

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.

IPR2022-00193

Patent No. 10,881,538

**DECLARATION OF NIGEL BULLER, M.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,881,538**

<i>Edwards v. Aortic Innovations</i> U.S. Patent 10,881,538 Edwards Ex. 1003

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1001	U.S. Patent No. 10,881,538 B1 (“ 538 patent ”)
1002	Excerpts from the prosecution history of the ’538 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.

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1016	Alkashkari, MD, et al., <i>Percutaneous Pulmonary Valve Implantation for RVOT Defects</i> , Cardiac Interventions Today, 21-29 (September/October 2010)
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)
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)
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)
1028	Tyagi, G.K., <i>Yarn structure and properties from different spinning techniques</i> , in ADVANCES IN YARN SPINNING 119-154 (C. A. Lawrence ed., 2010)
1029	Kothari, V K, <i>Hairiness properties of polyester-cotton blended yarns</i> , 29 Indian J. of Fibre & Textile Research 30-34 (Mar. 2004)
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).

Exhibit No.	Description
1048	PCT Publication No. WO 2011/051043 A1 to Essinger et al.
1049	Excerpts from the prosecution history of U.S. Patent No. 10,792,172
1050	Complaint from <i>Aortic Innovations, LLC v. Edwards Lifesciences Corp.</i> , 1:21-cv-01377-RGA (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

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Aortic Innovations, LLC, Exhibit 2008

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

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, “Edwards” or “Petitioner”) to provide my opinion regarding the patentability of claims 1-20 of U.S. Patent No. 10,881,538 (“the ’538 patent”). For the reasons discussed herein, I have concluded that claims 1-20 of the ’538 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 ’538 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 ’538 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. 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.

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

23. 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

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

- The subject matter described and claimed in the ’538 patent;
- The level of ordinary skill in the art pertaining to the ’538 patent;
- The teachings of the prior art; and
- Whether claims 1-20 of the ’538 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.

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

D. Materials Considered

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

27. I also have relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '538 patent.

II. APPLICABLE LEGAL STANDARDS

28. 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 '538 patent.

29. 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

30. 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

31. 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.

32. 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

33. 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.

34. 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.

35. 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 '538 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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 1-20 of the '538 patent would have been non-obvious, as further explained in Section XI below.

D. Person of Ordinary Skill in the Art

41. It is my understanding that when interpreting the claims of the '538 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 '538 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 '538 patent). I have been informed that all of the references relied upon in this Declaration qualify as prior art under either priority date.

42. 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.

43. 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

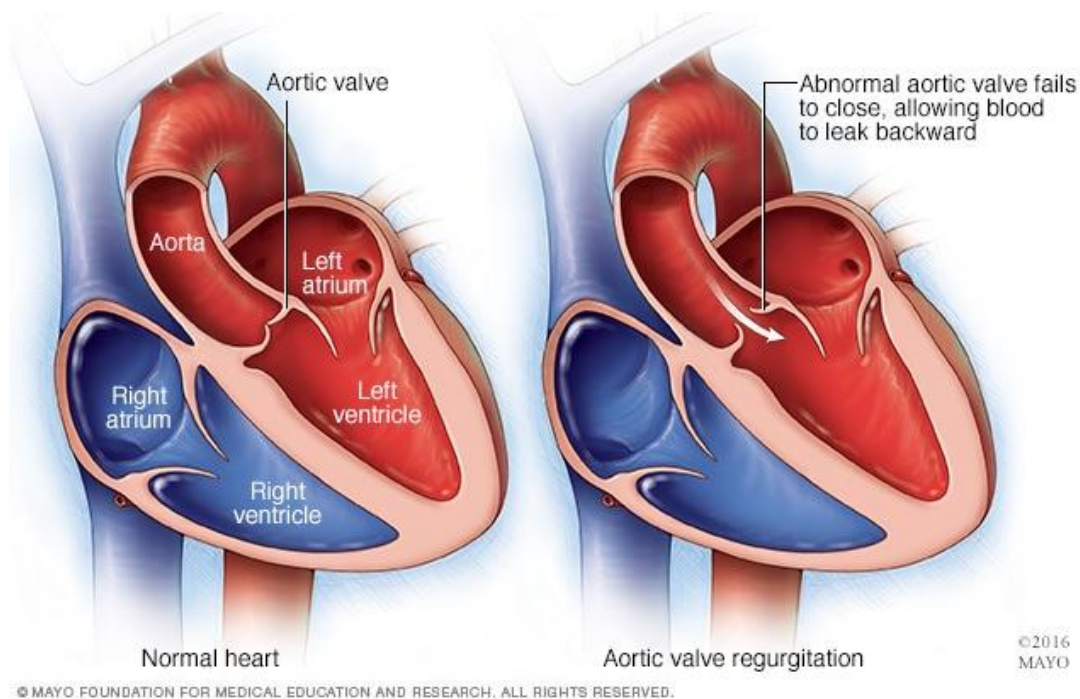
of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

44. Based on my review of the specification and claims of the '538 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 Aortic Valve

45. 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 '538 patent) towards the aorta.



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

46. The claims of the '538 patent require that “wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient.” See *e.g.*, Ex. 1001 ('538 patent) at claim 1. Claim 1 also recites “wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft 50 covering in response to compression from inflation of the balloon assembly.” However, as described below, persons of ordinary skill in the art would have understood that if the sealing material radially overlaps with the annulus and seals thereagainst, it must also radially overlap and seal against the leaflets.

47. The '538 patent identifies the annulus (identified by item #210) as the point where the aortic valve leaflets attach to the left ventricle:

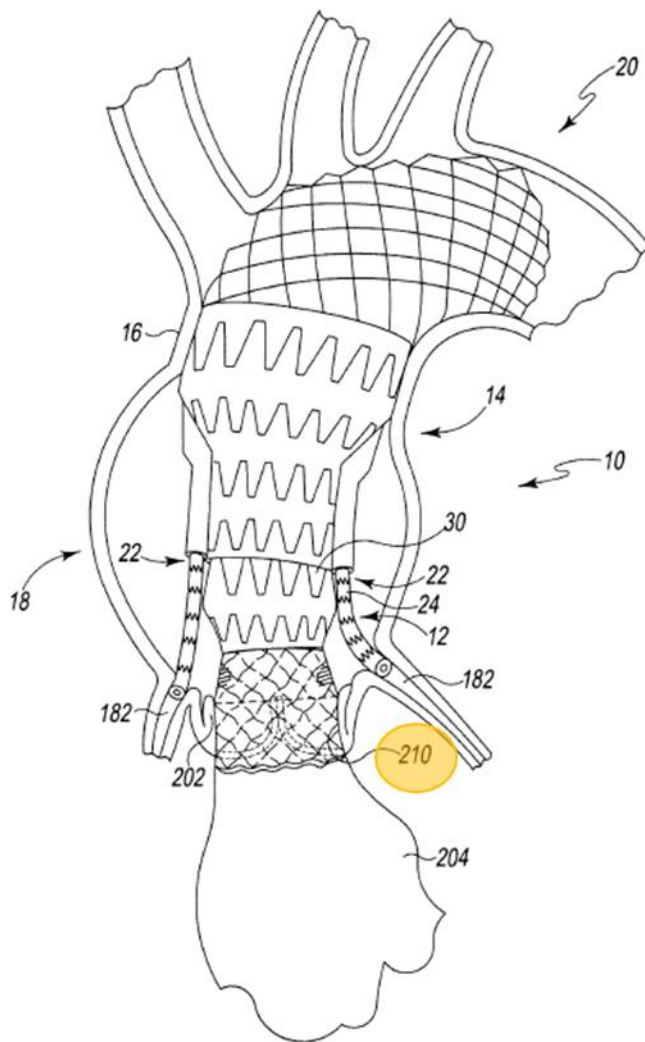
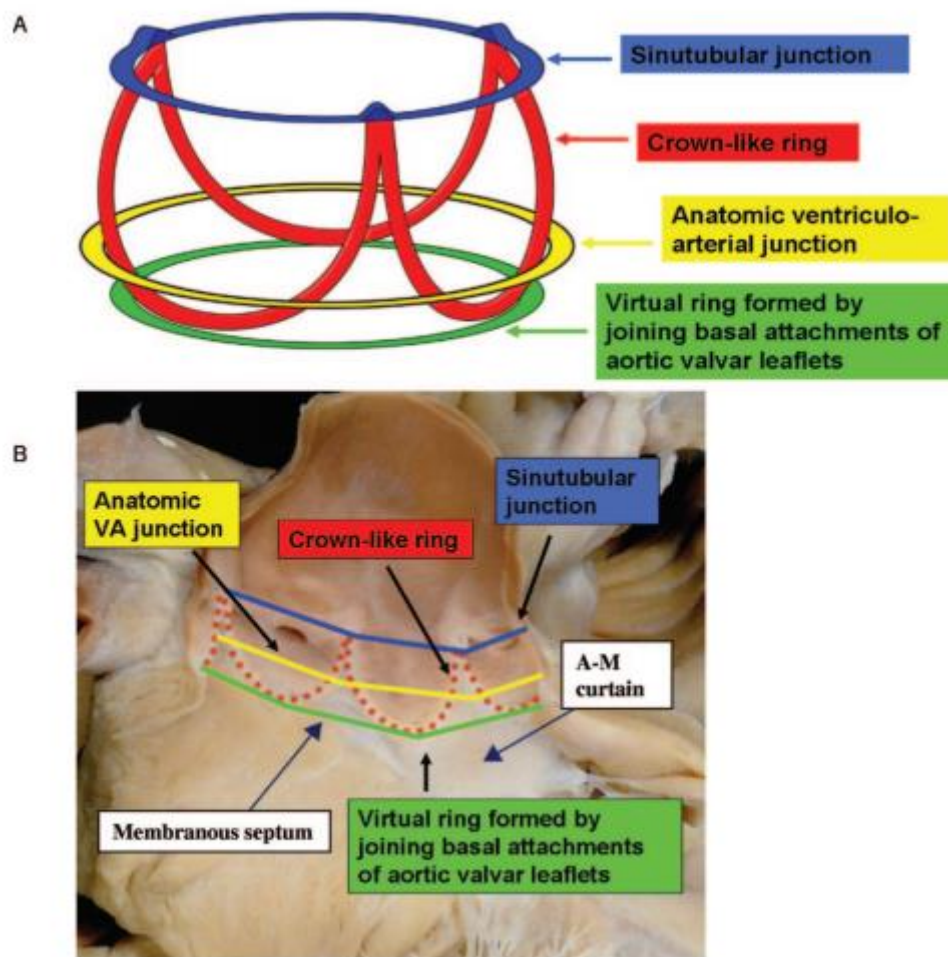


Fig. 2

See *e.g.*, *id.* at Fig. 2. This is further confirmed by the '538 patent's description that the "normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of the Valvsalve, the sinutubular junction, and the tubular portion." *Id.* at 1:52-54. The below image from a prior art journal article reflects

the structure of the aortic valve. The '538 patent identifies the green line as the annulus.

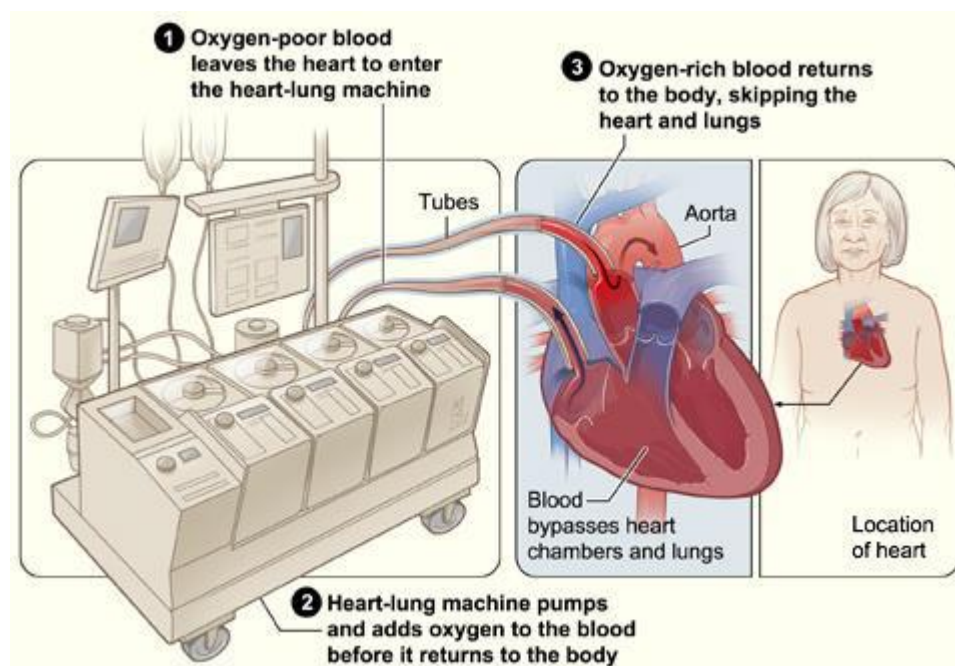


Ex. 1047 (Piazza) at Fig. 4. Because the “annulus” referred to in the '538 patent is the point where the leaflets begin, a person of ordinary skill in the art would have recognized that a sealing material pressing against the annulus must also press against the valve leaflets. *Id.* at 76. The journal 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.

B. Surgical Prosthetic Heart Valves

48. 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:

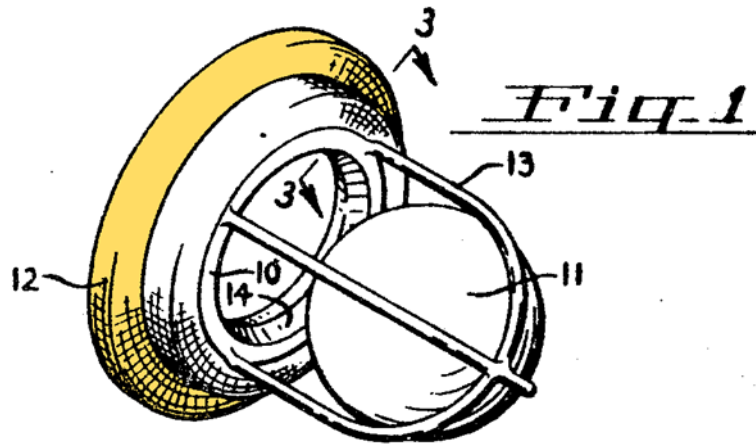


Available at http://www.daviddarling.info/encyclopedia/H/heart_surgery.html.

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

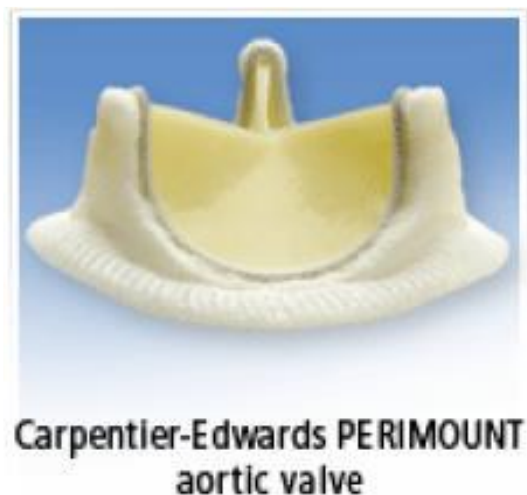
49. One of Edwards' first commercially available surgical valves was a ball and cage valve called the Starr-Edwards valve. U.S. Patent No. 3,365,728 (the "'728 patent"), which issued on January 30, 1968, details the features of this valve. **Ex. 1013** ('728 patent). Notably, even this early valve prosthesis 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. Thus, paravalvular leak was a well-recognized complication of surgical valve replacement as early as the 1960s.

50. 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 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).

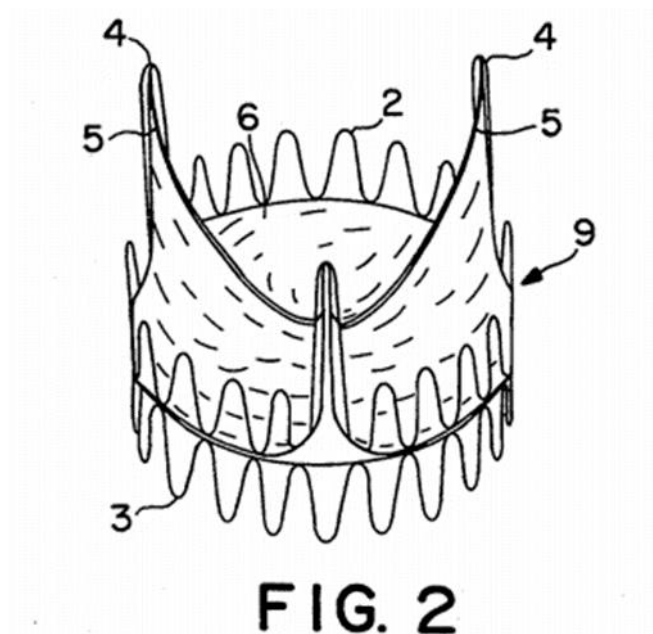
C. Transcatheter Heart Valve (“THV”) Technology

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

52. 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.

53. The Danish team published their results in 1992. **Ex. 1034** (Andersen, Henning, et al., *Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs*, European Heart Journal, 13:704-08 (1992)). There, Drs. Andersen, Hasenkam, and Knudsen described their hand-made THV, which included “a foldable biological cardiac valve inside a balloon expandable metallic stent.” *Id.*

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



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

55. 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.

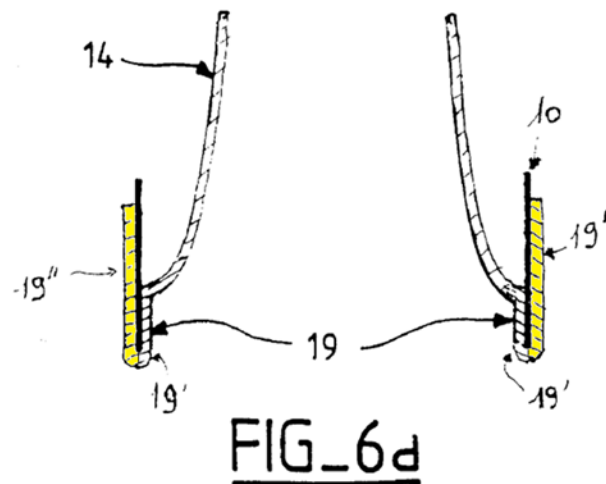
56. In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s. These designs provided the basis for a December 1996 patent application. A family of patents and patent applications stems from this 1996 application, including WO 98/29057 to Letac et al. (“Cribier patent publication”, **Ex. 1018**).

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

58. 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.

59. 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'']:

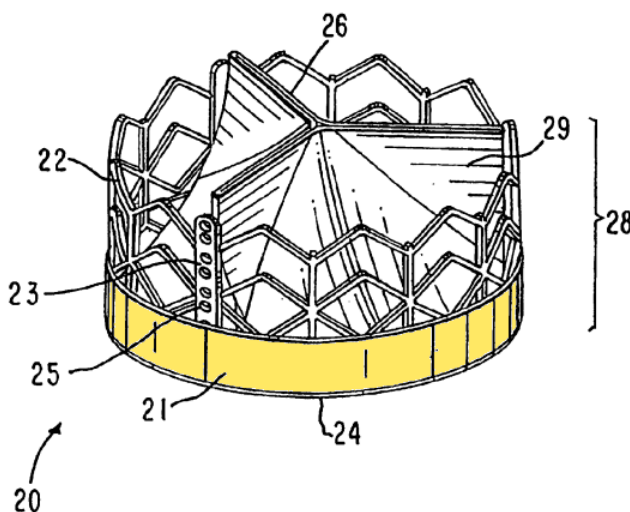


Id. at 22:23-26, Fig. 6d. The single-piece cover is a tubular structure that can be made with any of the materials disclosed for making the valve structure, which include fabric (*e.g.*, Dacron), biological material (*e.g.*, pericardium), or other synthetic materials (*e.g.*, polyethylene). *Id.* at 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.

60. Edwards's U.S. Patent No. 7,585,321 (referred to herein as "Cribier '321" **Ex. 1045**), claims priority to the Cribier patent publication and includes the THV embodiment having an internal cover that extends beyond and over the proximal end of the stent frame. *Id.* at 13:28-30, Fig. 6d.

61. 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

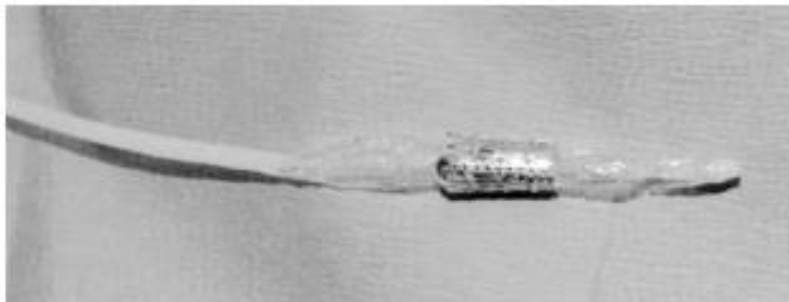
portion wrapped around the support stent at its inlet. *Id.* at 9:1-22, Fig. 1. The '460 patent further discloses that the cuff portion can be rolled up over the edge of the frame to provide a "sleeve-like" portion at the inlet. *Id.* at 8:47-50. This helps prevent leakage. *See id.* ("To prevent leakage 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.").

62. 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.

63. 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)).¹ The THV consisted of three bovine pericardial leaflets

¹ Dr. Cribier uses the phrase "percutaneous heart valve" or "PHV" to refer to his device. A PHV is the same as a transcatheter heart valve or THV.

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

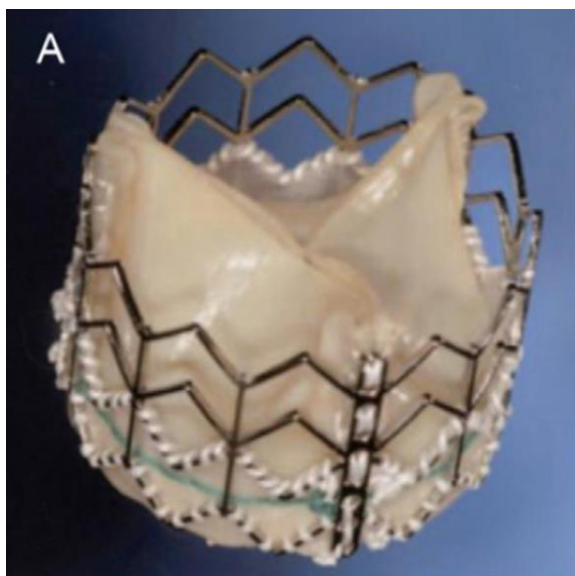


Id. at 3006, Fig. 1. Dr. Cribier implanted the THV using an antegrade approach from the right femoral vein. *Id.* at 3007. Dr. Cribier inserted a 24F sheath into the right femoral vein. The THV was “easily advanced through the sheath, across the interatrial septum, and within the diseased stenotic aortic valve.” *Id.* The balloon was then inflated to place the THV. *Id.* Dr. Cribier concluded that the implantation was successful and demonstrated “the feasibility of implanting a prosthetic heart valve percutaneously, with the use of standard interventional techniques, within the native diseased valve of a patient with calcific aortic stenosis.” *Id.* at 3008.

64. 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

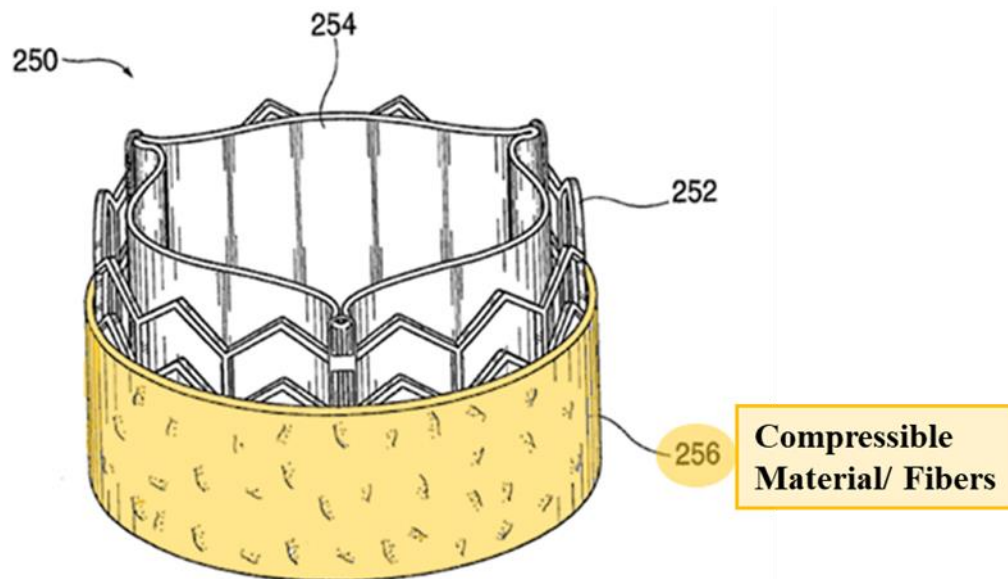
approach” for all cases. *Id.* at 701. Dr. Cribier’s work confirmed “that a bioprosthetic valve can be implanted percutaneously within the native diseased stenotic aortic valve of patients with end-stage life-threatening calcific aortic stenosis, using standard interventional techniques under local anesthesia.” *Id.*

65. 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.

66. In 2004, Edwards filed a patent application that formed the basis for PCT Patent Publication WO 2006/005015 A2, referred to herein as **Spenser II (Ex. 1011)**. Spenser II “provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis itself.” *Id.* at [0014]. Figure 22 (below) “illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.” *Id.* at [0085].



Id. at Fig. 22. As shown, “a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.” *Id.* at [00145]. The material “may extend entirely around the stent structure, such as in the form of a sleeve.” *Id.* “In

one preferred embodiment, the compressible material is formed from polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm.” *Id.* “In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped.” *Id.*

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

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

Id.

68. 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.

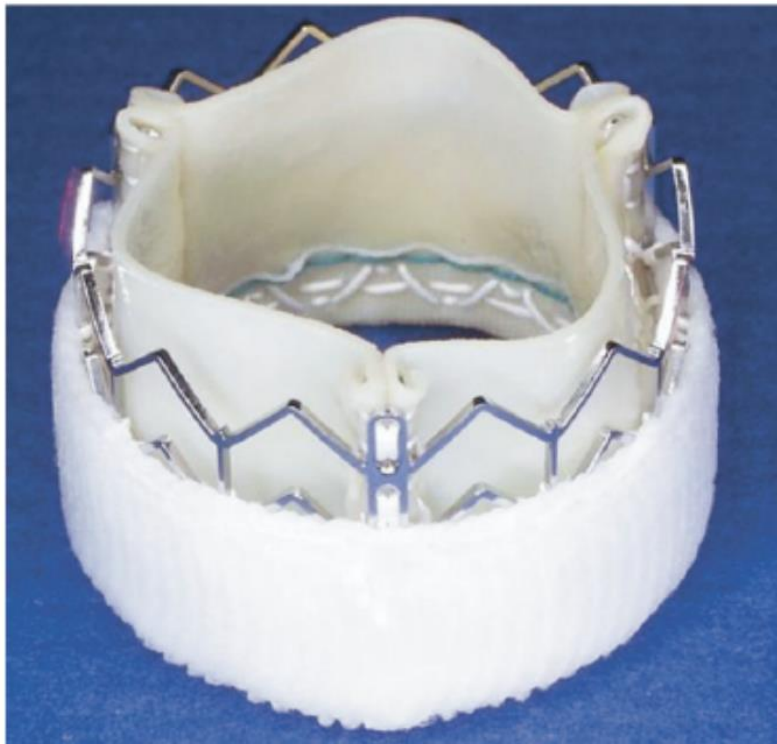


Fig 2. The fabric cuff surrounding the Cribier-Edwards transcatheter valve may provide a better seal for valve-in-valve applications (photograph courtesy of Edwards Lifesciences LLC, Irvine, CA).

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.”² *Id.* at e19.

69. 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 2010. *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

² “Paraprosthetic,” “perivalvular,” and “paravalvular” leakage are used interchangeably in the prior art to mean leaks around the prosthetic valve.

example, the **Cribier** publication 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)). 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).

70. 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.

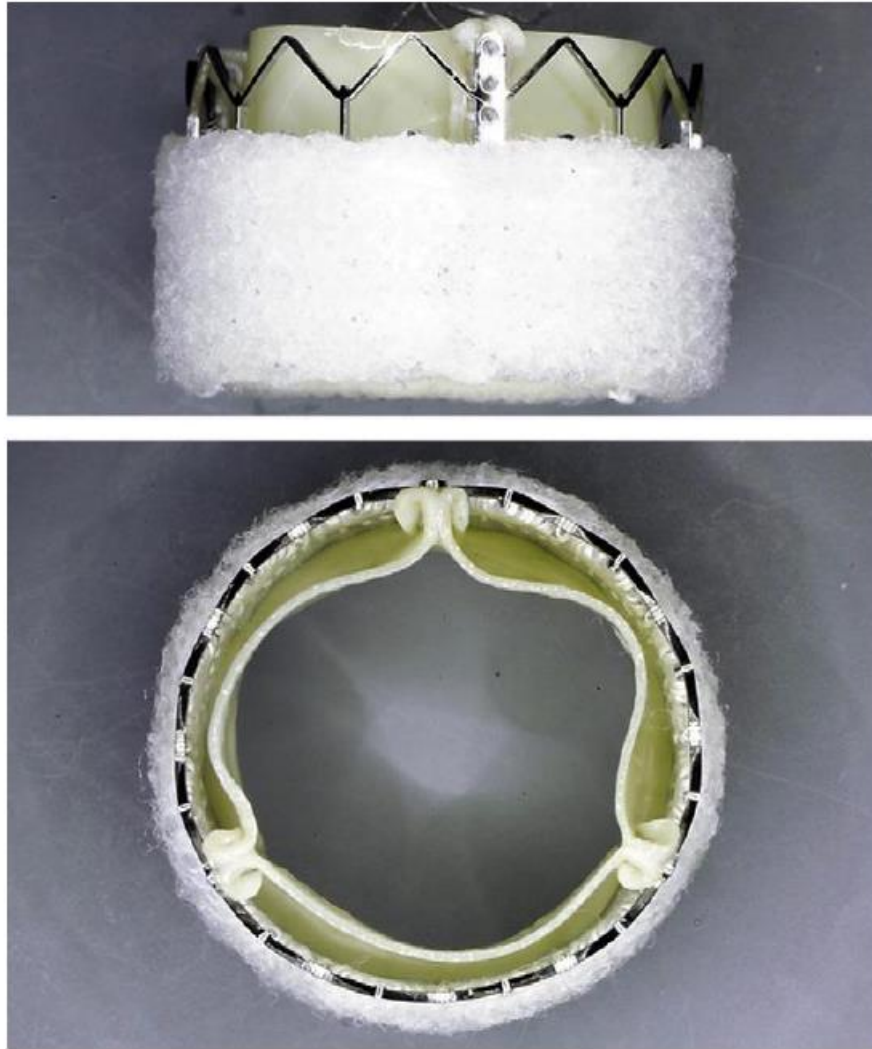
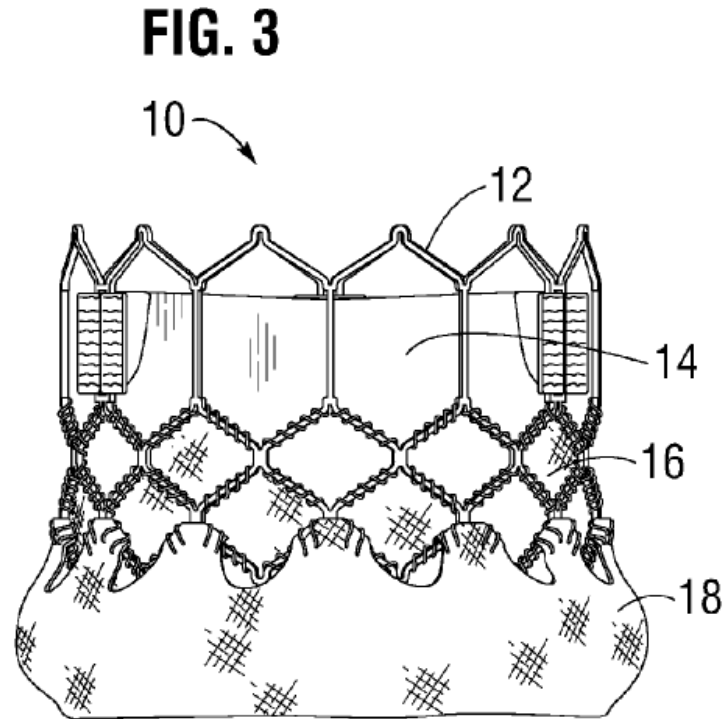


Fig. 1. Cloth valve.

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.*

71. 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.

72. The prior-art references identified above demonstrate that Petitioner (and its collaborators) invented and disclosed prosthetic heart valves, and specifically THVs, having an outer sealing material to reduce paravalvular leakage before November 2012. Moreover, by 2012, Petitioner had advanced THV technology to the point that persons of ordinary skill in the art had a number of options they could balance when adding an outer sealing material to a THV device. For example, the prior art demonstrates that persons of ordinary skill in the art had access to a wide range of suitable cloths and fabrics for use as a sealing material. *See e.g.*, Ex. 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.

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

74. Additionally, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. For example, the Retroflex 3 allowed the transfemoral introduction of SAPIEN 23 or

26 mm valves through 22 or 24 French sheaths. Ex. 1036 (Nietlispach) at 296-297. In contrast, the Novaflex delivery system, the successor to the Retroflex 3, allowed for a reduction in sheath size to 18 French for the 23 mm valve and 19 French for the 26mm valve. *Id.* The Novaflex incorporated an innovative feature where the heart valve was crimped on the inner catheter proximal to the inflatable balloon and then moved onto the balloon once the delivery system had been advanced into the aortic arch. *Id.*; *see also* Ex. 1037 (Le Patent Publication) at [0005]-[0006] (describing off balloon delivery). This unique feature enabled a reduction in sheath size.

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

IV. THE '538 PATENT

A. Summary of the '538 Patent

76. The '538 patent describes endograft devices for repairing ascending aortic aneurysms and replacing defective aortic heart valves and methods of implanting the devices. The majority of the embodiments combine multiple

components to form a structure that extends into the patient's ascending aorta and aortic arch.

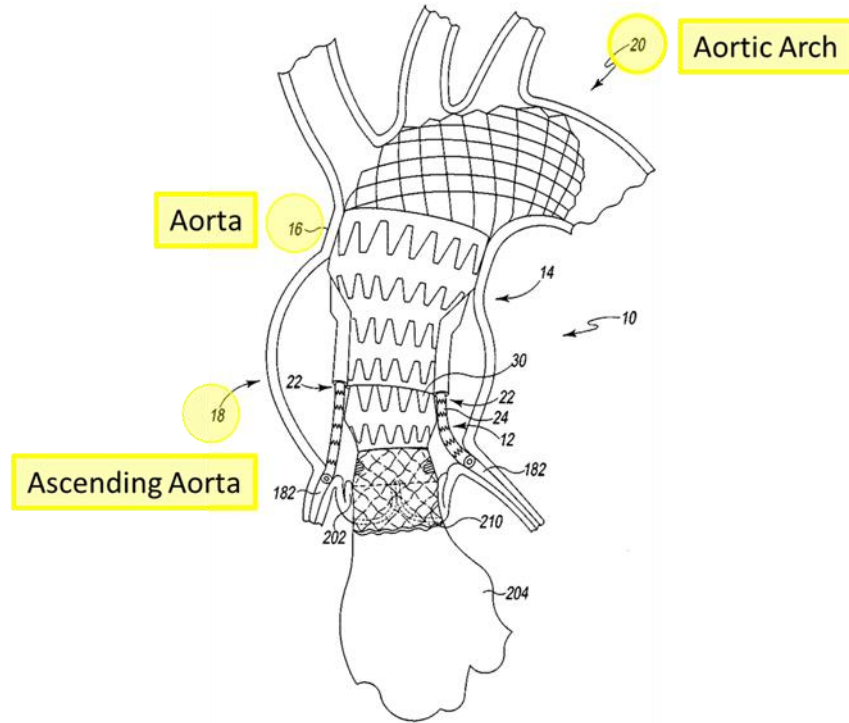


Fig. 2

77. However, the challenged claims of the '538 patent focus on a method of implanting a "heart valve assembly" for replacing an aortic heart valve. The '538 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** ('538 patent) 11:57-59; 17:43-45. The described "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":

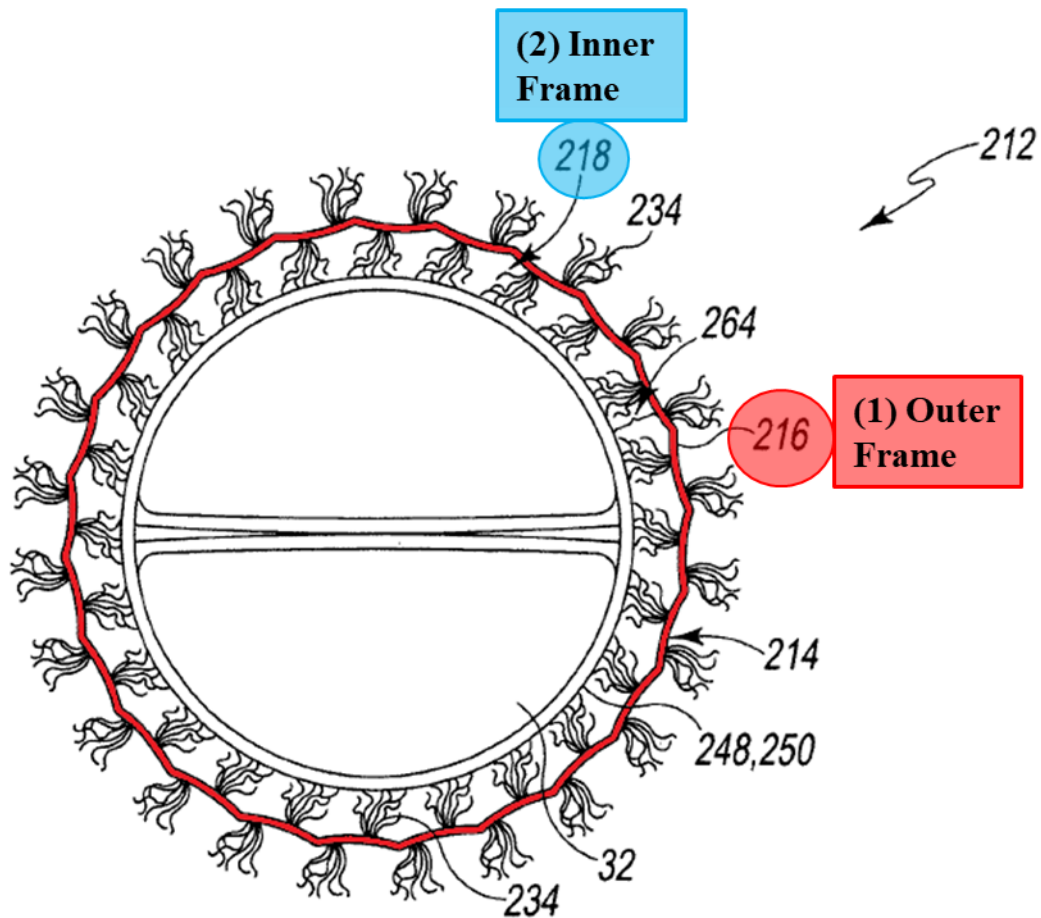
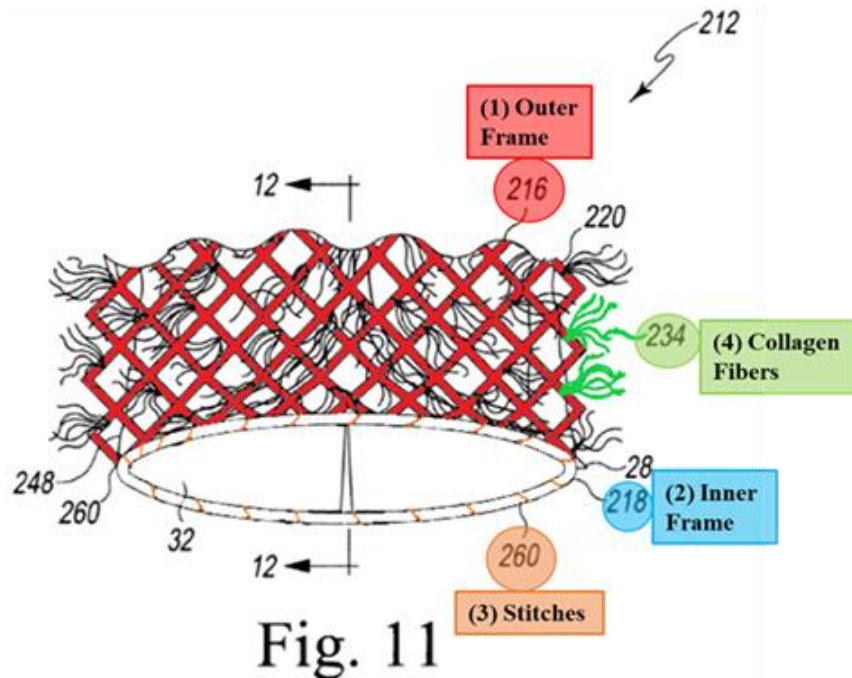


Fig. 13

Id. at 12:5-8, 17:54-57, Fig. 13.

