dimensions, density, or placement of the collagen fibers on the frame. Additionally, nothing in the '834 patent indicates that any of the figures are drawn to-scale.

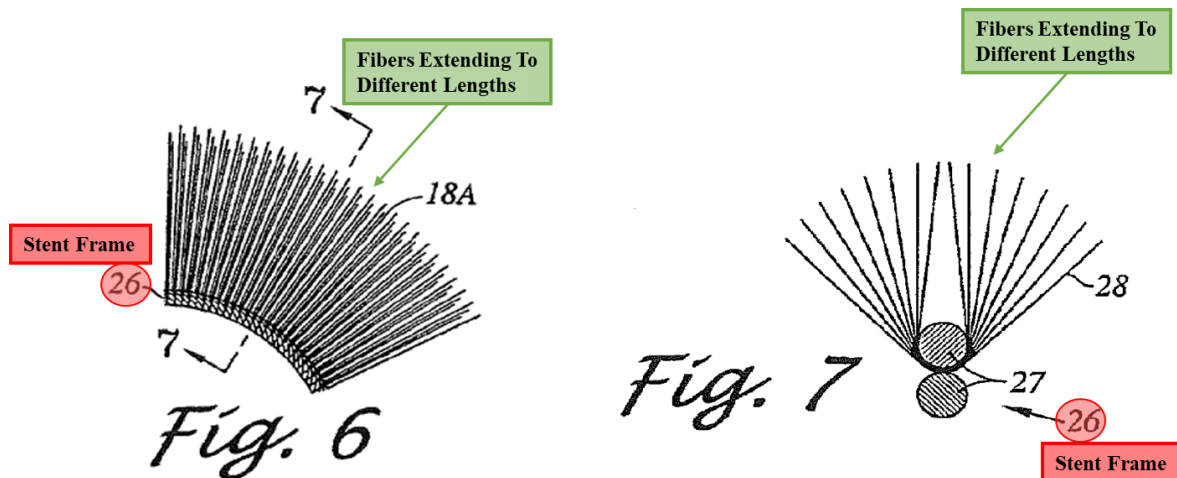
C. Claim 3

281. Claim 3 recites: "The prosthetic heart valve of claim 1, wherein the polymer covering extends further than a proximal end of the leaflet assembly." Spenser and Levi disclose the limitations of claim 3 for the reasons I explained in Grounds 1-2. *Supra* §VI.C.

D. Claim 4

282. Claim 4 recites: "The prosthetic valve of claim 1, wherein a distance that the first plurality of fibers extends from a centerline longitudinally through the frame varies along a length of the center line." Chuter discloses the limitations of claim 4.

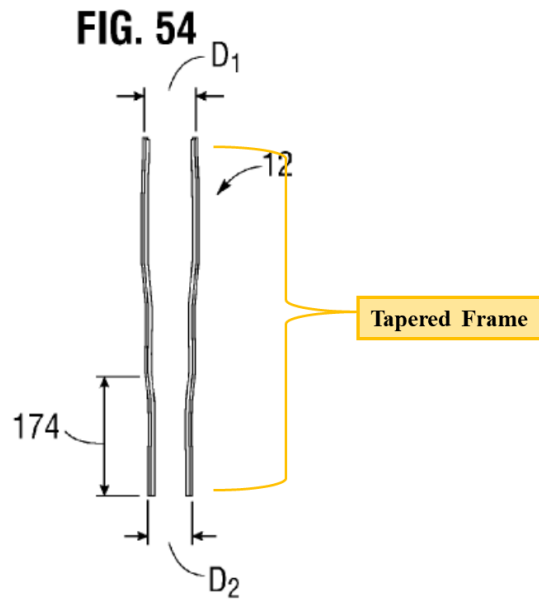
283. Figure 6 of Chuter discloses an embodiment having a fiber pile comprising of fibers extending to different lengths from a longitudinal centerline through the frame:



Ex. 1116 (Chuter) at Figs. 6-7.

