

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC**

Petitioners,

v.

Aortic Innovations, LLC

Patent Owner.

IPR2022-00556

Patent No. 10,987,236

**DECLARATION OF NIGEL BULLER, M.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,987,236**

<i>Edwards v. Aortic Innovations</i> U.S. Patent 10,987,236 Edwards Ex. 1003
--

TABLE OF CONTENTS

Page No.

I. INTRODUCTION	1
A. Engagement	1
B. Experience and Qualifications	2
C. Topics of Opinions	7
D. Materials Considered.....	8
II. APPLICABLE LEGAL STANDARDS	8
A. Claim Construction.....	8
B. Anticipation.....	9
C. Obviousness.....	9
D. Person of Ordinary Skill in the Art	13
III. BACKGROUND OF HEART VALVE TECHNOLOGY.....	14
A. Anatomy of the Heart and Background of Aortic Stenosis and Regurgitation	14
B. Anatomy of the Aortic Valve.....	19
C. Surgical Prosthetic Heart Valves.....	22
D. Transcatheter Heart Valve (“THV”) Technology	25
IV. THE ’236 PATENT	46
A. Summary of the ’236 Patent.....	46
B. The Challenged Claims	49

TABLE OF CONTENTS
(cont'd)

	Page No.
C. Prosecution History	51
V. SUMMARY OF IPR GROUNDS	54
VI. GROUND 1: CLAIMS 1-4 OBVIOUS OVER CRIBIER AND WALTHER.....	55
A. Claim 1	56
1. Preamble	56
2. Outer Frame	58
3. Inner Frame.....	59
4. Stitching.....	63
5. First Portion of Fibers.....	64
6. Second Portion of Fibers	81
7. First and Second Portion in Overlapping Radial Alignment.....	85
8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets	87
9. Free of an Outer Graft Covering Between First Portion of Fibers and Outer Frame	88
10. Radially Compressed Orientation and Radially Expanded Orientation	91
11. Balloon Expandable.....	91

TABLE OF CONTENTS **(cont'd)**

	Page No.
12. Compress Fibers to Form a Sealing Interface	92
B. Claim 2	94
C. Claim 3	95
D. Claim 4	99
VII. GROUNDS 2-3: CLAIMS 1-4 OBVIOUS OVER SPENSER AND WALTHER OR SPENSER II	102
A. Claim 1	105
1. Preamble	105
2. Outer Frame	106
3. Inner Frame.....	107
4. Stitching.....	110
5. First Portion of Fibers.....	111
a. Walther	112
b. Spenser II.....	117
6. Second Portion of Fibers	122
a. Walther	122
b. Spenser II.....	123
7. First and Second Portion in Overlapping Radial Alignment.....	125

TABLE OF CONTENTS **(cont'd)**

	Page No.
a. Walther	125
b. Spenser II.....	125
8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets	126
9. Free of an Outer Graft Covering Between the First Portion of Fibers and Outer Frame.....	128
a. Walther	128
b. Spenser II.....	129
10. Radially Compressed Orientation and Radially Expanded Orientation	131
11. Balloon Expandable.....	132
12. Compress Fibers to Form a Sealing Interface	132
a. Walther	133
b. Spenser II.....	133
B. Claim 2	134
C. Claim 3	136
1. Walther	136
2. Spenser II.....	136
D. Claim 4	138

TABLE OF CONTENTS
(cont'd)

	Page No.
1. Walther	138
2. Spenser II	138
VIII. GROUNDS 4-7: CLAIMS 1-4 ANTICIPATED OR OBVIOUS IN VIEW OF LEVI ALONE OR WITH WALTHER OR SPENSER II.....	140
A. Claim 1	142
1. Preamble	142
2. Outer Frame	143
3. Inner Frame.....	144
4. Stitching.....	146
5. First Portion of Fibers.....	147
a. Levi.....	148
b. Walther	151
c. Spenser II.....	155
6. Second Portion of Fibers	157
a. Levi.....	158
b. Walther and Spenser II.....	160
7. First and Second Portion in Overlapping Radial Alignment.....	161

TABLE OF CONTENTS
(cont'd)

	Page No.
8. First Sealing Interface in Overlapping Radial Alignment with Leaflets	162
9. Free of an Outer Graft Covering	163
10. Radially Compressed Orientation and Radially Expanded Orientation	165
11. Balloon Expandable.....	165
12. Compress Fibers to Form a Sealing Interface	166
B. Claim 2	167
C. Claim 3	169
D. Claim 4	171
IX. SECONDARY CONSIDERATIONS	173
X. CONCLUSION	173

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,792,172 B2 (“ 236 patent ”)
1002	Excerpts from the prosecution history of the ’236 patent
1003	Declaration of Nigel P. Buller, M.D.
1004	Curriculum Vitae of Nigel P. Buller, M.D.
1005	U.S. Provisional Application No. 61/567,458
1006	U.S. Provisional Application No. 61/723,446
1007	Walther, Thomas, et al., <i>Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves</i> , 40 Euro. J. of Cardio-thoracic Surgery 1120-1126 (April 2011) (“ Walther ”)
1008	U.S. Patent No. 9,393,110 B2 to Levi et al. (“ Levi ”)
1009	Conradi, Lenard, et al., <i>Transcatheter aortic and mitral valve interventions: update 2010</i> , 2(4) Interventional Cardiology 513-523 (2010)
1010	U.S. Patent No. 7,510,575 B2 to Spenser et al. (“ Spenser ”)
1011	WO 2006/005015 A2 to Spenser et al. (“ Spenser II ”)
1012	Cribier, Alain, et al., <i>Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach</i> , Herz, 34:347-56 (2009) (“ Cribier ”)
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.

Exhibit No.	Description
1016	Alkashkari, MD, et al., <i>Percutaneous Pulmonary Valve Implantation for RVOT Defects</i> , Cardiac Interventions Today, 21-29 (September/October 2010) (“Alkashkari”)
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	Yuksel, Uygur, <i>Balloon-Expandable Transcatheter Aortic Valve Implantation</i> , Cardiac Interventions Today (Aug./Sept. 2009)
1021	Walther, Thomas, et al., <i>Transapical Minimally Invasive Aortic Valve Implantation</i> , 116 [suppl I] Circulation I-240—I-245 (September 11, 2007) (“Walther II”)
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	Zajarias, Alan and Cribier, Alain G., <i>Outcomes and Safety of Percutaneous Aortic Valve Replacement</i> , 53 J. Am. College of Cardiology 20, 1829-1836 (May 19, 2009) (“Zajarias”)
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. (“Spenser Parent”)

Exhibit No.	Description
1027	Roselli, E.E., <i>Engineering transcatheter aortic valve devices: a surgeon's perspective</i> , 225 J. Engineering in Medicine, 207-219 (Mar. 1, 2011) ("Roselli")
1028	Tyagi, G.K., <i>Yarn structure and properties from different spinning techniques</i> , ("Tyagi")
1029	Kothari, V K, <i>Hairiness properties of polyester-cotton blended yarns</i> , 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004) ("Kothari")
1030	Cribier, Alain, et al., <i>Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis</i> , 43 J. of the Am. College of Cardiology 4, 698-703 (February 18, 2004)
1031	Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," <i>Transcatheter Aortic Valve Implantation</i> , edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114.
1032	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S. (November 2, 2011)
1033	Press Release: FDA Approves Expanded Indication for Edwards Lifesciences' Transcatheter Valve (October 19, 2012)
1034	Andersen, Henning, et al., <i>Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs</i> , European Heart Journal, 13:704-08 (1992)
1035	U.S. Patent No. 5,957,949 to Leonhardt et al.

Exhibit No.	Description
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	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)
1039	Amendment with RCE for Patent Application No. 17/213,251 filed July 27, 2021
1040	SAPIEN Instructions For Use
1041	Saia, Francesco, et al., <i>In-hospital and thirty-day outcomes of the SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: the S3U registry</i> , EuroIntervention 15:1240-1247 (2020)
1042	Press Release: Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark (March 2, 2010)
1043	Kainuma, Satoshi, et al., <i>Transcatheter aortic valve implantation: first trans-iliac experience in Japan</i> , General Thoracic Cardiovascular Surgery 59:273-276 (2011)
1044	Craido, Frank, <i>Iliac Arterial Conduits for Endovascular Access: Technical Considerations</i> , J. Endovasc. Ther. 14:347-351 (2007)
1045	U.S. Patent No. 7,585,321 B2 to Cribier et al. (“Cribier ’321”)
1046	Preliminary Amendment for Patent Application No. 17/096,253 filed November 30, 2020
1047	Piazza, Nicolo, et al., <i>Anatomy of the Aortic Valvar Complex and Its Implications for Transcatheter Implantation of the Aortic Valve</i> , Cir Cardiovascular Intervention 1:74-81 (2008).
1048	WO 2011/051043 A1 to Essinger et al.

Table of Exhibits, Page 4

Exhibit No.	Description
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from <i>Edwards Lifesciences Corp. v. Aortic Innovations, LLC</i> , IPR2021-01584 (Filed Sept. 28, 2021)
1051	U.S. Patent No. 6,730,118 B2 to Spenser et al.
1052	PCT Publication No. WO 2006/124649 A3 to Nguyen et al.
1053	U.S. Patent Pub. No. 2002/0052649 A1 to Greenhalgh
1054	U.S. Patent Pub. No. 2011/0098802 to Braido et al.
1055	Excerpts from the prosecution history of U.S. Patent No. 10,857,011
1056	Excerpts from the prosecution history of U.S. Patent No. 10,881,538
1057	U.S. Patent No. 7, 524,331 B2 to Birdsall (“Birdsall”)
1058	Reserved
1059	Declaration of Sylvia D. Hall-Ellis PhD
1060	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 (November 2011), obtained from the University of California Los Angeles Library
1061	European Journal of Cardio-thoracic Surgery MARC Record from the OCLC Database
1062	Library of Congress subject heading sh85059711
1063	Library of Congress subject heading sh85099890
1064	Library of Congress subject heading sh85023143

Exhibit No.	Description
1065	Azadani, Ali N., <i>Transcatheter Heart Valves for Failing Bioprostheses: State-of-the-Art Review of Valve-in-Valve Implantation</i> , Cir Cardiovascular Intervention 4:621-628 (2011).
1066	Cribier, Alain, et al., <i>Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach</i> , Herz, 34:347-56 (2009), obtained from the British Library
1067	Herz MARC Record from the British Library
1068	Library of Congress subject heading sh2009118412
1069	Herz MARC Record from the OCLC Database
1070	Curriculum Vitae of Sylvia D. Hall-Ellis PhD

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 1-4 of U.S. Patent No. 10,987,236 (“the ’236 patent”). For the reasons discussed herein, I have concluded that claims 1-4 of the ’236 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Declaration supports Edwards’ Petition for the above-captioned *inter partes* review (“IPR”) of the ’236 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 ’236 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.

C. Topics of Opinions

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

- The subject matter described and claimed in the ’236 patent;
- The level of ordinary skill in the art pertaining to the ’236 patent;
- The teachings of the prior art; and
- Whether claims 1-4 of the ’236 patent are anticipated and/or 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.

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

D. Materials Considered

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

28. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '236 patent.

II. APPLICABLE LEGAL STANDARDS

29. 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 '236 patent.

30. 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

31. 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. For the purposes of my analysis and opinions, and to the extent necessary, I have construed each claim term in accordance with its ordinary and customary meaning under the required standard.

B. Anticipation

32. 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.

33. 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

34. 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.

35. 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.

36. 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 '236 patent, e.g., minimally invasive devices for treating heart valves. The references are also pertinent to the problem the inventor was focused on, e.g., treating aortic regurgitation or stenosis through a minimally invasive procedure.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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 that

would suggest that claims 1-4 of the '236 patent would have been non-obvious, as further explained in Section X below.

D. Person of Ordinary Skill in the Art

42. It is my understanding that when interpreting the claims of the '236 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 '236 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 '236 patent). I have been informed that all of the references relied upon in this Declaration qualify as prior art under either priority date.

43. 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.

44. 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

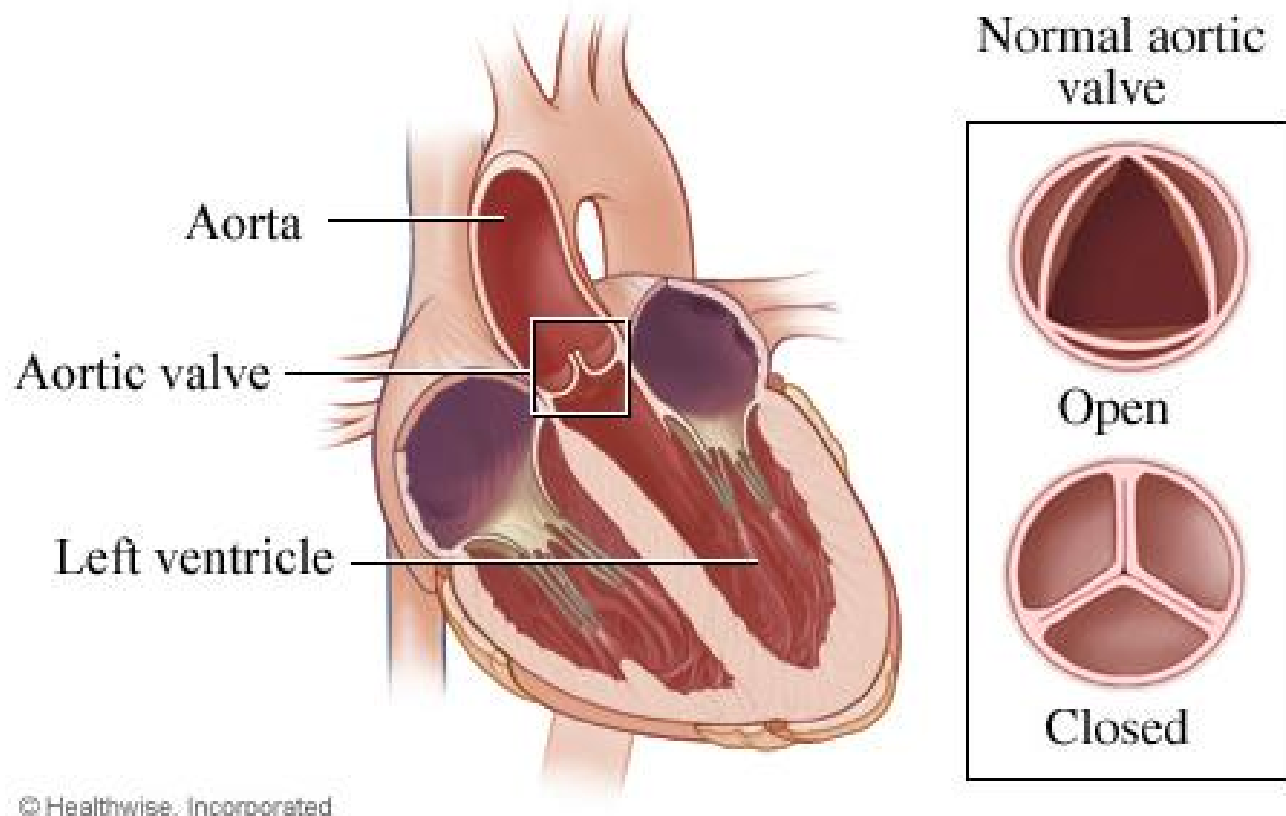
of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

45. Based on my review of the specification and claims of the '236 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

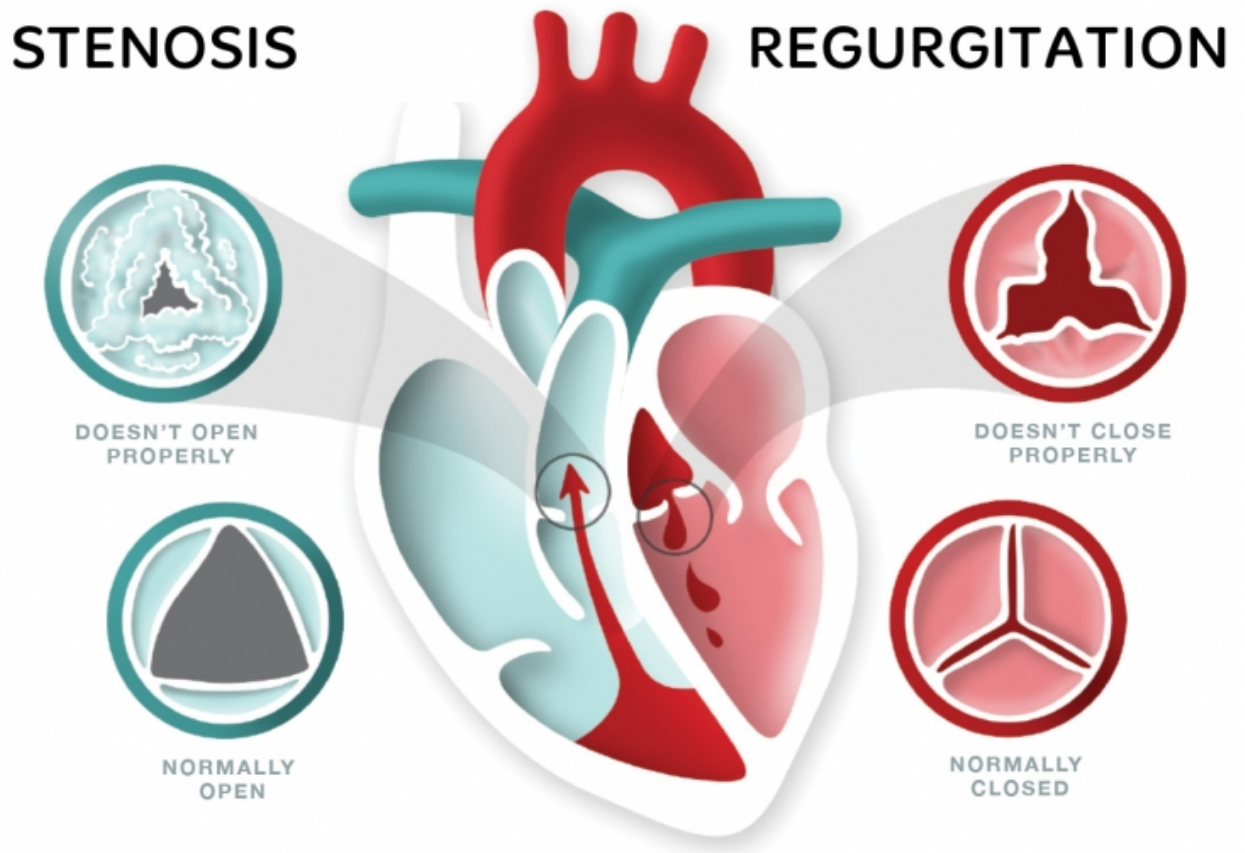
46. The human heart has two upper chambers, known as the left and right atriums, and two lower chambers, known as the left and right ventricles. The aortic valve connects the left ventricle with the aorta, the major artery that carries oxygenated blood from the heart to the rest of the body, on the left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

47. 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.



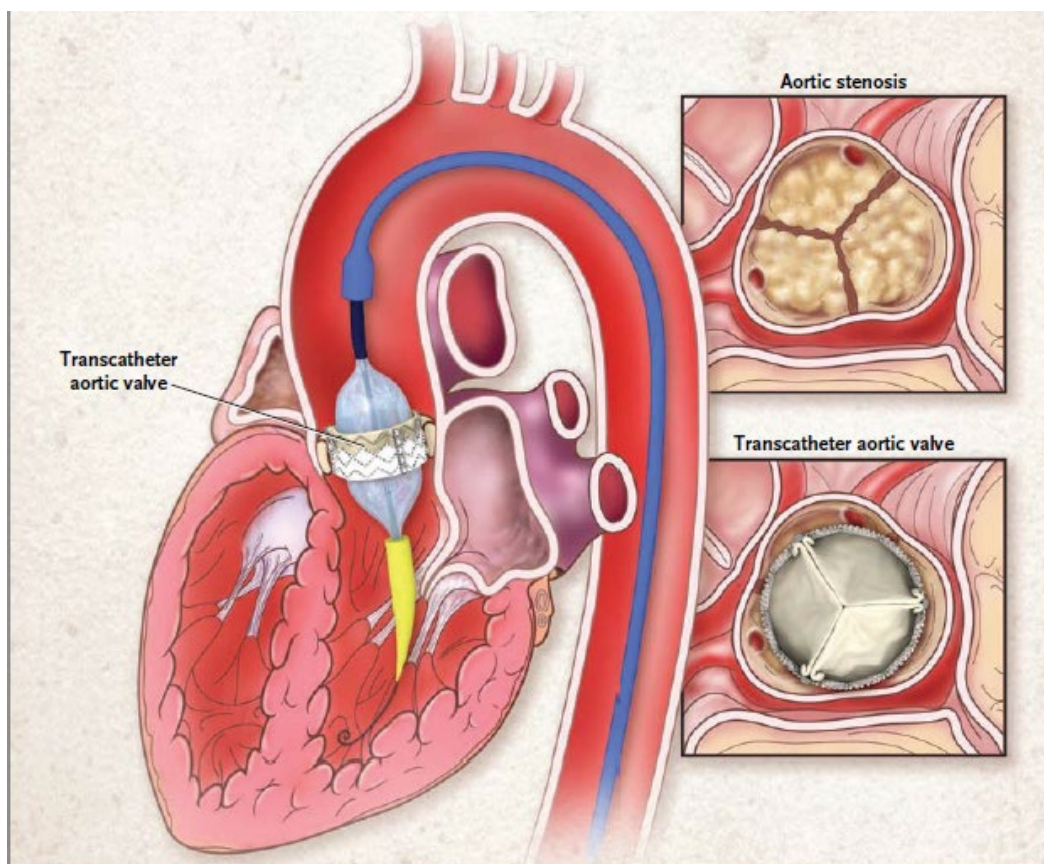
Available at <https://www.heartfoundation.org.nz/your-heart/heart-conditions/heart-valve-disease>. I note that the above image illustrates stenosis and regurgitation in two different heart valves. Persons of ordinary skill in the art, however, would have understood that both conditions could affect the aortic valve.

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

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

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

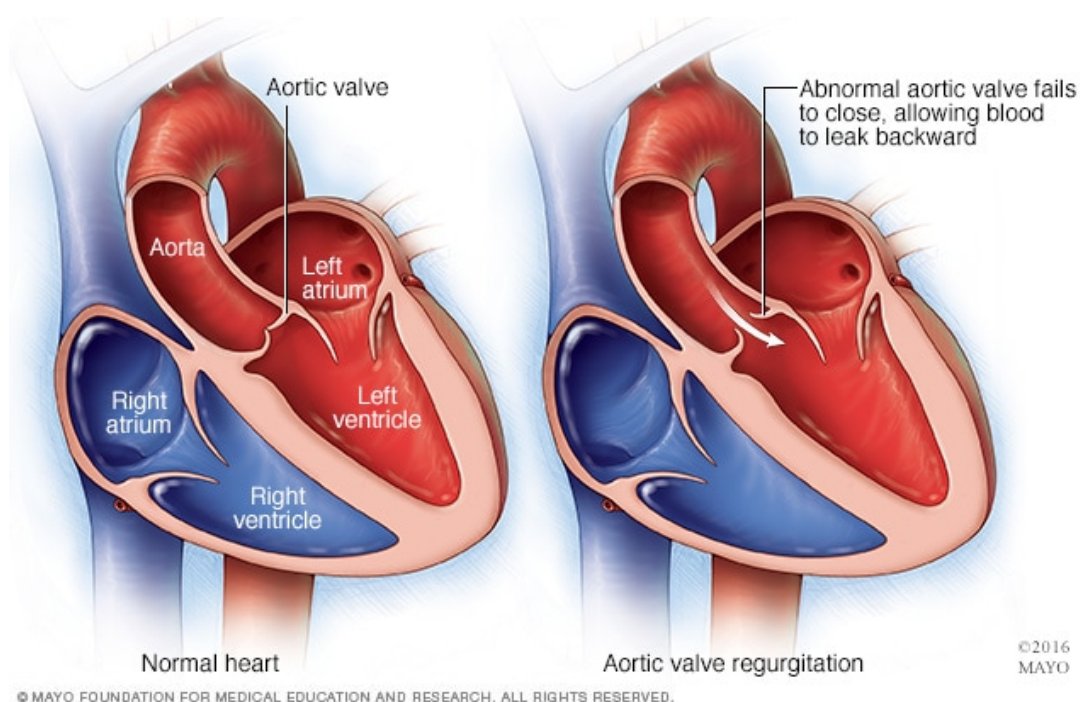
¹ "Paraprosthetic," "perivalvular," and "paravalvular" leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.



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

B. Anatomy of the Aortic Valve

50. 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 '236 patent) towards the aorta.



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

51. The claims of the '236 patent state that the “first portion of fibers” is “configured to form a first sealing interface against the against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst.” See e.g., Ex. 1001 ('236 patent) at claim 1. The claims further state that the transcatheter aortic valve is “configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve

leaflets of the aorta to seal thereagainst.” *Id.* As described below, persons of ordinary skill in the art would have understood that if the fibers radially overlap and press against the annulus of the aortic valve, they must also radially overlap and press against the leaflets.

52. The '236 patent identifies the annulus (identified by item #210) as the point where the aortic valve leaflets attach to the left ventricle:

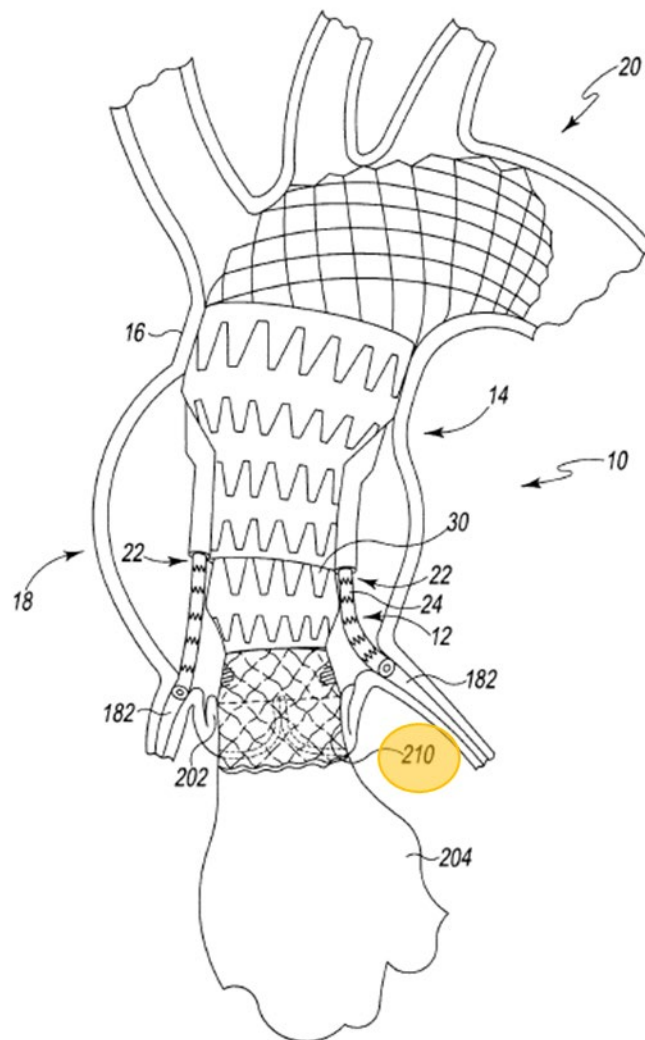
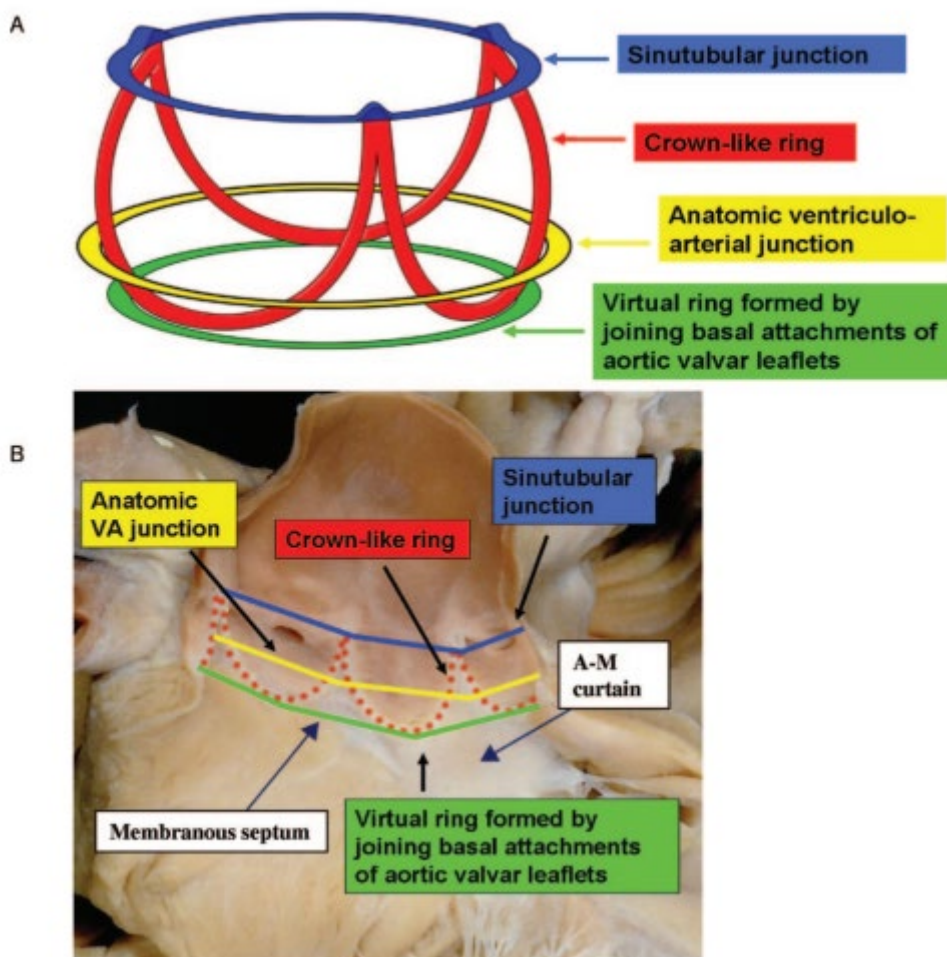


Fig. 2

See e.g., *id.* at Fig. 2. This is further confirmed by the '236 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valves, the sinutubular junction, and the tubular portion." *Id.* at 1:58-60. The below image from a prior art journal article reflects the structure of the aortic valve. The '236 patent identifies the green line as the annulus.

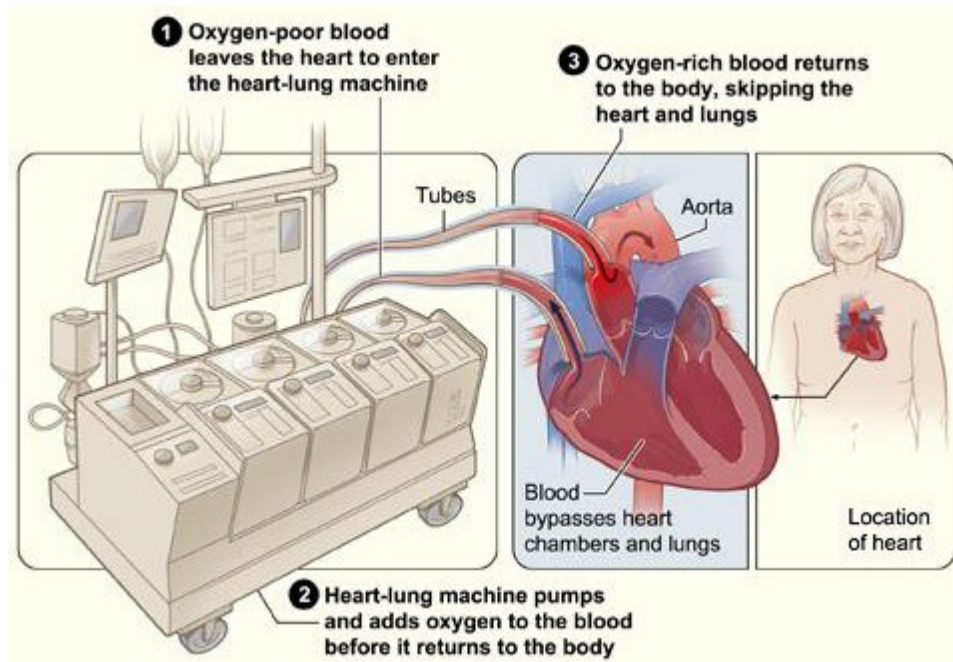


Ex. 1047 (Piazza) at Fig. 4. Because the "annulus" referred to in the '236 patent is the point where the leaflets begin, a person of ordinary skill in the art would have

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. SAPIEN, the valve disclosed in the Cribier and Walther references relied upon herein, was positioned within the annulus (i.e., intra-annular) and “once deployed, crushes the leaflets of the native valve against the wall.” *Id.* at 74.

