

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION AND  
EDWARDS LIFESCIENCES LLC,  
Petitioner,

v.

AORTIC INNOVATIONS LLC,  
Patent Owner.

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Case IPR2021-01527  
Patent 10,792,172

Case IPR2021-01584  
Patent 10,857,011

Case IPR2022-00034  
Patent 10,966,846

Case IPR2022-00193  
Patent 10,881,538

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**EXHIBIT 2051**

**SECOND DECLARATION OF DR. STEPHEN J.D. BRECKER**

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## I. INTRODUCTION

1. My name is Stephen J.D. Brecker. I have been retained as an expert witness to provide my independent opinion in regard to the matters at issue in *inter partes* review in the following cases involving these patents: IPR2021-01527 reviewing U.S. Patent No. 10,792,172 (the “’172 patent”); IPR2021-01584 reviewing U.S. Patent No. 10,857,011 (the “’011 patent”); IPR2022-00034 reviewing US Patent No. 10,966,846 (the “’846 patent”); IPR2022-00193 reviewing US Patent No. 10,881,538 (the “’538 patent”). Collectively, I refer to these patents as the “AI Patents.” I have been retained by Aortic Innovations LLC (“Aortic Innovations”), the Patent Owner in the above proceedings. Petitioner is Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively “Edwards” or “Petitioner”).

2. I am being compensated GB£625.00 per hour for my time spent working in connection with this case. My compensation is in no way related to the outcome of this litigation. If called as a witness, I would testify as to the statements and opinions contained in this report.

3. I am not a legal expert and offer no opinions on the law. However, I have been informed by counsel of the various legal standards that apply, and I have applied those standards in arriving at my conclusions.

## II. QUALIFICATIONS

4. I am an interventional cardiologist with a special interest in adult structural heart disease and valvular intervention. I have over 25 years of medical experience as a practicing interventional cardiologist. I am a Consultant Cardiologist at St. George's University Hospitals in London, U.K. and Professor of Cardiology at St. George's University of London. I have recently completed a six-year term as Chief of Cardiology at these institutions. I have performed over thirteen hundred transcatheter aortic valve replacement ("TAVR") procedures.

5. I graduated from St. Thomas' Hospital Medical School, London in 1984. Subsequently, I completed senior house officer posts at the Hammersmith Hospital, St. Thomas' Hospital, the Brompton Hospital, and the National Hospital for Nervous Diseases. I then completed registrar training in cardiology at St. Thomas' Hospital and the London Chest Hospital, before taking up a British Heart Foundation Junior Research Fellowship at the Royal Brompton Hospital. I was also a visiting fellow at Johns Hopkins Hospital, Baltimore, before becoming a Consultant Cardiologist and Honorary Senior Lecturer at St. George's in 1996. I am now Professor of Cardiology and Consultant Cardiologist at St. George's University Hospitals.

6. I have proctored over 600 TAVR procedures in which I assist and teach other physicians how to perform TAVR. I have been and remain a Global

proctor for Medtronic since 2010 at approximately 80 centers worldwide, including over 50 medical centers in the USA for the US Pivotal Trial of the Corevalve product. I have also proctored the TAVR procedure in the UK, Denmark, Belgium, Japan, India, Israel, Holland, Austria, Greece, Thailand, Vietnam, Singapore, Sri Lanka and South Korea.

7. I have performed TAVR procedures with Medtronic's Corevalve EvolutR, Evolut PRO and Evolut PRO+ products, as well as Boston Scientific's Lotus product and Edwards' Sapien products.

8. I have been active in the field of TAVR as a clinician, researcher, teacher, and innovator, and I have performed over 1,300 percutaneous TAVR procedures since 2007, including more than 200 cases between 2007 and 2012. I have proctored over 600 TAVR procedures and taught other physicians how to perform TAVR in 14 countries. I have performed TAVR operations with numerous devices including Edwards' SAPIEN products.

9. I have been a practising cardiologist since 1996 and I am aware of the technological advances since then.

10. I have experience, since 1996, of looking after cardiology patients with thoracic and abdominal aortic aneurysms and have over more than 20 years, worked closely with our vascular team in their management. St. George's Vascular Surgery are considered international leaders in this field and have carried

out many of the pivotal clinical trials in this area. I refer these patients for assessment and treatment and look after them before and after. On a daily basis I have always interacted with our vascular team and discussed cross-over technologies between our subspecialties. I have implanted covered coronary stents and peripheral stent grafts (probably around 30 procedures for management of iliofemoral perforations following TAVR procedures since 2007).

11. I am a named inventor on one patent, describing a specific TAVR guidewire, acquired by Medtronic.

12. I am a Fellow of the Royal College of Physicians, the European Society of Cardiology, the American College of Cardiology, the British Cardiovascular Society, and the British Cardiovascular Intervention Society.

13. I am the author or co-author of four books, 16 book chapters, and more than 130 peer-reviewed articles.

14. In my professional experience, I have become familiar with many problems faced by cardiologists, surgeons, and medical device engineers, in transcatheter aortic valve replacement and related topics.

15. A detailed record of my professional qualifications is set forth in the attached Exhibit A, which is my *curriculum vitae*, including a list of publications, awards, and professional activities. A list of the depositions, hearings, and trial at which I have testified is set forth in the attached Exhibit B.

### **III. BASES OF OPINIONS**

16. In the course of conducting my analysis and forming my opinions, I have reviewed materials including the exhibits filed by Petitioner and Patent Owner in each of the IPRs and any other exhibits and other documents cited herein.

### **IV. APPLICABLE LEGAL STANDARDS**

#### **A. Level Of Ordinary Skill In The Art**

17. My opinions in this declaration are based on the understandings of a person of ordinary skill in the art, which I understand is sometimes referred to as an “ordinary artisan” or by the acronyms “POSA,” “POSITA,” or “PHOSITA,” as of the time of the invention. I understand that Petitioner has asserted that the date of the invention is November 7, 2012, the filing date of provisional application 61/723,446. IPR2021-01527-Pet., 20; IPR2021-01584-Pet., 21; IPR2022-00034-Pet., 20; IPR2022-00193-Pet., 18. For the purposes of this declaration I will use this date as the date of the invention of the AI patents. I understand 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. By “relevant,” I mean relevant to the challenged claims of the AI patents.

18. I understand that factual indicators of the level of ordinary skill in the art include the various prior art approaches employed, the types of problems

encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field. I understand that, in assessing the level of skill of a person of ordinary skill in the art, one should consider the type of problems encountered in the art, the prior solutions to those problems found in the prior art references, the rapidity with which innovations are made, the sophistication of the technology, the level of education of active workers in the field, and my own experience working with those of skill in the art at the time of the invention.

19. In this case, Dr. Buller has asserted in his declaration that a person of ordinary skill in the art as of the time of the AI patent 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.

-01527-Ex. 1003 [Buller-Decl.] ¶45; -1584-Ex. 1003 ¶ 47; -00034-Ex. 1003 ¶ 47; -00193-Ex. 1003 ¶ 44.

20. I do not believe this level of ordinary skill is correct. In view of the types of problems confronting TAVRs with respect to endovascular delivery and paravalvular leakage, I believe the level of ordinary skill would be an interventional cardiologist with experience implanting, researching or designing

TAVRs in the 2010-2012 timeframe. Notably, many of Petitioner's references—Levi (filed Oct. 2011), Walther (available online, April 2011), Kainuma (2011)—are from this timeframe. My opinion on the level of ordinary skill is informed by the opinions proffered in Section VI of this declaration. Further elaboration on the level of ordinary skill is below.

21. The 2012 timeframe is critical to understanding the operative level of skill. The TAVR landscape in 2012 was extremely active both clinically and from a research and development perspective. Many called TAVR the most exciting innovation in interventional cardiology for decades and perhaps ever. By 2012, large numbers of TAVR procedures had been performed by interventional cardiologists. For an interventional cardiologist to claim skill in the art in 2012, it is my opinion he or she would have to have been involved in clinical implant procedures. Many cardiologists were also involved in clinical research concerning TAVRs - either by being involved in clinical trials (recruitment, trial design, steering committees), or working with industry in TAVR design (design panels, advisory boards, usability testing). If an individual had none of the above activities, my opinion would be that they could not be considered a POSITA in 2012. Cardiologists involved in the field and professing a level of ordinary skill would have been actively involved in at least one and typically at least 2 or 3 of the above domains.

22. As further discussed below, my opinions as stated in this declaration are valid even if the Board adopts a slightly different level of ordinary skill in the art.

**B. My Understanding Of Legal Standards**

23. When considering the AI patents and stating my opinions, I rely on the following legal standards as described to me by the attorneys for Aortic Innovations.

24. I understand that a patent claim is unpatentable if the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the purported invention.

25. I understand that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the invention in view of the prior art and in light of the general knowledge in the art as a whole. I also understand that obviousness is ultimately a legal conclusion based on underlying facts of four general types, all of which must be considered: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of non-obviousness, including any praise of the invention.

26. I also understand that obviousness may be established under certain circumstances by combining or modifying the teachings of the prior art. Specific teachings, suggestions, or motivations to combine any first prior art reference with a second prior art reference can be explicit or implicit, but must have existed before the date of purported invention. I understand that prior art references themselves may be one source of a specific teaching or suggestion to combine features of the prior art, but that such suggestions or motivations to combine art may come from the knowledge that a person of ordinary skill in the art would have had.

27. I understand that a reference may be relied upon for all that it teaches, including uses beyond its primary purpose, but also including teachings that lead away from the invention. I understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, although the mere disclosure of alternative designs does not teach away.

28. I further understand that whether there is a reasonable expectation of success in combining references in a particular way is also relevant to the analysis.

29. I understand that it is improper to use hindsight to combine references or elements of references to reconstruct the invention using the claims as a guide.

My analysis of the prior art is made from the perspective of a person of ordinary skill in the art at the time of the invention.

30. I am not offering any legal opinions in this declaration nor am I qualified to do so. I only consider such legal standards in framing my opinions and conclusions as well as placing assertions made by Petitioner in the Petition into the proper context. Additionally, from a subject matter perspective, I understand that the petitioner always has the burden of persuasion regarding a challenge of patentability of an invention under an *inter partes* review.

## V. CLAIMS-AT-ISSUE

### A. The '172 Patent

31. I understand that the following claims in the AI patents are at issue:

32. I understand that claims 1-7, and 9-12 of the '172 patent have been disclaimed. I understand that the remaining challenged claims, 8, and 13-17, are challenged by Petitioner with the following grounds.

| Ground | Remaining Claims Challenged | Asserted Pre-AIA 35 U.S.C. § | Asserted References  |
|--------|-----------------------------|------------------------------|----------------------|
| 1      | 8, 13-17                    | 103                          | Cribier + Walther    |
| 2      | 8, 13-17                    | 103                          | Spenser + Walther    |
| 3      | 8, 13-17                    | 103                          | Spenser + Spenser II |
| 6      | 8, 13-17                    | 102(e)                       | Levi                 |
| 7      | 8, 13-17                    | 103                          | Levi                 |
| 8      | 8, 13-17                    | 103                          | Levi + Walther       |
| 9      | 8, 13-17                    | 103                          | Levi + Spenser II    |

IPR2021-01527-Pet., 20-21.

**B. The '011 Patent**

33. I understand that claims 1-6, and 8-11 of the '011 patent have been disclaimed. I understand that the remaining challenged claims, 7, and 12, are challenged by Petitioner with the following grounds.

| Ground | Remaining Claims Challenged | Asserted Pre-AIA 35 U.S.C. § | Asserted References              |
|--------|-----------------------------|------------------------------|----------------------------------|
| 1      | 7, 12                       | 103                          | Spenser + Walther                |
| 2      | 7, 12                       | 103                          | Spenser + Spenser II             |
| 3      | 7, 12                       | 103                          | Cribier '321 + Walther           |
| 4      | 7, 12                       | 103                          | Cribier '321 + Spenser II        |
| 5      | 7, 12                       | 102(e)                       | Levi                             |
| 6      | 7, 12                       | 103                          | Levi                             |
| 7      | 7, 12                       | 103                          | Levi + Walther                   |
| 8      | 7, 12                       | 103                          | Levi + Spenser II                |
| 9      | 7, 12                       | 103                          | Levi + Cribier '321              |
| 10     | 7, 12                       | 103                          | Levi + Spenser                   |
| 11     | 7, 12                       | 103                          | Levi + Cribier '321 + Walther    |
| 12     | 7, 12                       | 103                          | Levi + Cribier '321 + Spenser II |
| 13     | 7, 12                       | 103                          | Levi + Spenser + Walther         |
| 14     | 7, 12                       | 103                          | Levi + Spenser + Spenser II      |

IPR2021-01574-Pet., 22.