78. The '538 specification 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 12:8-14, 13:14-17, 17:57-62, 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

12:39-44, 18:20-25. The inner frame [blue] is a “balloon-expandable tubular stent” constructed of metallic or polymeric material. *Id.* at 13:38-48. The inner frame is secured to the outer frame by a plurality of stitches [orange]. *Id.* at 14:3-5.



79. The '538 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 13:22-26, 13:48-52, 19:3-6.

80. The '538 specification discloses that the valve assembly may be implanted through a patient's common femoral artery by first passing a “stiff wire . . . through the aortic valve 202 and into the left ventricle 204.” *Id.* at 14:37-39, 19:21-22. Next, the delivery system of the valve assembly is passed through the

aortic valve, and a sheath is removed, allowing the self-expanding outer frame to “expand[] into engagement with the aortic annulus, thereby creating an interference fit between the frame 216 and the annulus 210.” *Id.*, 14:39-51, 19:22-30. Finally, the balloon-expandable inner frame is expanded, causing the inner frame to engage “the outer frame 216 and compress the collagen fiber/hydrogel coated proximal section 220 of the outer frame 216 against the aortic annulus 210.” *Id.*, 14:52-59, 19:31-38.

81. Claim 2 additionally recites that the graft covering “extends beyond a proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” *See id.* at claim 1. Based on my review of the specification of the ’538 patent, the specification does not describe such an embodiment, as the only description of a “covering material” is limited to a covering on the **outer surfaces** of the self-expanding outer frame or the balloon-expandable inner frame. *See e.g., id.* at 13:30-34, 13:48-54.

82. During prosecution of the ’538 patent, Patent Owner identified Figure 11 (above) as allegedly providing support for this limitation. *See* Ex. 1002 (’538 patent prosecution history) at 149. I disagree that Figure 11 provides supporting disclosure for this limitation. Patent Owner pointed to the “inner frame 218” in Figure 11 as “covering” an end of the outer frame 216. However, as I explained above, the specification teaches that “inner frame 218” is a balloon expandable

metal or polymeric stent. Ex. 1001 ('538 patent) at 13:38-48. The “inner frame 218” is never described in the specification as a “graft covering,” and thus “inner frame 218” in Figure 11 does not, and cannot, provide supporting disclosure for a graft covering that “extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” Figure 11 also does not depict any inner frame extending beyond and over the proximal end of the outer frame.

B. The Challenged Claims

83. The challenged claims include claims 1-20 of the '538 patent. Claims 1 and 11 are independent claims.

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

1. A method of implanting a transcatheter aortic valve assembly, comprising:

endovascularly positioning a guide wire through the aortic valve of a patient;

endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient, wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration,

wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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 graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame,

wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient;

inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation,

wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly,

wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

C. Claim Construction

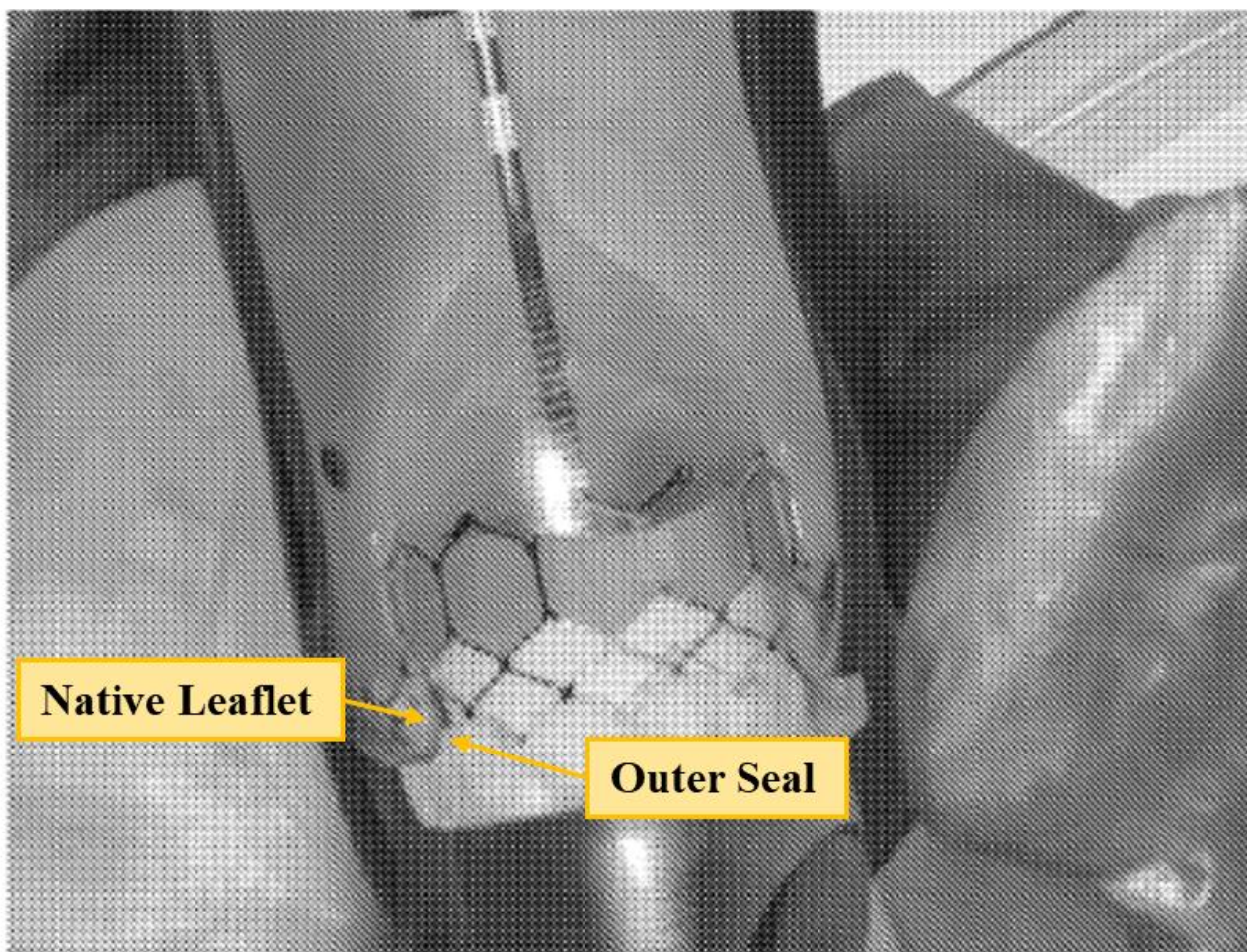
85. The claim terms should receive their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of filing and in accordance with the specification and prosecution history. I note that several of the terms recited in the challenged claims of the '538 patent are not used in the specification. For example, the specification does not recite the terms “fibrous network” or “graft covering.” For these terms, as I have done with all terms, I have applied the ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of filing and in accordance with the

specification and prosecution history, even though the specification and prosecution history provide limited information regarding the meaning.

D. Prosecution History

86. I have reviewed the '538 patent's prosecution history. I see that the Patent Examiner issued a single, non-final office action that included two prior-art based rejection. **Ex. 1002** ('538 patent prosecution history). None of the references I discuss in this Declaration were asserted in either rejection.

87. Although the Examiner did not discuss any of the prior art references I discuss in this Declaration, I am aware that Patent Owner characterized *Levi* in a Preliminary Amendment. Patent Owner argued that “[m]uch of the prior art teaches, when using an outer seal, to position the outer seal below the native leaflets.” *Id.* at 151. Patent Owner then provided an image of “a valve embodied by the art of record ***Levi*** . . . taken from online” as an example of such a valve. *See id.* (emphasis added). Patent Owner did not supply any source information for the provided image, which is reproduced below, but the image appears to depict a computer-generated graphic of Petitioner's SAPIEN 3 valve:



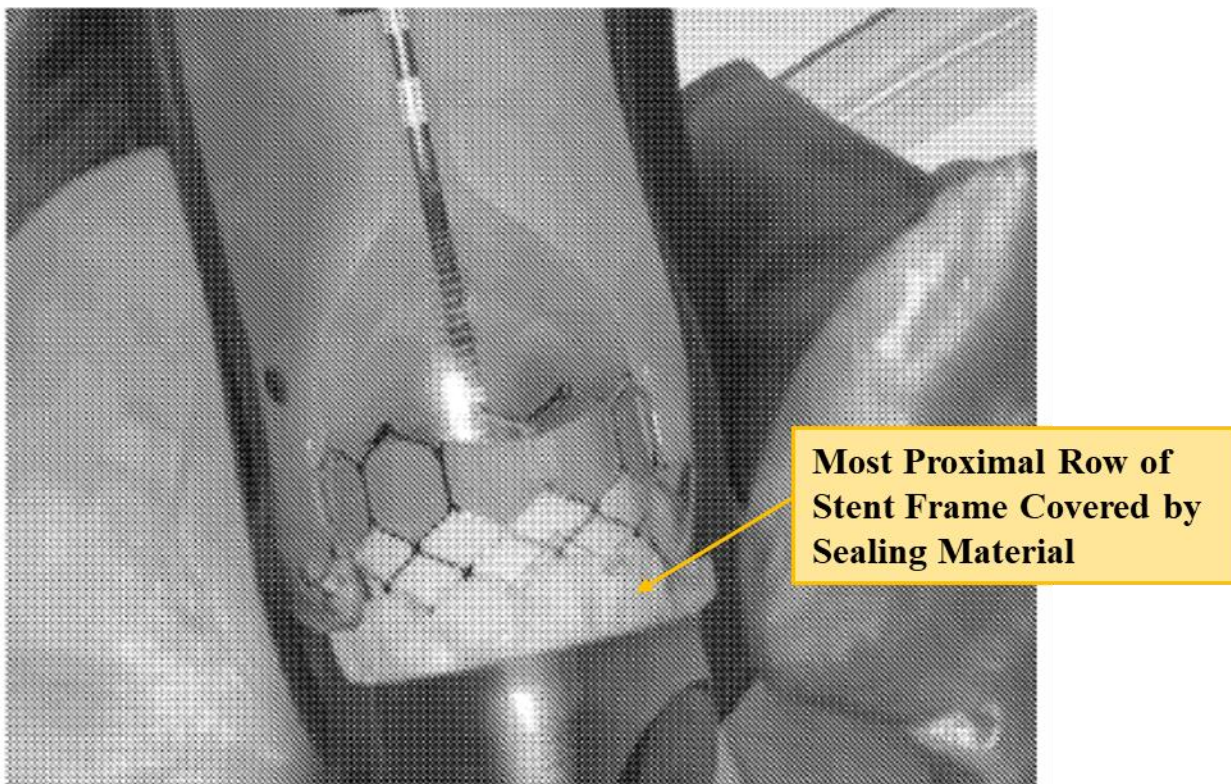
Id. at 152. There are several glaring issues with Patent Owner's argument and reliance on the above graphic.

88. First, the above image is, at best, a computer-generated graphic of one possible commercial embodiment of Levi. The image does not represent the scope of Levi's disclosure, as Patent Owner suggested during prosecution. Indeed, Patent Owner provides no information or support tying the image to Levi. Moreover, the computer-generated image does not necessarily reflect the placement or positioning of the heart valve in an actual patient. In clinical

practice, the patient's diseased leaflets would be highly calcified and would not necessarily resemble the smooth, symmetrical leaflets shown in the image. In addition, the positioning of the valve is performed using radiographic imaging, which does not allow for the precise positioning depicted in the image. Persons of ordinary skill in the art would therefore have understood that images such as the one relied on by Patent Owner are merely used to demonstrate theoretical placement and operation of the device, but they do not necessarily reflect the precise positioning of the device in actual patients.

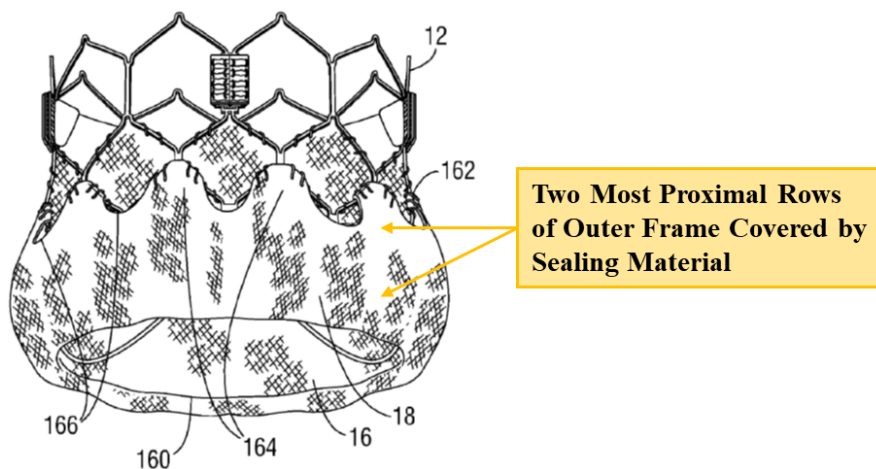
89. Second, as I show in the annotated version of the image above, the proximal end of the outer seal material overlaps with the bottom of the native leaflets. Thus, Patent Owner's argument is facially incorrect even as it applies to the image Patent Owner relies upon.

90. Third, the image provided by Patent Owner depicts a valve with an outer seal covering only the most proximal row of the frame:



However, as I explain in detail below, Levi discloses valve embodiments in which the outer skirt covers additional rows of the frame:

FIG. 42



Ex. 1008 (Levi) at Fig. 42; *infra* §IX.A.12. In such embodiments, the outer skirt would clearly overlap with the patient's native leaflets. Therefore, Patent Owner's

arguments in the Preliminary Amendment do not distinguish the claimed invention from Levi. Instead, Patent Owner’s arguments merely illustrate Patent Owner’s mischaracterization of the prior art during prosecution.

V. SUMMARY OF IPR GROUNDS

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

Ground	Claims Challenged	Unpatentability Basis	References
1	1, 8-11, 18-20	103	Cribier + Walther
2	2-3, 5-7, 12-13, 15-17	103	Cribier + Walther + Cribier ’321
3	1-20	103	Spenser + Walther
4	1-8, 10-18, 20	103	Spenser + Spenser II
5	1-8, 10-18, 20	102(e)	Levi
6	1-8, 10-18, 20	103	Levi
7	1-20	103	Levi + Walther
8	1-8, 10-18, 20	103	Levi + Spenser II

VI. GROUND 1: CLAIMS 1, 8-11, 18-20 OBVIOUS OVER CRIBIER AND WALTHER

92. 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.” *Id.*

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

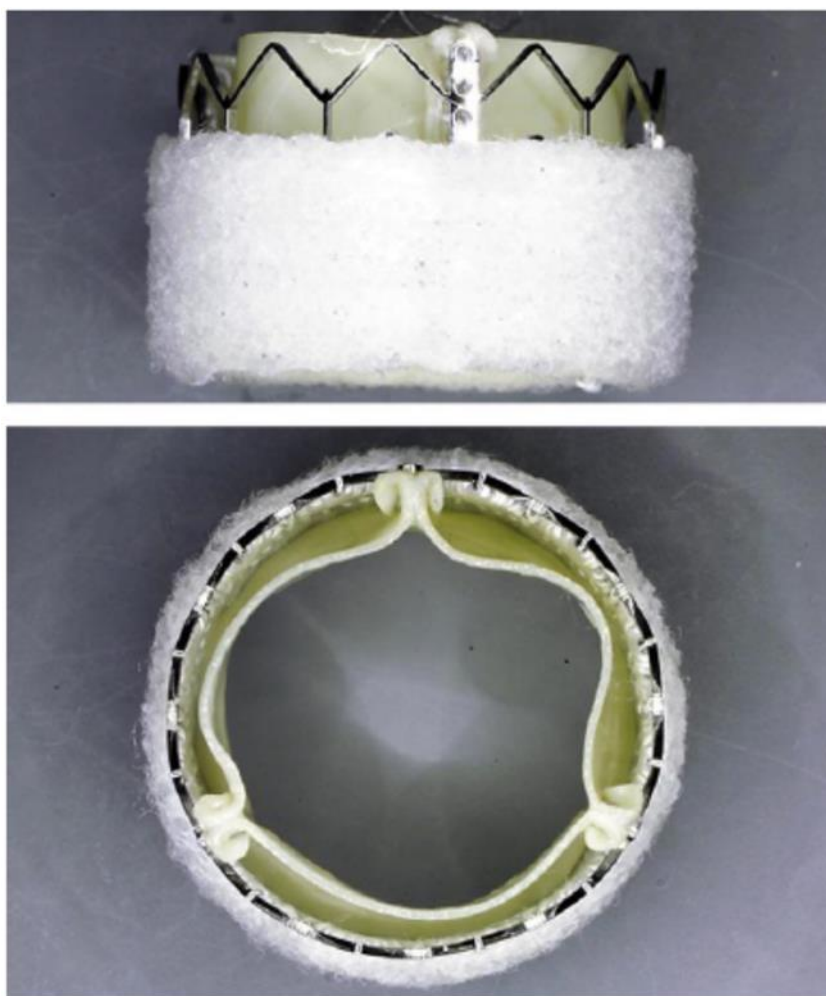


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at 1120-21, Figs. 1-3. Walther explicitly discloses that the modified SAPIENs were “identical” to SAPIEN except for the outer cloth. *Id.* at 1120. SAPIEN would have been well known to a person of ordinary skill in the art by November 2012. Walther generally describes SAPIEN but does not include some of the details about SAPIEN that are 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, 8, 10-11, 18, and 20 of the ’538 patent obvious.

A. Claim 1

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

1. Preamble

95. The preamble of claim 1 recites: “A method of implanting a transcatheter aortic valve assembly comprising.”

96. Cribier discloses a technique for transfemoral implantation of SAPIEN, which is a transcatheter aortic valve assembly. Ex. 1012 (Cribier) at Abstract, 350-355. 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.” *Id.* at 348. Cribier Figure 1 (below) provides a picture of SAPIEN:



**Edwards SAPIEN® THV
23 mm, 26 mm**

Id. at Fig. 1.

97. 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.

2. Endovascularly Positioning a Guidewire

98. Claim 1 next recites: “endovascularly positioning a guide wire through the aortic valve of a patient.” Cribier discloses this limitation.

99. Cribier discloses transfemoral delivery of SAPIEN through the patient's femoral artery. Ex. 1012 at Abstract, 350-355. Transfemoral delivery is "endovascular." Cribier discloses that during transfemoral implantation of SAPIEN, the native aortic valve is crossed "with an Amplatz Left-2 coronary catheter," and "[o]nce the valve is crossed, the transvalvular gradient can be measured before *advancing into the left ventricle* a 260 cm long, 0.035" Amplatz Extra *Stiff J Guidewire*® (COOK)." *Id.* at 352 (emphasis added). Cribier teaches that the guidewire "offers an optimal support for valve predilation as for valve implantation." *Id.* A person of skill in the art would thus use the guidewire to assist them in positioning the SAPIEN valve within the patient's native aortic valve.

3. Endovascularly Positioning the Transcatheter Aortic Valve Assembly

100. Claim 1 next recites: "endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient." Cribier and Walther render this limitation obvious.

101. I note that despite claiming endovascular delivery, the '538 patent does not contain any disclosure regarding how to size the disclosed valves for endovascular delivery. For example, the '538 patent never discloses the length, thickness, or width of the sealing material and fibers, the density of the fibers, or

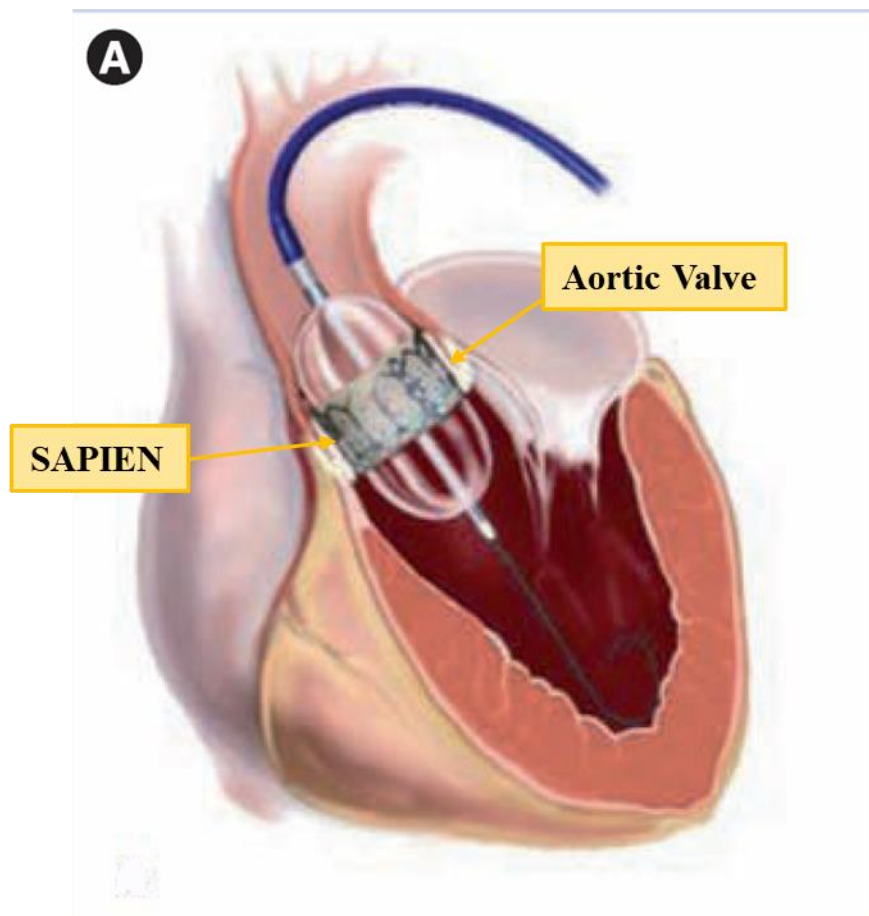
the crimp profile of the valve assembly. In my opinion, the dual-frame concept must rely on the prior art for all the dimensional teaching.

102. By 2012, persons of ordinary skill in the art would have been aware that SAPIEN could be endovascularly delivered through different blood vessels. For example, persons of ordinary skill in the art had successfully delivered SAPIEN through the common iliac artery, which is a larger artery than the femoral artery and can, therefore, accommodate bigger devices or achieve endovascular delivery in patients with diseased femoral arteries. Ex. 1043 (Kainuma, Satoshi, et al., *Transcatheter aortic valve implantation: first trans-iliac experience in Japan*, General Thoracic Cardiovascular Surgery 59:273-276 (2011); see also Ex. 1044 (Craido, Frank, *Iliac Arterial Conduits for Endovascular Access: Technical Considerations*, J. Endovasc. Ther. 14:347-351 (2007) (describing endovascular access through the common iliac artery). The common iliac artery also provide an alternative route for endovascular delivery when the femoral artery was too diseased or tortuous. *Id.* Delivery through the common iliac artery is endovascular delivery.

103. Additionally, as I explained in the previous section, Cribier describes the “retrograde transfemoral” approach for implanting SAPIEN, which is another type of endovascular delivery. *Supra* §VI.A.2. The femoral Cribier describes the successful delivery of SAPIEN using the “retrograde transfemoral” approach. Ex.

1012 (Cribier) at 347-356; *see also* Ex. 1009 (Conradi) at 515-517 (disclosing transfemoral and transapical approaches); Ex. 1023 (Webb) at 156-158 (same). Cribier also mentions the antegrade transseptal approach in which a SAPIEN was delivered through the femoral vein. Ex. 1012 (Cribier) at 348; *see also* Ex. 1030 (describing antegrade transseptal approach). The antegrade transseptal approach is yet another type of endovascular delivery.

104. In the transfemoral approach, SAPIEN is “introduced within the femoral artery, advanced to the native aortic valve under X-ray control, ***positioned across the aortic annulus***, and delivered by balloon inflation under rapid heart pacing.” Ex. 1012 (Cribier) at 347 (emphasis added). A person of ordinary skill in the art would therefore understand that endovascular delivery of SAPIEN via the transfemoral approach involved positioning SAPIEN through the patient’s native aortic valve. This is illustrated in Fig. 4a of Conradi, which shows the positioning of SAPIEN through the patient’s aortic valve during endovascular transfemoral delivery:



Ex. 1009 (Conradi) at Fig. 4A. A person of ordinary skill in the art would also understand that endovascularly implanting the SAPIEN through a patient's common iliac artery also involved positioning SAPIEN through patient's native aortic valve. See e.g., Ex. 1043 at 274, Fig. 2B (disclosing that SAPIEN was implanted in the "optimum position of the aortic annulus").

105. Walther discloses implanting the cloth-covered SAPIEN *in vitro* using Edwards' transapical delivery system (the Ascendra). Ex. 1007 (Walther) at 1121. Transapical delivery is a method for implanting prosthetic heart valves that includes inserting the valve between the ribs and through the heart wall.

106. 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 to reduce paravalvular leaks. The implanted SAPIEN provides sealing between the outer frame and the patient's anatomical wall to "minimize perivalvular leaks." *Id.* at 353; *see also id.* at 354 (describing issues that may cause "perivalvular insufficiency"); *see also* Ex. 1009 (Conradi) at 516-517, Fig. 4A; Ex. 1024 (Webb) at 156-158; Ex. 1012 (Cribier) at Abstract, 350-355; Ex. 1028 (Roselli) at 208-210, 214. However, despite the success of SAPIEN, 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.

107. 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. Walther discloses that the cloth-covered SAPIEN "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 both the transfemoral and transapical approaches and deemed the procedures 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). 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.

108. In my opinion, a person of ordinary skill in the art would have found it obvious, and been motivated, to endovascularly deliver a cloth-covered SAPIEN, similar to the one disclosed in Walther, in 2012. Persons of ordinary skill in the art generally preferred endovascular delivery to other forms of delivery, like open-heart surgery or transapical delivery, because it was often less invasive.

109. Persons of ordinary skill in the art would have been motivated to endovascularly deliver the Walther valve through the common iliac artery because the artery is large and would not have required any modifications to Walther's valve. Moreover, the femoral artery is upstream of the common iliac artery, so other than the access point for insertion of the device, the delivery of valves through the femoral and common iliac artery is the generally the same.

110. Persons of ordinary skill in the art also would have been motivated to endovascularly deliver the Walther valve through the femoral artery. Many persons of ordinary skill in the art considered the transfemoral approach "as the technique of first choice" and safer than the transapical approach, which was associated with "more adverse events and higher mortality rates." Ex. 1009 (Conradi) at 515-516; Ex. 1020 (Yuksel, Uygur, *Balloon-Expandable Transcatheter Aortic Valve Implantation*, Cardiac Interventions Today (Aug./Sept. 2009) at 52; Ex. 1043 (Kainuma) at 275.

111. A person of ordinary skill in the art would have possessed the skills necessary to adapt a cloth-covered SAPIEN, like the one in Walther, for transfemoral delivery. *Supra* §III.C. First, 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 an appropriately dimensioned cloth for endovascular delivery through, for example, the femoral artery. *Id.*; *see also e.g.*, Ex. 1011 (Spenser II) at [0055], [00145]; Ex. 1008 (Levi) 13:49-53. Second, by 2012, Petitioner had developed delivery systems having smaller diameters than those initially used with SAPIEN. *Supra* §III.C; Ex. 1036 (Nietlispach) at 295-297; Ex. 1037 (Le patent publication) at [0005]-[0006]. These delivery systems would have permitted a person of ordinary skill in the art to endovascularly deliver a valve having a greater diameter than SAPIEN alone. Third, by 2012, Petitioner had developed a variety of ways to adapt a heart valve's outer frame and leaflets to create additional space for an outer cloth. *Supra* §III.C; *see e.g.*, Ex. 1008 (Levi) at 6:31-49, 16:24-17:18; *infra* §IX.A. Persons of ordinary skill in the art would have found it obvious to utilize one or more of these known strategies to make the cloth-covered SAPIEN suitable for endovascular delivery, and particularly for transfemoral delivery.

112. A person of ordinary skill in the art would have had a reasonable expectation of success in endovascularly delivering the cloth-covered SAPIEN for

several reasons. First, Walther concludes that *in vivo* (i.e., in a patient) implantation of the cloth-covered valve “is feasible.” Ex. 1007 at 1125. Second, many references reported the successful transfemoral delivery of SAPIEN and, by 2012, SAPIEN was widely used globally and had been approved by the FDA. See e.g., Ex. 1009 (Conradi) at 517; Ex. 1012 (Cribier) at 355; Ex. 1032 (2011 FDA Approval). Third, persons of ordinary skill in the art had successfully implanted SAPIEN through the common iliac artery, which could accommodate the delivery of larger devices. Ex. 1043 (Kainuma). In view of these factors, a person of ordinary skill in the art would have reasonably expected success in endovascularly delivering a cloth-covered SAPIEN.

4. **Radially Compressed Orientation and Radially Expanded Orientation**

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

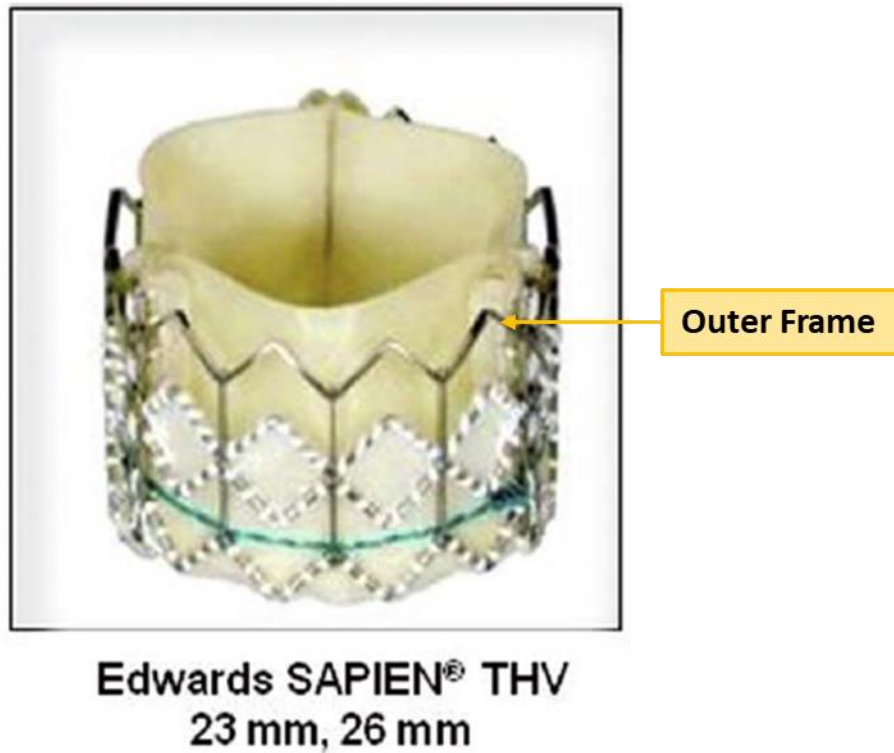
114. Cribier discloses that the SAPIEN is “***compressed*** using a crimping tool over the delivery balloon catheter to symmetrically reduce its overall diameter from its ***expanded size*** to its ‘mounted’ size.” Ex. 1012 (Cribier) at 348 (emphasis added). A person of ordinary skill in the art would have understood that SAPIEN’s “mounted size” is a radially 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. A person of ordinary skill in the art would have understood that SAPIEN is in a radially expanded position when, for example, it is expanded in the surgical valves (as in Walther) or a patient's native aortic valve (as in Cribier).

5. Outer Frame

115. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration.” Cribier also discloses this limitation.

116. 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 defines an open cell configuration and surrounds the other valve features, such as the heart valve leaflets, making it an “outer frame”:



Id. at Fig. 1.

6. Inner Frame

117. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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.

118. The claim states, “the inner frame ***includes*** a cylindrically extending graft covering.” I understand that during prosecution of a related patent that includes the same limitation – U.S. Patent No. 10,966,846 (the “’846 patent”) –

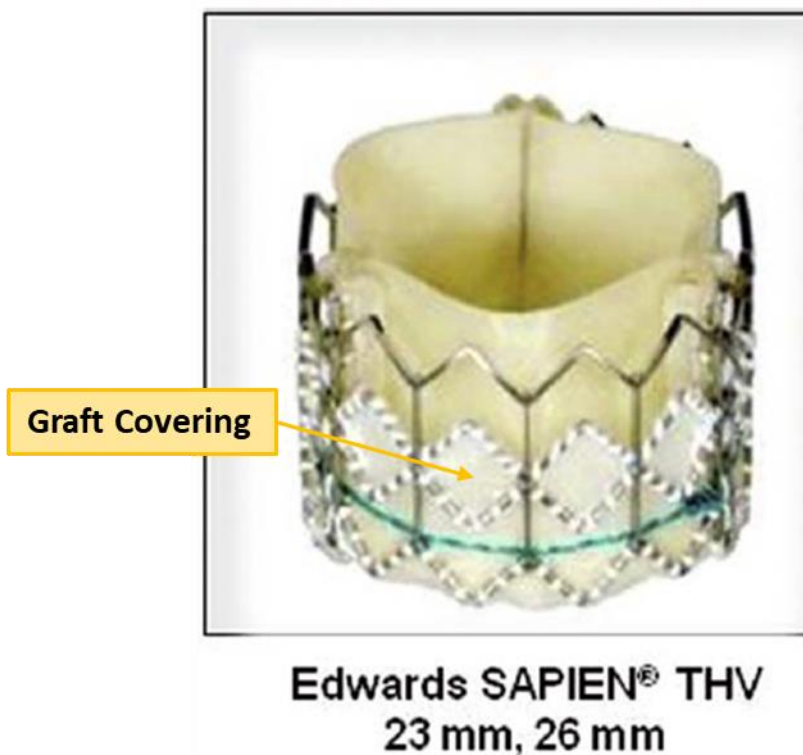
Patent Owner argued the “includes” language in claim 12 requires only an inner frame that *is* a graft covering. Specifically, Patent Owner attempted to distinguish prior art on the ground that it allegedly did not include a “graft forming the inner frame.” Ex. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 14. Patent Owner also argued that Petitioner’s SAPIEN 3 Ultra product is “covered by the claimed invention” because it “includes an inner frame that is a graft.” *Id.* at 21-22.

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



120. Cribier discloses that SAPIEN includes “a polyethylene terephthalate (PET) fabric cuff.” Ex. 1012 (Cribier) at 348, Fig. 1. The PET fabric cuff is a “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:



Id. at Fig. 1.

121. SAPIEN’s PET fabric cuff covers the inside surface of SAPIEN’s outer frame. Based on Patent Owner’s statements during prosecution of the related ’846 patent, and to the extent an “inner frame” can be a graft covering, SAPIEN’s PET fabric cuff satisfies this limitation.

122. Cribier also 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

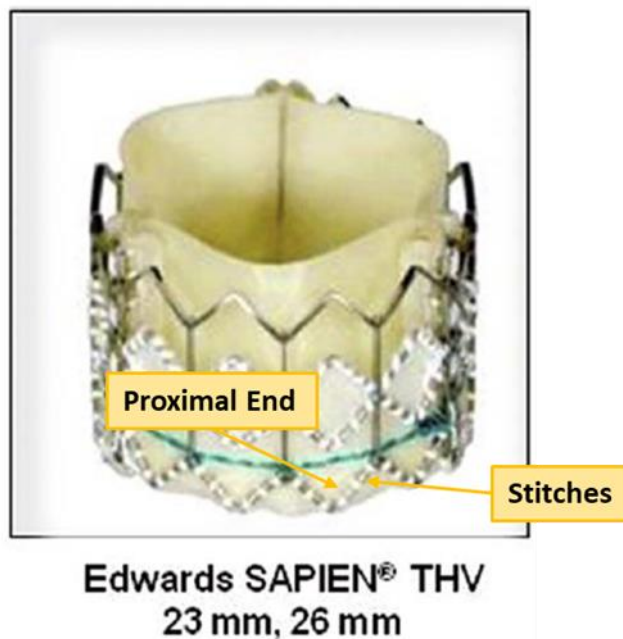
leaflets” constructed from bovine tissue. SAPIEN’s fabric cuff is stitched to the prosthetic leaflets along the blue suture line in the figure above, and thus the fabric cuff “engages” the prosthetic heart valve.

123. 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 the 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”).

7. Stitching

124. Claim 1 next recites: “wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame.” Cribier also discloses this limitation.

125. 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. The stitches along the bottom-most row of struts secure the proximal end of the graft covering to the proximal end of the outer frame:



Ex. 1012 (Cribier) at 348, Fig. 1; *see also* Ex. 1028 (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.”).

8. Fibrous Network

126. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame.” Cribier in combination with Walther renders this limitation obvious.