C. Surgical Prosthetic Heart Valves

53. Petitioner Edwards was founded by Miles “Lowell” Edwards in 1958. Edwards’ earliest work related to prosthetic heart valves that could be implanted surgically. Implantation of these devices involves an open surgical procedure that requires use of a heart-lung machine. In order to surgically implant a prosthetic heart valve, a surgeon opens a patient’s chest and the patient is connected to a heart-lung bypass machine, after which the heart can be arrested. The surgeon then surgically removes the diseased native valve and sutures the prosthetic valve in place. A diagram detailing the operation of a heart-lung machine is pictured below:

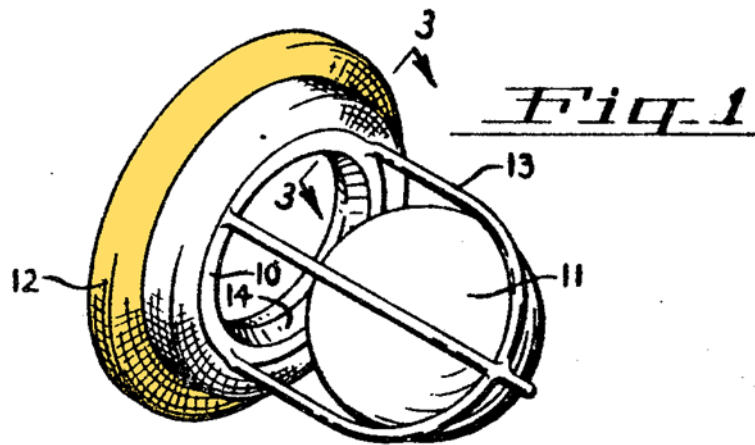


Available at http://www.daviddarling.info/encyclopedia/H/heart_surgery.html.

This procedure is used today for patients receiving a surgically implantable prosthetic heart valve.

54. One of Edwards' first commercially available surgical valves was a ball and cage valve called the Starr-Edwards valve. U.S. Patent No. 3,365,728 (the "'728 patent"), which issued on January 30, 1968, details the features of this valve. **Ex. 1013** ('728 patent). Notably, even this early valve prosthesis included a circumferentially oriented sewing ring that was adapted to extend into spaces in the tissue surrounding the implanted prosthesis to prevent leakage between the prosthetic valve and the surrounding tissue (*i.e.*, "paravalvular leak"). The '728 patent states:

Connected to the periphery of the valve ring is a suturable sewing ring [12] by which the valve may be connected by sutures with living tissue around the natural orifice in which the valve is implanted. The sewing ring is upholstered with a ring of compressible cushion material which will conform to irregularities in the bed in which the valve is placed whereby a good seal is established and leakage between the valve and the tissue is prevented.

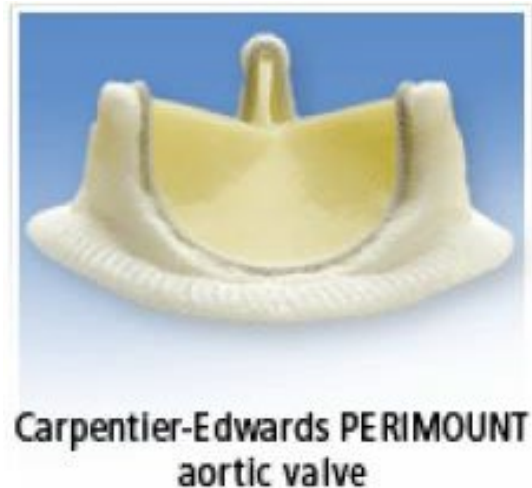


Id. at 1:38-46, 3:12-20, Figs. 1, 3.² Thus, paravalvular leak was a well-recognized complication of surgical valve replacement as early as the 1960s.

55. In addition to ball and cage valves, Edwards also developed surgically implantable valves with biological valve leaflets. The biological valve structure could be made with a whole excised valve or formed with pericardial tissue, primarily of bovine or porcine origin. Edwards' PERIMOUNT valve, for

² Highlighting and color has been added to all figures unless otherwise noted.

example, was first introduced in 1980 and included a tri-leaflet bovine pericardial valve and a frame having a fabric sewing ring akin to the Starr-Edwards valve:



See e.g., <https://www.edwards.com/gb/devices/heart-valves/aortic-pericardial> (describing Carpentier-Edwards PERIMOUNT valve).

D. Transcatheter Heart Valve (“THV”) Technology

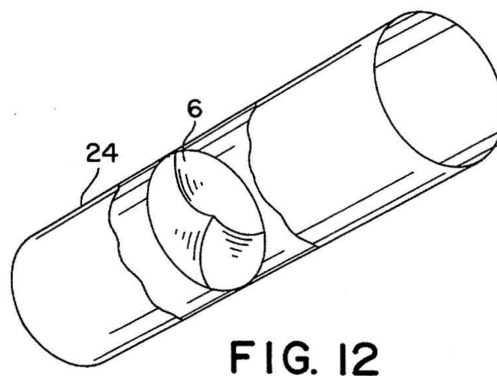
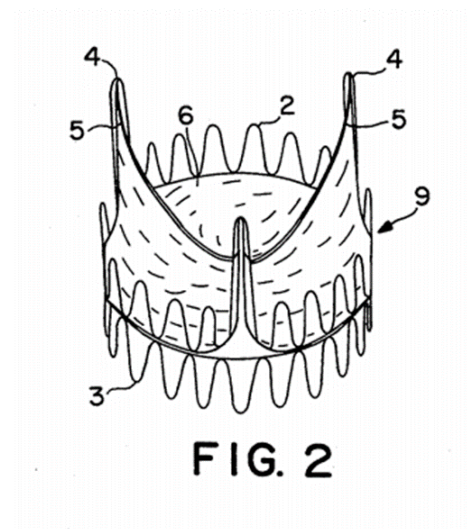
56. THV technology is aimed at providing a patient with a permanently implanted prosthetic heart valve that can be delivered via a catheter.

57. 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.

58. 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*, 13:704-708 (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.*, 704.

59. The Danish team’s work also led to several patents, including U.S. Patent No. 5,411,552 (“Andersen patent”). (Ex. 1014).



Id. at Figs. 2, 12. 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 external and internal surface of the THV. *Id.* at 2:21-27, 2:56-60, 4:3-16, 5:9-28, 7:17-29, Figs. 11-12.

60. The graft materials used on the external surface of early THVs were designed to conform to the surface of the surrounding tissue. These materials could be made with low-porosity woven fabrics. An early THV detailed in U.S. Patent No. 5,957,949 to Leonhardt et al. (**Ex. 1035**), which issued on September 28, 1999, details graft material to be used as an external cover on a THV:

Graft material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE. It is capable of substantially conforming to the surface of the living tissue to which stent 26 coerces it.

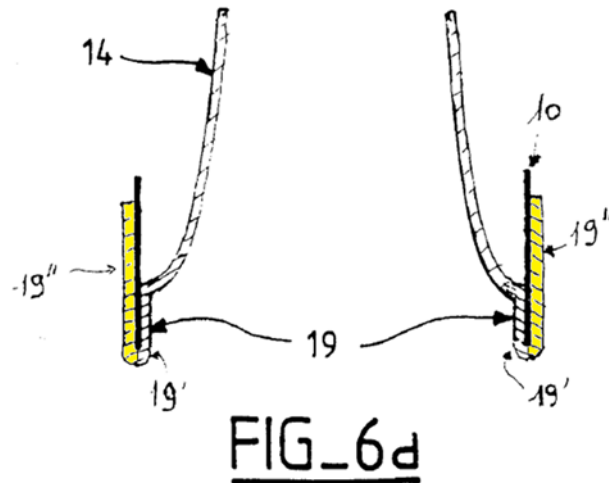
Ex. 1035 at 5:53-59.

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.” Ex. 1018 at 5:11-16.

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

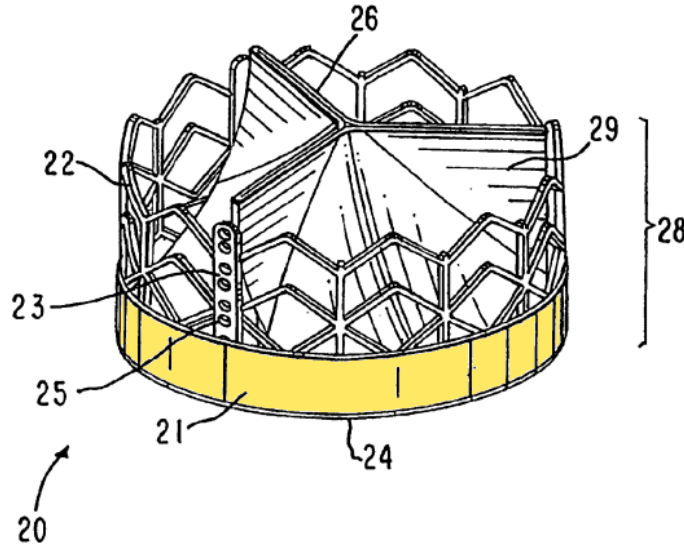
64. The embodiment in Figure 6d (below) illustrates an internal cover [19'] that extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10], which is then “rolled up to be applied to the external wall of the stent” to form an external cover [19"]:



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

65. In 2001, a company named Percutaneous Valve Technologies (“PVT”), which was co-founded by Dr. Cribier and three others (Stan Rowe, Stan

Rabinovich, and Dr. Martin Leon), filed a patent application on another THV design that included an external cover:



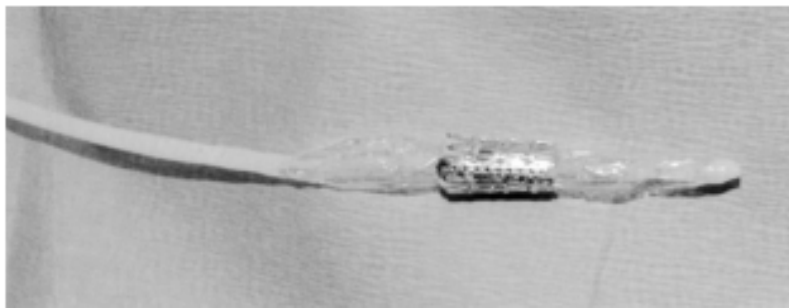
Ex. 1019 (U.S. Patent No. 6,893,460 B2 to Spenser *et al.* (“’460 patent”)) at Fig.

1. The ’460 patent discloses a THV having a tricuspid valve, a support stent including support beams for securing the commissures of the valve, and a cuff portion wrapped around the support stent at its inlet. *Id.* at 9:1-22, Fig. 1. The ’460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a “sleeve-like” portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* (“To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet.”). The cuff portion can be formed with PET (Dacron) fabric. *See id.* at 7:7-10, 10:57-11:10 (“Figs. 8a and 8b demonstrate a method of manufacturing a composite valve, which is based on

flexible PU 92 as the main body of the valve, rigid PU support beams 94 serving for the attachment area, and PET sleeve 96 portions for the valve inlet.”).

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

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



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

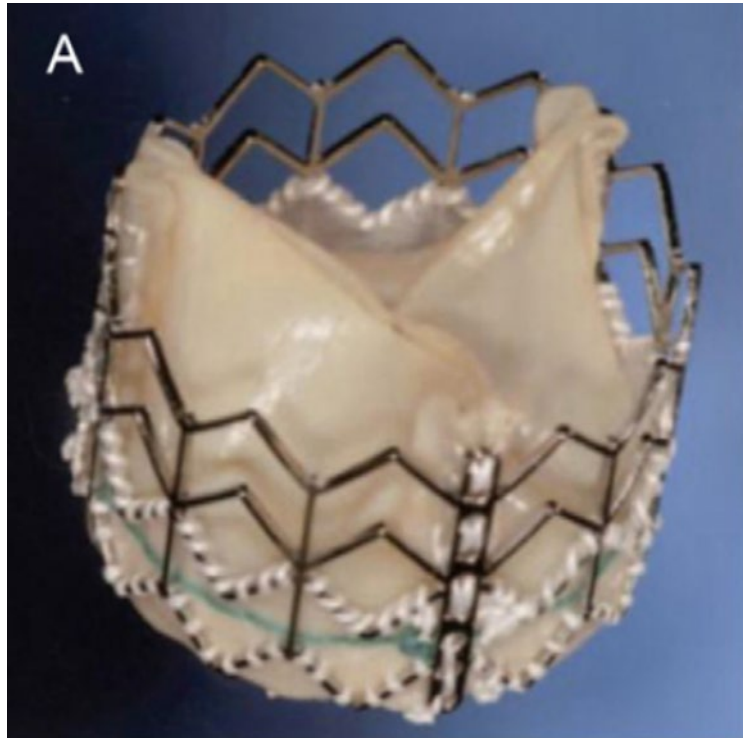
³ Dr. Cribier uses the phrase “percutaneous heart valve” or “PHV” to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

right femoral vein. The THV was “easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic valve.” *Id.* The balloon was then inflated to place the THV. *Id.* Dr. Cribier concluded that the implantation was successful and demonstrated “the feasibility of implanting a prosthetic heart valve percutaneously, with the use of standard interventional techniques, within the native diseased valve of a patient with calcific aortic stenosis.” *Id.* at 3008.

68. 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.*

69. 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.

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

another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.” *Id.* at [0085].

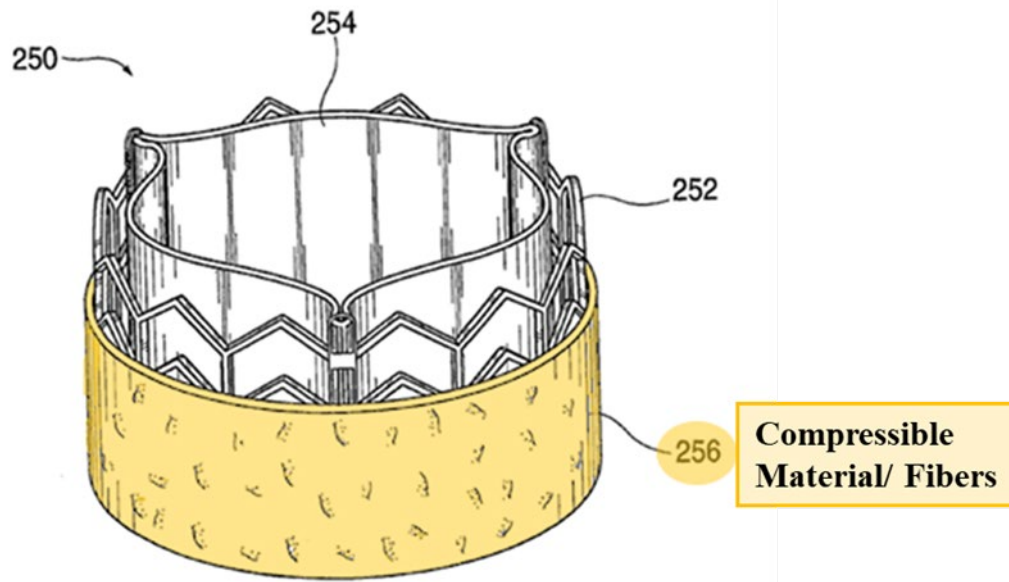


FIG. 22

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

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

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

Id.

72. 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.

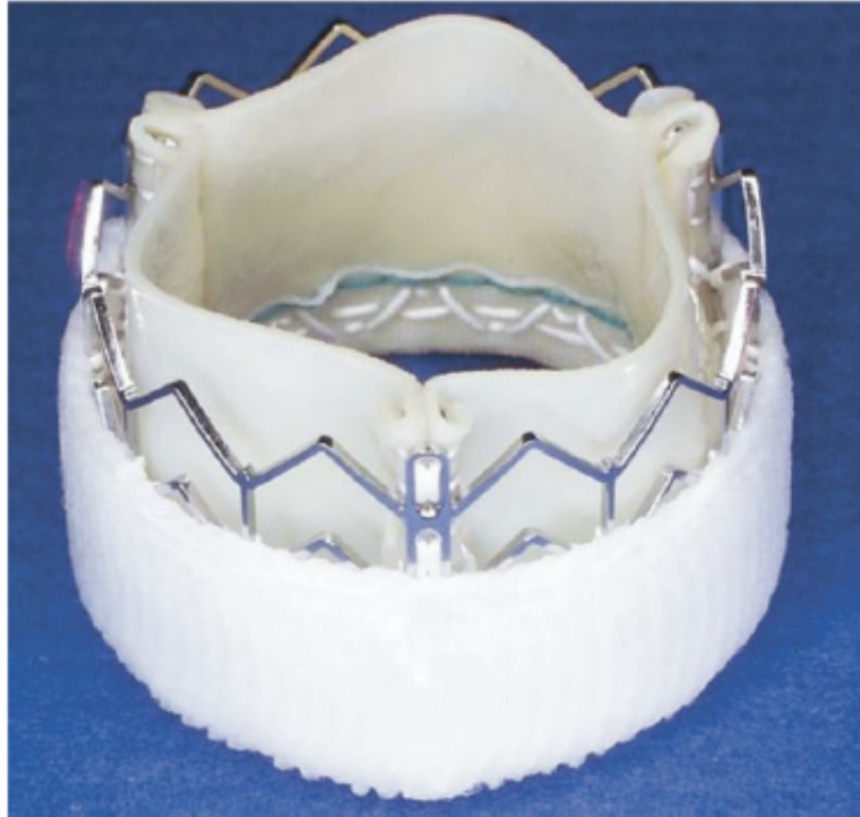


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

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.

73. By 2007, Edwards had modified the Cribier-Edwards valve to create SAPIEN, which included more durable bovine leaflets and a higher internal sealing

cuff. **Ex. 1023** (Webb) at 154. SAPIEN was the subject of a large clinical trial, referred to as the PARTNER Trial. **Ex. 1022** (Smith, Craig R., et al., *Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients*, 364 N. Engl. J. Med. 23, 2187-2198 (June 9, 2011)). The results of the PARTNER Trial were published in The New England Journal of Medicine in 2011. *Id.* SAPIEN addressed a long-felt need in the industry for an aortic valve replacement device that did not require open-heart surgery. In view of its pioneering status, SAPIEN's development and progress were avidly followed in the industry and SAPIEN was discussed in numerous publications and textbooks. *See e.g.*, **Ex. 1009** (Conradi), **Ex. 1016** (Alkashkari, MD, et al., *Percutaneous Pulmonary Valve Implantation for RVOT Defects*, Cardiac Interventions Today, 21-29 (September/October 2010)), **Ex. 1031** (Akin, Jodi and Sharma, Pooja, "Chapter 8: The Edwards SAPIEN Transcatheter Aortic Heart Valve System," *Transcatheter Aortic Valve Implantation*, edited by Patrick W. Serruys, et al., CRC Press, 2010, 102-114). For example, the **Cribier** publication, discussed in the grounds of unpatentability below, extensively discusses the transfemoral delivery of SAPIEN to a patient's heart valve. **Ex. 1012** (Cribier, Alain, et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien Heart Valve Using the Transfemoral Approach*, Herz, 34:347-56 (2009)).

74. 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.

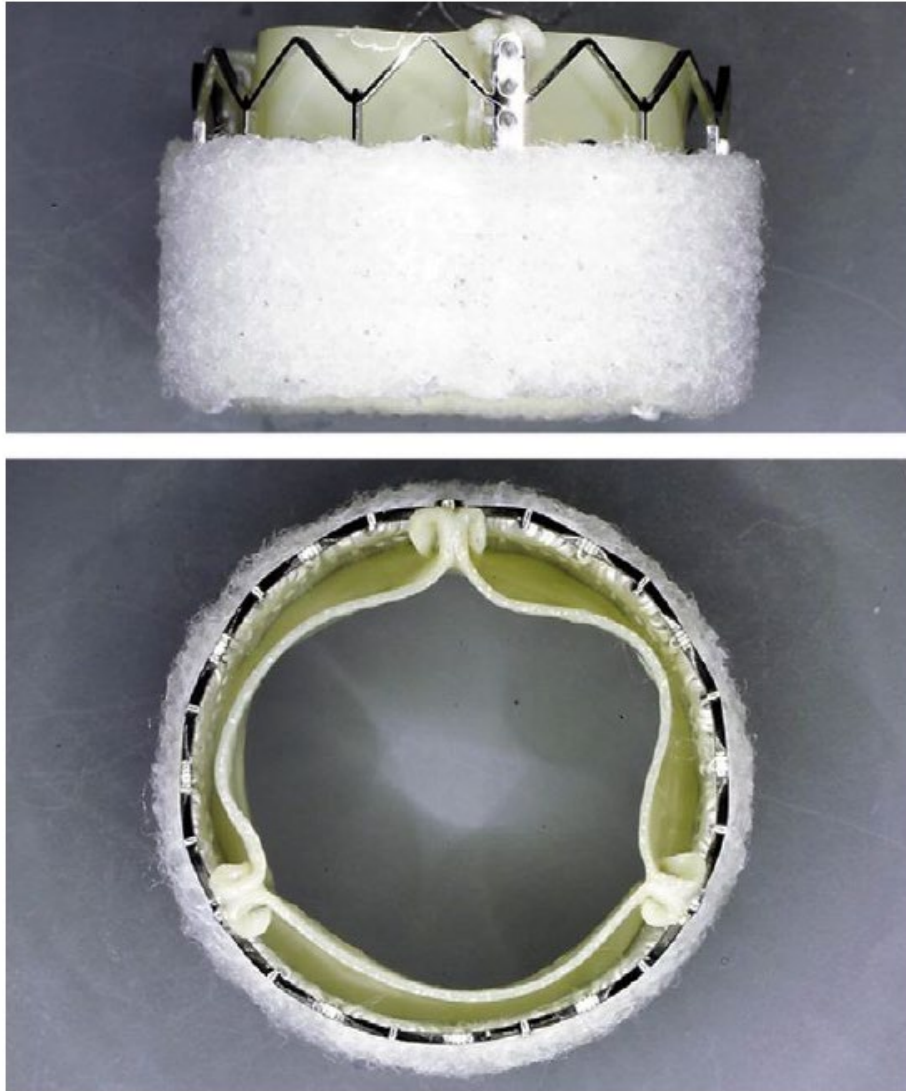
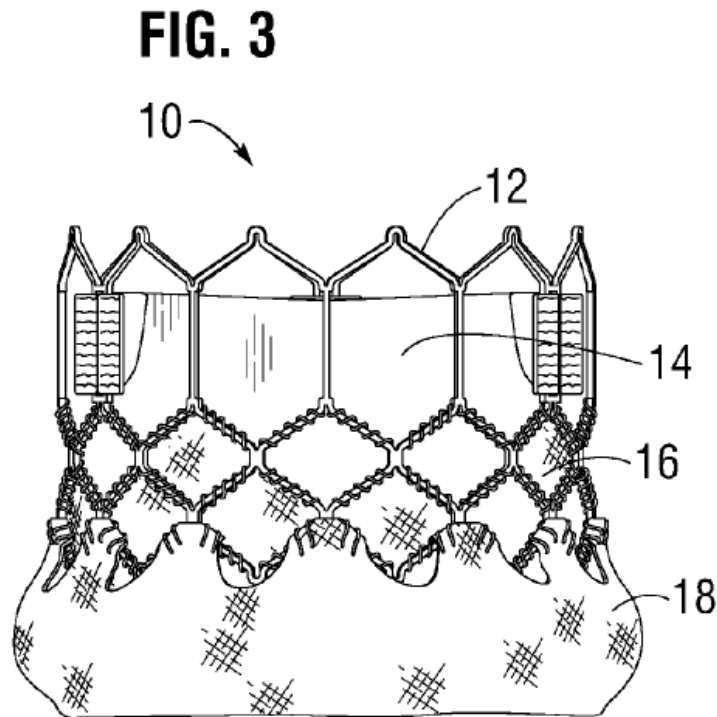


Fig. 1. Cloth valve.

Id. at Fig. 1. The 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.” *Id.* at 1120. The team concluded that the “SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent

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

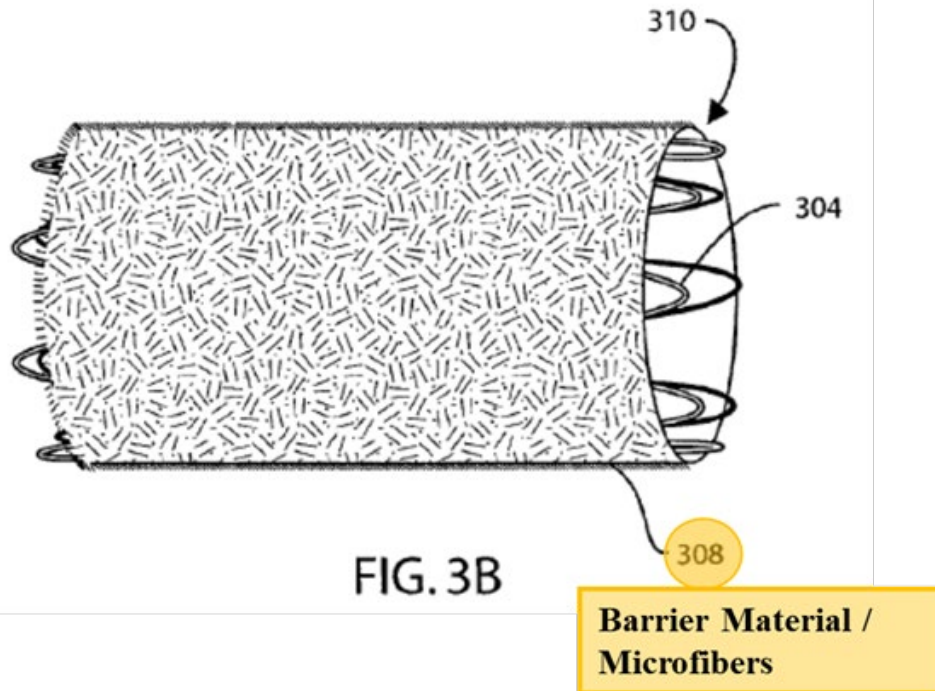
75. In October 2010, Edwards filed a provisional patent application that matured into U.S. Patent No. 9,393,110 B2, referred to herein as “**Levi**” (**Ex. 1008**). Levi discloses a THV with “four main components: a stent, or frame, 12, a valvular structure 14, an inner skirt 16, and an outer skirt 18”:



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

native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.” *Id.* at 14:3-7. “The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the valve 10.” *Id.* at 14:7-9.

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



Id. at 6:9-33, Fig. 3B. While Birdsall discloses implanting this embodiment within a vascular conduit, Birdsall’s disclosure of using a fibrous material to form a seal is not limited to this context. 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 heart valve. Indeed, like the other THVs discussed above, Birdsall’s valve is also designed for transcatheter, percutaneous implantation. *See id.* at 2:33-39.

77. The prior-art references identified above demonstrate that Petitioner invented and disclosed prosthetic heart valves, and specifically THVs, having fibers positioned outwardly of the valve frame for sealing against the patient’s native aortic valve and preventing 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 fibrous 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 the outer fibrous material. *See e.g.*, Ex. 1007 (Walther) at 1120-21; Ex. 1008 (Levi) at 13:49-53; Ex. 1010 (Spenser) at 13:4-25; Ex. 1011 (Spenser II) at [0085], [00145]; Ex. 1017 (Cheung) at e18-e19; Ex. 1018 (Cribier patent publication) at 8:16-23, 22:11-20. 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.

78. Additionally, by 2012, Petitioner had developed innovations for the heart valve frame and leaflets to further reduce the crimp profile of the heart valve assembly, thereby creating additional space for an outer fibrous 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." Ex.

1023 (Webb) at 154; *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 and several other techniques for minimizing the valve's crimped diameter to accommodate an outer fibrous material. Ex. 1008 (Levi) at 16:51-17:18. Likewise, Edwards had disclosed innovative leaflet designs and several other features to reduce the crimp profile of the valve and offset or minimize any increase in diameter caused by adding additional components, like a plurality of fibers, to the outside of the valve. *Id.* at 16:24-16:50; *infra* ¶¶295-296.

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

Patent Publication) at [0005]-[0006] (describing off balloon delivery). This unique feature enabled a reduction in sheath size.

80. 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 fibrous material. Thus, the challenged claims are not novel or nonobvious, but merely describe the predictable use of prior art elements according to their established functions.

81. Moreover, by 2012, several THVs were commercially available. Edwards received regulatory approval to commercially sell SAPIEN in Europe in 2007. **Ex. 1038** (Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve (Sept. 5, 2007)). In 2011, the FDA approved the transfemoral delivery of SAPIEN for the treatment of inoperable patients with severe symptomatic aortic stenosis. **Ex 1032** (2011 FDA Approval). In 2012, the FDA approved the use of SAPIEN to treat high-risk aortic stenosis patients using the transfemoral and transapical delivery approaches. **Ex. 1033** (2012 FDA Approval). Further, Edwards received regulatory approval to commercially sell its second generation valve, SAPIEN XT, in Europe in March 2010. **Ex 1042** (2010 FDA Approval).

82. Additionally, Edwards was not the only company to have commercialized a THV by 2012. Medtronic's Corevalve system also received

regulatory approval for commercial sales in Europe in 2007. (Ex. 1009, 514-515; 1027, 212-213).



Unlike SAPIEN, Corevalve included a self-expanding frame and further illustrates the diversity of innovations in the field by 2012. (*Id.*)

IV. THE '236 PATENT

A. Summary of the '236 Patent

83. The '236 patent describes endograft devices for repairing ascending aortic aneurysms and replacing defective aortic heart valves. The majority of the embodiments combine multiple components to form a structure that extends into the patient's ascending aorta and aortic arch.

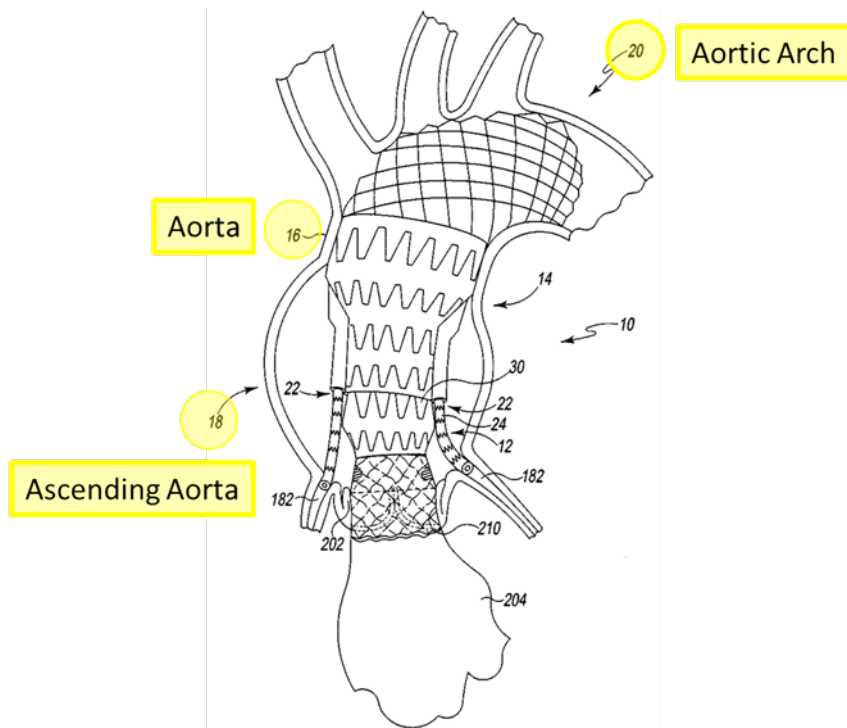


Fig. 2

84. However, the challenged claims of the '236 patent focus on a “transcatheter aortic valve assembly” for replacing an aortic heart valve. The '236 patent’s specification describes a heart valve assembly that includes a “dual-frame” extending from a proximal end (i.e., nearest the left ventricle) to a distal end (i.e., furthest from the left ventricle). **Ex. 1001** ('236 patent) 11:61-12:21; 17:45-47. The “dual-frame” includes a “self-expanding outer frame 216” [red] and a “balloon-expandable inner frame 218 [blue] that is secured to the self-expanding outer frame 216 and houses the valve 32”:

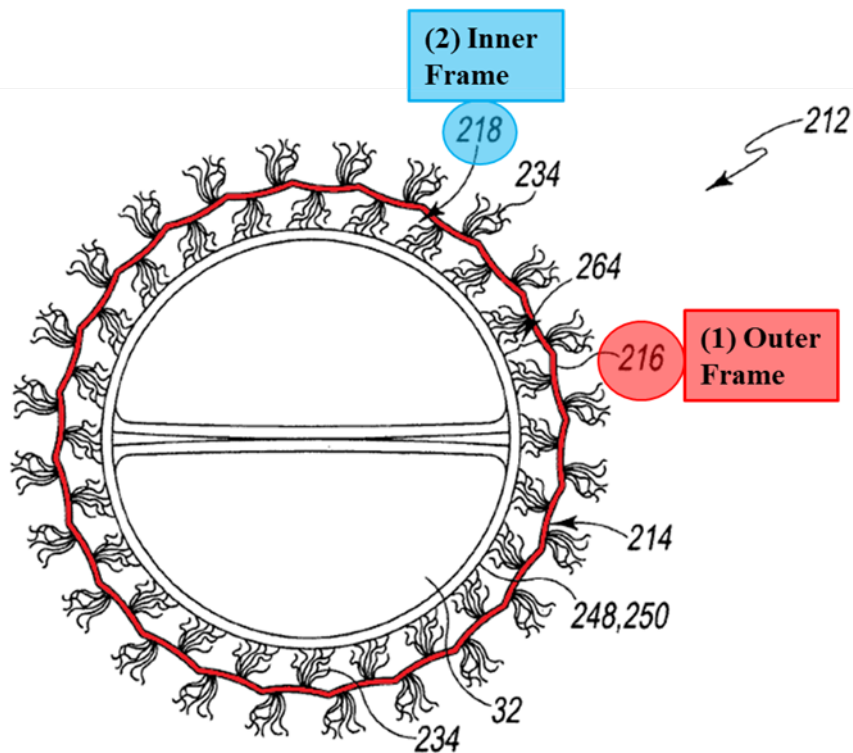
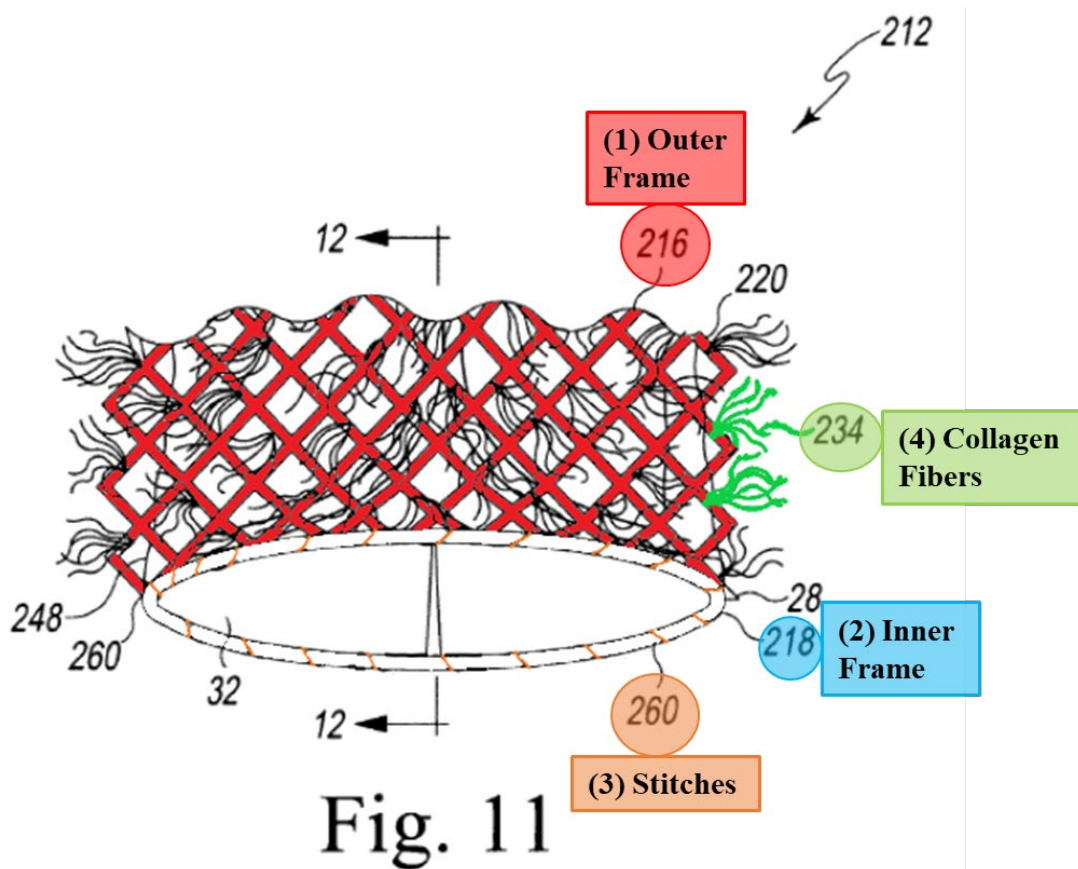


Fig. 13

Id. at 12:9-12, 17:56-59, Fig. 13.

