

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**EDWARDS LIFESCIENCES CORPORATION AND  
EDWARDS LIFESCIENCES LLC**

Petitioners,

v.

**AORTIC INNOVATIONS, LLC**

Patent Owner.

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Patent No. 11,491,033

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**DECLARATION OF NIGEL BULLER, M.D.  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 11,491,033**

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| Exhibit No. | Description                                                                                                                                                                                                                                                                       |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1001        | U.S. Patent No. 11,491,033 B2 (“ <b>’033 patent</b> ”)                                                                                                                                                                                                                            |
| 1002        | Excerpts from the prosecution history of the ’033 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. (“ <b>Levi</b> ”)                                                                                                                                                                                                                     |
| 1009        | Reserved                                                                                                                                                                                                                                                                          |
| 1010        | U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ <b>Spenser</b> ”)                                                                                                                                                                                                               |
| 1011        | WO 2006/005015 A2 to Spenser et al. (“ <b>Spenser II</b> ”)                                                                                                                                                                                                                       |
| 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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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                               |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                       |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                                                                                                                 |
| 1059-1071          | Reserved                                                                                                                                                                                                                                                 |
| 1072               | Deposition Transcript of Stephen Brecker from August 30, 2022                                                                                                                                                                                            |
| 1073               | Deposition Transcript of Stephen Brecker from August 31, 2022                                                                                                                                                                                            |
| 1074               | U.S. Patent No. 7,921,678 to Norris et al. (“Norris”)                                                                                                                                                                                                    |
| 1075-1105          | Reserved                                                                                                                                                                                                                                                 |
| 1106               | Estridge, Trudy & Dale Feldman, <i>Quantification of Vascular Ingrowth into Dacron® Velour</i> , 6 J. Biomaterials Applications 157-169 (1991) (“Estridge”)                                                                                              |
| 1107               | Hall, William C. et al., <i>Velour Fabrics Applied to Medicine</i> , 1 J. Biomed. Mater. Res. 179-196 (1967) (“Hall”)                                                                                                                                    |
| 1108               | Jonas, Richard A. et al., <i>Biological Sealants and Knitted Dacron: Porosity and Histological Comparisons of Vascular Graft Materials with and without Collagen and Fibrin Glue Pretreatments</i> , 41 Ann. Thorac. Surg. 657-663 (June 1986) (“Jonas”) |
| 1109               | Ko, Frank K., <i>Fabrics</i> , Encyclopedia of Biomaterials and Biomedical Engineering 1043-1061 (2008) (“Ko”)                                                                                                                                           |

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| Exhibit No. | Description                                                                                                                                                           |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1110        | Pourdeyhimi, B. & Text, C., <i>A Review of Structural and Material Properties of Vascular Grafts</i> , 2 J. Biomaterail App. 163-204 (1987) (“Pourdeyhimi”)           |
| 1111        | Scott, Steward M. et al., <i>A Collogen Coated Vascular Prosthesis</i> , 28 J. Cardiovascular Surg. 498-504 (1987) (“Scott”)                                          |
| 1112        | Stegmann, Th et al., <i>Clinical Experience with a New Collagen-coated Dacron Double-velour Prosthesis</i> , 34 Thorac. Cardiovasc. Surgeon 54-56 (1986) (“Stegmann”) |
| 1113-1115   | Reserved                                                                                                                                                              |
| 1116        | U.S. Patent Pub. No. 2011/0106240 to Chuter (“ <b>Chuter</b> ”)                                                                                                       |
| 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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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                              |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                        |
| 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, 2012                                                                |
| 1129               | C. C. Chu, <i>Understanding Implantable Textiles</i> , Advanced Textiles Source (May 21, 2018) (“Chu”)                          |
| 1130-1135          | Reserved                                                                                                                        |
| 1136               | Amendment submitted during prosecution of U.S. Patent No. 11,337,834 dated August 14, 2021 (“’834 patent Aug. 14, 2021 Amend.”) |
| 1137-1140          | Reserved                                                                                                                        |

Table of Exhibits 6

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 1-2 and 4-6 of U.S. Patent No. 11,491,033 (“the ’033 patent”). For the reasons discussed herein, I have concluded that claims 1-2 and 4-6 of the ’033 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 ’033 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 ’033 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 '033 patent;
- The level of ordinary skill in the art pertaining to the '033 patent;

- The teachings of the prior art; and
- Whether claims 1-2 and 4-6 of the '033 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 '033 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 '033 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 '033 patent cover Petitioner's SAPIEN 3 Ultra valve. *See* Ex. 1122; Ex. 1123 (Patent Owner's Infringement Contentions) at 2, 477-564. Patent Owner has also argued to the Patent Office that the SAPIEN 3 Ultra valve is covered by the claims of related patents during prosecution of the patents. *See* Ex. 1136 ('834 patent Aug. 14, 2021 Amend.) at 27-28. My interpretation and application of the prior art herein is based on Patent Owner's assertions regarding the scope of the claims of the '033 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 '033 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 '033 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 '033 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 1-2 and 4-6 of the '033 patent would have been non-obvious, as further explained in Section IX below.

**D. Person of Ordinary Skill in the Art**

46. It is my understanding that when interpreting the claims of the '033 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 '033 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 '033 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

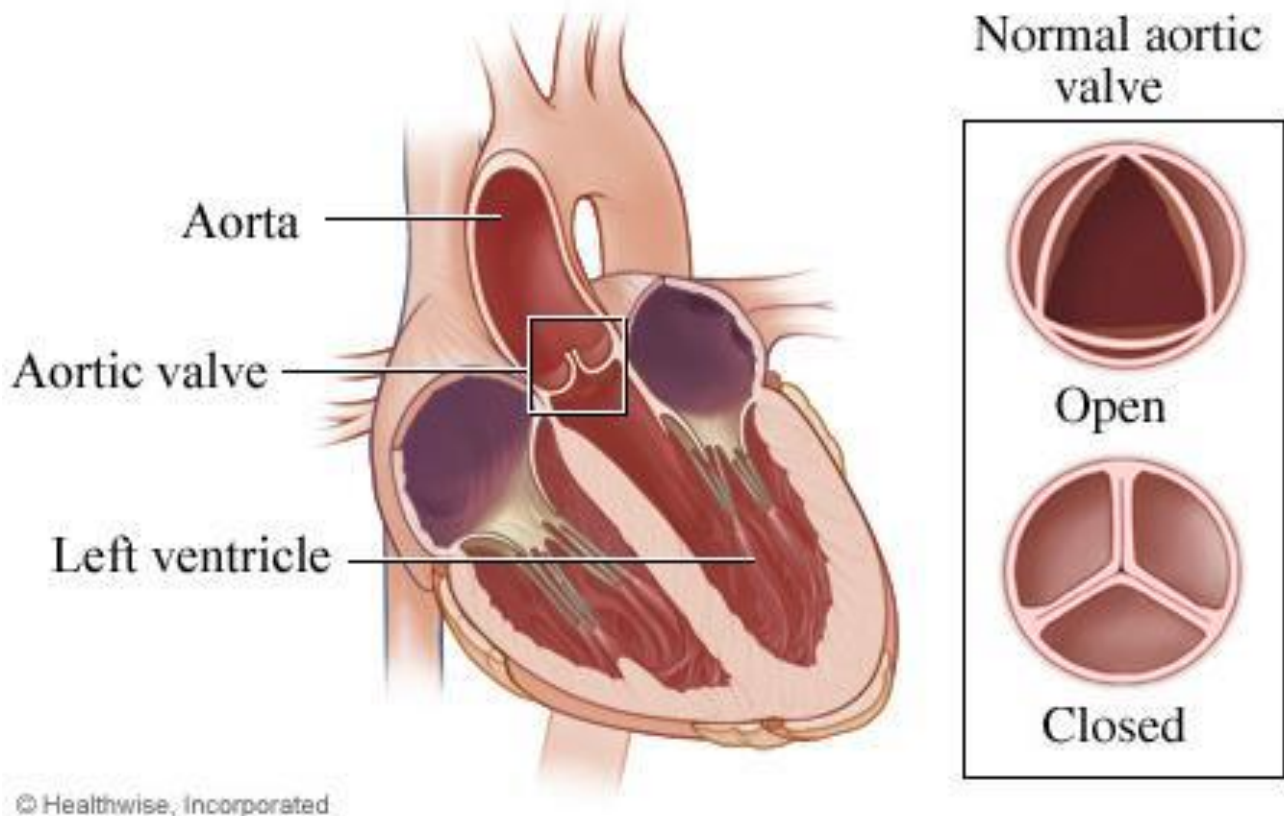
problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

49. Based on my review of the specification and claims of the '033 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**

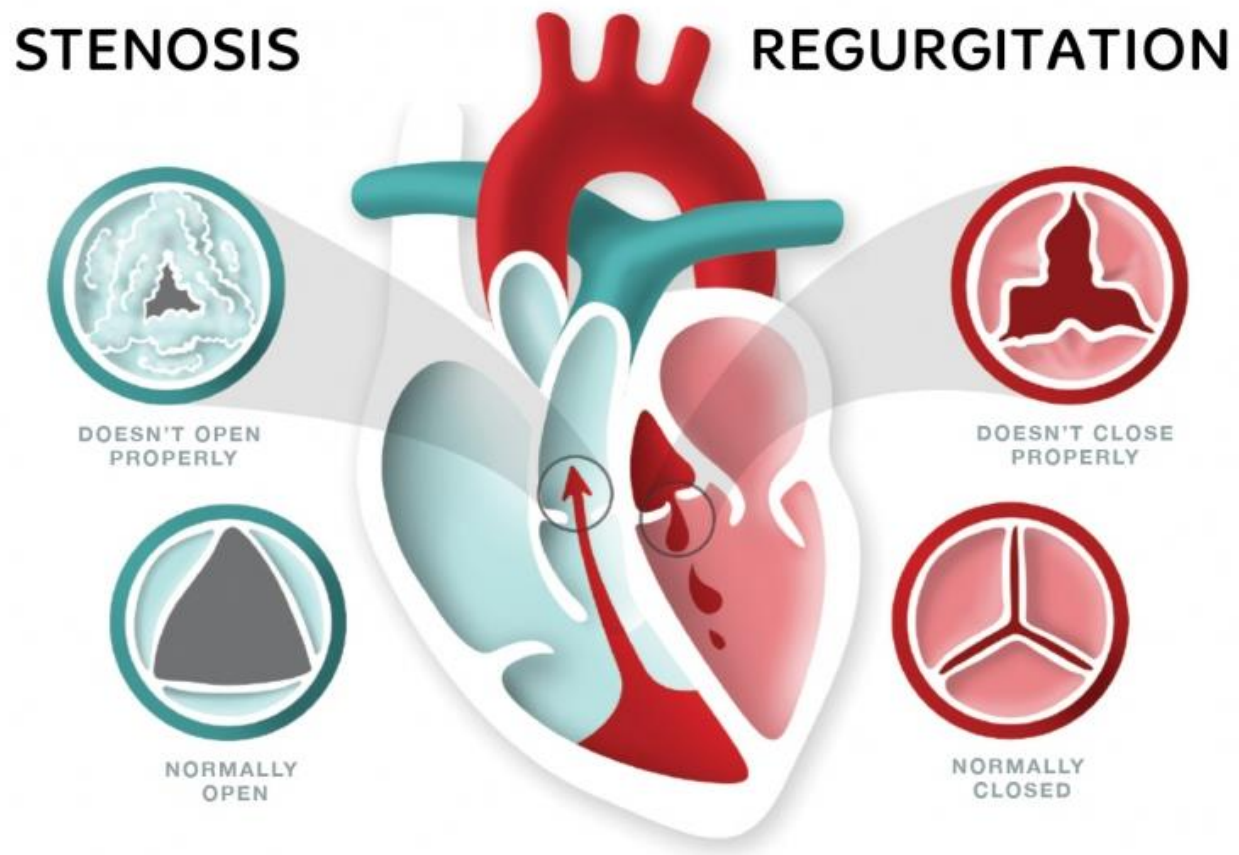
50. The human heart has two upper chambers, known as the left and right atriums, and two lower chambers, known as the left and right ventricles. The aortic valve connects the left ventricle with the aorta, the major artery that carries oxygenated blood from the heart to the rest of the body, on the left 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.

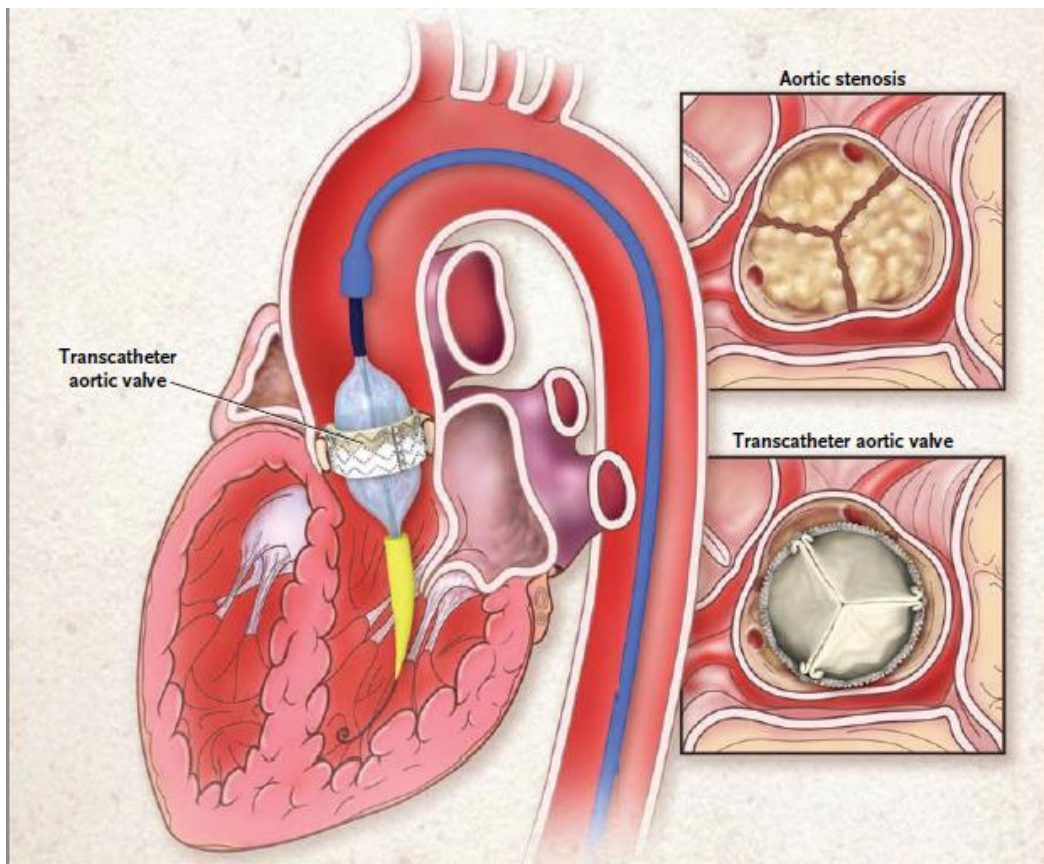
52. A common treatment for both aortic stenosis and aortic regurgitation is replacement of the diseased native aortic valve with a prosthetic heart valve. The prosthetic valve takes the place of the diseased native leaflets, and acts to

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").<sup>1</sup> 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:

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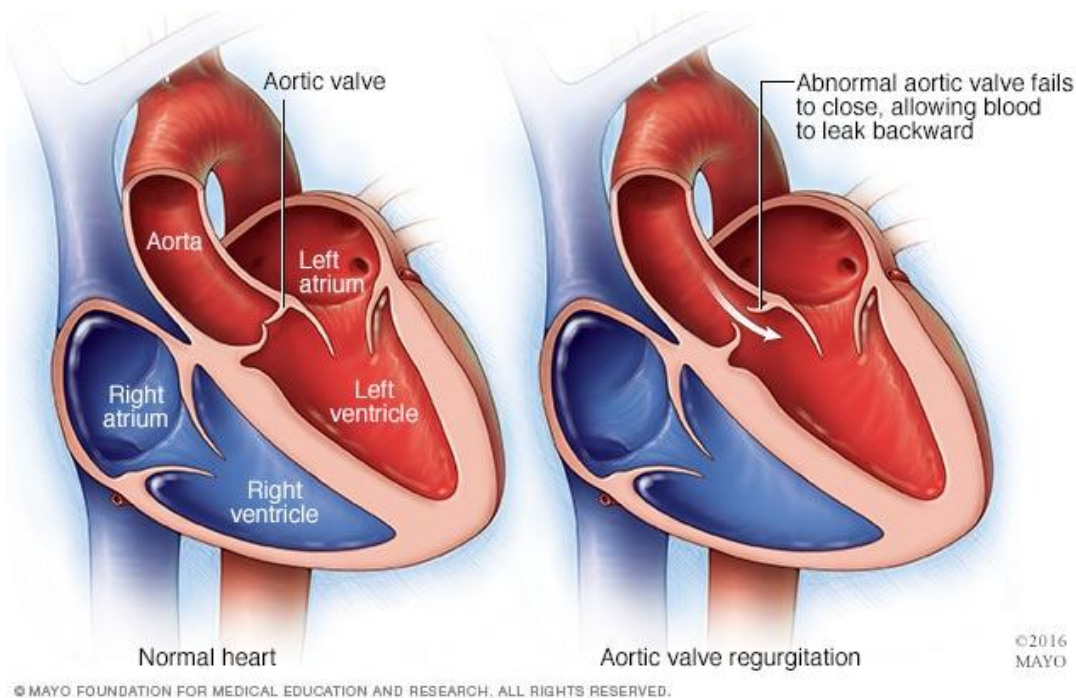
<sup>1</sup> "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



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 '033 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 '033 patent state that “in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: presses the sealing assembly against the native leaflets of the aorta.” See *e.g.*, Ex. 1001 ('033 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 '033 patent identifies the annulus (identified by item #210) as the crown-like structure where the aortic valve leaflets attach to the left ventricle:

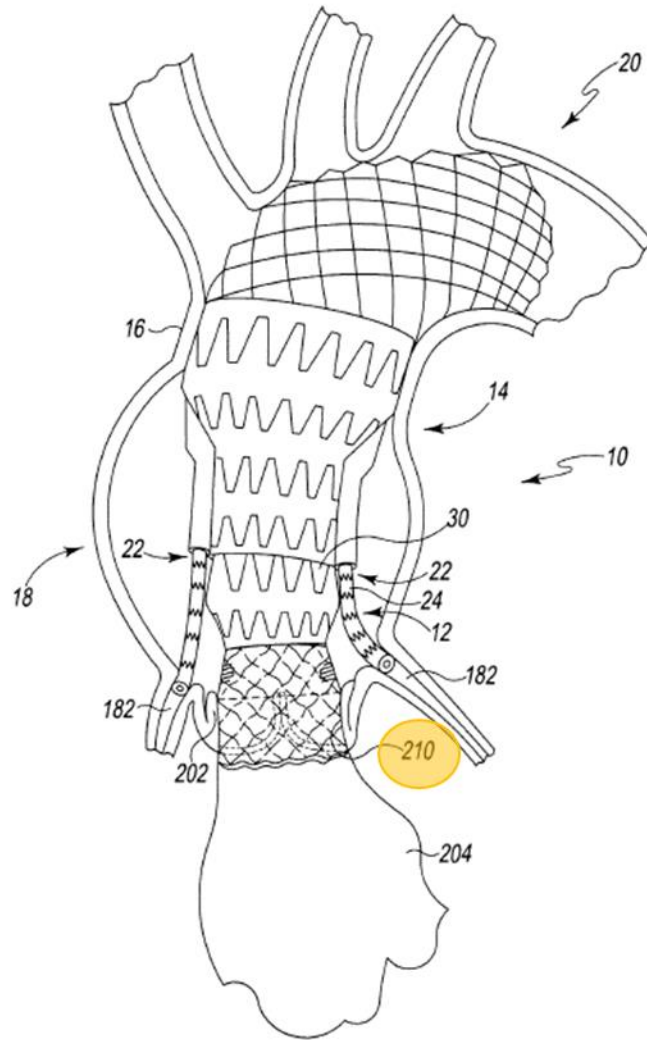
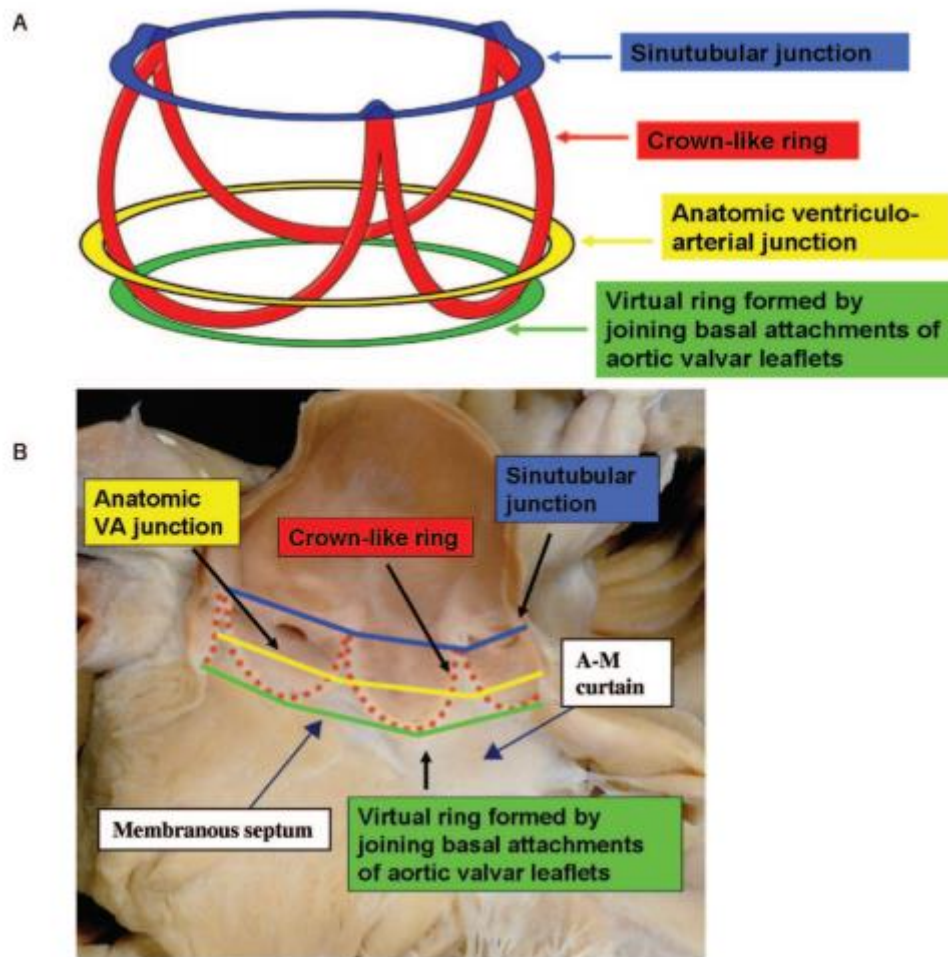


Fig. 2

*See e.g., id.* at Fig. 2.<sup>2</sup> This is further confirmed by the '033 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valsalva, the sinutubular junction, and the tubular portion." *Id.* at 1:66-2:1. The below image from a prior art journal article reflects the structure of the aortic valve. What the '033 patent identifies as the annulus 210 corresponds to a point in the center of the red crown-like ring illustrated below.