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

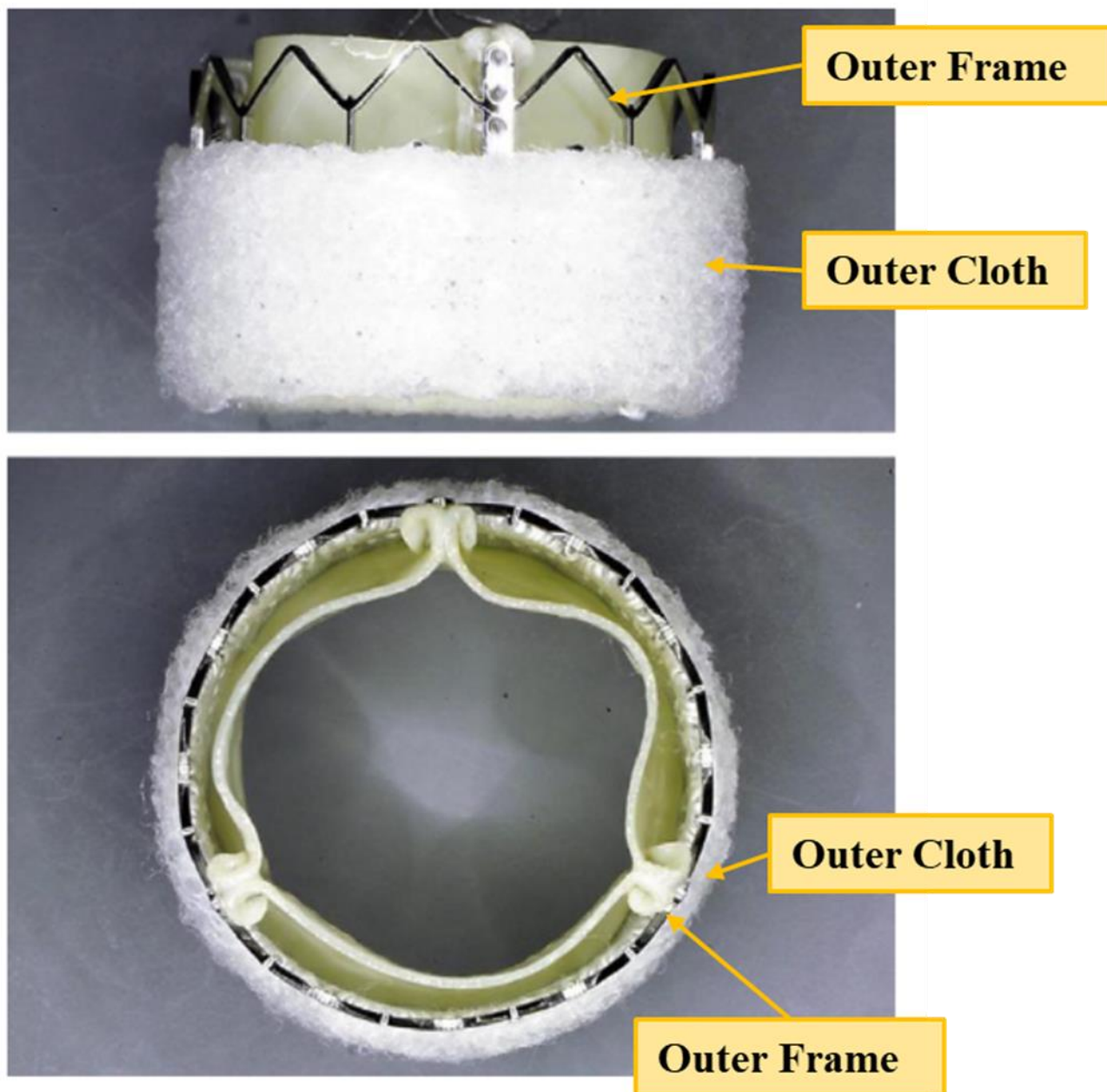
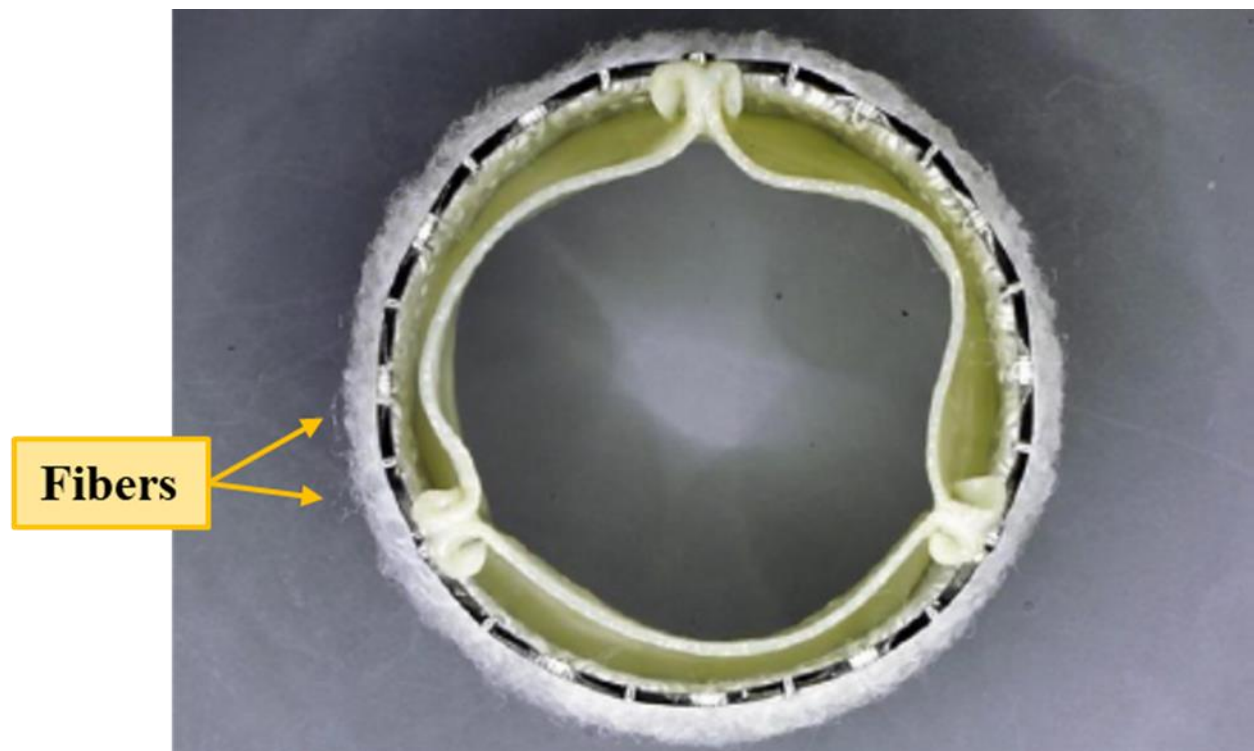


Fig. 1. Cloth valve.

Ex. 1007 (Walther) at Fig. 1.

128. Walther's outer cloth is composed of a plurality of interwoven fibers, some of which radially extend outwardly of the outer frame. In the figure below, one can see the fibers extending 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 interwoven fibers of Walther’s outer cloth are thus a “fibrous network” under the plain and ordinary meaning of that term. 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.

129. The above figure depicting fibers extending outwardly from the outer cloth 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 radially 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>.

130. Moreover, the fibrous network 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 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).

131. 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.

132. 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”:

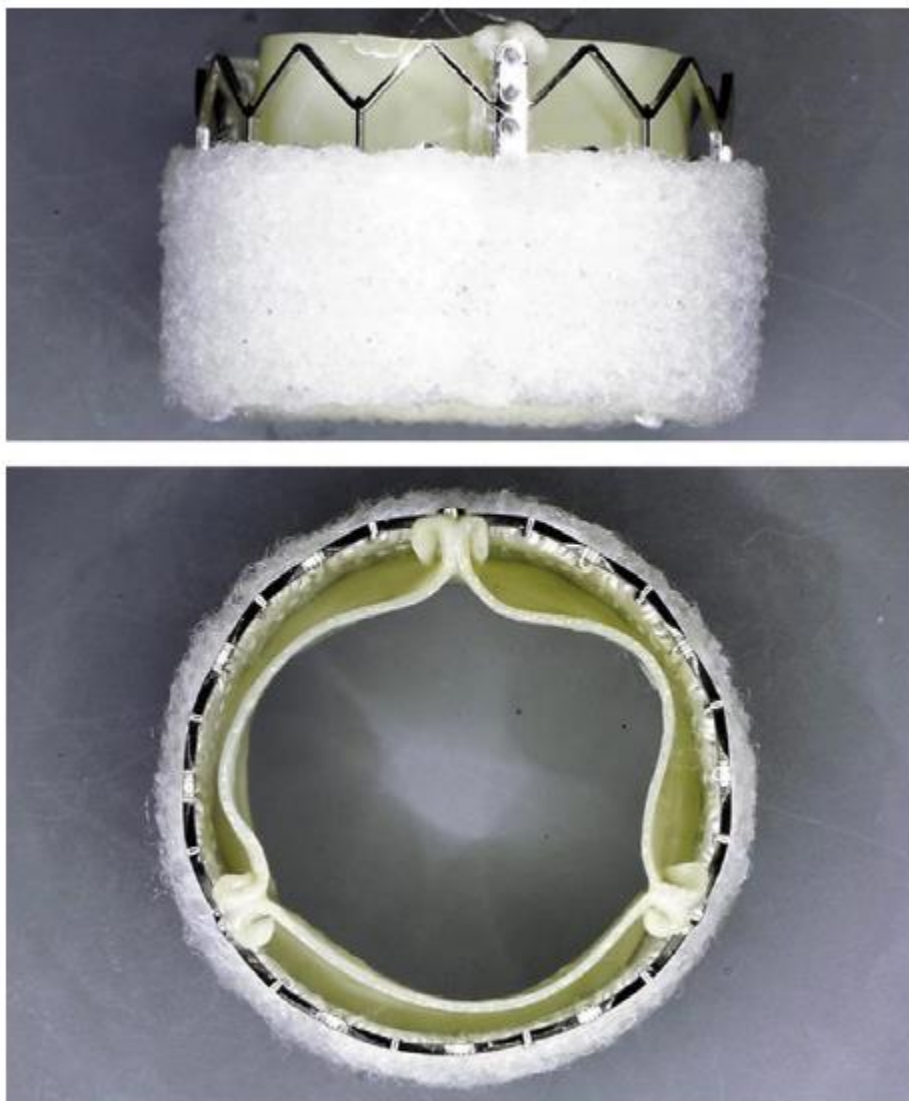
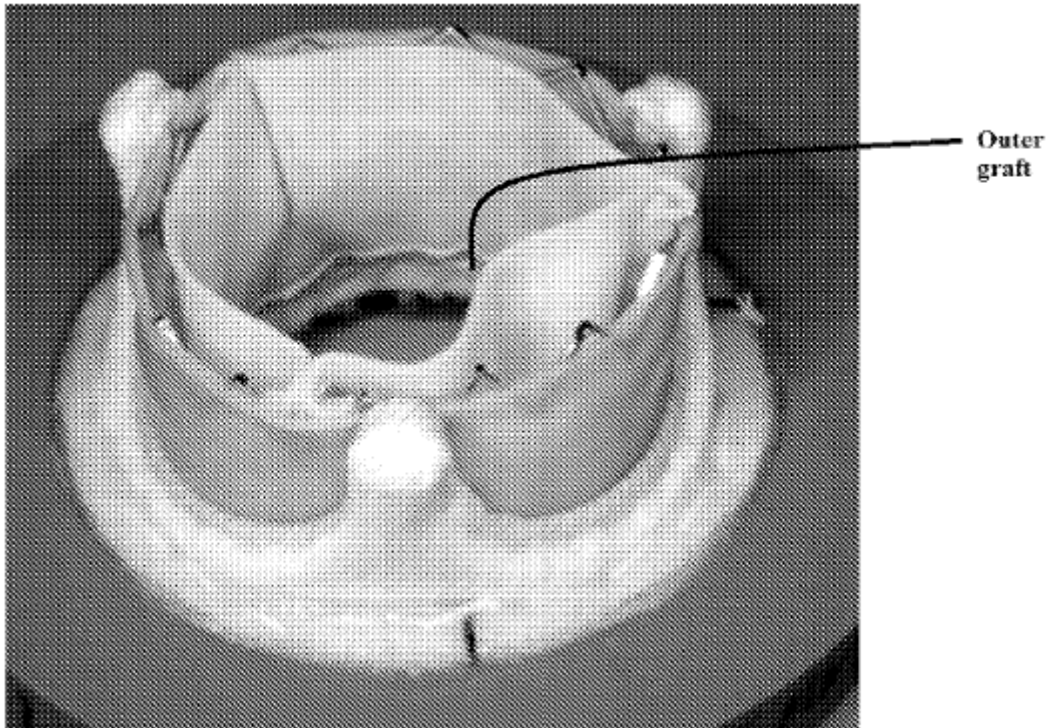


Fig. 1. Cloth valve.

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.

133. 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.

134. 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.

135. 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.

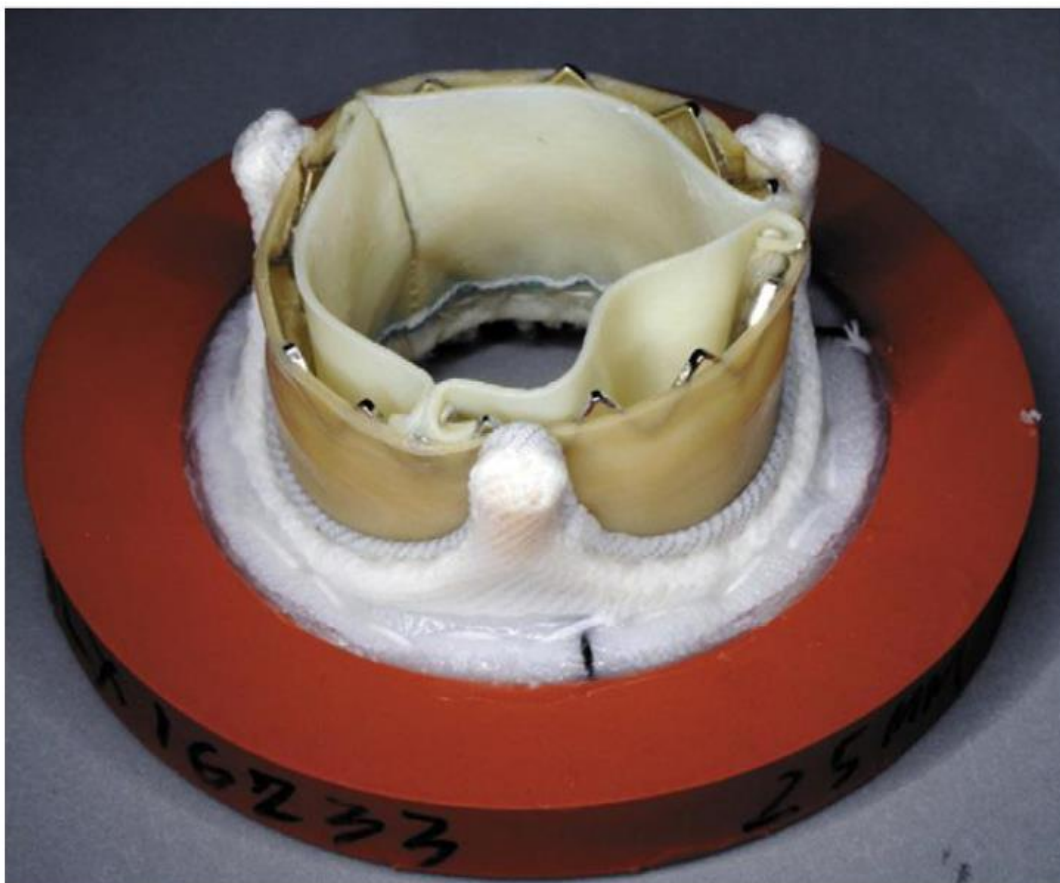


Fig. 2. Cloth THV valve deployed in surgical valve.

Ex. 1007 (Walther) at Fig. 2.

136. 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

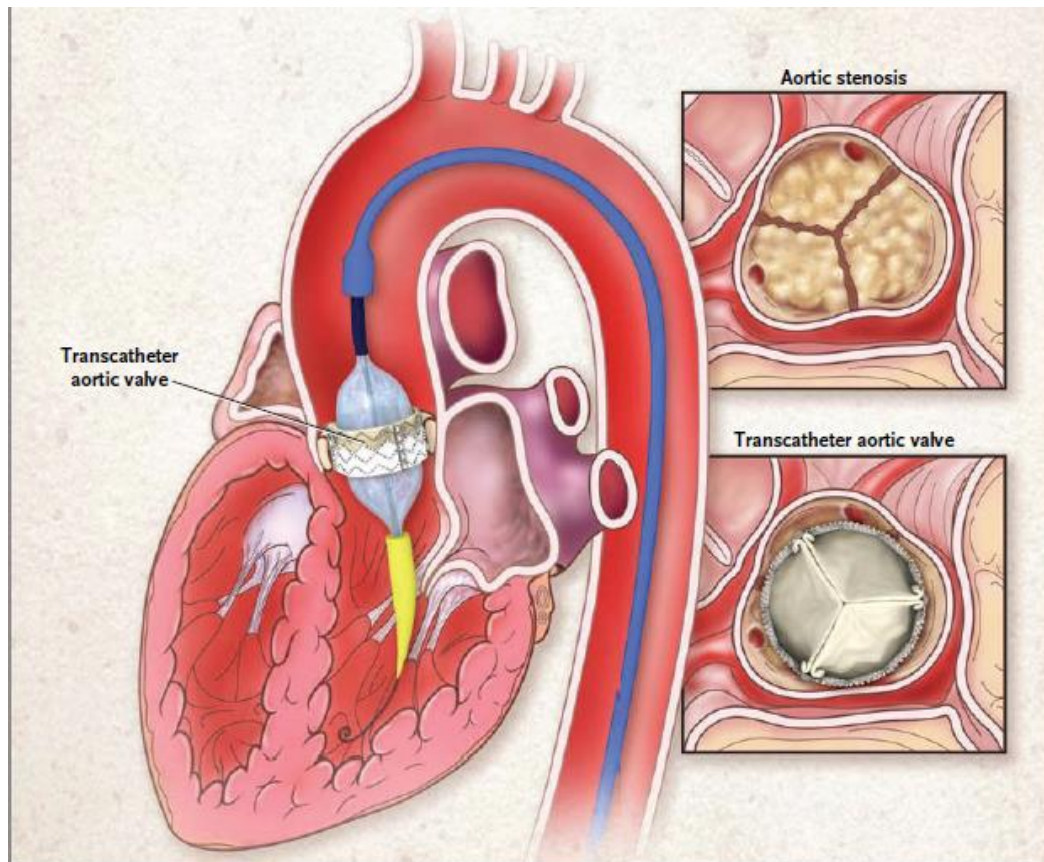
it in. You have four atmospheres and really it is just filling little gaps there.” Ex. 1007 (Walther) at 1126. Further, Walther concludes that the valve “demonstrated excellent hydrodynamic performance,” further eliminating any concerns that the outer cloth somehow disadvantageously impacts the orifice 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.

9. Overlapping Radial Alignment with Native Leaflets

137. Claim 1 next recites: “wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient.” Cribier and Walther render this limitation obvious.

138. As I explained above, Cribier discloses endovascular implantation of SAPIEN. *Supra* §§VI.A.2-3. A person of ordinary skill in the art would understand that during endovascular implantation, the SAPIEN is positioned such that the open cells of the outer frame are in radially overlapping alignment with the patient’s native leaflets. Cribier discloses that “one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT in order to minimize perivalvular leaks and avoid coronary occlusion.” Ex. 1012 (Cribier) at 353-354. When expanded in this position, SAPIEN presses against and replaces

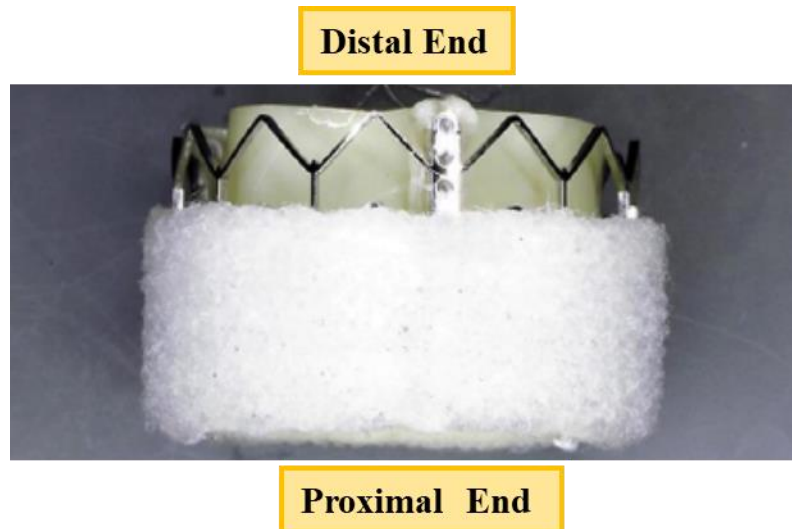
the patient's native aortic leaflets, as illustrated in Figure 1 of the New England Journal of Medicine publication below:



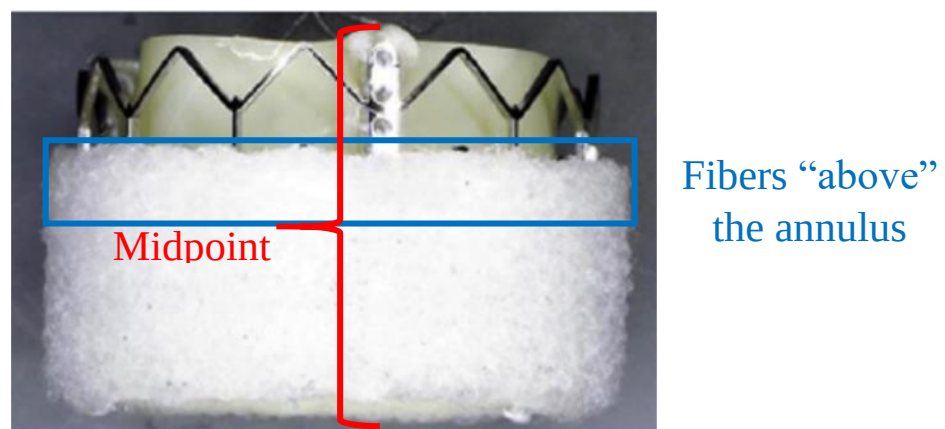
Ex. 1022 (Smith) 2189, Fig. 1; *see also* Ex. 1047 (Piazza) at 74 (disclosing that SAPIEN “is positioned within the aortic root and, once deployed, crushes the leaflets of the native valve against the wall”).

139. Walther discloses the expansion of a cloth-covered SAPIEN within a surgical valve made by Petitioner. Ex. 1007 (Walther) at 1121, Fig. 2. Expansion of the valve presses the outer cloth (i.e., outer seal) against the surgical valve's prosthetic leaflets. *Id.* at Fig. 2; *see also id.*, 1120-1121. A person of ordinary skill in the art would have understood that expanding the cloth-covered SAPIEN in a

native aortic valve, as described in Cribier, would press the outer cloth (i.e., outer seal) against the patient's native leaflets. As I explained previously, Walther's outer cloth covers the two proximal rows of SAPIEN's outer frame:



Id. at Fig. 1. If one third to half the cloth-covered SAPIEN rested above the annulus and the remainder in the LVOT, the fibers “above the annulus” would radially overlap with the native leaflets, as illustrated below:



See also supra §III.A (discussing the anatomy of the aortic valve and the location of the annulus and leaflets). In fact, Patent Owner admitted this was the case during prosecution of the related '846 patent. Patent Owner stated that the “limitation of the fibers covering at least two rows of open cells provides an improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets.” Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 25.

10. Inflating a Balloon Assembly

140. Claim 1 next recites: “inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation.” Cribier and Walther both disclose this limitation.

141. Cribier discloses that SAPIEN is deployed within a patient’s native aortic valve through “[b]alloon inflation . . . using manual injection of a 15:85 contrast/saline solution whose volume has been determined before valve crimping to obtain the optimal valve diameter (23 or 26 mm).” Ex. 1012, 353. Thus, a person of ordinary skill in the art would understand that delivery of SAPIEN involves inflating a balloon to expand SAPIEN from its crimped orientation to its expanded orientation with a diameter of 23 or 26 mm. Similarly, Walther discloses that the cloth-covered SAPIEN valves were expanded within various

surgical valves by a balloon catheter. Ex. 1007 (Walther) at 1122. Thus, a person of ordinary skill in the art would understand that delivery of the cloth-covered SAPIEN also involved expanding the valve through inflation of a balloon assembly.

11. Fibrous Network Seals

142. Claim 1 next recites: “wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly.” Cribier and Walther render this limitation obvious.

143. A person of ordinary skill in the art would have been motivated, and found it obvious, to endovascularly position Walther’s cloth-covered SAPIEN through a patient’s native aortic valve and position the outer cloth (i.e., fibrous network) in radially overlapping alignment with the patient’s native valve leaflets for the reasons I provided above. *Supra* §VI.A.9. Walther discloses the expansion of the cloth-covered SAPIEN within an Edwards surgical valve. Ex. 1007 (Walther) at 1121, Fig. 2. Expansion of the valve presses the outer cloth (i.e., fibrous network) against the surgical valve’s prosthetic leaflets, outer frame, and graft covering forming a seal to reduce paravalvular leak, as illustrated in Figure 2 below:

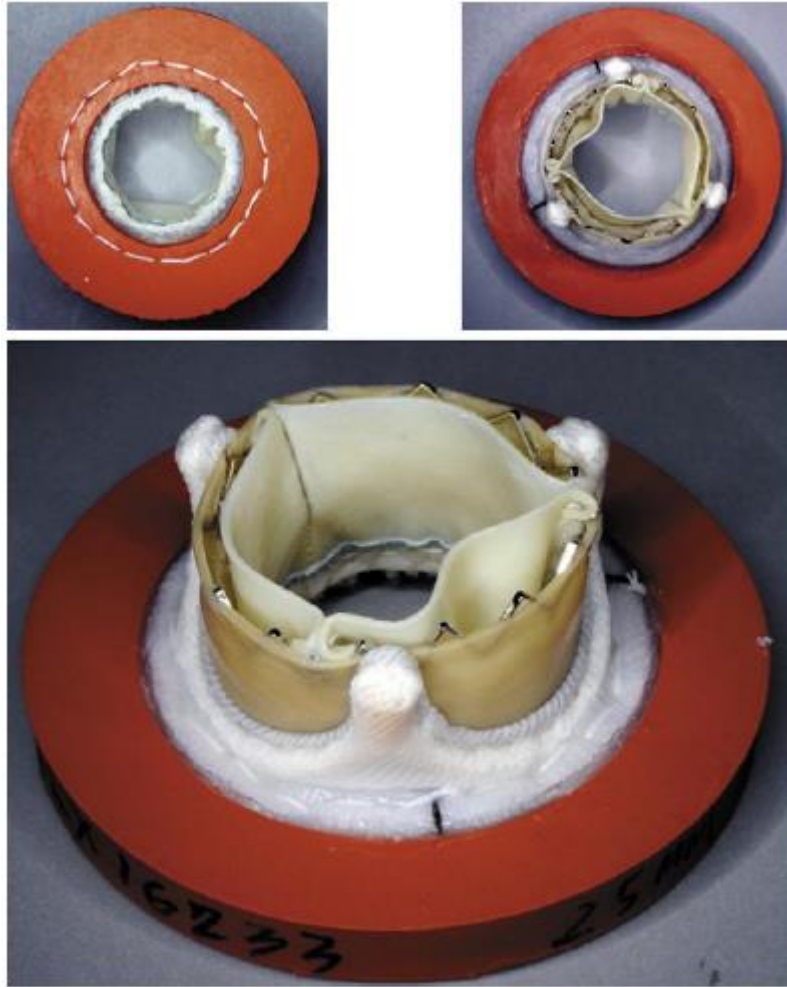


Fig. 2. Cloth THV valve deployed in surgical valve.

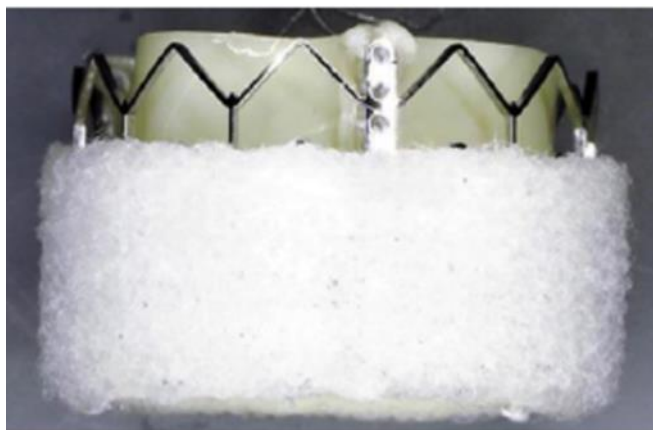
Id. at Fig. 2; *see also id.* at 1122-1126. If Walther's fibrous outer cloth did not seal against the valve leaflets, outer frame, and graft covering, the valve would not prevent paravalvular leaks. Without a seal, blood would leak between the leaflets, cloth, and the prosthetic valve, impairing the valve's hemodynamic performance. However, Walther concluded the valve "demonstrated excellent hydrodynamic performance," indicating the seal was successfully formed. *Id.* at 1125.

144. A person of ordinary skill in the art would have been motivated, and found it obvious, to endovascularly position Walther's cloth-covered SAPIEN through a patient's native aortic valve and position the outer cloth (i.e., fibrous network) in radially overlapping alignment with the patient's native valve leaflets for the reasons I provided above. *Supra* §VI.A.9. When expanded within a patient's native aortic valve, Walther's fibrous network would seal against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly for the same reasons that the outer cloth seals against those features in the surgical valve.

12. Two Rows of Grids

145. Claim 1 concludes by reciting: "wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration." Cribier in combination with Walther renders this limitation obvious.

146. Walther's outer cloth (i.e., fibrous network) covers two circumferentially extending rows of grids formed in SAPIEN's gridded configuration. Ex. 1007 (Walther) at 1121, Fig. 1. The side-by-side comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right) illustrates that Walther's outer cloth covers two circumferentially extending rows of grids formed in SAPIEN's gridded configuration:

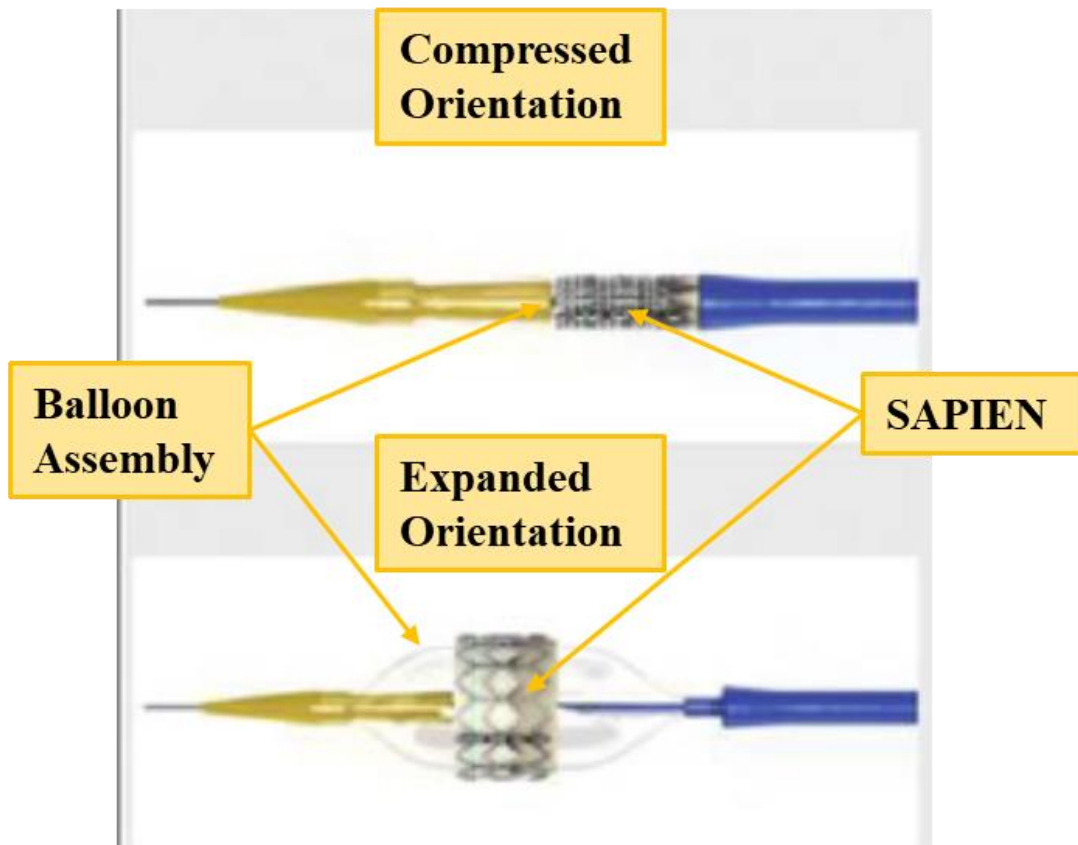


Comparing Ex. 1007 at Fig. 1 with Ex. 1012 at Fig. 1.

B. Claim 8

147. Claim 8 recites: “The method of claim 1, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the valve assembly is in the radially compressed orientation.” Cribier in combination with Walther renders this claim obvious.

148. Cribier discloses that prior to delivery, 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, Fig. 9 (emphasis added). Cribier’s Fig. 2 below depicts the SAPIEN mounted on the balloon catheter in both a radially compressed (top) and radially expanded (bottom) orientation and shows that the balloon assembly is “radially inwardly” of the valve assembly when in the compressed orientation:

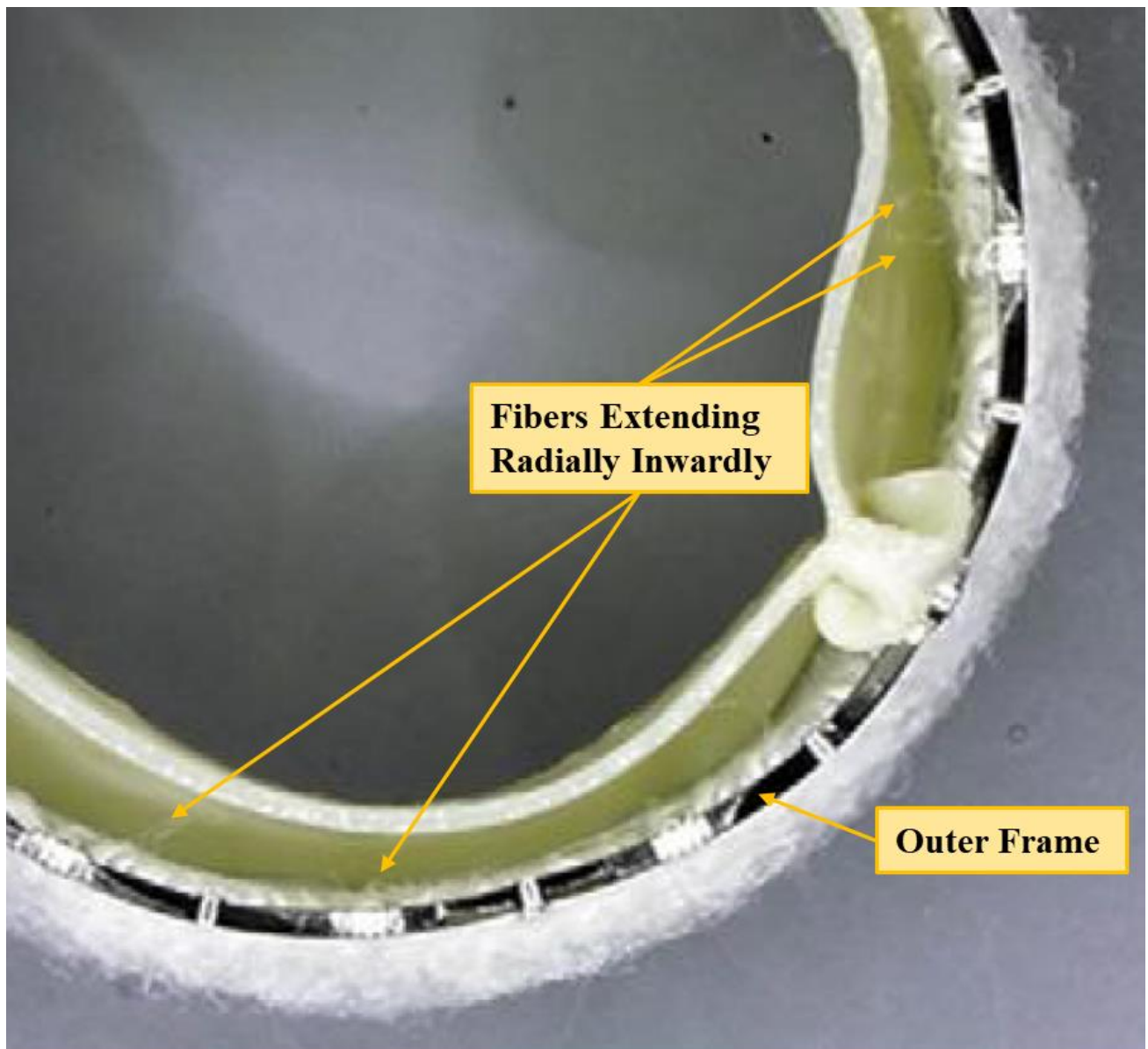


Id. Fig. 2 (excerpt).

C. Claim 9

149. Claim 9 recites: “The method of claim 1, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” Cribier and Walther render this claim obvious.

150. Walther’s outer cloth is a “fibrous network” for the reasons I provided in claim 1. *Supra* §VI.A.5. Walther’s outer cloth includes fibers that extend radially inwardly from SAPIEN’s outer frame. These fibers are clearly visible in Figure 1 of Walther below:

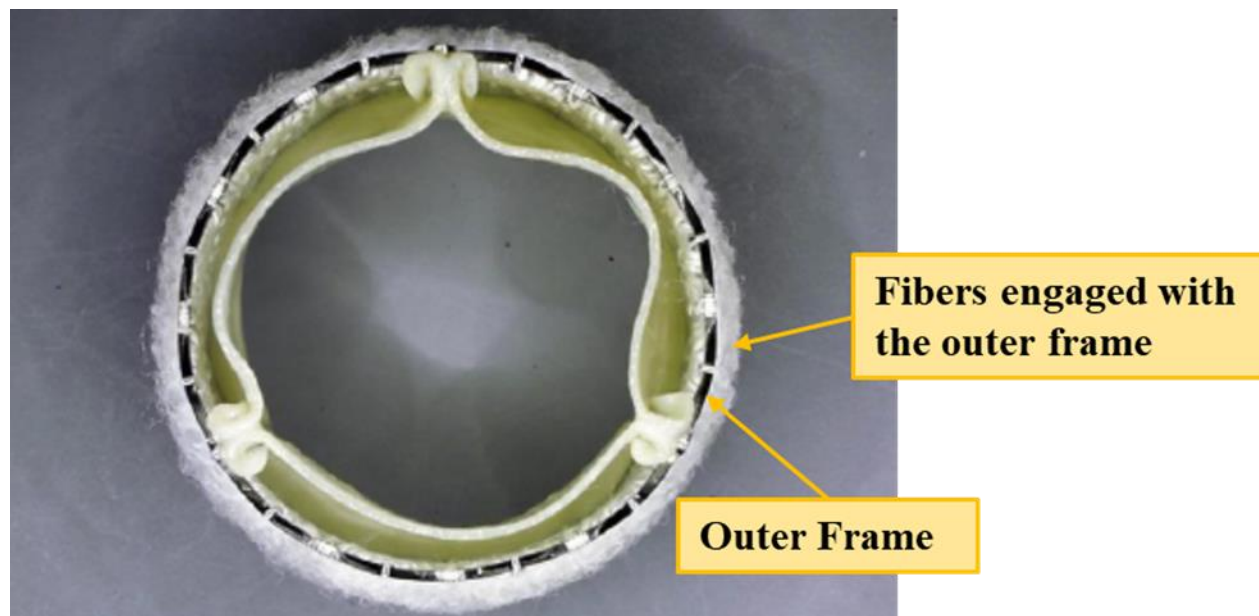


Ex. 1007 (Walther) at Fig. 1 (excerpt).

D. Claim 10

151. Claim 10 recites: “The “method of claim 1, wherein the fibrous network includes fibers directly engaged with the outer frame.” Cribier and Walther render this claim obvious.

152. 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 below:



Ex. 1007 at Fig. 1 (excerpt).

153. As I discussed in claim 1, Walther’s outer cloth includes a fibrous network composed of radially extending fibers. In fact, in the figure above, the radially extending fibers are visible. Because Walther’s outer cloth, which is made of woven fibers, is stitched to the frame, the fibers are “directly engaged with” SAPIEN’s outer frame.

E. Claim 11

154. Claim 11 recites:

11. A method of implanting a transcatheter aortic valve assembly, comprising:

endovascularly positioning a guide wire through the aortic valve of a patient;

endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient, wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration,

wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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 graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame,

wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient;

inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation,

wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,

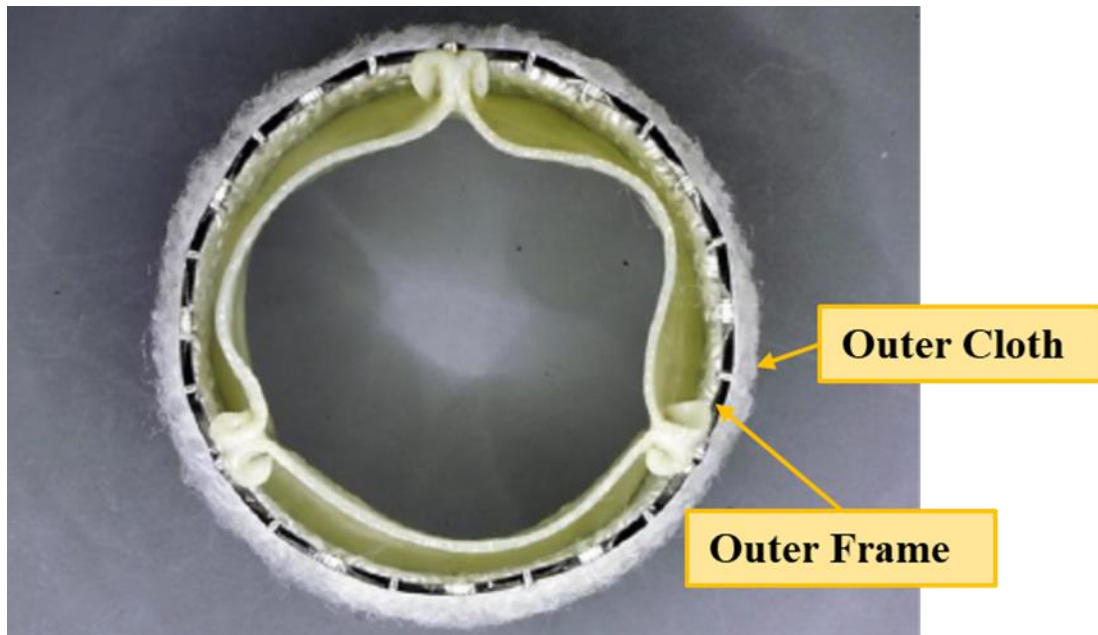
wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

155. Thus, claim 11 is an independent claim that mirrors the limitations recited in claim 1 with a single exception. Claim 11 recites “wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,” whereas claim 1 recites that the fibrous network seals against the

patient's native leaflets, the outer frame, and the graft covering. The combination of Cribier and Walther renders claim 11 obvious.