85. The '236 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 12:12-18 13:17-20, 17:59-64, 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 12:43-46, 18:22-25. The inner frame [blue] is a “balloon-expandable tubular stent” constructed of metallic or polymeric material. *Id.* at 13:41-51. The inner

frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:6-8.



86. The '236 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 13:25-28, 13:51-55, 19:5-8.

B. The Challenged Claims

87. The challenged claims include claims 1-4 of the '236 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. A transcatheter aortic valve assembly comprising:
 - an outer frame formed from a metallic material;
 - an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
 - wherein the outer frame is secured to the inner graft covering by stitching;
 - a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,
 - wherein the first portion of fibers is non-metallic; and
 - a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst,
 - wherein the second portion of fibers is non-metallic,
 - wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,
 - wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,
 - wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,
 - wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
 - wherein the valve assembly is balloon expandable to the radially expanded orientation and,
 - wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

C. Prosecution History

89. I have reviewed the '236 patent's prosecution history. I see that the Patent Examiner issued a single, non-final office action that included a single prior-art-based rejection. **Ex. 1002** ('236 Patent Prosecution History Excerpt) at 104-108. None of the references I discuss in connection to the grounds of unpatentability herein were asserted in the Examiner's rejection.

90. While the Patent Examiner did not discuss any of the prior art references included in the grounds of unpatentability discussed in this Declaration, I see that Patent Owner made representations about the prior art references Spenser II and Levi in a Preliminary Amendment during prosecution.

91. Regarding Spenser II, Patent Owner stated that Spenser II "appears to teach a band with fibers emanating therefrom in Fig. 22," but argued that "there is no graft forming the inner frame, thus the inner seal is missing." **Ex. 1002** ('236 Patent Prosecution History Excerpt) at 187. As explained more below, to the extent the valve in Figure 22 does not have an inner graft covering, a person of ordinary skill in the art would have found it obvious to combine Spenser II's compressible material with a valve having an inner graft covering, such as Spenser's Figure 44a.

92. Patent Owner also argued that persons of ordinary skill in the art would not add Spenser II's outer to a valve that included an inner seal due to

concerns about increasing the crimped profile of the valve, restricting expansion and foreshortening of the valve, and because Spenser II already provides a method for addressing PVL. *See id.* at 196. All of these concerns are unfounded, and none of them would have prevented a person of ordinary skill in the art from being motivated to add an outer seal such as Spenser II's to a valve having an inner seal. Indeed, Walther demonstrates that Patent Owner's concerns would not have deterred persons of ordinary skill in the art from doing so because Walther and colleagues did exactly what Patent Owner argues against. *See infra* §VI.A. Contrary to Patent Owner's arguments, Walther does not report any issues with the crimped profile, expansion, or foreshortening of its cloth-covered SAPIEN valve. Quite the opposite, Walther reports that its valve demonstrated "excellent hydrodynamic performance." Ex. 1007 (Walther) at 1125.

93. Patent Owner also argued that "Spenser [II] appears to include an outer graft covering between the fibers and the outer frame." Ex. 1002 ('236 Patent Prosecution History Excerpt) at 196. As I explain below, Spenser II contains no such disclosure of an "outer graft covering between the fibers and the outer frame." *Infra* §VII.A.9.b. Rather, Spenser II discloses a compressible material that "may resemble a cloth or fabric having small fibers extending from the surface of the material . . . disposed along the outer surface" of the stent. Ex. 1011 (Spenser II) at [00145]. There is no disclosure of an "outer graft covering"

between the fibers and the stent, and no such “outer graft covering” is depicted in Spenser II’s Figure 22. *See id.* at [00145], Fig. 22.

94. Regarding Levi, Patent Owner stated that Levi “appears to teach an inner and outer seal in Fig. 42,” but argued that Levi’s “seal . . . had a relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta.” Ex. 1002 (’236 Patent Prosecution History Excerpt) at 194-195. Patent Owner’s characterization of Levi is not supported by Levi’s disclosure for multiple reasons. First, Levi’s Figure 42 shows that Levi’s outer skirt may cover the bottom two rows of open cells of the frame, contrary to Patent Owner’s representations that it has a “relatively short height.” *See* Ex. 1008 (Levi) at Fig. 42. Second, there is no teaching or suggestion in Levi that its outer skirt seals below the patient’s native leaflets. Rather, Levi expressly teaches that its outer skirt “fill[s] 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 14:4-7. As I explained previously, the annulus is the point where the native aortic leaflets attach to the left ventricle, *supra* §III.B, and thus a person of ordinary skill in the art would have understood Levi to teach that its outer skirt seals against the native leaflets. Patent Owner appears to agree with this, as it stated that Levi’s outer seal

“extend[s] into crevices created by the native leaflets.” Ex. 1002 (’236 Patent Prosecution History Excerpt) at 194-195. Patent Owner’s argument that Levi’s outer seal does “not radially overlap[] with the leaflets at a most narrow spot of the ascending aorta” has no support in Levi’s disclosure, and in any event, is irrelevant, as no claim of the ’236 patent requires the outer seal to overlap or press against the native leaflets “at a most narrow spot of the ascending aorta.” *Id.*

V. SUMMARY OF IPR GROUNDS

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

Ground	Claims Challenged	Unpatentability Basis	References
1	1-4	Obvious	Cribier + Walther
2	1-4	Obvious	Spenser + Walther
3	1-4	Obvious	Spenser + Spenser II
4	1-4	Anticipated	Levi
5	1-4	Obvious	Levi
6	1-4	Obvious	Levi + Walther
7	1-4	Obvious	Levi + Spenser II

VI. GROUND 1: CLAIMS 1-4 OBVIOUS OVER CRIBIER AND
WALTHER

96. Cribier is one of the many prior art publications describing SAPIEN. **Ex. 1012** (Cribier). Cribier explains that SAPIEN “consists of a balloon-expandable stent with an integrated bovine pericardial valve.” *Id.* at 347. Cribier states that SAPIEN “can be implanted within the diseased aortic valve using either the retrograde transfemoral or antegrade transapical routes,” and it describes endovascularly delivering SAPIEN through the transfemoral route. *Id.*

97. Walther, as discussed above in my section covering “Transcatheter Heart Valve (“THV”) Technology,” discloses a modified SAPIEN having an added outer cloth:

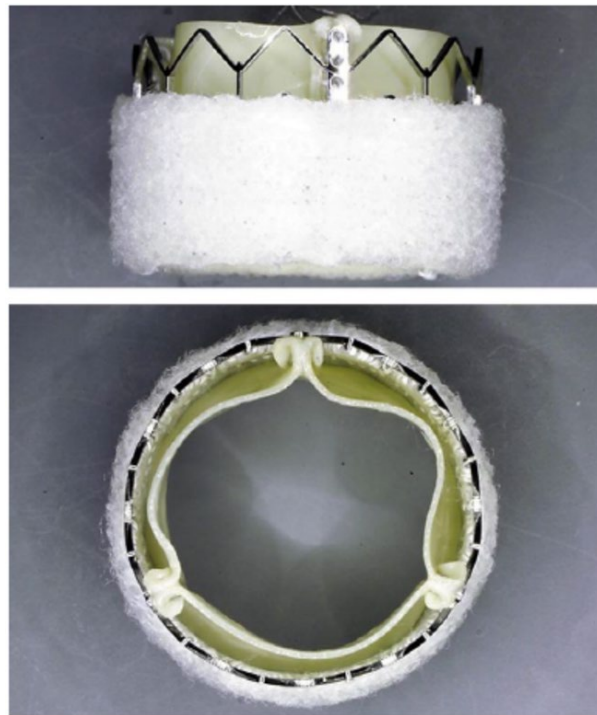


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at 1120-21, Figs. 1-3. Walther's modified SAPIEN is "identical" to SAPIEN except for the added outer cloth. *Id.* at 1120. Walther generally describes SAPIEN but does not include some of the details discussed in Cribier. Thus, I have combined the teachings of Cribier and Walther to provide a more comprehensive review of the features of the cloth-covered SAPIEN disclosed in Walther. Based on my review of these references, I believe that the combination of Cribier and Walther renders claims 1-4 of the '236 patent obvious.

A. Claim 1

98. Based on my review of the prior art, it is my opinion that Cribier in combination with Walther renders claim 1 obvious.

1. Preamble

99. The preamble of claim 1 recites: "A transcatheter aortic valve assembly comprising."

100. Cribier discloses SAPIEN, which is a transcatheter aortic valve assembly. Cribier states that SAPIEN "consists of a tubular slotted stainless-steel balloon-expandable stent with an integrated unidirectional trileaflet bovine tissue valve with a polyethylene terephthalate (PET) fabric cuff." Ex. 1012 (Cribier) at 348. Cribier Figure 1 (below) provides a picture of SAPIEN:



**Edwards SAPIEN® THV
23 mm, 26 mm**

Id. at Fig. 1. Cribier further discloses that SAPIEN is a “Transcatheter Heart Valve” that can be implanted within a patient’s native aortic valve. *Id.* at 347. Cribier specifically describes methods of “transcatheter aortic valve implantation with the Edwards-Sapien® heart valve using the transfemoral approach.” *Id.* at 348.

101. As shown in the figure above, SAPIEN’s fabric cuff is stitched to the inside of the balloon-expandable stent and also attached to the heart valve leaflets. The green suture line in Figure 1 above is one point of attachment between the fabric cuff and the heart valve leaflets.

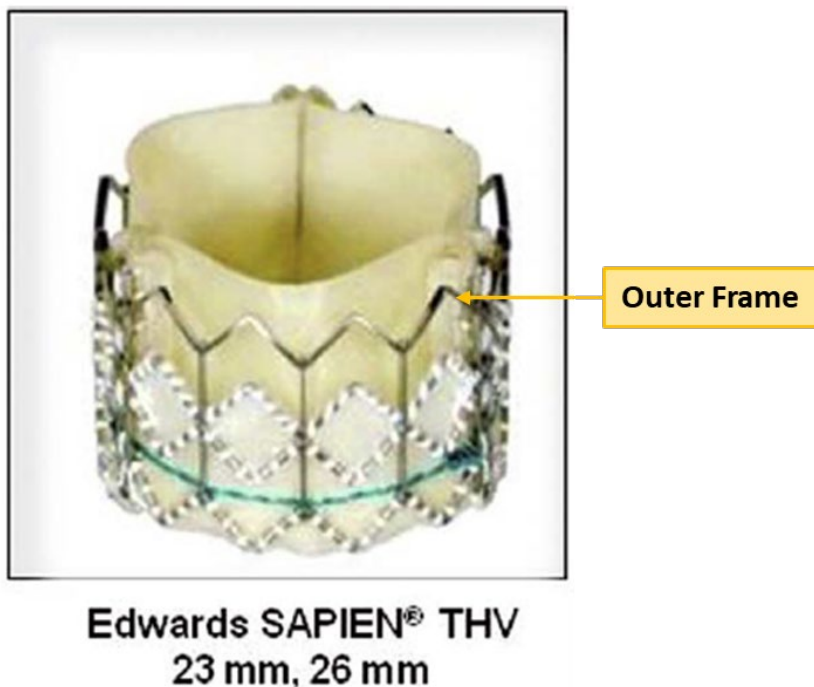
102. Walther similarly discloses SAPIEN with an outer PET cloth stitched to its perimeter. Ex. 1007 (Walther) at 1120-21, Fig. 1. Walther discloses that its

cloth-covered SAPIEN was “identical” to SAPIEN except for the added outer cloth. *Id.* at 1120. Walther also discloses delivering the cloth-covered SAPIENs through a catheter using Edwards’ Ascendra system, and thus Walther also discloses a “transcatheter aortic valve assembly.” *Id.* at 1121; *see also* Ex. 1031 (Akin) at 110. A person of ordinary skill in the art would have understood the term “transcatheter” to mean through a catheter; however, persons of ordinary skill in the art would not have understood “transcatheter” delivery to require delivery through a specific route within the body. For example, the ’236 patent discloses a transcatheter valve that “may be introduced transfemorally or through the subclavian artery or the apex of the heart.” Ex. 1001 (’236 Patent) at 6:43-47. And while the ’236 patent discloses that the valve is compressible and expandable, which is necessary for transcatheter deployment, the ’236 patent does not disclose any dimensions or sizing for the catheter or the compressed valve. The Ascendra system used to deliver Walther’s valves was typically introduced into the patient through the apex of the heart via the transapical approach. Ex. 1031 (Akin) at 110.

2. Outer Frame

103. Claim 1 next recites: “an outer frame formed from a metallic material.” Cribier discloses this limitation.

104. Cribier discloses that SAPIEN includes “a tubular slotted stainless-steel balloon-expandable stent.” Ex. 1012 (Cribier) at 348. As shown in Figure 1 below, the stent surrounds the other valve components, such as the heart valve leaflets, making it an “outer frame”:



Id. at Fig. 1.

3. Inner Frame

105. Claim 1 next recites: “an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.” Cribier also discloses this limitation.

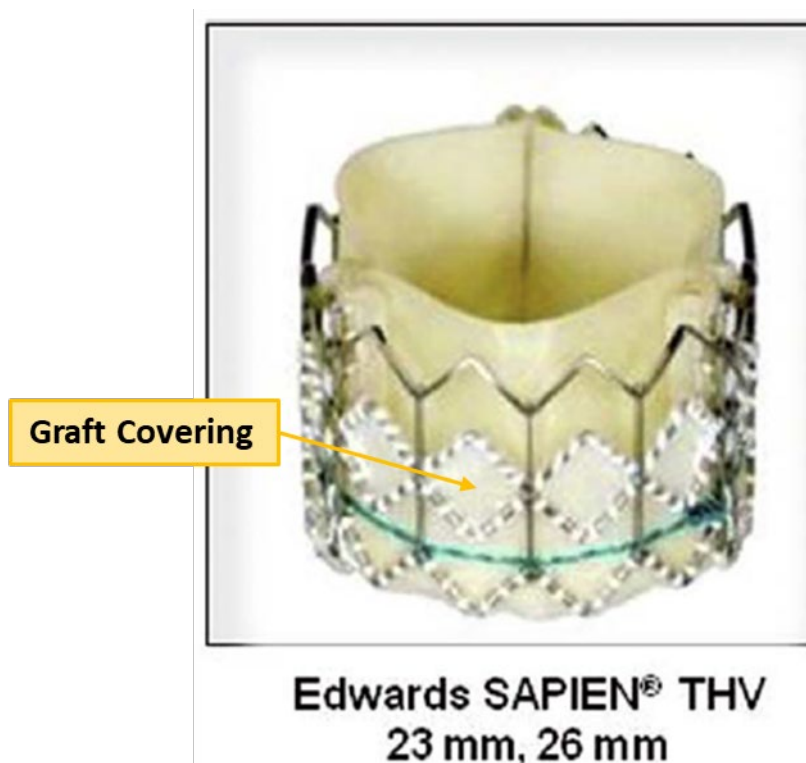
106. The claim states, “the inner frame *includes* a cylindrically extending polymeric inner graft covering.” I understand that during prosecution of the ’236 patent, Patent Owner argued the “includes” language requires only an inner frame that *is* a graft covering. Specifically, Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a “graft forming the inner frame.” Ex. Ex. 1002 (’236 Patent Prosecution History Excerpt) at 187. Similarly, during prosecution of a related patent – U.S. Patent No. 10,966,846 (the “’846 patent”) – Patent Owner argued the “includes” language is met by Petitioner’s SAPIEN 3 Ultra product because it “includes an inner frame that is a graft.” Ex. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 21-22.

107. I am aware that the SAPIEN 3 Ultra THV (pictured below) has only one frame:



108. Cribier discloses that SAPIEN includes a “unidirectional trileaflet bovine tissue valve.” Ex. 1012 (Cribier) at 348. A person of ordinary skill in the art would therefore have understood that SAPIEN includes three “prosthetic leaflets” constructed from bovine tissue.

109. Cribier also discloses that SAPIEN includes “a polyethylene terephthalate (PET) fabric cuff.” *Id.* at 348, Fig. 1. PET is a type of polyester and also a polymer and is a “polymeric graft covering.” Figure 1 below shows the fabric cuff, which is the whiter material that extends around the prosthetic heart valve, at the lower end of the outer frame. As shown in the figure, the fabric cuff is “cylindrically extending” and extends radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame:



SAPIEN's PET fabric cuff covers the inside surface of SAPIEN's outer frame. Based on Patent Owner's statements during prosecution, SAPIEN's inner fabric cuff is an inner frame that includes a graft covering, as required by claim 1. SAPIEN's fabric cuff is stitched to the prosthetic leaflets along the green suture line in the figure above, and thus the fabric cuff "engages" the prosthetic heart valve.

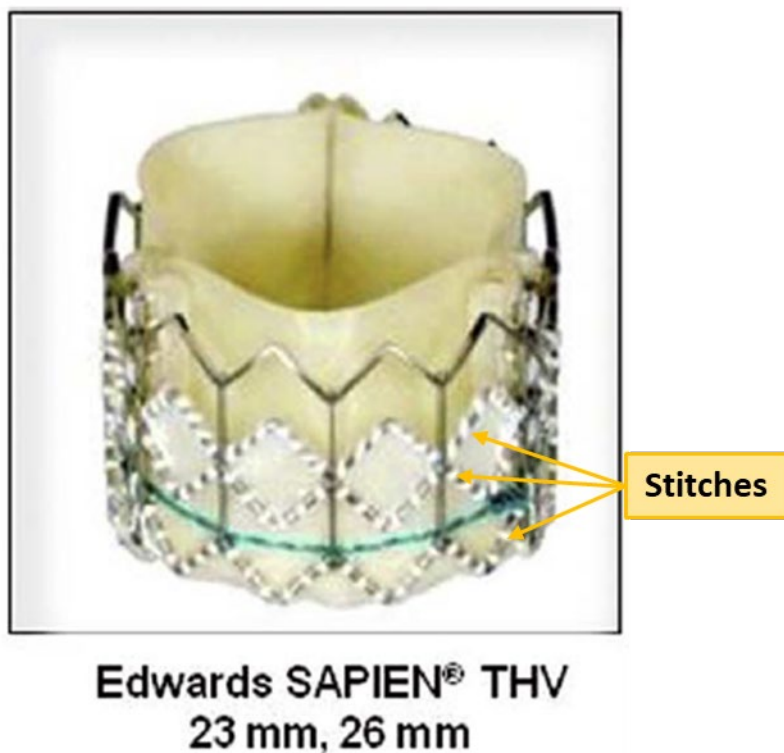
110. A person of ordinary skill in the art would have understood that the SAPIEN's PET fabric cuff provides sealing to the heart valve. Importantly, if the PET fabric cuff did not provide sealing to the heart valve, blood could leak around the valve and undermine the efficacy of the assembly. Further, many prior art publications recognized the sealing capabilities of SAPIEN's PET fabric cuff. *See e.g.*, Ex. 1009 (Conradi, Lenard, et al., *Transcatheter aortic and mitral valve interventions: update 2010*, 2(4) *Interventional Cardiology* 513-523 (2010)) at 514 (describing "polyester fabric sealing cuff"); Ex. 1023 (Smith) at 154 (SAPIEN included a "higher sealing cuff...to reduce paravalvular leaks."); Ex. 1025 (Zajarias, Alan and Cribier, Alain G., *Outcomes and Safety of Percutaneous Aortic Valve Replacement*, 53 *J. Am. College of Cardiology* 20, 1829-1836 (May 19, 2009)) at 1830 ("The stent has a polyethylene terephthalate fabric skirt that decreases perivalvular leaks."); Ex. 1028 (Roselli, E.E., *Engineering transcatheter aortic valve devices: a surgeon's perspective*, 225 *J. Engineering in Medicine*,

207-219 (Mar. 1, 2011)) at 213 (SAPIEN “includes both the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize the paravalvular leak”).

4. Stitching

111. Claim 1 next recites: “wherein the outer frame is secured to the inner graft covering by stitching.” Cribier also discloses this limitation.

112. As shown in Cribier’s Figure 1 (below), a plurality of white stitches secure SAPIEN’s fabric cuff to the outer frame along the three lower rows of the frame:



Ex. 1012 at 348, Fig. 1; *see also* Ex. 1027 (Roselli) at 213 (“The pericardial tissue is sewn to the frame using polytetrafluorethylene (PTFE) suture and includes both

the valve leaflets and a fabric cuff at the base of the device to optimize the seal and minimize paravalvular leak.”).

5. First Portion of Fibers

113. Claim 1 next recites: “a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic.” Cribier in combination with Walther renders this limitation obvious.

114. Walther’s PET outer cloth, pictured in Figure 1 below, is positioned radially outwardly of the outer frame:

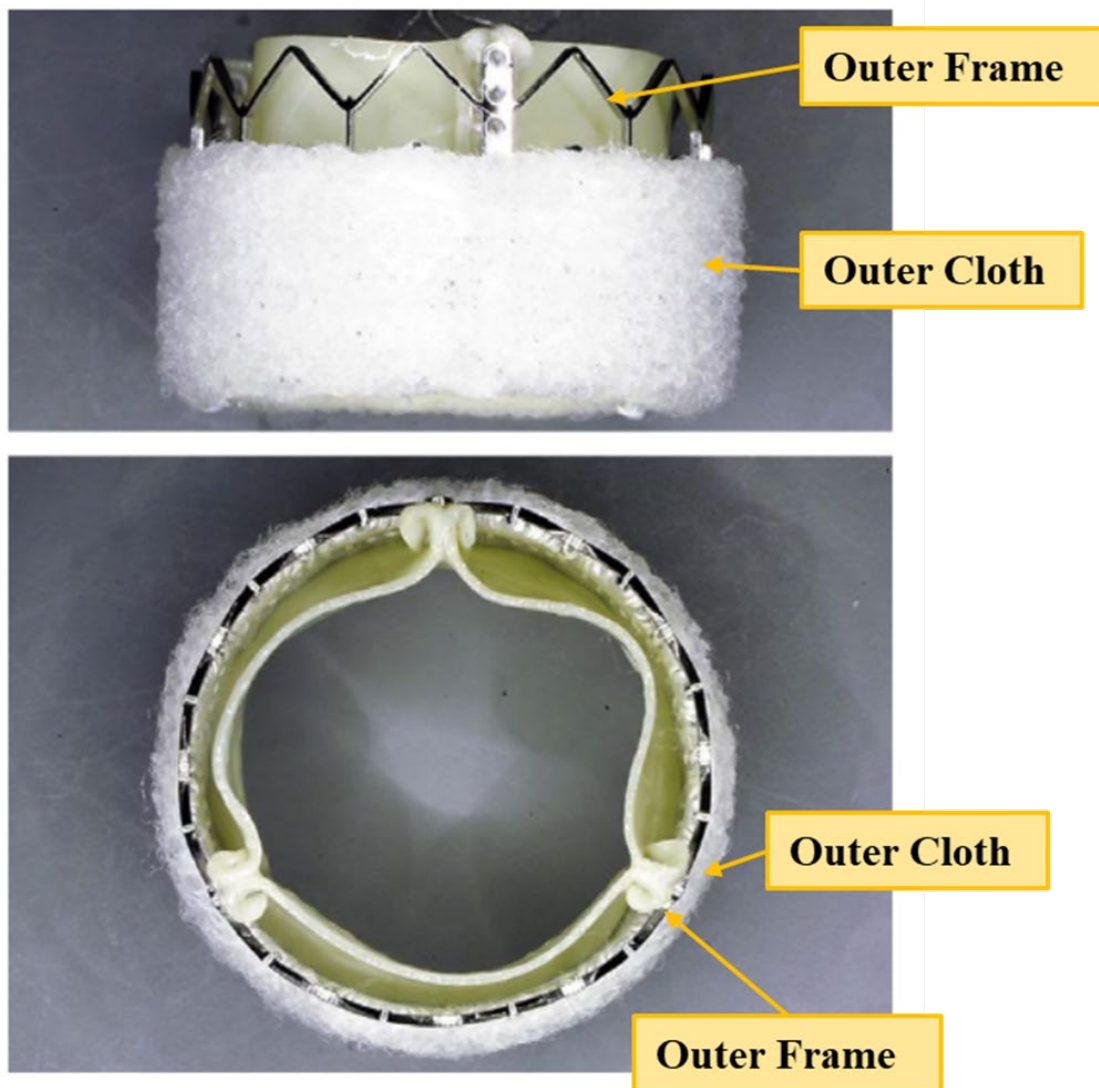
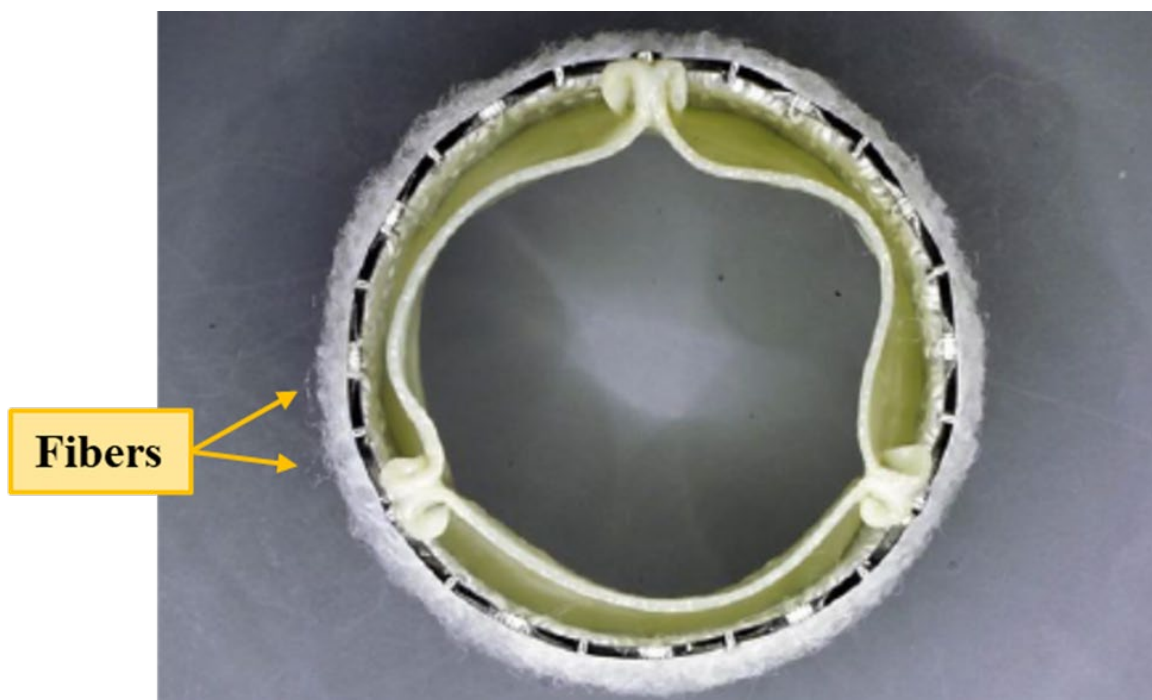


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at Fig. 1. Walther states that the outer cloth “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.” *Id.* at 1120. Based upon the tests, Walther concluded that “the Edwards SAPIEN + cloth THV implanted valve-in-valve within the CEP valve demonstrated excellent

hydrodynamic performance,” indicating that the valve performed its sealing function well. *Id.* at 1125.