### **C. The '846 Patent**

34. I understand that claims 1-5, and 7-12 of the '846 patent have been disclaimed. I understand that the remaining challenged claim (claim 6) is challenged by Petitioner with the following grounds.

| <b>Ground</b> | <b>Remaining Claim Challenged</b> | <b>Asserted Pre-AIA 35 U.S.C. §</b> | <b>Asserted References</b> |
|---------------|-----------------------------------|-------------------------------------|----------------------------|
| 1             | 6                                 | 103                                 | Cribier + Walther          |
| 2             | 6                                 | 103                                 | Spenser + Walther          |
| 3             | 6                                 | 103                                 | Spenser + Spenser II       |
| 4             | 6                                 | 102(e)                              | Levi                       |
| 5             | 6                                 | 103                                 | Levi                       |
| 6             | 6                                 | 103                                 | Levi + Walther             |
| 7             | 6                                 | 103                                 | Levi + Spenser II          |

IPR2022-00034-Pet., 21.

### **D. The '538 Patent**

35. I understand that claims 1-20 of the '538 patent are challenged by Petitioner with the following grounds.

| Ground | Claim Challenged       | Asserted Pre-AIA 35 U.S.C. § | Asserted 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                |

IPR2022-00193-Pet., 19.

## VI. OPINIONS

### A. Secondary Considerations Of Nonobviousness

36. I have been informed that secondary considerations, such as unexpected results, are an important factor in determining obviousness. All the AI patents share a common specification. For the purposes of this Section, I cite to the '846 patent and its file history (Ex. 1002 in IPR2022-00034) but my statements apply to all the other AI patents. I have reviewed the specification of the AI patents and it describes many innovative concepts, which are in turn reflected in the claims.

37. The specification discloses an outer frame that has a fibrous network or an outer seal or sealing material comprised of radially or outwardly extending fibers. The fibers in the figures are sparsely distributed and are clearly free of an

outer graft covering. The fibers form a seal upon compression in *in vivo* implantation:

# Patent's Figures Showing Fibers (Ex. 1001)

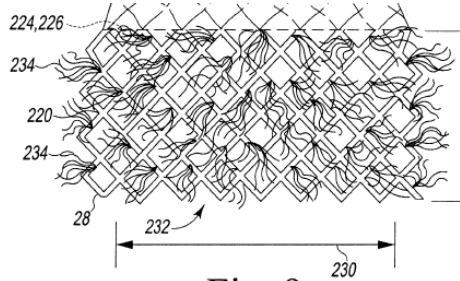


Fig. 9

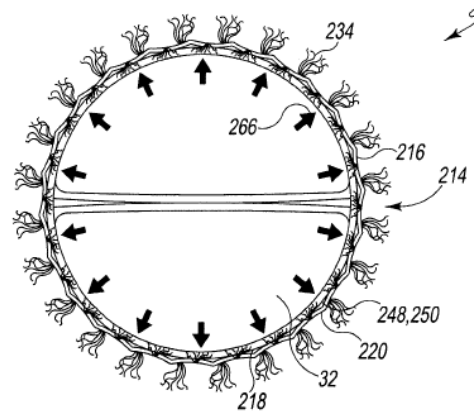


Fig. 14

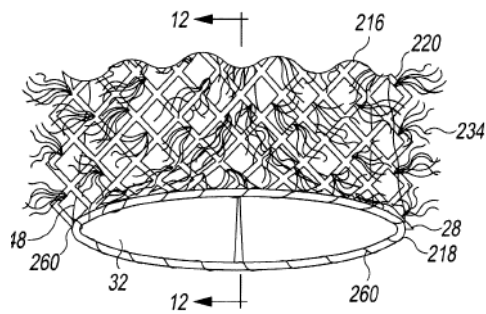


Fig. 11

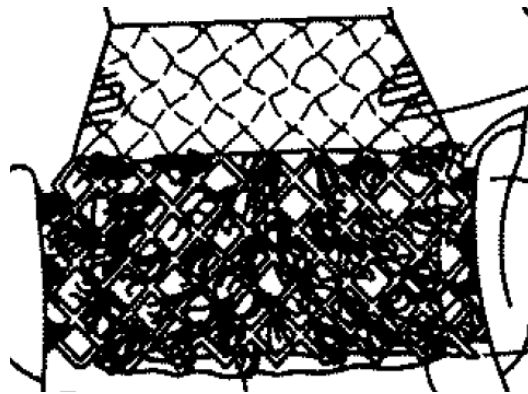


Fig. 15 (see also Fig. 16, similar)

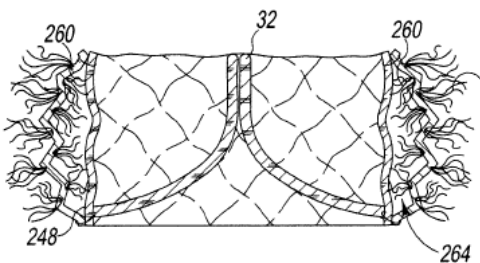


Fig. 12

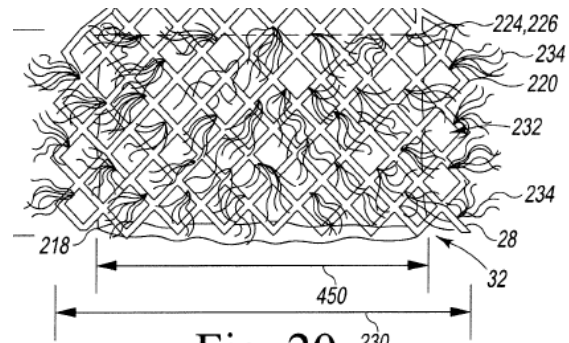
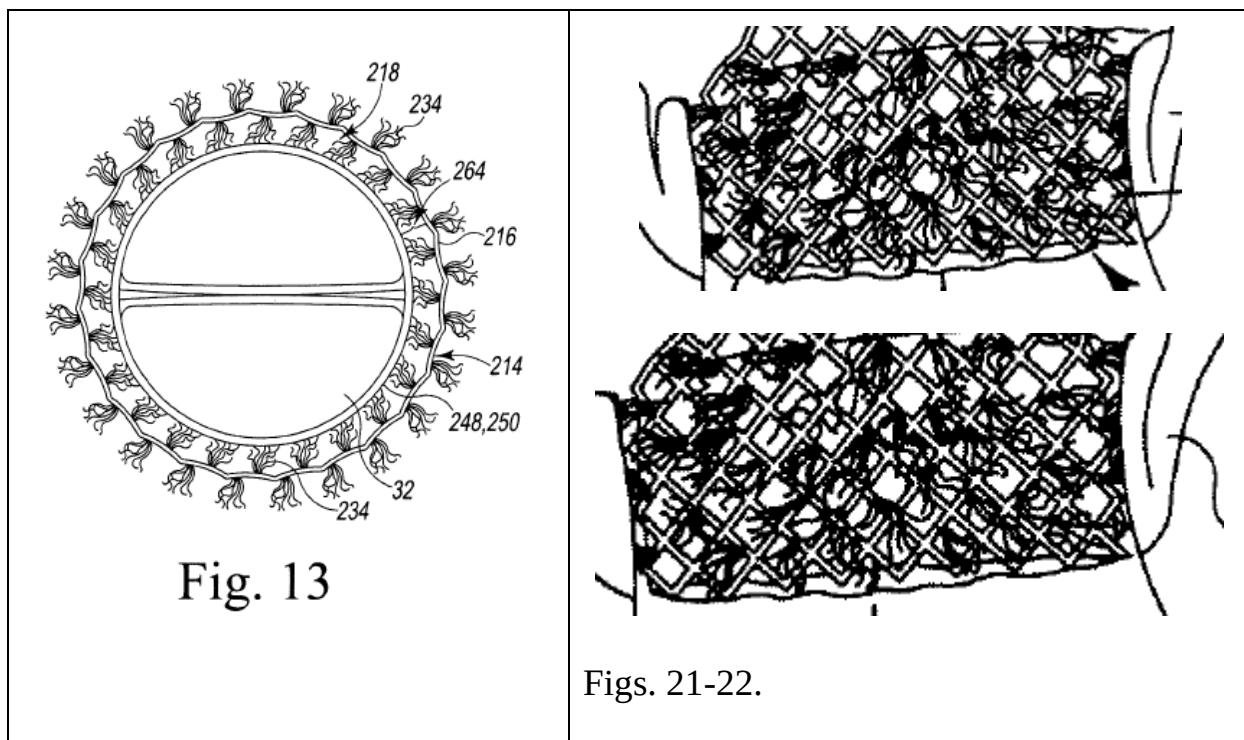
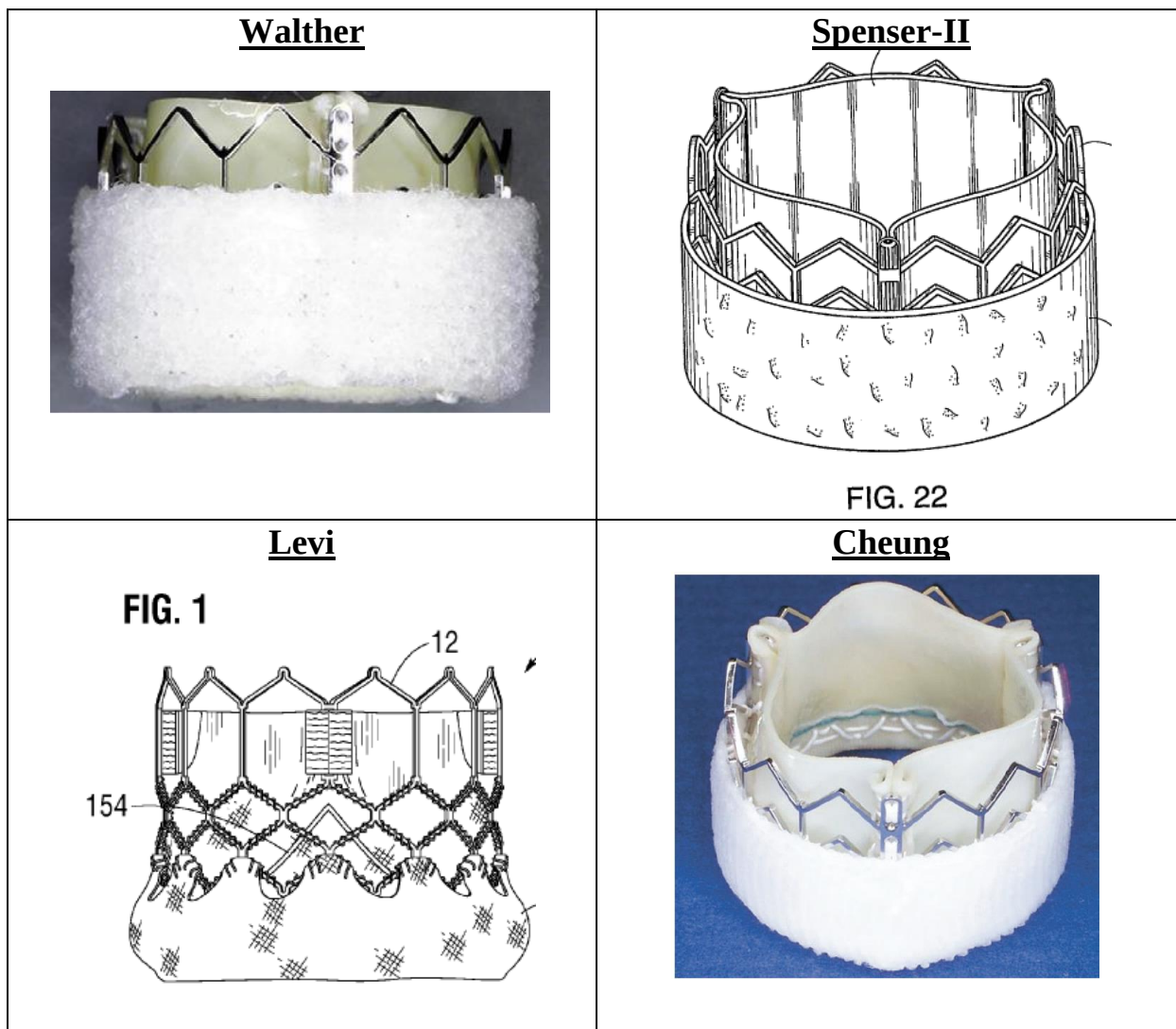


Fig. 20



38. The fibrous network, or outwardly or radially extending fibers address PVL. Ex. 1001 [’846] 12:43-47; 14:62-66, 18:22-27, 19:41-45. The sparsely distributed fibers are consistently displayed in the Patent’s figures. Petitioner/Dr. Buller’s outer coverings, by contrast, are opaque due to density, comprise an outer graft covering, and in Levi’s case, lack outwardly or radially extending fibers:



39. It is counter-intuitive that a sparse distribution of fibers as taught could create a seal. I had not seen any prior art TAVR with this arrangement of fibers. Similarly, Dr. Buller was unaware of *any* stent with fibers like those present in the Patent's figures. See Ex. 2052 [Buller-Depo.] 167:10-12; 169:5-25. Certainly, the prior art outer cloths identified by Petitioner in, *e.g.*, Walther, Cheung, Spenser-II, and Levi look nothing like what is presented in the Patent. By

including a sparse distribution of fibers without an outer graft covering, however, this arrangement allows for a narrow crimp profile.