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



Ex. 1047 (Piazza) at Fig. 4. Because the “annulus” referred to in the ’033 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.

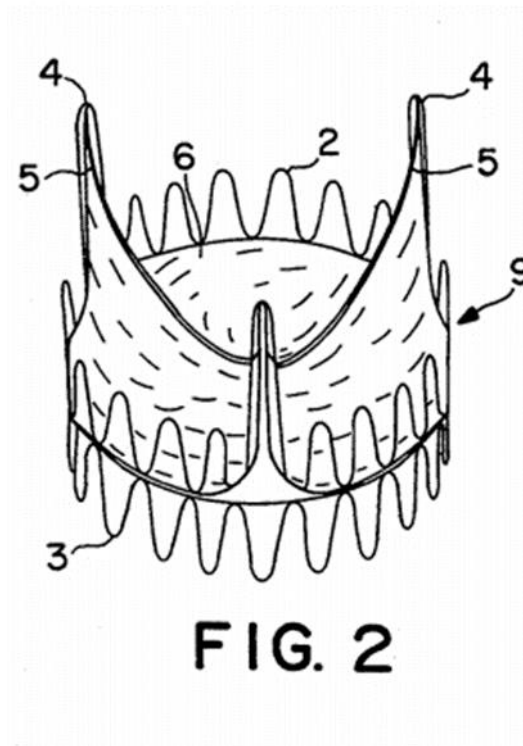
### C. Transcatheter Heart Valve (“THV”) Technology

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**).



*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.”).

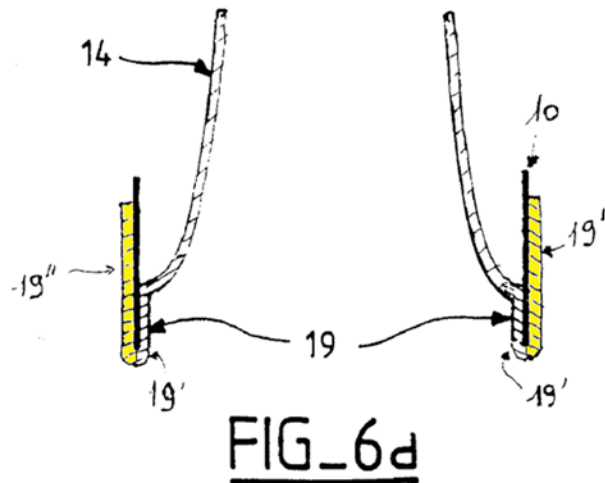
61. In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s. These designs provided the basis for a December 1996 patent application. A family of patents and patent applications

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.

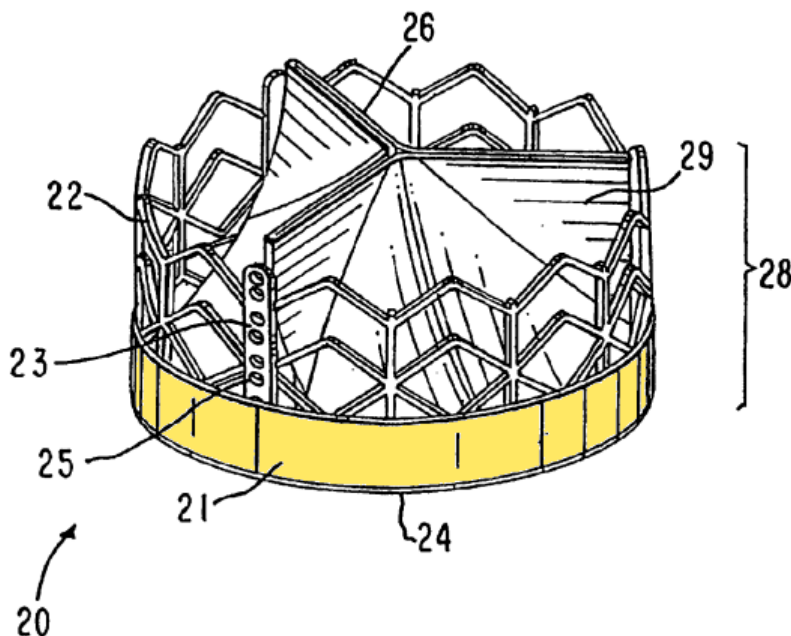
64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then “rolled up to be applied to the external wall of the stent” to form an external cover [19"]:



*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:



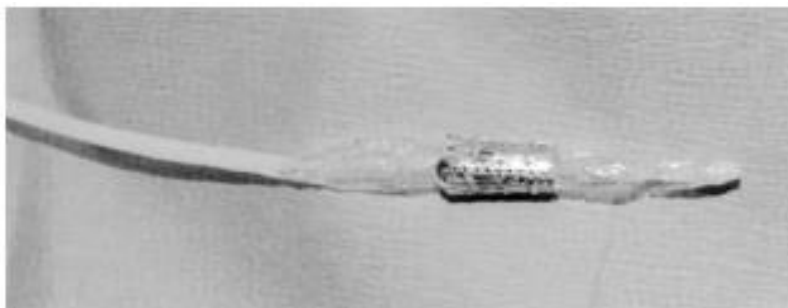
**Ex. 1019** (U.S. Patent No. 6,893,460 B2 to Spenser *et al.* (“’460 patent”)) at Fig.

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)).<sup>3</sup> The THV consisted of three bovine pericardial leaflets mounted within a tubular, slotted stainless steel balloon-expandable stent that was crimped onto a delivery balloon:



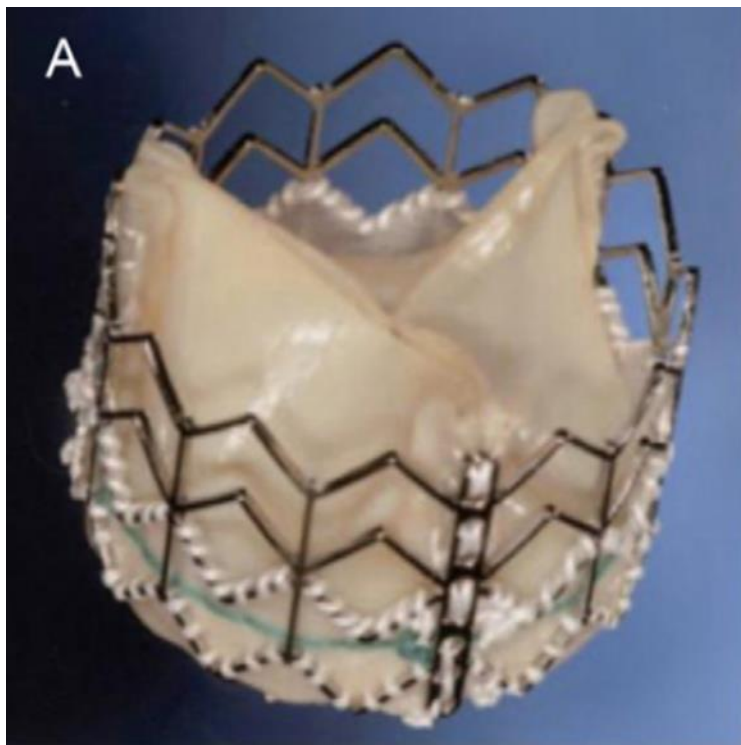
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<sup>3</sup> Dr. Cribier uses the phrase “percutaneous heart valve” or “PHV” to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

*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.,

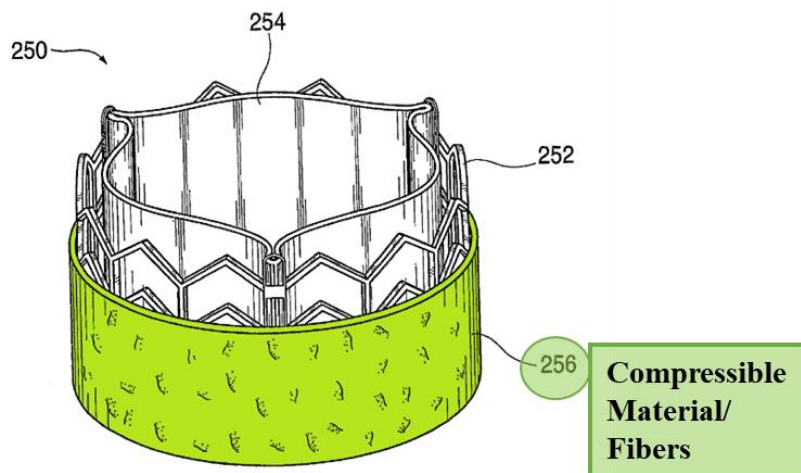
*Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches*, Archives of Cardiovascular Disease 105, 153-159 (March 16, 2012)). The Cribier-Edwards THV “was constructed from a laser-cut stainless steel tubular frame within which was sewn valve leaflets constructed 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.*

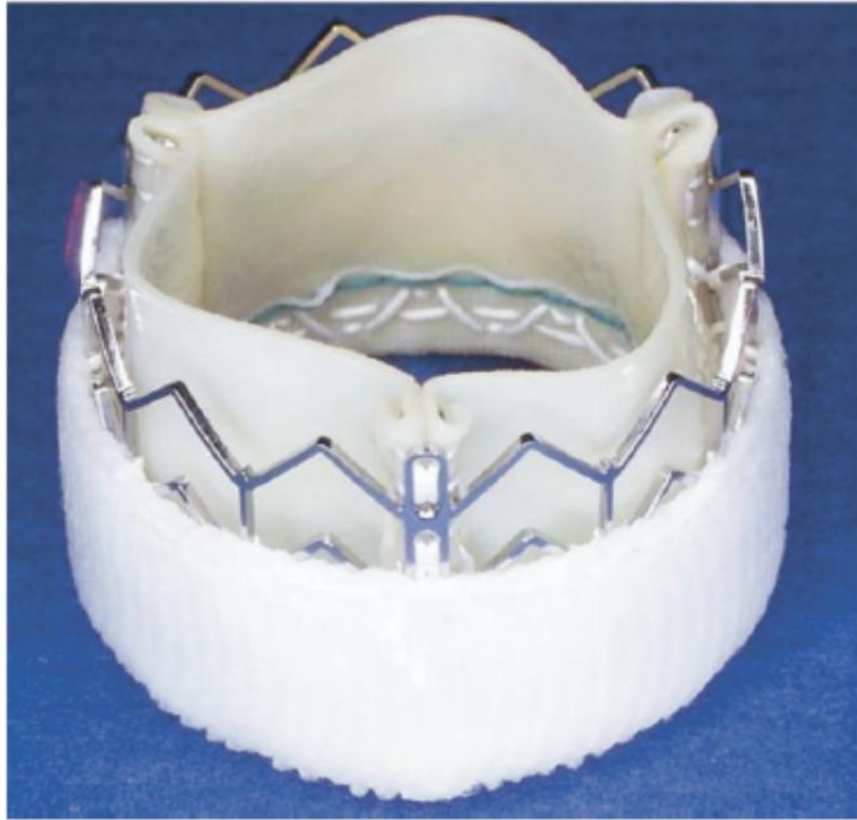


*Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).*

*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.

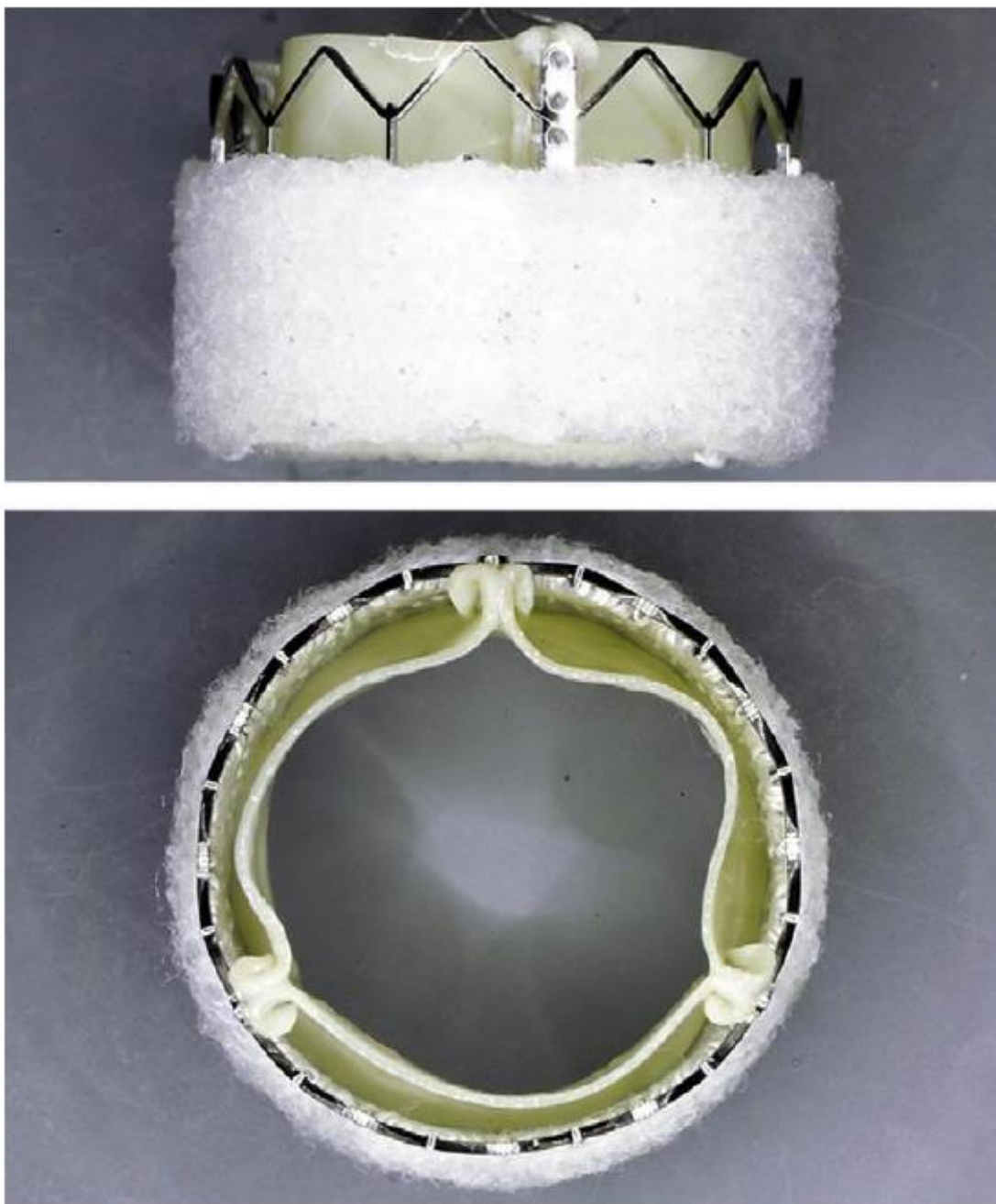
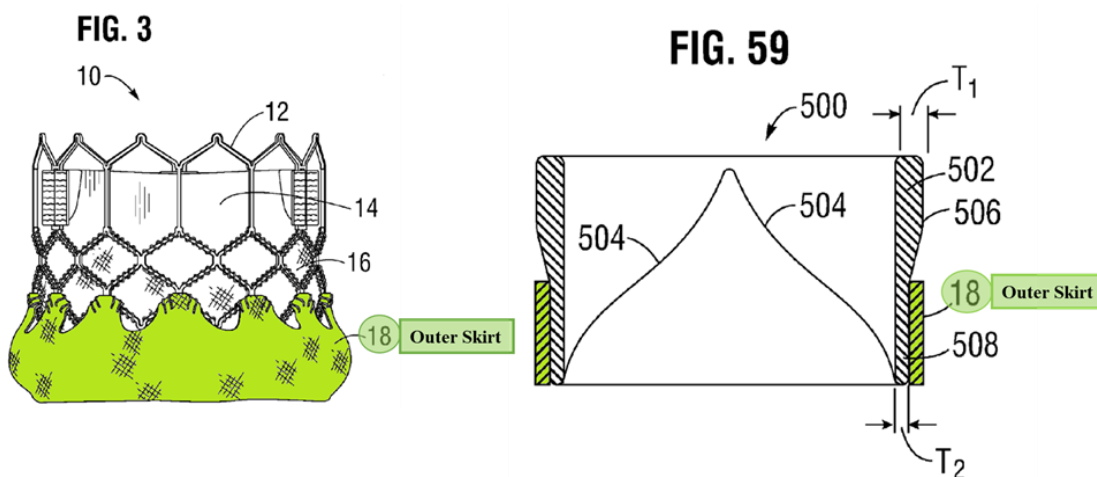


Fig. 1. Cloth valve.