115. Walther’s outer cloth is comprised of PET fibers that extend radially outwardly of the outer frame. The PET fibers are “non-metallic,” as required by claim 1. In the figure below, one can see the fibers extending radially outwardly from the outer frame all around the circumference of the valve. Additionally, several particularly long fibers are visible that extend outwardly of the outer frame illustrating that the fibers have different lengths:



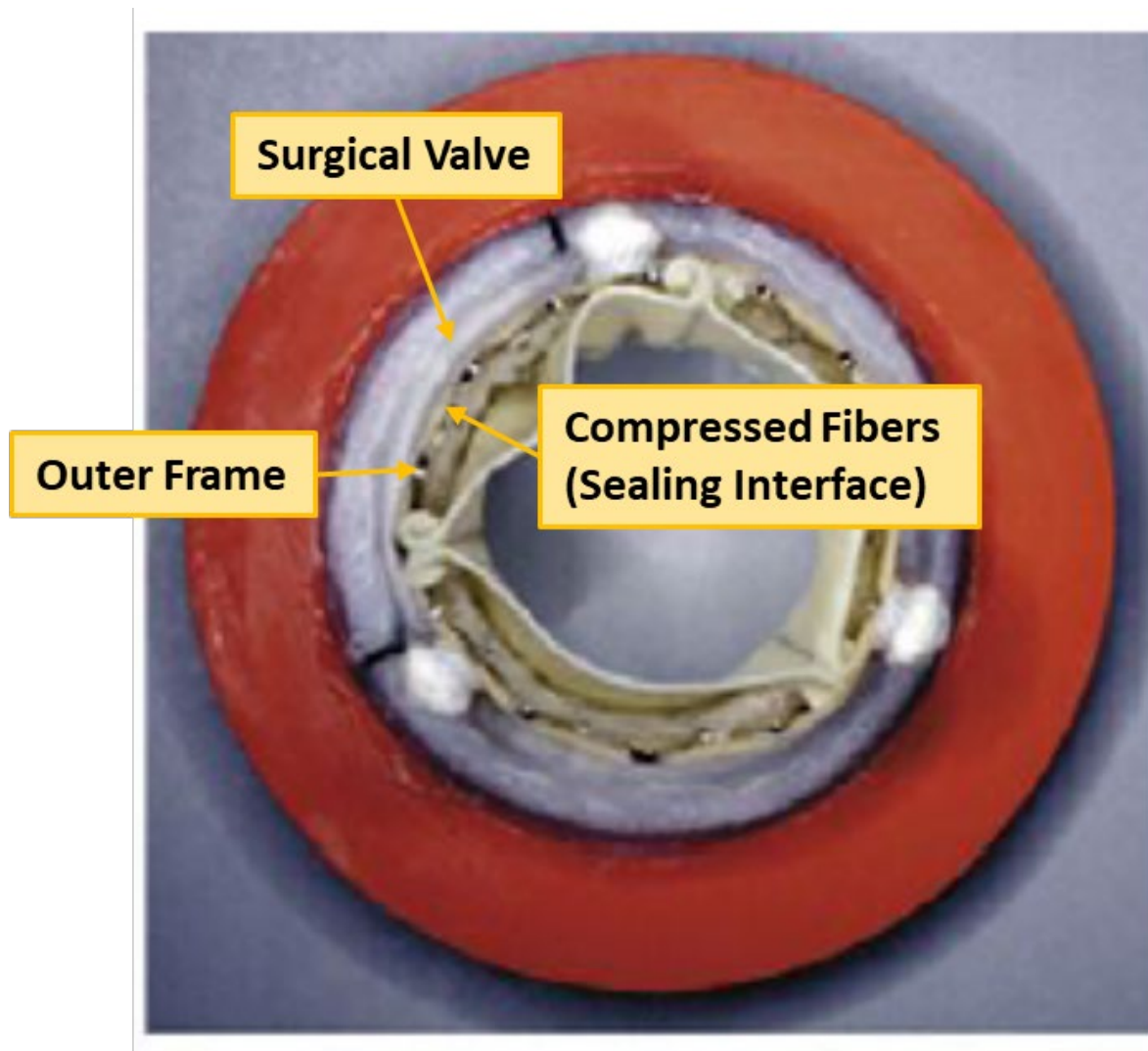
Id. at 1121, Fig. 1. The above figure depicting fibers extending radially outwardly from the outer frame is consistent with what a person of ordinary skill in the art would have expected from a cloth. A person of ordinary skill in the art would have expected outwardly extending fibers (like those shown above) because cloths

are known to be made of woven fibers and have some amount of “hairiness.” *See e.g., Ex. 1028 (Tyagi, G.K., Chapter 5: Yarn structure and properties from different spinning techniques, Advances in Yarn Spinning Technology (2010)); Ex. 1029 (Kothari, V K, Hairiness properties of polyester-cotton blended yarns, 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004)).* Additionally, Merriam-Webster defines “cloth” as “a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments.” *Available at:* <https://www.merriam-webster.com/dictionary/cloth>.

116. Moreover, the fibrous exterior of Walther’s outer cloth is not surprising. As demonstrated by Walther’s PET outer cloth and SAPIEN’s PET fabric cuff, PET can have a range of finishes. Here, Walther discloses that the PET outer cloth is required to “reduce paravalvular leaks” and “increase ‘fit’ within [Edwards’s] surgical Perimount valves.” Ex. 1007 (Walther) at 1120. A person of ordinary skill in the art would have been motivated to select an outer cloth having a fibrous finish, like the outer cloth shown in Figure 1 above, so that the radially extending fibers that extend outwardly of the outer frame fill the gaps between the SAPIEN and surgical valve. *See also id.* at 1126 (explaining that the outer cloth fills little gaps).

117. A person of ordinary skill in the art would have understood that the outwardly extending fibers of Walther's outer cloth constitute the "first portion" of fibers required by claim 1.

118. The outwardly extending fibers of Walther's outer cloth (i.e., the first portion) are configured to form a sealing interface against the patient's annulus and native valve leaflets when compressed thereagainst. Walther's cloth-covered SAPIEN is implanted within a surgical valve made by Petitioner. Ex. 1007 (Walther) at 1020, 1121. Walther discloses that the outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves...." *Id.* at 1120. The outer cloth creates a seal by compressing the radially extending fibers against the surgical valve, as shown in Walther's Figure 2 below:

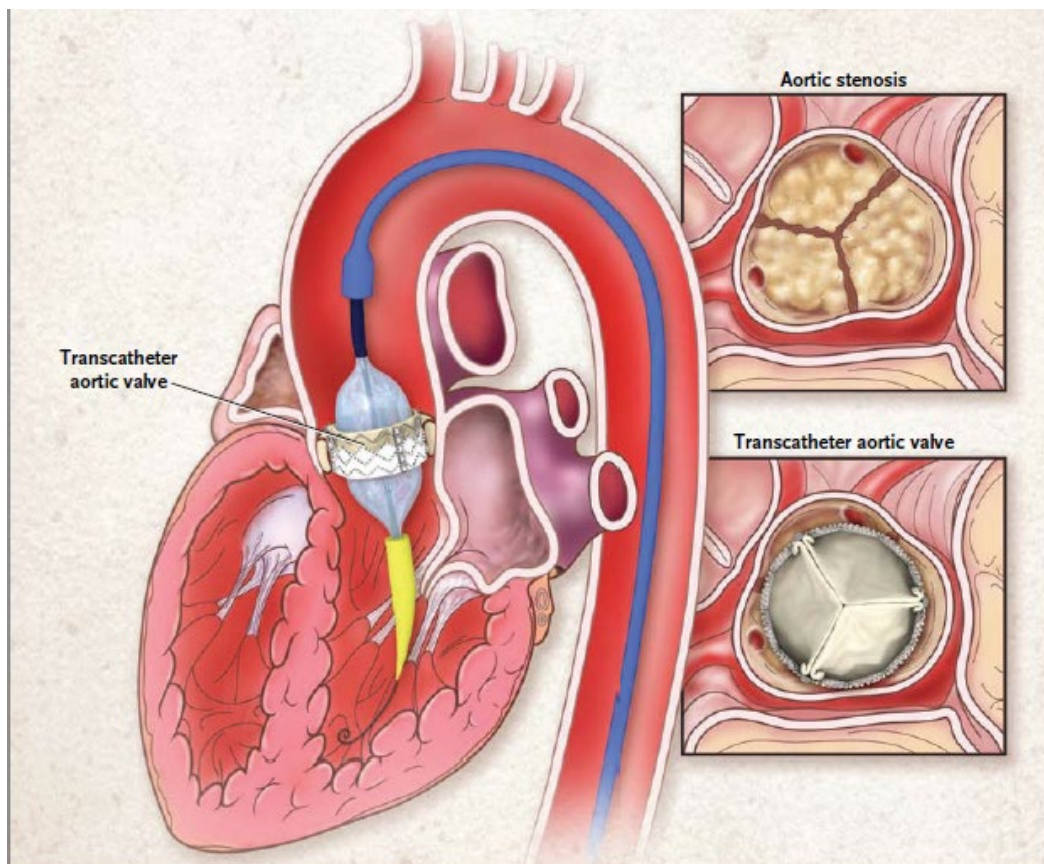


Id. at Fig. 2. A person of ordinary skill in the art would therefore have understood that expanding Walther's cloth-covered SAPIEN in a patient's native aortic valve would compress the outer cloth's outwardly extending fibers (i.e., the first portion) against the patient's annulus and native leaflets to form a sealing interface therewith.

119. This understanding of Walther would have been informed by a person of ordinary skill in the art's knowledge of the standard procedure for implanting

SAPIEN. Cribier discloses that SAPIEN “can be implanted within the diseased native aortic valve using either the retrograde transfemoral or antegrade transapical routes.” Ex. 1012 (Cribier) at 347; *see also id.* (disclosing that SAPIEN is “positioned across the aortic annulus”). When implanted, SAPIEN provides sealing between the outer frame and the patient’s anatomical wall to “minimize perivalvular leaks.” *Id.*, 353; Ex. 1009 (Conradi) at 516-517, Fig. 4A; Ex. 1022 (Smith) at 156-158; Ex. 1012, Abstract, 350-355; Ex. 1027 (Roselli) at 208-210, 214; Ex. 1047 (Piazza) at 74. SAPIEN’s outer frame presses against, and forms a seal with, the annulus and the native valve leaflets of the patient’s native aortic valve. *See, e.g.*, Ex. 1047 (Piazza) at 74 (disclosing that SAPIEN “is positioned within the aortic root and, once deployed, crushes the leaflets of the native valve against the wall”); Ex. 1009 (Conradi) at 516-517, Fig. 4A; *supra* §III.B. Cribier instructs that “before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion.” Ex. 1012 (Cribier) at 353. Consistent with the understanding in the art, the ’236 patent identifies the annulus as the point where the leaflets begin. Ex. 1001 (’236 patent) at 1:58-60, Fig. 2; *see also* Ex. 1047 (Piazza) at 76 (“[T]he annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the [aortic] leaflets.”). When

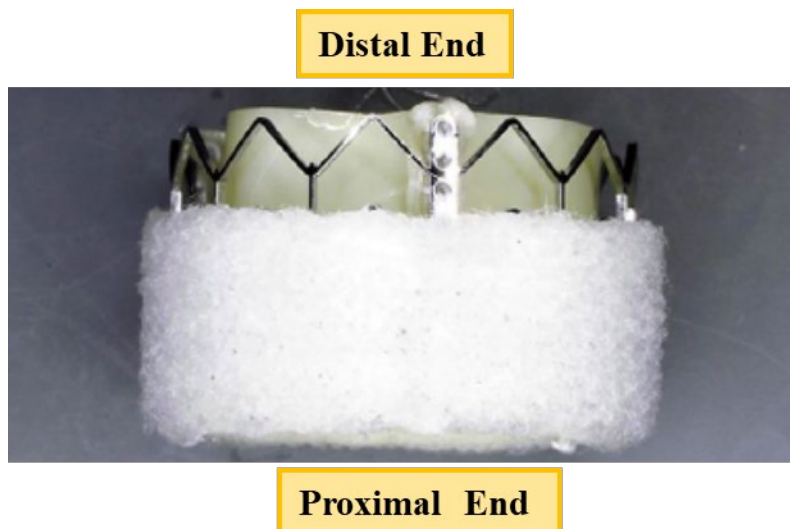
positioned and expanded as described in Cribier , SAPIEN presses against and replaces the patient's native aortic leaflets, as illustrated below:



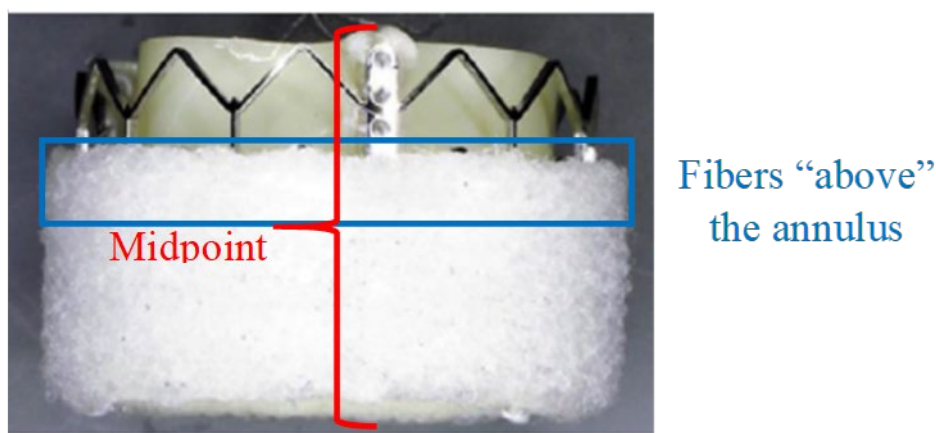
Ex. 1022 (Smith) at 2189, Fig. 1. The prior art even describes SAPIEN as “crush[ing] the leaflets of the native valve against the wall” when it is implanted.

Ex. 1047 (Piazza) at 74.

120. Expanding Walther's cloth-covered SAPIEN in a native aortic valve would press Walther's fibers against the patient's annulus and native leaflets to form a sealing interface. Walther's outer cloth covers approximately two-thirds of SAPIEN's frame, as shown below:



Ex. 1007 (Walther) at Fig. 1 (excerpt). If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, as taught by Cribier, the central fibers would press against the annulus and the fibers “above the annulus” would press against the leaflets:



Id.; see also Ex. 1047 (Piazza) at 74.

121. A person of ordinary skill in the art would have been motivated to combine SAPIEN, as described in Cribier, with Walther’s outer cloth because

Walther expressly discloses this combination. Ex. 1007 (Walther) at 1120-1121. A person of ordinary skill in the art would have had a reasonable expectation of success in adding an outer cloth (as described in Walther) with SAPIEN (as described in Cribier) because Walther describes how to make the combination, provides images of the combination, and concludes that the cloth-covered SAPIEN “demonstrated excellent hydrodynamic performance.” *Id.* at 1125. Additionally, Walther also discloses that the cloth-covered SAPIEN “has demonstrated acceptable *in vitro* central regurgitation performance in previous verification studies, meeting minimum performance requirements standard per ISO 5840:2005 section 7.2.3.” *Id.* at 1124.

122. A person of ordinary skill in the art would have found it obvious to deploy Walther’s cloth-covered SAPIEN within a patient’s native valve. Notably, claim 1 does not require endovascular delivery of the heart valve. Thus, a person of ordinary skill in the art would have understood that the size of the valve would not be an issue for delivery. *See e.g.*, Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation*, 116 [suppl I] *Circulation* I-240—I-245 (September 11, 2007)) at I-244 (“With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients”). Dr. Walther recognized size would not be an issue during the

Conference Discussion accompanying his publication stating that he hoped the valve would be available soon, “at least for the trans-apical approach, where tight crimping is not an issue.” Ex. 1007 (Walther) at 1126.

123. As explained previously, Walther describes deploying the cloth-covered SAPIEN within an Edwards surgical valve “to reduce paravalvular leak by creating a seal between the two valves.” Ex. 1007 (Walther) at 1120. Walther’s outer cloth creates a seal by pressing against the surgical valve. *See e.g., id.*, Fig. 2.

124. Persons of ordinary skill in the art well understood that paravalvular leaks could occur between SAPIEN’s outer frame and the patient’s anatomical wall by November 2012. *See e.g.*, Ex. 1012 (Cribier) at 354 (disclosing that the “vast majority of aortic insufficiency seen on post implantation angiography” with the SAPIEN valve “is perivalvular”; Ex. 1022 (Smith) at 2194 (reporting that 12.2% of patients who received transcatheter implantation of the SAPIEN valve experienced moderate or severe paravalvular leakage at 30 days). This well-known problem would have motivated a person of ordinary skill in the art to apply Walther’s known technique for reducing paravalvular leakage (adding an outer cloth to SAPIEN) to a known device (SAPIEN), which was ready for improvement. The performance of the cloth-covered SAPIEN would have been

predictable because, for example, Walther describes how the device performed in testing. Ex. 1007 (Walther) at 1124-25.

125. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying the cloth-covered SAPIEN in a patient's native aortic valve because Walther discloses that the valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." Ex. 1007 at 1125. Walther also discloses that the cloth-covered SAPIEN "demonstrated acceptable *in vitro* central regurgitation performance in previous verification studies." *Id.* at 1124. Moreover, persons of ordinary skill in the art had studied implantation of SAPIEN within a patient's native aortic valve using multiple delivery approaches, including transapical and transfemoral delivery and delivery through the common iliac artery, and deemed the procedure safe by November 2012. *See e.g.*, Ex. 1012 (Cribier) at 355 ("Transcatheter valve implantation with the Edwards-Sapien® Heart Valve can be done safely and efficiently using the transfemoral retrograde approach."); *id.*, 347 (recognizing that SAPIEN can be implanted using "antegrade transapical routes"); Ex. 1009 (Conradi) at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively); Ex. 1043 (Kainuma) at 273-276 (describing successful delivery through the common iliac artery). Additionally, the surgical valves described in Walther are designed

to replace and simulate the native aortic valve and POSITAs would have expected Walther's cloth-covered SAPIEN to perform similarly in either environment. A person of ordinary skill in the art would therefore have reasonably expected success in implanting the cloth-covered SAPIEN valve within a patient's native aortic valve.

126. I am aware that Patent Owner has made representations about Walther during the prosecution of a related application (U.S. Patent Application 17/213,251). During that prosecution, Patent Owner admitted that Walther describes a SAPIEN "where a graft may form part of the inner frame." Ex. 1039 (Patent Owner Amendment with RCE) at 6. However, Patent Owner also argued that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." *Id.* at 9. There is no support in Walther for this statement. Walther merely states that an "added poly(ethylene terephthalate) (PET) cloth was stitched onto the perimeter of each SAPIEN valve." Ex. 1007 (Walther) at 1121. Walther does not describe a "cloth base or outer graft" and a "fiber portion." Likewise, the figures do not show a "cloth base or outer graft" and a "fiber portion":

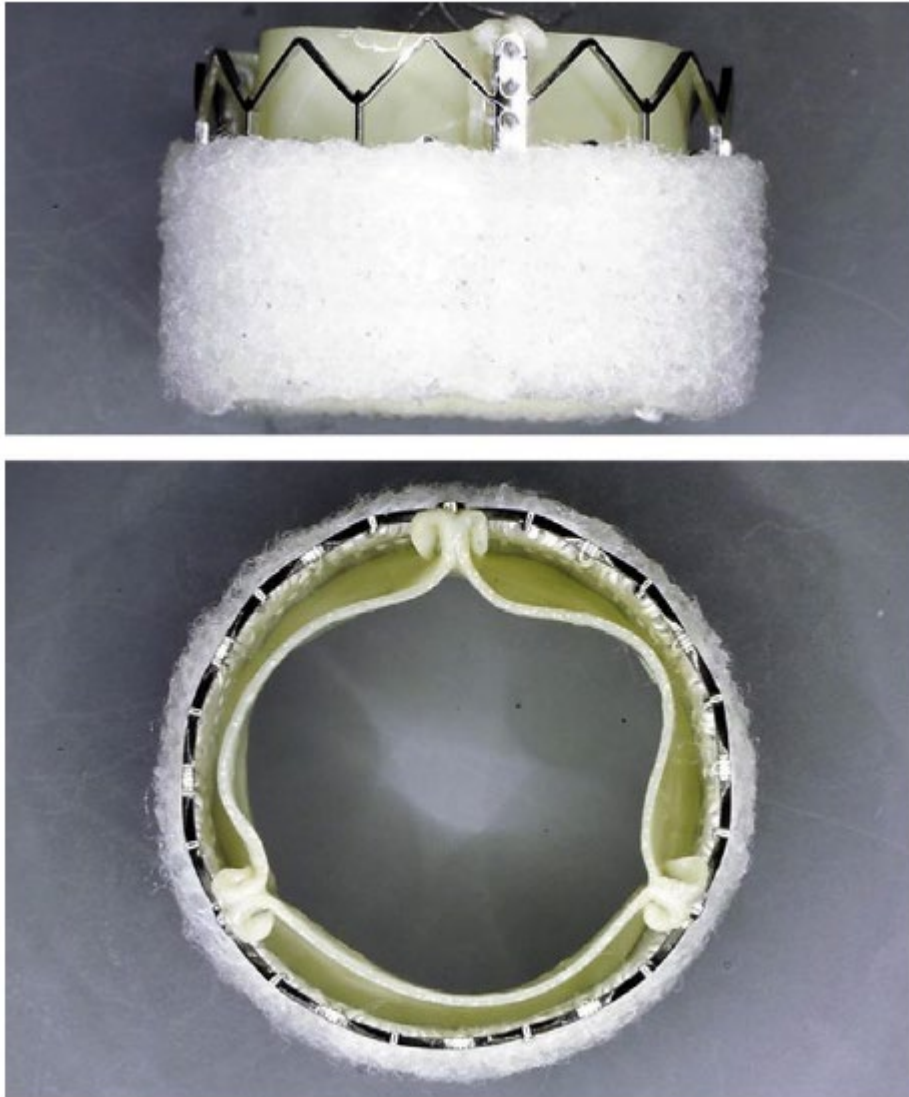


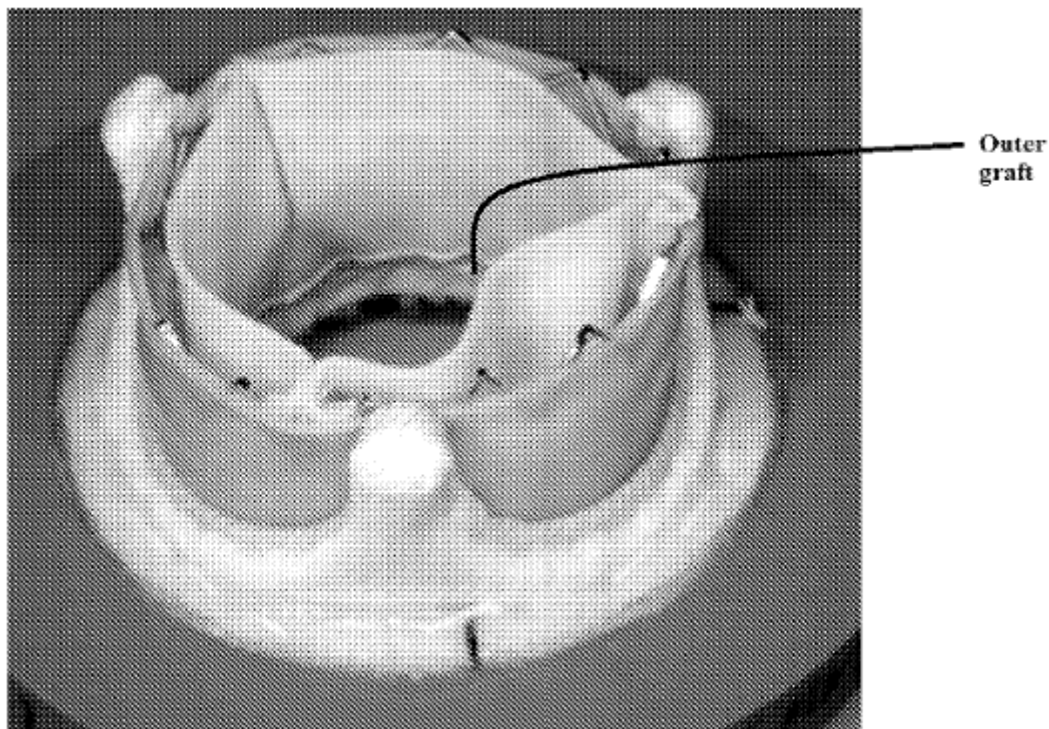
Fig. 1. Cloth valve.

The figures depict a single piece of PET. For this reason, a person of ordinary skill in the art would not have understood Walther to disclose “an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft,” as argued by Patent Owner. Ex. 1039 at 9.

127. Patent Owner also argued that Walther’s outer cloth is “wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets” and

thereby constricts the orifice area and impacts hemodynamics. Ex. 1039 (Patent Owner Amendment with RCE) at 9-10. Again, there is no support in Walther for this statement. Walther never states that its outer cloth is wrapped around the inflow end. To the contrary, Walther states that an “added poly(ethylene terephthalate) (PET) cloth was stitched onto the *perimeter* of each SAPIEN valve.” Ex. 1007 at 1121 (emphasis added). There is no reason to doubt Walther’s description.

128. Patent Owner argues that the below figure shows the outer cloth (labeled “Outer graft”) “flipped towards the prosthetic leaflets where the base/outer graft is then stitched to the metallic frame.” *Id.* at 9.



Patent Owner misunderstands the figure. In the above figure, Patent Owner's line labelled "Outer graft" points to a polytetrafluoroethylene (PTFE) suture that attaches the valve leaflets and inner fabric cuff to the frame. Ex. 1027 (Roselli) at 213. This same suture (green) is also visible on the outside of SAPIEN (with no outer cloth) as shown in the below figure from Cribier:



**Edwards SAPIEN® THV
23 mm, 26 mm**

Ex. 1012 (Cribier) at Fig. 1.

129. The below enlarged and color photograph from Walther shows that the outer cloth is not wrapped around the inflow end of the valve and sutured to the inside of the valve as Patent Owner argues. If the outer cloth was wrapped around and sutured, as Patent Owner argued, it would be visible in the below figure, but it is not.

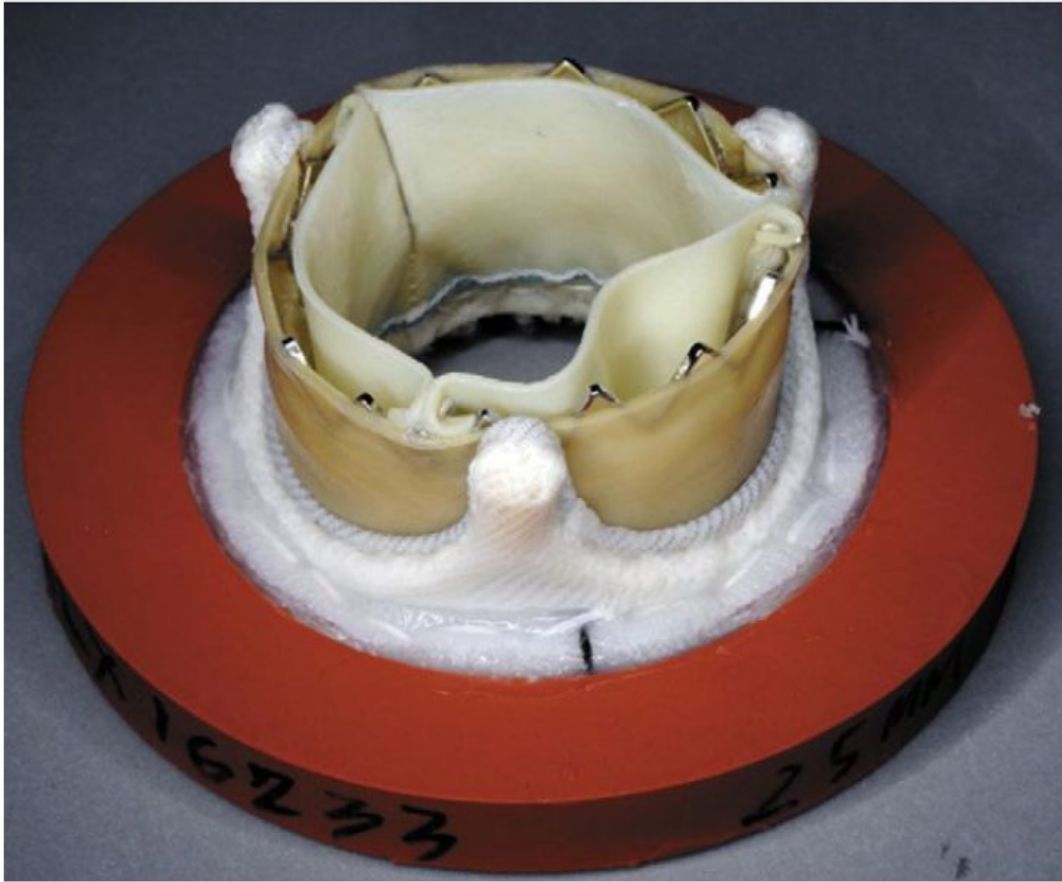


Fig. 2. Cloth THV valve deployed in surgical valve.

Ex. 1007 (Walther) at Fig. 2.

130. Further, because the outer cloth is not “wrapped around the inflow end of the valve and flipped towards the prosthetic leaflets,” a person of ordinary skill in the art would not have been concerned that the outer cloth would constrict the orifice area or impact hemodynamics. Dr. Walther was asked about this potential issue during a Conference Discussion occurring in conjunction with his paper and did not express any concern about this issue, stating: “I am not sure whether it changes the effective orifice area that much and I am pretty sure you just squeeze

it in. You have four atmospheres and really it is just filling little gaps there.” Ex. 1007 (Walther) at 1126. Further, Walther concludes that the valve “demonstrated excellent hydrodynamic performance,” further eliminating any concerns that the outer cloth somehow disadvantageously impacts the orifice area or hemodynamics. *Id.* at 1125-1126. For these reasons, a person of ordinary skill in the art would not have understood Walther’s outer cloth to wrap around the inflow end of the valve or negatively impact hemodynamics.

6. Second Portion of Fibers

131. Claim 1 next recites: “a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second portion of fibers is non-metallic.” Cribier in combination with Walther renders this limitation obvious.

132. As I explained in the preceding section, Walther discloses a SAPIEN with an outer cloth sutured to the exterior of the stent frame that includes a plurality of PET fibers that extend outwardly from the outer frame (i.e., the first portion). *Supra* §VI.A.5. In addition to the outwardly extending fibers on the outward-facing surface of the outer cloth, a person of ordinary skill in the art would have understood that Walther’s outer cloth also includes a plurality of PET fibers on the opposite side of the cloth on the inward-facing surface that press

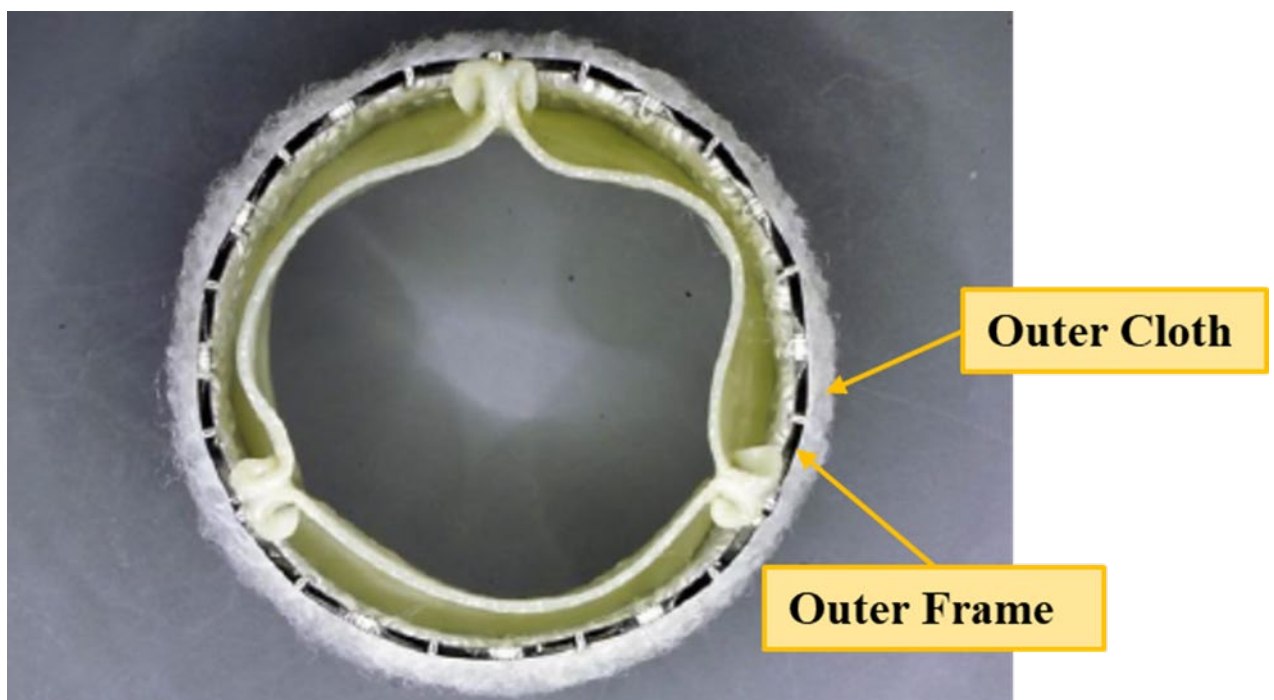
against the outer frame. These fibers pressing the outer frame are visible in Walther's Figure 1 below:



Ex. 1007 (Walther) at Fig 1 (excerpt). As shown above, some of the inwardly-facing fibers extend radially inwardly through the open cells of the outer frame. *Id.* A person of ordinary skill in the art would have understood that many of the inwardly-facing fibers do not pass through the open cells, but instead press against and form a sealing interface with the outer frame. As I explained above, cloths, including Walther's PET cloth, are generally made by weaving or knitting a plurality of fibers together to form a single piece of material. *Supra* §VI.A.5. Therefore, a person of ordinary skill in the art would expect Walther's PET cloth to

have fibers on both its outwardly-facing surface and its inwardly-facing surface because the entire cloth is formed from woven fibers. The inwardly-facing surface of the outer cloth, which presses against the outer frame, is the “second portion of fibers” required by claim 1. The fibers are PET and, therefore, “non-metallic.” *Supra* §VI.A.5.