40. Thus, the invention allows for an endovascularly-deliverable TAVR that limits PVL. It teaches how to achieve this end through, *e.g.*, outwardly or radially extending fibers or a fibrous network and the lack of an outer graft covering. I do not see such an outer seal in Petitioner's/Dr. Buller's references.

41. This case is about TAVRs and specifically, whether, in 2012, it was obvious to add a fibrous network or an outer seal or sealing material with “radially” or “outwardly extending fibers” and, in the case of the '846, lacking an outer graft covering to an endovascularly-deliverable TAVR. This is evident from the claimed invention and the references raised by Dr. Buller.

42. The '172, '011, and '846 patents include in their title, “[d]evice for **endovascular** aortic repair.” The claimed invention concerns an “endovascularly” delivered valve assembly including “a prosthetic heart valve having prosthetic leaflets.” The file history, moreover, focuses extensively upon TAVRs. *See, e.g.*, IPR2022-00034-Ex. 1002 [Pros.-Hist.] 133-151; IPR2021-01527-Ex.1002 [Pros.-Hist.] 273-278. TAVR was a revolutionary and disruptive but nascent technology. While the first TAVRs were a huge leap forward, the technology had a long way to go. Indeed, Larry Wood, Edwards' head of TAVR analogized the advances in TAVRs to a comparison between the Kitty Hawk and a 747:

Well, it's funny when we go back and we look at the first generation technology, I think it would probably be like the Wright brothers looking at a 747 and looking back at what they did and said, "Wow, I can't believe we'd fly that thing." It really is one of those moments when we go back and look at those initial devices, they seem so crude today compared to what we have now. ...

Ex. 2066 [Device-Talks<sup>1</sup>] 1:19:03-1:20:02; Ex. 2067 [Device-Talks Transcript] 23.

43. The first commercially available valve, the SAPIEN was available starting in 2007 in large-bore 22F or 24F delivery sheaths. The principal focus of Edwards' second-generation TAVR (SAPIEN XT, commercially available in 2011) was lowering the crimp size to 16-18F. Ex. 2052 [Buller-Depo.] 80:9-12; 16:19-20 ("the smaller, the better"). Concerns about PVL similarly became significantly more pronounced in 2010-2012, and practitioners were aware that an important percentage of patients were dying and/or having serious complications. *See, e.g.*, Ex. 2068 [Vasa-Nicotera] 859; Ex. 2069 [Kodali] 1; Ex. 2052 [Buller-Depo.] 231:6-18.

44. Thus, the issues in this case were at the forefront in the 2010-2012 time-frame after the first generation of TAVRs was released. Ex. 2052 [Buller-

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<sup>1</sup> <https://soundcloud.com/devicetalks/the-complete-history-of-the-sapien-tavr-from-pvts-emerging-idea-to-edwards-lifesciences-success>

Depo.] 231:6-18 (by 2010, obvious improvement needed to current generation of valves). *See also* Section IV.A, *supra*.

## **B. Endovascular Delivery**

45. All claims at issue in the AI patents either include the limitation, “wherein the valve assembly is delivered endovascularly” (the ’172 patent, the ’011 patent, the ’846 patent) or “endovascularly positioning the transcatheter aortic valve assembly through the aortic valve of the patient” (the ’538 patent).

### 1. Prior Testimony on Endovascular Delivery

46. I have previously submitted declarations with respect to the “delivered endovascularly” limitation in each of the IPRs. My testimony from IPR2022-00034 is representative of my prior testimony in the other IPRs regarding this issue. The following excerpts are from paragraphs 35-75 of my IPR2022-00034 declaration. *See also* IPR2021-01527-Ex. 2002, ¶¶35-75, IPR20221-01584-Ex. 2002, ¶¶35-72, IPR2022-00193-Ex. 2002, ¶¶34-75. To ensure this testimony is part of the post-institution record, I so testify again. *See* ¶¶47-87, *infra*. The citations to the Petition and exhibits in this section of my declaration are to those in IPR2022-00034.

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47. Each of these proposed combinations, however, is fundamentally flawed, as adding the outer cloth of Walther or Spenser II to Cribier, Spenser, or

Levi would make the resultant combination far too large to be “delivered endovascularly” as required. I will note that this is not a trivial issue.

Endovascular deployment of a transcatheter valve, a technology that only received FDA approval in 2011, shortly before the '846 provisional's November 7, 2012 filing date, allows a doctor to replace a failing aortic valve in a patient without open heart surgery. Ex. 2003 [TVT] 2-4. Particularly when the patient is older, with multiple comorbidities, avoiding open heart surgery, *i.e.* cutting open the breastbone of the patient with a large incision and requiring significant time in the intensive care unit thereafter, is an important advantage. Indeed, endovascular transcatheter replacement can allow discharge within a matter of a few days. However, this innovative and life-saving technique is only possible if the valve profile is small enough to pass through the peripheral arteries of the patient. If the valve is too large, it cannot pass through the arteries, thus restricting access to this life-saving technology to a transthoracic approach (transapical or direct aortic).

48. As discussed below, a POSITA would know that endovascular delivery requires the prosthetic heart valve to have a narrow delivery profile (*i.e.*, valve width when in the folded or crimped position). Petitioner asserts that the maximum delivery profile for endovascular delivery through the femoral artery (“transfemoral delivery”) is 8 mm (even at this size, the valve would only be capable of transfemoral delivery in roughly half of patients). Petitioner does not

argue, that a valve larger than 8 mm could be delivered *endovascularly* through any route. Section VI.A.1. Further, a POSITA would know that adding Walther's or Spenser II's outer cloth to Cribier, Spenser or Levi would result in a device with a delivery profile well over the 8 mm limit, rendering the resulting combinations incapable of "endovascular delivery." Section VI.A.2. Petitioner does not seem to explain how any of its proposed combinations could be delivered endovascularly in view of the increased delivery profile. Section VI.A.3. Finally, Petitioner does not adequately explain why a POSITA would be motivated to make these combinations in spite of the delivery size issue. Section VI.A.4.

a. *Endovascular Delivery Requires A Device With A Narrow (e.g., 8 mm) Delivery Profile.*

49. In order for a valve assembly to be delivered endovascularly, the valve's delivery profile must be narrow. Indeed, for endovascular delivery through the femoral artery, Petitioner, Dr. Buller, and the Spenser reference all explain that the "maximal size of a catheter ... should be ***no more than 8 mm in diameter.***" Pet., 68 (quoting Spenser, 27:65-67) (emphasis in Petition); Ex. 1003 [Buller-Decl.] ¶223 (same). A POSITA would have been aware that "many authorities" considered an 8 mm (24 French) sized delivery catheter "to be the [upper] limit[] for a transfemoral approach." Ex. 2004 [Clayton] 4. It is important to note, however, that an 8 mm delivery catheter would only be deliverable via the transfemoral endovascular route, in about half of all candidates for the procedure.

In fact, two landmark studies, the SOURCE Registry (reporting early commercial clinical results of Edwards' SAPIEN valve) and the PARTNER study (reporting TAVR data from 25 centers), show that transfemoral delivery of 22-24F Sapien systems was possible in only 45-70% of patients. Ex. 2005 [SOURCE-Registry] 1-3; Ex. 2006 [PARTNER] 1-4. A POSITA could conclude from these studies, therefore, that transfemoral delivery of the larger 24F (8 mm) delivery system in these studies would only be possible in less than approximately 50% of patients. This view is buttressed by experience of the POSITA cardiologist at the relevant time period, that around 50% of all SAPIEN implants had to be undertaken via the transapical route. Accordingly, a POSITA would understand that even if a device could fit the "maximal" 8 mm delivery catheter, the device would only be suitable for transfemoral delivery in half of patients. *Id.* Because of this, a POSITA would know that the design intent focused on making every element of the transcatheter valve smaller (leaflet thickness and frame strut thickness reduced as much as possible) in order to make the procedure transfemoral and truly percutaneous for the vast majority of patients. *See, e.g.,* Ex. 2007 [Corevalve] 1-5.

50. I see that Petitioner has not even asserted, much less demonstrated that a valve with a delivery profile larger than 8 mm could be delivered endovascularly through any pathway. Pet., 39-42, 67-69, 92-95. While Petitioner states that the common iliac artery "is a larger artery that can accommodate bigger

devices,” Petitioner does not provide any indication, or evidence, of a maximum allowable delivery profile for the iliac artery. Pet., 39. While Petitioner cites Kainuma for delivery through the common iliac artery, it is notable that Kainuma used the same 7.3 mm (22F) arterial sheath—*i.e.*, smaller than 8 mm—used “[f]or transfemoral delivery” in Cribier. Ex. 1043 [Kainuma] 3; Ex. 1012 [Cribier] 348. Additionally, I will note that Dr. Buller, Petitioner’s expert, states “the delivery of valves through the femoral and common iliac artery is [] **generally the same.**” Ex. 2008 [0193 Buller-Decl.] ¶109. To be clear, as discussed below, this statement displays a lack of understanding of the complexities and risk associated with a common iliac approach.

51. In sum, a POSITA would know that to be “delivered endovascularly,” a valve must have a narrow delivery profile (*e.g.*, less than 8 mm).

b. *Adding Walther’s Or Spenser II’s Outer Cloth To The Valves In Cribier, Spenser, Or Levi Would Make The Device Too Big For Endovascular Delivery.*

52. It is my opinion that a POSITA would know that the addition of the outer cloth in Walther or Spenser II to Cribier, Spenser, or Levi would significantly increase the delivery profile of the resulting combinations, pushing them far past an 8 mm delivery profile and, thus, rendering them incapable of being delivered endovascularly.

i. *Walther Combinations (Grounds 1-2, 6)*

53. The Petition, in Grounds 1, 2, and 6, relies upon Walther's "outer cloth" as the "outer seal." Pet., 29 (citing Ex. 1007 [Walther] 2). Below, we see an image of Walther's outer cloth:



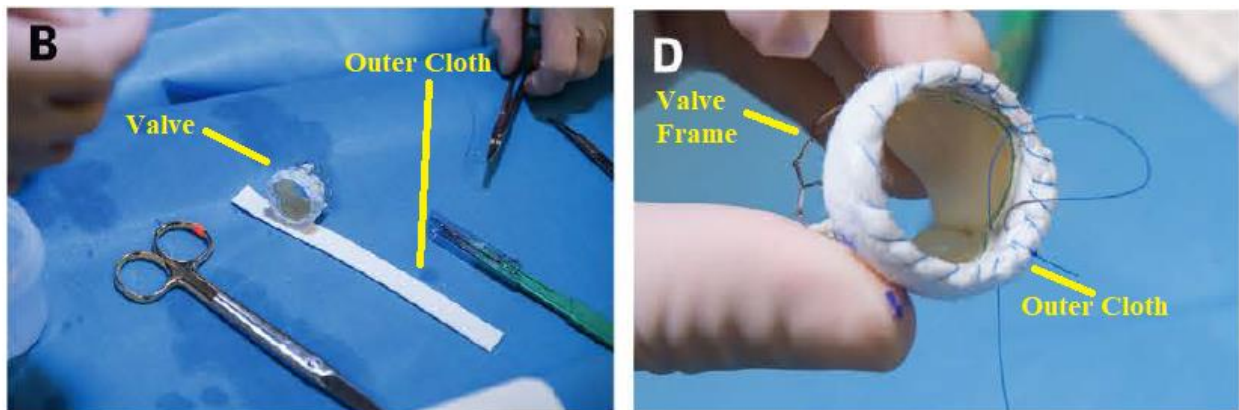
Pet., 29 (Showing Walther's Fig. 1 (excerpted) (annotations added); *see also id.*, 16, 24, 33-34, 38, 46.