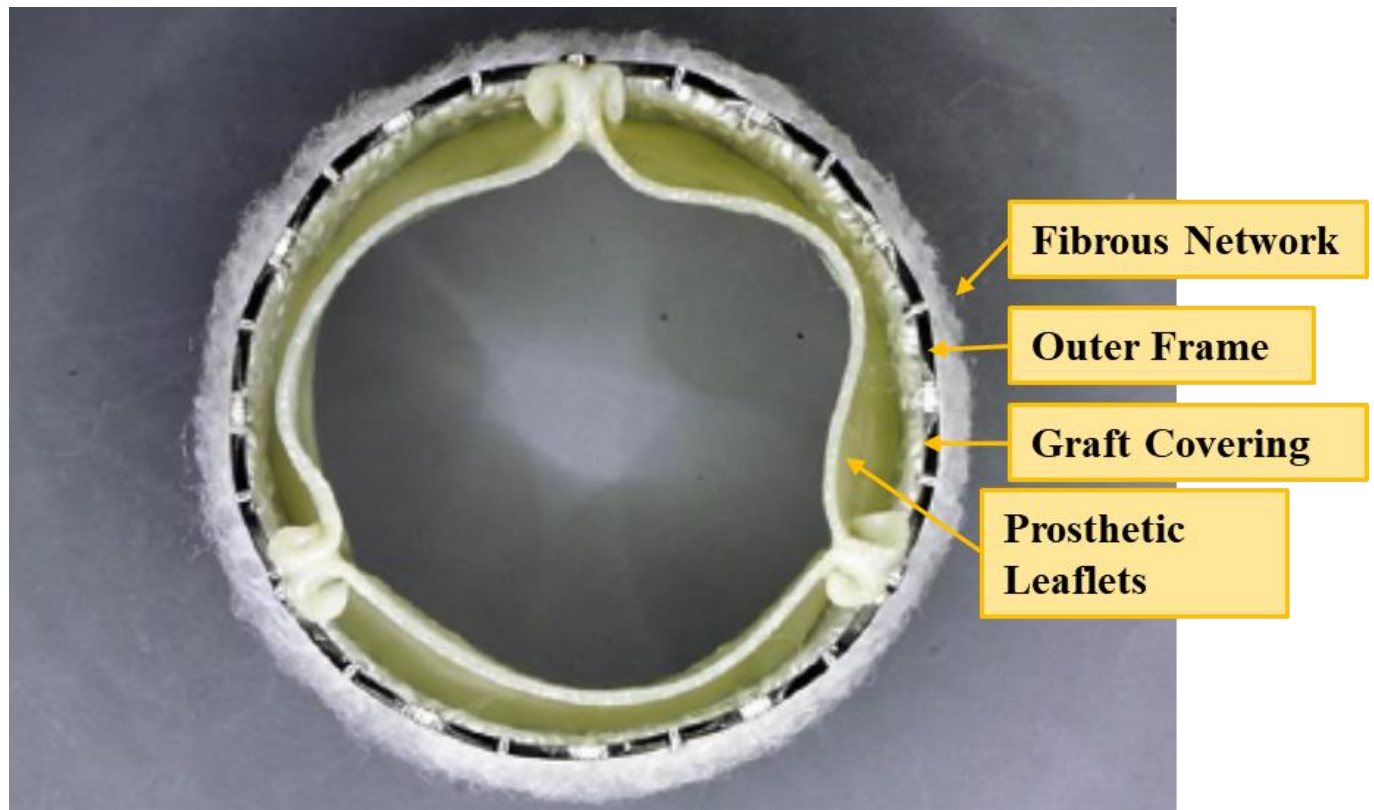
1. Fibrous Network Seal

156. As I explained in claim 1, Walther discloses a SAPIEN with an outer cloth (i.e., fibrous network) positioned radially outwardly of the outer frame:



Ex. 1007 (Walther) at 1121, Fig. 1 (excerpt). Also as I explained in claim 1, Walther's outer cloth is a "fibrous network," and a person of ordinary skill in the art would understand that the outer cloth forms a seal against the SAPIEN's outer frame and inner graft covering when the valve is expanded in a patient's native aortic valve. *Supra* §VI.A.11. Because the outer cloth is positioned around the perimeter of the outer frame, which is positioned externally to the SAPIEN's prosthetic leaflets, the seal that is formed between the outer cloth and SAPIEN's

outer frame/inner graft covering is “outwardly of the prosthetic leaflets.” This is visible in Walther’s Figure 1 below:



Ex. 1007 (Walther) at Fig. 1 (excerpt).

2. Remaining Limitations

157. Cribier and Walther render the remaining limitations of claim 11 obvious for the reasons I provided in claim 1. *Supra* §VI.A.

F. Claim 18

158. Claim 18 recites: “The method of claim 11, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the valve assembly is in the radially compressed orientation.” This limitation also

appeared in claim 8. Thus, Cribier and Walther render this claim obvious for the reasons I provided in claims 8 and 11. *Supra* §§VI.B, VI.D.

G. Claim 19

159. Claim 19 recites: “The method of claim 11, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” This limitation also appeared in claim 9. Thus, Cribier in combination with Walther renders this claim obvious for the reasons I provided in claims 9 and 11. *Supra* §§VI.C, VI.E.

H. Claim 20

160. Claim 20 recites: “The method of claim 11, wherein the graft wherein the fibrous network includes fibers directly engaged with the outer frame.” This limitation also appeared in claim 10. Thus, Cribier in combination with Walther renders this claim obvious for the reasons I provided in claims 10 and 11. *Supra* §§VI.C, VI.D.

VII. GROUND 2: CLAIMS 2-3, 5-7, 12-13, 15-17 OBVIOUS OVER

WALTHER AND CRIBIER AND CRIBIER ’321

161. Claims 2-3, 5-7, and 12-17 each require: “wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” Cribier ’321, Ex. 1045,

discloses this limitation, and I believe that Cribier in combination with Walther and Cribier '321 render claims 2-3, 5-7, and 12-17 obvious.

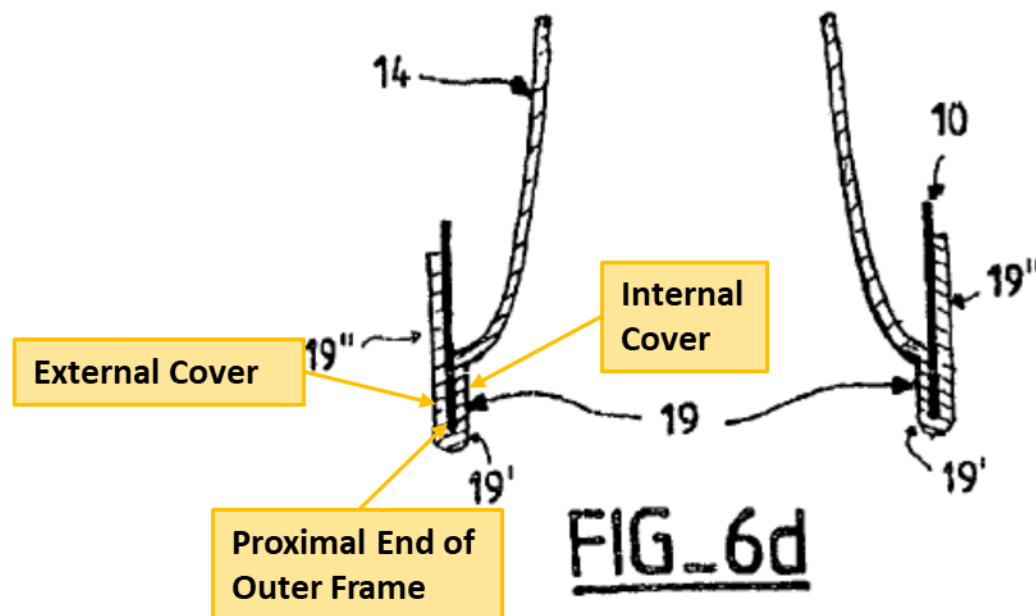
A. Claim 2

162. Claim 2 recites: “The method of claim 1, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” Cribier in combination with Walther and Cribier '321 render this claim obvious.

163. Cribier '321 discloses a THV “which is especially useful in the case of aortic stenosis” that comprises “a collapsible valvular structure and an expandable frame on which said valvular structure is mounted.” Ex. 1045 (Cribier '321) at Abstract. Cribier '321's THV also includes an “internal cover 19” that is “fixed to internal wall of the frame 10” and “prevents any passage of blood through the spaces between the bars 11 of the frame.” *Id.* at 12:28-32. The internal cover is “preferably made with the same tissue as the valvular structure.” *Id.* at 13:15-16. Cribier '321 discloses that the the valvular structure is preferably “made of synthetic biocompatible material such as TEFLON® or DACRON®, polyethylene, polyamide.” *Id.* at 5:15-17. Cribier '321's internal cover is therefore a “graft covering.”

164. Cribier '321 discloses that in one embodiment, “the internal cover 19 is extended at its lower end 19' to an external cover 19' which is rolled up to be

applied on the external wall of the stent 10.” *Id.* at 13:28-30. As shown in Fig. 6d of Cribier ’321 below, the internal cover (i.e., graft covering) 19 extends beyond and over the proximal end of the frame 10 to cover the proximal end of the frame:



Id. at Fig. 6d.

165. A person of ordinary skill in the art would have found it obvious to combine Cribier ’321’s teaching that the internal cover may be extended and wrapped around the proximal end of the frame with the SAPIEN’s fabric cuff disclosed in Cribier. A person of ordinary skill in the art would have been motivated to combine these teachings to strengthen the attachment of Cribier’s inner skirt to the stent frame, improve the sealing between the inner graft covering and the frame, and to provide a softer surface to reduce the risk of sharp metallic edges at the proximal end of the outer frame damaging the surrounding

biological tissues during delivery and implantation. See Ex. 1010 (Spenser) at 14:6-9; Ex. 1048 (Essinger) at [0098] (“[T]he skirt reduces risk of sharp edges in the framework of the stent that may jeopardize the integrity of the surrounding biological structures The protruding “petals” of the skirt 103 act as soft, dampening elements when bent over the tip of the [outer frame].”) Persons of ordinary skill in the art would understand that extending the inner graft covering around the proximal end of the frame would prevent blood from leaking between gaps between the inner skirt and the frame at the inlet of the valve. Moreover, such a combination would merely entail the combination of known elements to yield the predictable results.

166. Cribier and Cribier ’321 are from the same field of endeavor and share the same objective of providing a prosthetic valve device suitable for minimally invasive procedures. See, e.g., Ex. 1012 (Cribier) at 347-348; Ex. 1045 (Cribier ’321) at Abstract. Moreover, both references specifically relate to prosthetic heart valves owned and developed by Edwards. Cribier discloses transfemoral implantation of Edwards’ SAPIEN valve. Ex. 1012 (Cribier) at 347-348. The title page of Cribier ’321 indicates that the patent is assigned to Edwards. Ex. 1045, 1. A person of ordinary skill in the art would therefore have found it obvious to apply Cribier ’321’s teachings in the context of a similar Edwards’ prosthetic heart valve, to the Edwards’ SAPIEN valve disclosed in Cribier.

167. A person of ordinary skill in the art would have had a reasonable expectation of success in combining Cribier '321's extended internal cover with SAPIEN's fabric cuff disclosed in Cribier. The valve assemblies in Cribier and Cribier '321 share many common features; for example, both include a prosthetic valve member housed within a balloon-expandable metallic stent, and a polymeric graft covering positioned between the prosthetic valve and the stent secured with a plurality of stitches. *See, e.g.*, Ex. 1012 (Cribier) at 348, Fig. 1; Ex. 1045 (Cribier '321) at 5:15-18, 8:46-64, 9:27-30, 12:28-32, 13:15-16, 13:54-59, 14:31-35, 14:45-47. Additionally, Cribier '321 discloses suturing the "external cover" to the frame, which is consistent with how the graft covering is attached to SAPIEN's frame. Ex. 1045 (Cribier '321) at 13:54-62, 14:22-30. Given the strong similarity of these devices, a person of ordinary skill in the art would reasonably expect success in applying Cribier '321's teachings to the similarly constructed SAPIEN valve disclosed in Cribier.

168. Persons of ordinary skill in the art would not have expected extending SAPIEN's graft covering over the proximal end of the outer frame to impact the deliverability of Walther's cloth-covered SAPIEN. SAPIEN's graft covering is a thin material of PET fabric. Thus, extending the inner graft covering over the proximal end of the valve would case at most, a very small and insignificant increase in the valve's minimum crimped profile. Any such small increases in

diameter resulting from extending the covering to cover the frame's proximal end would not have prevented persons of ordinary skill in the art from endovascularly delivering the valve through at least the common iliac artery.

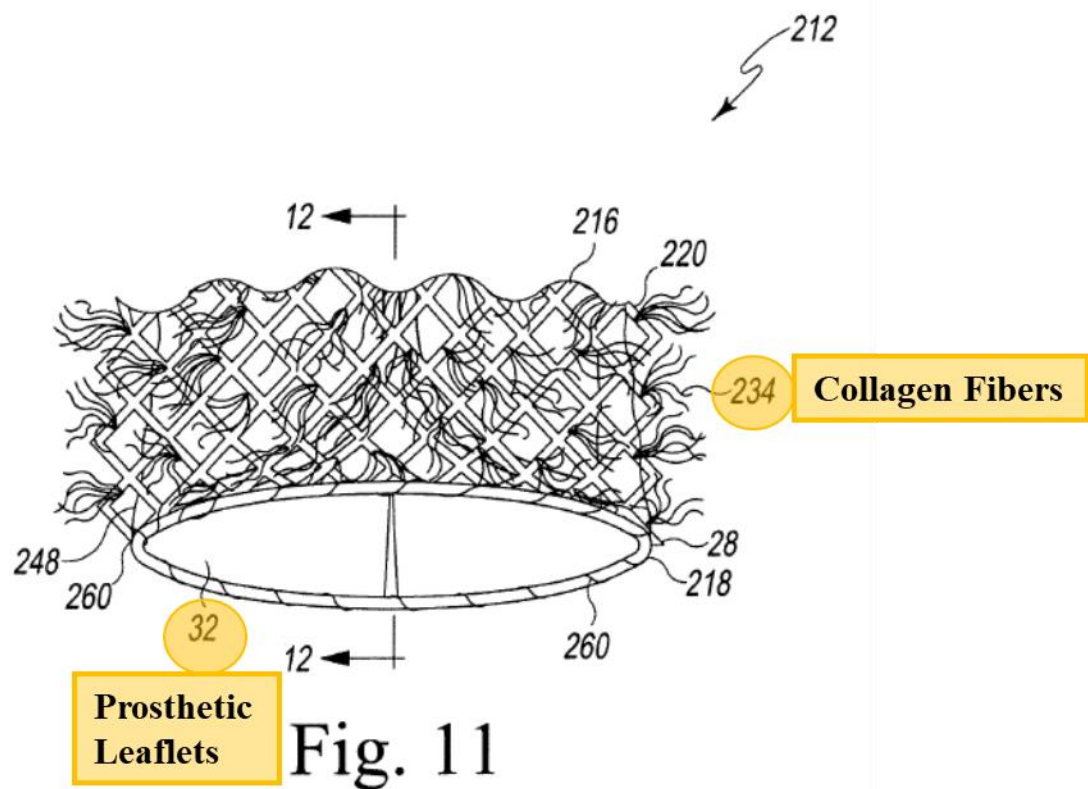
B. Claim 3

169. Claim 3 recites: “The method of claim 2, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” Cribier in combination with Walther and Cribier '321 render this claim obvious.

170. The '538 patent does not use the term “radially overlaps” outside of the claims; however, I understand that in a Preliminary Amendment during prosecution of the '538 patent, Patent Owner relied on Figure 11 of the '538 patent as providing support for the limitation requiring that the two rows of grids covered by the fibers “radially overlap with the prosthetic leaflets.” Ex. 1002 at 149-150.³

³ Patent Owner's representations in the Preliminary Amendment related to what was then claim 15, which recited: “The method of claim 2, wherein the fibers cover at least two circumferentially extending rows of grids formed in the open cell configuration and the at least two circumferentially extending rows radially overlap with the prosthetic leaflets.” Ex. 1002 at 149-150. Patent Owner subsequently amended claim 15 to recite the language that ultimately became claim 3 in the issued '538 patent, reproduced in paragraph 169 above. The

Figure 11 below illustrates the collagen fibers 234 the prosthetic leaflets 32, which Patent Owner has described as radially overlapping:

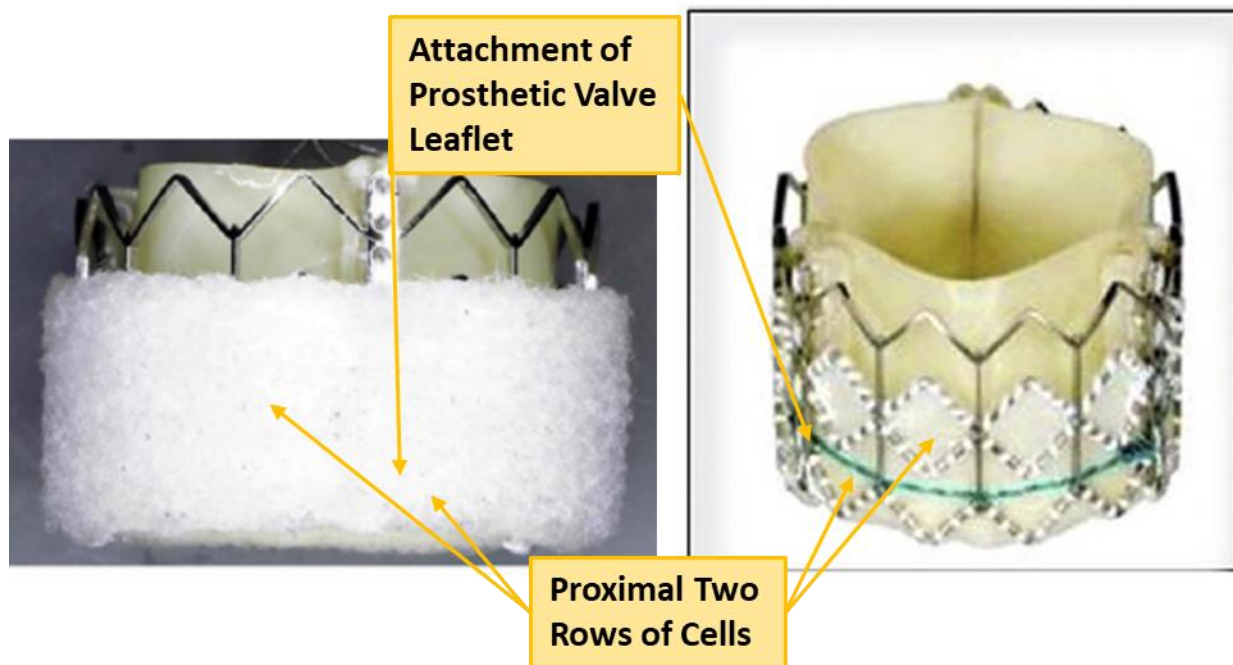


Ex. 1001, Fig. 11.

171. Walther's outer cloth and leaflets are positioned in the same way as the collagen fibers and leaflets in Figure 11 above. As I explained in claim 1, Walther's outer cloth (i.e., fibrous network) covers the two most proximal rows of cells in SAPIEN's outer frame. *Supra* §VI.A.12. SAPIEN's leaflets are sutured to the inner graft covering at the green suture line visible in Cribier's Figure 1 (below

differences in the language between originally filed claim 15 and claim 3 do not impact my analysis here.

right). As shown below, the green suture line is located within the proximal row of cells. Thus, the two proximal rows of cells covered by Walther's outer cloth radially overlap with SAPIEN's prosthetic leaflets, as illustrated in the side-by-side comparison of Walther's Figure 1 (left) and Cribier's Figure 1 (right) below:



Compare Ex. 1007 (Walther) at Fig. 1 (excerpt) with Ex. 1012 (Cribier) at Fig. 1.

C. **Claim 5**

172. Claim 5 recites: “The method of claim 3, wherein the outer frame is a singular, integral component.” Cribier discloses the limitations in claim 5, and based on claims 1 and 3, Cribier in combination with Walther and Cribier ’321 renders claim 5 claim obvious.

173. Cribier discloses that SAPIEN's frame is a "tubular slotted stainless-steel balloon-expandable stent." Ex. 1012 (Cribier) at 348. SAPIEN's frame was laser cut from a single stainless-steel tube. As shown below, SAPIEN's stent (i.e., outer frame) comprises a "singular, integral component":



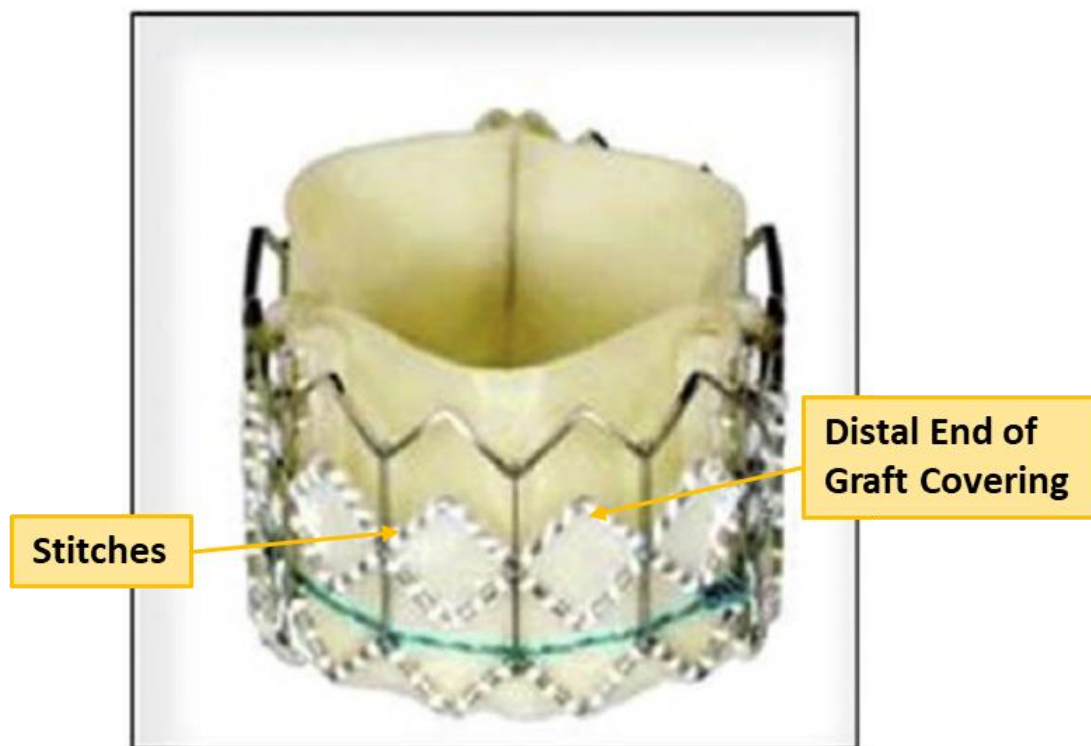
**Edwards SAPIEN® THV
23 mm, 26 mm**

Ex. 1012 (Cribier) at 348, Fig. 1.

D. Claim 6

174. Claim 6 recites: "The method of claim 3, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering." Cribier discloses the limitations in claim 6, and based on claims 1 and 3, Cribier in combination with Walther and Cribier '321 renders claim 6 claim obvious.

175. Cribier's Figure 1 (below) shows white stitches securing the PET graft covering to the metallic stent frame at the proximal (i.e., bottom) and distal (i.e., top) portions of the graft covering:

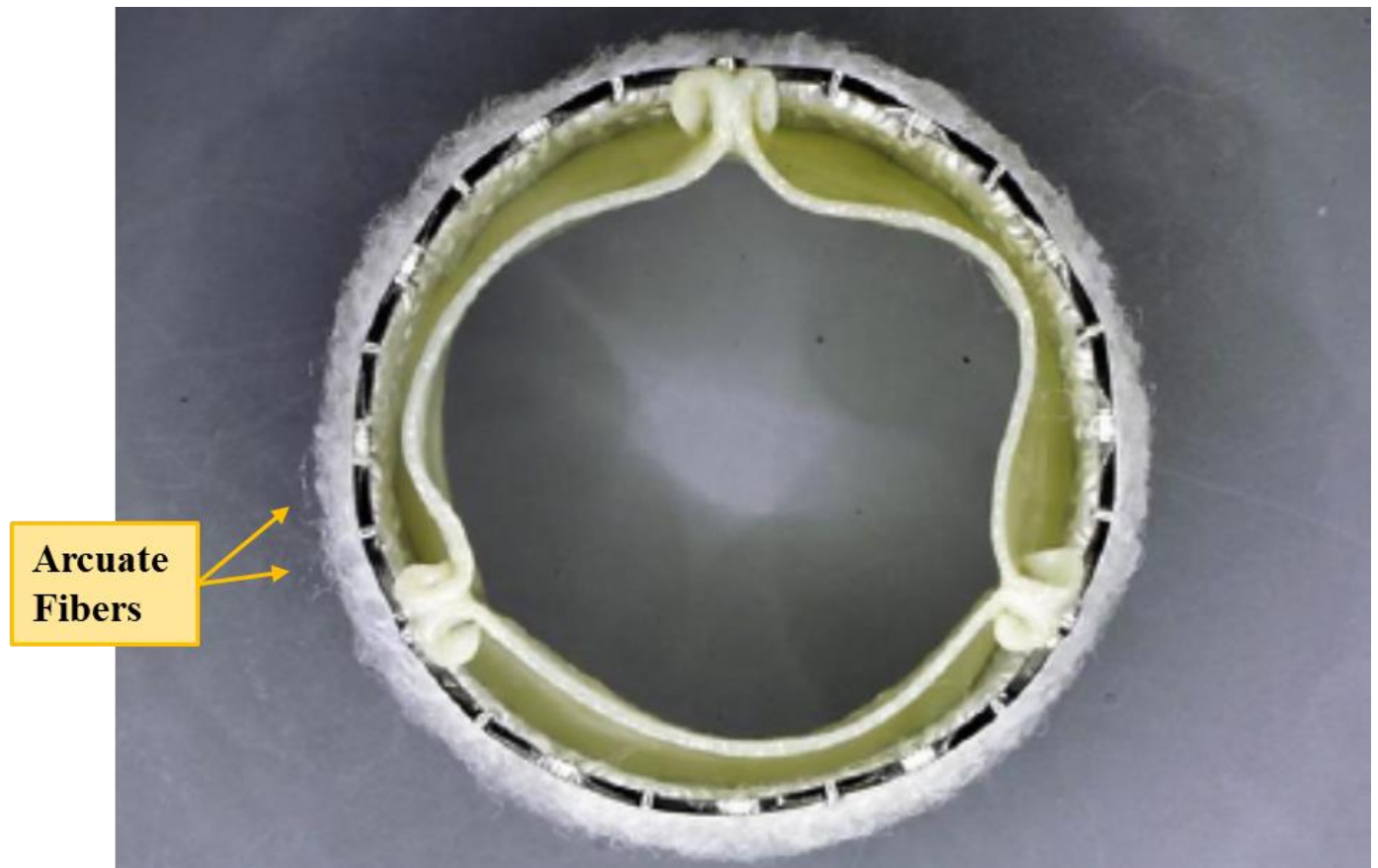


Ex. 1012 (Cribier) at Fig. 1. Several other prior art references show SAPIEN's sutures at the proximal and distal portions of the PET graft covering. *See also* Ex. 1009 (Conradi) at Fig. 1; Ex. 1025 (Zajarias) at Fig. 3B; Ex. 1028 (Roselli) at 213, Fig. 4(a).

E. Claim 7

176. Claim 7 recites: "The method of claim 3, wherein a portion of a length of a fiber of the fibrous network is arcuate." Cribier in combination with Walther and Cribier '321 render this claim obvious.

177. As I explained in claim 1, Walther discloses an outer PET cloth attached to the exterior of a SAPIEN valve that is a fibrous network that includes a plurality of outwardly extending fibers. *Supra* §VI.A.8. The outwardly extending fibers of Walther’s outer PET cloth are “arcuate” (i.e., curved). The arcuate shape of the fibers is visible in Figure 1 of Walther below:



Ex. 1007 (Walther) at Fig. 1 (excerpt).

F. Claim 12

178. Claim 12 recites: “The method of claim 11, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” This limitation also

appeared in claim 2. Thus, Cribier in combination with Walther and Cribier '321 renders this claim obvious for the reasons I provided in claims 2 and 11. *Supra* §§VI.D, VII.A.

G. Claim 13

179. Claim 13 recites: “The method of claim 12, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” This limitation also appeared in claim 3. Thus, Cribier in combination with Walther and Cribier '321 renders this claim obvious for the reasons I provided in claims 3 and 12. *Supra* §§VII.B, VII.F.

H. Claim 15

180. Claim 15 recites: “The method of claim 13, wherein the outer frame is a singular, integral component.” This limitation also appeared in claim 5. Thus, Cribier in combination with Walther and Cribier '321 renders this claim obvious for the reasons I provided in claims 5 and 13. *Supra* §§VII.C, VII.G.

I. Claim 16

181. Claim 16 recites: “The method of claim 13, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering.” This limitation also appeared in claim 6. Thus, Cribier in combination

with Walther and Cribier '321 renders this claim obvious for the reasons I provided in claims 6 and 13. *Supra* §§VII.D, VII.G.

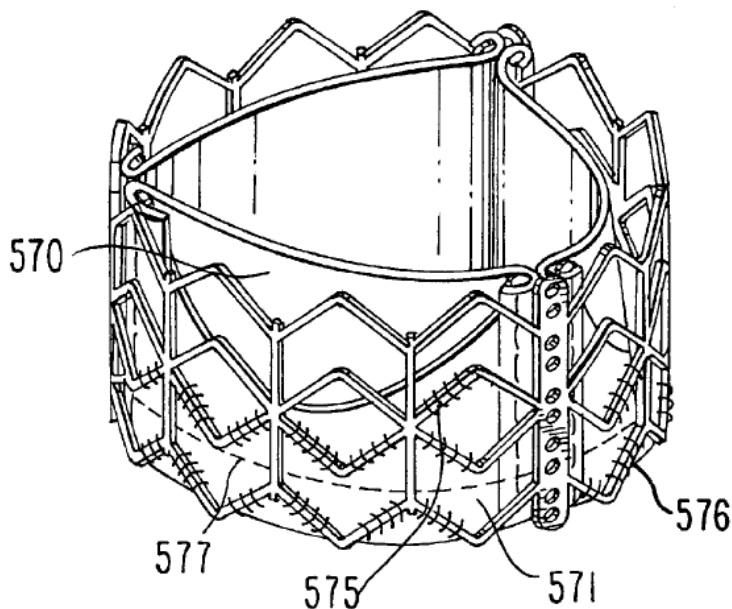
J. Claim 17

182. Claim 17 recites: “The method of claim 13, method of claim 13, wherein a portion of a length of a fiber of the fibrous network is arcuate.” This limitation also appeared in claim 7. Thus, Cribier in combination with Walther and Cribier '321 renders this claim obvious for the reasons I provided in claims 7 and 13. *Supra* §§VII.E, VII.G.

**VIII. GROUNDS 3-4: CLAIMS 1-20 OBVIOUS OVER SPENSER AND
WALTHER OR SPENSER II**

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

FIG. 44a



Ex. 1010, Fig. 44a.

184. 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, 8.

185. As I explained in Ground 1, Walther discloses a modified SAPIEN that includes an added outer cloth. *Supra* §VI.A.5. Similarly, Spenser II discloses a prosthetic stented valve that includes a layer of “compressible material” disposed along the outer surface of the stent structure” to reduce paravalvular leaks:

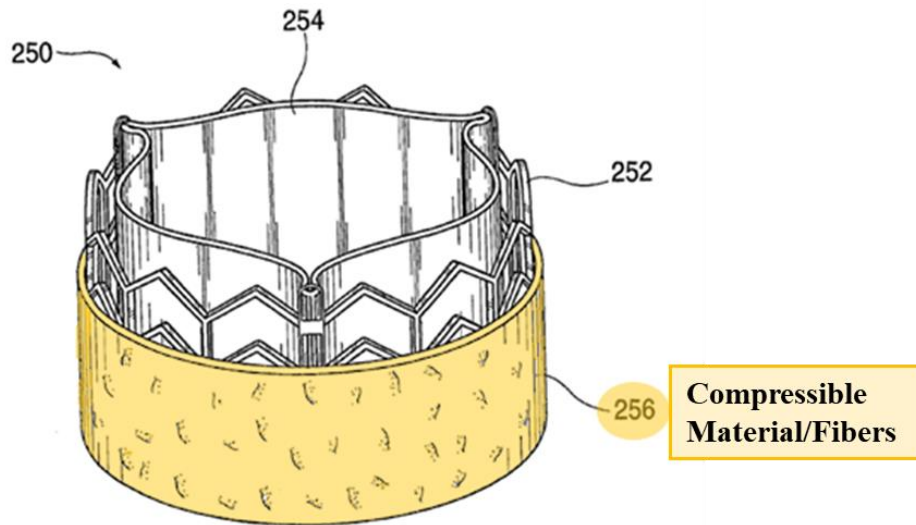


FIG. 22

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

186. For the reasons I provide in detail 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 1-20 obvious.

A. Claim 1

187. 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

188. The preamble of claim 1 recites: “A method of implanting a transcatheter aortic valve assembly comprising.” Spenser discloses this limitation.

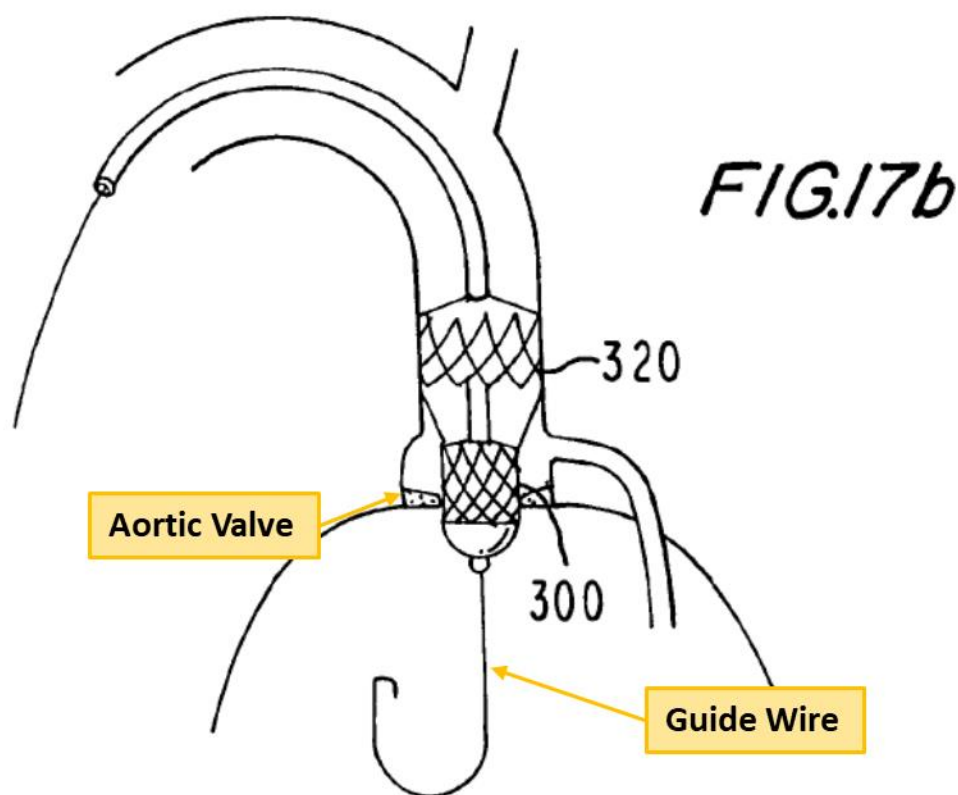
189. Spenser discloses a “valve prosthesis [device] for cardiac implantation” and discloses “inserting the valve assembly on a delivery device similar to a catheter, then ***implanting the valve at the desired location via a large blood vessel*** such as the femoral artery, in a procedure similar to other known interventional cardiovascular procedures.” Ex. 1010 (Spenser) at 1:13-15, 2:6-12 (emphasis added). Spenser discloses implanting its valve within a patient’s native aortic valve, and thus Spenser’s valve is a “transcatheter aortic valve assembly.” See e.g., *id.* at 14:15-20, Fig. 4.

2. Endovascularly Positioning a Guidewire

190. Claim 1 next recites: “endovascularly positioning a guide wire through the aortic valve of a patient.” Spenser also discloses this limitation.

191. Spenser discloses that “[a]n aspect of the present invention deals with the possibility of ***implanting the valve percutaneously***, i.e., inserting the valve assembly on a delivery device similar to a catheter, then implanting the valve at the desired location ***via a large blood vessel such as the femoral artery***, in a procedure similar to other known interventional cardiovascular procedures.” Ex. 1010 (Spenser) at 2:6-12 (emphasis added). Spenser further discloses a method of

endovascularly implanting its prosthetic valve in a patient's native aortic valve using a balloon catheter that is guided through the patient's vasculature to the native aortic valve using a guiding tool, such as a guide wire. *Id.*, 5:17-6:36, 17:5-10, 17:19-18:43. Spenser's Figure 17b illustrates the method of endovascularly delivering the valve and shows the guide wire positioned through the patient's aortic valve:



Id. at Fig. 17b.

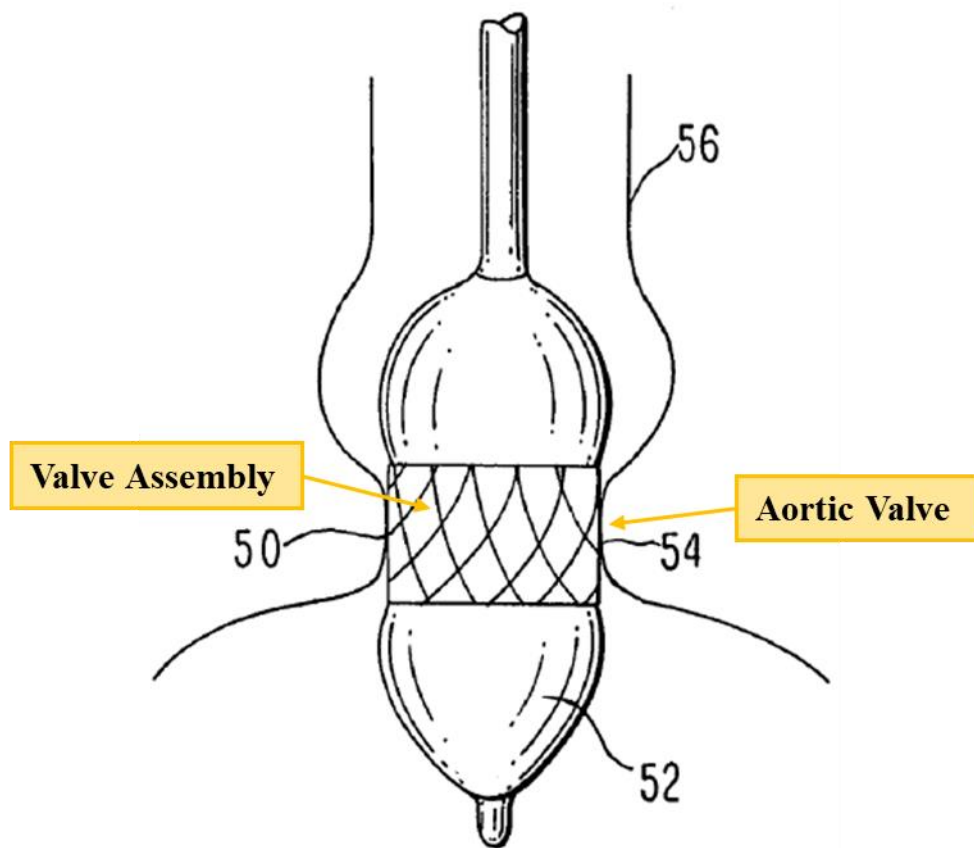
192. According to Spenser, Figure 44a illustrates a “preferred embodiment of the **present invention**.” *Id.* at 26:30-34 (emphasis added). A person of

ordinary skill in the art would have therefore understood that Spenser's disclosure of endovascular delivery would apply to the embodiment in Figure 44a. *See id.* at 2:6-12, 26:30-34.

3. **Endovascularly Positioning the Transcatheter Aortic Valve Assembly**

193. Claim 1 next recites: "endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient." Spenser in combination with Walther or Spenser II renders this limitation obvious.