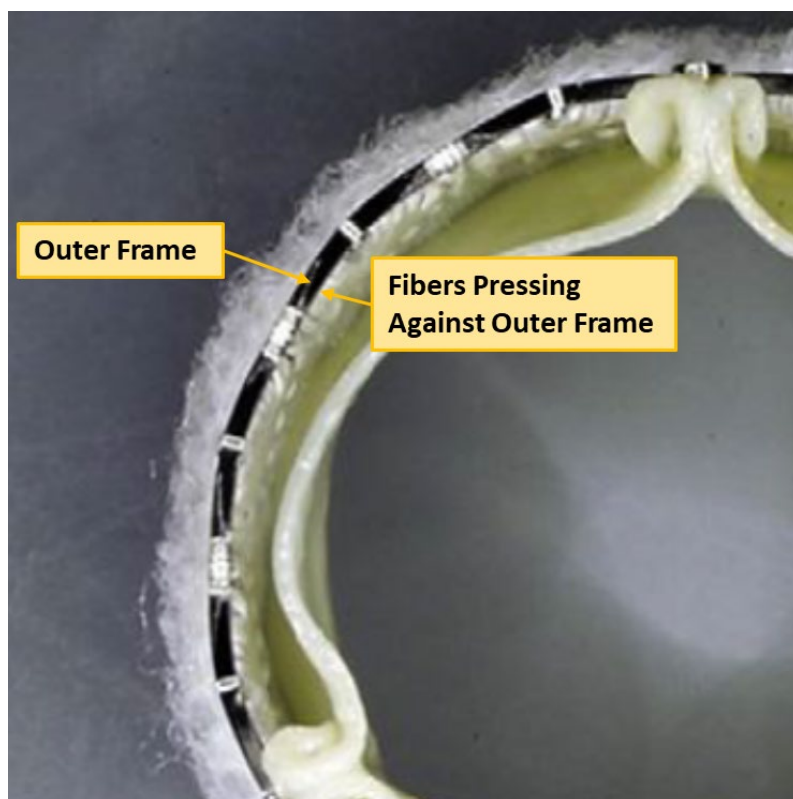
133. Walther discloses that the outer cloth is “stitched onto the perimeter of each SAPIEN valve.” Ex. 1007 (Walther) at 1121. The perimeter of the SAPIEN valve is the outer frame, as shown in Walther’s Figure 1 below:



Ex. 1007 (Walther) at Fig. 1 (excerpt). Therefore, the second portion of fibers, which press against the outer frame, are “carried by the outer frame.”

134. A person of ordinary skill in the art would also have understood that the PET fibers pressing against the outer frame (i.e., second portion) are

“configured to form a second sealing interface against the outer frame when . . . compressed thereagainst.” Because the fibers are stitched to the exterior surface of the outer frame, they would press against the outer frame when the valve is expanded, forming a “second sealing interface thereagainst.” *See e.g., id.* at Fig. 2. Again, this is visible in Walther’s Figure 1, which shows the cloth-covered SAPIEN in the expanded state:



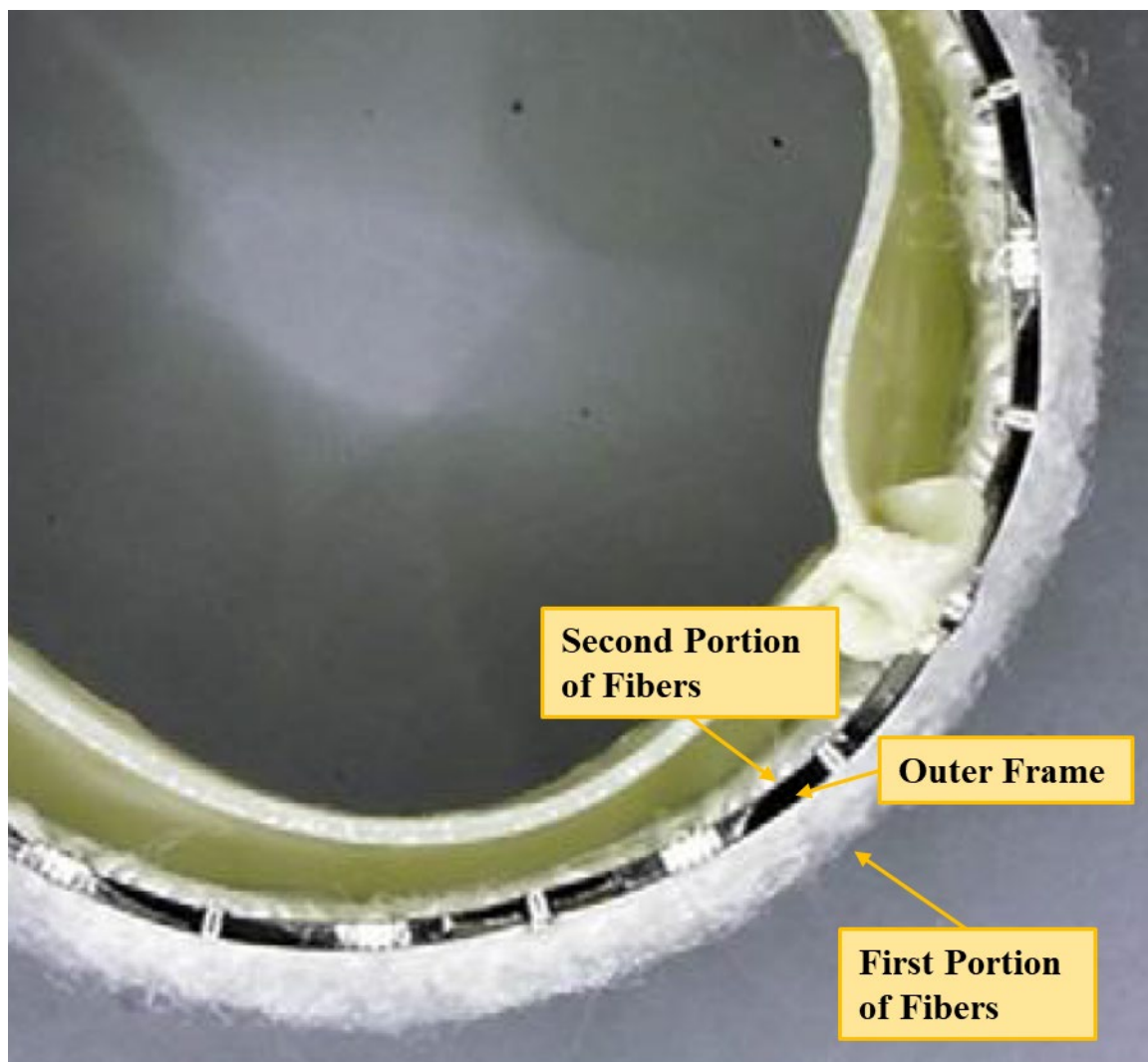
Id. at Fig. 1 (excerpt). The sealing interface formed between the second portion and the outer frame helps the outer cloth “reduce paravalvular leak.” *Id.* at 1120. The radially extending fibers of the outward-facing surface of the cloth (i.e., the first portion) would press against and seal the native tissue of the patient’s aortic

valve, preventing blood from leaking between the cloth and the native tissue. On the opposite side of the cloth, the fibers of the inward-facing surface of the cloth press against and seal the outer frame, preventing blood from leaking between the cloth and the outer frame. In this way, the two fiber portions of the outer cloth work together to reduce PVL.

7. First and Second Portion in Overlapping Radial Alignment

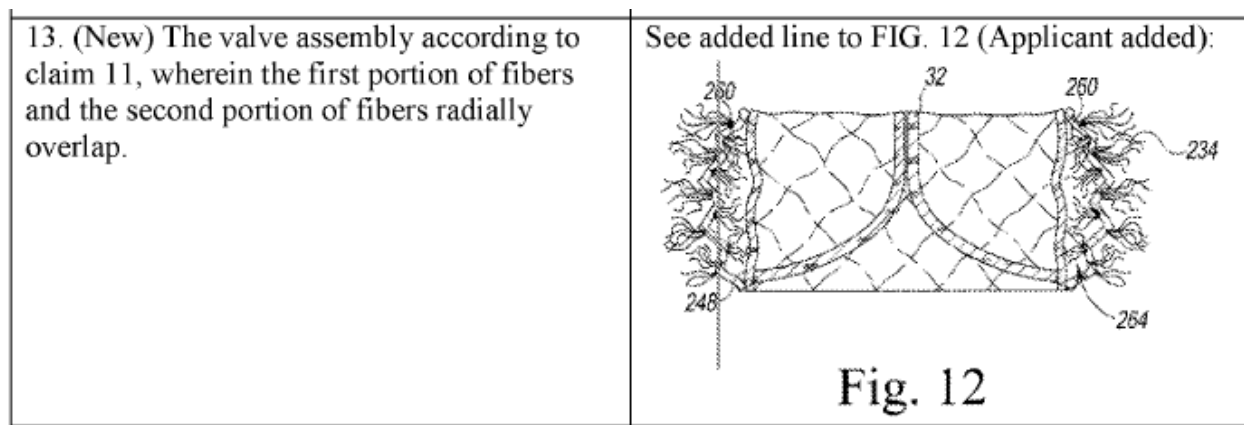
135. Claim 1 next recites: “wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment.” Cribier in combination with Walther renders this limitation obvious.

136. The outwardly extending fibers extending from the outward-facing surface of Walther’s outer cloth (i.e., first portion) and the inwardly-facing fibers extending from the inward-facing surface Walther’s outer cloth (i.e., second portion) are in “overlapping radial alignment” as shown in Walther’s Figure 1:



Ex. 1007 (Walther) at Fig. 1 (excerpt). Because Walther's outer cloth encircles the entire perimeter of the SAPIEN valve, a person of ordinary skill in the art would have understood that the outwardly facing fibers (i.e., first portion) and the inwardly facing fibers (i.e., second portion) radially overlap along the entire perimeter of the SAPIEN. In addition, because Walther's first portion of fibers and second portion of fibers are part of a single woven PET cloth, the first portion and the second portion would necessarily be in radially overlapping alignment.

137. This understanding is further confirmed by Patent Owner's representations during prosecution of the '236 patent. During prosecution, of the '236 patent, Patent Owner relied on Figure 12 to support originally filed claim 13, which recited that the "first portion of fibers and the second portion of fibers radially overlap":



Ex. 1002 ('236 Patent Prosecution History Excerpt) at 241. The fibers in Walther's outer cloth are arranged the same way. *See, e.g.*, Ex. 1007 (Walther) at Fig. 1. Therefore, Walther's first portion of fibers is in "overlapping radial alignment" with the second portion of fibers.

8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets

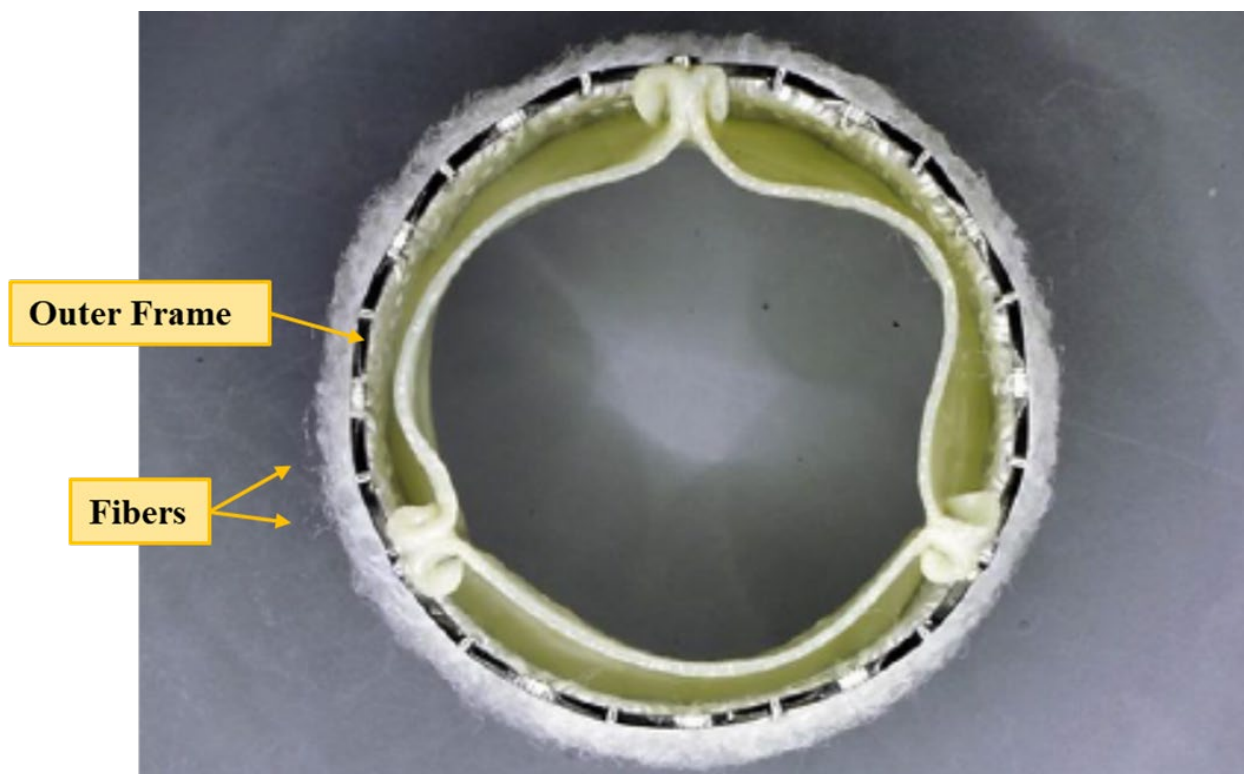
138. Claim 1 next recites: "wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst." Cribier in combination with Walther renders this limitation obvious.

As I explained above, when Walther's cloth-covered SAPIEN is implanted in a patient's native aortic valve, the fibers of the first portion would be in overlapping radial alignment with, and seal against, the patient's native aortic leaflets. *Supra* §VI.A.5. A person of ordinary skill in the art would have been motivated to implant Walther's cloth-covered SAPIEN in a patient's native aortic valve, and would have reasonably expected success in doing so, for the reasons I previously provided. *Id.*

9. Free of an Outer Graft Covering Between First Portion of Fibers and Outer Frame

139. Claim 1 next recites: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Cribier in combination with Walther renders this limitation obvious.

140. As shown below, the fibers of Walther's outer cloth are directly stitched to the metal bars of the outer frame:



Ex. 1007 (Walther) at Fig. 1. Walther does not state that there is any “outer graft covering” between the fibers and SAPIEN’s frame and no such “outer graft covering” is visible in the figures. *See id.* at 1120-1121, Figs. 1-2. Additionally, Walther discloses that the outer cloth was stitched to the perimeter of SAPIEN valves that were “identical” to the existing SAPIEN except for the outer cloth. *Id.* at 1120. A person of ordinary skill in the art would have understood that SAPIEN did not include any “outer graft covering” on the exterior of the outer frame, as shown in Cribier’s Figure 1 below:



**Edwards SAPIEN® THV
23 mm, 26 mm**

Ex. 1012 (Cribier) at Fig. 1. As shown above, there is no graft covering, or other material, on the exterior of SAPIEN's outer frame. Therefore, a person of ordinary skill in the art would have understood that when Walther's outer cloth was added to SAPIEN's outer frame, there was no "outer graft covering" between the outwardly extending fibers of the outer cloth (i.e., first portion) and the outer frame.

141. As I discussed above, I am aware that Patent Owner has made arguments about Walther during prosecution of a related patent application, asserting that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." Ex. 1039 (Patent Owner Amendment with RCE) at 9. Patent Owner's arguments about

Walther are unsupported and incorrect for the reasons I provided previously.
Supra §VI.A.5.

10. Radially Compressed Orientation and Radially Expanded Orientation

142. Claim 1 next recites: “wherein the valve assembly has a radially compressed orientation and a radially expanded orientation.” Both Cribier and Walther disclose this limitation.

143. Cribier discloses that the SAPIEN is “*compressed* using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its *expanded size* to its ‘mounted’ size.” Ex. 1012 (Cribier) at 348 (emphasis added). A person of ordinary skill in the art would have understood that SAPIEN’s “mounted size” is a compressed orientation. Similarly, Walther discloses that the cloth-covered SAPIEN valves were crimped and then expanded within various surgical valves by a balloon catheter. Ex. 1007 (Walther) at 1122, Fig. 4.

11. Balloon Expandable

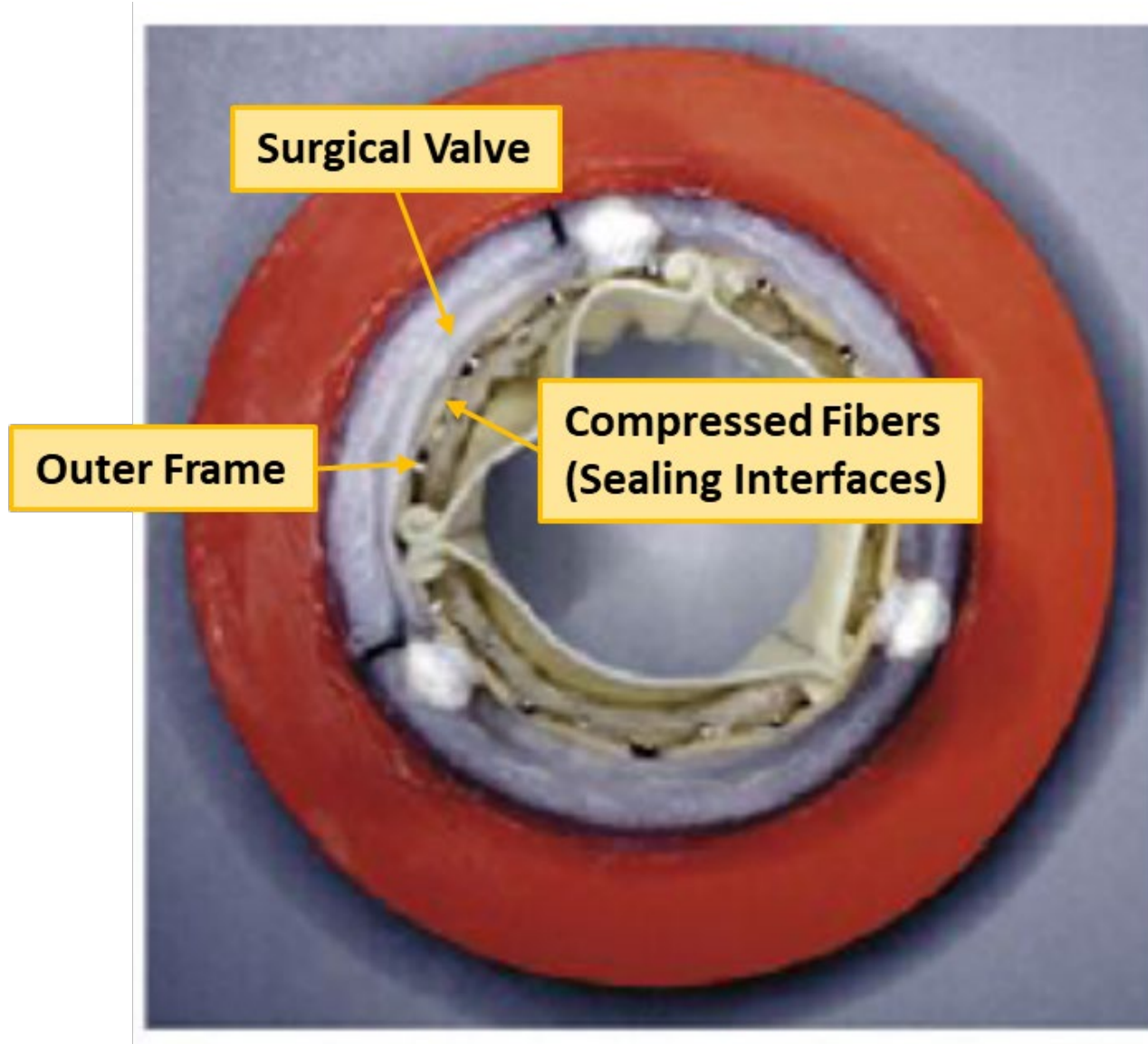
144. Claim 1 next recites: “wherein the valve assembly is balloon expandable to the radially expanded orientation.” Cribier and Walther both disclose this limitation.

145. Cribier discloses that SAPIEN consists of a “balloon-expandable stent.” Ex. 1012 (Cribier) at 348. Walther also discloses that SAPIEN includes a balloon-expandable stent. Ex. 1007 (Walther) at 1122.

12. Compress Fibers to Form a Sealing Interface

146. Claim 1 concludes by reciting: “wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.” Cribier in combination with Walther renders this limitation obvious.

147. Walther discloses implanting the cloth-covered SAPIEN in a surgical valve, and that the outer cloth “is designed to reduce paravalvular leak by creating a seal between the two valves....” Ex. 1007 (Walther) at 1120. Walther’s valve creates a seal by pressing the outer cloth against the surgical valve, compressing the fibers of the outer cloth against the surgical valve and SAPIEN’s outer frame to form sealing interfaces thereagainst:



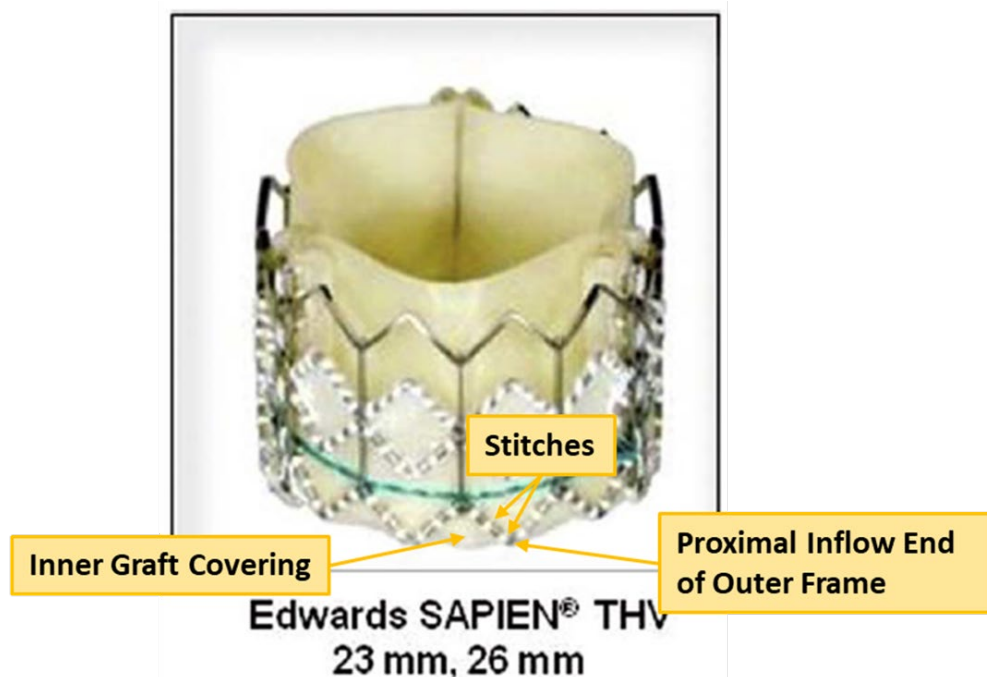
Id. at Fig. 2. Expansion of Walther's cloth-covered SAPIEN within a patient's native aortic valve would similarly compress the outwardly extending fibers of the outward-facing surface of the cloth (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and the inwardly extending fibers of the inward-facing surface of the cloth (i.e., second portion) against SAPIEN's outer frame to form a second sealing interface. As I explained above,

these sealing interfaces prevent blood from leaking around the outside of the valve or between the outer cloth and the stent. *Supra* §§VI.A.5-6.

B. Claim 2

148. Claim 2 recites: “The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.” Cribier in combination with Walther renders this claim obvious.

149. As I explained in claim 1, Cribier discloses that SAPIEN includes an inner PET fabric cuff (i.e., inner graft covering) that extends to the proximal inflow end of SAPIEN’s outer frame:



Ex. 1012 (Cribier) at 348, Fig. 1. As shown in the figure above, a plurality of white stitches extend between the fabric cuff (i.e., inner graft covering) and through the outer frame to secure the fabric cuff to the proximal inflow end of the outer frame. (*See* Ex. 1012, Fig. 1.

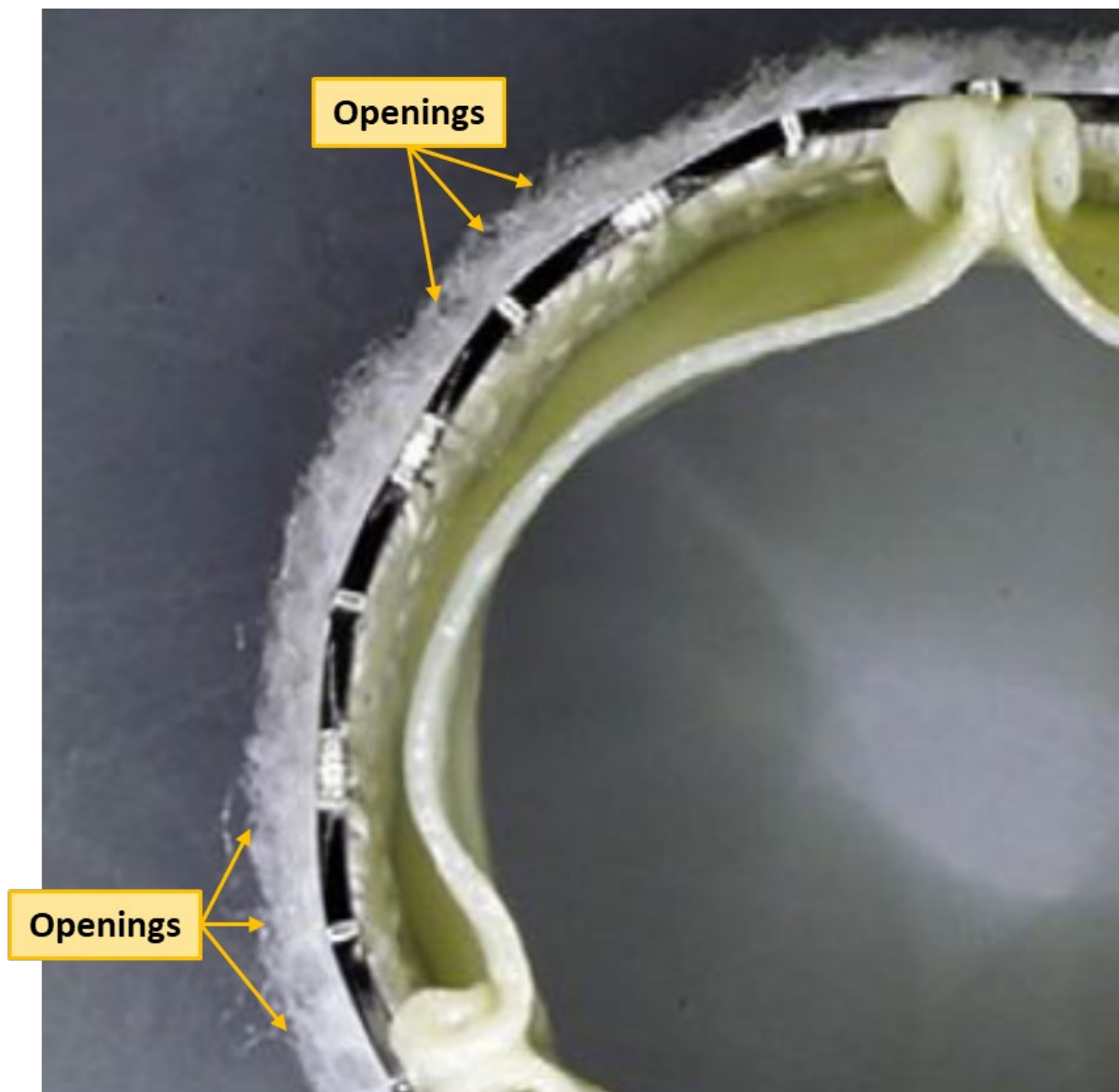
C. Claim 3

150. Claim 3 recites: “The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.” Cribier in combination with Walther renders this claim obvious.

151. First, I note that the ’236 patent does not claim or disclose how to size or arrange the fibers to provide “an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.” *See* Ex. 1001. For example, the ’236 patent never discloses the length or width of the fibers, the density of the fibers, or any particular arrangement of the fibers. *Id.* The ’236 patent also does not disclose the size of the “opening.” I note that the figures of the ’236 patent illustrate relatively large openings between the groups of collagen fibers. *See, e.g.,* Ex. 1001 (’236 Patent) at Figs. 8-9, 11-14. A person of ordinary skill in the art would have understood that fibers with such large openings between them would not be able to form a sufficient seal against the patient’s native tissue to prevent PVL. Therefore, persons of ordinary skill in the art would

have understood that the '236 patent's figures are merely schematic or conceptual, and do not accurately reflect the dimensions, density, or placement of the collagen fibers on the frame.

152. As I explained in claim 1, Walther discloses a SAPIEN with an added outer cloth that includes a plurality of radially extending fibers on the outward-facing surface of the cloth (i.e., first portion of fibers). *Supra* §VI.A.5. A person of ordinary skill in the art would have understood that Walther's outer cloth includes openings between the outwardly extending fibers created by spacing formed between adjacent fibers. *See* Ex. 1007 (Walther) at Fig. 1. These openings are the "opening[s] extending through a thickness" of the outwardly extending fibers required by claim 3, and are visible in the below excerpt of Walther's Figure 1:



Id. at Fig. 1 (excerpt). A person of ordinary skill in the art would have understood that any cloth or fabric that is composed of interwoven fibers, such as Walther's outer cloth pictured above, would necessarily include small openings between adjacent woven fibers. *See e.g.*, Ex. 1008, 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). The openings between fibers may be smaller in

densely-woven cloths/fabrics than in a loosely-woven cloth/fabrics, but a person of ordinary skill in the art would have understood that the openings exist.

153. As shown above, the fibers of Walther's outer cloth are sufficiently dense to prevent blood from flowing through the fibers, but loose enough to create small openings between the adjacent fibers. Ex. 1007 (Walther) at Fig. 1. Persons of ordinary skill in the art would have understood that the openings between the fibers must be small to enable the first portion of fibers to form an effective sealing interface with the native tissue. If the openings were too wide, blood may disadvantageously leak through the openings.

154. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of radially extending fibers such that even larger openings existed between the fibers. *Supra* §III.D; *see also e.g.*, Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. The exchange of Walther's cloth for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in

substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

D. Claim 4

155. Claim 4 recites: “The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” Cribier in combination with Walther renders this claim obvious.

156. Like claim 3, I note that the '236 patent does not claim or disclose how to size or arrange the fibers to provide “an opening extending through a thickness [of the second portion of fibers] that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” *See* Ex. 1001. For example, the '236 patent never discloses the length or width of the fibers, the density of the fibers, or any particular arrangement of the fibers. *Id.* The '236 patent also does not disclose the size of the “opening.” As I noted in the preceding section, persons of ordinary skill in the art would have understood that the '236 patent's figures are merely schematic or conceptual, and do not accurately represent the dimensions, density, or placement of the collagen fibers

on the frame because the openings shown between the groups of collagen fibers would be too large for the fibers to form a sufficient seal against the outer frame to prevent PVL.

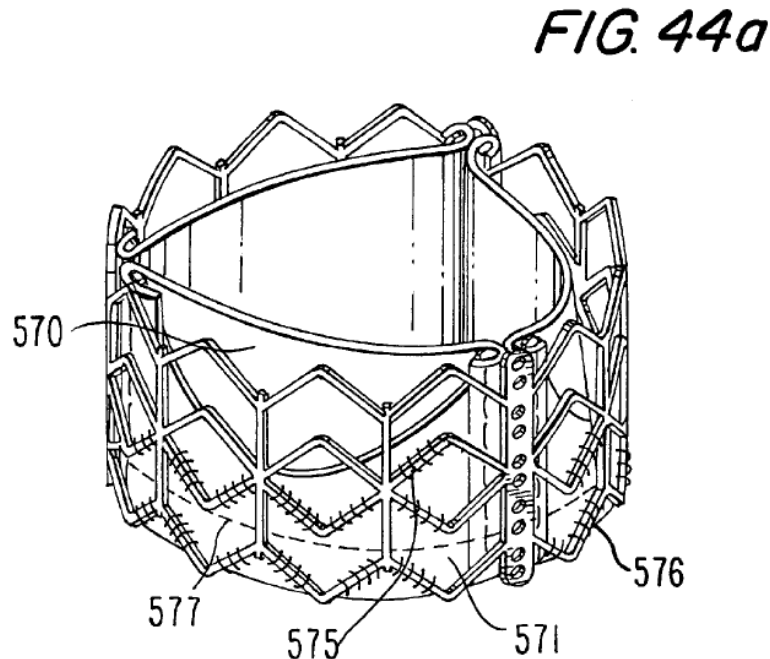
157. As I explained in claim 1, Walther discloses a SAPIEN with an added outer cloth that includes a plurality of radially extending PET fibers on its outward-facing surface (i.e., first portion) and a plurality of inwardly-facing PET fibers abutting SAPIEN's outer frame (i.e., second portion of fibers). *Supra* §VI.A.6. As I explained in the preceding section, a person of ordinary skill in the art would have understood that any woven fabric, including Walther's outer cloth, would include some openings between the interwoven fibers of the fabric. *See supra* §VI.C; *see also e.g.*, Ex. 1008, 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). A person of ordinary skill in the art would therefore have understood that openings necessarily exist between the woven PET fibers of the second portion of Walther's outer cloth that are the "opening[s] extending through a thickness" of the second portion required by claim 4. As I explained for claim 3, the fibers of Walther's cloth are sufficiently dense to prevent leakage of blood, but loose enough to create small openings between the adjacent fibers. *Supra* §VI.C. A person of ordinary skill in the art would have understood that these openings in the second portion extend to the outer frame because the second

portion abuts the exterior surface of the outer frame and is sutured thereto. *Supra* §VI.A.6.