284. Additionally, Chuter teaches that the individual extending fibers of the fiber pile “press against the inner luminal wall of the arterial system to form a seal” when its stents are implanted. *Id.* at [0059]. As I explained previously, persons of ordinary skill in the art would have understood that the diseased native leaflets of patient’s aortic valve would present a highly irregularly shaped surface due to calcium deposits on the leaflets. *Supra* §VI.B. Therefore, persons of ordinary skill in the art would have understood that when Chuter’s extending fibers press against the patient’s native leaflets, the fibers would extend to varying distances from a centerline extending longitudinally through the valve frame along a length of the centerline.

285. Additionally, as I discussed previously, Levi discloses that the inflow end of the frame may be tapered to a narrower diameter to accommodate an outer sealing material:



Ex. 1008 (Levi) at 8:43-51, Fig. 54. Persons of ordinary skill in the art would have understood that when Chuter’s fiber pile is added to Levi’s tapered frame, the fibers would extend to varying distances relative to a longitudinal centerline extending through the frame due to the tapered shape of the frame.

E. Claim 5

286. Claim 5 recites: “The prosthetic heart valve of claim 1, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first plurality of fibers extends over each of the at least two rows of cells.” Spenser *or* Levi in combination with Chuter renders claim 5 obvious.

287. Spenser and Levi disclose two rows of cells at the inflow end of the frame as I explained in Grounds 1-2. *Supra* §VI.E.

288. Persons of ordinary skill in the art would have found it obvious to position Chuter’s fiber pile to extend over at least the proximal two rows of cells

on Spenser's and Levi's valves. Persons of ordinary skill would have been motivated to do so because there are a finite number of places to position the fiber pile and 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 so that the fibers could form a seal and fill gaps between the native leaflets and the THV. This is reinforced by Chuter's teaching that the fibers of the fiber pile "fill the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel" in order to prevent blood from flowing around the outside of the stent device. Ex. 1116 (Chuter) at [0064].

289. Additionally, Levi discloses a sealing material extending over the proximal two rows of cells, providing persons of ordinary skill in the art with further motivation to select such an arrangement for Chuter's fiber pile. *See supra* §VI.E.

F. Claim 6

290. Claim 6 recites: "The prosthetic heart valve of claim 1, wherein the first plurality of fibers and the second plurality of fibers are non-metallic." Chuter discloses the limitations of claim 6.

291. Chuter discloses that "[t]he fibers of the fiber pile are biocompatible fibers which are known to the art. Suitable fibers include nylon fibers, polyester

fibers, Mylar brand fibers and the like.” Ex. 1116 (Chuter) at [0022]. Nylon, polyester, and Mylar fibers are non-metallic.

G. Claim 8

292. Claim 8 recites: “The prosthetic heart valve of claim 1, wherein the cells formed in the frame are gridded.” Spenser and Levi disclose the limitations of claim 8 for the reasons I explained in Grounds 1-2. *Supra* §VI.G.

H. Claim 9

293. Claim 9 recites: “The prosthetic heart valve of claim 1, wherein the prosthetic heart valve is free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame.” Spenser *or* Levi in combination with Chuter renders claim 9 obvious.

294. As I explained previously in Grounds 1-2, the valves in Spenser and Levi lack any nonporous graft covering on the outside of the valves. *Supra* §VI.H. Persons of ordinary skill in the art would have understood that there would not be any nonporous graft covering between the fibers in Chuter’s fiber pile and the frame of Spenser or Levi’s valve for at least two reasons.

295. First, as I explained previously, in Chuter’s embodiments including the fabric pile backing layer, persons of ordinary skill would have understood that the backing layer would preferably have been a porous material to maximize compressibility. *Supra* §VII.B. Accordingly, such embodiments would have been

free of any **nonporous** graft covering between the fibers and frame when added to Spenser's or Levi's valves.

296. Second, in Chuter's embodiments that do not include the backing layer, the fibers are attached directly to the frame, and therefore, there would be no material, including no nonporous graft covering, between the fibers and the frame when those embodiments are added to Spenser's and Levi's valves. Ex. 1116 (Chuter) at [0056]-[0057], Figs. 5-10.