194. As I explained above, Spenser discloses that its valve may be delivered endovascularly and discloses a method for such endovascular delivery. *Supra* §VIII.A.2. Spenser's endovascular delivery involves "inserting the valve assembly on a delivery device similar to a catheter, then ***implanting the valve at the desired location via a large blood vessel*** such as the femoral artery." Ex. 1010 (Spenser) 2:6-12 (emphasis added); *see also id.*, 5:17-6:36, 17:19-18:43, Figs. 17a-17b. Spenser's Figure 4 (below) "depicts implantable valve deployment in a natural aortic valve position in accordance with the present invention":



Id. at 8:66-67, 14:15-20, Fig. 4. As shown in the figure, the valve assembly is positioned through the patient's aortic valve. *See id.* This is consistent with a person of ordinary skill in the art's understanding of endovascular delivery and human anatomy. Such a person would understand that endovascularly delivering a prosthetic valve to the natural aortic valve position, as taught by Spenser, would necessarily require positioning the valve assembly through the patient's native aortic valve, allowing the prosthetic assembly to effectively replace the patient's diseased valve.

195. A person of ordinary skill in the art would have understood that Spenser's disclosure of endovascular delivery would apply to Figure 44a for the reasons I provided in the preceding section. *Supra* §VIII.A.2.

196. A person of ordinary skill in the art would have been motivated to add Walther's outer cloth to Spenser's Figure 44a for the reasons I provide below. *Infra* §VIII.A.5. A person of ordinary skill in the art would have been motivated to endovascularly position Spenser's Figure 44a combined with Walther's outer cloth or Spenser II's compressible material through a patient's aortic valve. As I explained in Ground 1, by 2012 perivalvular leak was a known issue with SAPIEN, which is similar (if not identical) to Spenser's Figure 44a. *Supra* §VI.A.3. Thus, persons of ordinary skill in the art would have been motivated to apply Walther's and Spenser II's known techniques for reducing perivalvular leaks (adding an outer cloth) to a known device (Spenser's Figure 44a), which was ready for improvement and would yield the predictable result of reducing perivalvular leaks.

197. As I also explained in Ground 1, persons of ordinary skill in the art generally preferred endovascular delivery to more invasive delivery methods and had successfully delivered SAPIEN through different blood vessels, including the femoral artery and the common iliac artery, by 2012. *Supra* §VI.A.3. Thus, persons of ordinary skill in the art would have been motivated to endovascularly

deliver the combined valve through at least the common iliac artery because the artery is large and could accommodate Spenser's Figure 44a with Walther's outer cloth or Spenser II's compressible material. Ex. 1043 (Kainuma). Indeed, Spenser merely provides the femoral artery as an example of a "large blood vessel" that can act as the access point for endovascular delivery. See Ex. 1010 (Spenser) at 2:6-12. A person of ordinary skill in the art would understand that the common iliac artery is yet another, even larger blood vessel, that could also serve as an access point for endovascular delivery to accommodate larger devices or achieve endovascular delivery in patients with diseased femoral arteries. Ex. 1043 (Kainuma); *see also* Ex. 1044 (Craido). A person of ordinary skill in the art would understand that changing the access point for insertion of the device would not affect the positioning of the device at the patient's native aortic valve.

198. A person of ordinary skill would have had a reasonable expectation that the combined assembly would be suitable for endovascular delivery. Walther discloses that the cloth-covered SAPIEN "demonstrated excellent hydrodynamic performance" and concluded that an in-patient implantation procedure "is feasible." See Ex. 1007 (Walther) at 1125. Similarly, Spenser II describes endovascularly positioning the valve having an outer compressible material through a patient's native valve. Ex. 1011 (Spenser II) at [0013]-[0014], [0017], [00144]-[00145]. Given the similarities between the valves in Walther, Spenser's

Figure 44a, and Spenser II's Figure 22, persons of ordinary skill in the art would have expected implantation in a native valve to work equally well if the outer cloth/compressible material were added to Spenser's Figure 44a.

199. Additionally, Spenser's Figure 44a is similar (if not identical) to SAPIEN. By 2012, SAPIEN had been endovascularly positioned through a patient's aortic valve many times and the FDA had approved the valve for such delivery. Ex. 1010 (Spenser) at 2:5-15, 12:8-36, 13:26-54; Exs. 1032-1033. Thus, persons of ordinary skill in the art would have been confident in implanting Figure 44a with Walther's outer cloth or Spenser II's compressible material within a patient's aortic valve.

200. Moreover, as I explained previously, Petitioner and persons of ordinary skill in the art had developed a number of methods to accommodate an outer cloth on an endovascularly delivered valve inserted through narrower vessels than the common iliac artery. *Supra* §VI.A.3. The methods include selecting cloths having different properties, modifying the prosthetic leaflets and their attachment to the frame, modifying the size and shape of the frame, and revising the delivery system to permit off-balloon delivery. *Id.* These available methods would have given persons of ordinary skill in the art confidence that an outer cloth could be added to the frame of Figure 44a and the valve assembly would remain acceptable for endovascular delivery.

201. Additionally, Spenser teaches that the “maximal size of a catheter inserted into the femoral artery should be ***no more than 8 mm in diameter***.” Ex. 1010 (Spenser) at 27:65-67 (emphasis added). Spenser’s prosthetic valve “has the ability to change its diameter from about ***4 mm*** to about 25 mm.” *Id.* at 27:67-28:2 (emphasis added). Spenser II discloses in one embodiment that the compressible material “has a thickness ranging from about 1 to 5 mm.” Ex. 1011 (Spenser II) at [00145]. A person of ordinary skill in the art would have reasonably expected that adding a compressible material 1 mm thick to Spenser’s 4 mm valve would have resulted in a device suitable for endovascular delivery through the femoral artery because the device’s crimped diameter would not have been more than 8mm. Additionally, a person of ordinary skill in the art would have recognized the availability of even thinner compressible materials that could be used to further reduce the profile.

4. Radially Compressed and Radially Expanded Orientation

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

203. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.4. Spenser teaches that its prosthetic valve “has the ability to change its diameter from about 4 mm [compressed orientation] to about 25 mm

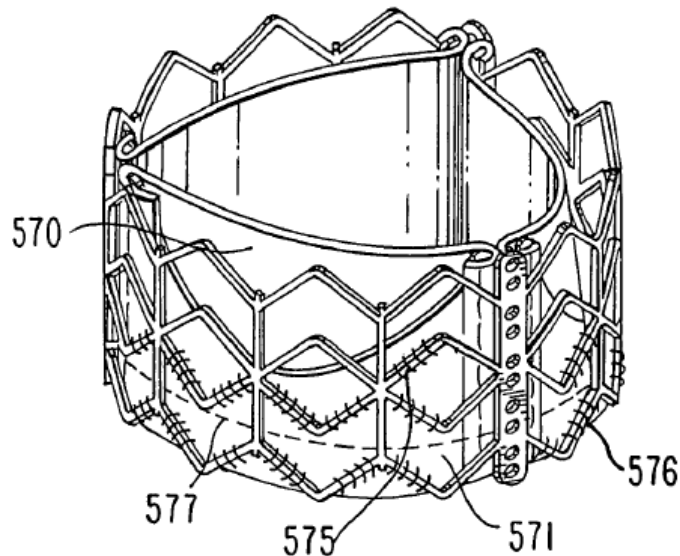
[expanded orientation].” Ex. 1010 (Spenser) at 27:67-28:2. Spenser II discloses a stented valve that comprises “an expandable stent structure” that may be “adapted for radial expansion using a balloon catheter.” Ex. 1011 (Spenser II) at [00144]. A person of ordinary skill in the art would understand 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 a balloon.

5. Outer Frame

204. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration.” Spenser discloses this limitation.

205. 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).

206. As shown in Figure 44a above, frame 575 defines an open cell configuration and 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.

6. Inner Frame

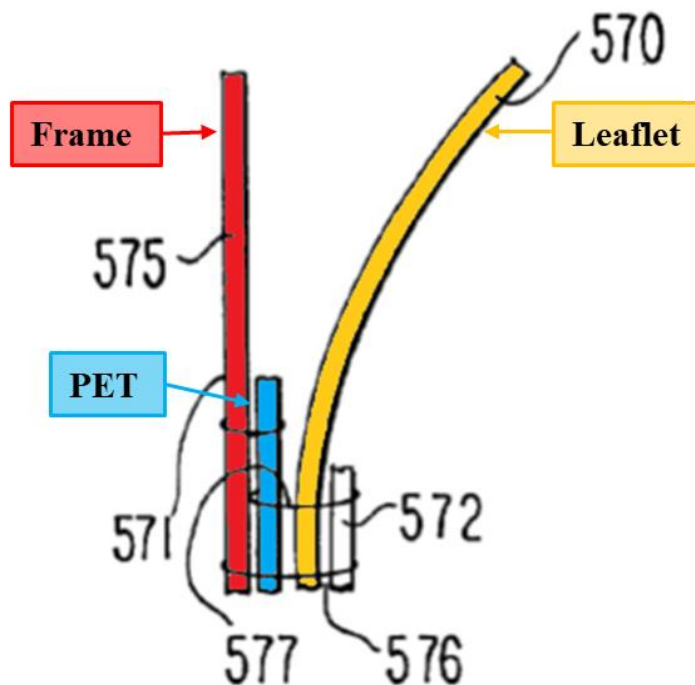
207. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic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

208. 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 also a polymer and is a “graft covering.”

209. 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.

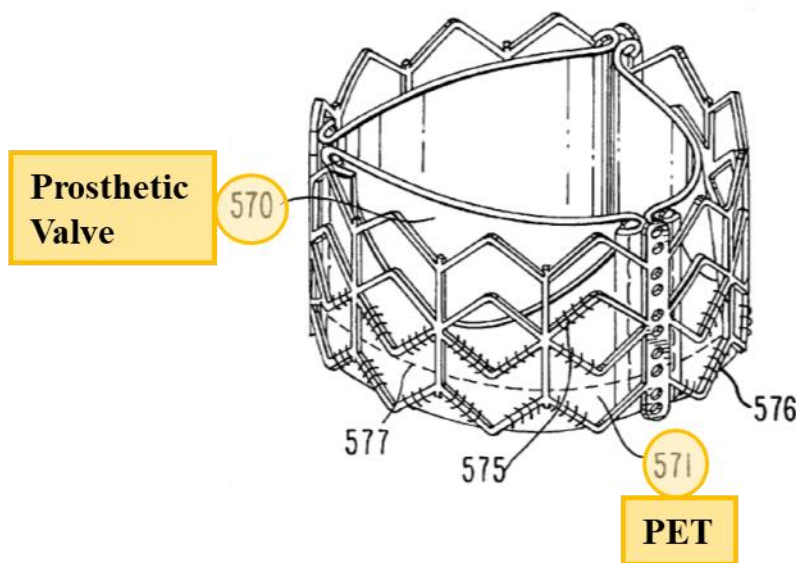
FIG. 44b



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

210. 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:

FIG. 44a



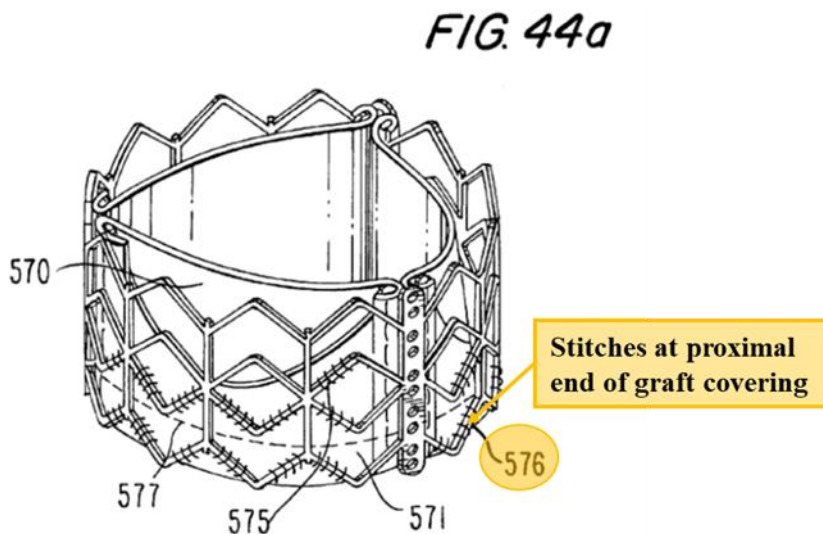
Id. at 26:30-34, Fig. 44a. Thus, based on Patent Owner’s statements during prosecution of the related ’846 patent, and if an inner frame can be a graft covering, PET 571 is an inner frame that includes a graft covering.

7. Stitching

211. Claim 1 next recites: “wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame.” Spenser also discloses this limitation.

212. 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.

213. Figure 44a illustrates that the bottom sutures secure the PET (graft covering) to the outer frame at the proximal ends thereof:



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

8. Fibrous Network

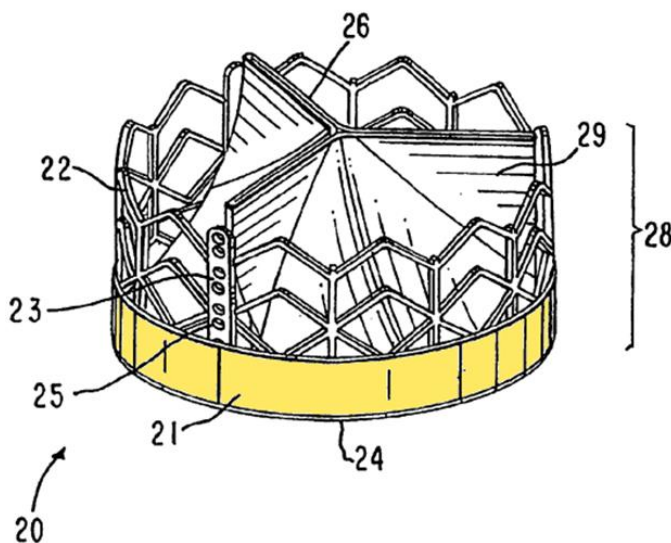
214. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame.”

a. Walther

215. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.8.

216. 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 for sealing around the valve. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. Additionally, Spenser suggests adding an outer cloth to Figure 44a by disclosing a similar valve with an outer cuff portion 21 for sealing around the valve:



Ex. 1010 (Spenser) at 13:22-25, Fig. 1. Adding Walther’s outer cloth to Figure 44a would have merely entailed applying a known technique (attaching an outer cloth) to a known device (Figure 44a) ready for improvement (enhanced sealing). A person of ordinary skill 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.

217. I also note that during prosecution of a related patent application (U.S. Patent Application No. 17/213,251), Patent Owner suggests, although does not explain, that foreshortening could be an issue in combining an outer cloth, like the one in Walther, 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 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 respond to the foreshortening of the stent frame during expansion. For example, Levi describes methods of building some slack into the outer cloth or skirt to allow for the 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

218. 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”:

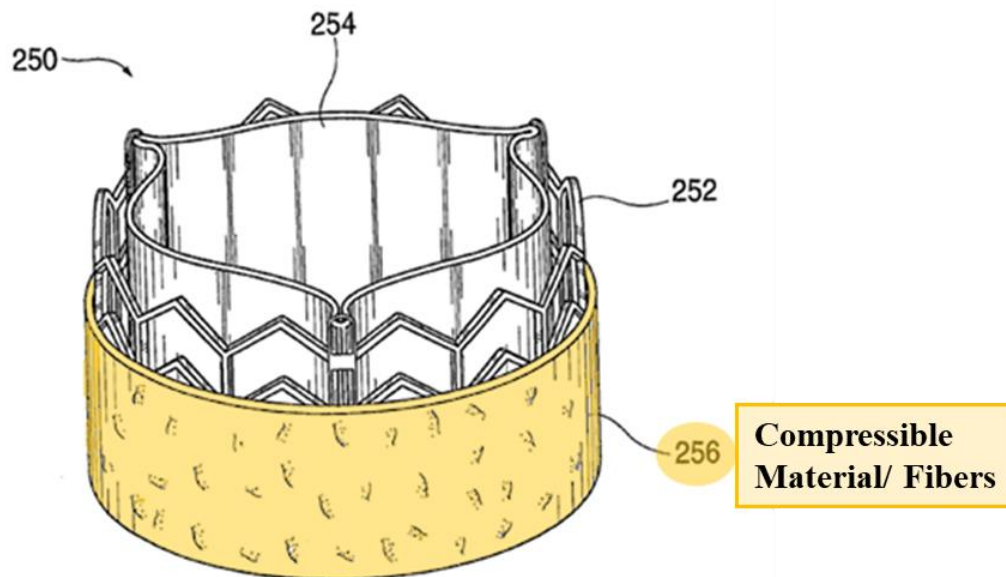


FIG. 22

Ex. 1011 (Spenser II) at [00145], Fig. 22. The compressible material is therefore positioned radially outwardly of the outer frame. 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). 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.* The cloth or fabric of the compressible material is therefore a “fibrous network.” 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.

219. 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 II discloses combining an outer compressible material with a heart valve that is similar (if not identical) to Spenser’s Figure 44a. *Compare* Ex. 1011 (Spenser II) at Fig. 22 *with* Ex. 1010 (Spenser) at Fig. 44a. Second, 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]. Third, 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.

220. As I explained previously, perivalvular leak was known to occur with the SAPIEN valve, which is similar (if not identical) to Spenser’s Figure 44a. *Supra* §VIII.A.3. 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.

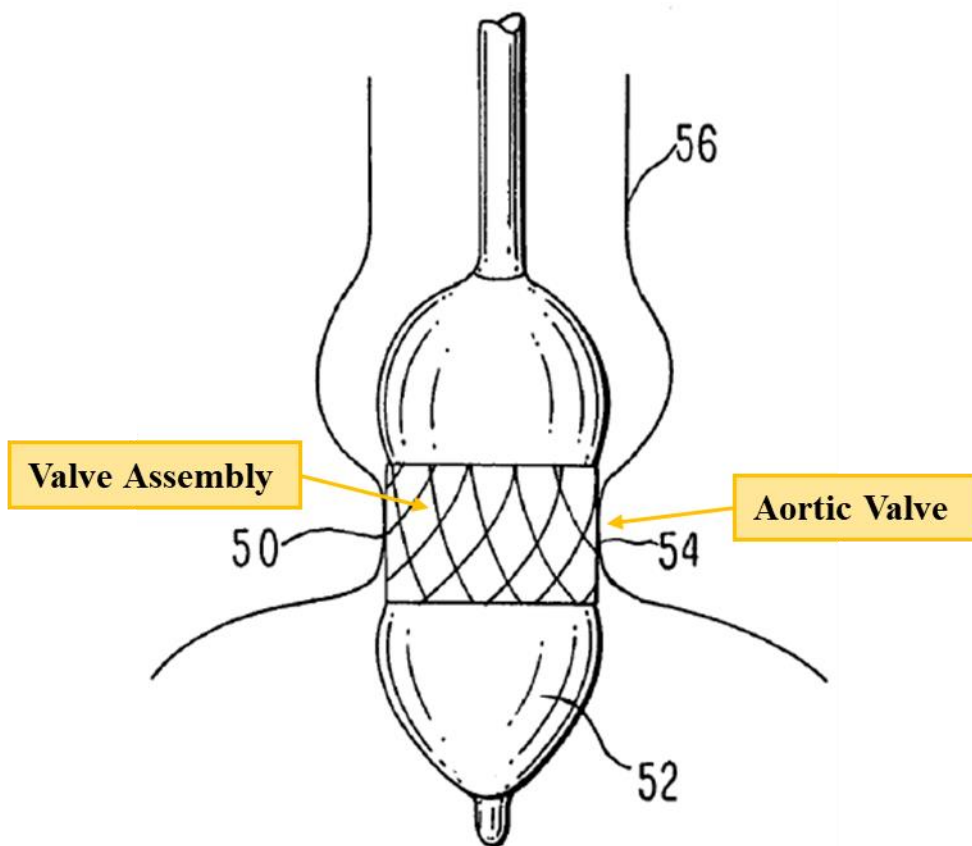
221. A person of ordinary skill would have had a reasonable expectation of success in combining Spenser II’s compressible material with Figure 44a because the valve assemblies in Spenser and Spenser II share many common features, including a balloon-expandable metallic stent having a gridded configuration 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]. Spenser II provides an image of a valve having an outer compressible material and describes how to add the compressible material to the exterior of the valve’s frame. *See* Ex. 1011 (Spenser II) at [00144]-[00145], Fig. 22. Moreover, Spenser already discloses valves having a sealing material positioned around the inlet, for example in Figure 1. Ex. 1010 (Spenser) at 13:22-25, claim 31, Fig. 1. A person of ordinary skill in the art would not have had any

concerns about stent foreshortening for the reasons provided in the previous section. *Supra* §VIII.A.8.a.

9. Overlapping Radial Alignment with Native Leaflets

222. Claim 1 next recites: “wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

223. 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 Fig. 4, 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 the figure, Spenser's valve radially overlaps with patient's aortic annulus. *Id.*, Fig. 4. Although not pictured in Fig. 4, a person of ordinary skill in the art would understand that the valve also radially overlaps with the patient's native aortic leaflets because the leaflets are attached to the annulus and extend distally therefrom. *Supra* §III.A. 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 (Spenser) at 8:66-67, 26:30-34.

224. As I explain below, when added to Spenser's Figure 44a, Walther's outer cloth and Spenser II's compressible material would cover at least the two proximal rows of Figure 44a's outer frame. *Infra* §VIII.A.12. As illustrated by Figure 4 above and understood by a person of ordinary skill in the art, positioning the valve 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 native aortic leaflets for the same reasons SAPIEN would overlap with the native leaflets. *Supra* §VI.A.9. In fact, Patent Owner admitted this was the case during prosecution of the related '846 patent. Patent Owner stated that the "limitation of the fibers covering at least two rows of open cells provides an

improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets.” Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 25. Thus, Walther’s outer cloth or Spenser II’s outer compressible material would radially overlap with the patient’s native aortic leaflets when the combined assembly is endovascularly delivered to the patient’s native aortic valve.

10. Inflating a Balloon Assembly

225. Claim 1 next recites: “inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation.” Spenser in combination with Walther or Spenser II renders this limitation obvious.

226. 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.*, 12:4-8, 14:10-14, 17:19-18:43 (disclosing balloon expandable assemblies). A person of ordinary skill in the art would therefore have understood that Figure 44a is balloon expandable. Spenser further discloses that the valve is deployed during endovascular delivery through inflating a balloon catheter. *Id.* at 5:55-57, 6:30-32, 17:44-46, 18:37-39.

227. A person of ordinary skill in the art would have 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 expanded with a balloon); Ex. 1011 (Spenser II) at [00144] (valve "adapted for radial expansion using a balloon catheter").

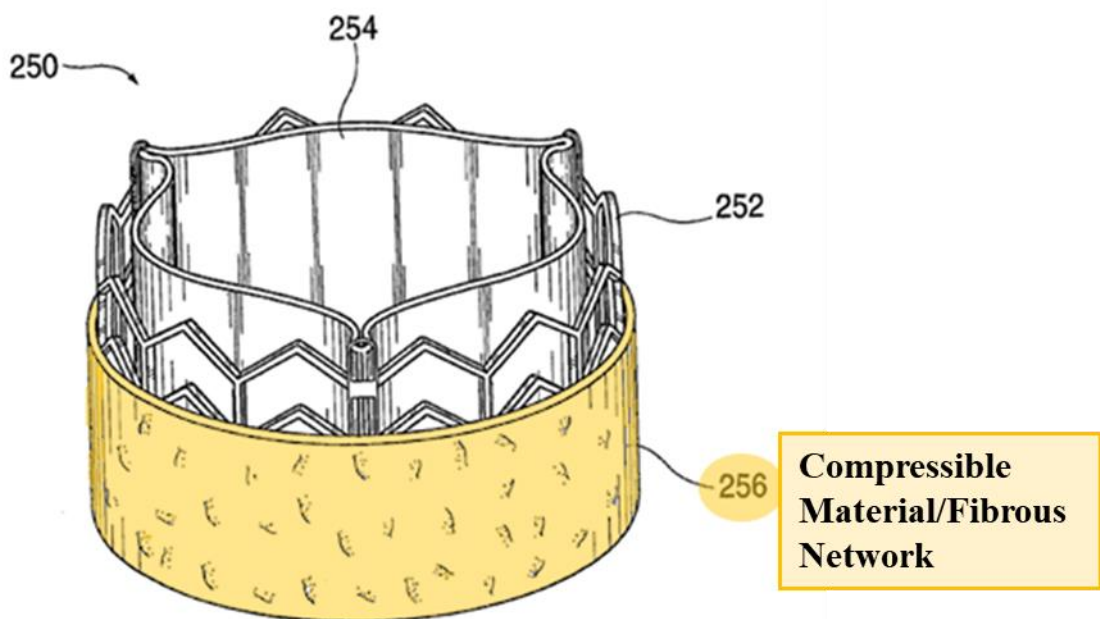
11. Fibrous Network Seals

228. Claim 1 next recites: "wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly." Spenser in combination with Walther and Spenser II render this limitation obvious.

229. If added to Spenser's Figure 44a, the fibrous network of Walther's outer cloth would seal against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly for the reasons I provided in Ground 1. *Supra* §VI.A.11. My analysis in Ground 1 applies here because Figure 44a is similar, if not identical, to SAPIEN and, therefore, the outer cloth would function the same on both devices and would provide the claimed seals. The outer cloth would overlap with the

patient's native leaflets and seal there against for the reasons I provided above.
Supra §VIII.A.9.

230. Similarly, Spenser II's valve includes a fibrous network, and the valve is expanded within the aortic valve with a balloon assembly, causing the fibrous network to seal against the native leaflets by filling the "gaps between the stented valve and the surrounding tissue."



Ex. 1011, [00145], Fig. 22. The compression of the fibrous network "creates a mechanical seal that prevents [PVL]." *Id.* at [00145]. In addition, the compressible material also seals against the outer frame and inner graft covering. If it did not, blood could leak between the components and the valve would not form the disclosed "mechanical seal." If Spenser II's compressible material were

added to Figure 44a, the fibrous compressible material would perform the same sealing function due to the similarities between the valves that I discussed previously. *Supra* §VIII.A.8.b.

12. Two Rows of Grids

231. Claim 1 concludes by reciting: “wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.” Spenser and Walther or Spenser II render this limitation obvious.

a. Walther

232. As I explained in Ground 1, Walther’s outer cloth covers two circumferentially extending rows of grids formed from SAPIEN’s open cell configuration. *Supra* §VI.A.12; Ex. 1007 (Walther) at 1121, Fig. 1. SAPIEN is similar (if not identical) to Spenser’s Figure 44a. Thus, if Walther’s outer cloth were added to the embodiment in Spenser’s Figure 44a, the cloth would cover the bottom two rows of grids of the support stent. The side-by-side comparison of Walther’s Figure 1 (left) and Spenser’s Figure 44a (right) below illustrates that Walther’s outer cloth would cover two circumferentially extending rows of grids formed by the gridded configuration:

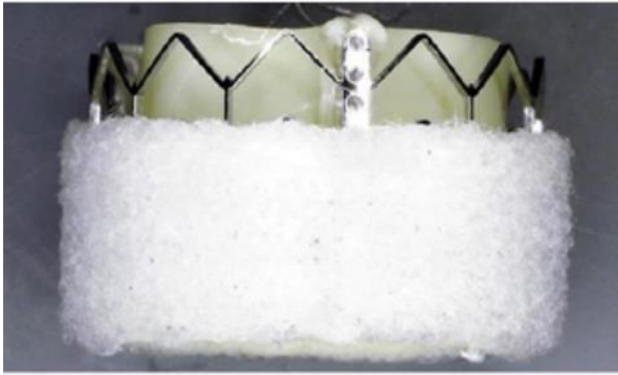
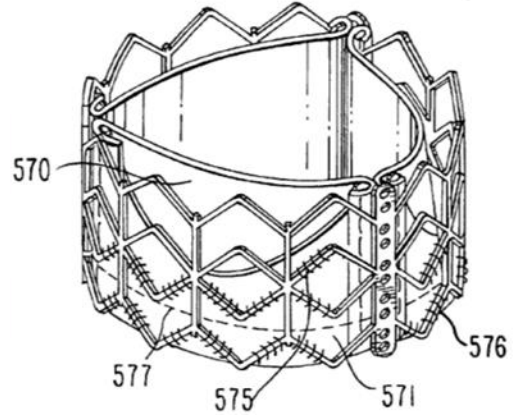


FIG. 44a



Ex. 1007 (Walther) at Fig. 1 (excerpt); Ex. 1010 (Spenser) at Fig. 44a.

b. Spenser II

233. As shown in Figure 22 below, Spenser II's compressible material covers the bottom two rows of grids formed by stent structure 252, leaving only the uppermost third row uncovered:

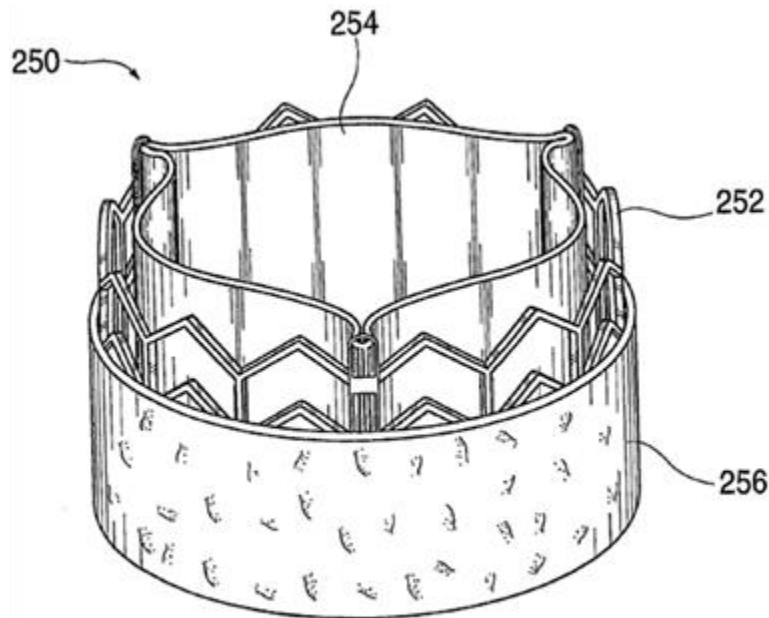


FIG. 22

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

234. 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:

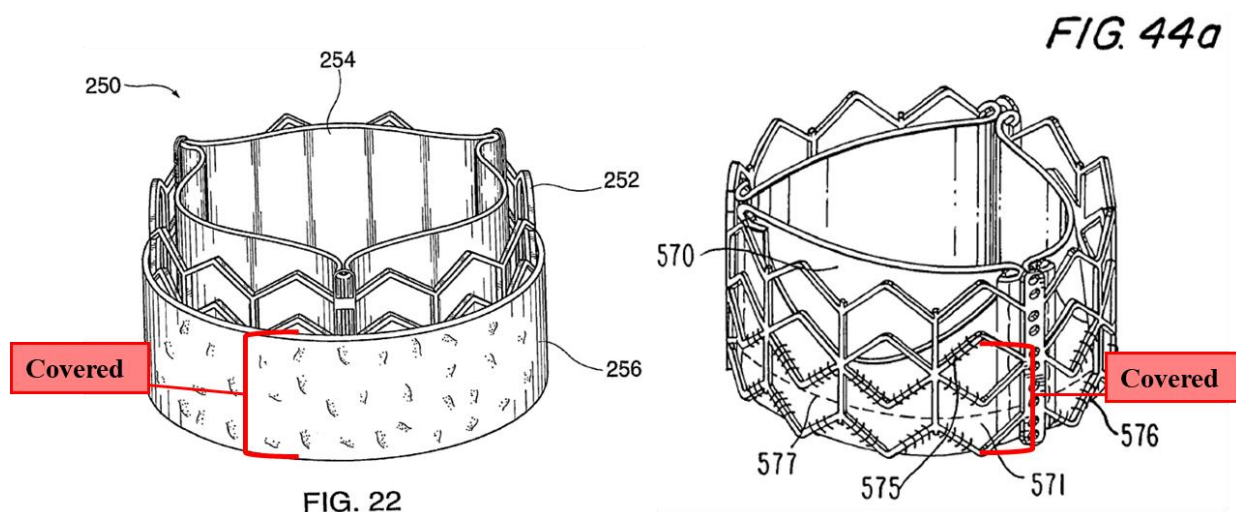


Fig. 1011 (Spenser II) at Fig. 22; Ex. 1010 (Spenser) at Fig. 44a.

235. If this claim requires the fibers to *entirely* cover two rows of grids, a person of ordinary skill in the art would have found it obvious to slightly increase the height of Spenser II's compressible material. Spenser II does not disclose that the compressible material cannot cover more of the frame. Further, Walther demonstrates that an outer covering that completely covers two rows of cells was known in the art. Moreover, as explained in Ground 1, a person of ordinary skill in the art would have had access to many different cloths having different dimensions

and sizes. *Supra* §§III.C, VI.A.8. Furthermore, a person of ordinary skill in the art would not have expected the minimal increase in height that would be necessary to entirely cover the second row of grids to impact the performance or deliverability of the valve.

B. Claim 2

236. Claim 2 recites: “The method of claim 1, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” Spenser in combination with Walther or Spenser II renders this claim obvious.

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

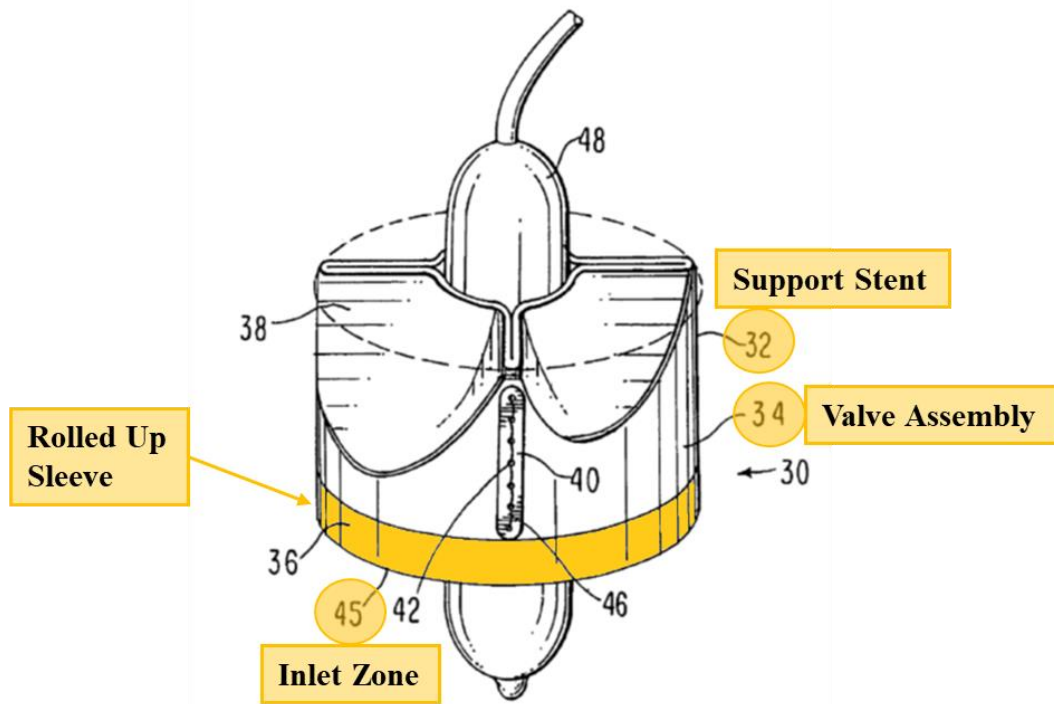
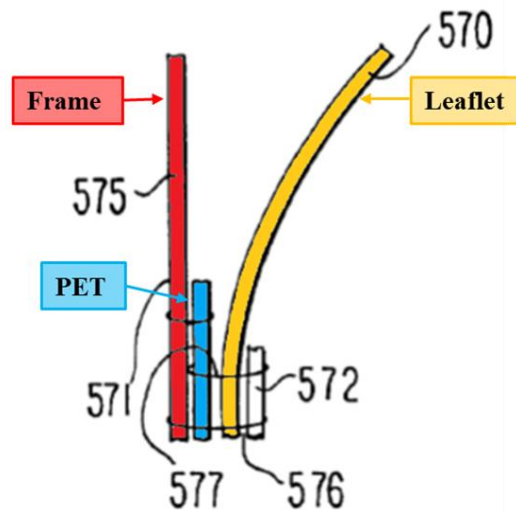


FIG. 2

Id. at Fig. 2.

238. As I explained in claim 1, Spenser's Figure 44a includes a piece of PET fabric (inner graft covering) positioned between the outer frame and the valve leaflets. *Supra* §VII.A.3.

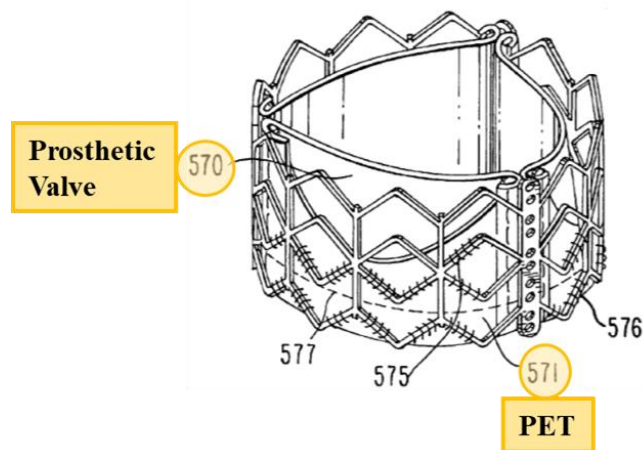
FIG. 44b



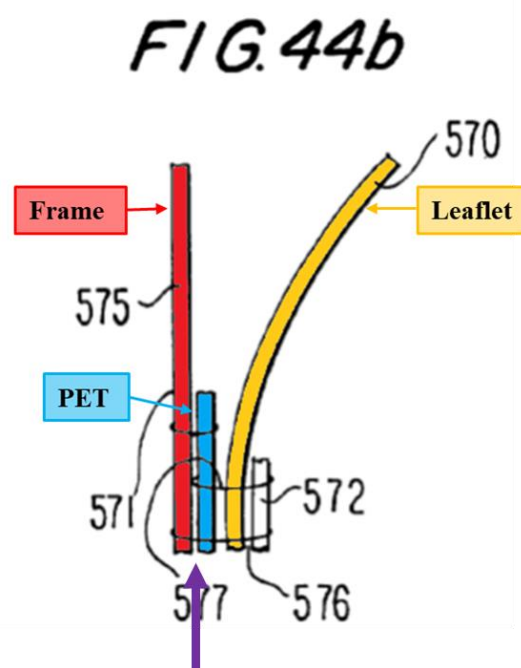
Ex. 1010 (Spenser) at Fig. 44b.

239. A person of ordinary skill in the art would have found it obvious to apply Spenser's teachings regarding the embodiment in Figure 2 to the inner PET fabric in Figure 44a and extend the inner PET fabric over the proximal end of the outer frame 575.

FIG. 44a



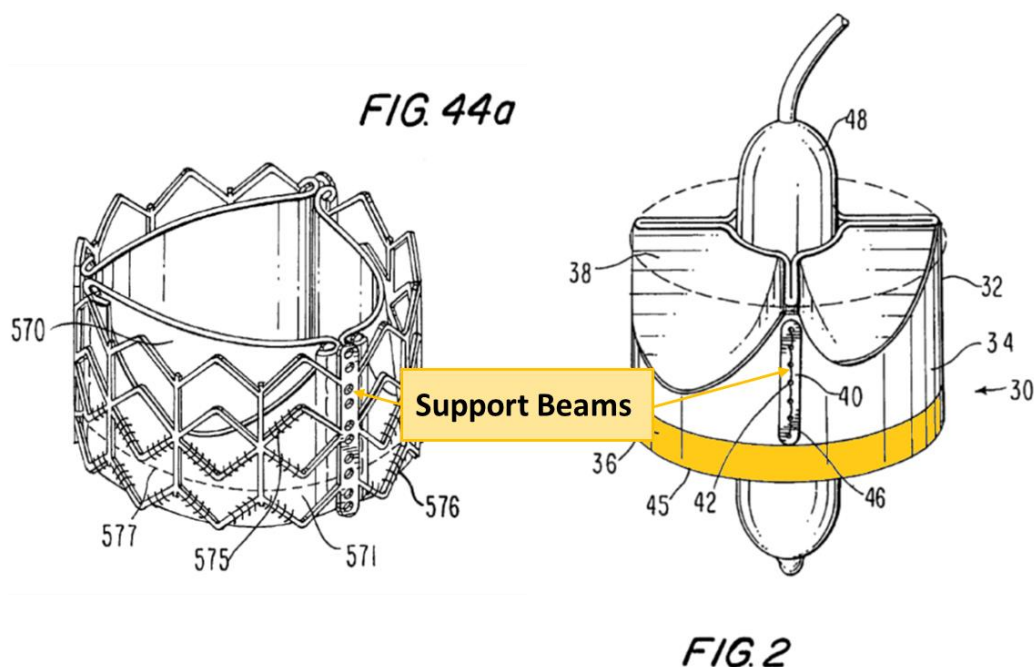
A person of ordinary skill in the art would have been motivated to extend PET 571 to “enhance[] the sealing of the device [in Figure 44a] at the valve inlet.” *Id.* at 14:6-9. A person of ordinary skill would have understood that extending the inner PET fabric over the proximal end of the outer frame would provide an additional seal between the inner PET and the outer frame at the valve inlet. This additional seal would ensure that blood does not leak through gaps between the PET fabric and the outer frame (and ultimately the outer seal), indicated by the purple arrow in Figure 44b below:



Id. at Fig. 44b. If the inner PET is not wrapped around the inlet end of the outer frame, a person of ordinary skill would understand that there is a greater possibility of blood seeping through the gaps at the interface between the inner PET fabric and the outer frame.