158. Moreover, as I explained in the preceding section, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of woven PET fibers such that even larger openings existed between the fibers. *Supra* §III.C; *see also e.g.*, Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. The exchange of Walther's cloth for a less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

**VII. GROUNDS 2-3: CLAIMS 1-4 OBVIOUS OVER SPENSER AND
WALTHER OR SPENSER II**

159. Spenser describes heart valve assemblies similar to SAPIEN including the below embodiment, which is shown in Figure 44a of Spenser:



Ex. 1010, Fig. 44a.

160. Embodiments of the Spenser patent were commercialized by Edwards and sold as the SAPIEN device. The SAPIEN Instructions for Use (“IFU”) identify Spenser as a patent that may cover SAPIEN. Ex. 1040, 6.

161. As I explained in Ground 1, Walther discloses a modified SAPIEN that includes an added outer cloth. *Supra* §VI.A. Walther’s modified SAPIEN is shown in Figure 1 of the article, below:

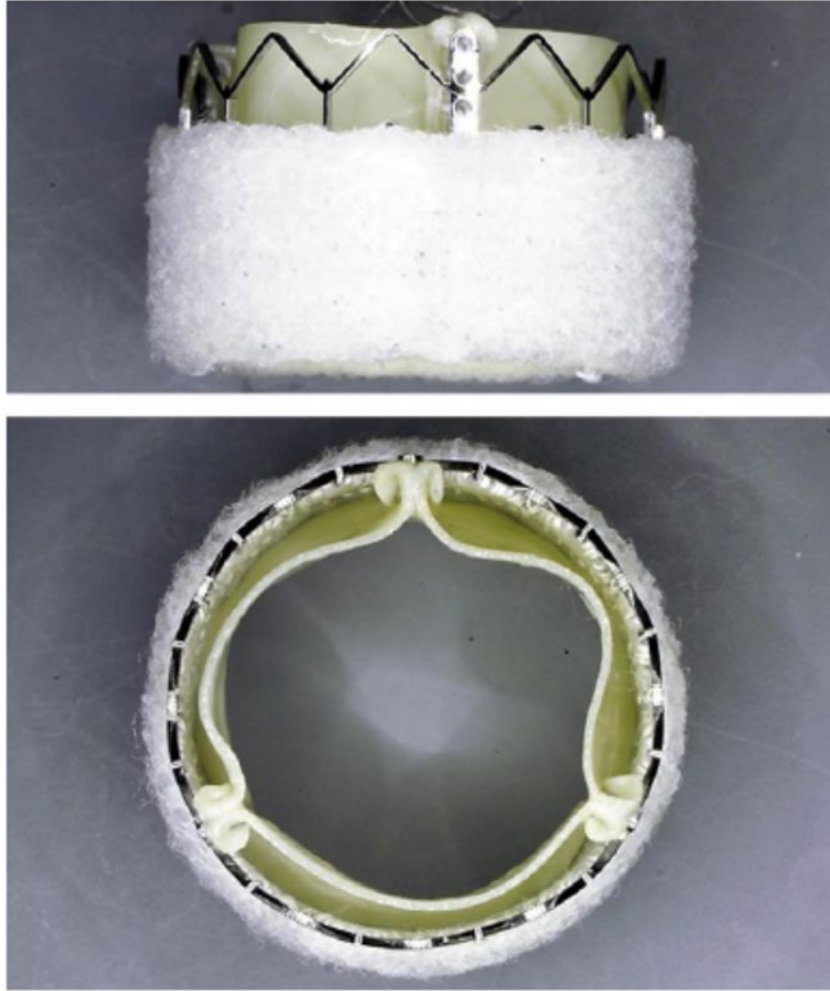


Fig. 1. Cloth valve.

162. Similar to Walther, 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:

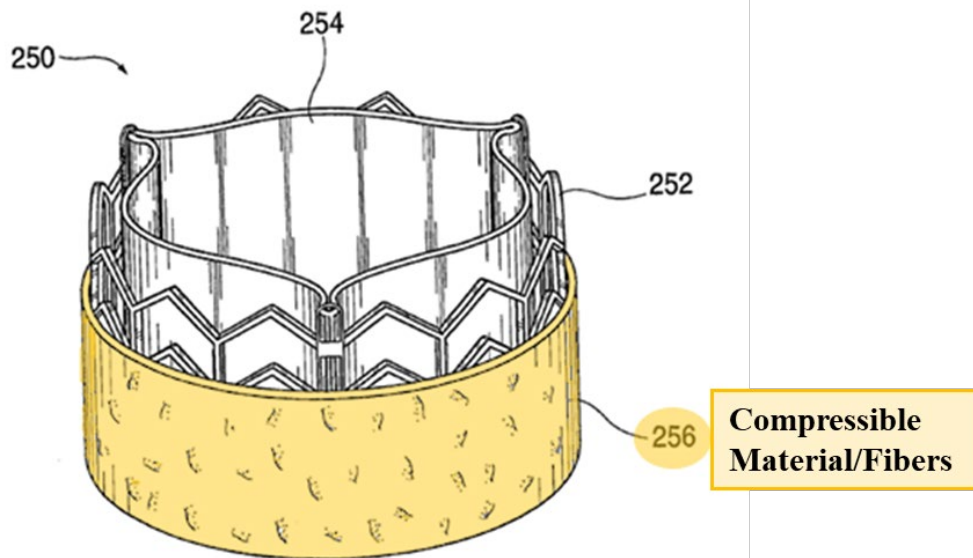


FIG. 22

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

163. For the reasons below, I believe that that a person of ordinary skill would have been motivated to combine Walther’s outer cloth or Spenser II’s outer compressible material with the heart valve assemblies in Spenser, including the assembly shown in Figure 44a. Based on my review of these references, I believe that the combination of Spenser and Walther or Spenser II renders claims 1-4 obvious.

A. Claim 1

164. Based on my review of the prior art, it is my opinion that the combination of Spenser and Walther or Spenser II renders claim 1 obvious.

1. Preamble

165. The preamble of claim 1 recites: “A transcatheter aortic valve assembly comprising.”

166. 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). Spenser discloses that its valve may be implanted “at the natural aortic valve position at the entrance to the left ventricle of a myocardium of a patient.” *Id.* at 1:13-15, 5:17-25, 5:65-6:3, 17:19-18:43. Spenser further discloses that its valve may be implanted by “inserting the valve assembly on a delivery device similar to a catheter.” *Id.* at 2:6-12.

167. Walther also discloses a “transcatheter aortic valve assembly” for the reasons I provided previously. *Supra* §VI.A.1. Likewise, Spenser II discloses a “transcatheter aortic valve assembly.” Spenser II discloses that its invention “is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve.” Ex. 1011 (Spenser II) at [0087]. Thus, a person of ordinary skill in the art would have understood that the stented valve 250 disclosed in Figure 22 is an

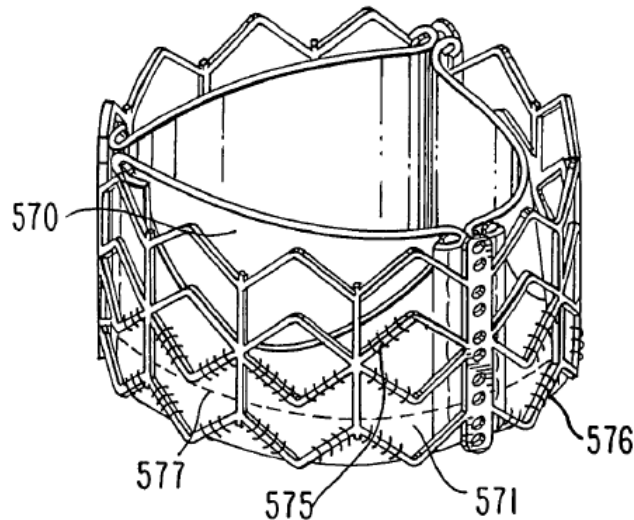
“aortic valve assembly.” *See id.* at [00144]. Spenser II further teaches that this valve is designed for implantation using a balloon catheter. *Id.* A person of ordinary skill in the art would have recognized that where an expandable valve is implanted using a balloon catheter, both the valve and the balloon would be advanced to the patient’s heart via a sheath or catheter, as was standard practiced in the art. Indeed, Spenser II confirms that percutaneous delivery of prosthetic valves involved delivery through a catheter. *See, e.g., id.* at [0033]-[0035], [0040]. Thus, a person of ordinary skill in the art would have understood that Spenser II’s stented valve 250 is a “transcatheter aortic valve assembly.”

2. Outer Frame

168. Claim 1 next recites: “an outer frame formed from a metallic material.” Spenser also discloses this limitation.

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

FIG. 44a



Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame).

170. As shown in Figure 44a above, frame 575 surrounds the other valve features, making it an “outer frame.” *Id.* at Fig. 44a-44b. Spenser further discloses that the frame may be made from metallic materials such as “nickel titanium.” *Id.* at 12:28-31.

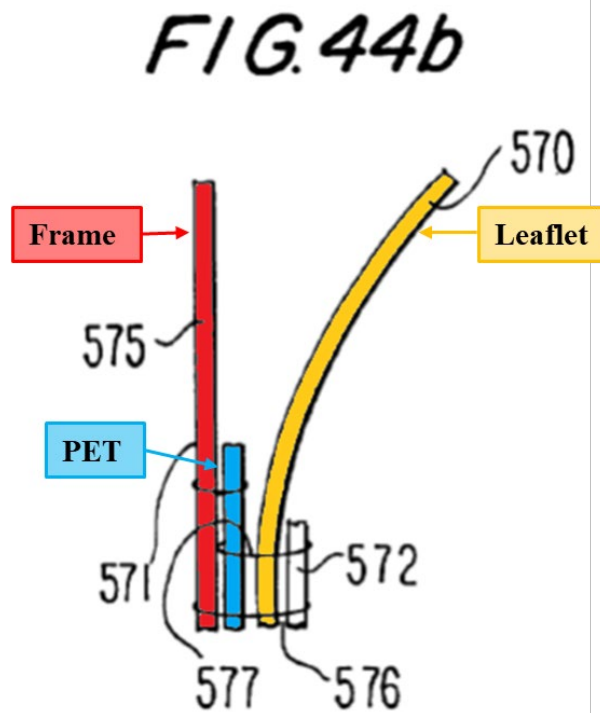
3. Inner Frame

171. Claim 1 next recites: “an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.” Spenser also discloses this limitation.

172. The embodiment in Figure 44a of Spenser includes an “additional piece of PET” 571 for “sealing and protecting the pericardium.” Ex. 1010 (Spenser) at 26:30-34, Figs. 44a-44c; *see also id.* claims 10, 30 (“including a fabric layer interposed between the valve assembly and support stent”). The “pericardium” is the prosthetic pericardial leaflets 570 (*see e.g.*, Figures 44a-b below). *Id.* at 26:30-54. PET is a type of polyester and is a “polymeric...graft covering.”

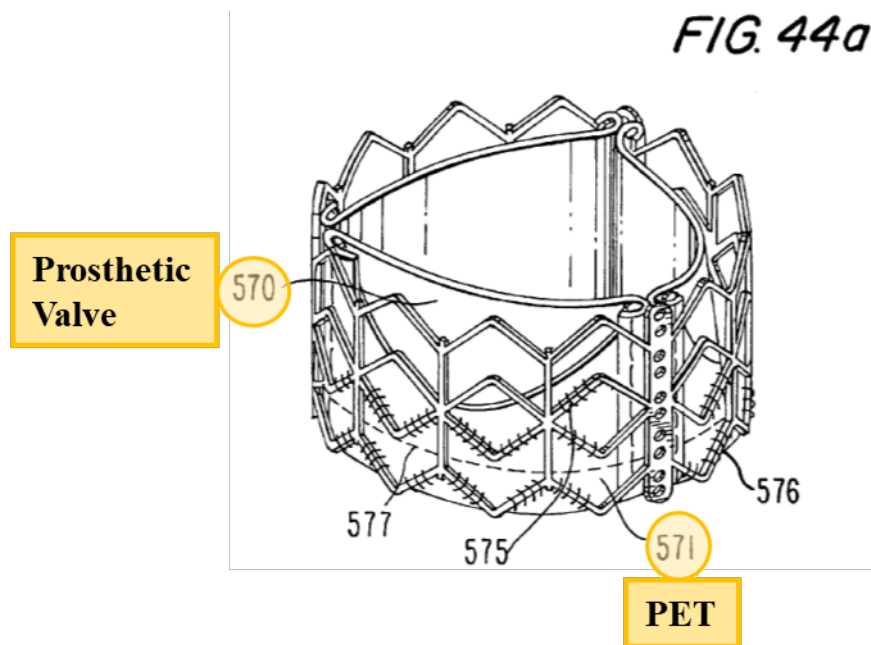
173. As shown in Figure 44b of Spenser below, the PET 571 [blue] is positioned “between the leaflets [570 yellow] and the frame [575 red]”⁴:

⁴ In Fig. 44b, the lead lines for 571 and 575 both point to the outer 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.



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

174. As shown in Figure 44b above and Figure 44a below, the PET 571 is “cylindrically extending” and extends radially outwardly of the prosthetic heart valve 570 and radially inwardly of the outer frame 575 for providing sealing to the heart valve:



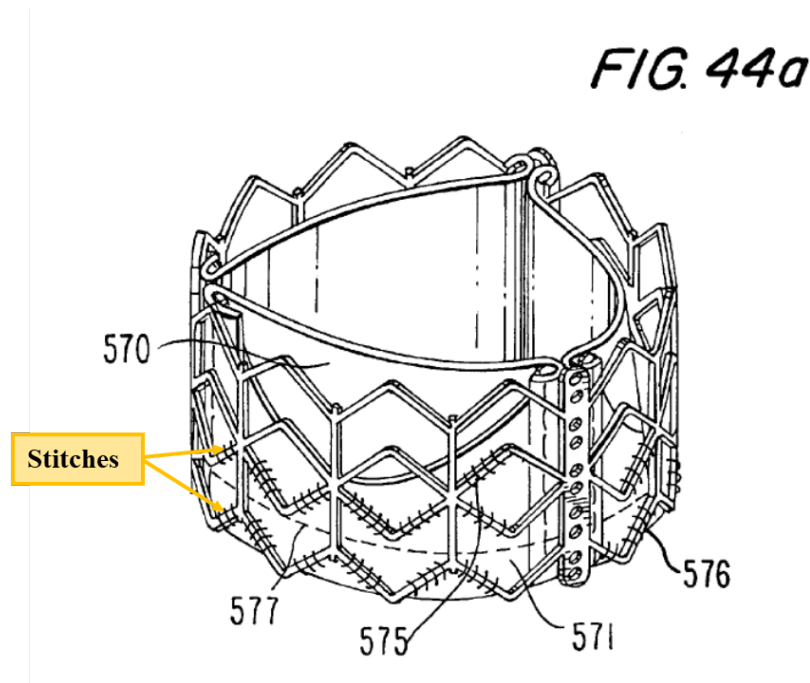
Id. at 26:30-34, Fig. 44a. Thus, based on Patent Owner’s statements during prosecution of related patents, *supra* §VI.A.3, and if an inner frame can be a graft covering, PET 571 is an “inner frame [that] includes a cylindrically extending polymeric inner graft covering.”

4. Stitching

175. Claim 1 next recites: “wherein the outer frame is secured to the inner graft covering by stitching.” Spenser also discloses this limitation.

176. Spenser discloses that a “[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a strong sealing line.” Ex. 1010 (Spenser) at 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30. Additionally, an “upper suture 578 connects the outer PET layer 571 to frame 575.” *Id.* at 26:47-48.

177. Figure 44a illustrates that the top and bottom sutures secure the PET (graft covering) to the outer frame with a plurality of stitches:



Id., Fig. 44a; *see also id.*, Fig. 44b (showing sutures).

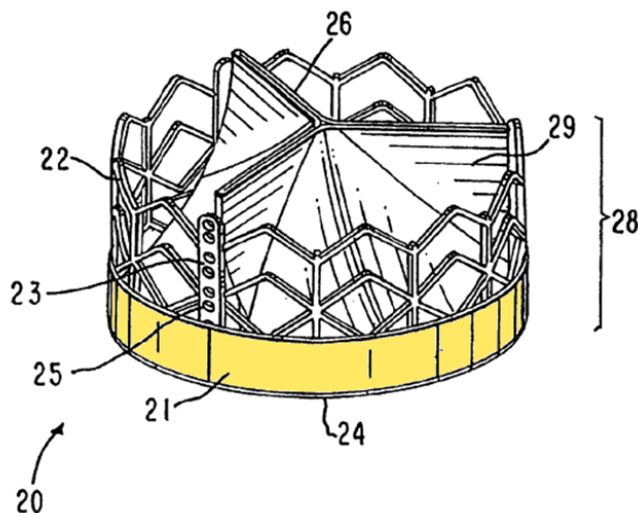
5. First Portion of Fibers

178. Claim 1 next recites: “a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

179. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.5.

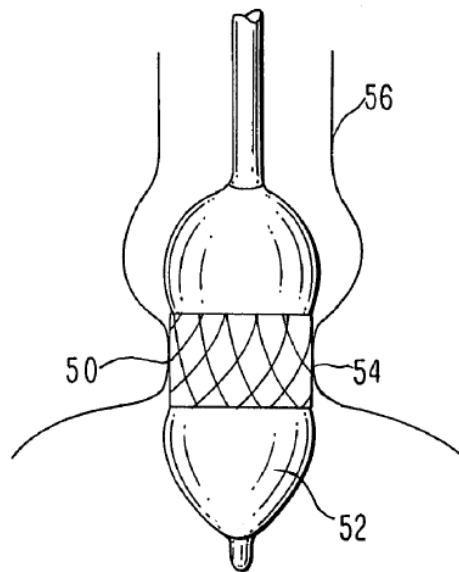
180. A person of ordinary skill would have been motivated by Walther to add an outer cloth, like Walther's outer cloth or a similar outer cloth, to Spenser's Figure 44a because Walther expressly discloses combining an outer cloth with SAPIEN, a heart valve having features similar (if not identical) to Figure 44a. Ex. 1007 (Walther) at 1120-1121. Moreover, Spenser suggests the combination by disclosing a valve similar to Figure 44a having an outer cuff portion 21 for sealing around the valve:



Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. A person of ordinary skill in the art would have had a reasonable expectation of success in combining an outer cloth with Figure 44a because Walther discloses how to combine a cloth with a similar

heart valve, provides images of the combination, and concludes that the cloth-covered valve “demonstrated excellent hydrodynamic performance.” *See* Ex. 1007 (Walther) at 1125.

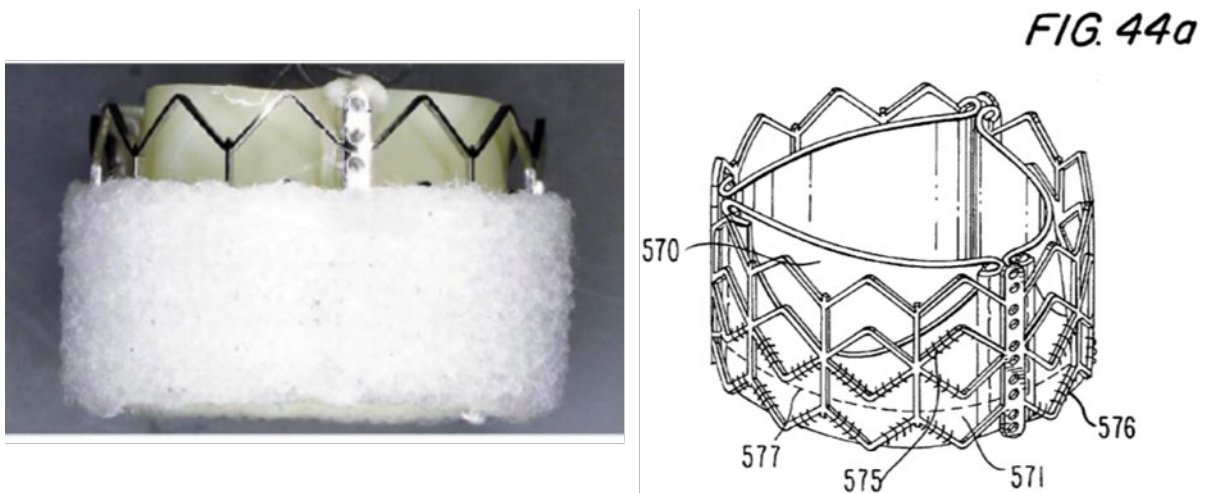
181. A person of ordinary skill in the art would have understood that when Walther’s outer cloth is added to Spenser’s Figure 44a, the outer cloth’s radially extending fibers (i.e., first portion) would be “configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst.” Spenser’s Figure 4 (below) shows Spenser’s valve deployed “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 in Figure 4, Spenser’s valve presses against the patient’s aortic annulus. Although not shown in Figure 4, persons of ordinary skill

in the art would have understood 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.

182. When added to Spenser's Figure 44a, Walther's outer cloth would cover at least the two proximal rows of Figure 44's outer frame, as illustrated by the comparison of Walther's Figure 1 (left) and Spenser's Figure 44a(right) below:



Compar Ex. 1007 (Walther) at Fig. 1 *with* Ex. 1010 (Spenser) at Fig. 44a. As illustrated by Spenser's Figure 4 and understood by a person of ordinary skill in the art, expanding Figure 44a would cause at least a portion of the proximal two rows to press against the patient's annulus and native aortic leaflets. Thus, expansion of Figure 44a would press the outwardly extending fibers of Walther's outer cloth against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst.

183. A person of ordinary skill would have found it obvious to deploy Spenser's Figure 44a combined with Walther's outer cloth within a patient's native valve. Spenser discloses methods of implanting the described valves, such as Figure 44a, at the native aortic valve. *See e.g.*, Ex. 1010 (Spenser) at 5:17-6:36 (listing delivery steps). A person of ordinary skill would have been motivated to apply Walther's known technique for reducing paravalvular leakage (adding an outer cloth to a valve frame) to Spenser's known prosthetic heart valves (*e.g.*, Figure 44a) for the same reasons I provided for Walther and SAPIEN. *Supra* §VI.A.5.

184. A person of ordinary skill in the art would have had a reasonable expectation of success in deploying Figure 44a with an outer cloth, like Walther's, in a patient's native aortic valve because Walther discloses that the cloth-covered valve "demonstrated excellent hydrodynamic performance" and concluded that an *in vivo* implantation procedure "is feasible." Ex. 1007 (Walther) at 1125. Additionally, Walther's cloth-covered valve was deployed within a surgical valve designed to emulate the native valve. Therefore, a person of ordinary skill in the art would have expected Walther's cloth-covered valve to function similarly in either environment. Moreover, Spenser describes endovascular implantation of its described valves, including Figure 44a, within the aortic valve and persons of ordinary skill in the art had successfully implanted SAPIEN, which is similar to

Figure 44a, within a patient's native aortic valve many times by November 2012. Ex. 1010, 2:6-12, 12:8-36, 13:26-54, 14:12-14; *see also e.g.*, Ex. 1012 at 355 (“Transcatheter valve implantation with the Edwards-Sapien® Heart Valve can be done safely and efficiently using the transfemoral retrograde approach.”); Ex. 1009 at 515-517 (transfemoral and transapical delivery of SAPIEN resulted in 30-day mortality rates of 6.4-7.4% and 11.6-18.6% respectively).

185. Additionally, claim 1 does not require endovascular delivery of the heart valve. Thus, a person of ordinary skill in the art would have understood that the size of the valve would not be an issue for delivery. *See e.g.*, Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation*, 116 [suppl I] *Circulation* I-240—I-245 (September 11, 2007)) at I-244 (“With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients”). Dr. Walther recognized the size of his cloth-covered valve would not inhibit delivery during the Conference Discussion accompanying his publication stating that he hoped the valve would be available soon, “at least for the trans-apical approach, where tight crimping is not an issue.” Ex. 1007 (Walther) at 1126. Therefore, a person of ordinary skill in the art would have reasonably expected success in implanting Figure 44a with Walther's cloth cover within a patient's native aortic valve.

186. I also note that during prosecution of a related patent application (U.S. Patent Application No. 17/213,251), Patent Owner suggested, without further explanation, that foreshortening could be an issue in combining an outer cloth, like Walther's, with a stent frame. Here, a person of ordinary skill in the art would not have been concerned by the combination of an outer cloth, like Walther's, with the frame in Spenser's Figure 44a because the frame in Figure 44a is almost identical to SAPIEN. Walther already establishes that Walther's outer cloth could be successfully added to SAPIEN. Additionally, by 2012, persons of ordinary skill in the art would have understood how to adjust and attach the outer cloth to a frame to account for foreshortening of the stent frame during expansion. For example, Levi describes methods of constructing and arranging the outer cloth or skirt to account for foreshortening. Ex. 1008 (Levi) at 13:32-14:14. For these reasons, any foreshortening of the stent would not have discouraged a person of ordinary skill in the art from adding an outer sealing material to a heart valve frame or led the person to believe that the combination would not be successful.

b. Spenser II

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

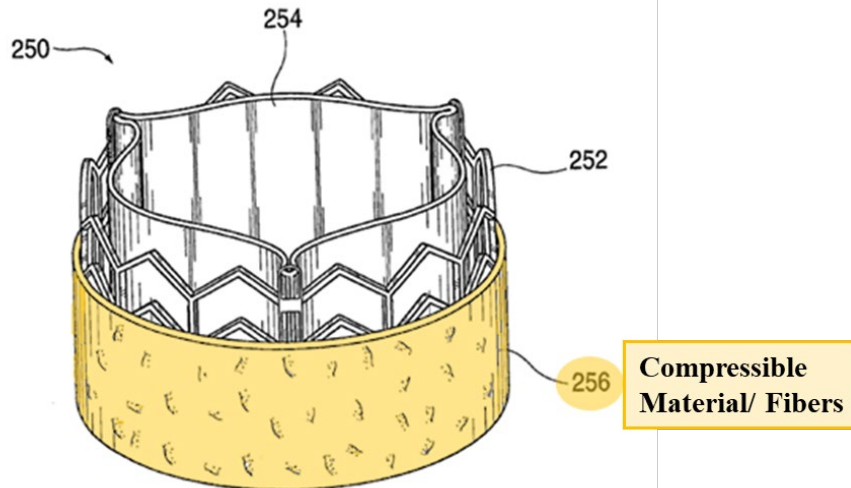


FIG. 22

Ex. 1011 (Spenser II) at [00145], Fig. 22. As shown, the compressible material is positioned externally to the outer frame. The compressible material also includes a plurality of outwardly extending fibers. Spenser II explains that the compressible material “*may resemble a cloth or fabric having small fibers extending from the surface of the material.*” *Id.* (emphasis added). A person of ordinary skill in the art would have understood that the fibers extending outwardly from outward-facing surface of the compressible material are a “first portion of fibers [that] extend radially outwardly of the outer frame.” Spenser II teaches that in a preferred embodiment, the compressible material is formed of PET. *Id.* PET fibers are “non-metallic.” Moreover, as in the case of Walther, Spenser II does not contain any disclosure that the compressible material is made of a cloth base or outer graft and a fiber portion. Rather, Spenser II consistently describes the compressible material as a “layer” or single piece of cloth or fabric.

188. 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.* Therefore, a person of ordinary skill in the art would have understood that the fibers extending from the outward-facing surface of Spenser II's compressible material (i.e., first portion) are "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst." Moreover, when added to the exterior of the stent in Spenser's Figure 44a, the compressible material would cover the bottom two rows of grids formed by the stent frame. A side-by-side comparison of Spenser II's Figure 22 (left) and Spenser's Figure 44a (right) confirms the compressible material would cover two rows of Figure 44a:

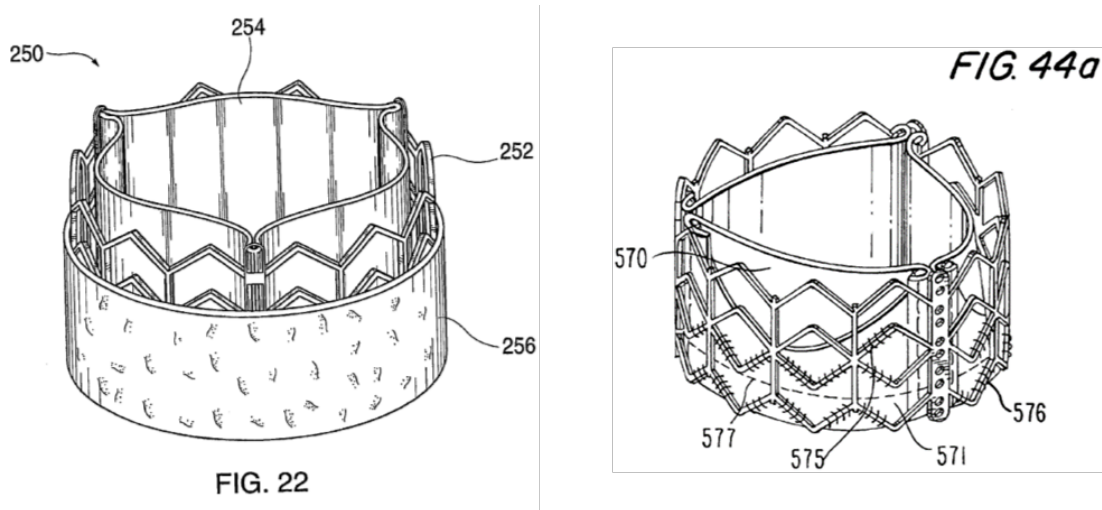


Fig. 1011 (Spenser II) at Fig. 22; Ex. 1010 (Spenser) at Fig. 44a. As I explained in the preceding section, expanding Spenser's Figure 44a within a patient's native

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* §VII.A.5.a. Thus, expansion of Figure 44a would press the radially extending fibers of Spenser II's compressible material against the patient's native annulus and aortic leaflets, forming a sealing interface thereagainst.

189. 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 are from the same field of endeavor and share the same objective of providing a prosthetic valve suitable for transcatheter delivery. *See, e.g.*, Ex. 1010 (Spenser) at Abstract, 2:5-15; Ex. 1011 (Spenser II) at Abstract, [0001], [0011]-[0014]. Second, the references share three common inventors, and Spenser II explicitly references U.S. Publication No. 2003/0153974 (Ex. 1015), which is a parent application of Spenser. Ex. 1011 (Spenser II) at [0009]; *see also* Ex. 1010 (Spenser) at 1 (claiming priority as a continuation-in-part to application No. 09/975,750); Ex. 1015 (publication of Application No. 09/975,750) at 1.

190. Also, as I explained previously, PVL was known to occur with SAPIEN, which is similar (if not identical) to Figure 44a. *Supra* §VI.A.5. A person of ordinary skill in the art would have 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,” as suggested by Spenser II. Ex. 1011 (Spenser II) at [0010], [0145]. Moreover, adding the compressible material to Figure 44a would merely entail the combination of known elements (Spenser’s prosthetic valve and Spenser II’s fibers) according to known methods (stitching the devices together) to yield the predictable result of reducing paravalvular leakage.

191. A person of ordinary skill would have had a reasonable expectation of success in combining Spenser II’s compressible material with Figure 44a because the valve assemblies in Spenser and Spenser II share many common features, including a balloon-expandable metallic stent having a gridded configuration that is configured for endovascular delivery. *See, e.g.*, Ex. 1010 (Spenser) at 2:5-15; 12:28-36, 13:26-54, 19:5-13; *see also, e.g.*, Ex. 1011 (Spenser II) at [0011]-[0015], [00144]. Moreover, Spenser already discloses valves having a sealing material positioned around the inlet, for example in Figure 1, which would have given persons of ordinary skill confidence that other sealing structures, such as Spenser II’s compressible material, could be successfully added to Spenser’s valves at the inlet. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. Additionally, Claim 1 is not limited to endovascular delivery, so a person of ordinary skill in the art would not have foreseen any potential issues stemming

from the valve diameter. Also, a person of ordinary skill in the art would not have had any concerns about stent foreshortening for the reasons provided in the previous section. *Supra* §VII.A.5.a.

6. Second Portion of Fibers

192. Claim 1 next recites: “a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second portion of fibers is non-metallic.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

193. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.6. A person of ordinary skill in the art would have been motivated to combine Walther’s outer cloth with Spenser’s Figure 44a with a reasonable expectation of success for the reasons I provided in the previous section. *Supra* §VII.A.5.a.