I. Claim 10

297. Claim 10 recites: "The prosthetic heart valve of claim 1, wherein the polymer covering is stitched to the frame." Spenser and Levi disclose the limitations of claim 10 for the reasons I explained in Grounds 1-2. *Supra* §VI.I.

J. Claim 11

298. Claim 11 recites: "The prosthetic heart valve of claim 1, wherein the frame extends distally further than the leaflet assembly." Spenser and Levi disclose the limitations of claim 11 for the reasons I explained in Grounds 1-2. *Supra* §VI.J.

K. Claim 12

299. Claim 12 recites: "The prosthetic heart valve of claim 1, wherein the polymer covering and the first plurality of fibers and the second plurality of fibers

are distinct elements.” Spenser *or* Levi in combination with Chuter renders claim 12 obvious.

300. Persons of ordinary skill in the art would have understood that when Chuter’s fiber pile is added to the outside of Spenser’s or Levi’s valve, the fiber pile and the inner PET layer/inner skirt would be “distinct elements” at least because the elements would be on the opposite sides of the frame and separately attached thereto.

301. In Chuter’s embodiments where the fiber pile includes a backing layer, persons of ordinary skill in the art would have understood that the individual outwardly extending fibers (first plurality) would be a distinct element from the fibers making up the backing layer (second plurality). This is evidenced by the distinct arrangement of the fibers of the backing layer and the individually extending fibers depicted and described in Chuter, and the fact that Chuter separately describes, illustrates, and identifies the backing layer and the extending fibers as distinct elements. *See* Ex. 1116 (Chuter) at [0054]-[0055], Figs. 1-4.

302. In Chuter’s embodiments lacking a “backing layer,” the fibers extending outwardly from the frame (first plurality) and the fibers extending inwardly from the frame (second plurality) are distinct elements at least because they are illustrated as separate fibers, positioned on opposite sides of the frame,

and separately attached thereto. *See* Ex. 1116 (Chuter) at [0056]-[0057], Figs. 5-10.

L. Claim 13

303. Claim 13 recites: “The prosthetic heart valve of claim 1, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient.” Levi and Spenser disclose the limitations of claim 13 for the reasons I explained in Grounds 1-2. *Supra* §VI.L. Spenser *or* Levi in combination with Chuter discloses a valve “configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient” for the reasons I explained in claim 1. *Supra* §VII.A.8.

M. Claim 14

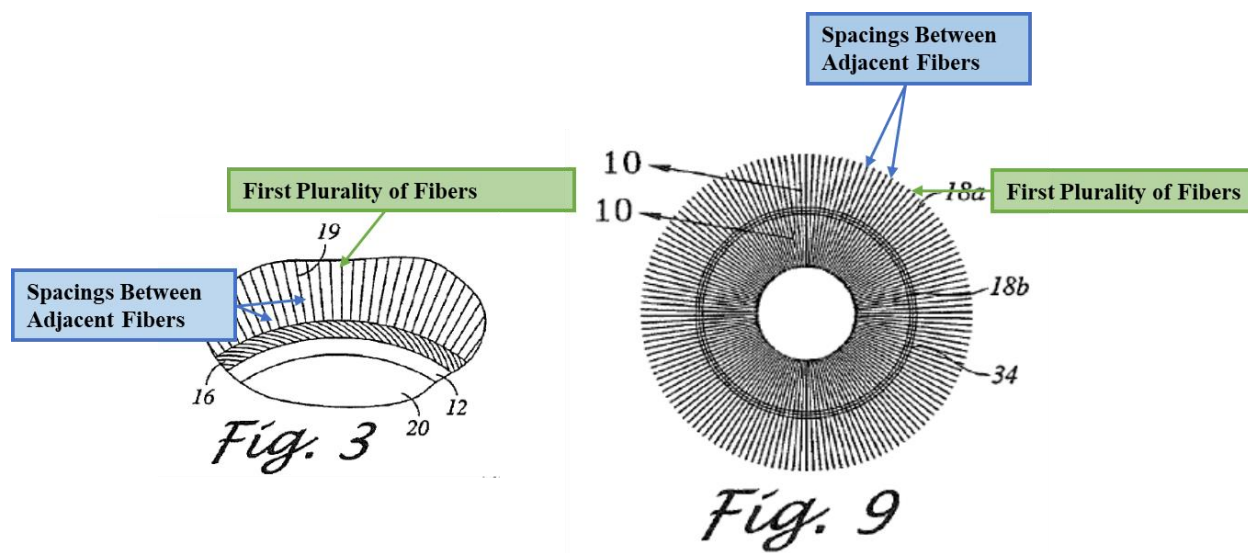
304. Claim 14 recites: “The prosthetic heart valve of claim 1, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.” Spenser and Levi disclose the limitations of claim 14 for the reasons I explained in Grounds 1-2. *Supra* §VI.M.