54. A POSITA would understand that Walther's thick outer cloth was not designed to be used on an endovascularly delivered device. This is clearly evident from Walther's use of an 11 mm (33 French) delivery catheter for its cloth valve, 3 mm (9 French size difference) over the 8 mm maximum for endovascular delivery through the femoral artery. Ex. 1007 [Walther] 2 ("The SAPIEN valves were deployed ... via the 33F Ascendra system"), 6 (Table 4) ("Cloth valve (33F delivery)"). Notably, Walther does not teach that its "cloth valve" can be crimped

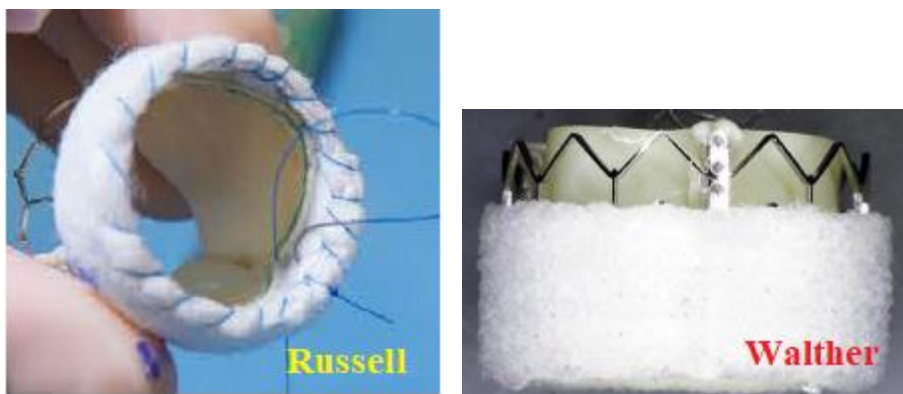
tightly enough for endovascular delivery. Instead, Walther explains that its system is suitable “for the [surgical] trans-apical approach where tight crimping is not an issue.” Ex. 1007 [Walther] 7. A POSITA would understand that, as Walther’s cloth is not suitable for “tight crimping,” it is therefore not suitable for endovascular delivery.

55. Moreover, a POSITA would know that if Walther’s outer cloth were added to a valve assembly (in the expanded state) and that valve assembly were then crimped, the cloth would bunch, adding significantly to the diameter of the crimped delivery profile.

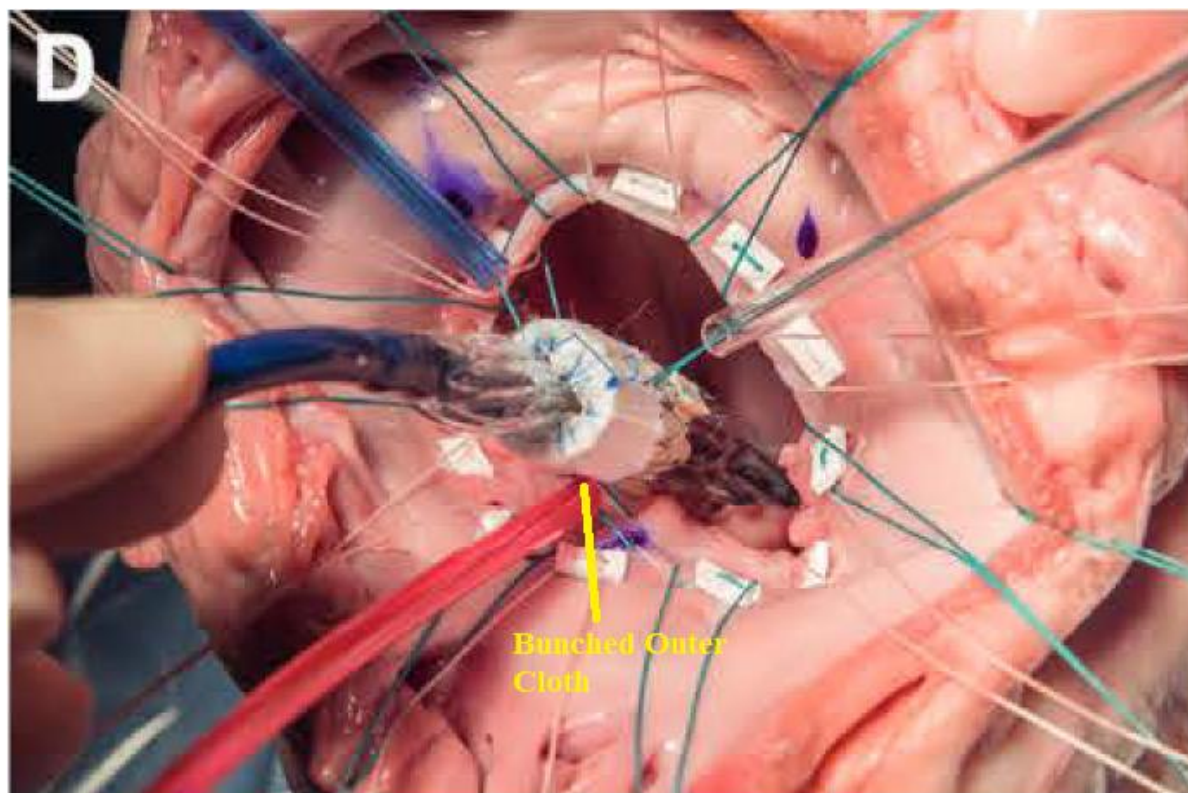
56. Bunching is clearly shown in Russell, a reference dated 6 years after the alleged time of invention. Ex. 2009 [Russell]. In Russell, similar to Walther, we see an outer cloth that is attached to a valve assembly as shown below.

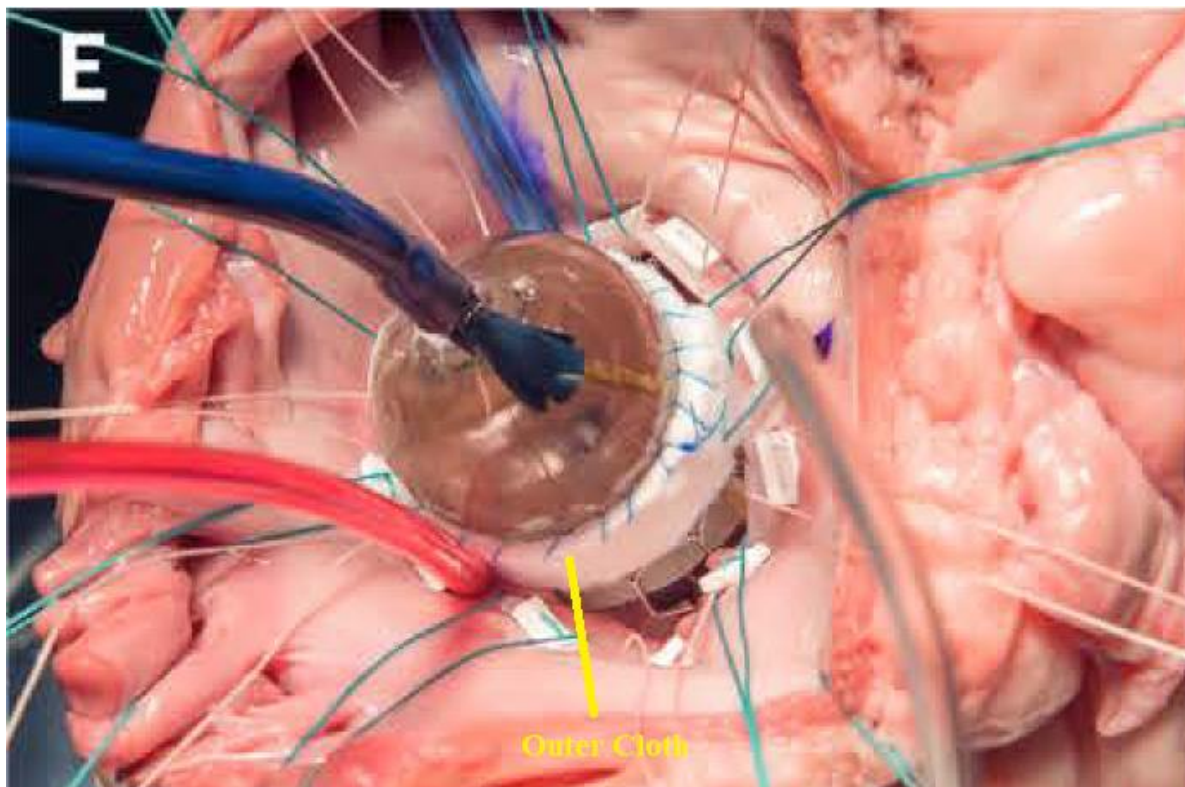
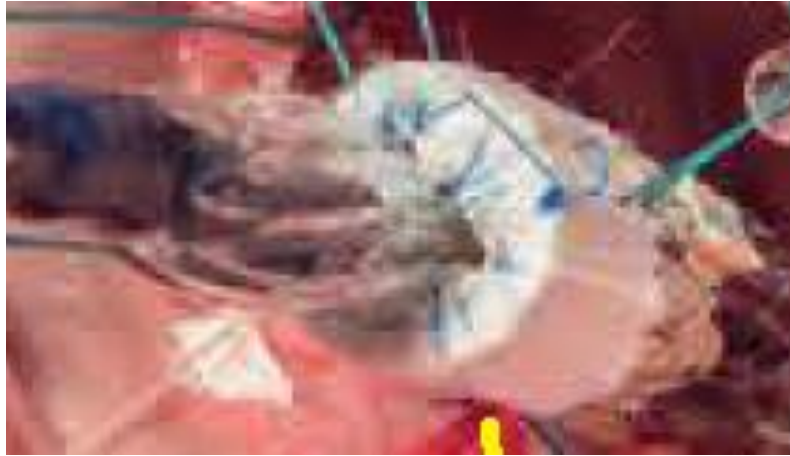


*Id.*, 5 (Fig. 2) (yellow annotations added). In fact, the cloth valves in Russell and Walther look very similar to one another.