*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, 16:51-54, 17:12-18, 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”:

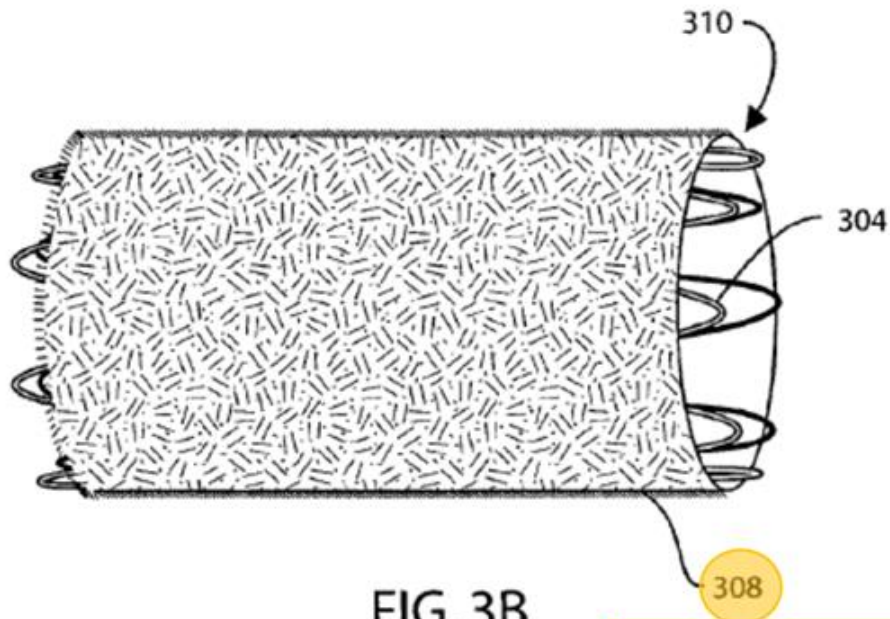


FIG. 3B

**Barrier Material /  
Microfibers**

*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 11:20-21; 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.5-8. 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, Petitioner's Retroflex 3 allowed the transfemoral introduction of

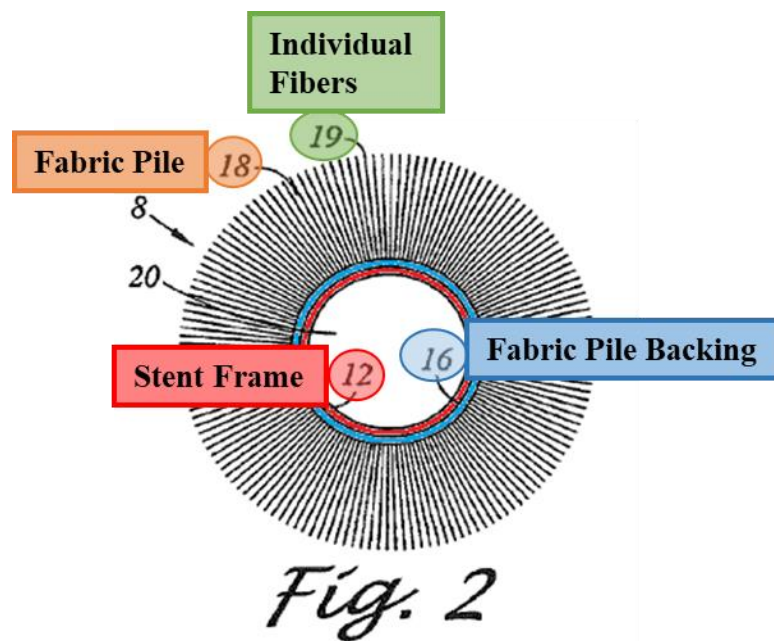
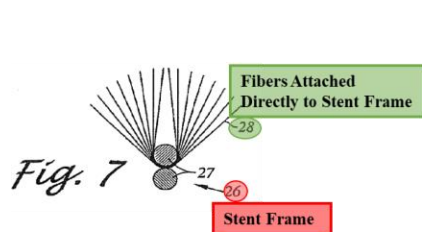
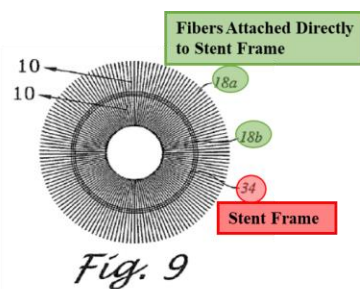
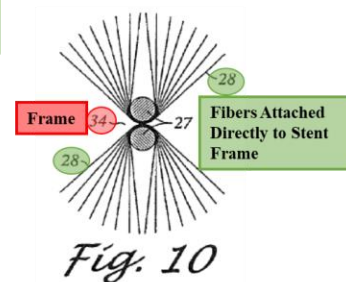
SAPIEN 23 or 26 mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, Petitioner's Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23 mm valve and 19 French for the 26mm valve. *Id.* The Novaflex 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” (Fig. 2) or they can be attached directly to the stent frame without any backing (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 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 been motivated to consider 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 ’033 PATENT**

##### **A. Summary of the ’033 Patent**

83. The ’033 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.



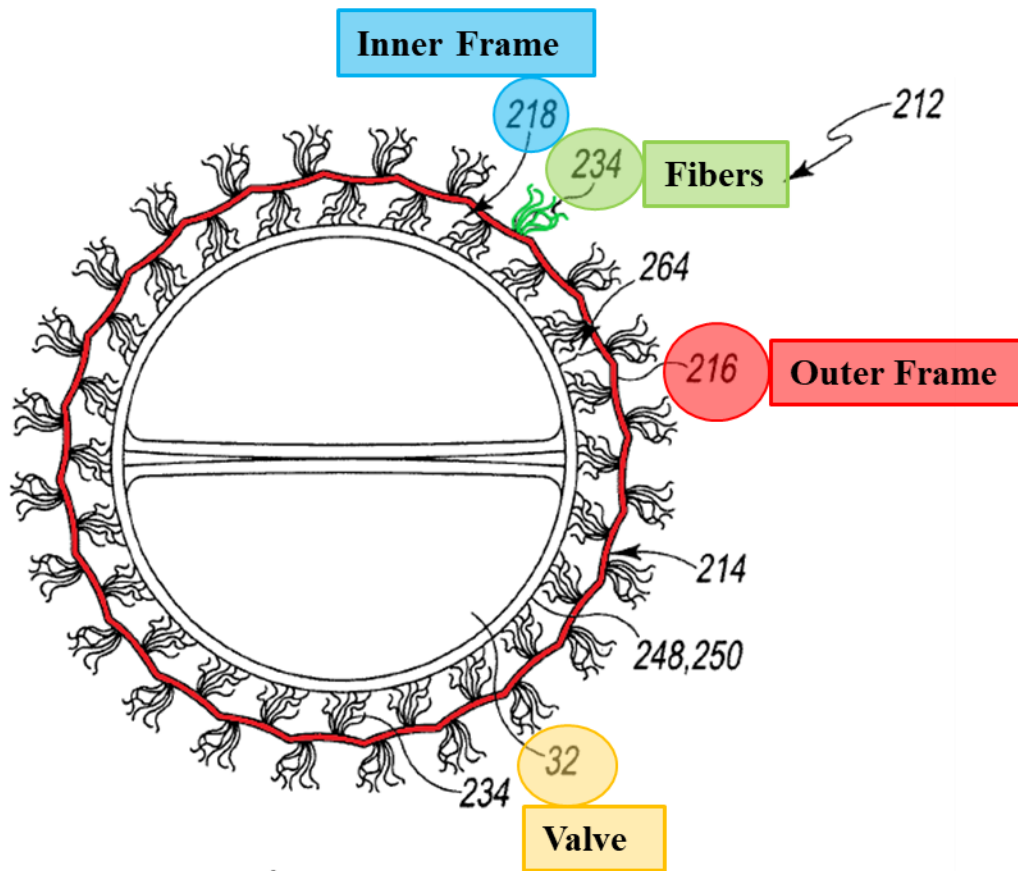
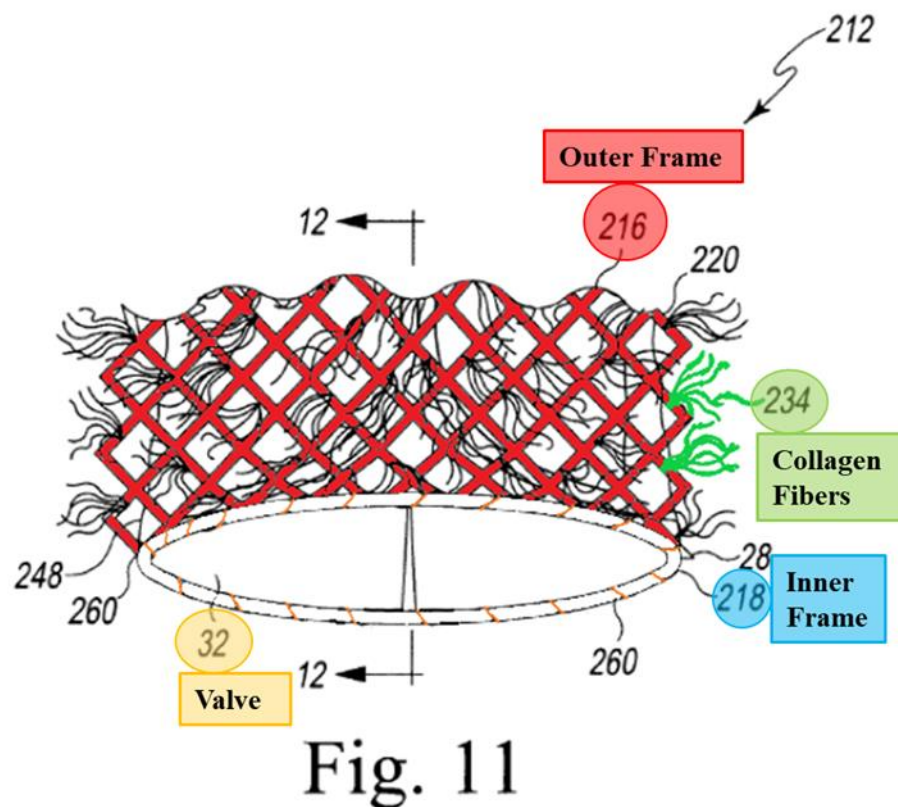


Fig. 13

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

85. The '033 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.



86. The '033 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 1-2 and 4-6 of the '033 patent. Claim 1 is the sole independent claim.

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 assembly having improved sealing for addressing paravalvular leakage for use in a patient, comprising:
  - a frame formed of a plurality of cells,
    - wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,
    - 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 about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage; and
  - a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage,
    - wherein the sealing assembly extends over each of the at least two rows of cells,
    - wherein the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation,
    - wherein the prosthetic heart valve assembly is sized and shaped to be endovascularly deployed through a femoral artery of the patient,
    - wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state,
    - wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state:
      - presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers
      - relative to the spacings thereby reducing the spacings; and
      - expands the polymer covering radially outwardly, wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.

Ex. 1001 ('033 patent) at claim 1.

### C. Prosecution History

89. I have reviewed the '033 patent's prosecution history. I see that the Patent Examiner issued a Non-Final Rejection of the pending claims on July 21, 2022, rejecting the claims as obvious over the combination of Nguyen et al. (WO 2006/124649) and Greenhalgh (US 2002/0052649). Ex. 1002 ('033 patent prosecution history) at 186-191.

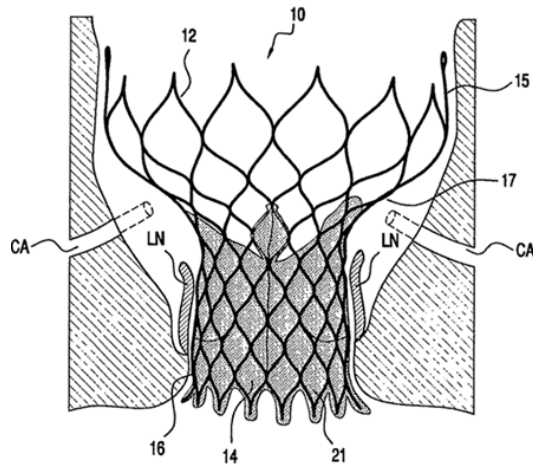
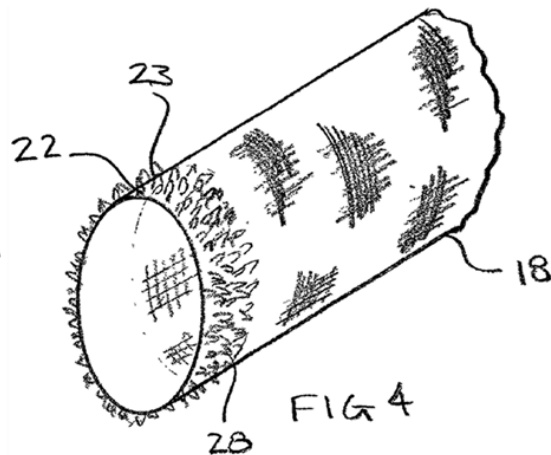


**FIG. 6**  
**Nguyen**



**Greenhalgh**

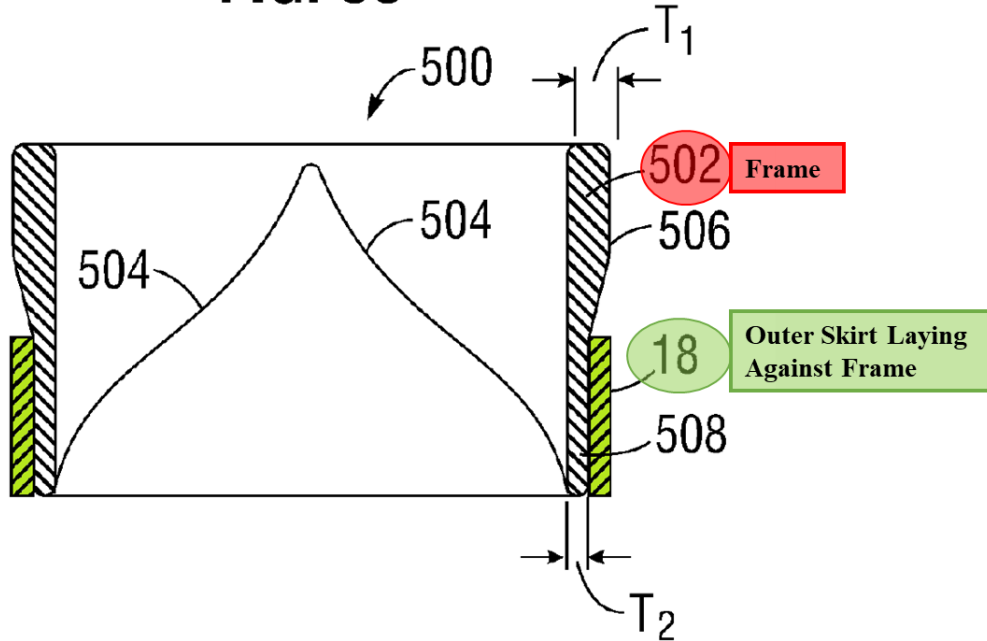
90. PO then cancelled the original claims and proposed new claims, which PO alleged were supported by Provisional Patent Application 61/723,446. *Id.* at 164-173. PO argued that the combination of Greenhalgh's outwardly extending fibers with Nguyen's endovascularly-deliverable heart valve would not be suitable for delivery through the femoral artery. *Id.* at 173-180. The Examiner subsequently allowed most of the pending claims but rejected claim 9 under 35

U.S.C. §112 because the limitation “the polymer covering forms an inner frame for supporting the leaflet assembly” was not supported by the original disclosure. *Id.* at 93-98. PO subsequently cancelled pending claim 9 and the Examiner issued a Notice of Allowance. *Id.* at 42-44, 84-88.

91. 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 in Amendments during prosecution.

92. For example, Patent Owner made arguments about Levi in a July 31, 2022 Amendment, arguing that “Levi discloses that known fabric skirts such as those in Greenhalgh cannot be secured on the exterior of the frame in a ‘lay flat’ position as claimed or else the valve cannot be crimped properly.” Ex. 1002 (’033 prosecution history excerpt) at 179. Levi contains no such teaching. To the contrary, Levi discloses embodiments having an outer sealing material laying against the frame as claimed in the ’033 patent:

**FIG. 59**



Ex. 1008 (Levi) at 16:51-54, 17:12-18, Fig. 59. To support its arguments, Patent Owner relied on the following portion of Levi, which discusses Levi's inner skirt:

*[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.*

Ex. 1002 ('033 prosecution history excerpt) at 180. Patent Owner's reliance on the above section of Levi is misplaced for several important reasons. First, the above passage relates to Levi's inner PET skirt, not an outer sealing material. See Ex. 1008 (Levi) at 9:24-10:4. This is important because the purpose of Levi's inner PET skirt and an outer sealing material are distinct. While both work to

prevent PVL, Levi's inner skirt does so by having a tightly woven PET fabric that will prevent the passage of blood through the radial thickness of the fabric, thereby preventing blood from leaking through the open cells of the metal frame below the leaflets. *See id.* at 9:7-11. Persons of ordinary skill in the art would have understood that the tight weaving of the inner skirt fabric would necessarily limit its stretchability. In contrast, an outer sealing material creates a seal between the outside surface of the THV and the patient's native tissues, preventing blood from leaking around the outside of the THV. *See, e.g., id.* at 14:3-7. An outer seal does not need to be tightly woven and impermeable to blood to accomplish this purpose. To the contrary, as I explain above and below, the prior art taught that loose, porous, and compressible materials, such as knitted velour fabrics, were preferable for outer sealing materials because of their enhanced ability to promote tissue ingrowth and their ability to compress and stretch as the THV is crimped and expanded. *See infra* §VI.A.8; *see also supra* §III.C-D. Therefore, persons of ordinary skill in the art would have recognized that the porous, stretchable materials used for outer seals would not cause the same restrictions on uniform crimping as described in Levi for the inner skirt.

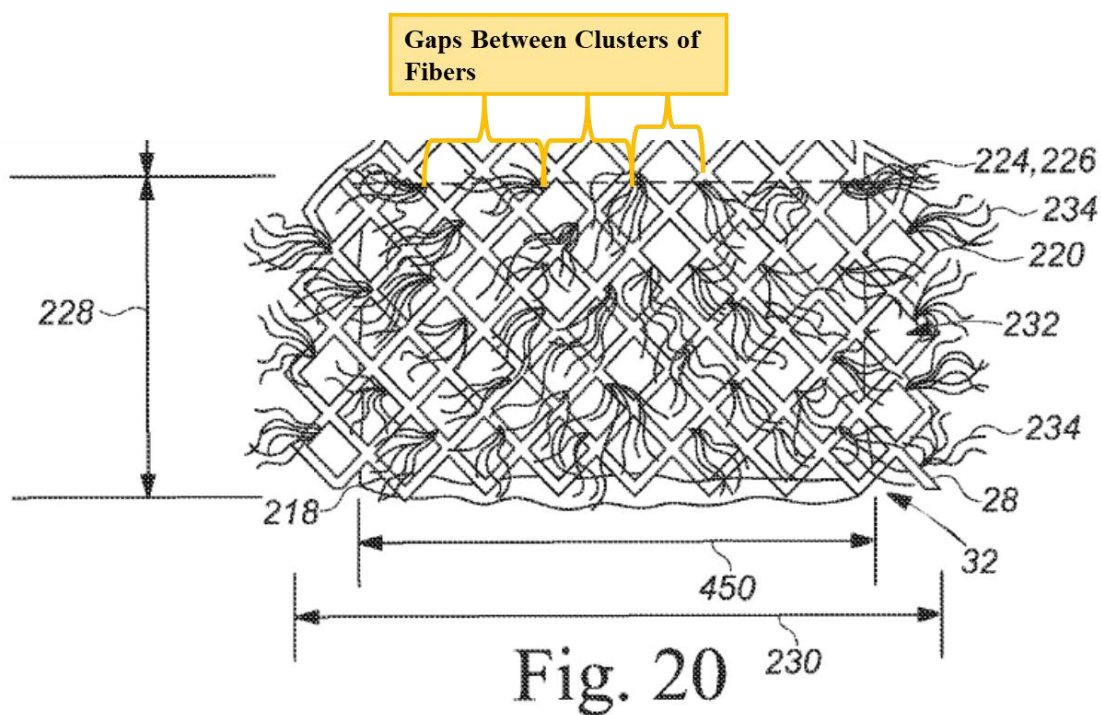
93. I also see that Patent Owner made arguments regarding the scope of the "spacings" claimed in the '033 patent. *See* Ex. 1002 ('033 patent prosecution history) at 28-30. Specifically, Patent Owner argued that the Board erred in its

Institution Decision for Patent Owner's '236 patent when the Board explained that "small openings inherently exist between the radially extending fibers" of the prior art. *Id.* According to Patent Owner, the "specification illustrates spacing between fibers that are an intentionally placed spacing, i.e., not just the spacing that may be inherent between radially extending fibers such as those that appear to be found in the Walther reference." *Id.* at 29. To the extent that Patent Owner was suggesting that the specification of the '033 patent requires or supports any specific size of "spacing" between the fibers, I disagree with Patent Owner's assertion.

94. Outside of the claims, the specification of the '033 patent does not mention any "spacings" between the fibers attached to the outer frame. *See* Ex. 1001 ('033 patent). Likewise, the patent never discloses any dimensions for the fibers, how the fibers are arranged on the outer frame, or the size of any spacings between the fibers. *Id.* There is no indication in the '033 patent that the figures are drawn to-scale. *Id.* Accordingly, I see nothing in the '033 patent that supports Patent Owner's assertion that the spacings must be an "intentionally placed spacing." *See* Ex. 1002 ('033 patent prosecution history) at 29. Additionally, I disagree with Patent Owner's suggestion that the spacings between the fibers of the prior art sealing materials are not "intentionally placed." Persons of ordinary skill in the art would have understood that the fibrous sealing materials in the prior

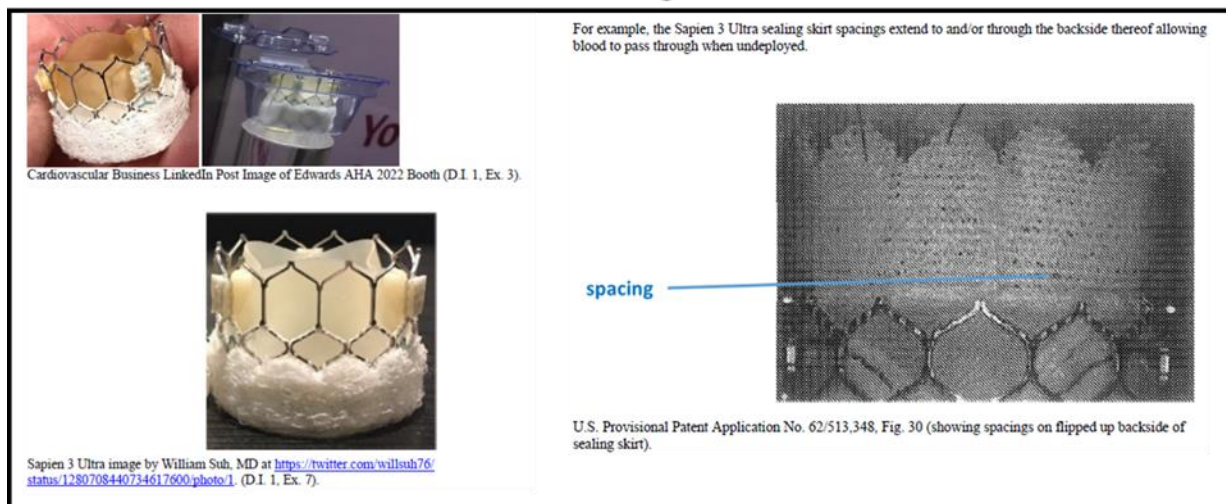
art are intentionally arranged, woven or knitted to have specific properties, such as compressibility and porosity, to achieve their intended purposes. *See infra* §VI.A.8. Thus, the positioning of the fibers in the materials, including the spacings between the fibers, are intentional.