N. Claim 15

305. Claim 15 recites: “The prosthetic heart valve of claim 1, wherein the first plurality of fibers defines a spacing that extends through a thickness thereof

that is created by a distance between adjacent fibers thereof.” Chuter discloses the limitations of claim 15.

306. Chuter discloses spacings between the individual outwardly-extending fibers (first plurality) that extend through a thickness thereof, as illustrated in Figures 3 and 9 below:



Ex. 1116 (Chuter) at Figs. 3, 9; *see also id.*, Figs. 2, 4-8, 10.

O. Claim 16

307. Claim 16 recites: “The prosthetic heart valve of claim 1, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.” Spenser and Levi disclose the limitations of claim 16 for the reasons I explained in Grounds 1-2. *Supra* §VI.O.

P. Claim 17

308. Spenser *or* Levi in combination with Chuter renders claim 17 obvious.

1. Preamble

309. The preamble of claim 17 recites: “An endovascular prosthetic heart valve for use in a patient.” If this preamble is limiting Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VI.A.1.

2. Frame

310. Claim 17 next recites: “a frame formed of plurality of struts that cooperate to form a plurality of cells.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.A.2.

3. Radially Expandable

311. Claim 17 next recites: “wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.A.3.

4. Leaflet Assembly

312. Claim 17 next recites: “a leaflet assembly within the frame.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* § VI.A.4.

5. Polymer Covering

313. Claim 17 next recites: “a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.P.5.

6. First Plurality of Fibers

314. Claim 17 next recites: “a first plurality of fibers that extend away from the frame.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.6.

7. First Plurality of Fibers Pressed Against Native Leaflets

315. Claim 17 next recites: “wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.8.

8. Second Plurality of Fibers

316. Claim 17 next recites: “a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of

fibers is in direct contact with the frame.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.9.