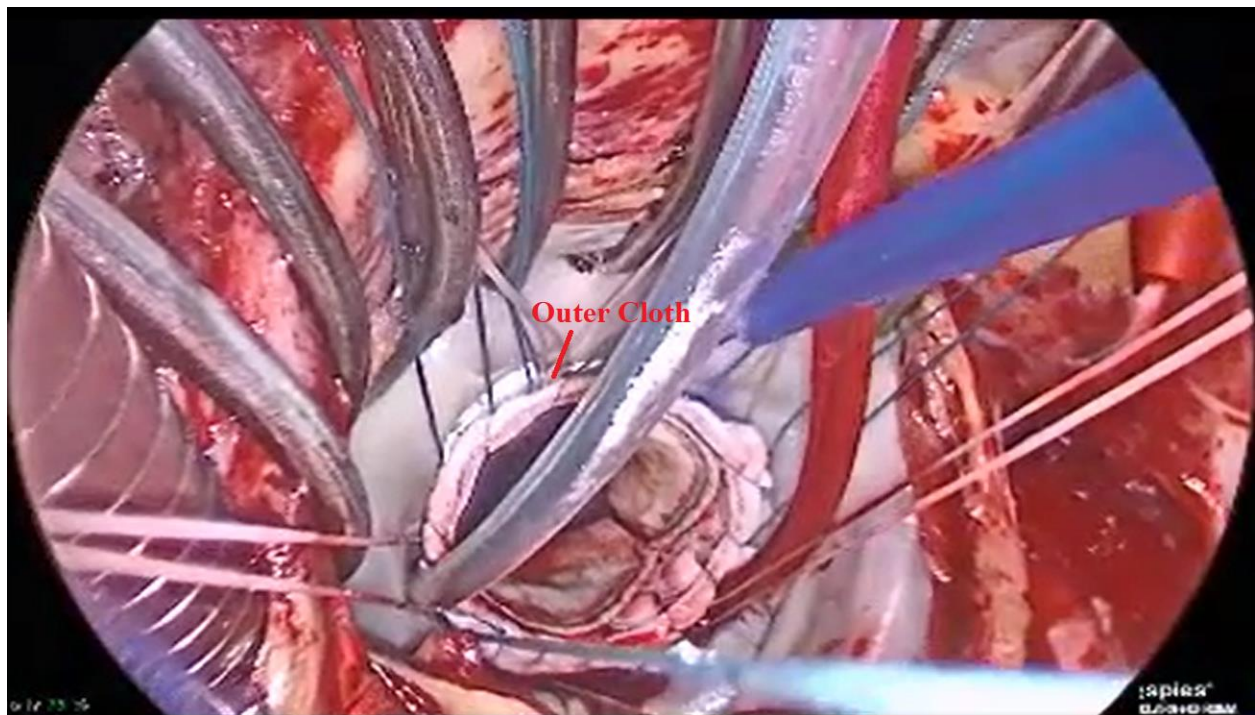
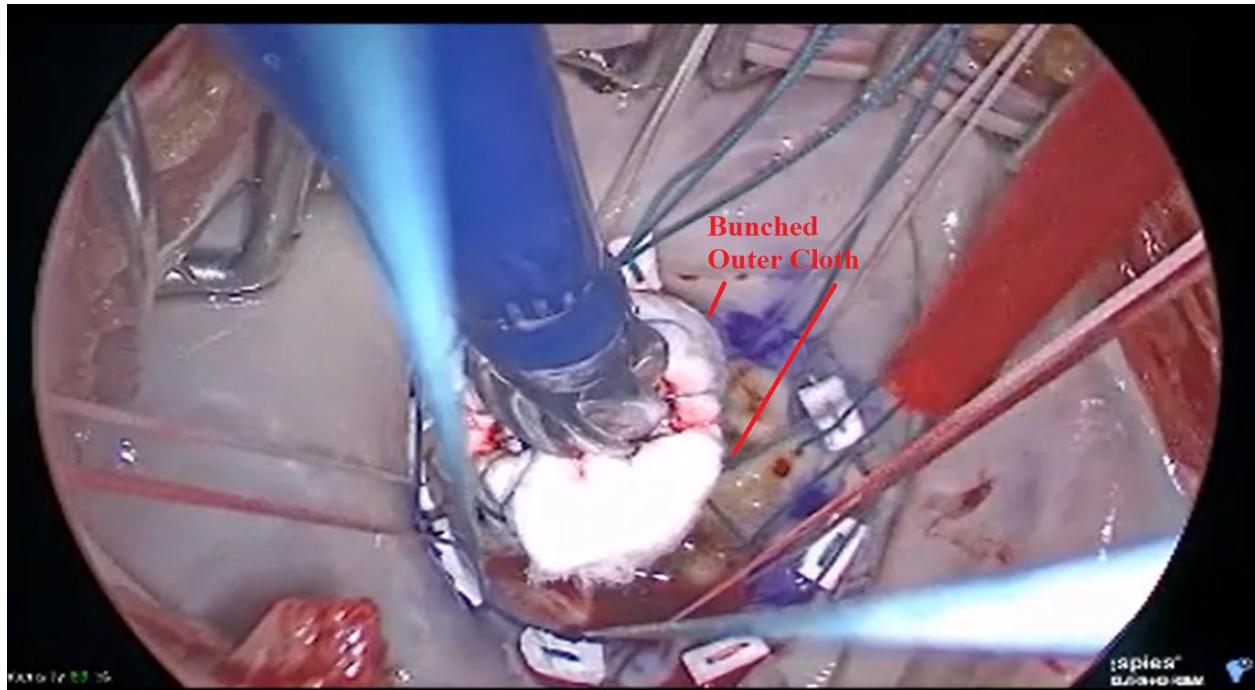
*Id.*; Ex. 1007 [Walther] 2 (Fig. 1). As shown in Russell, when the valve is in the crimped position (*i.e.*, in the image below) in the context of an open chest surgery using a trans-atrial route (*i.e.*, not endovascular), the outer cloth is bunched, and significantly thicker than when the valve is in the expanded position (image E).





Ex. 2009 [Russell] 7 (Fig. 4) (annotated). This bunching of the outer cloth when the valve is crimped is further shown in a video referenced in the Russell article which at 3:48-4:12 shows the crimped valve being positioned and at 5:00-5:30 shows the expanded valve. Ex. 2010 [Russell-Video]. As seen in the video, and in the screenshots therefrom below, the crimping causes the outer cloth to bunch up,

adding significant diameter to the delivery profile when compared to the cloth in the expanded position.



*Id.*, 3:55, 5:20. Indeed, as shown in the video, the surgeon is required to use forceps in order push the bunched up outer cloth into position in the annulus of the mitral valve (which is much larger than the femoral artery).



*Id.*, 3:49. Thus, a POSITA would know that such a bunched up outer cloth would prevent any valve from being crimped tightly enough to be delivered endovascularly.

57. Petitioner does not account for the bunching that occurs when a cloth covered valve is crimped or even attempt to explain how the valve could remain suitable for endovascular delivery with a bunched outer cloth. Indeed, Petitioner, does not explain, much less demonstrate, what the delivery profile would be for any of its asserted combinations involving Walther's outer cloth. Pet., 39-42, 67-

69, 94-95. Despite Petitioner’s statement that the maximum allowable delivery profile for endovascular delivery through the femoral artery is 8 mm, Pet., 68, Petitioner never even asserts that any of its proposed Walther combinations would have a delivery profile of 8 mm or less. *Id.*, 39-42, 67-69, 94-95. Petitioner confirms that the absolute smallest delivery profile of any of its asserted valves **without** the Walther cloth is around 4 mm. Pet., 68 (citing Ex. 1010 [Spenser] 27:65-28:2); *see also* Ex. 1008 [Levi] 8:56-59. It is my opinion that a POSITA would understand that the addition of a cloth, like the cloth shown in Walther or Russell, would result in a bunched outer cloth when the valves were crimped, adding significantly to the delivery profile, and increasing the delivery profile well above 8 mm. *See* Ex. 2009 [Russell]; Ex. 2010 [Russell-Video]. Accordingly, the Petitioner’s proposed addition of Walther’s outer cloth to the devices in Cribier, Spenser, or Levi, would not result in a valve that can be “delivered endovascularly.”

*ii. Spenser II Combinations (Grounds 3, 9)*

58. As with Walther, the addition of Spenser II’s outer cloth to Spenser or Levi would make the resulting device too big for endovascular delivery. Petitioner relies upon the compressible material/fibers in Spenser II’s Figure 22 as the alleged “outer seal.” Petitioner appears to acknowledge that Spenser II is “similar[]” to Walther in this regard (Pet., 47) and, like Walther, the “compressible

material ‘may resemble a cloth or fabric ....’” Pet., 55 (citing Ex. 1011 [Spenser II] ¶145).

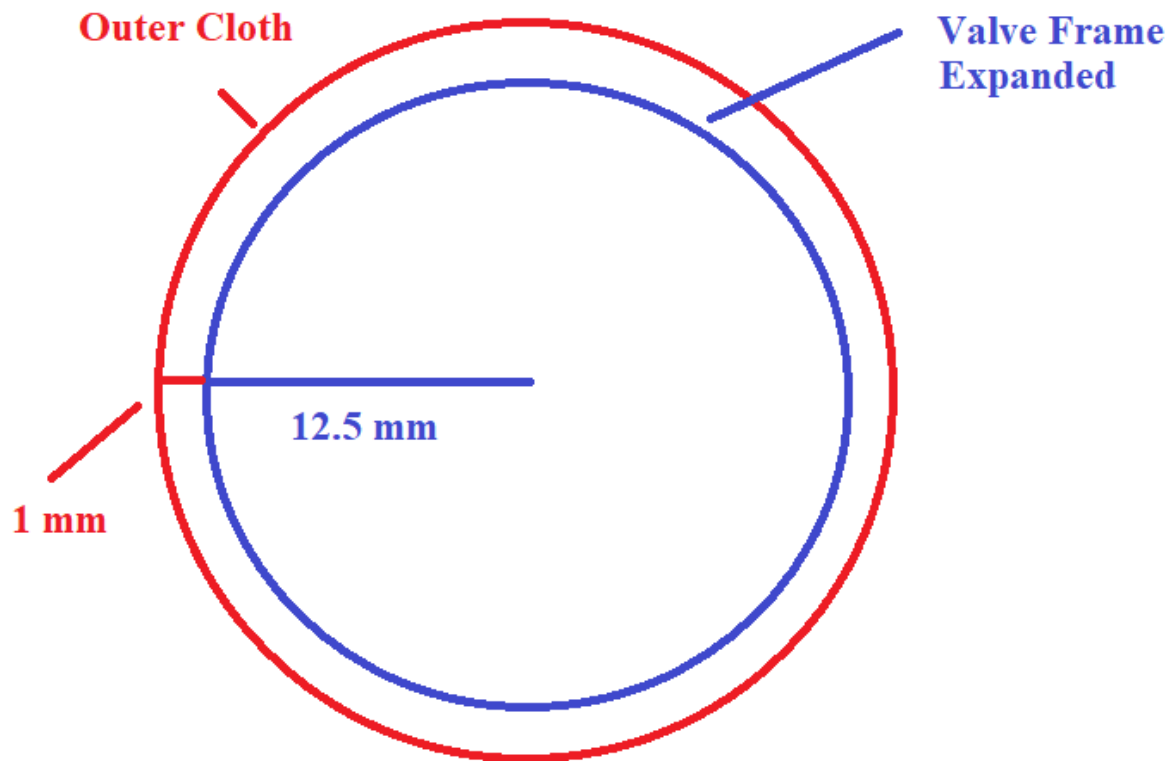
59. Just as with Walther’s cloth discussed above, *see* Section VI.A.2.a, a POSITA would know that Spenser II’s outer cloth would bunch up when the valve is crimped, significantly increasing the delivery profile. Further, as discussed above, Petitioner does not show, or even clearly contend, that a valve over 8 mm could be delivered endovascularly.

60. It was well-recognized at the time that adding an external material (like Spenser II’s cloth) to a transcatheter valve would significantly add to the delivery profile and was in direct conflict to all design imperatives, which was to downsize devices. A POSITA would expect Petitioner’s proposed Spenser II-Spenser/Levi combinations to have a delivery profile well-over 8 mm. This would render such a design impractical for endovascular delivery, as demonstrated by Russell.

61. Spencer II describes a compressible material, 1-5mm thick. Ex. 1011 [Spenser II] ¶145. While it is not possible to determine precisely how much Spenser II’s cloth would affect delivery profile, by way of illustration, it is possible to calculate an estimate of the impact based on dimensions in Spenser II/Spenser/Levi, and some reasonable assumptions. In short, by looking at a cross-section of Petitioner’s proposed combination of an outer cloth wrapped around a

valve in the expanded state, we can estimate a minimum amount by which the outer cloth increases the area of that cross-section. Once we have done that, we can derive a conservative minimum estimate of how much that same amount of cloth would necessarily increase the diameter of a cross-section of the device when the valve is reduced to the crimped state, assuming the cloth was evenly distributed around the crimped valve, and did not compress further when crimped.