194. As I explained in Ground 1, Walther’s outer cloth is stitched to and carried by SAPIEN’s outer frame. *Supra* §VI.A.6. A person of ordinary skill in the art would have been motivated to stitch Walther’s outer cloth to Figure 44a’s frame in the same way because Walther describes this method of attachment, stitching is simple, and stitching would have been known to persons of ordinary

skill in the art. The combination of Walther's outer cloth with Figure 44a would therefore include a second portion of fibers carried by the outer frame. The second portion of fibers of Walther's outer cloth would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" for the reasons I provided in Ground 1. *Supra* §VI.A.6.

b. Spenser II

195. Spenser II also discloses this limitation. As I explained in the preceding section, Spenser II discloses a compressible material disposed along the exterior of an expandable valve stent that "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that a PET cloth or fabric would be constructed of a plurality of woven PET fibers. For example, Merriam-Webster defines "cloth" as "a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments." *Available at*: <https://www.merriam-webster.com/dictionary/cloth>. Therefore, a person of ordinary skill would have understood that the PET cloth or fabric of Spenser II's compressible material would include radially extending PET fibers on both its outward-facing surface (i.e., a first portion of fibers) and radially extending fibers on its inward-facing surface that would press against the bars of the outer frame

when disposed along the exterior thereof. A person of ordinary skill in the art would have understood that the PET fibers on the inward-facing surface of the compressible material abutting the outer frame are the “second portion of fibers” required by claim 1. A person of ordinary skill in the art would have understood that the compressible material’s second portion of fibers are “carried by” the outer frame because Spenser II discloses that the compressible material “is disposed along an outer surface of the stent structure 252,” as shown in Figure 22 below:

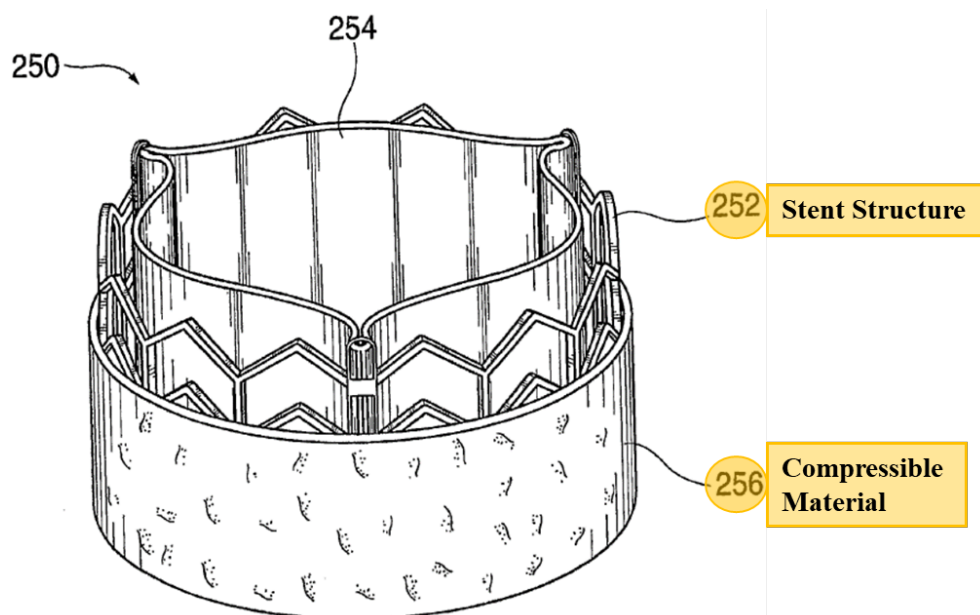


FIG. 22

Id. at [00145], Fig.22. Additionally, because the fibers are disposed along the exterior surface of the outer frame, a person of ordinary skill in the art would have understood that the woven PET fibers of the second portion are “configured to form a second sealing interface against the outer frame when . . . compressed thereagainst,” as shown in Figure 22 above. *See id.* at Fig. 22.

7. First and Second Portion in Overlapping Radial Alignment

196. Claim 1 next recites: “wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

197. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.7.

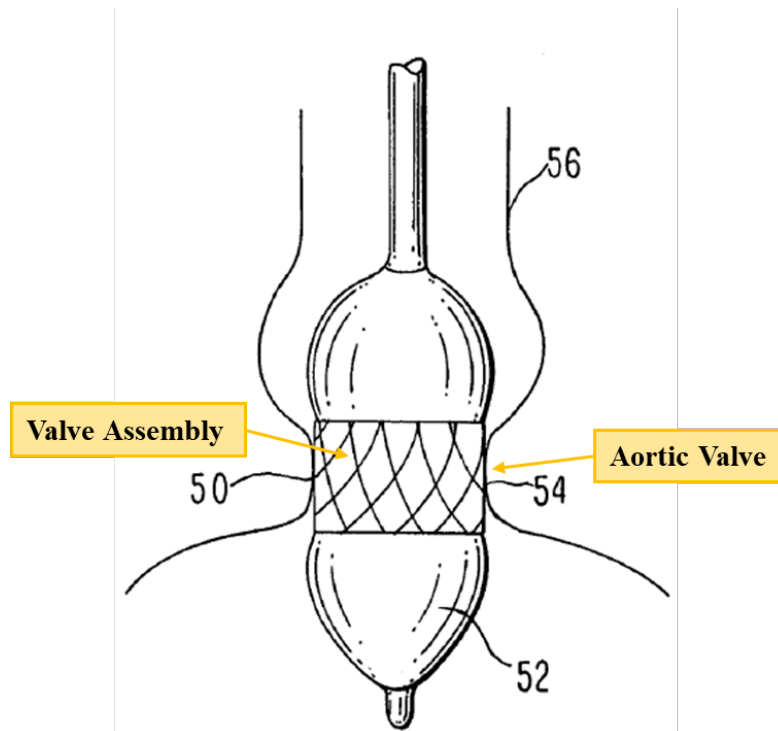
b. Spenser II

198. Spenser II also discloses this limitation. Spenser II discloses that its compressible material “may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material.” Ex. 1011 (Spenser II) at [00145]. As I explained above, a person of ordinary skill in the art would have understood that such a PET cloth or fabric would include radially fibers extending from both its outward-facing surface (a first portion) and its inward-facing surface (a second portion). *Supra* §§VII.A.5-6. Because the two portions of fibers are part of a single PET cloth disposed along the exterior of the outer frame, a person of ordinary skill in the art would have understood that the two portions of fibers, located on opposite surfaces of the compressible material, are in overlapping radial alignment for the same reasons I discussed in Ground 1 with respect to Walther’s outer cloth. *See supra* §VI.A.7.

8. First Sealing Interface Positioned in Overlapping Radial Alignment with Native Valve Leaflets

199. Claim 1 next recites: “wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

200. 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 (disclosing placement at the aortic valve). As shown in Figure 4, the valve radially overlaps with the patient’s aortic annulus. *Id.* at Fig. 4.

Although not pictured in Fig. 4, a person of ordinary skill in the art would have understood that the valve also radially overlaps with the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. A person of ordinary skill in the art would have understood Figure 4 to illustrate the placement of Figure 44a because Figure 4 describes "the present invention" and Figure 44a is referred to as a "preferred embodiment of the present invention." Ex. 1010, 8:66-67, 26:30-34.

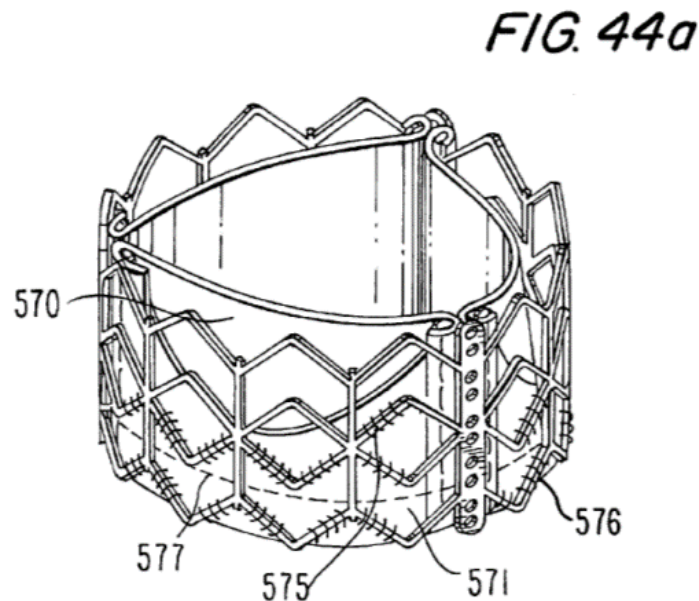
201. As I explained previously, when added to the exterior of Spenser's Figure 44a, both Walther's outer cloth and Spenser II's compressible material would cover the proximal two rows of grids formed by the frame. *Supra* §VII.A.5. As illustrated by Spenser's Figure 4 and understood by a person of ordinary skill in the art, positioning Spenser's Figure 44a across the patient's native aortic valve as taught in Spenser would cause at least a portion of the proximal two rows of the outer frame to radially overlap the patient's annulus and native aortic leaflets. Thus, the combination of Spenser's Figure 44a and Walther's outer cloth or Spenser II's compressible material results in a valve "configured to be positioned in a patient" so that the radially extending fibers of the outward-facing surface of the outer cloth/compressible material (i.e., first portion) radially overlap with the patient's native aortic leaflets to seal thereagainst.

9. **Free of an Outer Graft Covering Between the First Portion of Fibers and Outer Frame**

202. Claim 1 next recites: “wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame.” Spenser and Walther or Spenser II render this limitation obvious.

a. **Walther**

203. Walther’s outer cloth is “free of an outer graft covering between the first portion of fibers and the outer frame” for the reasons I provided in Ground 1. *Supra* §VI.A.9. Additionally, Spenser’s Figure 44a does not include any “outer graft covering” on the exterior of the outer frame 575:



Ex. 1010, Fig. 44a. As shown in Figure 44a, there is no graft covering on the exterior of the frame, and Spenser does not disclose any such material in the embodiment in Figure 44a. *See id.* at 26:30-54, Fig. 44a-c. Therefore, a person of

ordinary skill in the art would have understood that when Walther's outer cloth is added to the exterior of Figure 44a's outer frame, there would be no "outer graft covering" between the outwardly extending fibers of the outward-facing surface of the outer cloth (i.e., the first portion) and the outer frame.

204. Additionally, as I explained in Ground 1, I am aware that Patent Owner has made arguments about Walther during prosecution of a related patent application, asserting that Walther describes a valve with "an outer seal made of a cloth base or outer graft and a fiber portion extending from the cloth base/outer graft." Ex. 1039 (Patent Owner Amendment with RCE) at 9. Patent Owner's arguments about Walther are unsupported and incorrect for the reasons I provided previously. *Supra* §VI.A.9.

b. Spenser II

205. Spenser II's compressible material is also "free of an outer graft covering between the first portion of fibers and the outer frame." Spenser II discloses that the compressible material, which "may resemble a cloth or fabric having small fibers extending from the surface of the material," is "disposed along the outer surface" of the stent. Ex. 1011 (Spenser II) at [00145]. Spenser II does not disclose or suggest any "outer graft covering" between the radially extending fibers of the compressible material (i.e., first portion) and the stent. Therefore, a person of ordinary skill in the art would have understood that there is no such

“outer graft covering” between the fibers of the compressible material and the outer frame. Moreover, as I explained in the preceding section, Spenser’s Figure 44a does not include any “outer graft covering” on the exterior of the outer frame 575. *Supra* §VII.A.9.a. Therefore, a person of ordinary skill in the art would have understood that when Spenser II’s compressible material is added to the exterior of Figure 44a’s outer frame, there would be no “outer graft covering” between the radially extending fibers of the compressible material (i.e., first portion) and the outer frame.

206. I am aware that in a preliminary amendment during prosecution of the ’236 patent, Patent Owner argued that “Spenser [II] appears to include an outer graft covering between the fibers and the outer frame.” Ex. 1002 (’236 Patent Prosecution History Excerpt) at 196. Patent Owner provided no support or explanation for this assertion, however, and Patent Owner’s argument is not supported by Spenser II’s disclosure. As I explained above, Spenser II does not include any teaching or disclosure suggesting any “outer graft covering” between the fibers of the compressible material and the outer frame. *See* Ex. 1011 (Spenser II) at [00145]. On the contrary, Spenser II describes the compressible material as a single PET cloth or fabric that is disposed along the exterior of the stent. *See id.* Therefore, a person of ordinary skill in the art would have understood that there is

no “outer graft covering” between the fibers of Spenser II’s compressible material and the outer frame.

10. Radially Compressed Orientation and Radially Expanded Orientation

207. Claim 1 next recites: “wherein the valve assembly has a radially compressed orientation and a radially expanded orientation.” Spenser, Walther, and Spenser II all disclose this limitation.

208. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.10. Spenser teaches that its prosthetic valve “has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm [expanded orientation].” Ex. 1010 (Spenser) at 27:67-28:2. A person of ordinary skill in the art would have understood that Spenser’s 4 mm diameter corresponds to the valve’s compressed orientation and the 25 mm diameter corresponds to the valve’s expanded orientation. Spenser II discloses a stented valve that comprises “an expandable stent structure” that may be “adapted for radial expansion using a balloon catheter.” Ex. 1011 (Spenser II) at [00144]. A person of ordinary skill in the art would have understood that a balloon expandable stent structure, as disclosed in Spenser II, would include a radially compressed and a radially expanded configuration. Indeed, by definition, a balloon expandable stent is capable of being expanded from a narrower, compressed orientation to an expanded orientation by inflation of the balloon.

11. Balloon Expandable

209. Claim 1 next recites: “wherein the valve assembly is balloon expandable to the radially expanded orientation.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

210. Spenser discloses that the valve assembly depicted in Figure 44a “resembles the valve shown in Fig. 43.” Ex. 1010 (Spenser) at 26:34-35. The valve shown in Figure 43 may be “inflated by a balloon . . . [such that] the frame is expanded to the full diameter.” *Id.* at 26:19-22; *see also id.* at 12:4-8, 14:10-14, 17:19-18:43 (balloon-expandable assemblies). A person of ordinary skill in the art would therefore have understood that Figure 44a is balloon expandable. A person of ordinary skill in the art would have further understood that Figure 44a would remain balloon expandable after adding either Walther’s outer PET cloth or Spenser II’s outer compressible material, as both references explicitly disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. *See* Ex. 1007 (Walther) at 1122 (cloth-covered SAPIEN was balloon-expandable); Ex. 1011 (Spenser II) at [00144] (valve “adapted for radial expansion using a balloon catheter”).

12. Compress Fibers to Form a Sealing Interface

211. Claim 1 concludes by reciting: “wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second

portion of fibers to form the respective first sealing interface and second sealing interface.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

a. Walther

212. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.12. Walther’s outer cloth would behave in the same way if it were added to Figure 44a because Figure 44a and SAPIEN are similar, if not identical. Therefore, when Walther’s outer cloth is added to Spenser’s Figure 44a, expansion of the valve within a patient’s native aortic valve would be configured to (1) compress the outwardly extending fibers on the outward-facing surface of the compressible material (i.e., first portion) against the patient’s annulus and native leaflets to form a first sealing interface and (2) compress the PET fibers on the inward-facing surface of the compressible material (i.e., second portion) against Figure 44a’s outer frame to form a second sealing interface.

b. Spenser II

213. Spenser II also discloses this limitation. Spenser II teaches 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.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have understood that the

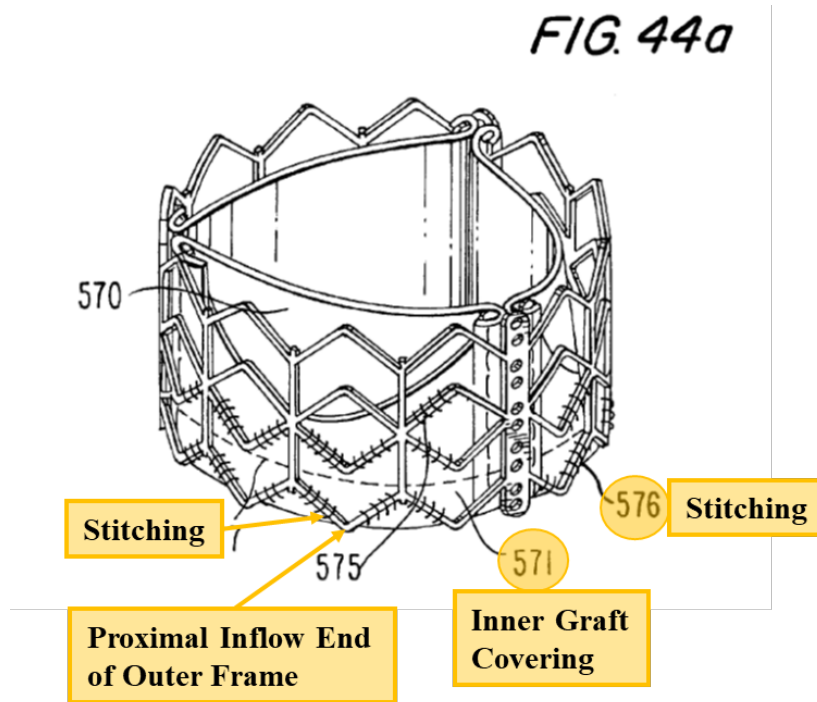
compressible material “creates a mechanical seal” (i.e., sealing interface) by (1) compressing the radially extending fibers of the compressible material (i.e., first portion) against the patient’s annulus and native leaflets and (2) compressing the woven PET fibers of the inward-facing surface (i.e., second portion) against the stent’s outer frame. Similar to Walther, these two sealing interfaces would work cooperatively to seal around the exterior of the valve and reduce paravalvular leakage. For example, the first sealing interface prevents blood from leaking between the outward-facing surface of the compressible material and the native tissue of the patient’s aortic valve. The second sealing interface prevents blood from leaking between the inward-facing surface of the compressible material and the exterior of the outer stent frame.

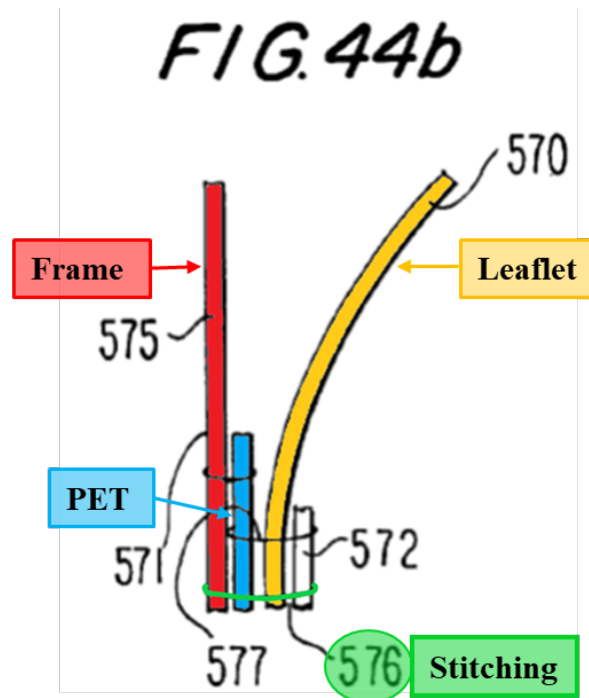
B. Claim 2

214. Claim 2 recites: “The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.” Spenser discloses the limitations in claim 2 and, in combination with Walther or Spenser II, renders claim 2 obvious.

215. Spenser discloses that a “[b]ottom attachment suture 576, connects the three layers, the leaflet and both PET layers [571, 572] to the frame and forms a

strong sealing line.” Ex. 1010 (Spenser) 26:45-47, Figs. 44a-44c; *see also id.* claims 10, 30. Figures 44a and 44b illustrate that PET 571 (i.e., inner graft covering) extends to the proximal inflow end of the outer frame, and that bottom sutures 576 extend between PET 571 and through the outer frame to secure PET 571 to the proximal inflow end of the outer frame:





Id., Figs. 44a, 44b.

C. Claim 3

216. Claim 3 recites: “The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.” Spenser in combination with Walther or Spenser II renders this claim obvious.

1. Walther

217. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.C.

2. Spenser II

218. Spenser II also discloses this limitation or renders it obvious. Spenser II discloses that the compressible material “may resemble a cloth or fabric having

small fibers extending from the surface of the material.” Ex. 1011 (Spenser II) [00145]. A person of ordinary skill in the art would have understood that the radially extending fibers would extend from various different locations along the material and would thus have understood that the compressible material would include openings between the radially extending fibers formed by spacing between the adjacent fibers. Indeed, a person of ordinary skill in the art would have understood that such “openings” would exist in any cloth or fabric material with radially extending fibers such as Spenser II’s compressible material. *Supra* §VI.C. A person of ordinary skill in the art would have further understood that the openings define a plurality of “opening[s] extending through a thickness” of the radially extending fibers for the same reasons I explained previously with respect to Walther. *Id.*

219. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of outwardly extending fibers such that even larger openings existed between the fibers. *Supra* §III.D. The exchange of Spenser II’s compressible material for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the

crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

D. Claim 4

220. Claim 4 recites: “The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” Spenser in combination with Walther or Spenser II renders this claim obvious.

1. Walther

221. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.D.

2. Spenser II

222. Spenser II also discloses this limitation. As I explained in claim 1, a person of ordinary skill in the art would have understood that Spenser II’s compressible material, which may be a PET cloth or fabric, includes a plurality of

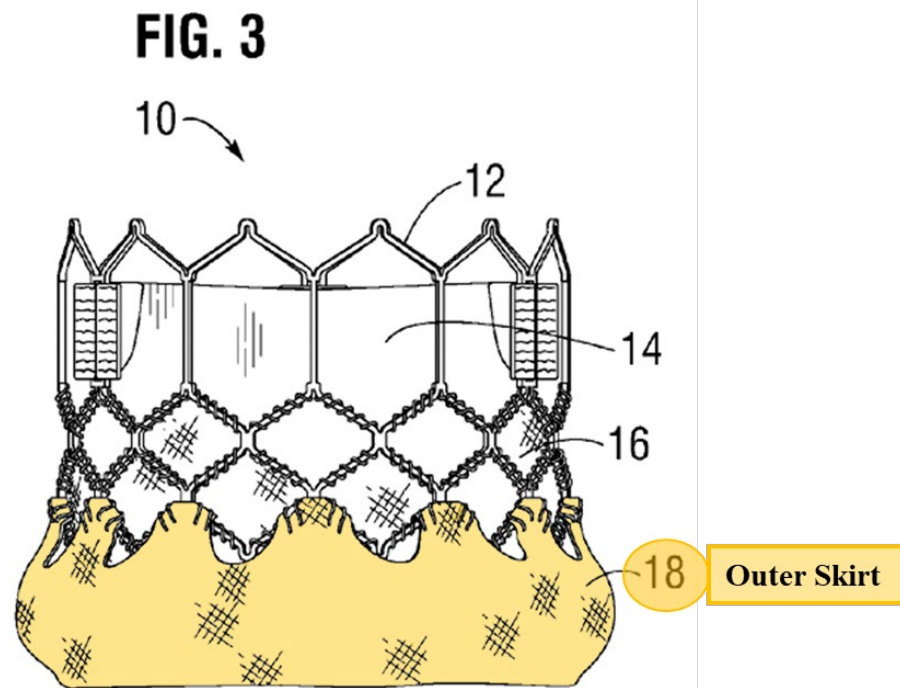
PET fibers on the inward-facing surface of the compressible material that define a “second portion of fibers.” *Supra* §VII.A.6.b. A person of ordinary skill in the art would have further understood that any woven fabric, including Spenser II’s PET cloth/fabric, would include at least some gaps between the interwoven fibers of the fabric. *See supra* §VI.C; *see also e.g.*, Ex. 1008 (Levi) 10:48-57 (discussing spacing between fibers of woven PET fabric skirt). A person of ordinary skill in the art would therefore have understood that openings exist between the PET fibers of the second portion of Spenser II’s compressible material which define “opening[s] extending through a thickness” of the second portion. Similar to Walther’s outer cloth, the fibers of Spenser II’s fabric/cloth would be sufficiently dense to prevent blood from leaking through the cloth/fabric, but loose enough to include small openings between the adjacent fibers. A person of ordinary skill in the art would have further understood that at least some of these openings extend to the outer frame because the compressible material is disposed along the exterior of the outer frame, and the fibers of the inward-facing surface of the compressible material (i.e., second portion) directly abut and are compressed against the outer frame.

223. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected a cloth with a lower density of fibers such that even larger

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

**VIII. GROUNDS 4-7: CLAIMS 1-4 ANTICIPATED OR OBVIOUS IN
VIEW OF LEVI ALONE OR WITH WALTHER OR SPENSER II**

224. Levi discloses a prosthetic heart valve assembly having an outer skirt of woven PET fabric secured to the exterior surface of an outer frame, as shown in Figure 3 below:



Ex. 1008 (Levi) at 13:50-53, 13:62-66, Fig. 3. As I explain in detail below, Levi's outer skirt of woven PET fabric is a sealing material that includes a first and second portion of fibers, as required by the claims of the '236 patent. Therefore, based on my review of the prior art, I believe Levi discloses or suggests every limitation of claims 1-4 and anticipates or renders the claims obvious.

225. However, even if Levi does not disclose or suggest a first and second portion of fibers, Walther and Spenser II do, as I explained previously. I believe that a person of ordinary skill in the art would have found it obvious to combine Levi with Walther or Spenser II for the reasons I provide in detail below. In fact, Levi expressly discloses methods of adapting the outer frame to accommodate sealing materials, like the sealing materials in Walther and Spenser II. Ex. 1008

(Levi) at 14:26-35. Therefore, I believe that Levi in combination with Walther or Spenser II renders obvious claims 1-4.

A. Claim 1

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

1. Preamble

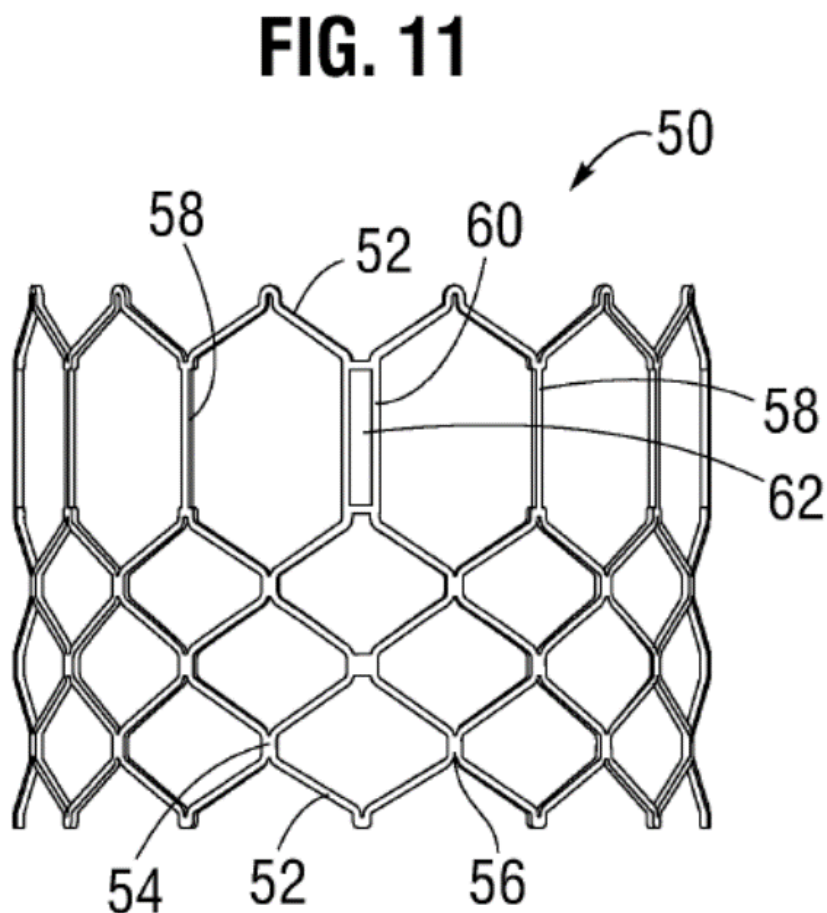
227. The preamble of claim 1 recites: “A transcatheter aortic valve assembly comprising.”

228. Levi discloses a “transcatheter aortic valve assembly.” Levi discloses “embodiments of a prosthetic heart valve, and delivery systems for implanting heart valves.” Ex. 1008, 1:16-17. Levi teaches that its valve is “adapted to be implanted in the native aortic annulus.” *Id.* at 5:53-54. Levi further discloses that due to known “drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches” were developed in which “collapsible transcatheter heart valves . . . 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.” *Id.*, 1:57-67.

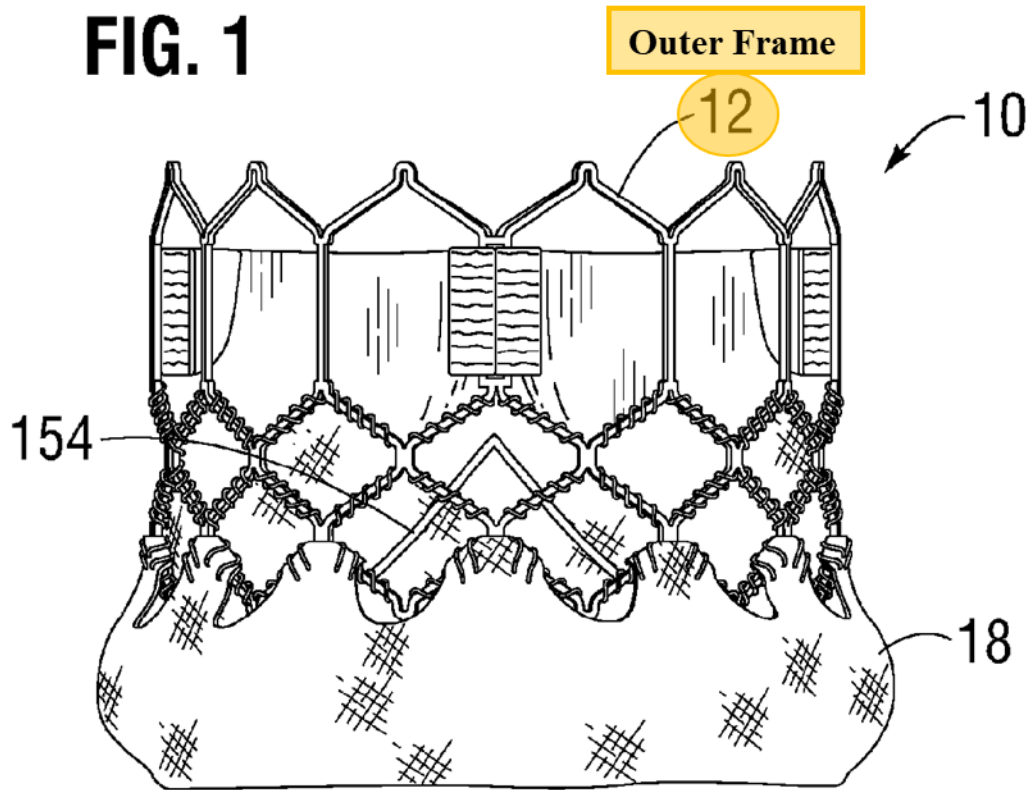
2. Outer Frame

229. Claim 1 next recites: “an outer frame formed from a metallic material.” Levi also discloses this limitation.

230. Levi discloses an expandable frame formed from metal (e.g., stainless steel) as shown in Figure 11 below:



Ex. 1008 (Levi) at 6:17-24, Fig. 11. As shown in Figure 42 below, the frame 12 surrounds the other components of the valve and is thus an “outer frame”:



Id. at Fig. 42.

3. Inner Frame

231. Claim 1 next recites: “an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.” Levi also discloses this limitation.

232. 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 PET skirt therefore provides sealing to the heart valve. The inner skirt is constructed of “a tough, tear resistant material such as polyethylene terephthalate (PET).” *Id.* at 9:11-16. PET is a type of polyester and also a polymer and is a “polymeric...graft covering.” The inner skirt is engaged to the valvular structure “via one or more thin PET reinforcing strips. *Id.* At 9:25-29. The “valvular structure 14 can comprise three leaflets 40, collectively forming a leaflet structure.” *Id.* at 5:59-62, Fig. 2. The three leaflets of the valvular structure are “prosthetic leaflets.” Levi’s inner skirt 16 [yellow] is cylindrically extending and extends radially outwardly of prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red] as illustrated in Figure 2 below:

FIG. 10

10

16 Inner Skirt

12 Outer Frame

40

122

40

122

40

18

14 Prosthetic Valve

122

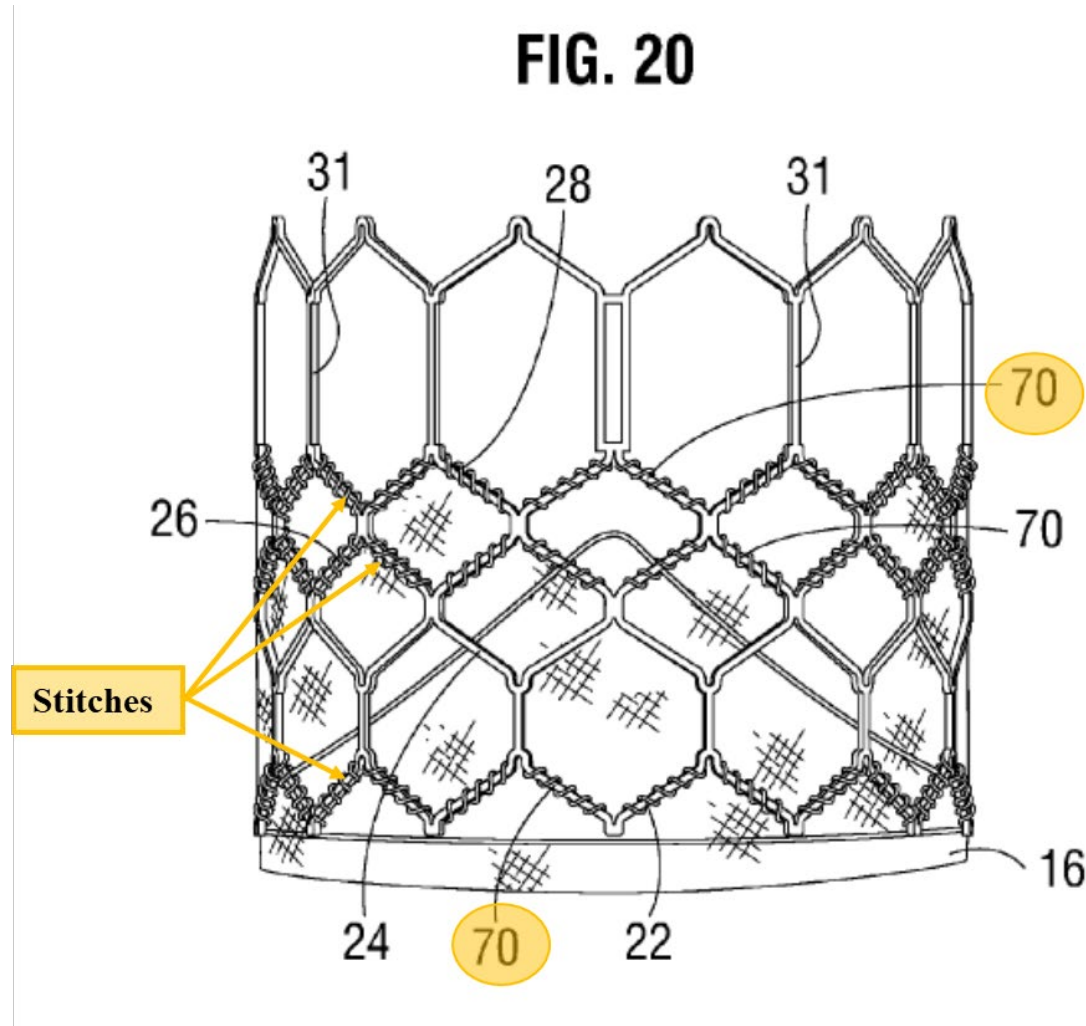
40

Outer Frame

4. Stitching

- 146 -

234. Levi's inner skirt 16 is secured to the frame 12 via a plurality of sutures 70 at the top and bottom of the skirt, as shown in Figure 20 below:



Ex. 1008, 9:24-25, 10:11-30, Figs. 20, 39.