9. Endovascularly Deployed

317. Claim 17 next recites: “wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.7.

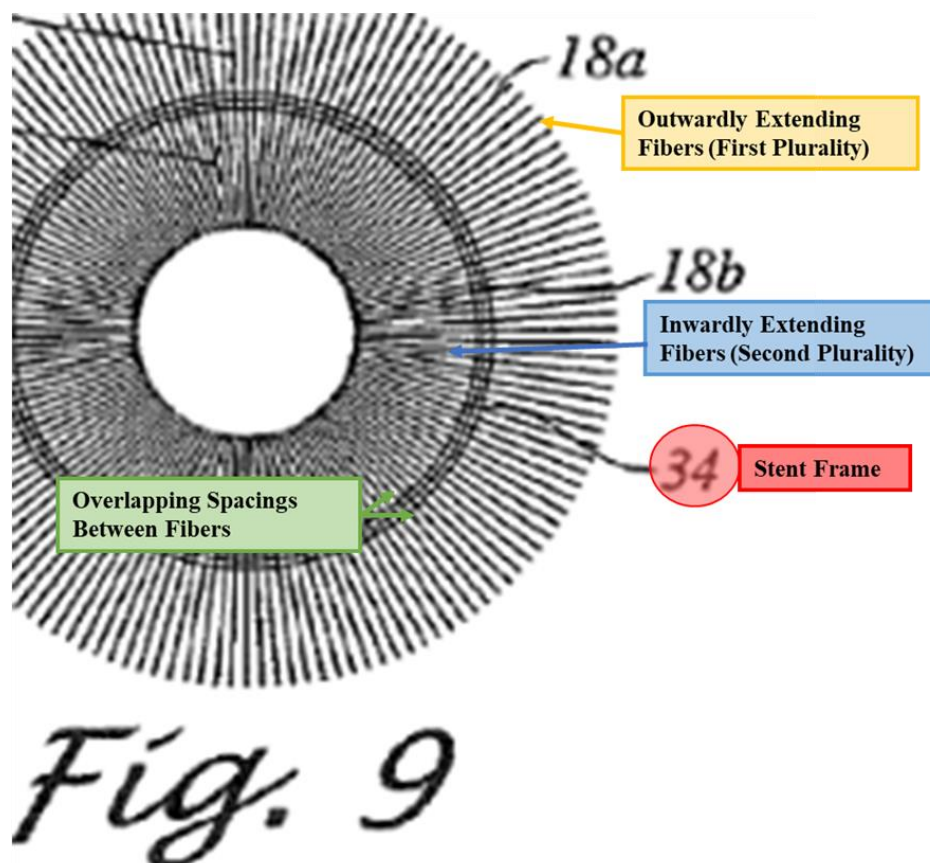
10. Spacing

318. Claim 17 next recites: “wherein the prosthetic heart valve defines a spacing extending through a thickness of the first plurality of fibers that is created by a distance between adjacent fibers thereof, through a thickness of the second plurality of fibers created by a distance between adjacent fibers thereof, and through the plurality of cells of the frame.” Spenser *or* Levi in combination with Chuter renders this limitation obvious.

319. First, I note that as I explained previously in claims 2 and 15, the ’834 patent does not include any teaching or disclosure regarding how to size or arrange the collagen fibers to provide spacings between the fibers. *Supra* §§VII.B, N.

320. Chuter’s fiber pile discloses spacings between adjacent fibers in both the first and second plurality of fibers for the reasons I explained in claims 2 and

15. *Supra* §§VII.B, N. Because Spenser's and Levi's frames define a plurality of open cells, the spacings that extend to the frame will also extend through the open cells of the frame. Because the first plurality of fibers and second plurality of fibers radially overlap along the outer cloth/compressible material, the spacings between the adjacent fibers would also radially overlap.



Ex. 1116 (Chuter) at Fig. 9. Therefore, persons of ordinary skill in the art would have understood that at least some of the overlapping spacings would extend through a thickness of the first plurality, the second plurality, and the open cells of the frame.

11. Seal About Spacing

321. Claim 17 concludes by reciting: “wherein, compression of the first plurality of fibers and the second plurality of fibers in response to expansion of the prosthetic heart valve compresses the first plurality of fibers relative to the spacing to create a seal thereabout.” Spenser *or* Levi in combination with Chuter renders this limitation obvious.

322. Chuter teaches that the individual extending fibers of its fiber pile “fill the gaps between the outer wall of the expandable graft and the inner wall of the vascular vessel.” Ex. 1116 (Chuter) at [0064]. Chuter further teaches that when the device is deployed and expanded within a patient, “fabric pile 18C press against the inner luminal wall of the arterial system to form a seal.” *Id.* at [0059]. Persons of ordinary skill in the art would have understood that a similar compression and seal would occur when Chuter’s fiber pile is added to Spenser’s or Levi’s valve and expanded within a patient’s native aortic valve.

Q. Claim 18

323. Spenser *or* Levi in combination with Chuter renders claim 18 obvious.

1. Preamble

324. The preamble of claim 18 recites: “An endovascular prosthetic heart valve for use in a patient.” If this preamble is limiting Spenser *or* Levi in

combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.1.