95. To the extent Patent Owner is suggesting that the claims require spacings of equivalent size to those illustrated in the figures of the '033 patent, such a suggestion cannot be reconciled with Patent Owner's position in its infringement contentions regarding the SAPIEN 3 Ultra valve. The figures of the '033 patent illustrate fibers that are arranged in groups or clusters around the outer frame, with gaps between the clusters that span at least the width of the open cells of the frame:



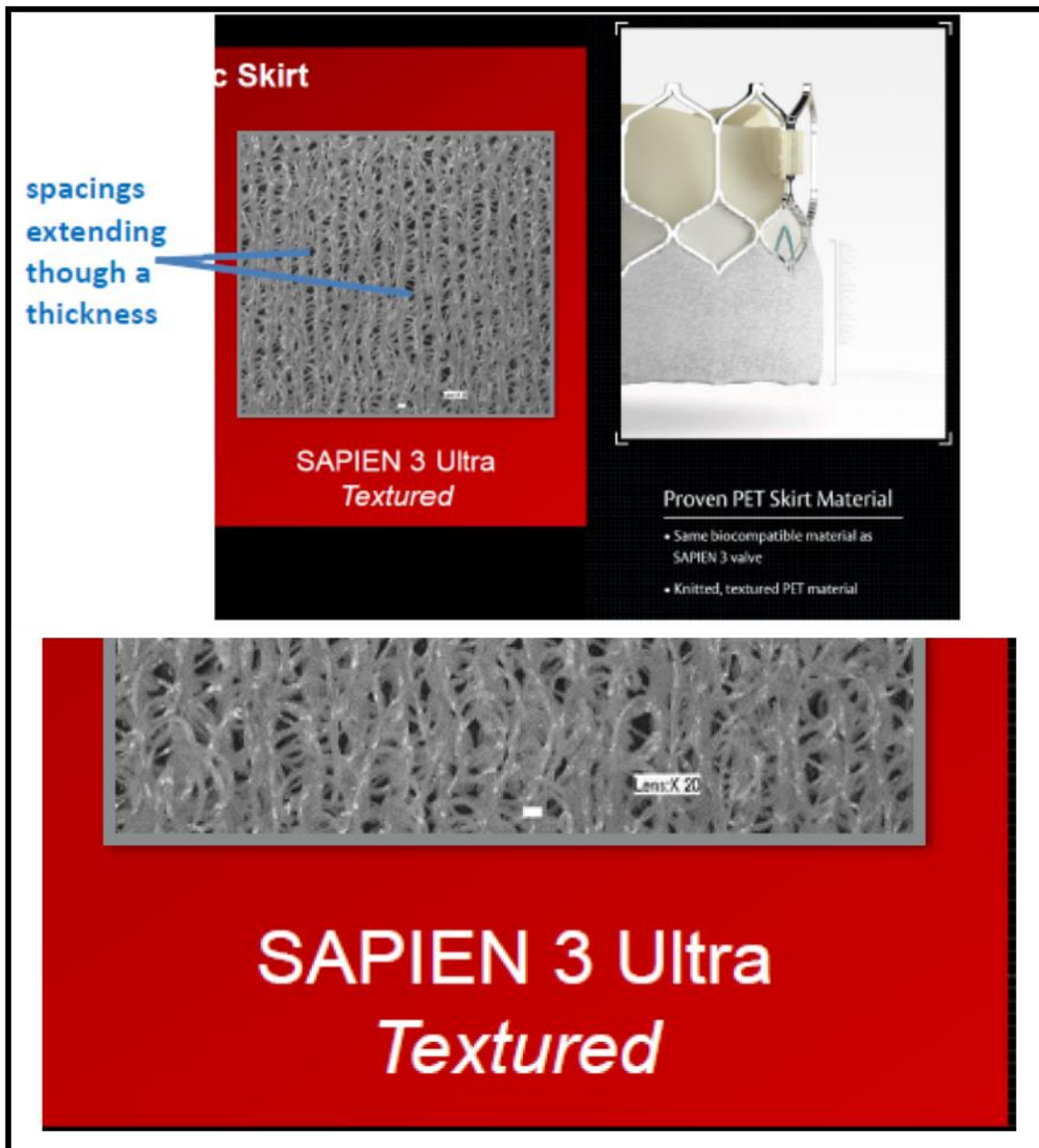
Ex. 1001 ('033 patent) at Fig. 20. As can be seen in the images Patent Owner relies upon in its infringement contentions, the outer skirt of the SAPIEN 3 Ultra valve covers the openings between the struts of the frame; there are no spacings between the fibers that span the width of the open cells:

### Patent Owner's Infringement Contentions



Ex. 1123 (PO Infringement Contentions) at 543. Rather, Patent Owner attempts to identify spacings in an alleged image of the SAPIEN 3 Ultra valve's outer skirt that appears to have been magnified by **20 times** to assert that the SAPIEN 3 Ultra valve meets the "spacing" limitation of the claims:

## Patent Owner's Infringement Contentions



*Id.* at 542. Thus, Patent Owner appears to be asserting inconsistent and irreconcilable positions regarding the size of the “spacings” required by the claims in the context of the prior art versus the context of Petitioner’s SAPIEN 3 Ultra

valve. This further illustrates the error in Patent Owner’s reading of the claims to require a certain size of “spacing” between the fibers.

## **V. SUMMARY OF IPR GROUNDS**

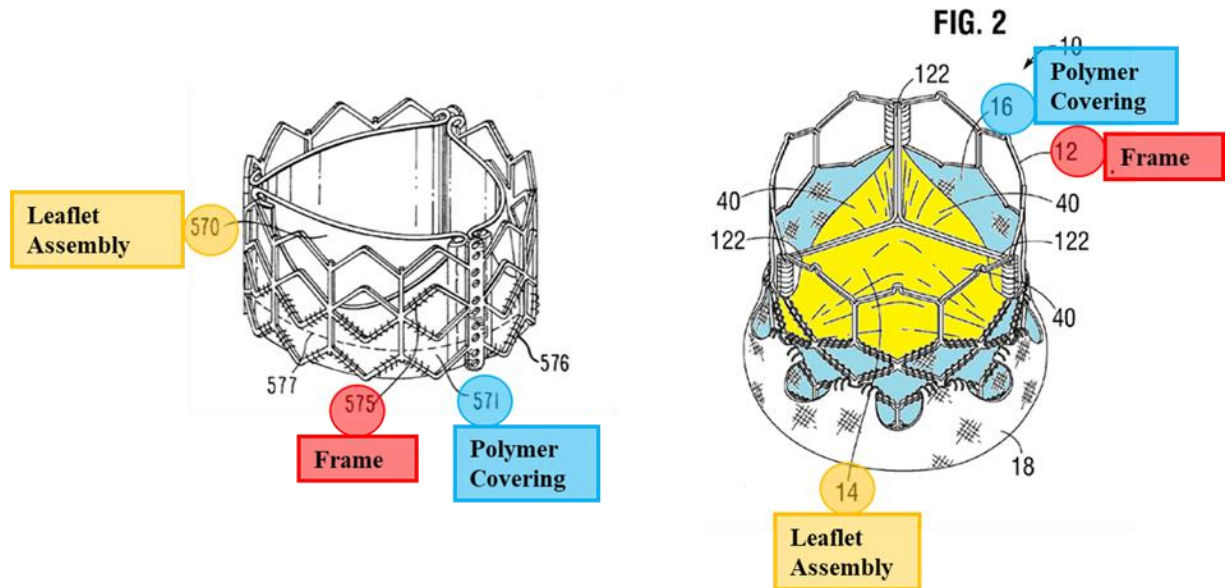
96. I address the following grounds of unpatentability in this Declaration:

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

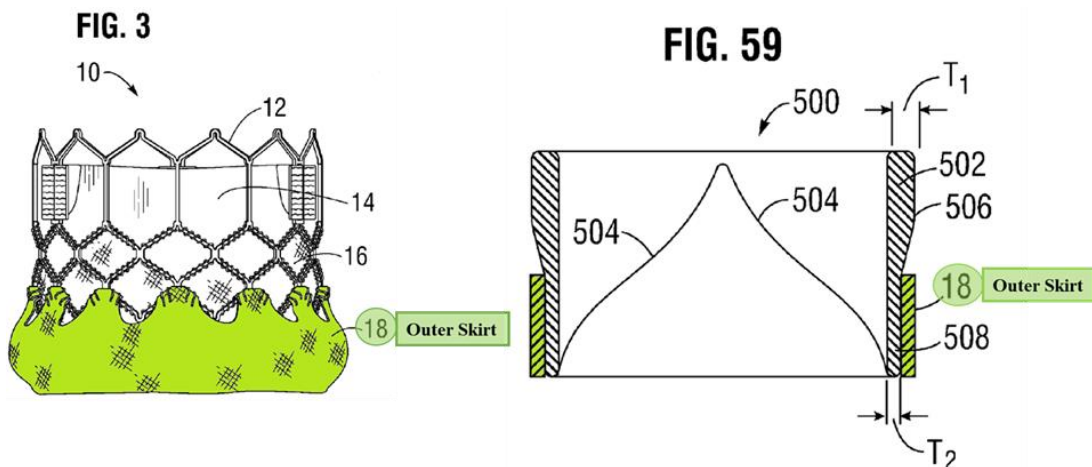
## **VI. GROUNDS 1-2: CLAIMS 1-2 AND 4-6 OBVIOUS OVER SPENSER**

### **OR LEVI AND SPENSER II**

97. Spenser (left) and Levi (right) describe heart valve assemblies having a frame, a polymer 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 polymer skirt secured to the exterior surface of the frame, as shown in Figure 3 below:



Ex. 1008 (Levi) at 13:50-53, 13:62-66, 16:51-54, 17:12-18, Figs. 3, 59.

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

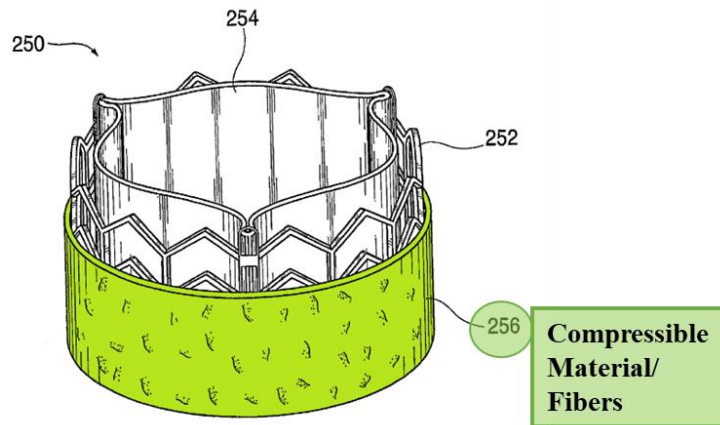


FIG. 22

Ex. 1011 (Spenser II) at [00144]-[00145], Fig. 22. Spenser II explains that in certain configurations, the compressible material “may resemble a cloth or fabric having small fibers extending from the surface of the material” (i.e., a plurality of arcuate fibers that extend away from the frame). *Id.* at [00145].

99. For the reasons I provide in detail below, and previously adopted by the Board, 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 1-2 and 4-6 obvious.

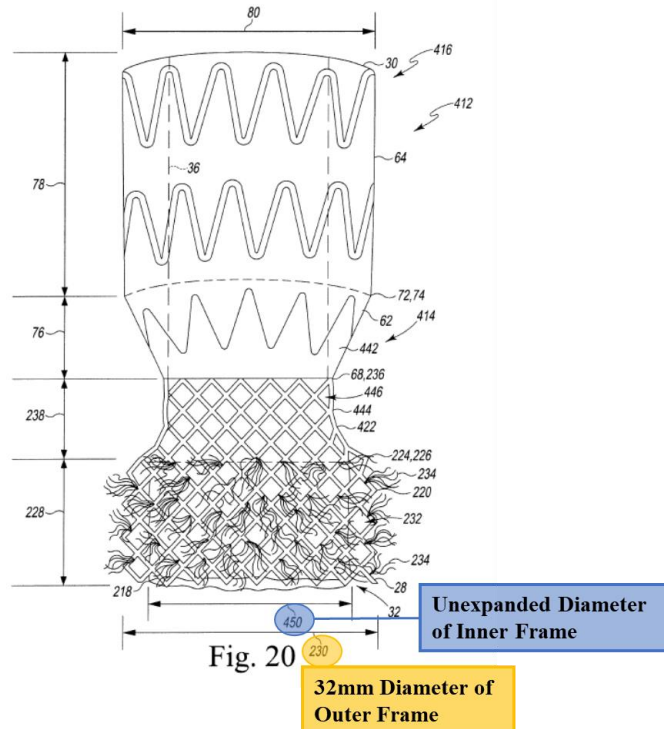
#### A. Claim 1

100. 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

101. The preamble of claim 1 recites: “An endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient.” If this preamble is limiting Spenser **or** Levi in combination with Spenser II renders this limitation obvious.

102. I note that despite claiming an endovascular prosthetic heart valve, the '033 patent does not contain any disclosure regarding how to size the disclosed valves for endovascular delivery. For example, the '033 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 20 mm due to the gap 264 between the unexpanded inner frame the expanded outer frame.



See Ex. 1001 ('033 patent) at 12:40-43, 14:18-30, 18:21-24, 19:29-34, Fig. 20.

103. 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).

104. 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.

105. Spenser II describes using catheters to endovascularly deliver heart valves “through a body duct to a target location.” Ex. 1011 (Spenser II) at [0009],

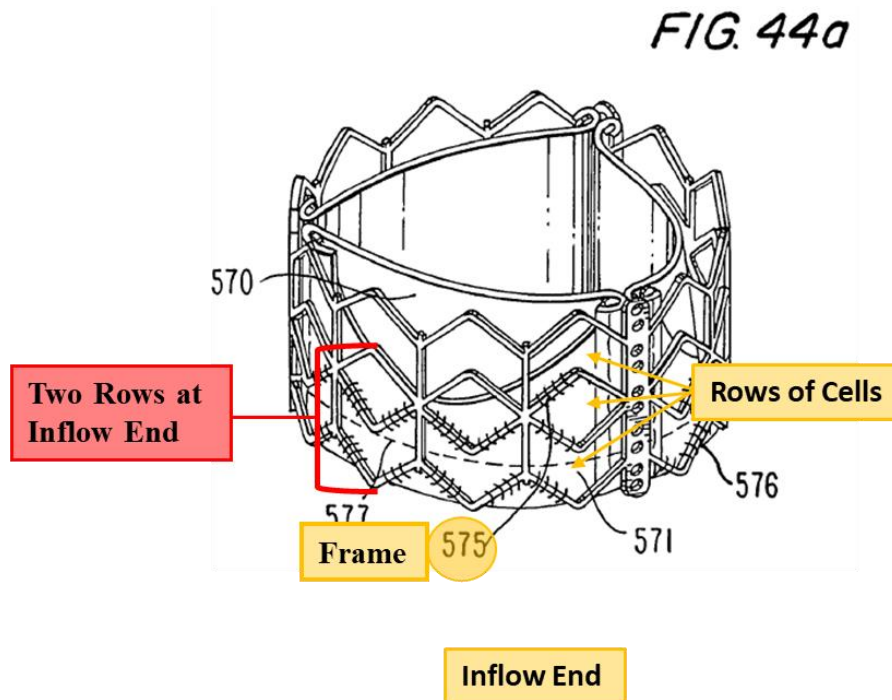
[0014], [0017], [00144]-[00145]. Persons of ordinary skill in the art would have understood the description of endovascular delivery to apply to the covered stented valve with the compressible material in Figure 22 because Spenser II discloses that the “present invention provides a series of new **percutaneous** 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). Spenser II discloses “improved sealing for addressing paravalvular leakage in a patient” as I explain in section VI.A.5 below.

## 2. **Frame**

106. Claim 1 next recites: “a frame formed of a plurality of cells, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation.” Spenser and Levi disclose this limitation.

### a. **Spenser**

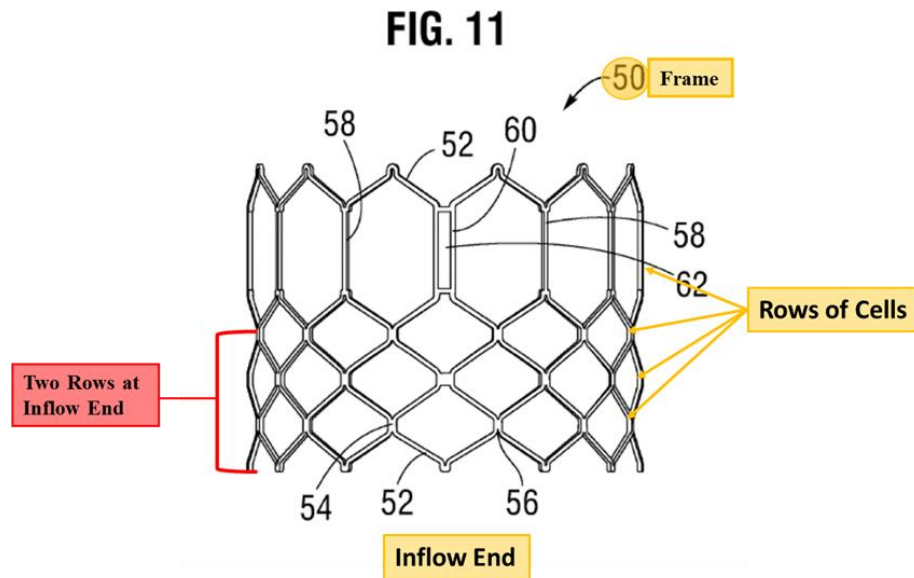
107. Figure 44a of Spenser illustrates “an implantable prosthetic valve in accordance with [a] preferred embodiment of the present invention” that includes “frame 575”:



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame). As shown, the frame is formed of a plurality of struts that form a plurality of cells, including two rows of cells at the inflow end of the frame. *Id.* at Fig. 44a-44b. Spenser’s valve, including the frame, “has the ability to change its diameter from about 4 mm [radially compressed orientation] to about 25 mm [radially expanded orientation].” *Id.* at 27:67-28:2.

**b. Levi**

108. Levi discloses an expandable metal frame formed from a plurality of cells, including two rows of cells at the inflow end of the frame, as shown in Figure 11 of Levi below:



Ex. 1008 (Levi) at 6:17-7:3, Fig. 11. Levi’s valve, including the frame, is “radially collapsible and expandable.” *Id.* at Abstract. 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.” *Id.* at 6:20-24.

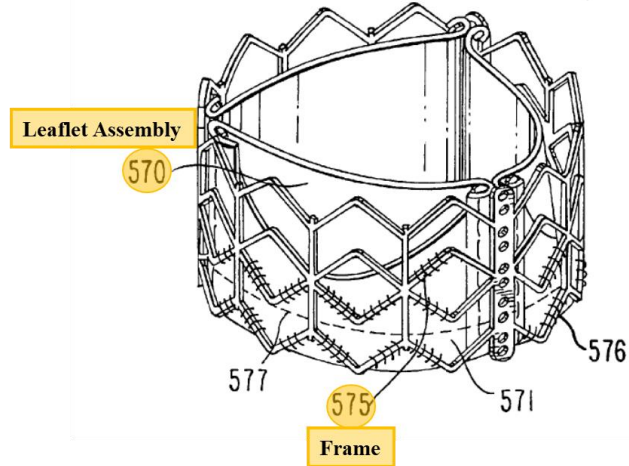
### 3. Leaflet Assembly

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

#### a. Spenser

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

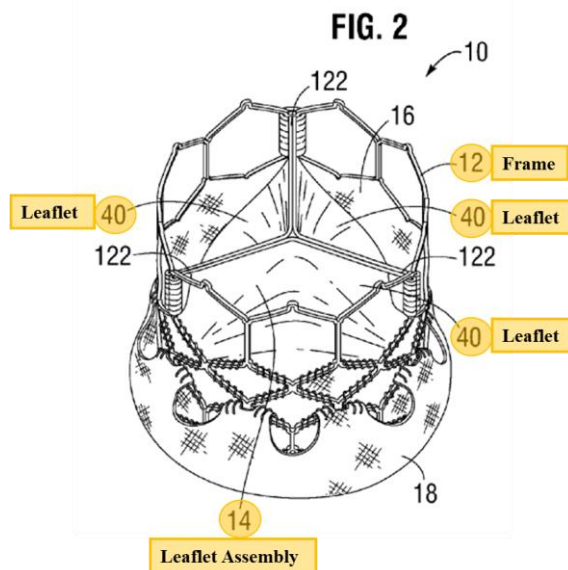
**FIG. 44a**



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

**b. Levi**

111. 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.

#### **4. Polymer Covering**

112. Claim 1 next recites: “a polymer covering about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage.” Spenser and Levi also disclose this limitation.