62. Spenser II provides that its cloth “has a thickness ranging from about 1 to 5 mm.” Ex. 1011 [Spenser] ¶145. Spenser and Levi both teach a valve that has a diameter of 25 mm and 26 mm respectively when fully expanded. Ex. 1010 [Spenser] 27:67-28:2; Ex. 1008 [Levi] 8:56-59. Accordingly, even if we were to assume a POSITA used the thinnest possible cloth in Spenser II, Petitioner’s proposed combination using the smaller Spenser 25 mm diameter (12.5 mm radius) expanded valve covered by a 1 mm cloth resulting in a 27 mm diameter (13.5 mm radius) valve, as illustrated below.



From this we can conservatively estimate how much cloth is required for a cross-section of the proposed device ( $A_{\text{cloth}}$ ) by calculating the total area of a cross-section of the cloth-covered valve ( $\pi*(13.5 \text{ mm})^2$ ) and subtracting the area of a cross-section of just the valve ( $\pi*(12.5 \text{ mm})^2$ ).

$$A_{\text{cloth}} = \pi*(13.5 \text{ mm})^2 - \pi*(12.5 \text{ mm})^2 = 81.68 \text{ mm}^2$$

Accordingly, Petitioner's proposed combination requires 81.68 mm<sup>2</sup> of outer cloth in a given cross-section of the device.

63. Petitioner asserts that Spenser's device, when crimped—without the cloth—would have a diameter of about 4 mm. Pet., 68 (citing Ex. 1010 [Spenser] 27:67-28:2). The cross-section area of the crimped valve would therefore have an

area of 12.57 mm<sup>2</sup> ( $A_{\text{crimped}} = \pi * (2 \text{ mm})^2 = 12.57 \text{ mm}^2$ ). If the 81.68 mm<sup>2</sup> cloth were added to the 12.57 mm<sup>2</sup> of crimped valve, the cloth-covered crimped valve would have a total area of 94.25 mm<sup>2</sup>. Even if we were to assume that the cloth would form a perfect circle around the crimped valve, and no portions of the cloth would bulge more in certain areas (as Russell indicates)—two assumptions that artificially reduce the diameter significantly—this would mean that the radius of the crimped Spenser valve with the uncompressed Spenser II outer cloth would be at a minimum 5.48 mm.

$$\text{Radius}_{\text{crimped}} = \sqrt{(94.25 / \pi)}$$

Accordingly, using conservative estimates, Petitioner’s proposed combination of Spenser’s valve with the Spenser II’s outer cloth would have a diameter of at least 10.96 mm (when the valve is crimped and the cloth uncompressed)—similar to Walther’s 11 mm delivery—over 36% too large for transfemoral delivery (Ex. 1010 [Spenser] 27:65-67) and endovascular delivery more generally. While Spencer II describes its cloth as “compressible material,” there is no information or data presented on how compressible the cloth is. Furthermore, in my clinical experience of compressing such devices, pressure on one area of the cloth leads to bunching and expansion in another and therefore it is unlikely there would be a large reduction in the achieved caliber of the device (and a large reduction would be required to achieve 8 mm). As noted, however, this is a rough conservative

estimate that likely underestimates the effects of the bulging shown in Russell.

This effect therefore will counteract the effect of compressibility.

64. Thus, adding Spenser II's cloth to either Spenser or Levi would render the resulting device inappropriate for endovascular delivery.

65. In sum, it is my opinion that a POSITA would know that adding the outer cloths in Walther or Spenser II to Cribier, Spenser, and Levi would result in a combined device too large to be "delivered endovascularly."

c. *Petitioner's Arguments Do Not Demonstrate That These Proposed Combinations Could Be "Delivered Endovascularly."*

66. In discussing the combination of Walther's outer cloth with Cribier, Spenser or Levi, Petitioner first argues that any of these combinations could have been delivered endovascularly through the iliac artery. Pet., 39 ("POSITAs had successfully delivered SAPIEN through the common iliac artery, which is a larger artery that can accommodate bigger devices."). Petitioner cites Ex. 1043 [Kainuma] for this proposition, but, Kainuma does not seem relevant whatsoever as it does not involve or even mention *any* cloth-covered valve like Walther's. Additionally, as I have discussed above, while Petitioner contends that the common iliac artery "is a larger artery that can accommodate bigger devices," Petitioner does not identify the maximum allowable delivery profile for the iliac artery or explain how any of its Walther combinations would fit within that profile.

Indeed, Petitioner does not even clearly contend that a valve with a delivery profile larger than 8 mm (the maximum size for the femoral artery) could be delivered through the common iliac artery. Pet., 39. In fact, Kainuma, cited for delivery via the common iliac artery, used a 7.3 mm (22F) sheath, less than the 8 mm maximum for endovascular transfemoral delivery.

67. Moreover, I do not see any explanation in the Petition of what the delivery profile would be for any of the proposed Walther combinations or how that delivery profile would allow for endovascular delivery. Pet., 39-42, 67-69, 94-95. Instead, as Petitioner acknowledges, Walther was an in-vitro (*i.e.* bench-top) test using the 33F (11 mm) Ascendra delivery system designed for surgical transapical delivery, not endovascular delivery. Pet., 39; Ex. 1007 [Walther] 2, 7; *see also* Ex. 1017 [Cheung] 1-2 (showing clinical implantation of Walther's 9000MIS cloth valve via transapical delivery). I see no explanation in the Petition, however, of how adding Walther's cloth to a different SAPIEN valve would yield a different result—a valve capable of endovascular delivery—particularly when Walther explains that its cloth-covered valve is suitable for delivery approaches “where tight crimping is not an issue.” Ex. 1007 [Walther] 7.

68. Significantly, even if we assumed, for the sake of argument, that any of the Walther combinations could be delivered endovascularly via the common

iliac artery, I see no explanation of why a POSITA would be motivated to do so as the common iliac artery is only accessible through an invasive surgery.

69. I do not believe a POSITA would be motivated to conduct an endovascular surgery via the common iliac artery. Indeed, to the contrary, a POSITA would, for several important reasons, have been strongly motivated to move away from using the common iliac artery. The principal benefit of an endovascular delivery, *e.g.*, via the transfemoral approach is that it is a non-invasive approach wherein a purely percutaneous method may be used and the patient may be discharged from hospital in a matter of days. Transfemoral delivery rapidly became the overwhelmingly dominant approach, and has remained so ever since. An “endovascular” delivery via the common iliac artery, by contrast, is far more invasive, involves major vascular surgery, is associated with numerous complications and has been used very rarely. It has **never** been used in the overwhelming majority of implanting hospitals. To reach the common iliac artery, a surgeon would need to utilize a large incision typically used for renal (kidney) transplant surgery. The vessels lie deep in the retroperitoneal space. There is a need for surgical dissection through the anatomical layers of the anterior abdominal wall, including multiple layers of abdominal muscles. Arterial control by means of vascular clamps is required. In many cases because of the difficulties of access, vascular surgeons prefer anastomosing a graft onto the common iliac

vessel as it can be easier to access and close a graft than the native common iliac artery itself. Ex. 2012 [Retroperitoneal-Video]. Make no mistake, this is major vascular surgery in patients undergoing TAVI and requires an experienced vascular surgical team to undertake it safely. It carries with it major risks of vascular injury, dissection, vessel rupture, infection, bleeding, renal failure and a requirement for post-operative intensive care. Compared to a femoral surgical cutdown, iliac artery cutdown is associated with greater blood loss (2.6-fold greater blood loss), 82% longer procedure time, 1.5 days additional hospital stay, and 1.8-fold higher rate of perioperative complications. Ex. 2013 [Lee] 1. Whilst this approach allows a larger caliber device to be used for an ***abdominal aneurysm repair*** for example, no responsible cardiologist in the field of transcatheter valve replacement, where the devices are lower profile, would have any motivation at all to use this approach. Indeed, designing a transcatheter valve which mandated this approach would be considered perverse. This explains why Petitioner Edwards states that its 26F (8.6 mm) Ascendra+ delivery system is “[d]esigned for transapical and transaortic delivery,” and ***not*** for delivery via the common iliac artery. Ex. 2014 [Ascendra] 1; Ex. 2015 [Ascendra-FDA].

70. Kainuma, a reference cited by Petitioner but not a part of any combinations, does not suggest otherwise. Indeed, Kainuma accessed the common iliac artery with the invasive “retroperitoneal approach” discussed above. Ex. 1043

[Kainuma] 3. Furthermore, Kainuma itself confirms that “[w]e consider transfemoral access as the technique of choice because it is less invasive than the transapical approach...”

71. Next, Petitioner argues that a POSITA would have been motivated and capable of “adapt[ing] the cloth-covered SAPIENs for transfemoral delivery.” Pet., 40, 69. Petitioner contends that (1) a POSITA “would have had access to a range of suitable cloths,” (2) Petitioner itself “had developed delivery systems having smaller diameters than those initially used with SAPIEN,” and (3) Petitioner itself “had developed a variety of ways to adapt a heart valve’s outer frame and leaflets to create additional space for an outer cloth.” *Id.*, 40; *see also id.*, 68. I note that Petitioner, however, does not point to any particular further modification of these asserted combinations, or otherwise explain how such an (unspecified) combination would allow for endovascular delivery.

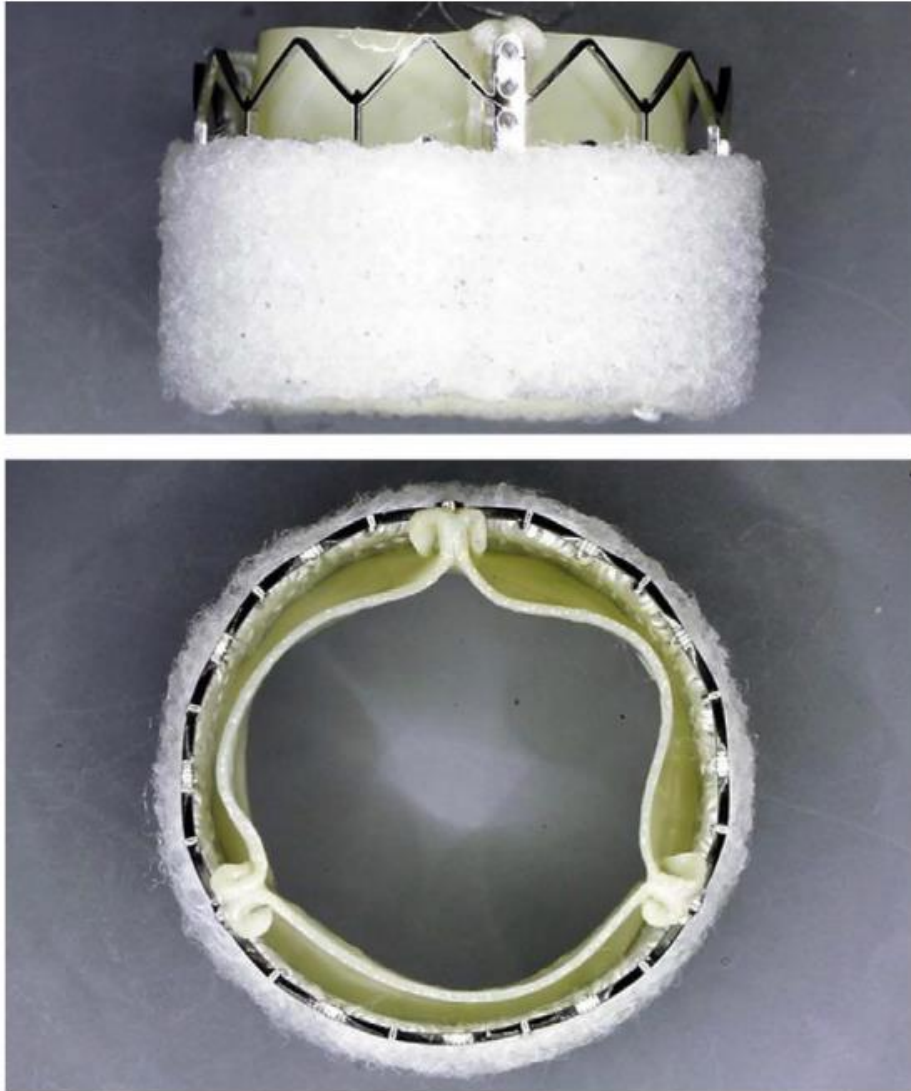
72. Additionally, Petitioner’s assertion that “ POSITAs would have had access to a range of suitable cloths having varying thicknesses and densities” seems to ignore the cloth’s function in Walther and Spenser II. Walther states, “[w]hen a Sapien™ valve is expanded in the CEP valve, the rigid base does not easily conform to the profile of the expanded stent frame, which leaves gaps between the two valves....” Ex. 1007 [Walther] 1. Thus, Walther seals by having a thick outer skirt that closes the “gaps between the two valves” so as to conform

“the rigid base ... to the profile of the expanded stent frame.” *Id.* In other words, a POSITA would understand that a certain thickness is necessary and selecting a smaller cloth suitable for endovascular delivery would have frustrated Walther’s purpose. Spenser II has the exact same issue, explaining that its “compressible material **expands** after deployment at a treatment site ... [and] fills the gaps between the stented valve and the surrounding tissue.” Ex. 1011 [Spenser II] ¶145. This indicates that Spenser II must have a certain level of thickness in order to “expand” as intended.