2. Frame

325. Claim 18 next recites: “a frame formed of plurality of struts that cooperate to form a plurality of cells.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.A.2.

3. Two Rows of Cells

326. Claim 18 next recites: “wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame.” Spenser and Levi disclose this limitation as I explained in claim 5. *Supra* §VII.E.

4. Radially Expandable

327. Claim 18 next recites: “wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.A.3.

5. Leaflet Assembly

328. Claim 18 next recites: “a leaflet assembly within the frame.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.A.4.

6. Polymer Covering

329. Claim 18 next recites: “a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.” Spenser and Levi disclose this limitation as I explained in Grounds 1-2. *Supra* §VI.P.5.

7. Plurality of Fibers

330. Claim 18 next recites: “a plurality of fibers that extend away from the frame.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.6.

8. Endovascularly Deployed

331. Claim 18 next recites: “wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.7.

9. Plurality Pressed Against Native Leaflets

332. Claim 18 next recites: “wherein the plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient.” Spenser *or* Levi in combination with Chuter renders this limitation obvious as I explained in claim 1. *Supra* §VII.A.8.

10. Spacing

333. Claim 18 next recites: “wherein the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame.” Spenser **or** Levi in combination with Chuter renders this limitation obvious as I explained in claim 17. *Supra* §VII.P.10.

11. Seal About Spacing

334. Claim 18 next recites: “wherein, compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacing to create a seal thereabout.” Spenser **or** Levi in combination with Chuter renders this limitation obvious as I explained in claim 17. *Supra* §VII.P.11.

12. Fibers Extend Over Two Rows of Cells

335. Claim 18 concludes by reciting: “wherein the plurality of fibers extends over each of the at least two rows of cells.” Spenser **or** Levi in combination with Chuter renders this limitation obvious as I explained in claim 5. *Supra* §VII.E.

VIII. GROUNDS 5-6: CLAIMS 1-6, 8-18 OBVIOUS OVER SPENSER OR LEVI IN COMBINATION WITH CHUTER AND SPENSER II

336. As I explained above, Spenser *or* Levi in combination with Chuter renders obvious claims 1-6 and 8-18 because those combinations disclose every element of the claims and persons of ordinary skill in the art would have been motivated to add Chuter's fiber pile to Spenser's and Levi's valves to prevent PVL with a reasonable expectation of success. *Supra* §VII. Spenser II would have provided persons of ordinary skill in the art additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves.

337. Spenser II teaches the addition of a compressible material to the outside of a THV for preventing PVL. Ex. 1011 (Spenser II) at [00145]; *supra* §VI.A.6. Persons of ordinary skill in the art would have recognized Chuter's fiber pile as one such compressible material that could be used on THV's to prevent PVL according to Spenser II's teachings. Accordingly, claims 1-6 and 8-18 would have been obvious over the combination of Spenser *or* Levi with Chuter and Spenser II.

IX. SECONDARY CONSIDERATIONS

338. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '834 patent. For example, I

am not aware of any products sold by Patent Owner that would be covered by the '834 patent and, therefore, I am not aware of any commercial success.

339. Further, given that the devices claimed in the '834 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.

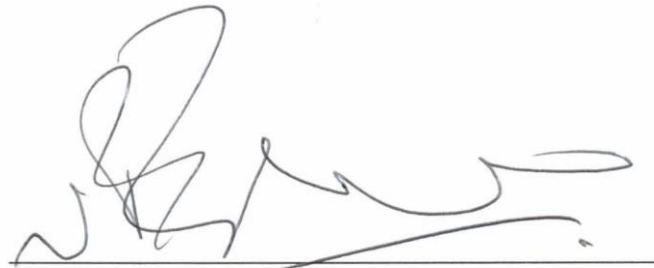
X. CONCLUSION

340. For the foregoing reasons, it is my opinion that claims 1-6 and 8-18 of the '834 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.

341. 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.

342. 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 June 28, 2023.



Dr. Nigel P. Buller