##### **a. Spenser**

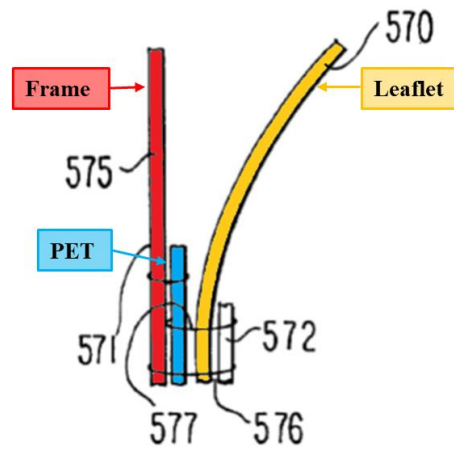
113. The embodiment in Figure 44a of Spenser includes an “additional piece of PET” 571 for “sealing and protecting the pericardium.” Ex. 1010 (Spenser) at 26:30-34, Figs. 44a-44c; *see also id.* claims 10, 30 (“including a fabric layer interposed between the valve assembly and support stent”). PET stands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

114. As shown in Figure 44b of Spenser below, the PET 571<sup>4</sup> [blue] is positioned “between the leaflets [570 yellow] and the frame [575 red]”:

---

<sup>4</sup> 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.

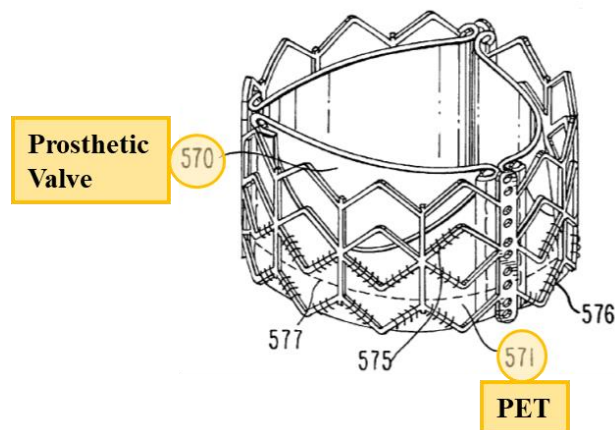
**FIG. 44b**



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

115. As shown in Figure 44b above and Figure 44a below, the PET 571 is positioned radially inwardly of the frame 575:

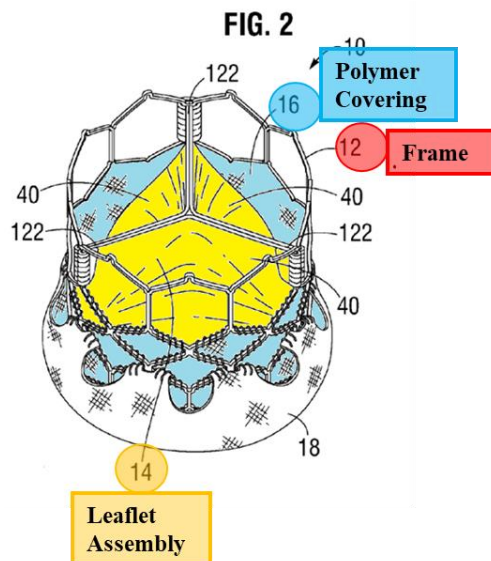
**FIG. 44a**



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

**b. Levi**

116. 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 polymer and, therefore, Levi’s inner skirt is a “polymer covering.” The inner skirt is attached to the valvular structure “via one or more thin PET reinforcing strips” and is thus “engaged with” the leaflet assembly. *Id.* at 9:25-29. Levi’s inner skirt 16 [blue] is positioned radially inwardly of the frame 12 [red] and provides sealing to the leaflets [yellow]:



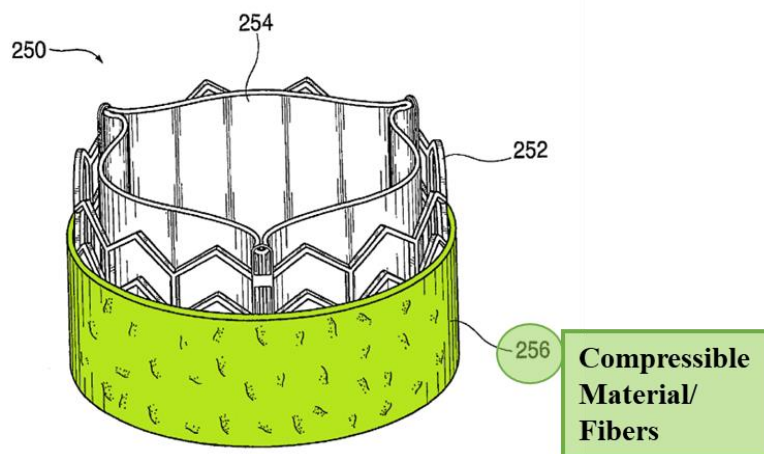
Ex. 1008 (Levi) at Fig. 2.

## 5. Sealing Assembly

117. Claim 1 next recites: “a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage, wherein the sealing assembly extends over each of the at least two rows of cells.” Spenser **or** Levi in combination with Spenser II renders this limitation obvious.

118. 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.

119. 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. Spenser II explains that “[i]n certain configurations the compressible material may resemble a cloth or fabric having

small fibers extending from the surface of the material.” *Id.* The fibers “may be straight, curved or hook-shaped.” *Id.* 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.* Spenser II’s compressible material is therefore a “sealing assembly” as claimed in claim 1.

**a. Spenser and Spenser II**

120. 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) at 64; *see also* Ex. 1118 (’011 FWD) at 68; Ex. 1119 (’538 FWD) at 80-81. I agree with the Board’s conclusion.

121. 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

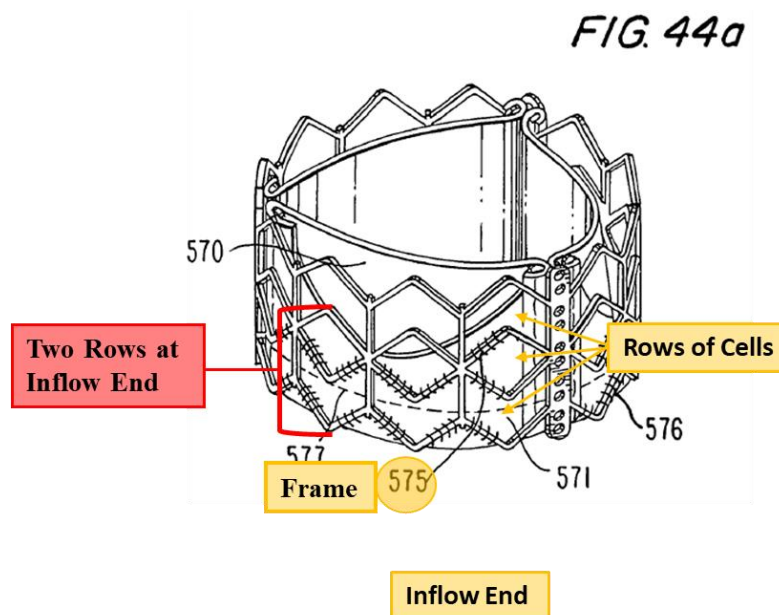
II) at [0009-00010] (explaining that Spenser’s parent application describes similar heart valves but does not address “leaks that can occur around the implanted valve”).

122. 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.

123. 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 open cells that supports prosthetic leaflets, and being radially compressible for endovascular delivery. *See supra* §§ VI.A.2-3; *infra* §VI.A.7. 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

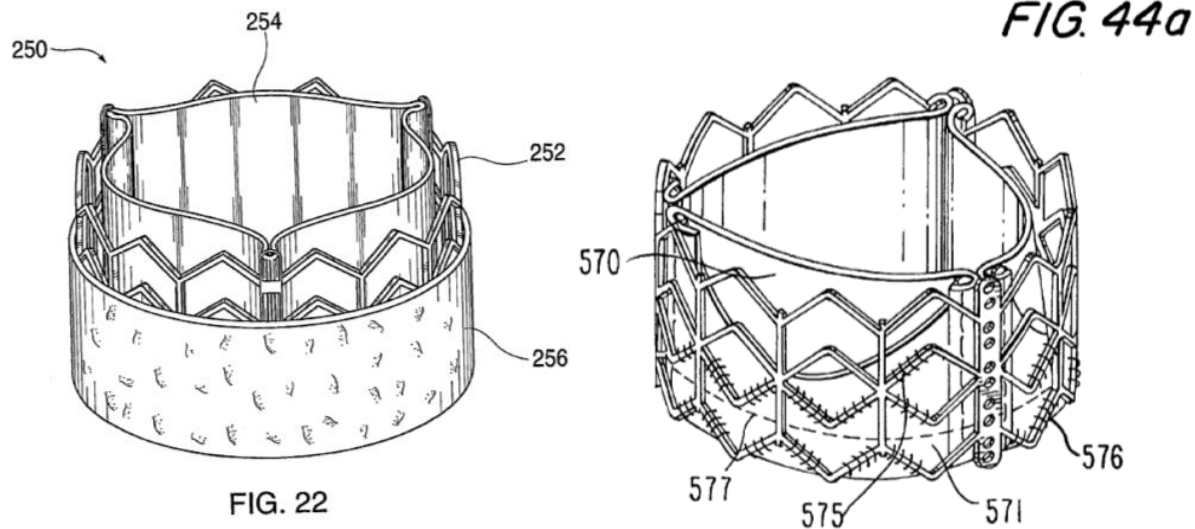
thus have been confident that other sealing structures with superior sealing capabilities, such as Spenser II's compressible material, could be successfully added to Spenser's valves at the inlet. Also, a person of ordinary skill in the art would not have had any concerns about stent foreshortening because 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].

124. As I explained previously, Spenser's Figure 44a includes a frame that has two rows of cells at the inflow end:



Ex. 1010 (Spenser) at Fig. 44a. Spenser's Figure 44a and Spenser II's Figure 22 include similar frames having the same number of rows, and when Spenser II's compressible material is added to Spenser's Fig. 44a, the compressible material

would extend over at least the 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):



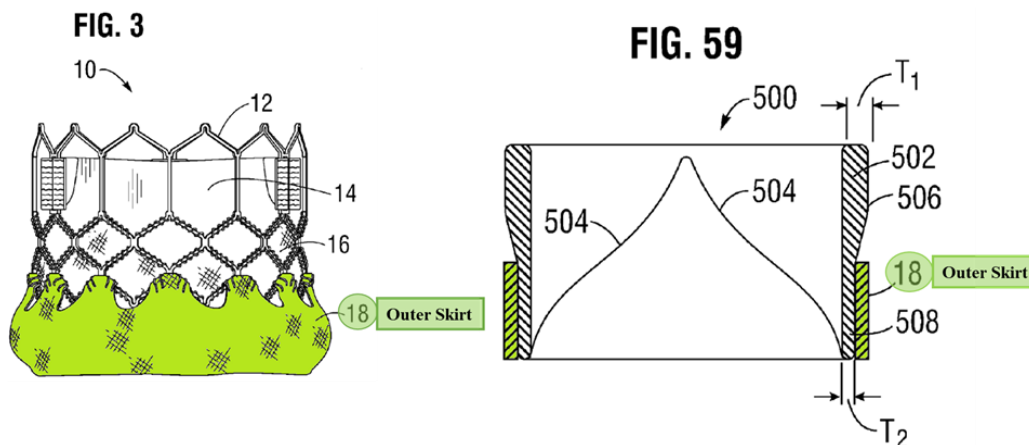
Ex. 1010 (Spenser) at Fig. 44a; Fig. 1011 (Spenser II) at Fig. 22.

125. 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 different cloths having different dimensions and sizes. *Supra* §III.C-D; *infra* §VI.A.7. 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.

**b. Levi and Spenser II**

126. Levi discloses an outer skirt 18 secured to the exterior surface of the frame for preventing PVL. Ex. 1008 (Levi) at 13:50-53, 13:62-66, 16:51-54, 17:12-18.



*Id.* at Figs. 3, 59.

127. 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.

128. 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]. Moreover, while Levi discloses embodiments of the outer skirt that billow away from the frame after expansion, Levi also discloses embodiments where the outer

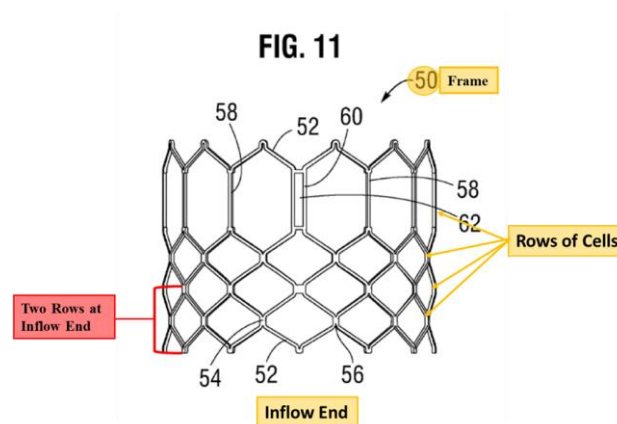
skirt is in contact with the frame after expansion. *See e.g.*, Ex. 1008 (Levi) at 16:51-54, 17:12-18, Fig. 59.

129. 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 compressible. *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.

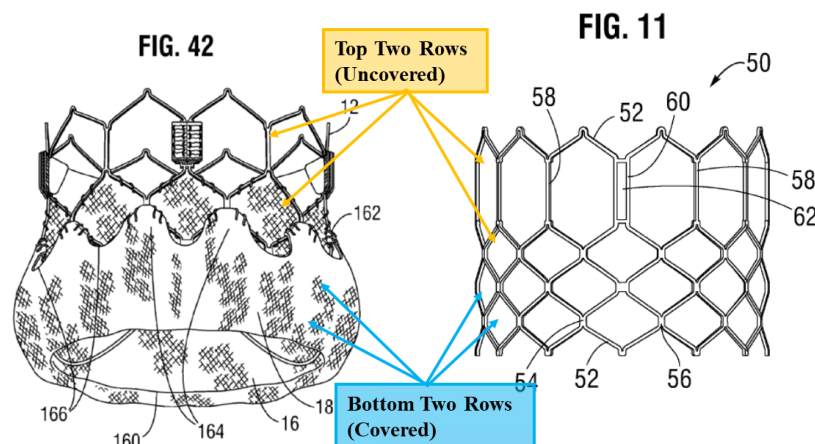
130. Moreover, Levi suggests mounting “**additional components**” to Levi's valve. Ex. 1008 (Levi) at 16:41-45 (emphasis added.) A person of ordinary skill in the art would have understood that Spenser II's compressible material would be a potential “additional component.” Moreover, as I discuss below, 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.

131. As I explained above, Levi's frame includes two rows of cells at the inflow end of the frame:



Ex. 1008 (Levi) Fig. 11. Levi discloses that the outer skirt may be mounted to the “lower half” of the valve, which encompasses the proximal two rows of cells of the frame, as shown in Figure 42:

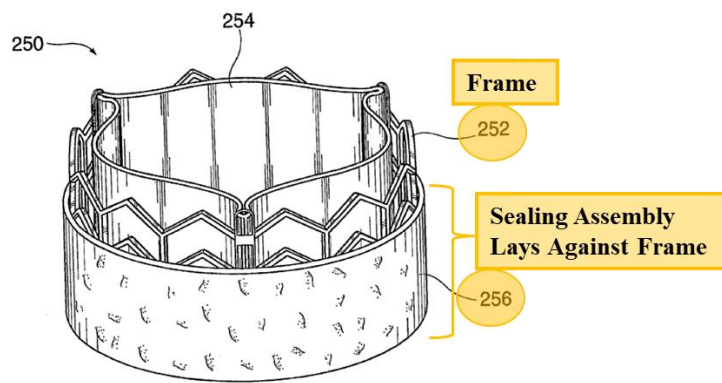


*Id.* at Figs. 11, 42. Spenser II discloses a sealing material that extends over the bottom two rows of cells formed by the frame as I explained above. *Supra* §VI.A.5.a. Thus, persons of ordinary skill in the art would have been motivated to attach Spenser II’s compressible material to Levi’s frame in the same location, and expected success in doing so, because the references demonstrate that extending the material over the bottom two rows creates an effective seal.

**6. Sealing Assembly Lays Against the Frame**

132. Claim 1 next recites: “wherein the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation.” Spenser **or** Levi in combination with Spenser II renders this limitation obvious.

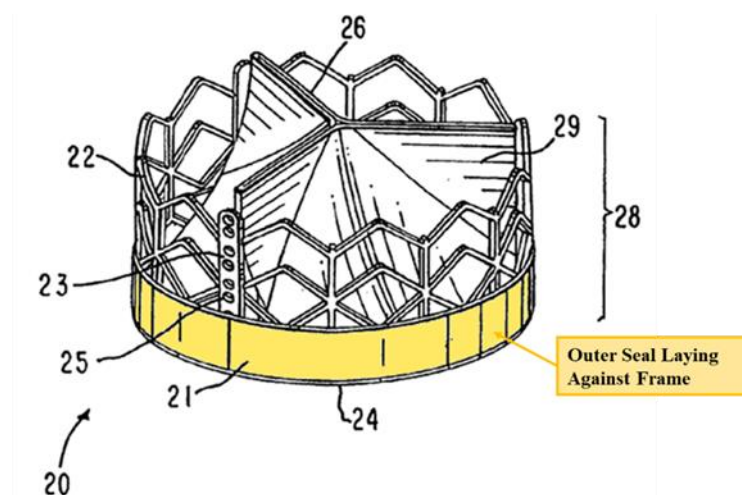
133. Spenser II’s compressible material is “disposed along an outer surface of the stent structure 252,” and therefore, the compressible material (sealing material) “lays against” the frame of the stented valve, as illustrated in Fig. 22:



Ex. 1011 (Spenser II) at [00145], Fig. 22. Figure 22 illustrates the valve in its expanded state; however, the compressible material would similarly lay against the frame when the valve is crimped to its radially compressed orientation because the compressible material is disposed along the exterior of the frame. *Id.* As I explained previously, when the material is compressed, the fibers are forced closer together thereby reducing the spaces between the fibers and decreasing the volume of the material. *See e.g.*, Ex. 1074 (Norris) at 8:45-50 (“the ground layer 20 can have a porosity that can provide some space into which the loops can be compressed”). Consequently, the fibers of the compressible material are more densely packed but still lay against the frame, particularly when the valve is loaded into a crimping apparatus or delivery sheath. *See id.* at 5:7-22 (explaining that the delivery catheter applies “a compressive pressure” on the valve). Additionally, persons of ordinary skill in the art would have appreciated that the compressible material is sutured to the frame in a manner like Spenser’s inner skirt and, therefore, cannot separate from the frame. Ex. 1010 (Spenser) at 26:29-54, Figs. 44a-44c; Ex. 1011 (Spenser II) at [00145], Fig. 22. In fact, in other embodiments, Spenser II expressly discloses outer sealing materials that are sutured to the frame. Ex. 1011 (Spenser II) at [00142], Figs. 20e-20f. Additionally, Walther expressly discloses that its “cloth was stitched onto the perimeter of each SAPIEN valve,” further establishing that a person of ordinary

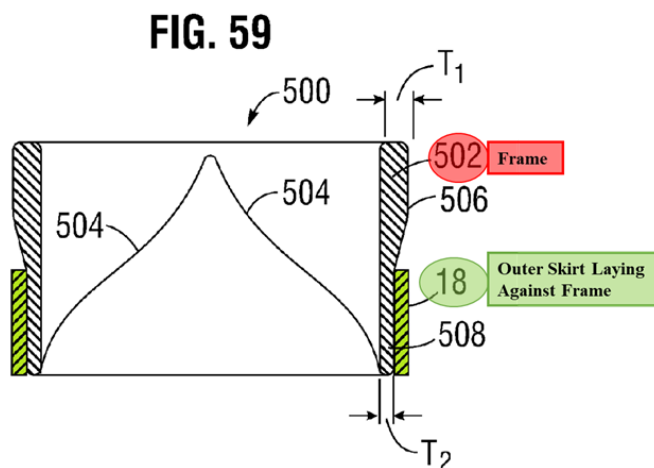
skill in the art would have understood that the compressible material could be stitched to the frame. Ex. 1007 (Walther) at 2. Persons of ordinary skill in the art would have been motivated and expected success in attaching Spenser II's compressible material to Spenser's Figure 44a or Levi's valve in the same way, such that the material would be in contact with the frame of Figure 44a or Levi's valve. Thus, Spenser II's compressible material would lay against Spenser's or Levi's frames when added thereto in both the expanded and compressed orientations.

134. Additionally, both Spenser and Levi disclose embodiments that would have motivated a person of ordinary skill in the art to position Spenser II's compressible material so that it lays against the frame when added to Spenser's or Levi's valves. Spenser discloses an embodiment having an outer seal that lays against the frame at the proximal end:



Ex. 1010 (Spenser) at 13:22-25, Fig. 1. Levi also discloses embodiments having

an outer skirt that lays against the frame:



Ex. 1008 (Levi) at 16:51-54, Fig. 59. Thus, Spenser, Levi, and Spenser II all suggest a sealing assembly that lays against the frame of the THV, and these teachings would have given a person of ordinary skill in the art a reasonable expectation of success in combining Spenser II's compressible material with Spenser's or Levi's valves.