240. Additionally, a person of ordinary skill in the art would have been motivated to extend the cuff over the proximal end to reduce the risk that the edges of the frame would damage the surrounding tissue. Ex. 1048 (Essinger) at [0098]. This modification would have merely entailed applying a known technique (extending the cuff) to a known device (SAPIEN) ready for improvement (enhanced sealing and reduce frame exposure).

241. A person of ordinary skill in the art would have reasonably expected success in extending the inner PET fabric over the proximal end of Figure 44a's outer frame because Figures 2 and 44a describe similar heart valves. See Ex. 1010 at 14:41-43, 26:30-54. Both valves include an inner PET layer that is stitched to a gridded, metallic, balloon-expandable support stent that has three parallel support beams for attaching leaflets:



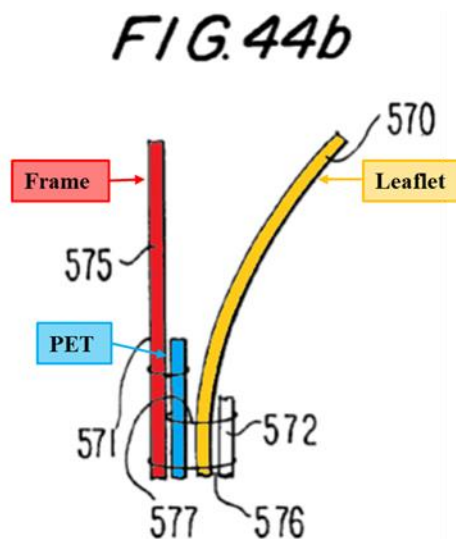
Id. at 13:62-14:3; 26:30-54, Figs. 2, 44a. A person of ordinary skill in the art would have reasonably expected that the teachings of Figure 2 would also apply to Figure 44a due to these similarities (and the fact that the Figures are described in the same patent).

242. A person of ordinary skill in the art would have been motivated to add Walther's outer cloth or Spenser II's compressible material to Spenser's Figure 44a even if Figure 44a had an inner graft covering extending over the proximal end of the frame because the outer cloth/compressible material serves a different purpose than the extended graft covering. As explained above, the extended graft covering prevents blood from leaking between the inner and outer frames. *See* Ex. 1010 (Spenser) at 26:30-34. In contrast, the outer cloth/compressible material prevents blood from leaking between the valve and surrounding tissue. *See* Ex. 1007 (Walther) 1120; Ex. 1011 (Spenser II) at [00145]. Moreover, a person of ordinary skill in the art would have understood that Spenser's inner PET layer would be a thin fabric, and thus wrapping the PET around the proximal end of the frame would not have a substantial effect on the valve's profile. Therefore, a person of ordinary skill in the art would not have been discouraged from adding the outer cloth/compressible material to Spenser 44a's frame having the extended inner PET layer.

C. **Claim 3**

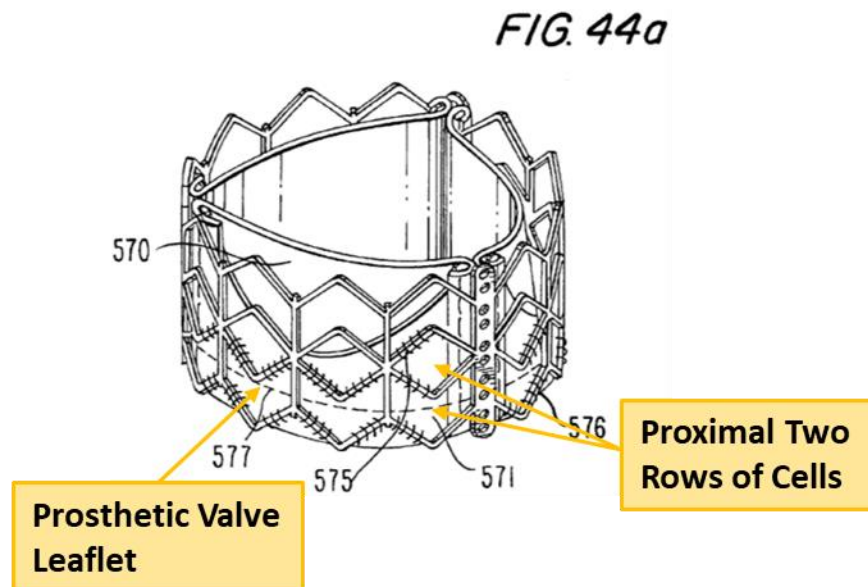
243. Claim 3 recites: “The method of claim 2, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” Spenser in combination with Walther or Spenser II render this claim obvious.

244. As I explained in claim 1, if Walther’s outer cloth or Spenser II’s compressible material were added to Spenser’s Figure 44a, the cloth would extend over the bottom two rows of grids of the support stent. *Supra* §VIII.A.12. The prosthetic leaflets in Figure 44a extend to the proximal end of the frame, as illustrated in Fig. 44b below:



Ex. 1010 (Spenser) at Fig. 44b. Because the prosthetic leaflets extend to the proximal end of the frame, the two proximal rows of cells covered by Walther’s outer cloth/Spenser II’s compressible material would radially overlap with Figure

44a's prosthetic leaflets based on Patent Owner's arguments regarding Figure 11 and "radially overlaps" during prosecution. *Supra* §VII.B. This is also illustrated by Spenser's Figure 44a, which illustrates that the suture 577, which connects the prosthetic leaflets to the PET 571, radially overlaps with the most proximal row of cells of the outer frame:



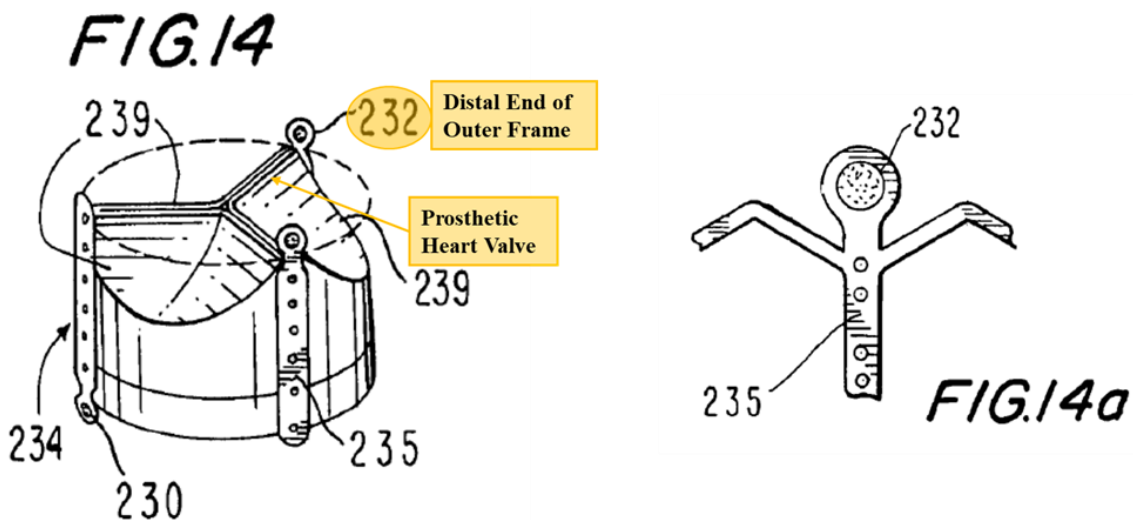
Id., 26:5642-44, Fig. 44a. Because the most proximal row of cells would be covered by Walther's outer cloth or Spenser II's compressible material, *supra* §VIII.A.12, the outer cloth/compressible material would radially overlap with the prosthetic leaflets as well.

D. Claim 4

245. Claim 4 recites: "The method of claim 3, wherein the outer frame extends distally further than the prosthetic heart valve." Spenser discloses the

limitations in claim 4 and, in combination with Walther or Spenser II, renders claim 4 obvious.

246. Spenser discloses the limitations in claim 2 in at least two ways. First, Spenser discloses heart valves having “heavy metal markers [232] on the stent, which markers allow observation and thereby adjustment of orientation while placing the device in the required location:”



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

metallic frame 420:

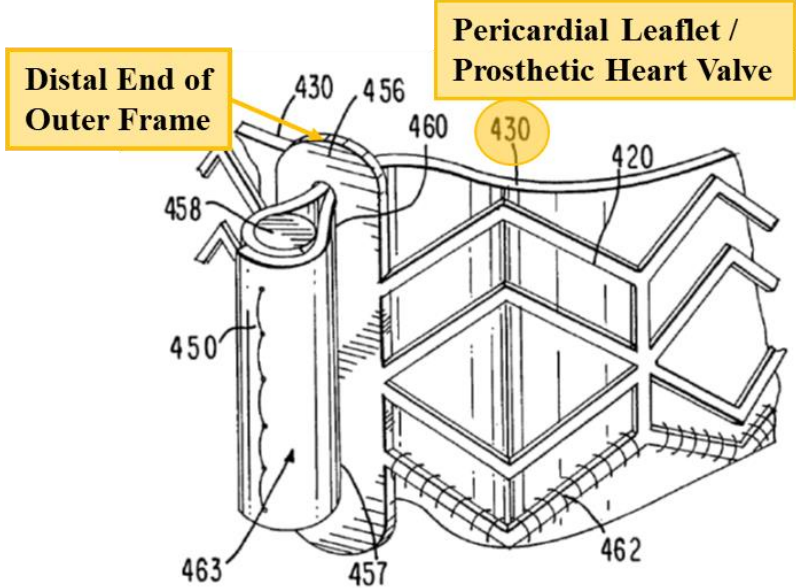


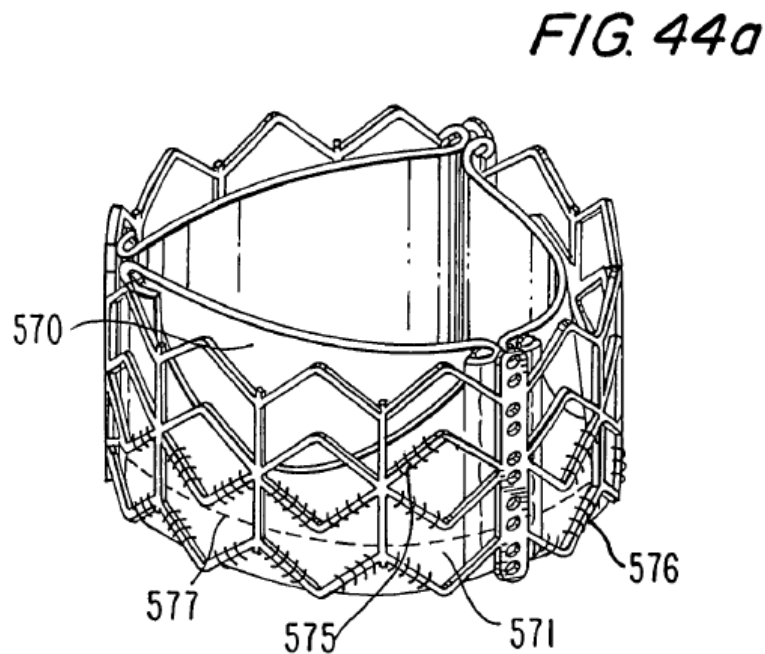
FIG. 28

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

E. Claim 5

248. Claim 5 recites: “The method of claim 3, wherein the outer frame is a singular, integral component.” Spenser discloses the limitations in claim 5 and, in combination with Walther or Spenser II, renders claim 5 obvious.

249. Figure 44a includes “frame 575”:

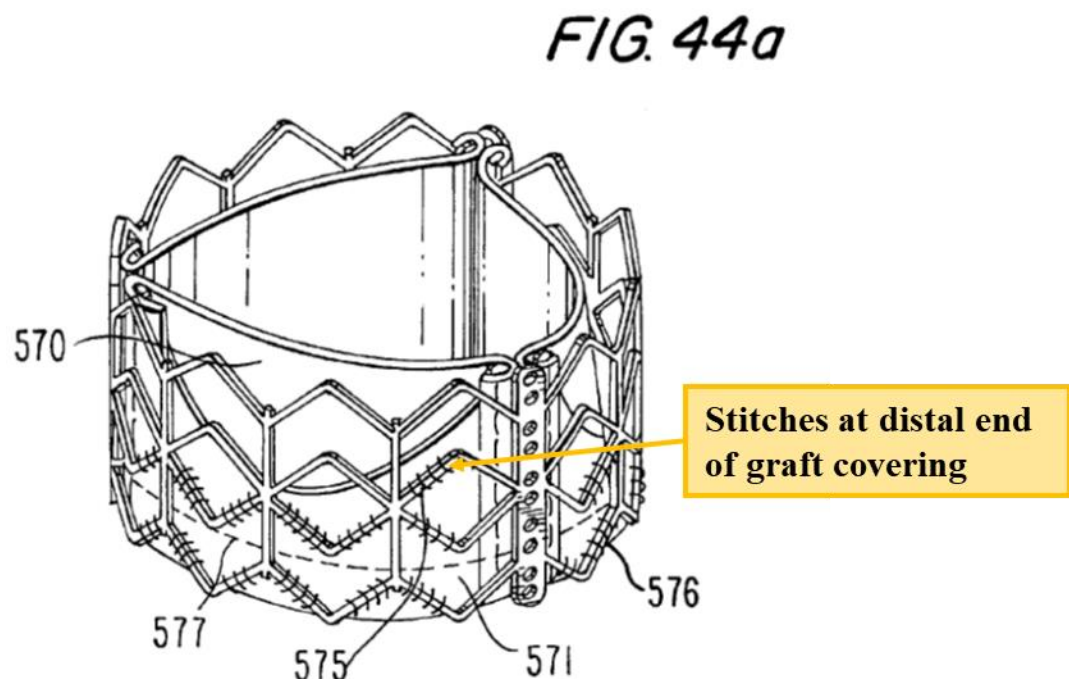


Ex. 1010 (Spenser) at 26:30-34; *see also id.* at 19:5-13 (describing frame). As shown in figure 44a above, the vertically straight bars of the frame are each connected by four rows of interconnected, angular struts that form the open celled construction of the frame. *See id.* Because each of the bars of the frame are interconnected, frame 575 is a singular, integral component. *Id.* at Fig. 44a-44b.

F. Claim 6

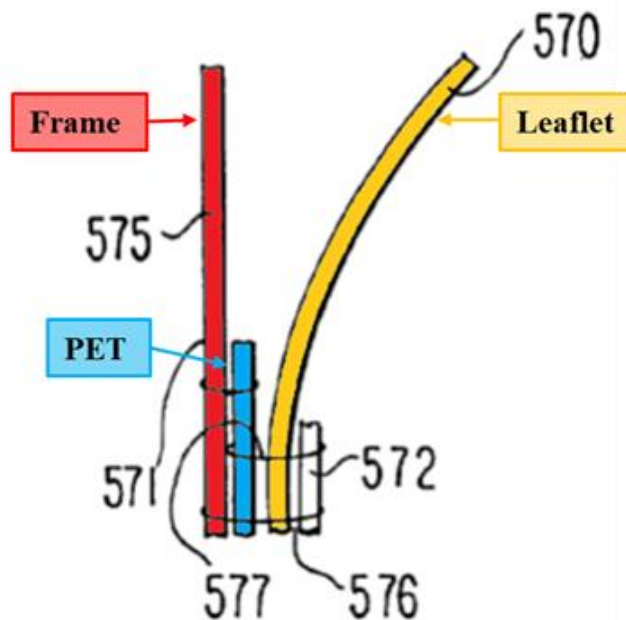
250. Claim 6 recites: “The method of claim 3, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering.” Spenser discloses the limitations in claim 6 and, in combination with Walther or Spenser II, renders claim 6 obvious.

251. Spenser’s PET layer 571, which is a graft covering, is attached to the frame 575 with bottom suture 576 and upper suture 578. Ex. 1010 (Spenser) at 26:42-48, Figs. 44a-44c. Figure 44a below shows that the sutures secure the PET layer 571 to the outer frame with a plurality of stitches at the distal (top) and proximal (bottom) bottom of the graft covering:



Id. at Fig. 44a. The sutures are further shown in Figure 44b, below.

FIG. 44b



G. Claim 7

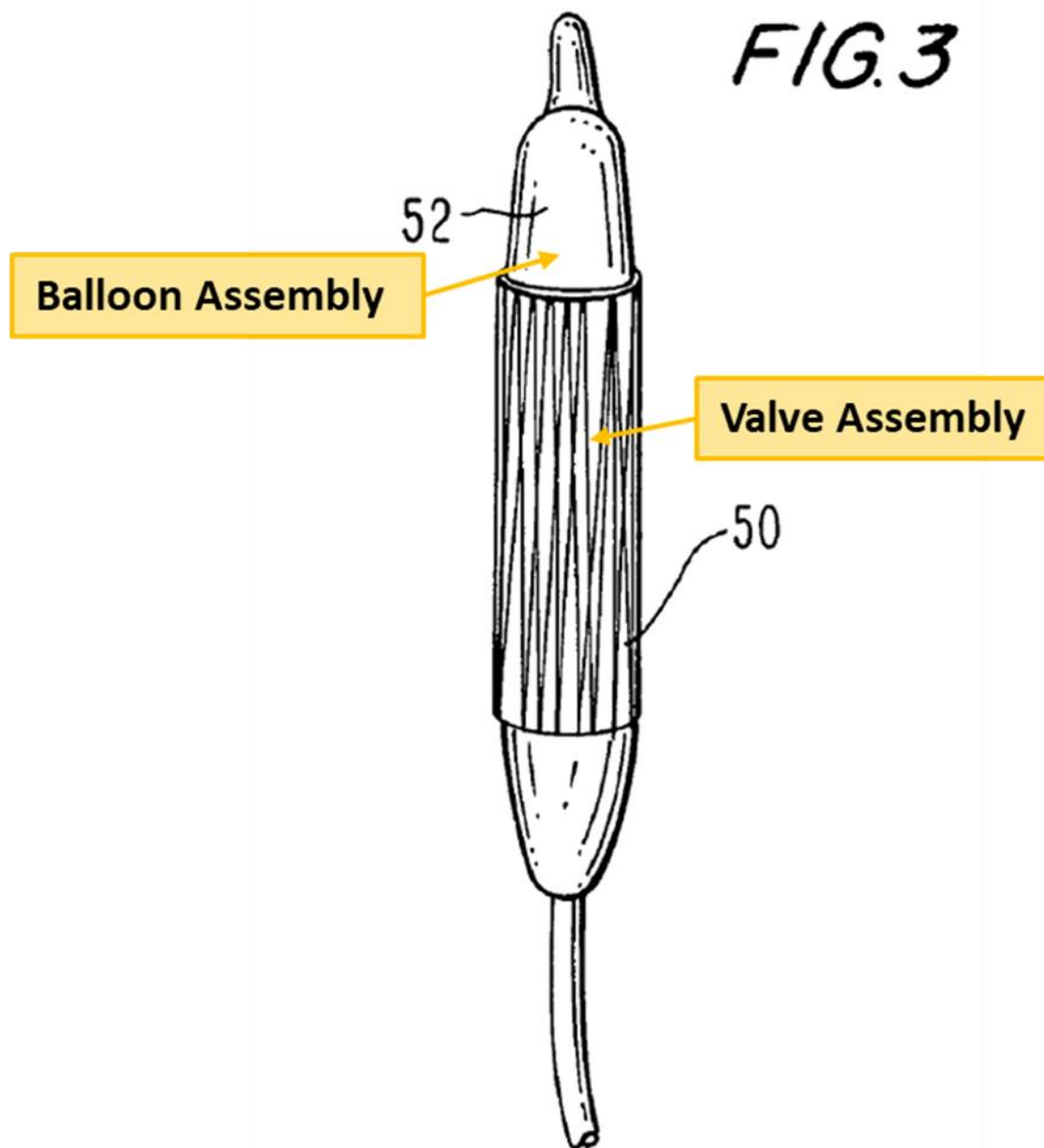
252. Claim 7 recites: “The method of claim 3, wherein a portion of a length of a fiber of the fibrous network is arcuate.” Spenser in combination with Walther or Spenser II renders claim 7 obvious.

253. Walther discloses arcuate fibers for the reasons I provided in Ground 2. *Supra* §VII.E. Spenser II also discloses arcuate fibers. Spenser II discloses that the radially extending fibers of the outer compressible material “may be straight, ***curved or hook-shaped.***” Ex. 1011 (Spenser II) at [00145] (emphasis added). Curved or hook-shaped fibers are arcuate.

H. Claim 8

254. Claim 8 recites: “The method of claim 1, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the valve assembly is in the radially compressed orientation.” Spenser discloses the limitations in claim 8 and, in combination with Walther or Spenser II, renders claim 8 obvious.

255. Spenser’s Figure 3 illustrates “an implantable valve according to the present invention mounted over a stent with an inflatable balloon, in a crimped position”:



Ex. 1010 (Spenser) at 8:63-65, Fig. 3. As shown in the figure, the “inflatable balloon 52” is positioned radially inwardly of the valve stent 50 when the valve is in the crimped position.

I. Claim 9

256. Claim 9 recites: “The method of claim 1, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” Spenser in combination with Walther renders claim 9 obvious.

257. Walther’s outer cloth, which is a “fibrous network,” includes fibers that extend radially inwardly from SAPIEN’s outer frame for the reasons I provided in Ground 1. *Supra* §VII.C. When added to Spenser’s Figure 44a, at least some of the outer cloth’s fibers would similarly extend radially inwardly of Figure 44a’s outer frame because Figure 44a is similar (if not identical) to SAPIEN.

J. Claim 10

258. Claim 10 recites: “The “method of claim 1, wherein the fibrous network includes fibers directly engaged with the outer frame.” Spenser in combination with Walther or Spenser II renders claim 10 obvious.

1. Walther

259. As I explained in Ground 1, Walther’s outer cloth (i.e., fibers) is stitched to and is directly engaged with SAPIEN’s outer frame. *Supra* §VI.C. A person of ordinary skill would have been motivated to attach Walther’s outer cloth to Figure 44a’s frame in the same way (i.e., by stitching) because Walther describes this method of attachment and the method (stitching) is simple and

would have been known to persons of ordinary skill in the art. A person of ordinary skill would have expected success in stitching Walther's outer cloth to Figure 44a for the reasons I provided in claim 1. *Supra* §VIII.A.8. Because the fibers of Walther's outer cloth would be stitched directly to Spenser's outer frame, the combination of Walther's outer cloth with Figure 44a would include fibers that are "directly engaged" with the outer frame.

2. Spenser II

260. Spenser II discloses that the compressible material 256 "is disposed along an outer surface of the stent structure 252":

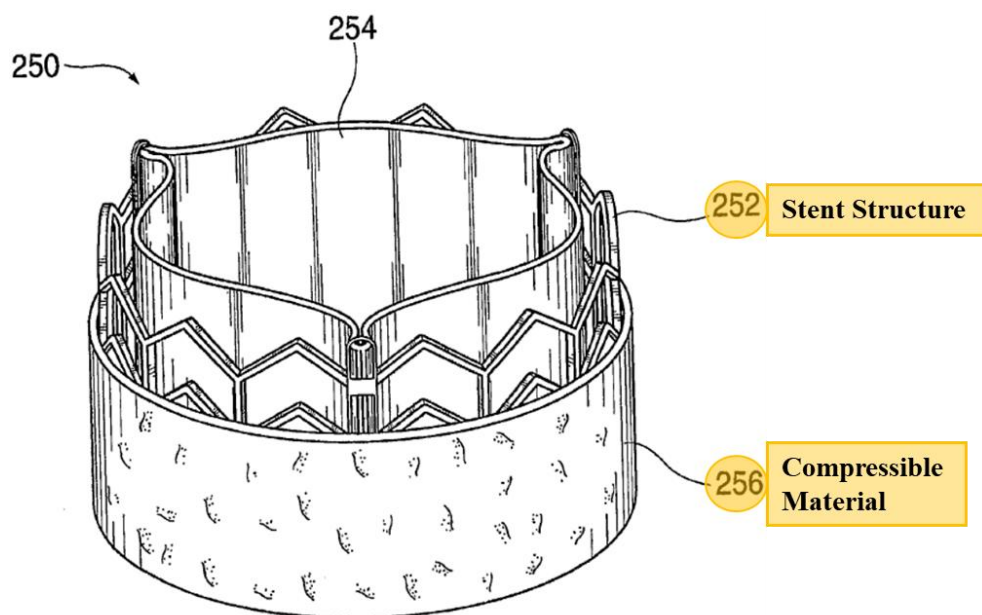


FIG. 22

Ex. 1011 (Spenser II) at [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." *Id.* Thus, if Spenser II's compressible material were

added to the outer frame in Spenser's Figure 44a as shown in Figure 22 (above), the fibers extending from the compressible material would be "disposed along [the] outer surface" of Spenser's outer frame. *Id.* Thus, the fibers of the compressible material would be "directly engaged" with the outer frame of Spenser's Figure 44a.

K. Claim 11

261. Claim 11 recites:

11. A method of implanting a transcatheter aortic valve assembly, comprising:

 endovascularly positioning a guide wire through the aortic valve of a patient;

 endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient, wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation,

 wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration,

 wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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 graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

 wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame,

 wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient;

 inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation,

wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,

wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

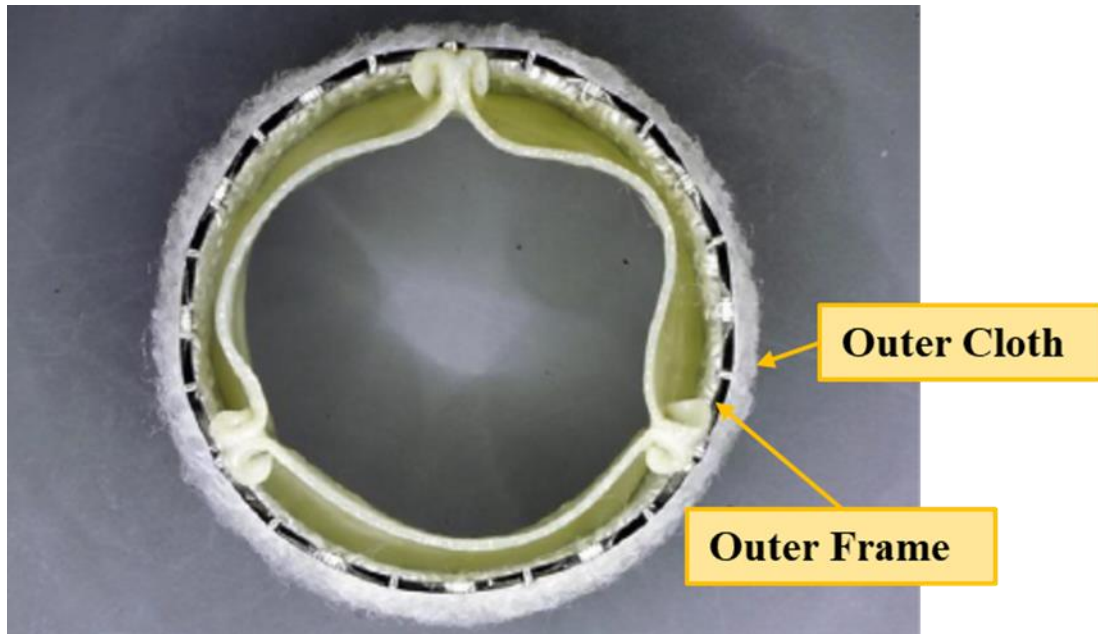
262. Thus, claim 11 is an independent claim that mirrors the limitations recited in claim 1 with a single exception. Claim 11 recites “wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,” whereas claim 1 recites that the fibrous network seals against the patient’s native leaflets, the outer frame, and the graft covering. I believe that the combination of Spenser and Walther or Spenser II renders claim 11 obvious.

1. Fibrous Network Seals

263. Spenser in combination with Walther or Spenser II renders this limitation obvious.

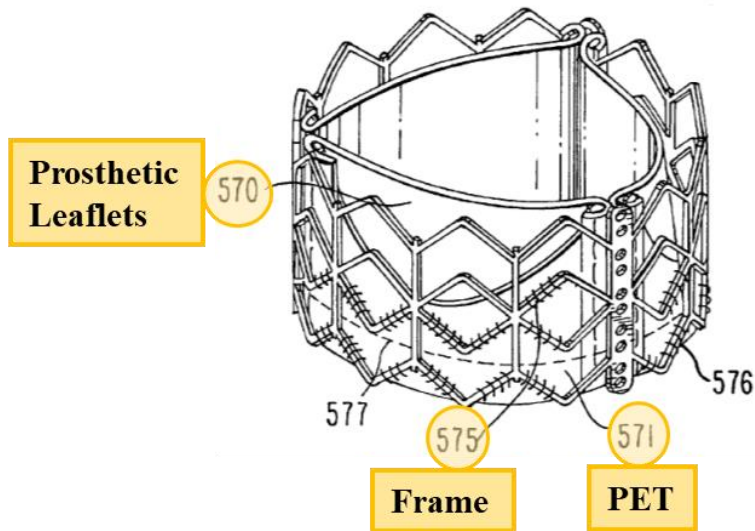
a. Walther

264. Walther discloses a SAPIEN with an outer cloth positioned radially outwardly of the outer frame:



Ex. 1007 (Walther) at 1121, Fig. 1. As I explained in claim 1, the outer cloth is a “fibrous network,” and a person of ordinary skill in the art would understand that the outer cloth would seal against the outer frame and inner graft covering of Spenser’s Figure 44a when the valve is expanded within a patient’s native aortic valve. *Supra* §VIII.A.11. As shown below, the frame and graft covering are outward of the prosthetic leaflets, as would any outer cloth/material added to the frame’s exterior:

FIG. 44a

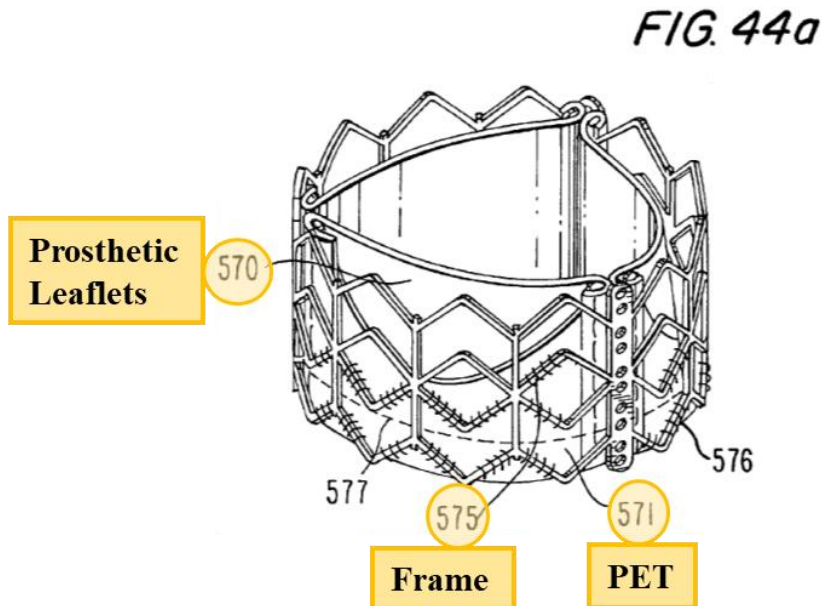


Ex. 1010 (Spenser) at Fig. 44a. Indeed, because Figure 44a’s prosthetic leaflets are surrounded by the internal surface of the outer frame and inner graft covering, while Walther’s outer cloth would be positioned around the external surface of the outer frame and inner graft covering, any seal between the outer cloth and the outer frame/inner graft covering would necessarily be “outwardly of the prosthetic leaflets.”

b. Spenser II

265. As I explained in claim 1, Spenser II discloses an outer compressible material that is a “fibrous network” positioned around the external surface of the outer frame. *Supra* §VIII.A.8. As I also explained in claim 1, a person of ordinary skill in the art would understand that the compressible material would seal against the outer frame and the graft covering of Spenser’s Figure 44a when the combined

valve is expanded within a patient's native aortic valve. *Supra* §VIII.A.11. As shown below, the frame and graft covering are outward of the prosthetic leaflets, as would any outer cloth/material added to the frame's exterior:



Ex. 1010 (Spenser) at Fig. 44a. Indeed, because Figure 44a's prosthetic leaflets are surrounded by the internal surface of the outer frame and inner graft covering, while Spenser II's compressible material would be positioned around the external surface of the outer frame and inner graft covering, any seal between the compressible material and the outer frame/inner graft covering would necessarily be "outwardly of the prosthetic leaflets."

2. Remaining Limitations

266. Spenser in combination with Walther or Spenser II renders the remaining limitations of claim 11 obvious for the reasons I provided in claim 1. *Supra* §VIII.A.

L. Claim 12

267. Claim 12 recites: “The method of claim 11, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” This limitation also appeared in claim 2. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 2 and 11. *Supra* §§VIII.B, VIII.J.

M. Claim 13

268. Claim 13 recites: “The method of claim 12, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” This limitation also appeared in claim 3. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 3 and 12. *Supra* §§VIII.C., VIII.K.

N. Claim 14

269. Claim 14 recites: “The method of claim 13, wherein the outer frame extends distally further than the prosthetic heart valve.” This limitation also appeared in claim 4. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 4 and 13. *Supra* §§VIII.D, VIII.L.

O. Claim 15

270. Claim 15 recites: “The method of claim 13, wherein the outer frame is a singular, integral component.” This limitation also appeared in claim 5. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 5 and 13. *Supra* §§VIII.E, VIII.L.

P. Claim 16

271. Claim 16 recites: “The method of claim 13, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering.” This limitation also appeared in claim 6. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 6 and 13. *Supra* §§VIII.F, VIII.L.

Q. Claim 17

272. Claim 17 recites: “The method of claim 13, method of claim 13, wherein a portion of a length of a fiber of the fibrous network is arcuate.” This limitation also appeared in claim 7. Thus, Spenser in combination with Walther and Spenser II renders this claim obvious for the reasons I provided in claims 7 and 13. *Supra* §§VIII.G, VIII.L.

R. Claim 18

273. Claim 18 recites: “The method of claim 11, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the

valve assembly is in the radially compressed orientation.” This limitation also appeared in claim 8. Thus, Spenser in combination with Walther or Spenser II render this claim obvious for the reasons I provided in claims 8 and 11. *Supra* §§VIII.H, VIII.J.

S. Claim 19

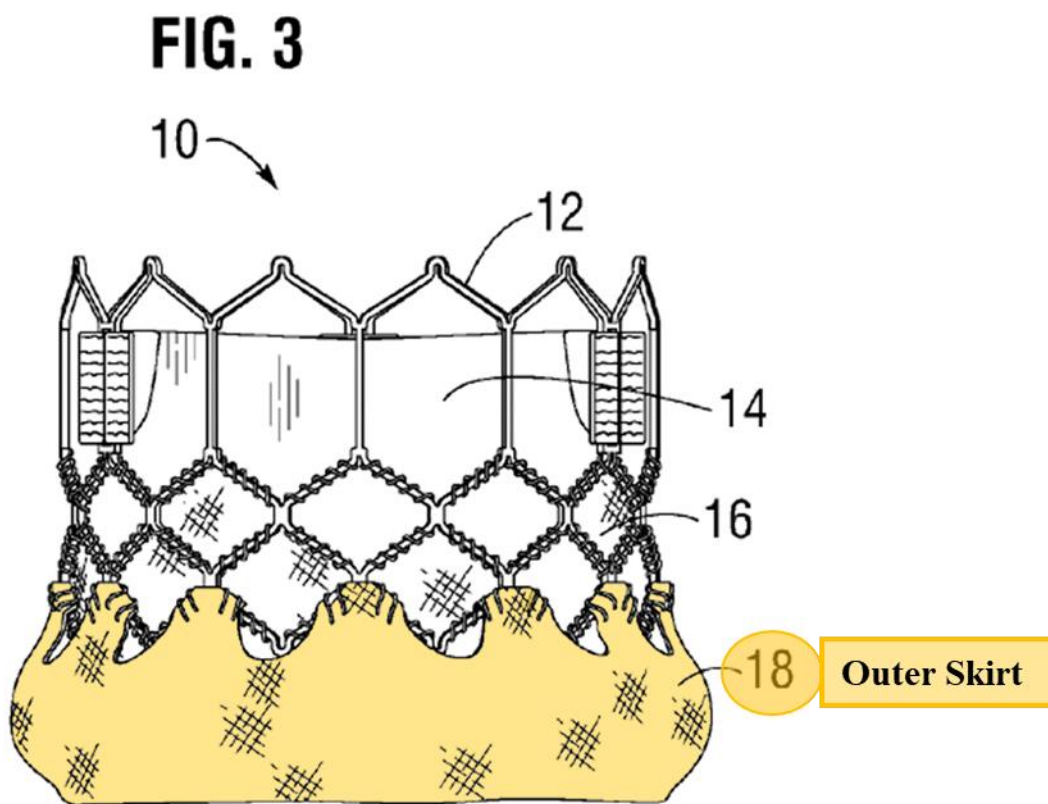
274. Claim 19 recites: “The method of claim 11, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” This limitation also appeared in claim 9. Thus, Spenser in combination with Walther renders this claim obvious for the reasons I provided in claims 9 and 11. *Supra* §§VI.I, VI.K.

T. Claim 20

275. Claim 20 recites: “The method of claim 11, wherein the graft wherein the fibrous network includes fibers directly engaged with the outer frame.” This limitation also appeared in claim 10. Thus, Spenser in combination with Walther or Spenser II renders this claim obvious for the reasons I provided in claims 10 and 11. *Supra* §§VIII.I, VIII.J.

IX. GROUNDS 5-8: CLAIMS 1-20 ANTICIPATED OR OBVIOUS IN VIEW
OF LEVI ALONE OR WITH WALTHER OR SPENSER II

276. 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 fibrous network as required by the claims of the '538 patent. Therefore, based on my review of the prior art, it is my opinion

that Levi discloses or suggests every limitation of claims 1-20 and anticipates or renders the claims obvious.

277. However, even if Levi does not disclose or suggest a fibrous network, Walther and Spenser II do, as I explained previously. *Supra* §§VI.A.8, VIII.A.8. It is my opinion that a person of ordinary skill in the art would have found it obvious to combine the fibrous networks from Walther or Spenser II with Levi for the reasons I provide in detail below. In fact, Levi expressly discloses methods of adapting the outer frame to accommodate a sealing material. Ex. 1008 (Levi) at 14:26-35. Therefore, it is my opinion that Levi in combination with Walther or Spenser II renders obvious claims 1-20.

A. Claim 1

278. 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

279. The preamble of claim 1 recites: “A method of implanting a transcatheter aortic valve assembly comprising.” Levi discloses this limitation.

280. Levi discloses “embodiments of a prosthetic heart valve, and delivery systems for implanting heart valves.” Ex. 1008 (Levi) at 1:17-19. 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. Thus, Levi discloses a method of implanting a transcatheter aortic valve.

2. Endovascularly Positioning a Guidewire

281. Claim 1 next recites: “endovascularly positioning a guide wire through the aortic valve of a patient.” Levi also discloses this limitation.

282. Levi 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.” Ex. 1008 (Levi) at 1:57-67. Levi discloses that these minimally-invasive approaches involve “advanc[ing] the transcatheter heart valve through the femoral artery or vein.” *Id.* at 2:4-5. Levi cites to U.S. Patent No. 6,730,118 (the “’118 patent”) as one example of such a percutaneous approach and expressly incorporates the ’118 patent by reference. *Id.* at 1:62-63. The ’118

patent describes the delivery of transcatheter heart valves through, for example, the femoral artery. Ex. 1051 ('118 patent) at 5:14-67, 28:37-48. The Spenser reference which I discussed above is a divisional of the '118 patent and therefore shares a common specification with the '118 patent. See Ex. 1010 (Spenser) at 1. As I explained in Grounds 3-4, Spenser discloses a method of endovascularly implanting a prosthetic heart valve that involves positioning a guidewire through a patient's native aortic valve. *Supra* §VIII.A.2; Ex. 1051 ('118 patent) at 5:14-67, Figs. 16a-17b. Because Levi expressly incorporates the '118 Patent by reference, a person of ordinary skill in the art would understand that Levi's valve may also be implanted endovascularly using the technique taught by Spenser. Therefore, a person of ordinary skill in the art would understand that Levi discloses endovascular delivery of its heart valve that involves positioning a guidewire through the patient's native aortic valve.