73. I will note that Petitioner additionally argues that Walther states that “implantation of the cloth-covered valve ‘is feasible,’” but Walther does not say that **endovascular** implantation “is feasible.” *Id.*, 41-42; Ex. 1007 [Walther]; *see also* Ex. 1017 [Cheung] 2-3 (implanting the Walther valve transapically). To the contrary, Walther states that it is designed for transapical delivery where “tight crimping is not an issue.” Ex. 1007 [Walther] 7. Additionally, Petitioner contends that the “common iliac artery ... could accommodate large valves” but does not show delivery of a cloth-covered valve through the common iliac artery, or why a POSITA would design a valve that needed to be delivered through such an invasive way. Pet., 42; *see also* ¶¶54-58, *supra*.

74. Finally, for the Levi-Walther combination only, Petitioner argues that Levi teaches that “[w]hen crimped, the frame 12 has a reduced diameter region

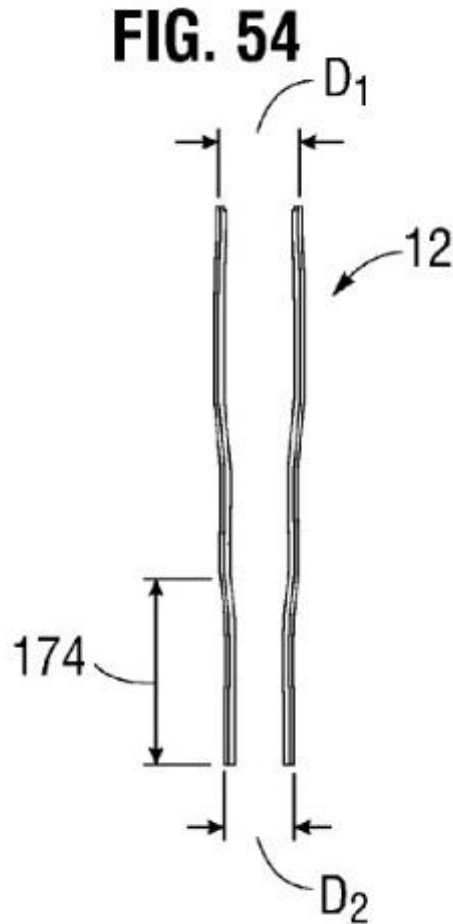
extending along a portion of the frame ... that generally corresponds to the region of the frame covered by the outer skirt 18” so that the outer skirt “does not increase the overall crimp profile of the valve,” and that “Walther’s outer cloth ... would also cover the reduced diameter region.” Pet., 94. Petitioner, however, provides no explanation of how Levi’s supposed “reduced region” 174 would be able to accommodate Walther’s far thicker outer cloth, particularly when Walther’s thick outer cloth covers such a large portion of the valve, not just Levi’s “reduced region”:



Ex. 1007 [Walther] Fig. 1.

75. In fact, Levi states that the inflow end (area indicated by 174) had a crimped profile of 12 F compared to a 14 F profile at the remainder of the valve.

Ex. 1008 [Levi] 8:56-59 (“In one example, the frame of a 26-mm valve, when crimped, had a diameter D1 of 14 French at the outflow end of the valve and a diameter D2 of 12 French at the inflow end of the valve.”).



Ex. 1008 [Levi] Fig. 54. Thus, this 2F reduced diameter portion would have only allowed for an outer seal that was 0.33 mm (1F) thick (when crimped) before the seal would extend radially beyond the non-reduced diameter portion of Levi's frame. This is far less than the 1.0 to 5.0 mm seal of Spenser II (which is *far* greater when crimped, see ¶¶50-52, *supra*) or the outer skirt depicted in Walther.

76. Furthermore, Walther's outer skirt appears to clearly be taller than Levi's outer skirt, and the Walther skirt would clearly cover more [of the reduced diameter region 174] if that "generally corresponds to the region of the frame

covered by the outer skirt 18.” Thus, if the seal of Walther could even be added to Levi, the seal would necessarily extend distally beyond the area of reduced diameter 174.

77. In discussing the combination of Spenser II’s outer cloth with Spenser, Petitioner first contends that “POSITAs would have reasonably expected that Spenser’s Figure 44a combined with ... Spenser II’s compressible material would be suitable for endovascular delivery through at least the common iliac artery.” Pet., 68. Per the analysis provided above in Section VI.A.2.b, even using the most conservative calculations—the Spenser II combinations would have a delivery profile well over the 8 mm limit for endovascular delivery. Thus, Petitioner’s assertion that the combination could be delivered through the common iliac artery is both unsubstantiated (Pet., 68), contrary to the record evidence, and completely ignores the complications associated with accessing the common iliac artery (*see* ¶¶54-58, *supra*).

78. The Petition then argues that Spenser “teaches that the ‘maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter’” and that “adding a compressible material 1 mm thick to Spenser’s 4-mm valve would have resulted in a device suitable for endovascular delivery.” Pet., 68-69 (emphasis removed). Despite citing the thickness of Spenser’s cloth on its own when on a valve in the expanded state, and the diameter of Spenser’s

crimped valve (*i.e.* not the expanded state) ***without an outer cloth***, Petitioner does not explain what the delivery profile would be for its proposed combination. *Id.* Indeed, as discussed above, Petitioner is not making a fair comparison, for the Spenser II's outer cloth would only be 1 mm in the expanded position. In the crimped position, the 1 mm becomes much thicker and even if we were to conservatively exclude bulging (*see* ¶¶50-52, *supra*), the combined diameter of Spenser II's cloth with Spenser/Levi would, using conservative assumptions, still be far too large for endovascular delivery.

79. Finally, for the Levi-Spenser II combination, Petitioner argues that Spenser II's compressible material would cover Levi's "reduced region." Pet., 94. This argument fails for the reasons discussed above.

80. In sum, Petitioner's arguments do not demonstrate that its combinations could be "delivered endovascularly" as required by claim 6.

d. *Petitioner does not adequately explain why a POSITA would be motivated to make these combinations in spite of the delivery size issue*

81. It would be clear to a POSITA that each of the primary references (Cribier, Spenser, and Levi) teaches a heart valve designed with a narrow delivery profile so that the valve could be delivered ***transfemorally***. As explained below, these references note the tight size constraints needed in order to create a device that is small enough to fit within the femoral artery.

82. Cribier’s title makes clear that it is directed towards “the Transfemoral Approach”:

## Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien® Heart Valve Using the Transfemoral Approach

Ex. 1012, 347. Cribier’s disclosure likewise confirms the concern for transfemoral delivery. *Id.* (“This article is aimed at describing the updated ***transfemoral technique***. ... the THV with its delivery system is ***introduced within the femoral artery***...”). While Cribier mentions an “antegrade transapical route[],” Cribier makes clear that it “is aimed at describing the updated transfemoral technique.” *Id.*

83. A POSITA would understand that Spenser is similarly concerned with transfemoral delivery. *See* Ex. 1010 [Spenser] 2:6-11 (discussing “... implanting the valve at the desired location via a large blood vessel such as the ***femoral artery***”). Indeed, Spenser seems to assert that its point of novelty is designing a valve capable of reducing to a very narrow diameter (***4 mm***) in order to fit within the femoral artery:

A typical size of an aortic prosthetic valve is from about 19 to about 25 mm in diameter. ***A maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter.*** The present

invention introduces a device, which has the ability to change its diameter from about 4 mm to about 25 mm. Artificial valves are not new; however, artificial ***valves in accordance with the present invention possess the ability to change shape and size for the purpose of delivery and as such are novel.***

*Id.*, 27:64-28:5. Therefore, the purpose of Spenser’s invention is to produce a valve that can be small enough to fit into the femoral artery. I note that Petitioner agrees, in a related IPR, that Spenser’s heart valve is “configured for endovascular delivery.” Ex. 2031 [1527 Petition], 6; 60 (same), 68 (similar).

84. Similar to Spenser, Levi stresses the importance of a narrow design capable of transfemoral delivery. In the Background of the Invention, Levi notes the “drawbacks associated with conventional open-heart surgery,” and alludes to other references concerning “minimally-invasive surgical approaches.” Ex. 1008 [Levi] 1:57-59. Levi further indicates that “[a]n ***important design parameter*** of a transcatheter heart valve ***is the diameter of the folded or crimped profile***” and that this is “important because it directly influences the physician’s ability to advance through the ***femoral artery*** or vein.” Ex. 1008 [Levi] 2:1-7; 14:60-64 (similar); 6:46-49 (similar). Levi also teaches that “a smaller profile allows for treatment of a wider population of patients, with enhanced safety.” *Id.*, 2:5-7. Thus, a POSITA would understand that the problem Levi is trying to solve is how to make a valve with a delivery profile small enough to fit within the “femoral artery or vein.”

85. It is not surprising that these references concern devices designed for a very narrow profile, suitable for transfemoral delivery. As Petitioner and Dr. Buller acknowledge in a related IPR, the “transfemoral approach” is “‘the technique of first choice’ and safer than the transapical approach, which was associated with ‘more adverse events and higher mortality rates.’” Ex. 2031 [1527 Petition] 40 (quoting Ex. 1009 [Conradi] 515-516); Ex. 2032 [1527 Buller-Decl.] ¶129 (same). I agree that a POSITA would know that transfemoral delivery would have been the overwhelmingly preferred approach. See EX. 2016 [Tanawuttiwat] (transfemoral was “first-line method in many centers”), Ex. 2017 [Doshi] (“The preferred access for TAVR is transfemoral”).

86. Given the importance placed on transfemoral delivery in Cribier, Spenser, and Levi, Petitioner does not explain why a POSITA would be motivated to modify these devices that would make them incapable of transfemoral delivery. In particular, I will note that for the Levi-Walther/Spenser II combinations, Petitioner appears to argue that “POSITAs would have also found it obvious to replace Levi’s bulging outer skirt with Walther’s outer cloth or Spenser II’s compressible material” and would have been motivated to use either “Walther’s outer cloth because the cloth prevents PVL and promotes tissue ingrowth,” or “Spenser II’s compressible material because its radially extending fibers prevent PVL.” IPR2022-00034-Pet., 86. Petitioner further contends that this “would have

merely entailed substitution of one known element (outer cloth/compressible material) for another (Levi's outer skirt) to yield the predictable results of reducing PVL" and that "POSITAs would have found it obvious to select **any one** of these finite, predictable options." *Id.* 86-87. Petitioner gives no explanation, however, for why a POSITA would choose Walther's outer cloth or Spenser II's compressible material to prevent leakage when Levi already has an outer skirt for that exact purpose. *Id.* In fact, if "Walther's outer cloth," Spenser II's, and "Levi's bulging PET" skirt all "yield the predictable results of reducing paravalvular leakage," and a "POSITA would have found it obvious to select **any one**" of these "options," as Petitioner claims (*id.*), then a POSITA would not be motivated to choose the options that would render the device **incapable of transfemoral delivery**.

87. In sum, Petitioner has not demonstrated that any of its proposed combinations of Walther's or Spenser II's cloths with the valves in Cribier, Spenser, or Levi render obvious a "valve assembly" that "is delivered endovascularly," which includes an "outer seal [that] is attached to the outer frame" of the valve.