## **7. Endovascularly Deployed**

135. Claim 1 next recites: "wherein the prosthetic heart valve assembly is sized and shaped to be 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**

136. 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 through the femoral artery. 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.

137. 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.

138. 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.

139. 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.

140. 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).

141. 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 an uncompressed, 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.

142. 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 uncompressed, 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.* at 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.

143. 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 would be suitable for endovascular delivery through the femoral artery.

**b. Levi and Spenser II**

144. 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 (Spenser's Parent) at 2:3-13. Indeed, during other IPR proceedings, Patent Owner has admitted that Levi includes transfemoral delivery. *See, e.g.,* Ex. 1124 ('011 POPR) at 37.

145. 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.

146. 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 through the femoral artery.

147. 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.

148. 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.* at 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.

149. 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.

## **8. Spacings in the Sealing Assembly**

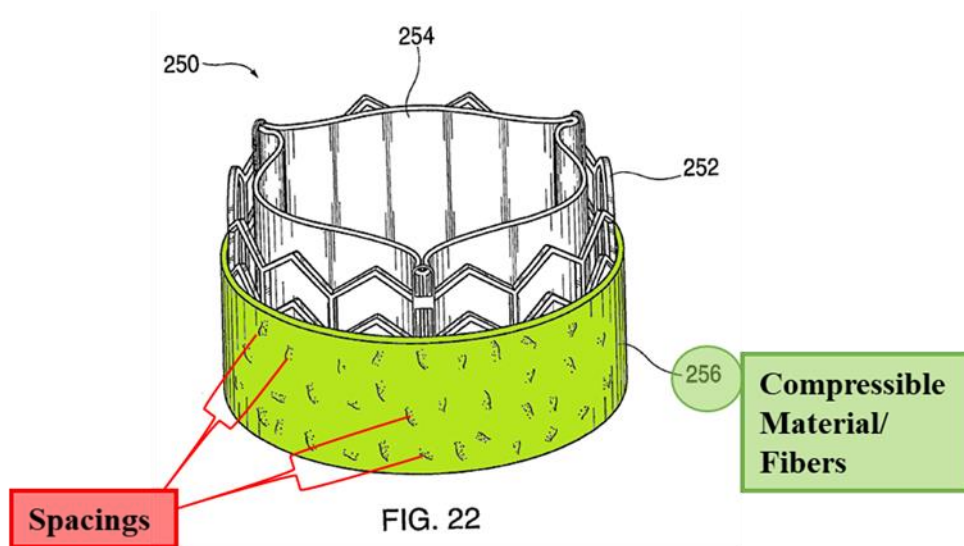
150. Claim 1 next recites: "wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow

fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

151. First, I note that the ’033 patent does not claim or disclose how to size or arrange the fibers to provide “spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state.” *See* Ex. 1001. For example, the ’033 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 ’033 patent also does not disclose the size of the “spacings.” The figures of the ’033 patent illustrate openings that are the width of a cell between the groups or clusters of collagen fibers. *See, e.g.,* Ex. 1001 (’033 Patent) at Figs. 8-9, 11-14. A person of ordinary skill in the art would have understood that fibers openings the width of a cell 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 ’033 patent does not provide any guidance on these aspects. Therefore, persons of ordinary skill in the art would have understood that the ’033 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 '033 patent indicates that any of the figures are drawn to-scale.

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



Ex. 1011 (Spenser II) at [00145], Fig. 22. These illustrated spacings extend “through a thickness of the sealing assembly,” the “thickness” being at least the length of the extending fibers. *See id.* The valve illustrated in Figure 22 is not shown implanted in a native heart valve and is therefore in an “undeployed state.” *Id.*

153. The illustrated spacings in Figure 22 of Spenser II are consistent with the written description of the compressible material. Spenser II describes the

material 256 as “compressible.” *Id.* A person of ordinary skill in the art would have understood that a material must have spaces between the fibers making up the material to be compressible. *See, e.g.*, Ex. 1109 (Ko) at 1048 (“[W]eft knits have high extensibility and are extremely comfortable and compressible.”); Ex. 1110 (Pourdeyhimi) at 172 (“Single jersey [knitted] grafts are inherently more porous than wovens. The increased porosity (see Figure 5) in this class of grafts results in a greater degree of yarn mobility. In consequence, these grafts are more compliant, easier to handle and suture.”); Ex. 1129 (Chu) at 4. Porous materials with spacings between the fibers are also more flexible than tightly woven, nonporous materials, which also contributes to their enhanced compressibility. *See*, Ex. 1109 (Ko) at 1048; Ex. 1110 (Pourdeyhimi) at 172; Ex. 1129 (Chu) at 4.

154. 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 have understood 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:

FIG. 37

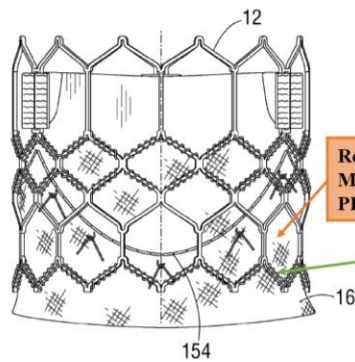
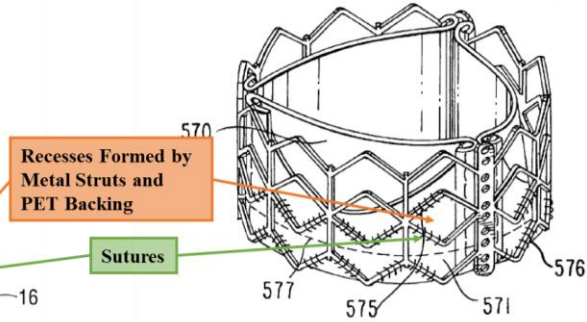
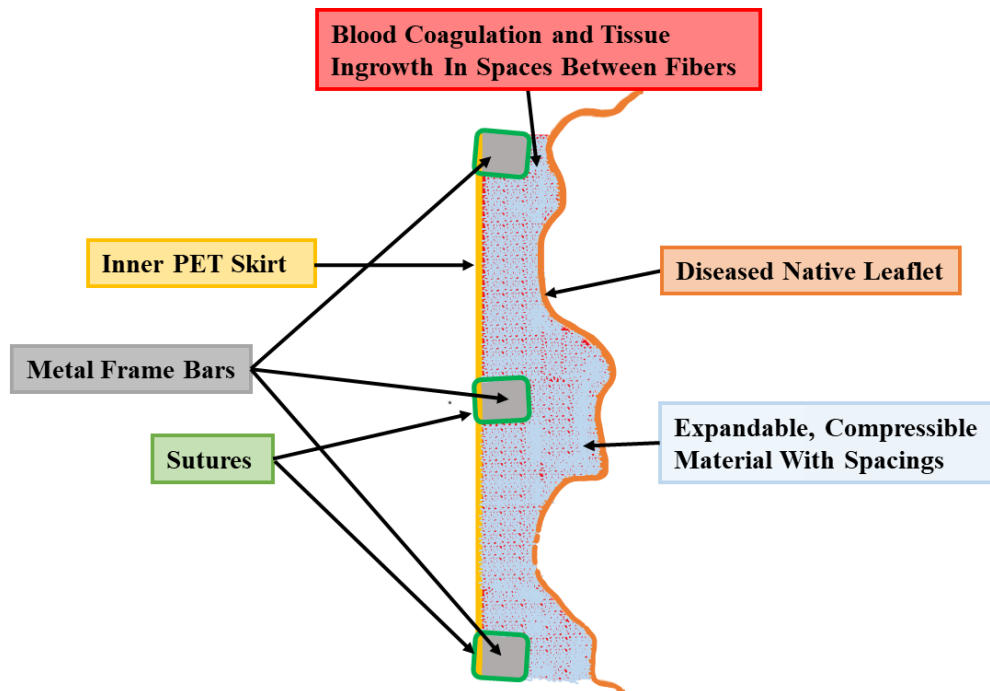


FIG. 44a



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.

155. Spenser II also discloses that the fibers of the compressible material “may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that a fabric, cloth, or other material with spacings

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

156. Persons of ordinary skill in the art would have understood that the spacings between the fibers in Spenser II’s compressible material would have been sufficiently large to allow fluid to pass through the spacings when the material was not compressed for several reasons. First, as I explained above, the compressible material must have spacings in its undeployed state to accommodate the compression of the material, and persons of ordinary skill in the art would have understood that the spacings that permit compression also mean that the material is porous and would permit the flow of fluid therethrough. Second, Spenser II explains that the “compressible material expands after deployment at

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

needed.”). Finally, Spenser II does not contain any suggestion that the porous, compressible material must prevent the flow of fluid thereof in its undeployed state.

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

158. Persons of ordinary skill in the art would have understood that porous velour and velour-like fabrics and cloths would have spacings between the fibers making up the material that extend through a thickness of the fabric and would allow fluid to pass therethrough when the fabric is uncompressed (i.e., in an “undeployed” state). Indeed, because of their permeability, procedures were developed to “preclot” or impregnate the porous velour-like materials used in the prior art with nonporous materials like collagen to temporarily reduce their permeability when the velour materials were used as a vascular or arterial prosthesis, where leakage of blood through the thickness of the material could be harmful to the patient. *See, e.g.*, Ex. 1108 (Jonas) at 657 (“Pretreatments with biological sealants are available to temporarily reduce the porosity of knitted Dacron at the time of implantation with subsequent resorption of the sealant.”); Ex. 1111 (Scott) at Summary (“[W]oven, double velour Dacron vascular graft was made nonporous by coating it with a layer of collagen prepared from fresh, young calf skin.”); Ex. 1112 (Stegmann) at Summary (“The present study describes the clinical application and results of a new knitted Dacron double-velour prosthesis (primary porosity: 1,400cc/min/cm<sup>2</sup>), coated with cross-linked bovine collagen; the resulting porosity for implantation is 0cc/min/cm<sup>2</sup>.”).

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

as Spenser II's compressible material would does not change regardless of whether the fabric/cloth is formed of knitted or woven fibers. Whether a cloth is formed by weaving or knitting does not determine whether the fabric is porous or nonporous. Instead, the porosity of the material is determined by how tightly the fibers of the fabric are packed together. Although knitted fabrics are generally more porous than woven fabrics, both woven and knitted fabrics can be manufactured with varying degrees of porosity and both can have porosities that allow fluid to pass therethrough when uncompressed. *See, e.g.*, Ex. 1129 (Chu) at 4 ("Since the numbers of intersections of both weft and warp yarns are closely related to the mechanical and physical properties of the resulting fabrics, a significant reduction in these numbers would make the fabrics more flexible and porous."); Ex. 1109 (Ko) at 1049 ("By controlling the stitch (loop) density, a wide range of pore geometries can be generated."). Critically, however, persons of ordinary skill in the art would have known that the velour and velour-like fabrics commonly used in the prior art for sealing cardiovascular devices, whether woven or knitted, were designed to be porous to improve compressibility, conformability, and tissue ingrowth. *See, e.g.*, Ex. 1129 (Chu) at 4; Ex. 1106 (Estridge) at 158 ("The most commonly used porous soft tissue biomaterial is Dacron<sup>5</sup> velour. This material has been used extensively as an artificial vascular graft material and in

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

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.”).

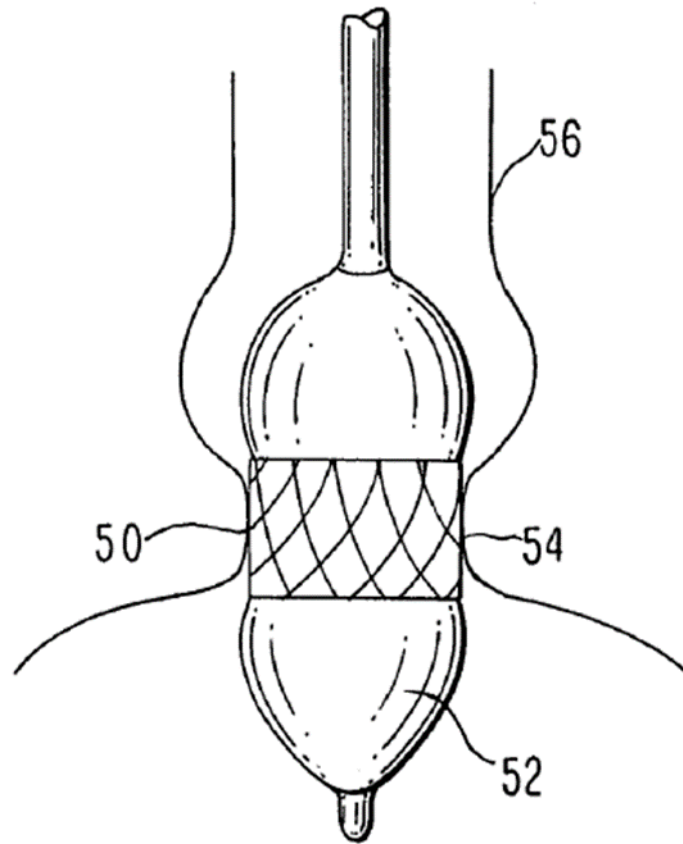
**9. Sealing Assembly Presses Against Native Leaflets**

160. Claim next recites: “wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers relative to the spacings thereby reducing the spacings.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

**a. Spenser and Spenser II**

161. 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.

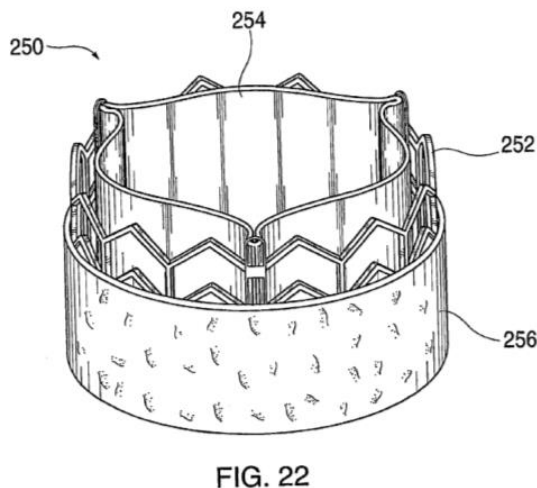
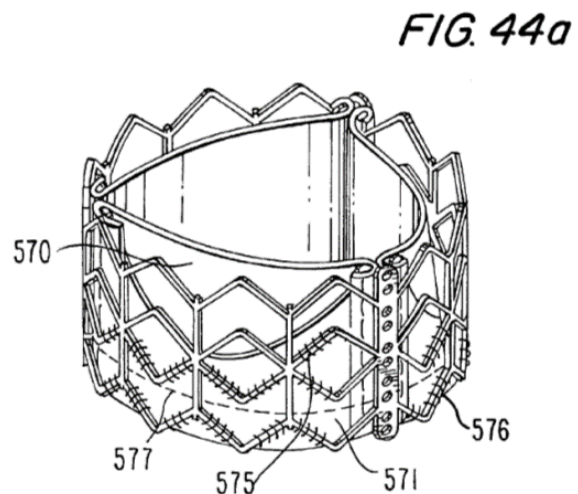
162. Spenser's Figure 4 (below) "depicts deployable valve deployment in a natural aortic valve position in accordance with the present invention":



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.

163. 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):



164. 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* ¶162. This would “impart compression of the sealing assembly [compressible

material] that compresses the plurality of fibers relative to the spacings thereby reducing the spacings.” See, Ex. 1011 (Spenser II) at [00145] (teaching that the compressible material “fills the gaps between the stented valve and the surrounding tissue” which “creates a mechanical seal that prevents paravalvular leakage”).

**b. Levi and Spenser II**

165. 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.

166. 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. This would "impart compression of the sealing assembly [compressible material] that compresses the plurality of fibers relative to the spacings thereby reducing the spacings." See, Ex. 1011 (Spenser II) at [00145] (teaching that the compressible material "fills the gaps between the stented valve and the surrounding tissue" which "creates a mechanical seal that prevents paravalvular leakage").

**10. Polymer Covering Expands Radially Outwardly**

167. Claim 1 next recites: "wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: . . . expands the polymer covering radially outwardly." Spenser **or** Levi in combination with Spenser II renders this limitation obvious.

168. As I explained previously, Spenser's inner PET covering (i.e., polymer covering) is attached to the inner surface of the frame with stitches. *Supra* §VI.A.4.a. Similarly, Levi's inner skirt (i.e., polymer covering) is attached to the inner surface of its frame with stitches. *Supra* §VI.A.4.b. Therefore, when Spenser's or Levi's valve is expanded from the compressed orientation to the

expanded orientation, the polymer covering, which is stitched to the frame, would also “expand radially outwardly.”

#### **11. Compression Creates Paravalvular Seal**

169. Claim 1 finally recites: “wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.” Spenser *or* Levi in combination with Spenser II renders this limitation obvious.

170. Spenser II discloses a compressible material disposed along the frame of a THV “[t]o reduce or prevent paravalvular leakage.” Ex. 1011 (Spenser II) at [00145]. As I explained above, Spenser II illustrates, and persons of ordinary skill in the art would have understood, that Spenser II’s compressible material has spacings extending through a thickness of the material between the fibers of the material. *Supra* §VI.A.8. Spenser II teaches that “[t]he compressible material expands after deployment at a treatment site [and a]s the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue” which “creates a mechanical seal that prevents paravalvular leakage.” Ex. 1011 (Spenser II) at [00145]. These disclosures teach a person of ordinary skill in the art that the fibers of Spenser II’s compressible material would be compressed relative to the spacings between the fibers of the material when the valve is

deployed within a patient, reducing the spacings between the fibers and creating the paravalvular seal around the valve.

171. As explained above, both Spenser and Levi disclose polymer coverings for sealing around the leaflet assembly. *Supra* §VI.A.4. Persons of ordinary skill in the art would therefore have understood that when Spenser II's compressible material is added to Spenser's or Levi's valve, the compressible material and the inner polymer covering would "cooperatively create a paravalvular seal about the frame and the native leaflets." Specifically, the polymer covering would prevent blood from leaking through the open cells of the frame and the compressible material would prevent blood from leaking around the outside of the THV, between the frame and the patient's native tissue.

**B. Claim 2**

172. Claim 2 recites: "The prosthetic heart valve assembly of claim 1, wherein the frame is self-expanding." Spenser and Levi disclose the limitations of claim 2.

173. Spenser's frame can be self-expanding or balloon-expandable. Ex. 1010 (Spenser) at 21:15-34, 26:1-37, Figs. 26a, 43a, 44a. For example, Spenser discloses embodiments of the THV with a self-expanding frame in Figure 26a, which closely resembles the embodiment in Figure 44a:

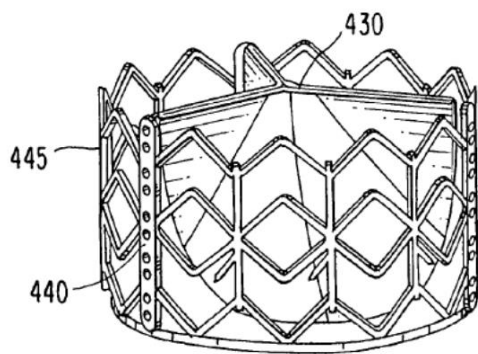


FIG. 26a

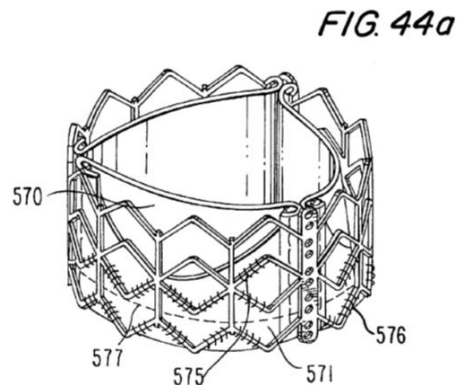


FIG. 44a

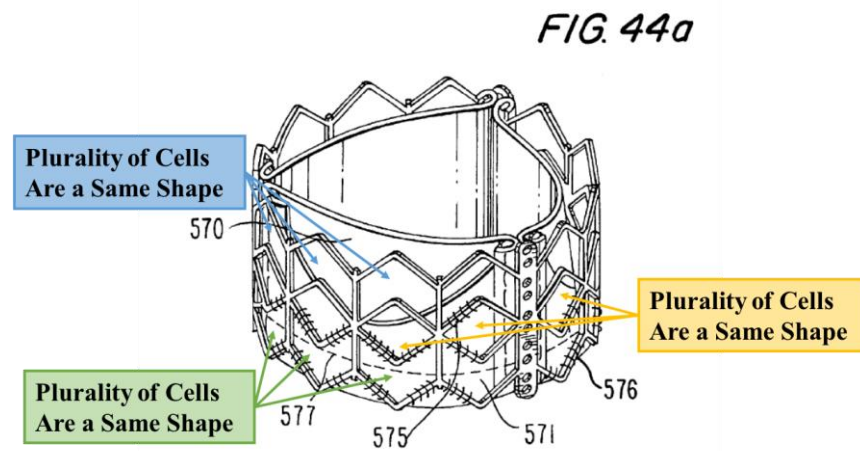
*Id.* at 21:15-34, Figs. 26a, Fig. 44a. Given the similarity of the embodiment in Figure 44a and Figure 26a, persons of ordinary skill in the art would have understood that the valve in Figure 44a may use the self-expanding frame from Figure 26a. Spenser also discloses that the embodiment in Figure 44a “resembles the valve shown in Figure 43,” and Spenser expressly teaches that the valve in Figure 43 is balloon-expandable. *Id.* at 26:1-37. Accordingly, viewing Spenser’s disclosure as a whole, persons of ordinary skill in the art would have understood that Spenser’s valves, including the valve in Figure 44a, may be either self-expanding or balloon-expandable.