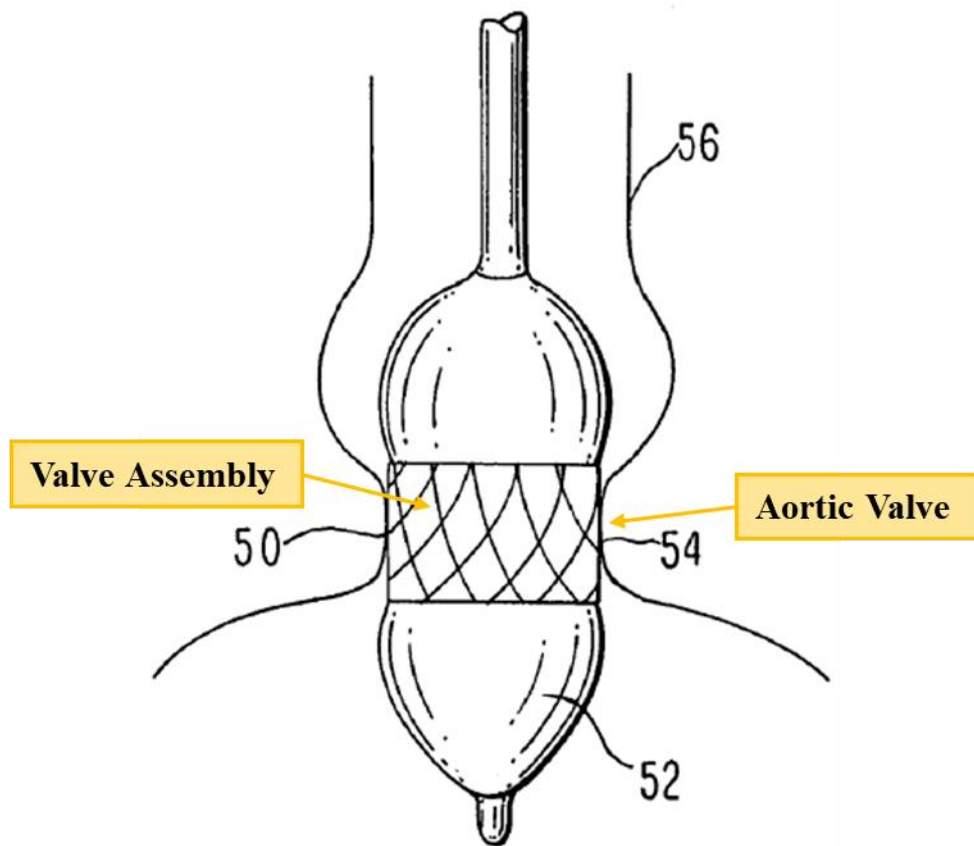
3. Endovascularly Positioning the Transcatheter Aortic Valve Assembly

283. Claim 1 next recites: “endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient.” Levi discloses this limitation or renders it obvious alone or with Walther or Spenser II.

a. Levi

284. Levi discloses percutaneously (i.e., endovascularly) advancing the valve through the femoral artery or vein using a catheter and implanting the valve

at the native aortic annulus. Ex. 1008 (Levi) at 1:57-2:7, 5:53-56, 6:46-49. Also, as I explained in the previous section, Levi expressly incorporates a divisional of Spenser, the '118 patent, by reference. *Id.* at 1:62-63; *see also* Ex. 1010 (Spenser) at 1. As I explained in Grounds 3-4, Spenser discloses a method of endovascularly implanting a prosthetic valve that involves positioning the valve assembly through the patient's native aortic valve as shown in Figure 4:



Ex. 1010 (Spenser) at Fig. 4; Ex. 1051 ('118 patent) at Fig. 4; *supra* §VIII.A.3. Because Levi incorporates the '118 Patent by reference, a person of ordinary skill in the art would understand that Levi's valve may also be implanted

endovascularly using the technique taught by Spenser and would thus be endovascularly positioned through a patient's native aortic valve.

285. Levi discloses several features to enable such endovascular delivery. *See id.* at 6:46-49. For example, Levi discloses that its frame is preferably constructed of nickel-cobalt-chromium-molybdenum alloy, which allows for less material to be used so that “the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly ***for percutaneous delivery to the treatment location in the body.***” Ex. 1008 (Levi) at 6:31-49 (emphasis added); *see also id.* at 7:10-12. Levi discloses that “[b]y minimizing the diameter of the valve when mounted on the delivery shaft, the assembly can ***[be] contained within a smaller diameter catheter and thus can be passed through smaller vessels in the body*** and can be less invasive in general.” *Id.* at 14:60-64 (emphasis added). A person of ordinary skill in the art would have therefore understood that Levi's valve is delivered endovascularly.

b. Levi and Walther or Spenser II

286. 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 after replacing Levi's outer skirt with Walther's outer cloth or Spenser II's compressible material, the resulting device would remain suitable for endovascular deployment. For example, even if the addition of Walther's outer

cloth or Spenser II's compressible material resulted in some small increase in the valve diameter, a person of ordinary skill in the art would have recognized that the valve could still be endovascularly delivered through the patient's common iliac artery. Ex. 1043 (Kainuma).

287. Additionally, Levi teaches that “[w]hen crimped, the frame 12 has a reduced diameter region extending along a portion of the frame . . . that generally corresponds to the region of the frame covered by the outer skirt 18” so that the outer skirt “does not increase the overall crimp profile of the valve.” Ex. 1008 (Levi) at 8:46-54; *see also id.* at 2:22-35, 14:22-35, 16:38-45, 17:14-18. Walther's outer cloth or Spenser II's compressible material would also cover the reduced diameter region, which would reduce any risk that the outer cloth/compressible material would disadvantageously increase the crimp profile. *Id.* at 8:46-54.

288. Levi additionally discloses several other features that minimize the crimped profile of the valve and would enable endovascular delivery of a valve equipped with Walther's outer cloth or Spenser II's compressible 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 endovascular delivery of a valve with a fibrous outer seal.

289. Levi discloses that “[i]n one example, the frame of a 26-mm valve, when crimped, had a diameter D_1 of 14 French at the outflow end of the valve and a diameter D_2 of 12 French at the inflow end of the valve.” *Id.* at 8:56-59. A person of ordinary skill in the art would have understood that adding Walther’s outer cloth or Spenser II’s compressible material (which is described as being 1 mm thick in some embodiments) to Levi’s valve would result in a device suitable for endovascular delivery through, for example, the common iliac artery or a smaller artery such as the femoral artery. In addition, as discussed in Ground 1, a person of ordinary skill in the art would have had access to a range of suitable cloths and materials having varying thicknesses and densities and could have selected an appropriately dimensioned cloth/material for endovascular delivery. *Supra* §VI.E.

290. Levi also expressly suggests adding other components, like Walther’s outer cloth or Spenser II’s compressible material, to the inflow portion of the outer frame, stating “if additional components are mounted to that portion of the valve, such as an outer skirt 18, the reduced profile of that portion of the valve can help offset or minimize the increase in diameter caused by the additional component.” Ex. 1008 (Levi) at 16:41-45. A person of ordinary skill in the art would have

understood that Walther's outer cloth or Spenser II's compressible material would be a potential "additional component." For these reasons, a person of ordinary skill in the art would have reasonably expected success in adding materials like Walther's outer cloth or Levi's compressible material to Levi's valve.

4. Radially Compressed Orientation and Radially Expanded Orientation

291. Claim 1 next recites: "wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation." Levi, Walther, and Spenser II all disclose this limitation.

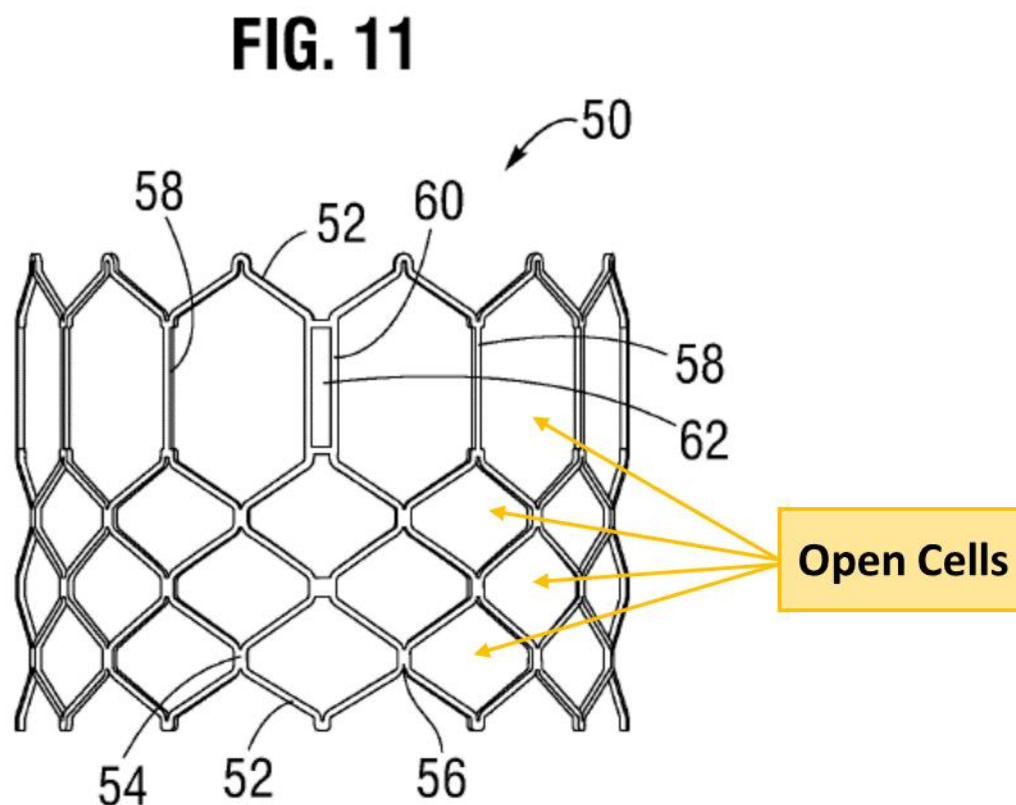
292. Walther discloses this limitation for the reasons I provided in Ground 1. *Supra* §VI.A.4. Spenser II discloses this limitation for the reasons I provided in Grounds 3-4. *Supra* §VIII.A.4. Levi discloses that its prosthetic heart valve is "radially collapsible and expandable." Ex. 1008 (Levi) at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

5. Outer Frame

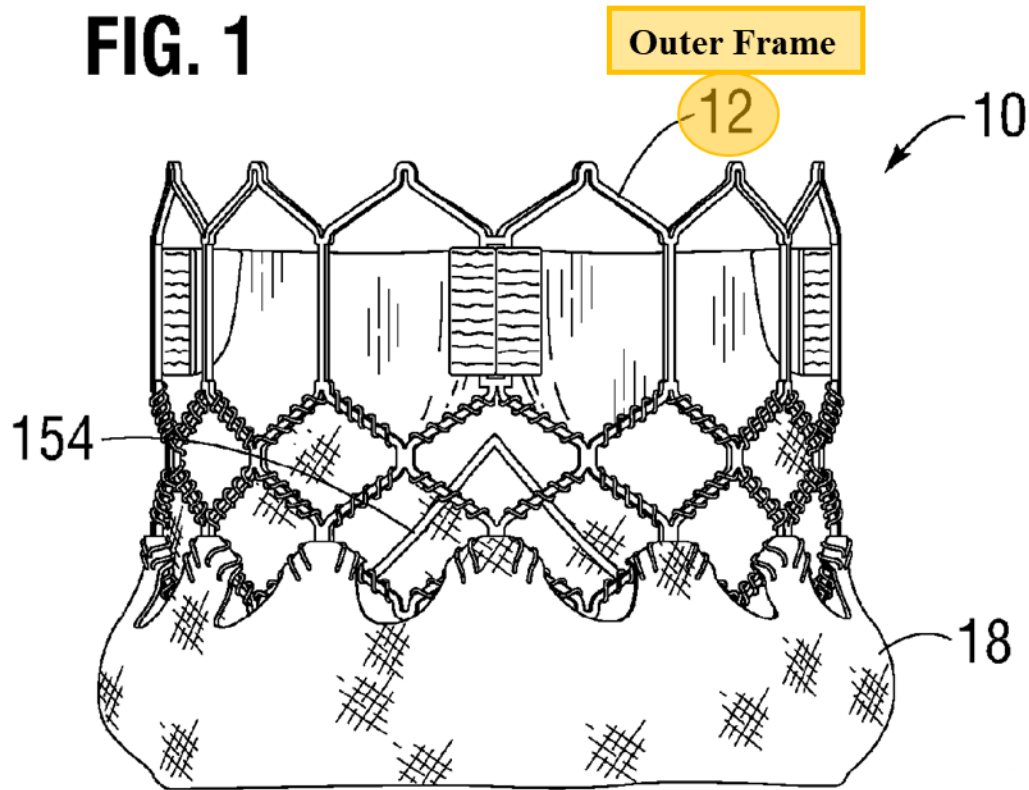
293. Claim 1 next recites: "wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic

material and defines an open cell configuration.” Levi also discloses this limitation.

294. Levi discloses an expandable frame formed from metal (e.g., stainless steel) that defines an open cell configuration, as shown in Figure 11 below:



Ex. 1008 (Levi) at 6:17-24, Fig. 11. As shown in Figure 1 below, the frame 12 surrounds the other components of the valve and is thus an “outer frame”:



Id. at Fig. 1.

6. Inner Frame

295. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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.

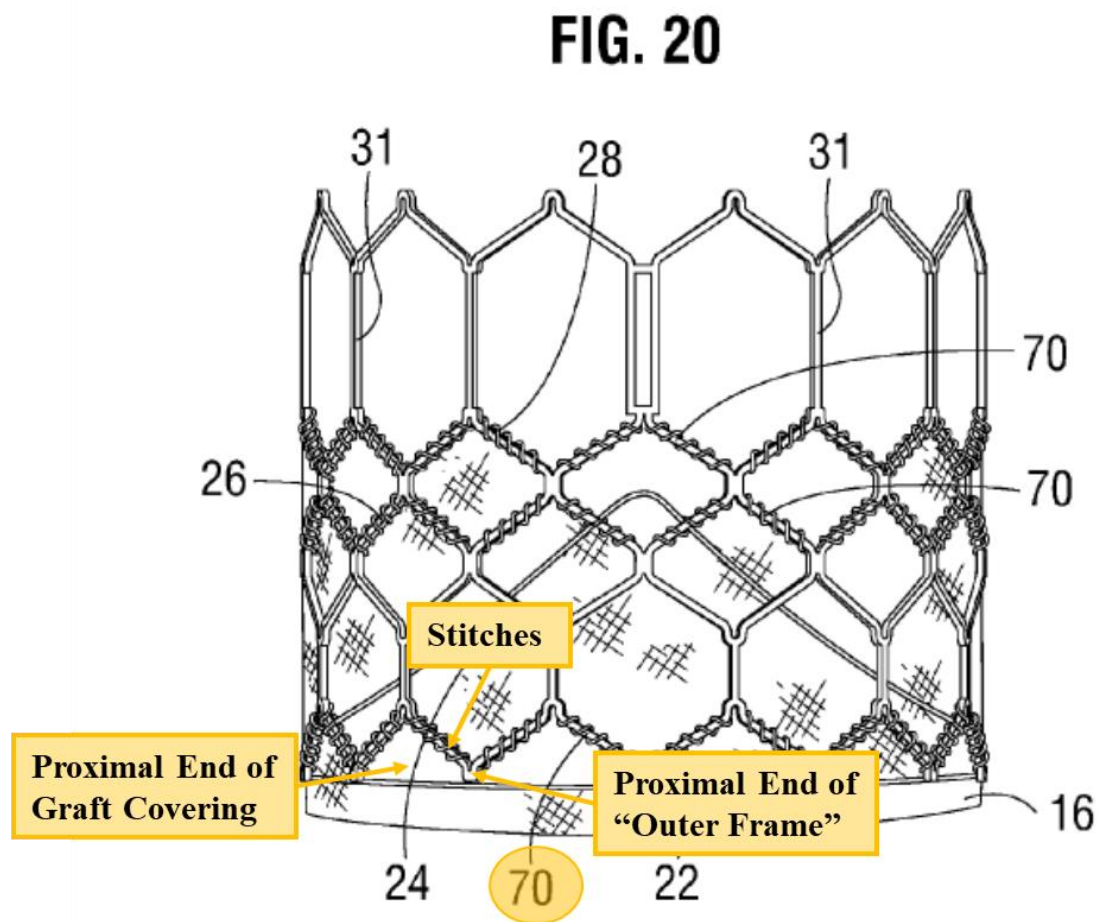
296. Levi discloses an “inner skirt 16 ... to assist in forming a good seal between the valve and the native annulus by blocking the flow of blood through

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 prosthetic heart valve. The inner skirt is constructed of “a tough, tear resistant material such as polyethylene terephthalate (PET).” *Id.* at 9:11-16. PET, for example, is a “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 at least partially radially outwardly of prosthetic valvular structure 14 [blue] and radially inwardly of the outer frame 12 [red] as illustrated in Figure 2 below:

7. Stitching

297. Claim 1 next recites: “wherein the outer frame is secured to the graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame.” Levi also discloses this limitation.

298. The proximal end of Levi’s inner skirt 16 is secured to the frame 12 via a plurality of sutures 70 at the proximal end of the frame and graft covering:



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

8. Fibrous Network

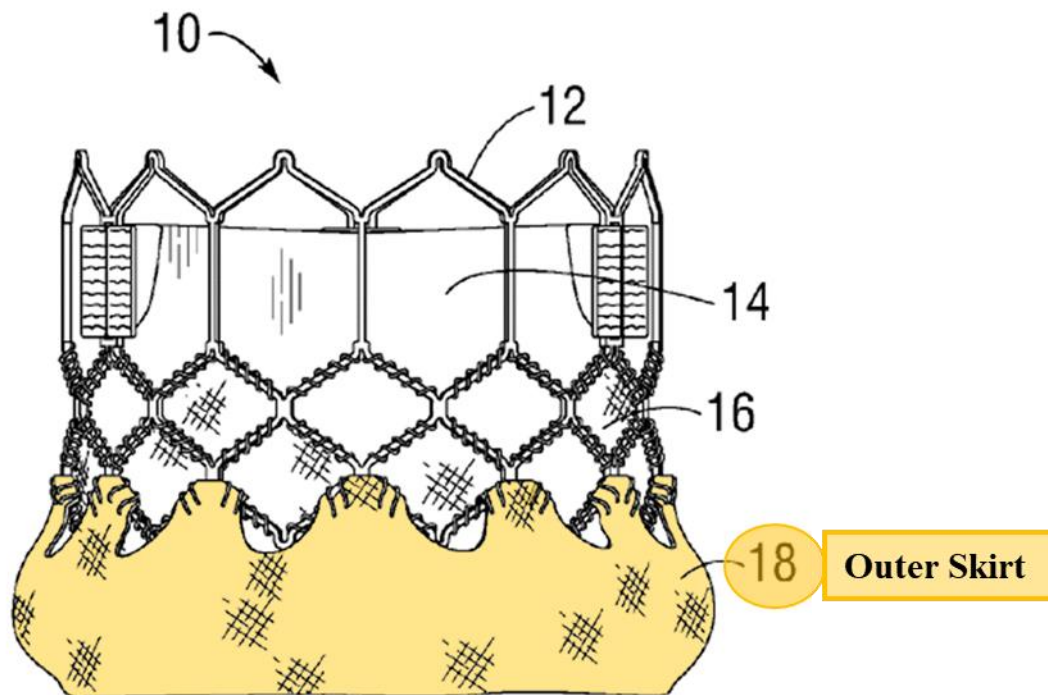
299. Claim 1 next recites: “wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame.” Levi anticipates this limitation or renders it obvious alone or with Walther or Spenser II.

a. Levi

300. Levi discloses this limitation or renders it obvious.

301. 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:

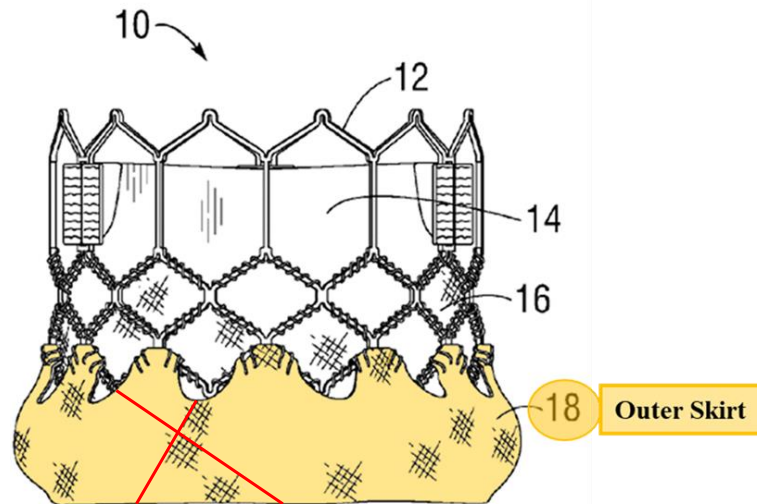
FIG. 3



Id. at Fig. 3.

302. A person of ordinary skill in the art would have understood that Levi's outer skirt formed from "woven PET fabric" is woven from a plurality of fibers, yarns, or strands. *See id.* at 9:52-56, 13:50-53. Levi's outer skirt includes checkered markings to illustrate that the outer skirt is made of woven PET threads or fibers (*see* red lines illustrating two fibers):

FIG. 3



Id. at Fig. 3. The plurality of woven fibers of Levi’s outer skirt are thus a “fibrous network” that is positioned radially outwardly of the outer frame. *See id.* at 13:62-14:2.

303. Additionally, 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 “fibrous network,” a person of ordinary skill would have nonetheless understood that Levi’s outer skirt includes a “fibrous network” composed of protruding fiber ends extending radially outwardly from the body of the outer skirt.

b. Levi and Walther or Spenser II

304. 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* §VIII.A.8.

305. 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 or Spenser II’s compressible material. Persons of ordinary skill in the art would have known that Levi’s outer skirt, Walther’s outer cloth, and Spenser II’s compressible material were interchangeable. While the specific materials have slightly different constructions, they were all designed for use with balloon-expandable heart valves to prevent paravalvular leakage and could sufficiently compensate for any elongating or foreshortening of the valve during compression and expansion. Ex. 1007 (Walther) at 1122; Ex. 1012 (Cribier) at Fig. 2 (illustrating foreshortening of SAPIEN valve); Ex. 1011 (Spenser II) at [00144];

Ex. 1008 (Levi) at 6:17-28. A person of ordinary skill in the art would have understood that a velour-like woven PET cloth or fabric, such as Walther's outer cloth or Spenser II's compressible material, would be capable of stretching to compensate for any elongation or foreshortening of the stent that occurs when it is compressed and expanded. This understanding is confirmed by Walther's finding that its cloth-covered SAPIEN demonstrated "excellent hydrodynamic performance," which conveys to a person of ordinary skill that the valve did not experience any issues with foreshortening or elongation as the valve was crimped and expanded. Ex. 1007 (Walther) at 1125. Moreover, even if Walther's outer cloth or Spenser II's compressible material were not sufficiently stretchy to accommodate the elongation and foreshortening of the valve, Levi expressly teaches how to adapt a PET fabric to address this problem. Levi teaches that the fibers that make up the fabric can be rotated such that they are non-perpendicular to the upper and lower edges of the fabric, for example at 45 degree angles relative to the upper and lower edges, which allows the fabric to "undergo greater elongation in the axial direction" as the valve is crimped and expanded. Ex. 1008 (Levi) at 9:52-10:47. Thus, to the extent Walther's outer cloth or Spenser II's compressible material presented any issues for the elongation or foreshortening of the valve, a person of ordinary skill in the art would have found it obvious to apply Levi's teachings to address those issues. A person of ordinary skill would

have been motivated to use Walther's outer cloth or Spenser II's compressible material with Levi's valve because Walther discloses that its outer cloth prevents paravalvular leakage, increases the fit between the implanted prosthetic valve and the existing valve, and promotes tissue ingrowth and Spenser II's teaches that its compressible material reduces or prevent paravalvular leakage and "may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage." See Ex. 1007 (Walther) at 1120; Ex. 1011 (Spenser II) at [00145]. Moreover, the combination of Walther's outer cloth or Spenser II's compressible material and Levi would merely entail substitution of one known element (Walther's outer cloth or Spenser II's compressible material) for another (Levi's bulging PET) to yield the predictable results of reducing paravalvular leakage.

306. The field of heart valves had a finite number of options to address paravalvular leakage in November 2012. Walther, Spenser II, and Levi disclose three such methods. A person of ordinary skill would have found it obvious to select any of these finite, predictable options and, as I explain below, would have had a reasonable expectation of success in doing so. Further, persons of ordinary skill in the art would have found it obvious to try each material because the different constructions provide unique potential advantages. As discussed above, Walther discloses that its fibrous outer cloth promotes tissue ingrowth. Ex. 1007 at 1120. Alternatively, Spenser II's compressible material "may be adapted to

encourage coagulation of blood to further fill the gaps and prevent leakage.” Ex. 1011 at [00145]. Meanwhile, Levi’s outer skirt can “bulge outwardly as the frame foreshortens” and “can fill in gaps between the frame 12 and the surrounding native annulus.” Ex. 1008 at 13:66-14:7.

307. A person of ordinary skill would have had a reasonable expectation of success in substituting Walther’s outer cloth (or a similar cloth) or Spenser II’s compressible material for Levi’s outer PET skirt. The valve frames in Walther, Spenser II, and Levi share many common features, including being balloon-expandable and formed of interconnected metal struts. See Ex. 1008 (Levi) at 6:17-24, Fig. 11; Ex. 1007 (Walther) at Fig. 1; Ex. 1011 (Spenser II) at [00145], Fig. 22. Further, 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. 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. A person of ordinary skill in the art would have understood that Levi’s valve with Walther’s outer cloth or Spenser II’s compressible material would be suitable for endovascular delivery for the reasons I provided above. *Supra* §IX.A.3.

308. Moreover, Levi suggests adding other components, like Walther's outer cloth or Spenser II's compressible material, 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 or Spenser II's compressible material would be a potential "additional component." For all of these reasons, a person of ordinary skill would have reasonably expected success in using Walther's outer cloth or Spenser II's compressible material on Levi's valve.

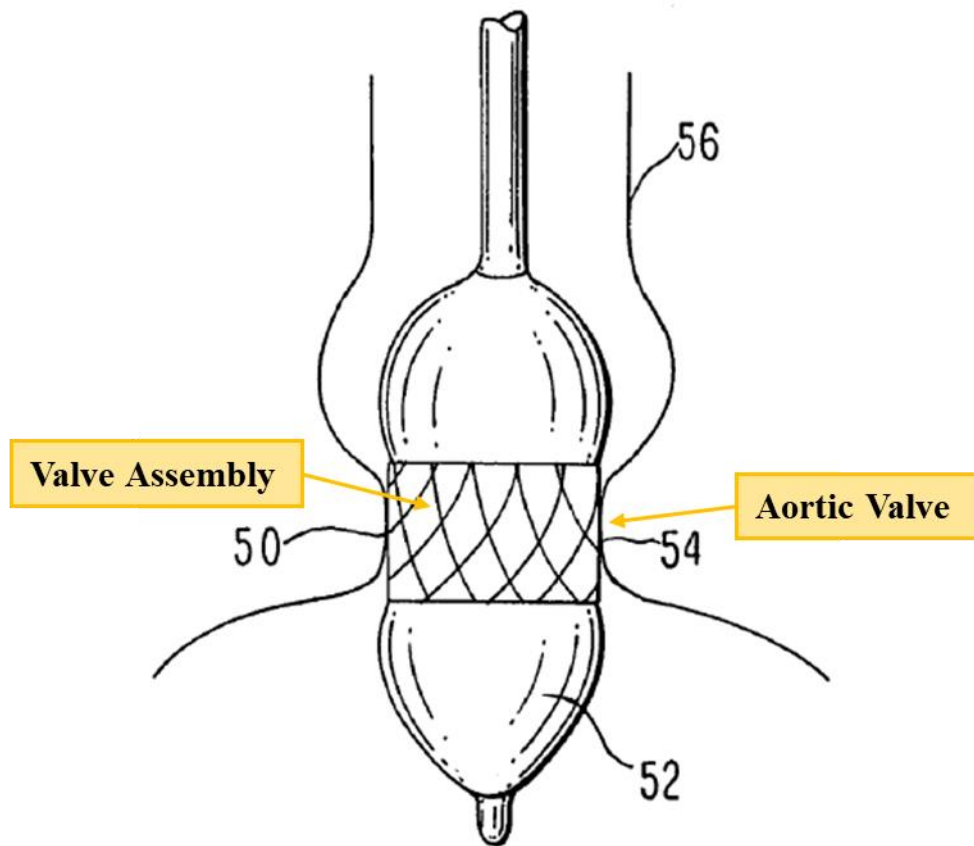
9. Overlapping Radial Alignment with Native Leaflets

309. Claim 1 next recites: "wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient." Levi also discloses this limitation.

310. Levi discloses that the valve illustrated in Figures 1-3 "is adapted to be implanted in the **native aortic annulus**" and that 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 (emphases added). As explained below, Levi discloses embodiments where the outer skirt covers at least two rows of the frame. *Infra* §IX.A.12. A person of ordinary skill in the art would understand when the outer skirt is positioned to “fills gaps between the frame 12 and the surrounding native annulus,” the outer skirt would be positioned in overlapping radial alignment with the native aortic leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.C. In fact, Patent Owner admitted this was the case during prosecution of the related ’846 patent. Patent Owner stated that the “limitation of the fibers covering at least two rows of open cells provides an improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets.” Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 25.

311. Moreover, as I explained above, Levi expressly incorporates the ’118 patent by reference, which is a parent to Spenser. *Supra* §IX.A.3. 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 Fig. 4; *see also id.* at 5:17-6:36, 17:19-18:43, Figs. 17a-17b (disclosing placement at the aortic valve); Ex. 1051 ('118 patent) at Fig. 4. As shown in figure 4, the valve is positioned in overlapping radial alignment with the patient's native aortic annulus. *Id.* at Fig. 4. Although not pictured, a person of ordinary skill in the art would understand that the valve is also positioned in overlapping radial alignment with the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. *Supra* §III.C. Because Levi incorporates the '118 Patent by reference, a person of ordinary skill in the art would understand that Levi's valve may also be endovascularly implanted using

the technique taught by Spenser and the '118 patent, and would thus be similarly positioned in overlapping radial alignment with the patient's native aortic leaflets.

312. As I explain below, if Levi's outer skirt were replaced with Walther's outer cloth or Spenser II's compressible material Walther's outer cloth, and Spenser II's outer compressible material would cover at least the two proximal rows of Levi's outer frame. *Infra* §IX.A.12. As illustrated by Figure 4 and understood by a person of ordinary skill in the art, positioning Levi's valve across the patient's native aortic valve as taught in Spenser and the '118 patent would cause at least a portion of the proximal two rows of Levi's outer frame to radially overlap the patient's native aortic leaflets. Thus, Levi's outer skirt, Walther's outer cloth, and Spenser II's outer compressible material would radially overlap with the patient's native aortic leaflets during endovascular delivery for the same reasons I provided in Grounds 1-4. *Supra* §§VI.A.9, VIII.A.9.

10. Inflating a Balloon Assembly

313. Claim 1 next recites: "inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation." Levi, Walther, and Spenser II disclose this limitation.

314. 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 or equivalent expansion mechanism.” Ex. 1008 (Levi) at 6:17-28. Thus, Levi teaches expanding a balloon assembly to expand its valve from a compressed state to an expanded state.

315. 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].

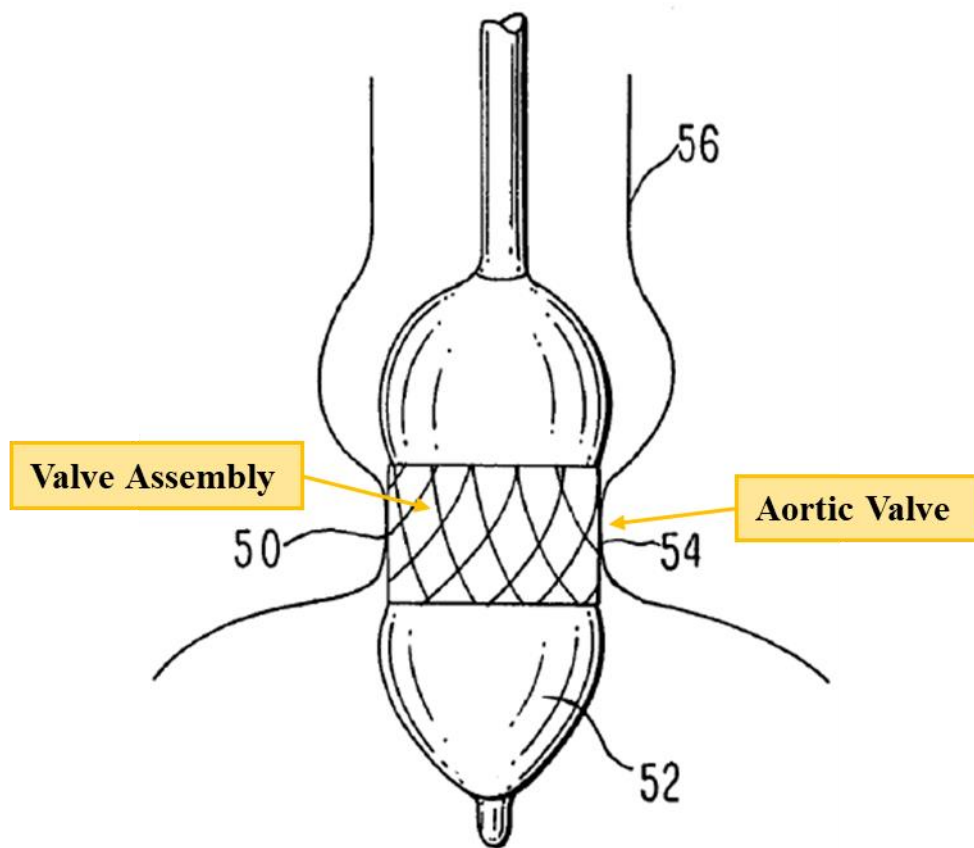
11. Fibrous Network Seals

316. Claim 1 next recites: “wherein the fibrous network seals against the native valve leaflets of the patient, the outer frame, and the graft covering in response to compression from inflation of the balloon assembly.” Levi anticipates this limitation or renders it obvious alone or with Walther or Spenser II.

317. Levi discloses that the valve illustrated in Figures 1-3 “is adapted to be implanted in the *native aortic annulus*” and that 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 (emphases added). The outer skirt thus seals against the outer frame and the graft covering of the valve to

form a “good fluid-tight seal between the valve and the native annulus.” *Id.* A person of ordinary skill in the art would also understand when the outer skirt “fills gaps between the frame 12 and the surrounding native annulus,” the outer skirt would press against and seal the native aortic leaflets, which are attached to the native annulus and extend distally therefrom. *Supra* §III.C. Indeed, during prosecution of the related ’846 patent, Patent Owner admitted that Levi’s outer skirt would “extend[] into crevices by the native leaflets” when implanted in a patient. Ex. 1046 (Preliminary Amendment for Patent Application No. 17,096,253) at 21.

318. Moreover, as I explained above, Levi expressly incorporates the ’118 patent by reference, which is a parent to Spenser. *Supra* §IX.A.3. 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 Fig. 4; *see also id.* at 5:17-6:36, 17:19-18:43, Figs. 17a-17b (disclosing placement at the aortic valve). As shown in figure 4, the valve presses against the patient's native aortic annulus. *Id.* at Fig. 4. Although not pictured, a person of ordinary skill in the art would understand that the valve also presses against the patient's native aortic leaflets, which are attached to the annulus and extend distally therefrom. *Supra* §III.C. Because Levi incorporates the '118 Patent by reference, a person of ordinary skill in the art would understand that Levi's valve may also be endovascularly implanted using the technique taught by

Spenser, and would thus similarly press the valve against the patient's native aortic leaflets.

319. As I explain below, Levi's outer skirt, Walther's outer cloth, and Spenser II's outer compressible material would cover at least the two proximal rows of Levi's outer frame. *Infra* §IX.A.12. As illustrated by Figure 4 and understood by a person of ordinary skill in the art, expanding Levi's valve would cause at least a portion of the proximal two rows of the outer frame to press against and seal the patient's native aortic leaflets. Thus, expansion of Levi's valve would cause Levi's outer skirt, Walther's outer cloth, or Spenser II's outer compressible material to seal against the native aortic leaflets of the patient.

320. Levi further discloses that the outer skirt "cooperates with the inner skirt to avoid [PVL] after implantation of the valve[.]" Ex. 1008 (Levi) at 14:3-14. Thus, the outer skirt seals against the outer frame and graft covering to prevent blood from leaking through the valve. *Id.* If the outer skirt did not form a seal with the leaflets, blood could leak around the device. Indeed, because the outer skirt is attached to the exterior surface of the frame, the outer skirt would press against and seal the metal bars of the frame when compressed against the patient's native tissue. Similarly, the outer would seal against Levi's inner PET skirt through the open cells formed in the outer frame to "cooperate[] with the inner skirt to avoid [PVL] after implantation of the valve[.]" *Id.*

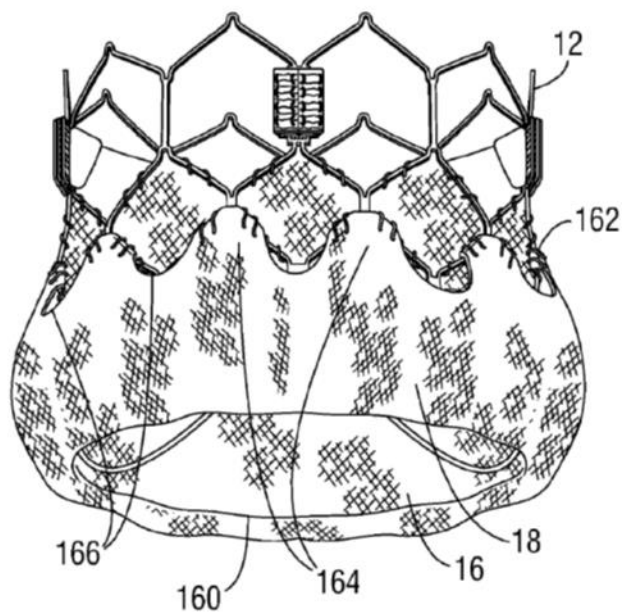
321. As I explained in Grounds 1-4, Walther's outer cloth and Spenser II's compressible material also form a seal against the native valve leaflets, outer frame, and graft covering in response to compression from inflation of the balloon assembly. *Supra* §§VI.A.11, VIII.A.11. If Walther's outer cloth or Spenser II's compressible material replaced Levi's outer skirt, the outer cloth/compressible material would continue to seal against these features. Persons of ordinary skill in the art would have been motivated to add the outer cloth/compressible material to Levi's frame in the same way the materials were added to the original valves so that the seals covered the same amount of Levi's valve because Walther and Spenser II teach that such positioning is effective at creating the seals. Thus, the outer cloth/compressible material would seal in the same way when added to Levi's valve. *Supra* §§VI.A.11, VIII.A.11.

12. Two Rows of Grids

322. Claim 1 concludes by reciting: "wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration." Levi anticipates this limitation or renders it obvious alone or with Walther or Spenser II.