5. First Portion of Fibers

235. Claim 1 next recites: “a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst, wherein the first portion of fibers extend

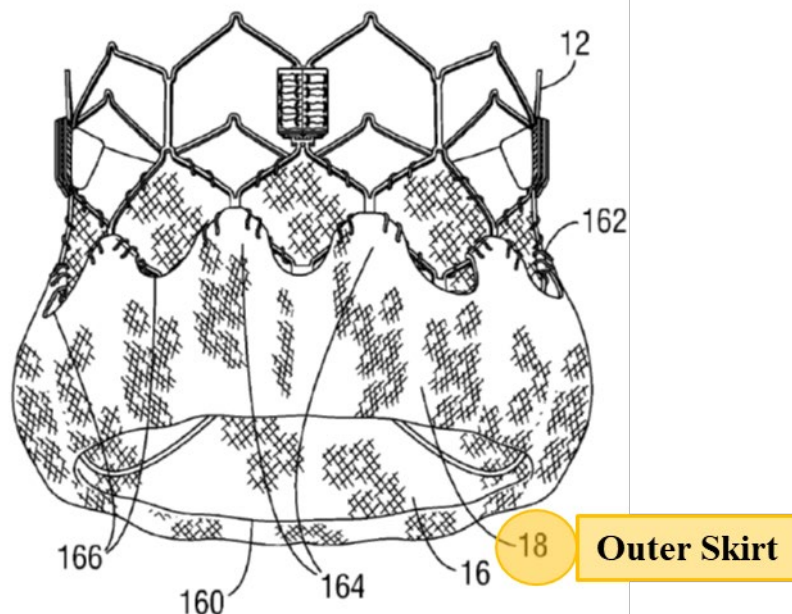
radially outwardly of the outer frame, wherein the first portion of fibers is non-metallic.” Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

a. Levi

236. Levi discloses this limitation or renders it obvious.

237. Levi discloses this limitation in two ways. Levi discloses an outer skirt of woven PET fabric secured to the exterior surface of the frame. Ex. 1008 (Levi) at 13:50-53, 13:62-66. The outer skirt is thus positioned radially outwardly of the outer frame. Levi teaches that the outer skirt is constructed with excess material that “does not lie flat against the outer surface of the frame 12,” but bulges radially outwardly as the frame expands and foreshortens. *Id.* 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. The bulging outer skirt [yellow] is shown in Figure 3 below:

FIG. 42



Id. at Fig. 42. A person of ordinary skill in the art would have understood that the PET fibers, which are non-metallic, form Levi's outer skirt constitute a "first portion" of fibers. *See id.* at 9:52-56, 13:62-14:2. As shown in Figure 3 above, the outer skirt "does not lie flat against," but "bulge[s] outwardly" from the outer frame. Therefore, the plurality of woven PET fibers that make up Levi's outer skirt (i.e., first portion) "extend radially outwardly from the outer frame." Additionally, the skirt "fill gaps" in the surrounding tissue and becomes folded or pinched by the tissue in those locations causing the fibers to extend radially outwardly of the outer frame. *Id.* at 14:3-7.

238. Alternatively, a person of ordinary skill in the art would have understood that the outer surface of the woven PET fabric of Levi's outer skirt would not be entirely smooth, but would necessarily have fibers, or strands, that extend radially outwardly from the surface of the fabric. A person of ordinary skill in the art would have known that textile polyester yarn, such as PET yarn, exhibits a property known as "hairiness," which describes the "amount and length of fibre ends and loops protruding from the body of the yarn." Ex. 1028 (Tyagi) at 124. The hairiness of yarn can be influenced by a number of factors, and a person of ordinary skill in the art would have understood that polyester fabrics, such as PET, would exhibit at least some level of hairiness. *See id.*; *see also* Ex. 1029 (Kothari) at 32 (disclosing that 100% polyester yarn included between 50 and 150 hairs per meter). Therefore, even if the woven PET fabric of the outer skirt does not itself constitute a "first portion of fibers," a person of ordinary skill would have nonetheless understood that Levi's outer skirt includes a "first portion of fibers" extending radially outwardly from the surface of the outer skirt.

239. As I noted above, Levi teaches that the outer skirt is constructed with excess material that "does not lie flat against the outer surface of the frame 12," but bulges radially outwardly as the frame expands and foreshortens. *Id.* 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. A person of ordinary skill in the art would have understood that 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. *Supra* §III.B. Indeed, during prosecution, Patent Owner admitted that Levi’s outer skirt would “extend[] into crevices created by the native leaflets.” Ex. 1002 (’236 Patent Prosecution History Excerpt) at 194. Therefore, Levi’s outer skirt (i.e., first portion of fibers) is “configured to form a first sealing interface against the annulus and native valve leaflets of the patient” when the outer skirt is pressed thereagainst.

b. Walther

240. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.5.

241. It is my opinion that a person of ordinary skill in the art would have found it obvious to replace Levi’s bulging outer PET skirt with Walther’s outer cloth. A person of ordinary skill would have been motivated by Walther’s disclosure that its outer cloth prevents paravalvular leakage, increases the fit between the implanted prosthetic valve and the existing valve, and promotes tissue ingrowth. *See* Ex. 1007 (Walther) at 1120. Moreover, the combination of Walther’s outer cloth and Levi would merely entail substitution of one known

element (Walther's outer cloth) for another (Levi's bulging PET) to yield the predictable results of reducing paravalvular leakage.

242. The field of heart valves had a finite number of options to address paravalvular leakage in November 2012. Walther and Levi disclose two such methods. A person of ordinary skill would have found it obvious to select either of these finite, predictable options and, as I explain below, would have had a reasonable expectation of success in doing so.

243. A person of ordinary skill would have had a reasonable expectation of success in substituting Walther's outer cloth (or a similar cloth) for Levi's PET skirt. Walther discloses that the cloth-covered SAPIEN valves displayed "excellent hydrodynamic performance" and that *in vivo* implantation of the valve "is feasible." Ex. 1007 (Walther) at 1125. Claim 1 does not require endovascular delivery so a person of ordinary skill in the art would not have expected the size of the valve to impact deliverability. *See e.g.*, Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation*, 116 [suppl I] *Circulation* I-240—I-245 (September 11, 2007)) at I-244 ("With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients").

244. Moreover, Levi suggests adding other components, like Walther's outer cloth, to its valve by disclosing that the inflow portion of the outer frame has a narrower crimped diameter so that "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." Ex. 1008 (Levi) at 16:41-45 (emphasis added). A person of ordinary skill would have understood that Walther's outer cloth would be a potential "additional component."

245. Levi additionally discloses several other features that minimize the crimped profile of the valve to accommodate 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 minimize 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 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. 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 addition of a fibrous outer seal without disadvantageously increasing the valve's crimped profile.

246. Additionally, the valve frames in Walther and Levi share many common features, including being balloon-expandable and formed of rows of open cells that are interconnected by metal struts. *See supra* §VI.A.2,11, VIII.A.2. Further, Walther discloses that the cloth-covered SAPIEN valves

displayed “excellent hydrodynamic performance” and that in-patient implantation of the valve “is feasible,” suggesting that other cloth-covered valves would achieve similar success. Ex. 1007 (Walther) at 1125. For all of these reasons, a person of ordinary skill would have reasonably expected success in using Walther’s outer cloth on Levi’s valve.

c. Spenser II

247. Spenser II discloses this limitation for the reasons I provided in Grounds 2-3. *Supra* §VII.A.5.b.

248. In my opinion, a person of ordinary skill in the art would have found it obvious to replace Levi’s bulging 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 bulging PET) for another (compressible material) to yield the predictable results of reducing paravalvular leakage.

249. Moreover, as I discussed in the prior section, the field of heart valves had a finite number of options to address paravalvular leakage in November 2012.

Supra §VIII.A.5.b. Spenser II and Levi disclose two such ways. 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].

250. A person of ordinary skill would have had a reasonable expectation of success in substituting Spenser II's compressible material for Levi's outer skirt. The stent frames in Levi and Spenser II have many similar features, including being metallic and balloon-expandable. *Supra* §§VII.11, VIII.A.2. 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, Abstract, 2:1-7; Ex. 1011 (Spenser II) at Ex. 1008, 1:57-67, 6:46-49. 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. Additionally, claim 1 does not require endovascular delivery so a person of ordinary skill in the art

would not have expected the size of the valve to impact deliverability. *See e.g.*, Ex. 1021 (Walther, Thomas, et al., *Transapical Minimally Invasive Aortic Valve Implantation*, 116 [suppl I] *Circulation* I-240—I-245 (September 11, 2007)) at I-244 (“With the transapical technique no limitation in sheath diameter exists, allowing for the implantation of large and eventually cuffed prostheses to achieve a functionally optimal result for patients”).

251. 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 explained in the preceding section, 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. *Supra* §VIII.A.5.b. 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.

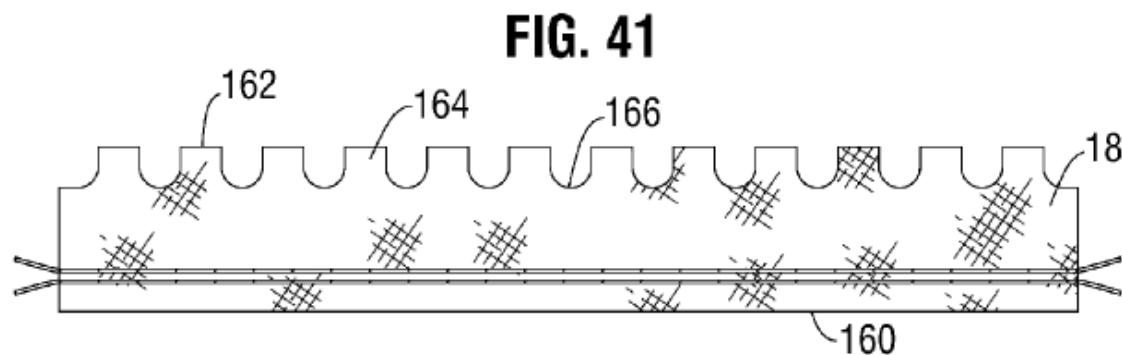
6. Second Portion of Fibers

252. Claim 1 next recites: “a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst, wherein the second

portion of fibers is non-metallic.” Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

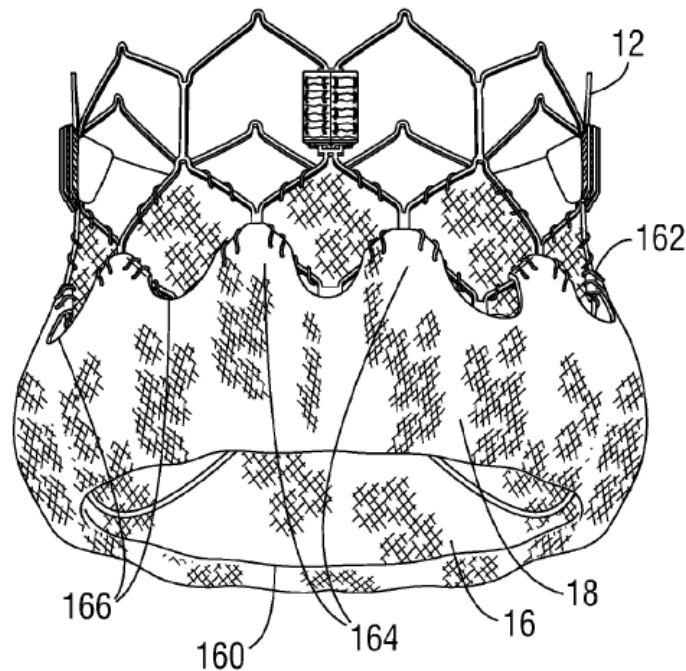
a. Levi

253. Levi discloses this limitation in two ways. First, as I explained previously, Levi discloses an inner skirt of woven PET fabric secured to the interior surface of the outer frame. *Supra* §VIII.A.5.a. Levi’s outer skirt includes “an upper edge 162 defining a plurality of alternating projections 164 and notches 166” shown in Figure 41 below:



Ex. 1008 (Levi) at 13:53-55, Fig. 41. Levi further teaches that “[a]s shown in Figure 43, each projection 164 can be sutured to the second rung II of struts 24 of the frame 12.” *Id.*, at 13:58-59. Levi also explains that “[t]he corners 162 of the projections 164 can be folded over the respective struts of rung II and secured with sutures 168.” *Id.*, 13:60-61. Figure 42 of Levi shows the projections folded over the struts and secured with sutures:

FIG. 42



Id. at Fig. 42.

254. The non-metallic fibers that comprise the corners 162 that are wrapped around the struts and reside on the interior of the frame are the “second portion of fibers” required by claim 1. As shown in Figure 42, the corners are sutured to and “carried by” the outer frame. *Id.* Likewise, the corners are configured to “form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst.” As the outer skirt bulges outward, the outer skirt pulls upon the corners and compresses the fibers forming the corners against the outer frame. This compression creates a sealing interface between the corners of the outer skirt and frame. By wrapping the corners around the struts before they are sutured, the outer skirt is attached more securely to the

outer frame. Thus, the compression between Levi's second portion and the outer frame also helps create the sealing interface between the outer skirt and the patient's native tissue by holding the skirt against the frame.

255. Alternatively, a person of ordinary skill in the art would have understood that Levi's outer skirt would include small fibers extending from its surface due to the hairiness of the fabric. *Supra* §VIII.A.5.a. A person of ordinary skill in the art would have understood that these small fibers would extend both from the outward-facing surface of outer skirt, and the inward-facing surface of the skirt. As I explained previously, the outer skirt is "carried by" the frame and forms a seal between the valve and native tissue. *Supra* §VIII.A.5.a. When the valve is expanded to form the seal against the native tissue, the interior surface of the outer skirt presses against and is compressed against the outer frame. The small fibers extending from the interior surface of the outer skirt therefore "form a second sealing surface against the outer frame when the second portion of fibers is compressed thereagainst."

b. Walther and Spenser II

256. Alternatively, Walther and Spenser II disclose this limitation as for the reasons I provided in Grounds 1-3. *Supra* §§VI.A.6, VII.A.6.b. A person of ordinary skill in the art would have been motivated to combine Walther's outer cloth or Spenser II's compressible material with Levi's valve with a reasonable

expectation of success for the reasons I provided in the previous section. *Supra* §VIII.A.5.

257. Levi's outer skirt is stitched to and carried by Levi's outer frame. *Supra* §VIII.A.6.a. A person of ordinary skill in the art would have been motivated to stitch Walther's outer cloth or Spenser II's compressible material to Levi's frame because Levi describes this method of attachment and stitching is simple and would have been known to persons of ordinary skill. The combination of Walther's outer cloth or Spenser II's compressible material with Levi's valve would therefore include a second portion of fibers "carried by" the outer frame. The second portion of fibers of Walther's outer cloth or Spenser II's compressible material would be "configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst" for the same reasons I provided in Grounds 1-3. *Supra* §§VI.A.6, VII.A.6.

7. First and Second Portion in Overlapping Radial Alignment

258. Claim 1 next recites: "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment." Levi discloses this limitation or renders it obvious alone or with Walther and Spenser II.

259. Levi discloses this limitation in two ways. First, as described above, the fibers that comprise the corners are wrapped around the struts and oppose the fibers in the rest of the outer skirt. *Supra* §VIII.A.6.a. Thus, the fibers in the

corners and the outer skirt are in overlapping radial alignment. Alternatively, the small fibers extending from the outward-facing and inward-facing surfaces of the outer skirt are in overlapping radial alignment with each other because they are located on opposite sides of the outer skirt and are both part of the same PET fabric. *See supra* §VI.A.7.

260. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.A.7, VII.A.7.

8. First Sealing Interface in Overlapping Radial Alignment with Leaflets

261. Claim 1 next recites: “wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst.” Levi discloses this limitation and renders it obvious in combination with Walther or Spenser II.

262. Levi’s valve “is adapted to be implanted in the native aortic annulus” and, when the frame is expanded, the outer skirt will “fill 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.” Ex. 1008 (Levi) at 5:52-54, 14:3-7. A person of ordinary skill in the art would have understood that to “fill in gaps between the frame 12 and the surrounding native annulus,” the fibers of the outer skirt (i.e., first portion) would be positioned in radially overlapping alignment with

the patient's native valve leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.B.

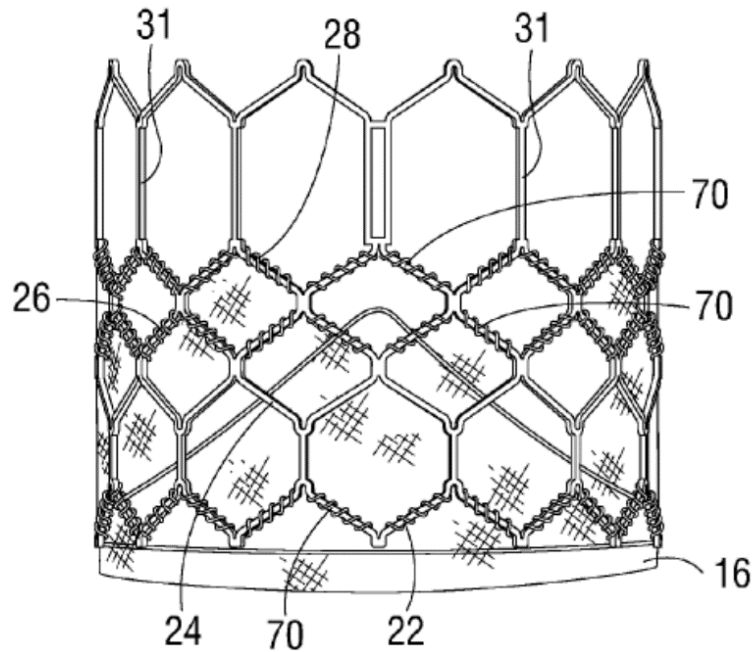
263. Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's compressible material, a person of ordinary skill in the art would have understood that the fibers of the outer cloth/compressible material, rather than the outer skirt, would be positioned to radially overlap with the patient's native leaflets.

9. Free of an Outer Graft Covering

264. Claim 1 next recites: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Levi discloses this limitation and renders it obvious in combination with Walther or Spenser II.

265. Levi's valve is free of an "outer graft covering" between the fibers of the outer skirt and the outer frame. Levi teaches that the outer skirt is sutured to the exterior of the outer frame. Ex. 1008 (Levi) 13:58-61. Levi does not include any "outer graft covering" on the exterior of the outer frame, as shown in Figure 20 below, which illustrates the valve without the outer skirt attached:

FIG. 20



Id. at Fig. 20. Therefore, a person of ordinary skill in the art would have understood that when the outer skirt is stitched to the exterior of the outer frame, there would be no “outer graft covering” between the fibers of the outer skirt (i.e., first portion) and the outer frame.

266. Alternatively, Levi in combination with Walther or Spenser II render this limitation obvious. A person of ordinary skill in the art would have understood that when Levi’s outer skirt is replaced with Walther’s outer cloth or Spenser II’s compressible material, there would be no “outer graft covering” between the radially extending fibers of the outer cloth/compressible material (i.e.,

first portion) and the outer frame because Levi does not include any “outer graft covering” on the exterior of the outer frame.

10. Radially Compressed Orientation and Radially Expanded Orientation

267. Claim 1 next recites: “wherein the valve assembly has a radially compressed orientation and a radially expanded orientation.” Levi, Walther, and Spenser II all disclose this limitation.

268. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.8. Spenser II discloses this limitation for the reasons I provided in Grounds 3-4. *Supra* §VII.A.8. Levi teaches that “[w]hen constructed of a plastically-expandable material, the frame 12 (and thus the valve 10) *can be crimped to a radially compressed* state on a delivery catheter and then *expanded* inside a patient by an inflatable balloon or equivalent expansion mechanism.” Ex. 1008 (Levi) at 6:20-24 (emphasis added).

11. Balloon Expandable

269. Claim 1 next recites: “wherein the valve assembly is balloon expandable to the radially expanded orientation.” Levi discloses this limitation or renders it obvious in combination with Walther or Spenser II.

270. Levi discloses that “the frame 12 (and thus the valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon.” Ex. 1008 (Levi) at 6:17-28. Thus, a

person of ordinary skill in the art would have understood that Levi's valve is balloon expandable.

271. Alternatively, if Levi's outer skirt was replaced with Walther's outer cloth or Spenser II's outer compressible material, a person of ordinary skill in the art would have understood that the resulting valve would remain balloon expandable because both Walther and Spenser II disclose that the outer cloth/compressible material may be added to a balloon-expandable valve. *See* Ex. 1007 (Walther) at 1122; Ex. 1011 (Spenser II) at [00144].

12. Compress Fibers to Form a Sealing Interface

272. Claim 1 concludes by reciting: "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface." Levi discloses this limitation or renders it obvious alone or in combination with Walther or Spenser II.

273. Levi discloses that its outer skirt (i.e., first portion of fibers) "fill 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." Ex. 1008 (Levi) at 14:3-7. A person of ordinary skill in the art would have understood that Levi's valve "form[s] a good fluid-tight seal" by compressing the fibers of the outer skirt against the patient's annulus and native valve leaflets to form a sealing interface

thereagainst. Also as I explained previously, the second portion of fibers of the outer skirt's corners, which are wrapped around the struts of the frame, are pulled against and form a seal with the outer frame when the valve is expanded. *Supra* §VIII.A.6.a.

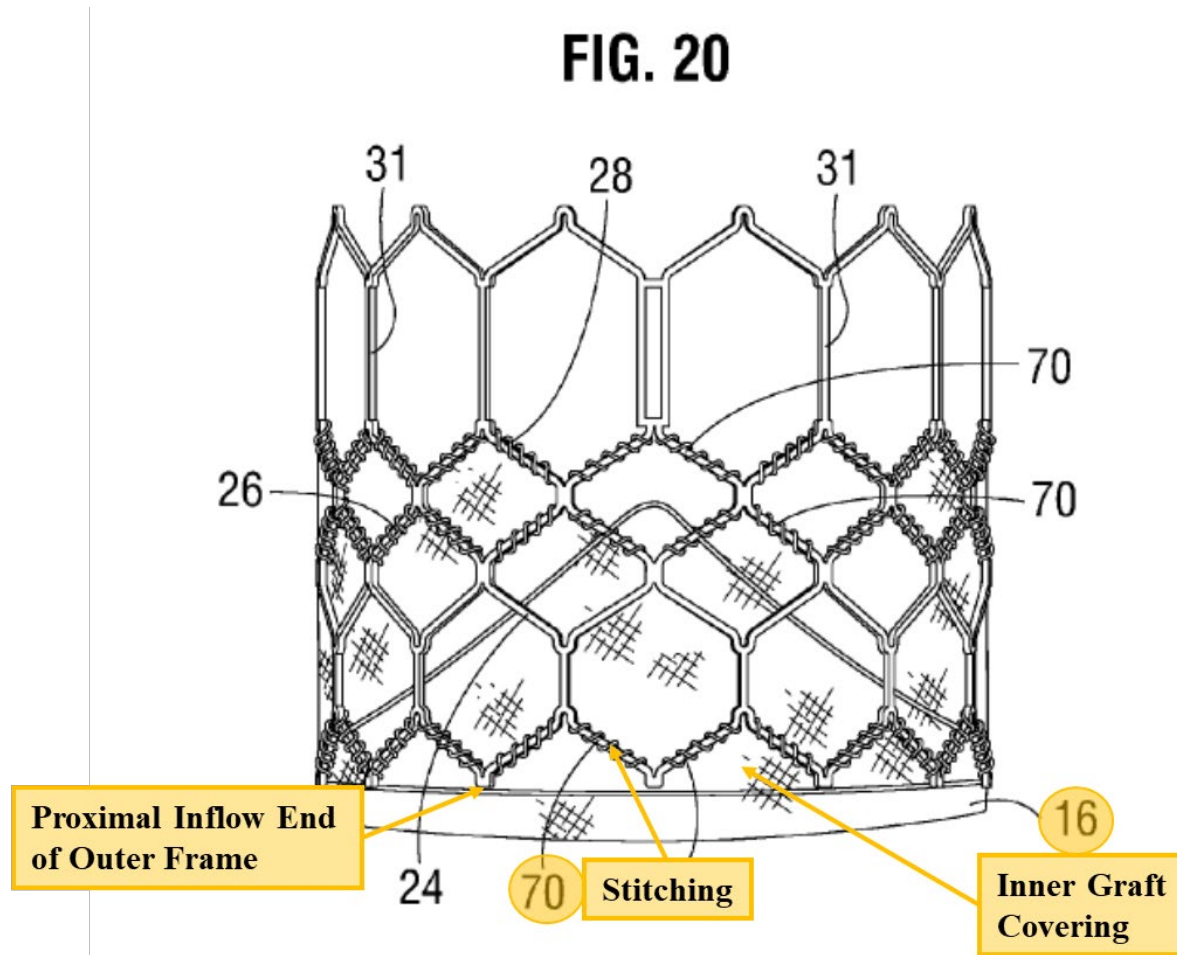
274. Alternatively, Walther and Spenser II disclose this limitation as explained in Grounds 1-3. *Supra* §§VI.A.12, VII.A.12. Therefore, when Walther's outer cloth or Spenser II's compressible material is added to Levi's valve, expansion of the valve within a patient's native aortic valve would be configured to (1) compress the outwardly extending fibers of the outward-facing surface of the outer cloth/compressible material (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and (2) compress the PET fibers of the inward-facing surface (i.e., second portion) against the valve's outer frame to form a second sealing interface.

B. Claim 2

275. Claim 2 recites: "The valve assembly according to claim 1, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." Levi discloses the limitations in claim 2. And based on claim 1,

Levi anticipates claim 2 or renders it obvious alone or in combination with Walther or Spenser II.

276. Levi's inner skirt (i.e., inner graft covering) extends to the proximal inflow end of the outer frame, as shown in Figure 20 below:



Ex. 1008 (Levi) at Fig. 20. As shown in the figure above, a plurality of sutures 70 extend between the inner skirt and through the outer frame, securing the inner skirt to the proximal inflow end of the outer frame. *See id.*

C. Claim 3

277. Claim 3 recites: “The valve assembly of claim 1, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.” Levi discloses the limitations in claim 3 and anticipates claim 3 or renders claim 3 obvious alone or in combination with Walther or Spenser II.

278. Levi’s outer skirt (i.e., first portion of fibers) may be constructed of “woven PET” fabric. Ex. 1008 (Levi) at 13:50-53. A person of ordinary skill in the art would have understood that woven PET fabric, including Levi’s outer skirt, would include openings between the interwoven fibers of the fabric. *See, e.g., id.* at 10:48-57 (discussing spacing between the woven fibers of the inner PET skirt). A person of ordinary skill in the art would therefore have understood that openings existed between the woven PET fibers of the Levi’s outer skirt which define “opening[s] extending through a thickness” of the outer skirt.

279. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable PET fabrics having varying thicknesses and densities and could have selected a fabric with a lower density of woven fibers such that even larger openings existed between the fibers. *See id.* at 10:48-57. A person of ordinary skill in the art would have been motivated to do so to facilitate further axial elongation of the outer skirt as the valve is expanded to provide a more

uniform and predictable crimping profile. *Id.* at 10:35-57 (explaining that “the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction” which helps ensure a uniform crimped profile). Additionally, the exchange of Levi’s outer skirt for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

280. Alternatively, a person of ordinary skill in the art would have understood that small fibers would extend from the outer surface of the outer skirt as I explained above. *Supra* §VIII.A.5.a. A person of ordinary skill in the art would have understood that the small fibers would occur at spaced intervals, thereby defining openings between the small fibers, similar to the openings between the fibers of Walther’s outer cloth discussed in Ground 1. *Supra* §VI.C.

These openings would extend through a thickness of the small fibers extending from the surface of the outer skirt.

281. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.C, VII.C.

D. Claim 4

282. Claim 4 recites: Claim 4 recites: “The valve assembly of claim 1, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.” Levi discloses the limitations in claim 3 and anticipates claim 3 or renders claim 3 obvious alone or in combination with Walther or Spenser II.

283. Just as Levi’s outer skirt (first portion of fibers) would have defined openings between the adjacent woven fibers, the corners of the outer skirt (second portion of fibers), which are made from the same PET and carried by the frame, would define an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers. Likewise, the fibers extending from the inwardly-facing surface of the outer skirt would also define such openings for the same reasons as the small fibers extending from the outwardly-facing surface. At least some of these openings would extend to the outer frame because the second

portion of fibers in the outer skirt directly abuts, and is compressed against, the outer frame when the valve is expanded.

284. Moreover, by 2012 persons of ordinary skill in the art would have had access to a range of suitable PET fabrics having varying thicknesses and densities and could have selected a fabric with a lower density of woven fibers such that even larger openings existed between the fibers. *See id.* at 10:48-57. A person of ordinary skill in the art would have been motivated to do so to facilitate further axial elongation of the outer skirt as the valve is expanded to provide a more uniform and predictable crimping profile. *Id.* at 10:35-57 (explaining that “the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction” which helps ensure a uniform crimped profile). Additionally, the exchange of Levi’s outer skirt for less dense cloth would have merely entailed a simple substitution of one known element for another to obtain predictable results. A person of ordinary skill in the art would have found it obvious to try, and been motivated to try, clothes of varying densities to reduce the crimped profile of the device while still achieving adequate reduction in paravalvular leakage provided by the fibers. A person of ordinary skill in the art would have expected success in substituting one known cloth for another because the method of attaching the cloths to valves was well known (e.g., stitching) and persons of ordinary skill in the art had demonstrated that cloths

could effectively treat paravalvular leakage when added to a heart valve. *See e.g.*, Ex. 1007 (Walther) at 1120-1121.

285. Alternatively, Walther and Spenser II disclose this limitation for the reasons I provided in Grounds 1-3. *Supra* §§VI.D, VII.D.

IX. SECONDARY CONSIDERATIONS

286. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '236 patent. For example, I am not aware of any products sold by Patent Owner that would be covered by the '236 patent and, therefore, I am not aware of any commercial success.

287. Further, given that the devices claimed in the '236 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

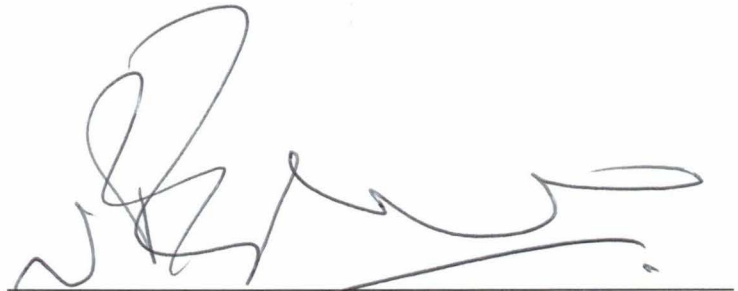
288. For the foregoing reasons, it is my opinion that claims 1-4 of the '236 patent are anticipated and/or rendered obvious by the prior art discussed above in

view of the knowledge of one of ordinary skill in the art at the time of the alleged invention.

289. 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.

290. 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.

Dated: February 4th 2022.



Dr. Nigel P. Buller