174. Levi also discloses that its frame can be self-expanding or balloon-expandable. Ex. 1008 (Levi) at 6:17-30.

#### C. **Claim 4**

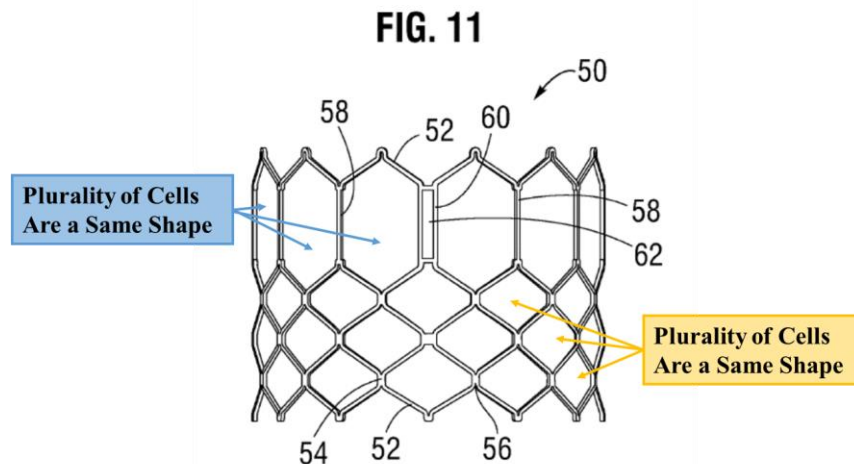
175. Claim 4 recites: “The prosthetic heart valve assembly of claim 1, wherein the plurality of cells are a same shape.” Spenser and Levi disclose the limitations of claim 4.

176. Spenser discloses a frame having a plurality of cells that are a same shape:



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

177. Levi also discloses a frame having a plurality of cells that are a same shape:



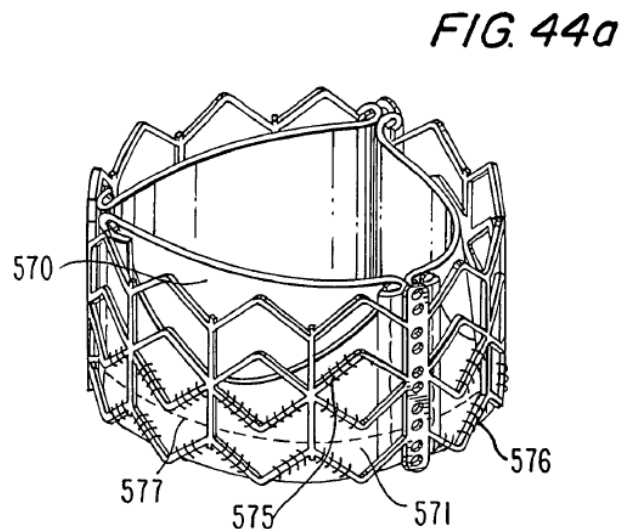
Ex. 1008 (Levi) at Fig. 11.

**D. Claim 5**

178. Claim 5 recites: “The prosthetic heart valve assembly of claim 1, wherein the frame is integrally formed.” Spenser and Levi disclose the limitations of claim 5.

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

180. Spenser’s Figure 44a includes “frame 575,” which is integrally formed:



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

bars of the frame are interconnected, frame 575 is integrally formed. *Id.* at Fig. 44a-44b.

181. Levi's frame is also integrally formed. Levi discloses that its outer frame "comprises multiple rows of circumferentially extending, angled struts 52 [yellow] that are connected to each other at nodes, or connecting portions, 54 and 56 [blue]." Ex. 1008 (Levi) at 8:61-64. Levi further discloses that "[t]he uppermost row of struts 52 are connected to an adjacent row of struts by a plurality of axially extending struts 58 [red] and commissure window frame portions 60 [red]." *Id.* at 8:64-67. Levi's Figures 11-12 illustrate the outer frame:

**FIG. 11**

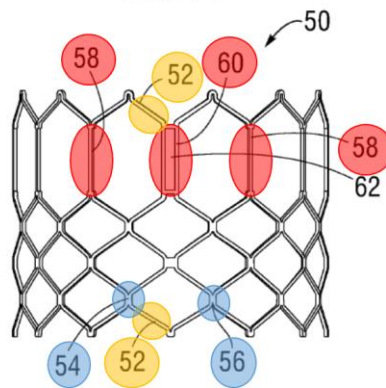
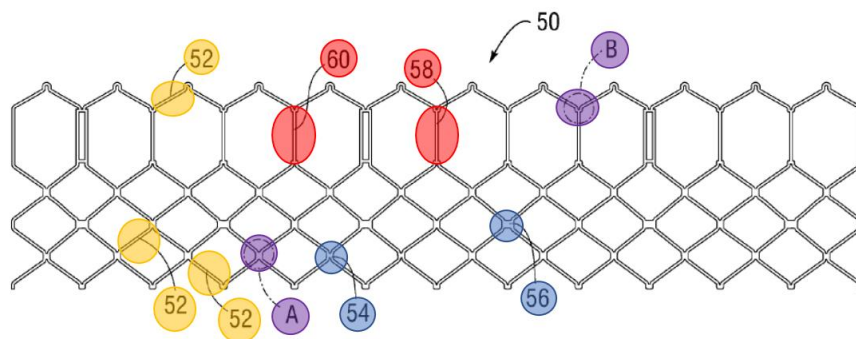


**FIG. 12**



*Id.* at Figs. 11, 12. Because the metallic bars of the outer frame are interconnected, as shown in the figures above, the frame is integrally formed. *See id.* at 6:50-7:17, 9:4-6, Figs. 4-10, 13-14.

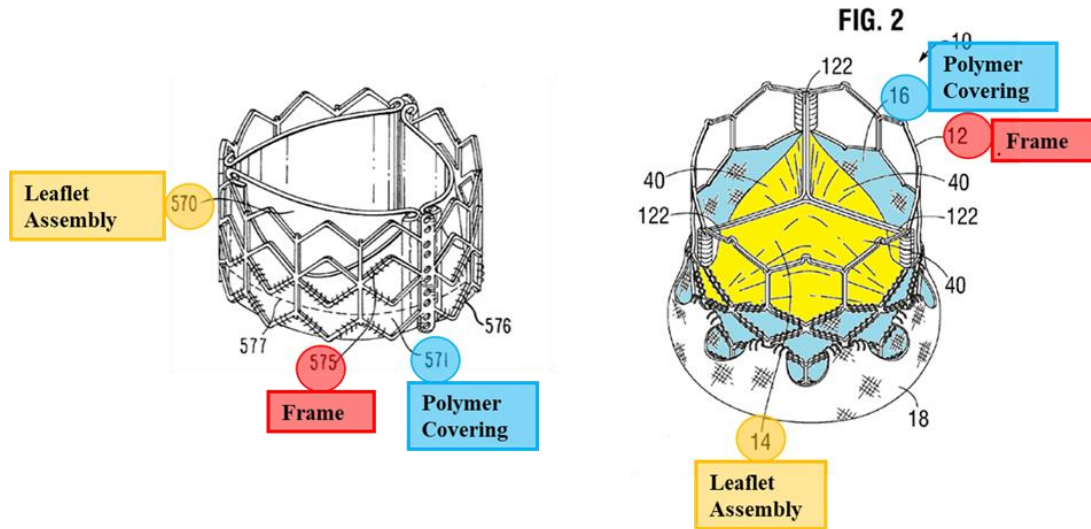
**E. Claim 6**

182. Claim 6 recites: “The prosthetic heart valve assembly of claim 1, wherein the plurality of fibers define fibers that extend outwardly to a tip of each respective fiber.” Spenser *or* Levi in combination with Spenser II renders this claim obvious.

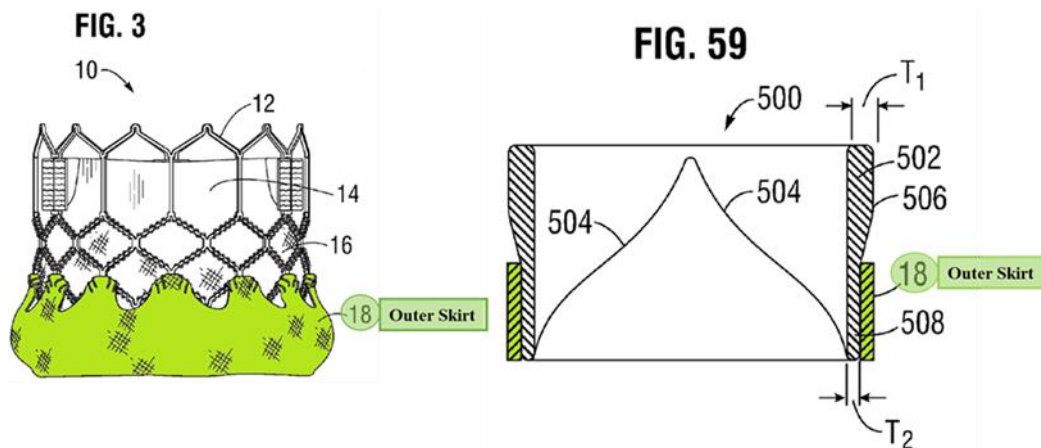
183. Spenser II discloses a compressible material (i.e., sealing assembly) disposed along the frame of a TVH that “[i]n certain configurations may resemble a cloth or fabric having small fibers extending from the surface of the material.” Ex. 1011 (Spenser II) at [00145]. The fibers “may be straight, curved or hook-shaped.” *Id.* Persons of ordinary skill in the art would have understood that Spenser II’s “straight, curved or hook-shaped” fibers that extend from the compressible material would “extend outwardly to a tip of each respective fiber.”

**VII. GROUNDS 3-4: CLAIMS 1-2 AND 4-6 OBVIOUS OVER SPENSER  
OR LEVI IN COMBINATION WITH CHUTER**

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

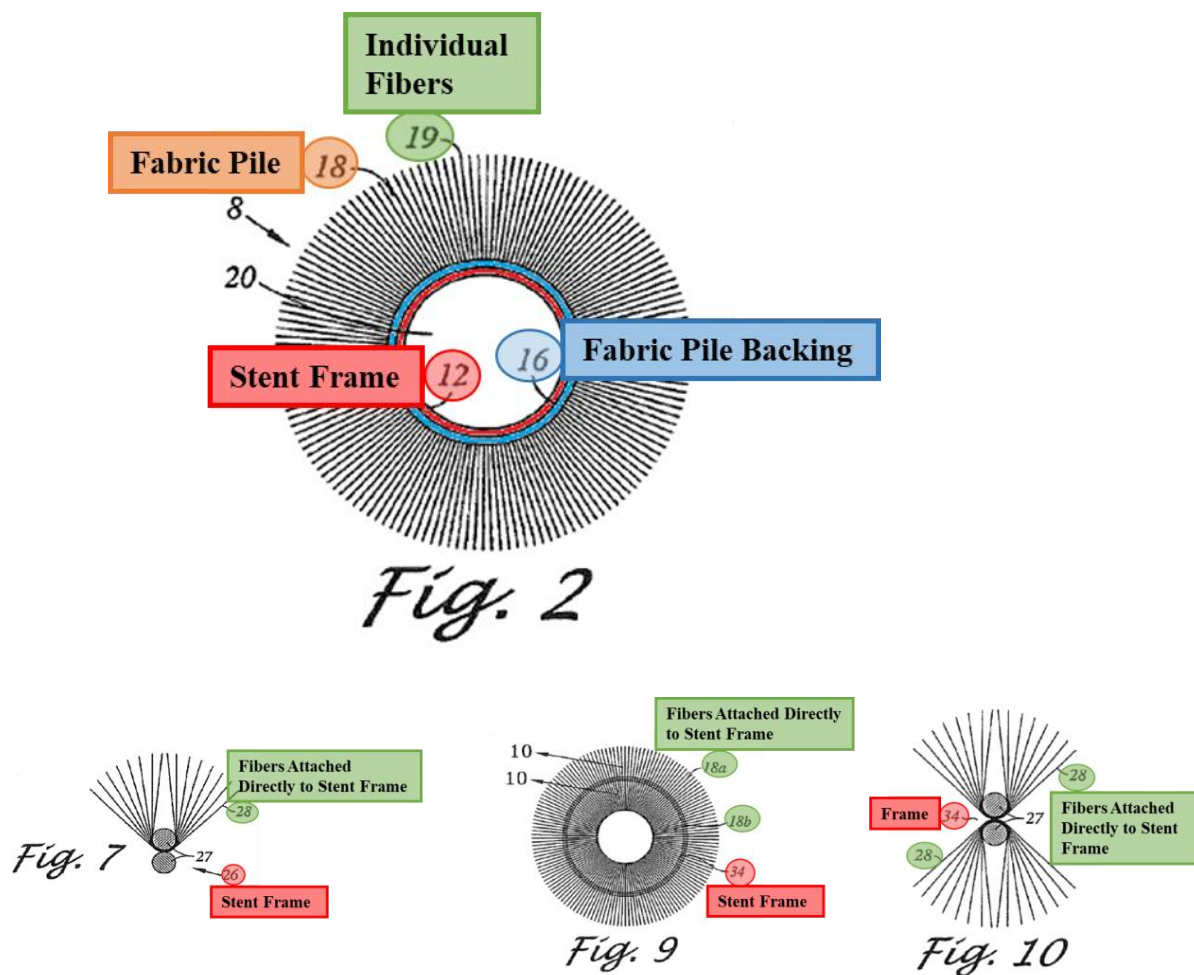


Ex. 1010 (Spenser) at 11:66-12:17, Fig. 44a; Ex. 1008 (Levi) at Fig. 2. Levi also discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame for preventing PVL. Ex. 1008 (Levi) at 13:50-66, 16:51-54, 17:12-18, Figs. 3, 59.



185. Chuter discloses embodiments of endovascularly delivered intravascular stents for either maintaining patency or occluding diseased vessels. See Ex. 1116 (Chuter) at Abstract, [001]. Chuter discloses stents having a “fiber pile” attached to the stent frame that is composed of outwardly extending

individual fibers which are “adapted to form a foundation for tissue growth between the fiber pile and the luminal wall of a vascular vessel.” Chuter teaches that the individual fibers of the “fiber pile” can either extend from a “fabric pile backing” (Fig. 2) or they can be attached directly to the frame without any backing (Figs. 7, 9-10), as shown in Figures 2, 7, and 9-10 below:



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

186. 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 1-2 and 4-6.

**A. Claim 1**

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

**1. Preamble**

188. The preamble of claim 1 recites: "An endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient." If this preamble is limiting Spenser or Levi in combination with Chuter renders this limitation obvious for the reasons I explained in Grounds 1-2 above for endovascular delivery, *supra* §VI.A.1, and sections VII.A.5-7 below for both endovascular delivery and "improved sealing for addressing paravalvular leakage."

## **2. Frame**

189. Claim 1 next recites: “a frame formed of a plurality of cells, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, 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.2.

## **3. Leaflet Assembly**

190. 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.3.

## **4. Polymer Covering**

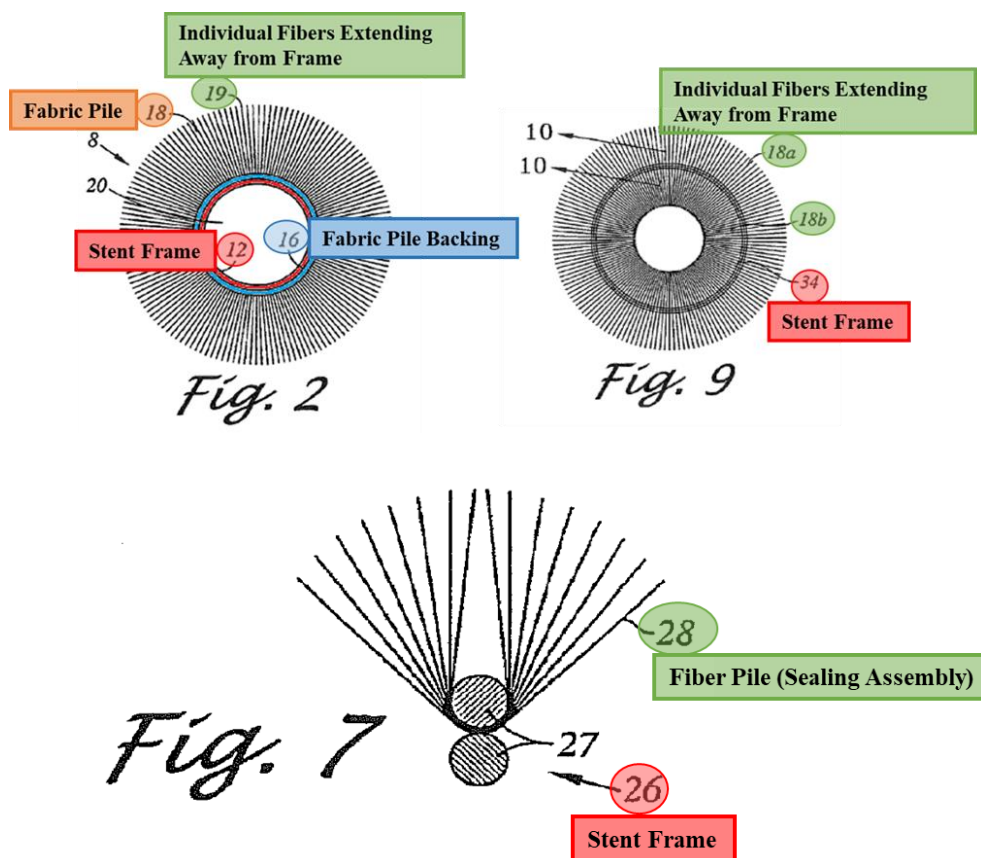
191. Claim 1 next recites: “a polymer covering about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* § VI.A.4.

## **5. Sealing Assembly**

192. Claim 1 next recites: “a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage, wherein the sealing assembly extends over each of the at

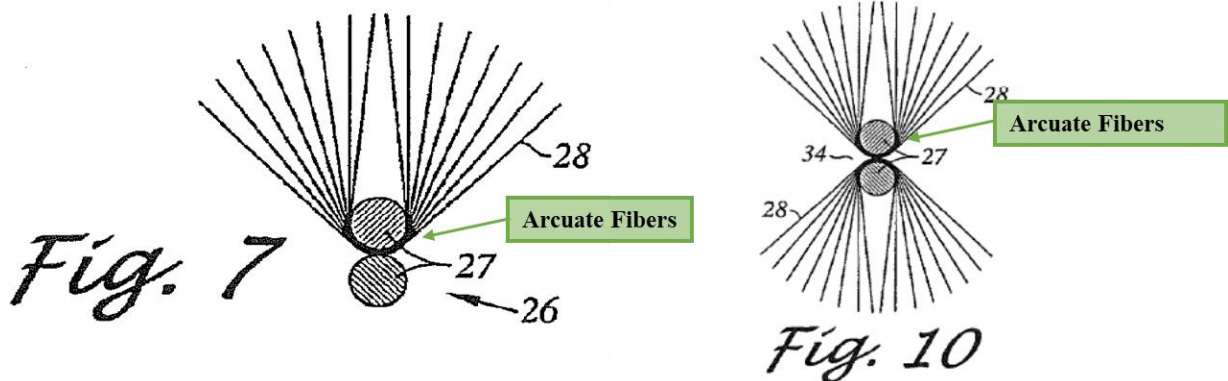
least two rows of cells.” Spenser *or* Levi in combination with Chuter renders this limitation obvious.

193. 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, 7, and 9:



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

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



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

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

196. Chuter also discloses that the "fibers of the fiber pile are biocompatible fibers which are known to the art" and may "include nylon fibers, polyester fibers, Mylar brand fibers and the like" and further teaches that the fibers are flexible and get "push[ed] down" when the device is crimped. *Id.* at [0022], [0062]. Persons of ordinary skill in the art would therefore have

understood that while Chuter's figures illustrate portions of the fibers as straight, not all (and likely none) of the fibers would have been perfectly straight, and at least some of the flexible fibers would be arcuate.

**a. Spenser and Chuter**

197. 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 have merely entailed applying Chuter's known technique for reducing leaks around a frame (adding a fabric pile) to Spenser's known valves, which were ready for improvement and, as discussed below, would yield predictable results.

198. 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.

199. First, Chuter teaches that its invention can be employed on a variety of stents, including both self-expanding and balloon-expandable stents. Ex. 1116, [0003]. Indeed, Chuter discloses that its fiber pile may be used on the same balloon-expandable stent frames described in the '033 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 '033 patent similarly incorporates by reference U.S. Patent No. 5,102,417 for "[e]xamples of balloon-expandable stents." Ex. 1001 ('033 patent) at 7:46-53. The '417 patent, which is incorporated into the '033 patent, is a continuation-in-part of the '762 patent incorporated in Chuter, and those two patents disclose the same balloon-expandable stent frames. See Ex. 1127 ('417 patent); Ex. 1126 ('762 patent).