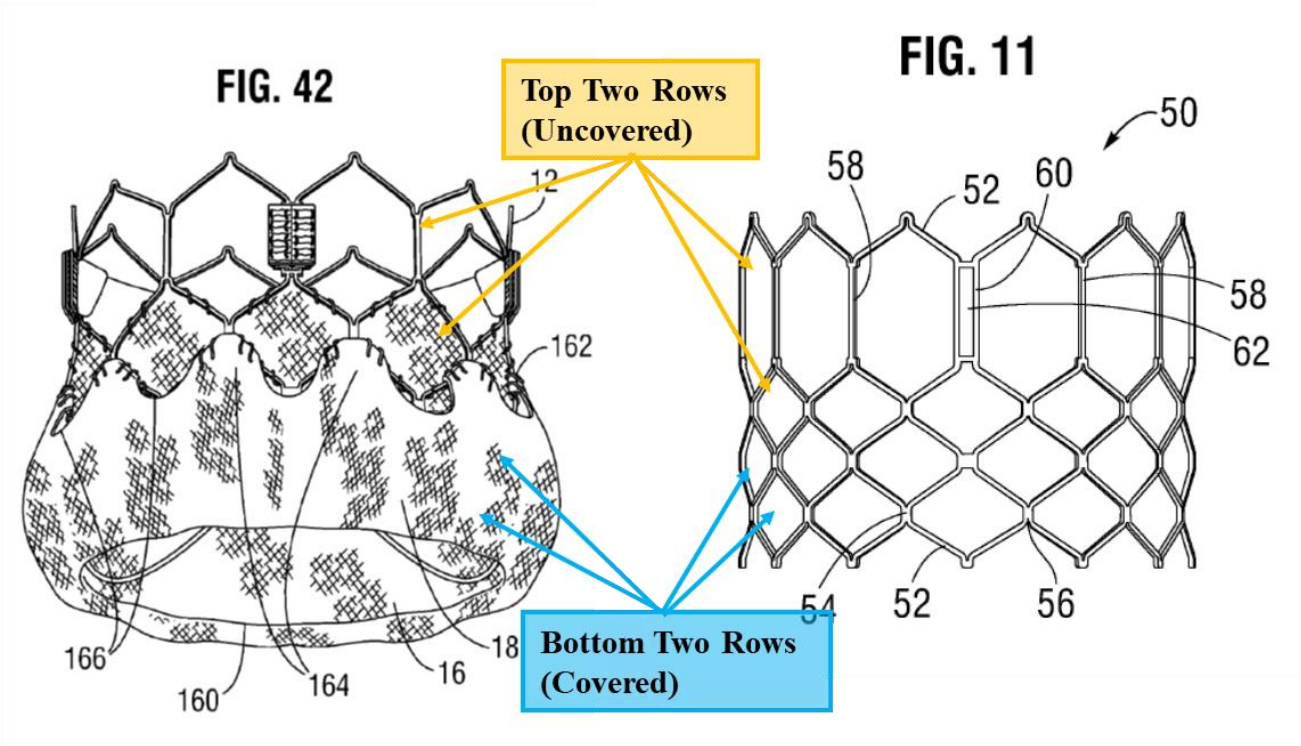
323. Figure 42 of Levi below shows that the outer skirt covers the bottom two rows of open cells formed by the outer frame:

FIG. 42



Ex. 1008 (Levi) at Fig. 42.

324. The side-by-side comparison of Figures 11 and 42 of Levi below confirms that the outer skirt in Figure 42 covers at least two rows of the gridded configuration:



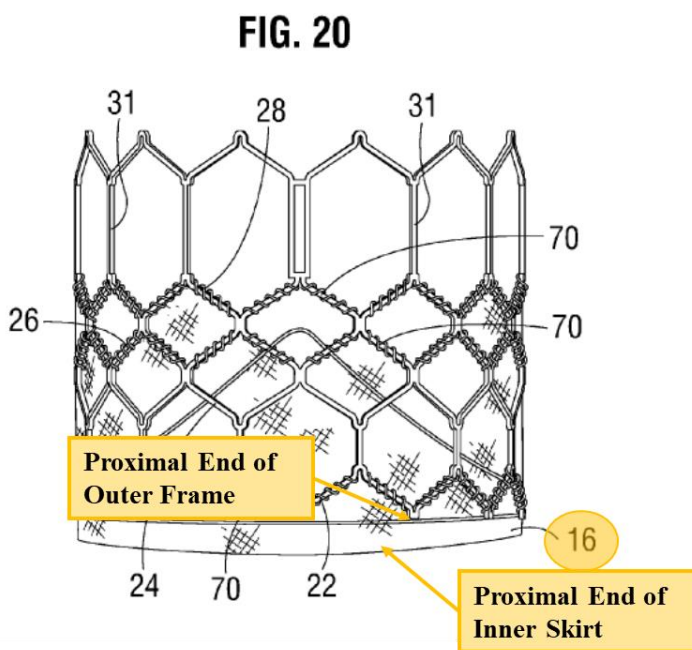
Compare *id.* at Fig. 42 with *id.* at Fig. 11.

325. Alternatively, Walther and Spenser II disclose this limitation. Both Walther and Spenser II disclose a sealing material that covers the bottom two rows of grids formed by the stent frame. Ex. 1007 (Walther) at 1121, Fig. 1; Ex. 1011 (Spenser II) at [00145], Fig.22; *supra* §§VI.A.12, VIII.A.12. A person of ordinary skill in the art would have been motivated to attach Walther's outer cloth or Spenser II's outer compressible material to Levi's outer frame in the same way, and expected success in doing so, because the references demonstrate that covering the bottom two rows is effective at creating a seal. The combined device would therefore include fibers covering the bottom two rows of cells formed by Levi's outer frame.

B. Claim 2

326. Claim 2 recites: “The method of claim 1, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.” Levi anticipates this claim or renders it obvious alone or with Walther or Spenser II.

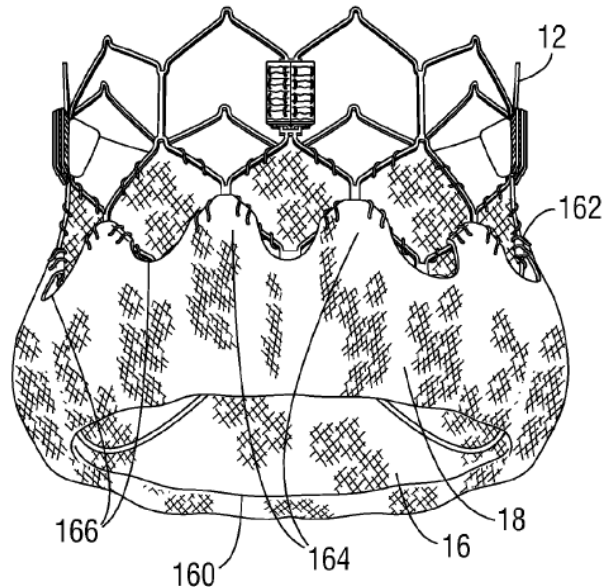
327. Levi discloses an inner PET skirt sutured to the interior surface of the stent frame. *Supra* §VIII.A.3. As shown in Figure 20 below, the lower edge of Levi’s inner skirt extends beyond the proximal end of the outer frame:



Ex. 1008 (Levi) at Fig. 20.

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

FIG. 42



Id. at Fig. 42. Because the inner skirt extends beyond the proximal end of the outer frame, a person of ordinary skill in the art would have understood that the attachment of the skirts necessarily causes the lower edge of the inner skirt 16 to extend over the proximal end of the outer frame to cover the proximal end of the outer frame. This is particularly true when the outer skirt bulges outwardly from blood flow and pulls the proximal portion of the inner skirt over the distal end of the frame. Thus, Levi discloses this limitation.

329. Alternatively, persons of ordinary skill in the art would have found it obvious to extend Levi's inner skirt over the proximal end of the frame to cover the proximal end. Levi discloses that the "upper edge portion [distal] of the [inner] skirt is wrapped around the upper surfaces of struts 28 and secured in place with sutures 70." *Id.* at 10:12-26, Fig. 20. Levi teaches that this wrapping

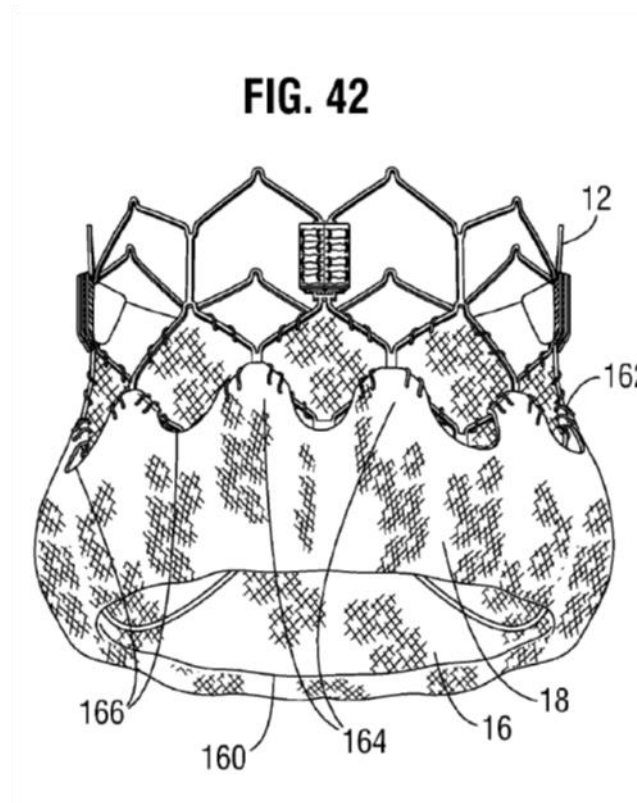
“provides for a stronger and more durable attachment of the skirt to the frame.” *Id.*, 10:26-28. A person of ordinary skill in the art would have been motivated to apply this same technique to the lower (proximal) edge of the inner skirt to create a stronger attachment between the inner skirt and frame. Indeed, because the inner skirt extends beyond the proximal end of the frame, persons of ordinary skill in the art would have found it obvious to wrap Levi’s inner skirt over the proximal end and secure the inner skirt to the outside of the frame using this wrapping technique. Persons of ordinary skill in the art would have expected success in attaching the inner skirt in this way because Levi already discloses that it was successful for the distal end of the skirt. In this configuration, persons of ordinary skill in the art would have recognized that the outer skirt could still be stitched to the inner skirt. Thus wrapping the proximal end of Levi’s inner skirt around the outer frame would not compromise Levi’s outer skirt and, because the inner skirt is made of a thin material, would not have significantly affected the valve’s crimped profile.

C. Claim 3

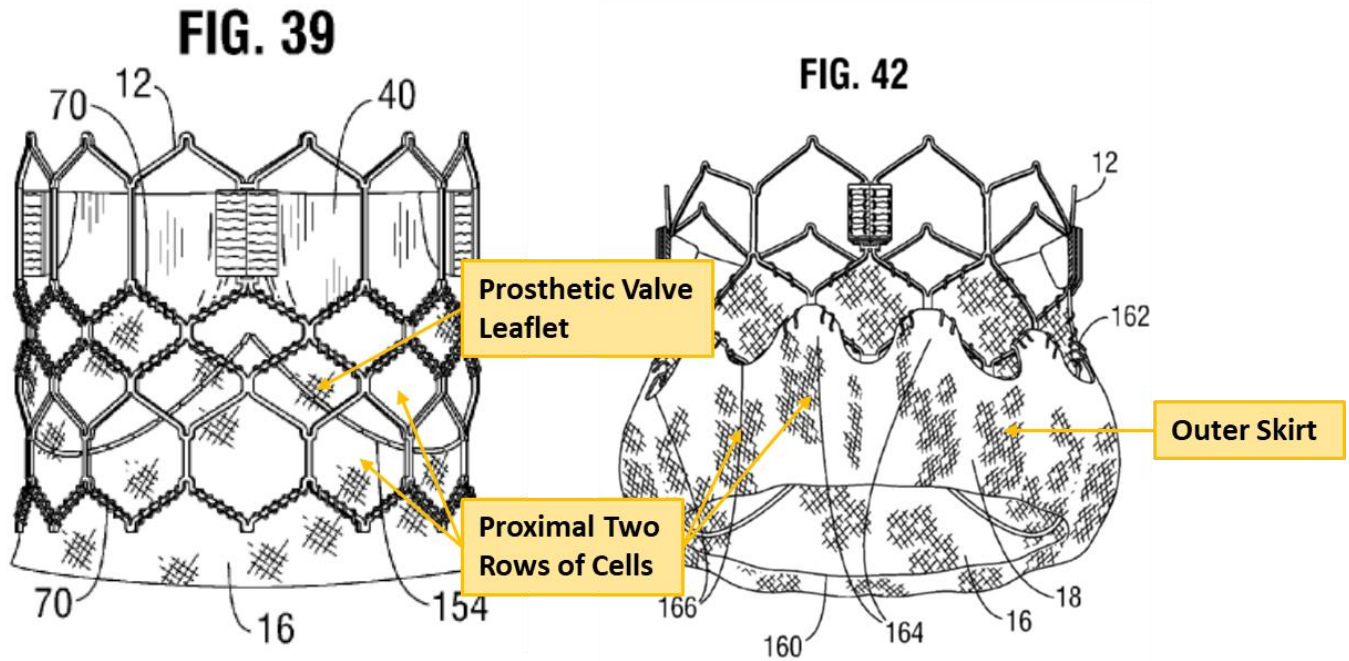
330. Claim 3 recites: “The method of claim 2, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” Levi

discloses the limitations in claim 3 and anticipates claim 3 or renders claim 3 obvious alone or in combination with Walther or Spenser II.

331. Figure 42 of Levi (below) shows that the outer skirt may cover the bottom two rows of open cells formed by the outer frame:



Ex. 1008 (Levi) at Fig. 42. A side-by-side comparison of Figures 39 and 42 confirms that the proximal two rows of cells covered by the outer skirt in Figure 42 radially overlap with the prosthetic valve leaflets based on Patent Owner's arguments regarding Figure 11 and "radially overlaps" during prosecution (*supra* §VII.B):



Compare *id.* at Fig. 39 with *id.* at Fig. 42. Levi teaches that suture line 154 connects the valve leaflets to the inner skirt. *Id.* at 13:33-35. As shown in Figure 39, suture line 154 radially overlaps with the bottom two rows of grids. *Id.* at Fig. 39. Because the leaflets must extend down into the valve at least to suture line 154, and a person of ordinary skill in the art would understand that the leaflets radially overlap with the outer skirt.

332. Alternatively, Walther and Spenser II disclose this limitation. Both references disclose a sealing material that covers the bottom two rows of grids formed by the stent frame, which radially overlap with the prosthetic leaflets. Ex. 1007 (Walther) at 1121, Fig. 1; Ex. 1011 (Spenser II) at [00145], Fig.22; *supra* §VIII.C. A person of ordinary skill in the art would have been motivated to attach Walther's outer cloth or Spenser II's compressible material to Levi's outer frame

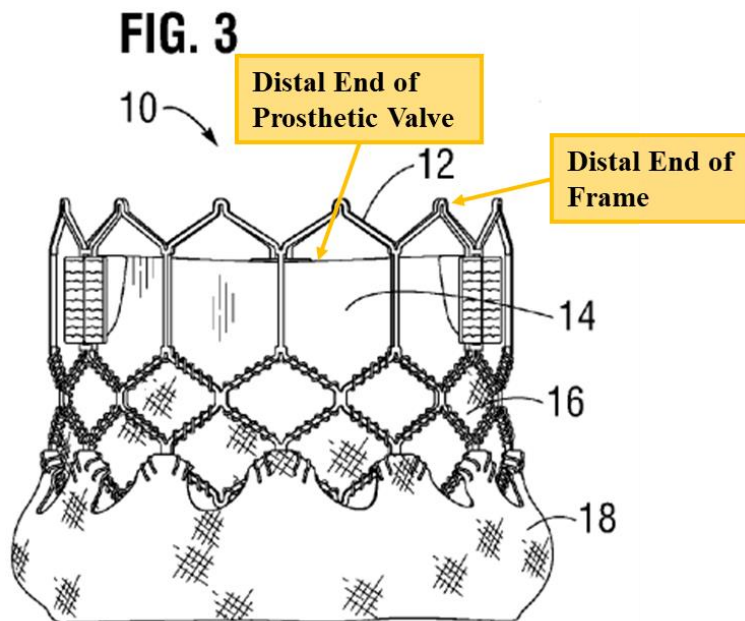
in the same way, and expected success in doing so, because the references demonstrate that covering the bottom two rows is effective at creating a seal. The combined device would include fibers covering the bottom two rows of cells formed by Levi's outer frame, which radially overlap with the prosthetic leaflets as I explained above.

D. Claim 4

333. Claim 4 recites: "The method of claim 3, wherein the outer frame extends distally further than the prosthetic heart valve." Levi discloses the limitations in claim 4 and anticipates claim 4 or renders claim 4 obvious alone or in combination with Walther or Spenser II.

334. Levi discloses a prosthetic heart valve having a radially compressible and expandable stent frame. Ex. 1008 (Levi) at 6:17-20, 6:31-40. Levi discloses that "the inflow and outflow ends of a frame generally tend to over-expand more so than the middle portion of the frame due to the 'dog boning' effect of the balloon used to expand the valve." *Id.* at 8:8-11. "To protect against over-expansion of the leaflet structure 14," Levi teaches that the "***leaflet structure desirably is secured to the frame 12 below the upper row of struts 32.***" *Id.* at 8:11-13 (emphasis added). Levi teaches that this configuration helps ensure that the leaflets do not "protrude outwardly beyond the outflow end of the frame when the valve is crimped," protecting the leaflets from damage that may be caused by a

“pushing mechanism or stop member [of the balloon catheter] that pushes against or abuts the outflow end of the valve.” *Id.* at 8:21-39. When the leaflet structure is secured to the frame below the upper row of struts, as in Figure 3 below, the frame 12 extends distally further than the prosthetic valve 14:



Id. at Fig. 3.

E. Claim 5

335. Claim 5 recites: “The method of claim 3, wherein the outer frame is a singular, integral component.” Levi discloses the limitations in claim 5 and anticipates claim 5 or renders claim 5 obvious alone or in combination with Walther or Spenser II.

336. Levi discloses that its outer frame “comprises multiple rows of circumferentially extending, angled struts 52 [yellow] that are connected to each

other at nodes, or connecting portions, 54 and 56 [blue].” Ex. 1008 (Levi) at 8:61-64. Levi further discloses that “[t]he uppermost row of struts 52 are connected to an adjacent row of struts by a plurality of axially extending struts 58 [red] and commissure window frame portions 60 [red].” *Id.* at 8:64-67. Levi’s Figures 11-12 illustrate the outer frame:

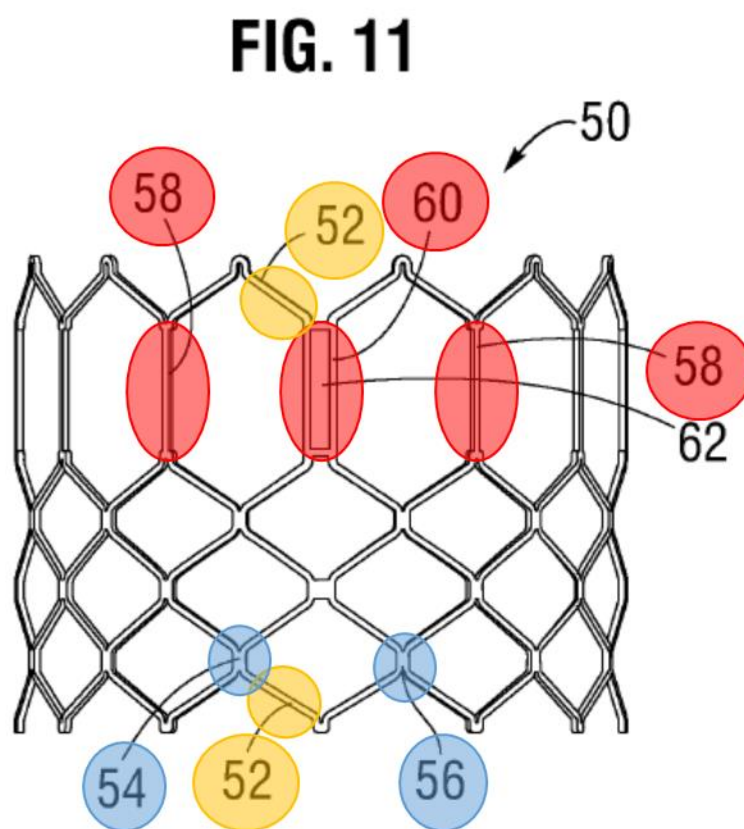
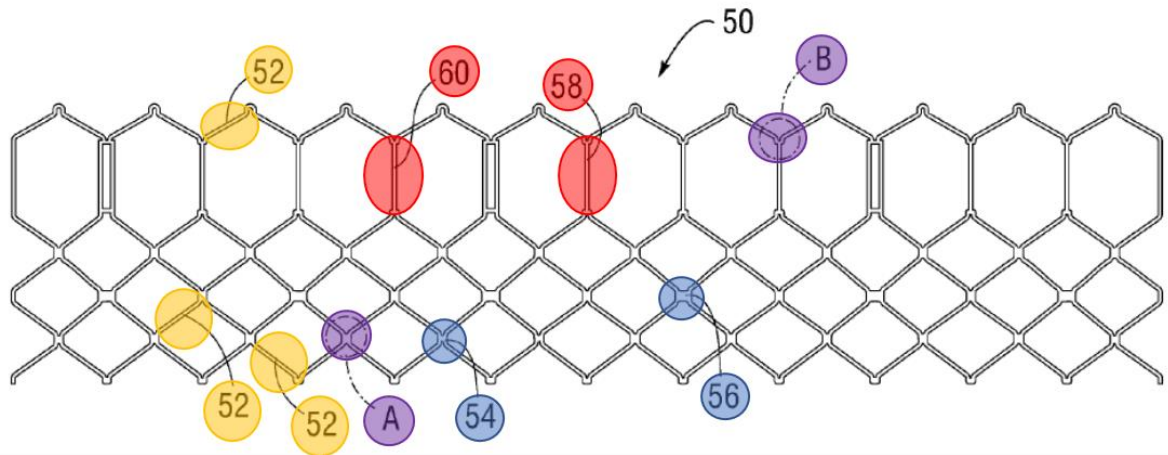


FIG. 12



Id. at Figs. 11, 12.

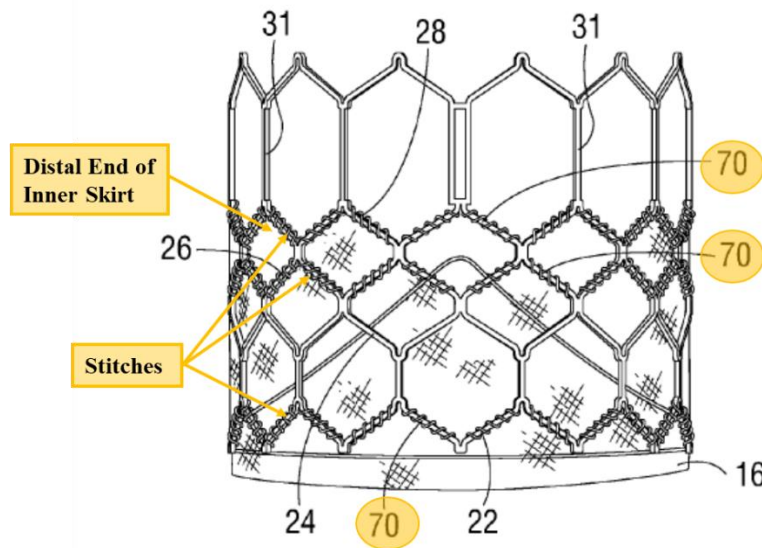
337. Because all of the metallic bars of the outer frame are interconnected, as shown in the figures above, the outer frame is a singular, integral component. *See id.* at 6:50-7:17, 9:4-6, Figs. 4-10, 13-14.)

F. Claim 6

338. Claim 6 recites: “The method of claim 3, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering.” Levi discloses the limitations in claim 6 and anticipates claim 6 or renders claim 6 obvious alone or in combination with Walther or Spenser II.

339. As shown in Figure 20 below, Levi teaches that sutures 70 secure the inner skirt to the frame 12 using a plurality of stitches at the distal (i.e., top) and proximal (i.e., bottom) ends of the inner skirt:

FIG. 20



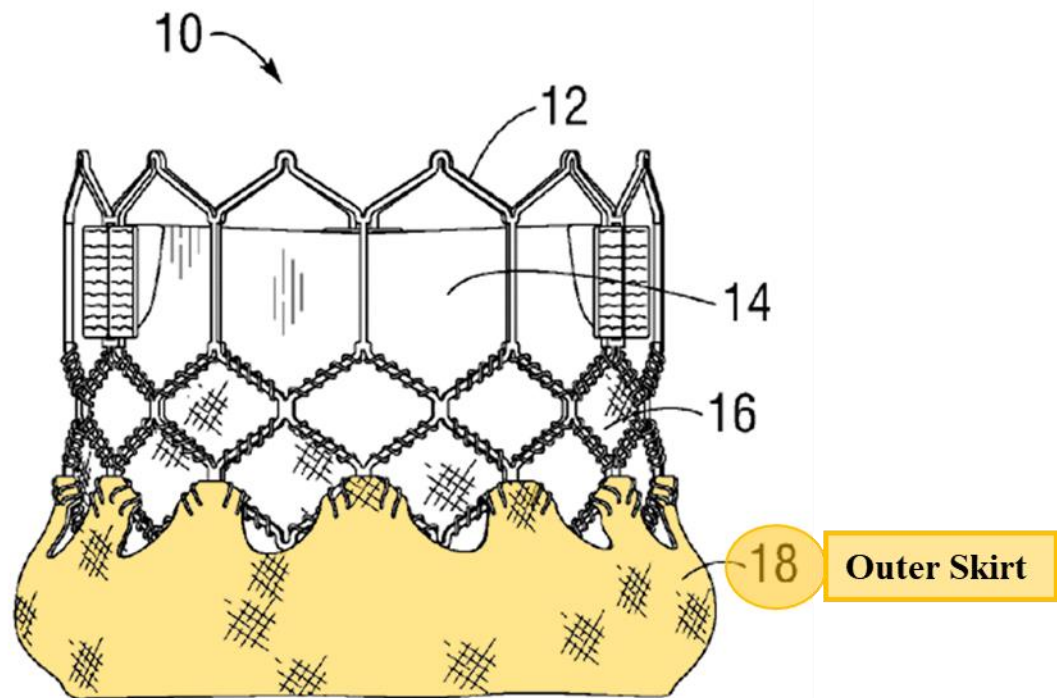
Ex. 1008 (Levi) at 9:24-25, 10:11-30, Figs. 20, 39.

G. Claim 7

340. Claim 7 recites: “The method of claim 3, wherein a portion of a length of a fiber of the fibrous network is arcuate.” Levi discloses the limitations in claim 7 and anticipates claim 7 or renders claim 7 obvious alone or in combination with Walther or Spenser II.

341. As I explained in claim 1, Levi’s outer skirt, which is comprised of a plurality of woven PET fibers, discloses a fibrous network. *Supra* §IX.A.8. A person of ordinary skill in the art would understand that a portion of a length of the fibers of Levi’s outer skirt are arcuate because the outer skirt has a generally curved, bulging shape as shown in Figure 3:

FIG. 3



Ex. 1008 (Levi) at Fig. 3.

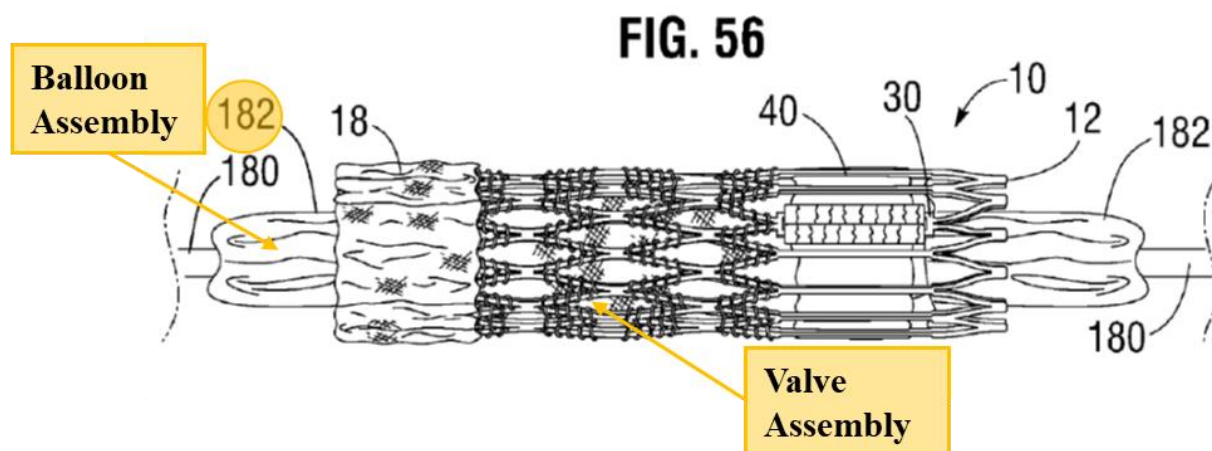
342. Alternatively, Walther's outer PET cloth and Spenser II's outer compressible material disclose arcuate fibers for the reasons I provided in Grounds 2-4. *Supra* §§VII.E, VIII.G. A person of ordinary skill in the art would have been motivated to use Walther's outer cloth or Spenser II's outer compressible material on Levi's valve with a reasonable expectation of success for the reasons I provided explained in claim 1. *Supra* §IX.A.8.

H. Claim 8

343. Claim 8 recites: "The method of claim 1, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the

valve assembly is in the radially compressed orientation.” Levi discloses the limitations in claim 8 and anticipates claim 8 or renders claim 8 obvious alone or in combination with Walther or Spenser II.

344. Levi’s Figure 56 illustrates the prosthetic valve assembly “mounted in a radially collapsed configuration for delivery into the body.” Ex. 1008 (Levi)_ at 14:18-19. “The shaft 180 comprises an inflatable balloon 182 for expanding the balloon within the body, *the crimped valve 10 being positioned over the deflated balloon.*” *Id.* at 14:19-22 (emphasis added). As shown below, the balloon assembly 182 is positioned “radially inwardly” of the valve assembly 10:



See *id.* at Fig. 56

I. Claim 9

345. Claim 9 recites: “The method of claim 1, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” Levi in combination with Walther renders claim 9 obvious.

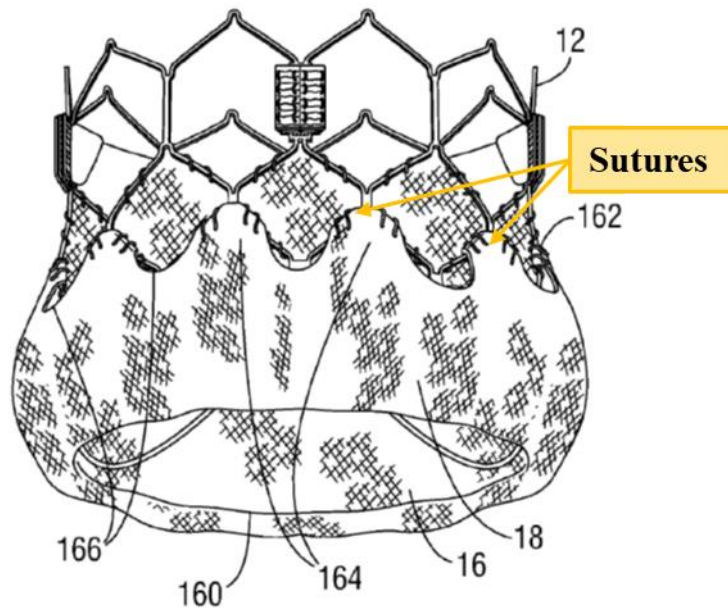
346. Walther's outer cloth includes fibers extending radially inwardly of the outer frame for the reasons I provided in Ground 1. *Supra* §VI.C. Therefore, when Walther's outer cloth is added to Levi's valve, at least some of the fibers of the outer cloth would extend radially inwardly of Levi's outer frame, as they do in Walther.

J. Claim 10

347. Claim 10 recites: "The "method of claim 1, wherein the fibrous network includes fibers directly engaged with the outer frame." Levi discloses the limitations in claim 10 and anticipates claim 10 or renders claim 10 obvious alone or in combination with Walther or Spenser II.

348. Levi discloses that the outer skirt (i.e., fibers) is sutured to the outer stent frame, as shown in Figure 42 below:

FIG. 42



Ex. 1008 (Levi) at 13:58-61, Fig. 42. Thus, because the fibers of the outer skirt are sutured directly to the metal bars of the outer frame, Figure 42 includes fibers that are “directly engaged with the outer frame.”

349. Alternatively, Levi in combination with Walther or Spenser II discloses this limitation. Walther’s outer cloth and Spenser II’s outer compressible material are directly engaged with their respective outer frames. *Supra* §§VI.C, VIII.I. A person of ordinary skill in the art would have been motivated to add Walther’s outer cloth or Spenser II’s compressible material to Levi’s support frame in the same way (e.g., by suturing) because Levi describes this method of attachment and suturing is simple and known to persons of

ordinary skill in the art. A person of ordinary skill in the art would have expected success in stitching Walther's outer cloth or Spenser II's compressible material to Levi's support stent for the reasons explained in claim 1. *Supra* §IX.A.8. Therefore, the combination of Levi with Walther's outer cloth or Spenser II's compressible material would include fibers directly engaged with the outer frame.

K. Claim 11

350. Claim 11 recites:

11. A method of implanting a transcatheter aortic valve assembly, comprising:

 endovascularly positioning a guide wire through the aortic valve of a patient;

 endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient, wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation,

 wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration,

 wherein the transcatheter aortic valve assembly includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending 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 graft covering by stitching at a proximal end of the graft covering and at a proximal end of the outer frame,

 wherein the transcatheter aortic valve assembly includes a fibrous network positioned at least partially radially outwardly of the outer frame,

 wherein the transcatheter aortic valve is positioned so that the fibrous network of the transcatheter aortic valve assembly is in overlapping radial alignment with native valve leaflets of the patient;

inflating a balloon assembly to expand the transcatheter aortic valve assembly from the radially compressed orientation into the radially expanded orientation,

wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,

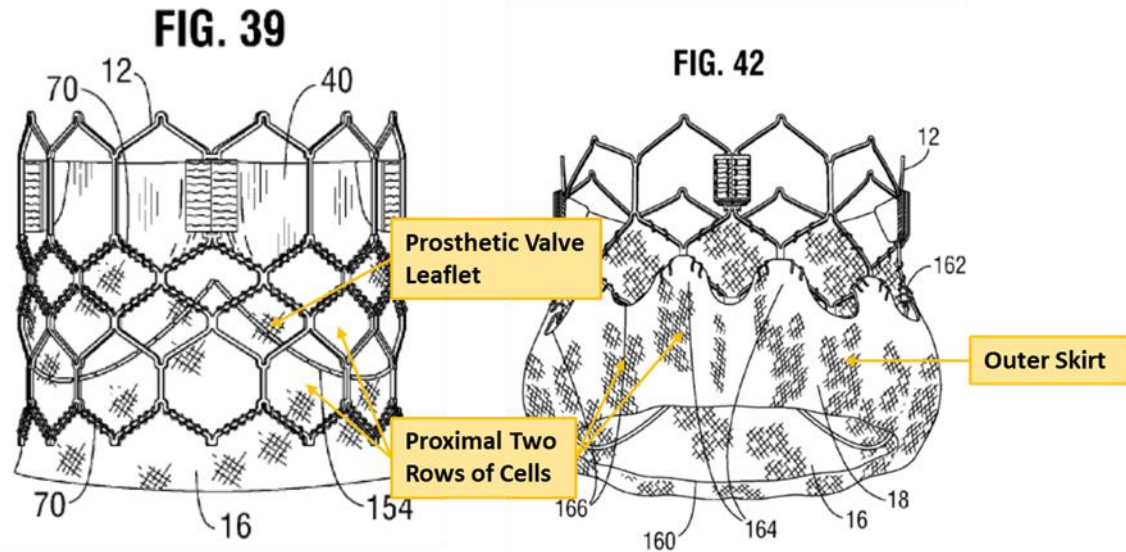
wherein the fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration.

351. Thus, claim 11 is an independent claim that mirrors the limitations recited in claim 1 with a single exception. Claim 11 recites “wherein the fibrous network seals against the aortic valve assembly outwardly of the prosthetic leaflets,” whereas claim 1 recites that the fibrous network seals against the patient’s native leaflets, the outer frame, and the graft covering. Levi anticipates this claim or renders it obvious alone or with Walther or Spenser II.

1. Fibrous Network Seal

352. Levi anticipates this limitation or renders it obvious alone or with Walther or Spenser II.

353. As I explained in claim 1, Levi’s outer skirt, Walther’s fibrous outer cloth, and Spenser II’s compressible material would seal against the outer frame and PET graft covering of Levi’s valve. *Supra* §IX.A.11. As shown below, the frame and inner graft covering are outward of the prosthetic leaflets, as would any skirt, cloth, or material added to the frame’s exterior:



Ex. 1008 (Levi) at Figs. 39, 42. Therefore, the fibrous network formed by Levi's outer skirt, Walther's outer cloth, or Spenser II's compressible material would seal against the aortic valve assembly outwardly of the prosthetic leaflets.

2. Remaining Limitations

354. Levi anticipates or renders obvious the remaining limitations of claim 11 alone or with Walther or Spenser II for the reasons I provided in claim 1. *Supra* §IX.A.

L. Claim 12

355. Claim 12 recites: "The method of claim 11, wherein the graft covering extends beyond the proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame." This limitation also appeared in claim 2. Thus, Levi anticipates this claim or renders it obvious alone

or in combination with Walther or Spenser II for the reasons I provided in claims 2 and 11. *Supra* §§IX.B, IX.J.

M. Claim 13

356. Claim 13 recites: “The method of claim 12, wherein the fibrous network that extends over at least two circumferentially extending rows of grids formed in the open cell configuration radially overlaps with the prosthetic leaflets.” This limitation also appeared in claim 3. Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 3 and 12. *Supra* §§IX.C, IX.K.

N. Claim 14

357. Claim 14 recites: “The method of claim 13, wherein the outer frame extends distally further than the prosthetic heart valve.” This limitation also appeared in claim 4. Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 4 and 13. *Supra* §§IX.D, IX.L.

O. Claim 15

358. Claim 15 recites: “The method of claim 13, wherein the outer frame is a singular, integral component.” This limitation also appeared in claim 5. Thus, Levi anticipates this claim or renders it obvious alone or in combination with

Walther or Spenser II for the reasons I provided in claims 5 and 13. *Supra* §§IX.E, IX.L.

P. Claim 16

359. Claim 16 recites: “The method of claim 13, wherein the outer frame and the graft covering are attached by stitches at a distal end of the graft covering.” This limitation also appeared in claim 6. Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 6 and 13. *Supra* §IX.F, IX.L.

Q. Claim 17

360. Claim 17 recites: “The method of claim 13, method of claim 13, wherein a portion of a length of a fiber of the fibrous network is arcuate.” This limitation also appeared in claim 7. Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 7 and 13. *Supra* §§IX.G, IX.L.

R. Claim 18

361. Claim 18 recites: “The method of claim 11, wherein the balloon assembly is radially inwardly of the transcatheter aortic valve assembly when the valve assembly is in the radially compressed orientation.” Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 8 and 11. *Supra* §IX.H, IX.L.

S. Claim 19

362. Claim 19 recites: “The method of claim 11, wherein the fibrous network includes fibers extending radially inwardly from the outer frame.” This limitation also appeared in claim 9. Thus, Levi in combination with Walther renders this claim obvious for the reasons I provided in claims 9 and 11. *Supra* §IX.I, IX.K.

T. Claim 20

363. Claim 20 recites: “The method of claim 11, wherein the graft wherein the fibrous network includes fibers directly engaged with the outer frame.” This limitation also appeared in claim 10. Thus, Levi anticipates this claim or renders it obvious alone or in combination with Walther or Spenser II for the reasons I provided in claims 10 and 11. *Supra* §IX.I, IX.L.

X. SECONDARY CONSIDERATIONS

364. I am not aware of any secondary considerations of nonobviousness. I understand that Patent Owner does not practice the '538 patent. For example, I am not aware of any products sold by Patent Owner that would be covered by the '538 patent and, therefore, I am not aware of any commercial success.

365. Further, given that the devices claimed in the '538 patent are not new, and were invented long before November 2012, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching

away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

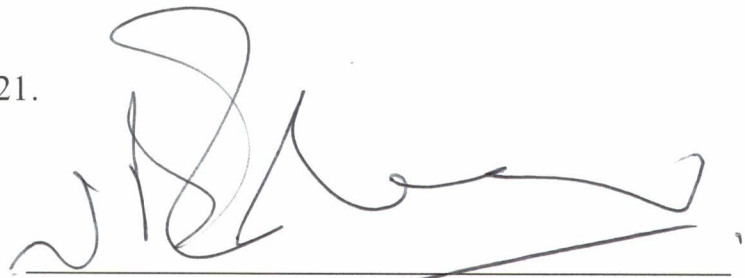
XI. CONCLUSION

366. For the foregoing reasons, it is my opinion that claims 1-20 of the '538 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.

367. 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.

368. 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: November 12, 2021.



Dr. Nigel Buller, M.D.