200. Second, Chuter teaches that “[v]irtually any expanding stent can be used in” its embodiment “having a fiber pile on its external surface about the tubular side wall of the stent, the graft made of fiber adapted to form a foundation for tissue growth between the luminal wall and the endovascular prosthesis to incorporate the endovascular prosthesis with the vascular vessel.” Ex. 1116 (Chuter) at [0012]. As I explained above, persons of ordinary skill in the art would have understood that the frame in Spenser’s Figure 44a is an expanding stent frame. *Supra* §VI.A.2. While the preferred embodiment in Chuter includes a double-wire frame, Chuter’s invention is not limited to such frames and encompasses many frames. Accordingly, persons of ordinary skill in the art would have understood that Chuter’s teaching of individual outwardly extending fibers secured directly to a stent frame would broadly apply to “[v]irtually any expanding stent,” including the expanding stent frame taught by Spenser.

201. Additionally, the ’033 patent never discloses how the collagen fibers, or any other fibers, are attached to the frame of the described valves, and thus the patent presumes that persons of ordinary skill in the art would have known how to attach individual fibers to the frame of a THV. *See* Ex. 1001 (’033 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 '033 patent, does not provide “an explicit description of how [the collagen fibers] are attached or secured other than stating that they are attached and secured, and the assumption is that that would be by known biomedical engineering methods.” Ex. 1073 (Brecker Tr. Vol. II), 313:18-314:1. This same “assumption” would also need to apply to Chuter’s fiber pile.

202. Spenser discloses two rows of cells at the inflow end of the frame as I explained in Grounds 1-2. *Supra* §VI.A.2. Persons of ordinary skill in the art would have found it obvious to position Chuter’s fabric pile to extend over at least the proximal two rows of cells on Spenser’s valves and would have been motivated to do so to ensure that the extending fibers of the fiber pile would overlap with, and press against, the patient’s diseased native aortic leaflets when the valve was implanted, which is necessary for the fibers to form a seal and fill gaps between the native leaflets and the THV. Moreover, multiple references, including Levi and Spenser II, disclosed that having fibers that extend over at least the proximal two rows of cells provided effective sealing. *See* Ex. 1011 (Spenser II) at [00145], Fig. 22; Ex. 1008 (Levi) at Fig. 42.

**b. Levi and Chuter**

203. Persons of ordinary skill in the art would have been motivated to replace 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.5.b, VII.A.5.a. 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), [0012]-[0013], [0017]-[0020], [0064]. Thus, replacing Levi's outer skirt with Chuter's fiber pile would have merely entailed substitution of one known element (Chuter's fiber pile) for another (Levi's outer skirt) to yield the predictable results of reducing PVL.

204. 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 and Chuter. *Supra* §VII.A.5.a.

205. Levi discloses two rows of cells at the inflow end of the frame as I explained in Grounds 1-2. *Supra* §VI.A.2. 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 Levi's valves and would have been motivated to do so to ensure that the extending fibers of the fiber pile would overlap with, and press against, the patient's diseased native aortic leaflets when the valve was implanted, which is necessary for the fibers to form a seal and fill gaps between the native leaflets and the THV. Additionally, Levi discloses a sealing material

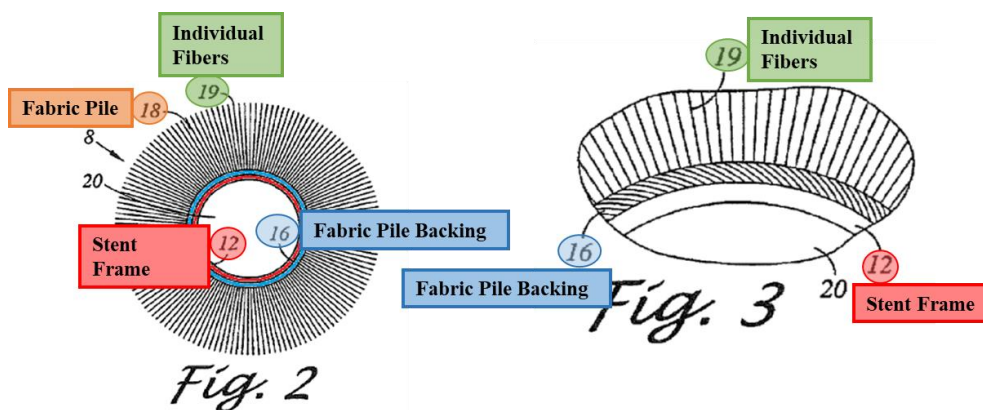
extending over the proximal two rows of cells, providing persons of ordinary skill with further motivation to select such an arrangement for Chuter's fiber pile.

## 6. Sealing Assembly Lays Against the Frame

206. Claim 1 next recites: "wherein the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation." Spenser *or* Levi in combination with Chuter renders this limitation obvious.

207. Chuter discloses this limitation in two ways.

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



Ex. 1116 (Chuter) at [0054]-[0055], Figs. 2-3. Persons of ordinary skill in the art would have understood that the "fabric pile backing" is composed of fibers, as illustrated in Chuter's Figure 3. *Id.* at Fig. 3. Such a configuration was well known in the prior art. For example, the Norris reference discloses a compressible

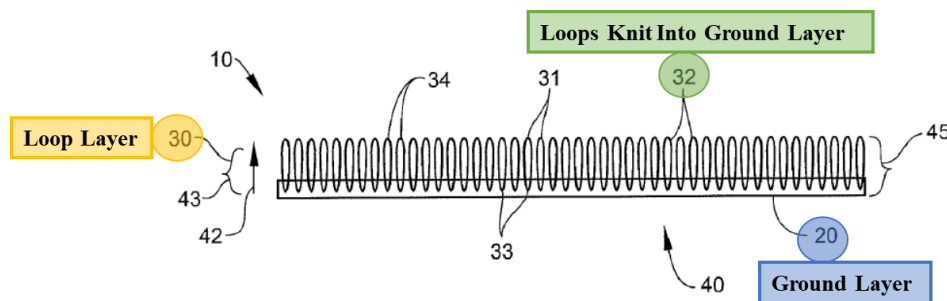
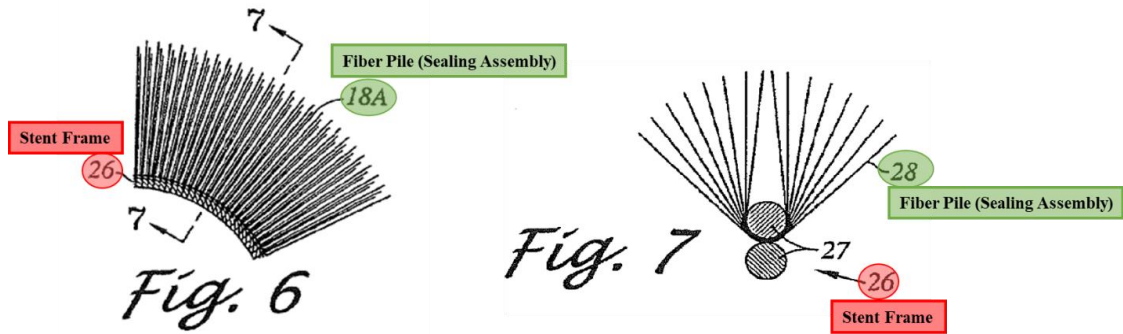


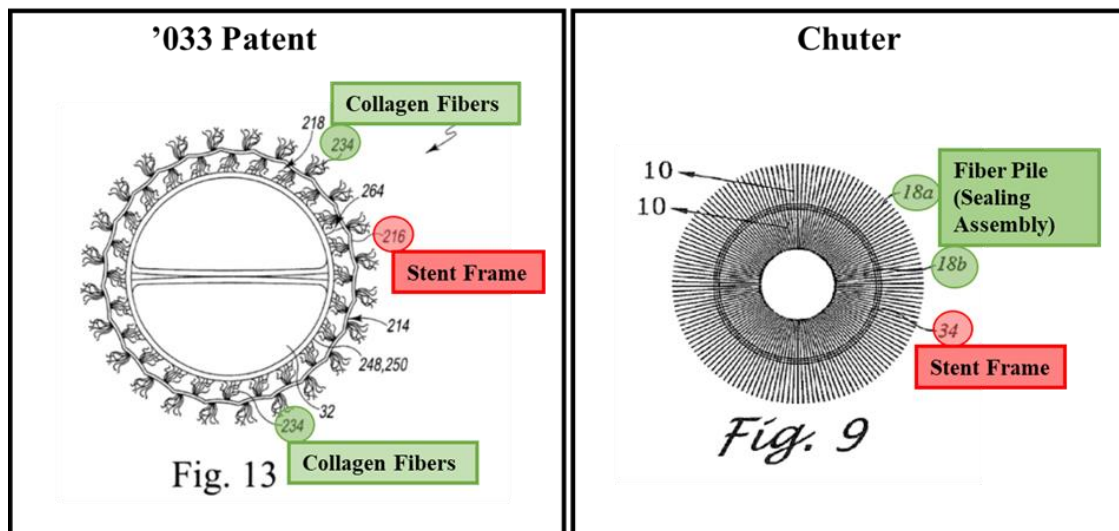
Fig. 1

See Ex. 1074 (Norris) at 4:22-26, Fig. 1. As illustrated in Chuter's Figures 2 and 3 above, the fibers of Chuter's fabric pile backing lay against the stent frame. Ex. 1116 (Chuter) at Figs. 2-3. Persons of ordinary skill in the art would have understood that the fiber pile would lay against the frame in both the expanded and compressed orientations because Chuter teaches that the backing is attached directly to the frame and persons of ordinary skill in the art would have been motivated to attach Chuter's fiber pile to Spenser's and Levi's valves in the same way. Persons of ordinary skill in the art would have further been motivated to securely attach the fiber pile to the frame to prevent the fibers from separating in the patient, which could cause significant injury. Therefore, the fiber pile lays against the frame when the valve is compressed or expanded.

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



Ex. 1116 (Chuter) at [0056]-[0057], Figs. 5-10. As illustrated in Figures 6 and 7, the fibers in these embodiments lay against the stent frame. *Id.* at [0057], Figs. 6-7. Persons of ordinary skill in the art would have been motivated to use such an arrangement when adding Chuter's fiber pile to Spenser's or Levi's valves because it would minimize the amount of material that is added to the exterior of the valve, reducing the overall impact on the crimped profile of the valve. Notably, in such embodiments, Chuter's fibers lay against the frame in the same way as the collagen fibers depicted in the '033 patent:



*Compare* Ex. 1001 ('033 patent) at Fig. 13 *with* Ex. 1116 (Chuter) at Fig. 9. Persons of ordinary skill in the art would have understood that the fibers would lay against the frame in both the expanded and compressed orientations because Chuter teaches attaching the fibers directly to the frame and persons of ordinary skill in the art would have been motivated to secure the fiber pile to Spenser's and Levi's valves in the same way. And as I explained above, persons of ordinary skill in the art would have been motivated to securely attach the fibers to the frame to ensure that the fibers cannot separate from the frame, when the valve is compressed or expanded, so the fibers would lay against the frame in both positions.

## **7. Endovascularly Deployed**

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

211. 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.

212. 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.* at [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.

213. 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.

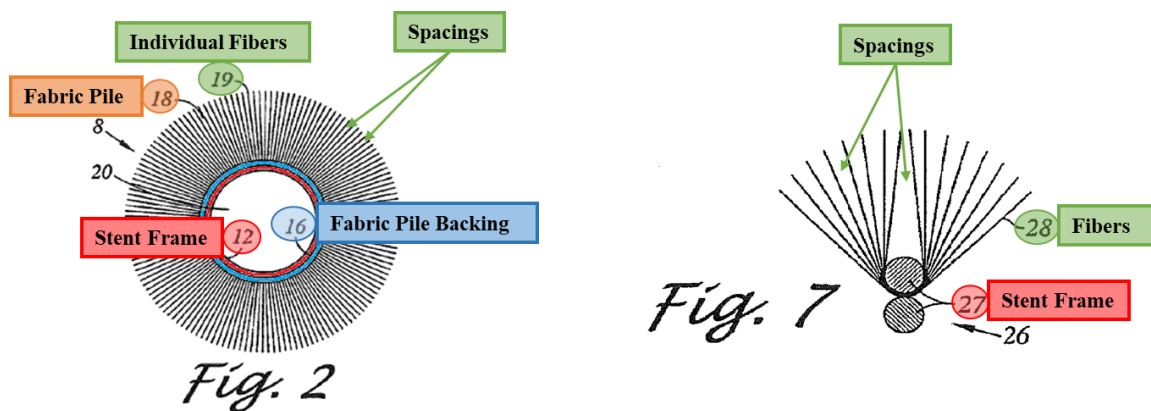
214. Further, as I explained in Grounds 1-2, Levi teaches numerous methods for adapting its valves to allow for an external sealing material, such as Chuter's fiber pile, to be added to the valve without significantly impacting the crimped profile. *Supra* §VI.A.7. These teachings would have further 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. Spacings in the Sealing Assembly**

215. Claim 1 next recites: "wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state." Chuter discloses this limitation.

216. As I explained above, Chuter discloses embodiments wherein the fiber pile includes a fabric pile backing and embodiments wherein the individual

fibers of the fiber pile are attached directly to the frame. *Supra* §VII.A.5. In both embodiments, there are spacings between the individual fibers in the fiber pile that “extend through a thickness” of the fiber pile (i.e., sealing assembly) and would “allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state.” See Ex. 1116 (Chuter) at Figs. 2, 7. These spacings are illustrated in Figures 2 and 7 of Chuter:



*Id.* at Figs. 2, 7. Indeed, persons of ordinary skill in the art would have understood that when the individual fibers of the fiber pile are attached directly to struts of Spenser’s or Levi’s frames, consistent with Chuter’s teachings regarding the embodiment illustrated in Figure 7, there would necessarily be spacings between adjacent fibers that span at least the width of the open cells between the struts. This is because there would be no fibers, or other material, traversing the openings between the struts, as would be the case when a backing is employed. Persons of ordinary skill in the art would have further understood that spacings spanning the width of the open cells would allow fluid to pass therethrough when

the valve is undeployed, meaning that the fibers have not been compressed against the patient's tissue to form a seal.

217. Adding Chuter's fiber pile to Spenser's or Levi's valve would not change the spacings or porosity of the material when the valve is undeployed, meaning that the fibers have not been compressed against the patient's native tissue to form a seal. Like the '033 patent, Chuter illustrates plainly visible spacings between the fibers. Persons of ordinary skill in the art would have understood that such visible spacings would be large enough to allow fluid to pass therethrough when the fibers are in an uncompressed state. Persons of ordinary skill in the art would have been motivated to attach the fiber pile to Spenser's or Levi's frames in the same way they are attached to Chuter's frame.

#### **9. Sealing Assembly Presses Against Native Leaflets**

218. Claim 1 next recites: "wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers relative to the spacings thereby reducing the spacings." Spenser *or* Levi in combination with Chuter renders this limitation obvious.

219. 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. *Supra* §VI.A.9. 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” 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 diseased leaflets to prevent blood from flowing around the outside of the THV. Persons of ordinary skill in the art would have understood that when Chuter’s fibers are pressed against the patient’s native leaflets, this would “impart compression” of the fibers relative to the spacings thereby reducing the spacings because persons of ordinary skill in the art would have known that nylon, polyester, or Mylar brand fibers, such as those disclosed in Chuter, would be flexible and compressible. *See id.* at [0022].

**10. Polymer Covering Extends Radially Outwardly**

220. Claim 1 next recites: “wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: . . . expands the polymer covering radially outwardly.” Spenser and Levi disclose this limitation for the reasons I explained in Grounds 1-2. *Supra* §VI.A.10.

## 11. Compression Creates Paravalvular Seal

221. Claim 1 finally recites: “wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.” Spenser **or** Levi in combination with Chuter renders this limitation obvious.

222. As I explained above, Chuter teaches endovascular stents having a fiber pile comprised of outwardly extending polymeric or nylon fibers that “press against the inner luminal wall of the arterial system to form a seal” when the stent is implanted. Ex. 1116 (Chuter) at [0059]. Persons of ordinary skill in the art would have understood that when Chuter’s fiber pile is added to Spenser’s or Levi’s valves, the fiber pile would press against the patient’s native aortic leaflets when the valves are implanted, reducing the spacings between the fibers of the fiber pile and forming a paravalvular seal around the valve. *Supra* §VII.A.9.

223. As I explained above, both Spenser and Levi disclose polymer coverings for sealing around the leaflet assembly. *Supra* §VI.A.4. Persons of ordinary skill in the art would therefore have understood that when Chuter’s fiber pile is added to Spenser’s or Levi’s valve, the fiber pile and the inner polymer covering would “cooperatively create a paravalvular seal about the frame and the native leaflets.” Specifically, the polymer covering would prevent blood from

leaking through the open cells of the frame and the fiber pile would prevent blood from leaking around the outside of the THV, between the frame and the patient's native tissue.

**B. Claim 2**

224. Claim 2 recites: “The prosthetic heart valve assembly of claim 1, wherein the frame is self-expanding.” Spenser and Levi disclose the limitations of claim 2 for the reasons I explained in Grounds 1-2. *Supra* §VI.B. Chuter also discloses that its fiber pile can be used on either self-expanding or balloon-expandable frames. Ex. 1116 (Chuter) at [0003], [0011].

**C. Claim 4**

225. Claim 4 recites: “The prosthetic heart valve assembly of claim 1, wherein the plurality of cells are a same shape.” Spenser and Levi disclose the limitations of claim 4 for the reasons I explained in Grounds 1-2. *Supra* §VI.C.

**D. Claim 5**

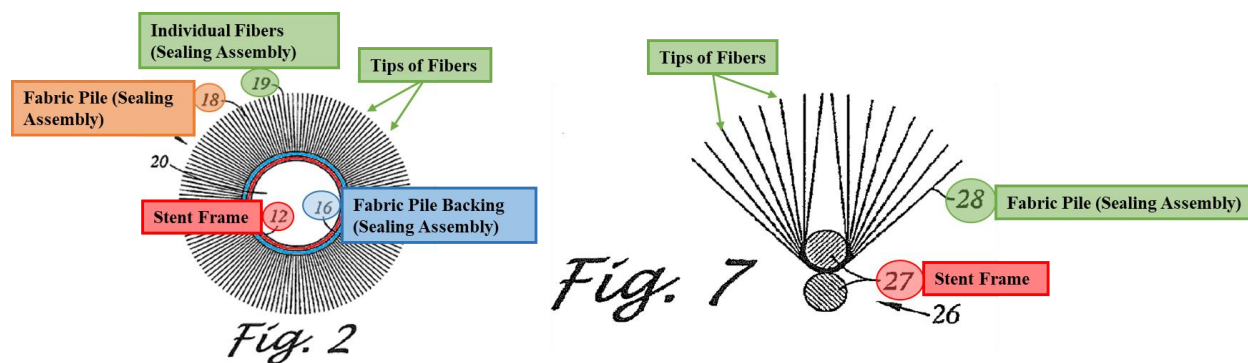
226. Claim 5 recites: “The prosthetic heart valve assembly of claim 1, wherein the frame is integrally formed.” Spenser and Levi disclose the limitations of claim 4 for the reasons I explained in Grounds 1-2. *Supra* §VI.D.

**E. Claim 6**

227. Claim 6 recites: “The prosthetic heart valve assembly of claim 1, wherein the plurality of fibers define fibers that extend outwardly to a tip of each

respective fiber.” Spenser *or* Levi in combination with Chuter renders this claim obvious.

228. The individual extending fibers of Chuter’s fiber pile (i.e., sealing assembly) extend outwardly to a tip of each respective fiber, as illustrated in Figures 2 and 7:



Ex. 1116 (Chuter) at Figs. 2, 7.

#### **VIII. GROUNDS 5-6: CLAIMS 1-2 AND 4-6 OBVIOUS OVER SPENSER OR LEVI IN COMBINATION WITH CHUTER AND SPENSER II**

229. As I explained above, Spenser *or* Levi in combination with Chuter renders obvious claims 1-2 and 4-6 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.

230. 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.5. 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 1-2 and 4-6 would have been obvious over the combination of Spenser *or* Levi with Chuter and Spenser II.

#### **IX. SECONDARY CONSIDERATIONS**

231. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '033 patent. For example, I am not aware of any products sold by Patent Owner that would be covered by the '033 patent and, therefore, I am not aware of any commercial success.

232. Further, given that the devices claimed in the '033 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.

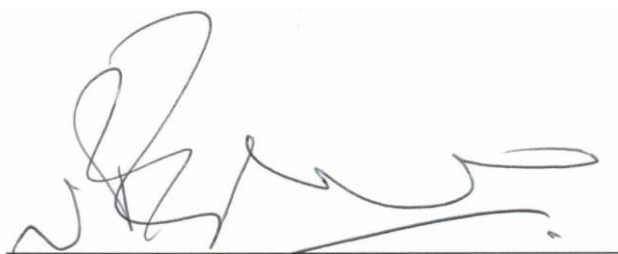
## **X. CONCLUSION**

233. For the foregoing reasons, it is my opinion that claims 1-2 and 4-6 of the '033 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.

234. 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.

235. 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 August 14, 2023.



Dr. Nigel P. Buller