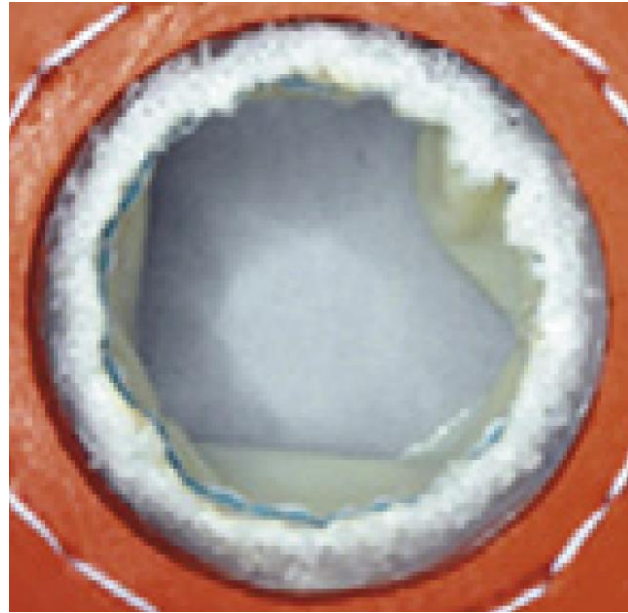
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2. Dr. Buller and Petitioner Fail To Demonstrate That Any Of Their Proposed Combinations Disclose Or Render Obvious A Valve With An “Outer Seal” That Is Delivered “Endovascularly”

- a. *Dr. Buller and Petitioner’s References Indicate That Each TAVR With A Walther-Like Outer Cloth Required A 33F Delivery Sheath.*

88. Below I have included excerpts from Figures 1 and 2 of Walther showing its outer cloth.



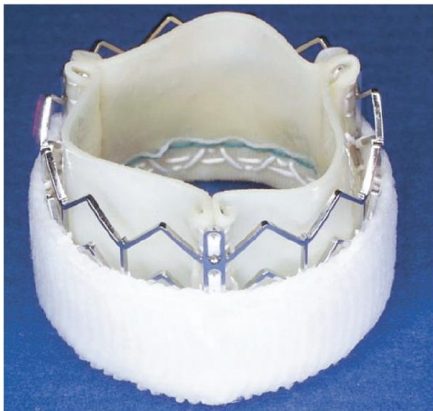


89. Walther's thick outer cloth precludes endovascular delivery. I'm not aware of **any** TAVR endovascularly-delivered by **any** route with such a thick outer cloth. Walther's valve is for a non-endovascular transapical approach where "tight crimping is not an issue." Ex. 1007 [Walther] 1126; Ex. 2052 [Buller-Depo.] 207:22-208:7 (no suggestion Walther or Cheung deliverable transfemorally or via common iliac). And Walther (the author) emphasized in June 2012—just before the priority date—that "[l]arger sheath diameters can be used with the [transapical] access," and "[s]olutions for improving paravalvular leakage may also be implemented into clinical practice through the TA approach" as, "theoretically these solutions **require** the larger diameters afforded by the TA route." Ex. 2058 [Walther-II] 216. Like Dr. Buller, I am not aware of any TAVR with an outer cloth like the ones seen in Walther, Spenser-II, and Cheung, that has ever been

endovascularly delivered by any route. Ex. 2052 [Buller-Depo.] 105:16-21, 107:25-108:4.

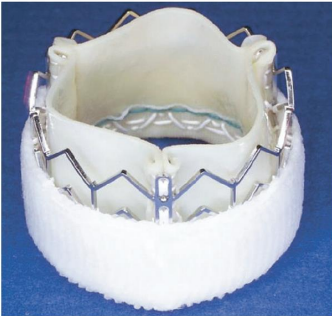
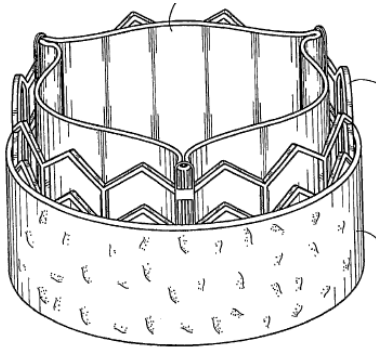
90. Walther's SAPIEN with cloth was delivered "via the 33F Ascendra system." Ex. 1007 [Walther] 1121. This is hardly surprising in view of Walther's thick outer cloth and there is no indication that any smaller delivery system would have been feasible.

91. Like Walther, Cheung adds an outer cloth and, indeed, both Cheung and Walther use the same model number "9000MIS." Compare Ex. 1007 [Walther] 1120 with Ex. 1017 [Cheung] e19. I agree with Dr. Buller that Cheung's cloth is "very similar" to Walther's (Ex. 2052 [Buller-Depo.] 198:11-18, 200:7-14):

| Walther                                                                             | Cheung                                                                               |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|  |  |

92. Cheung, like Walther, required a 33F delivery sheath. Ex. 1017 [Cheung] e19; Ex. 2052 [Buller-Depo.] 203:14-204:2; 207:4-7 (not aware of suggestion in Cheung that it could be delivered endovascularly); 207:22-208:7, 186:3-6. Thus, Cheung only further confirms that Walther’s cloth was not suitable for endovascular delivery.

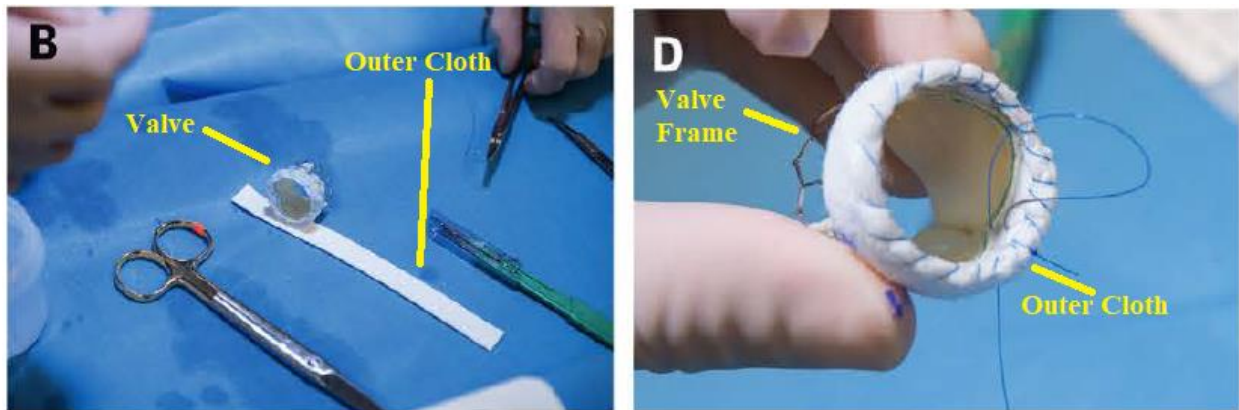
93. Given the manifest similarities between Walther, Cheung, and Spenser-II, a POSITA would expect Spenser-II’s Figure 22 to also have a large crimp profile:

| Walther                                                                            | Cheung                                                                             | Spenser-II                                                                                                                          |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
|  |  |  <p data-bbox="1166 1318 1256 1346">FIG. 22</p> |

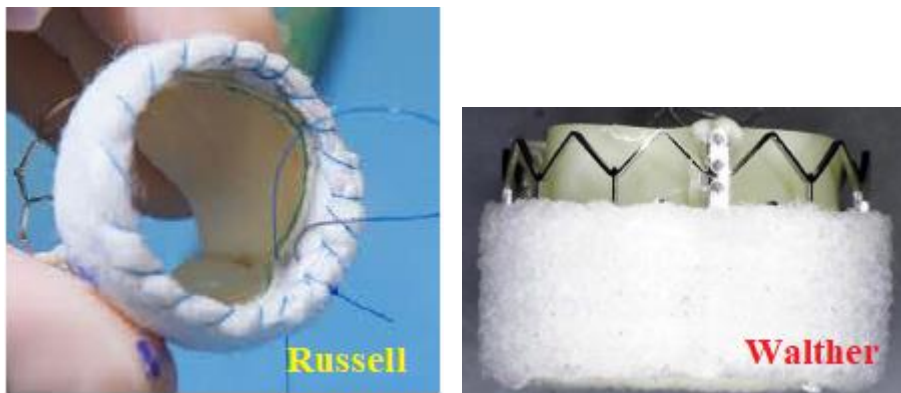
94. Indeed, Dr. Buller referred to Walther as a “real-world experiment or the concept which was taught in the Spenser 2 patent” and/or as a “real-world embodiment of Spenser 2’s Figure 22.” Ex. 2052 [Buller-Depo.] 104:18-105:7. And, in fact, my rough calculations suggest that Spenser-II would have a similarly large crimp profile. See ¶¶60-64.

b. *Dr. Buller Does Not Account For Bunching*

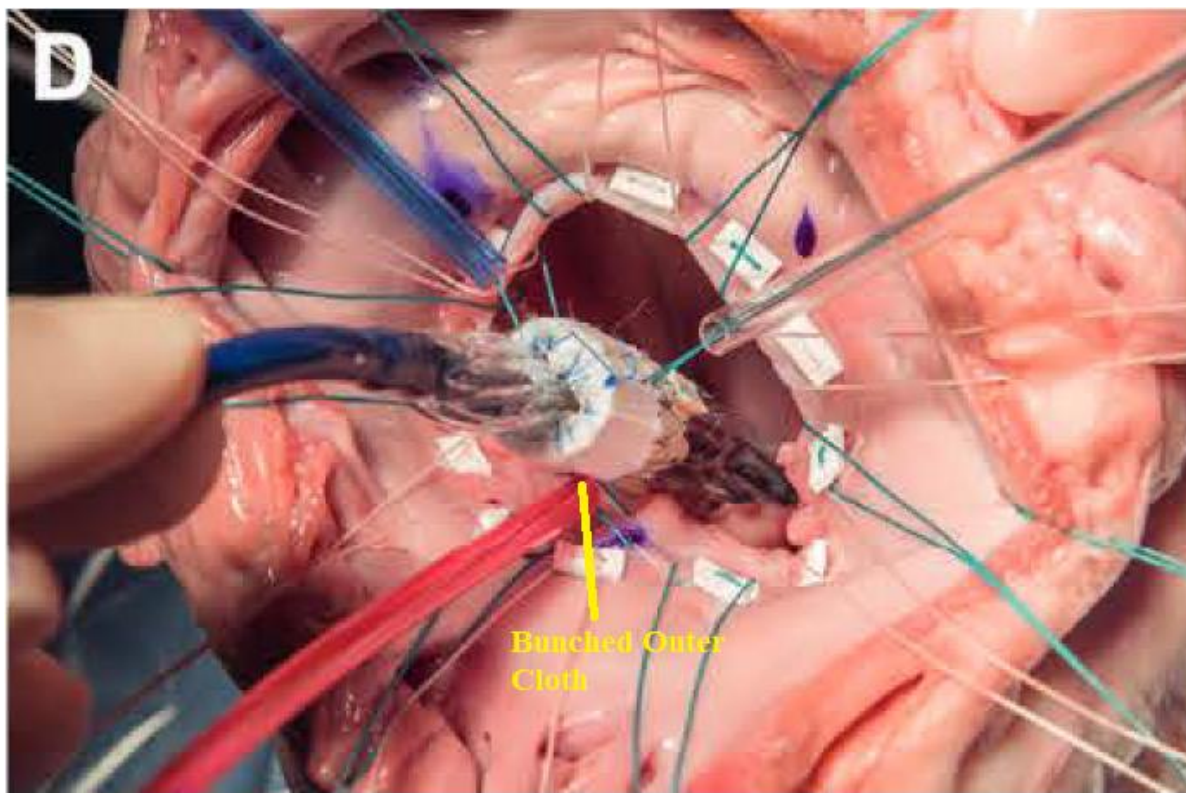
95. While crimped, Walther's and Spenser-II's outer cloth would bunch, adding significantly to the diameter. Bunching is clearly shown in Russell which includes an outer cloth similar to Walther's and Spenser-II's Fig. 22:

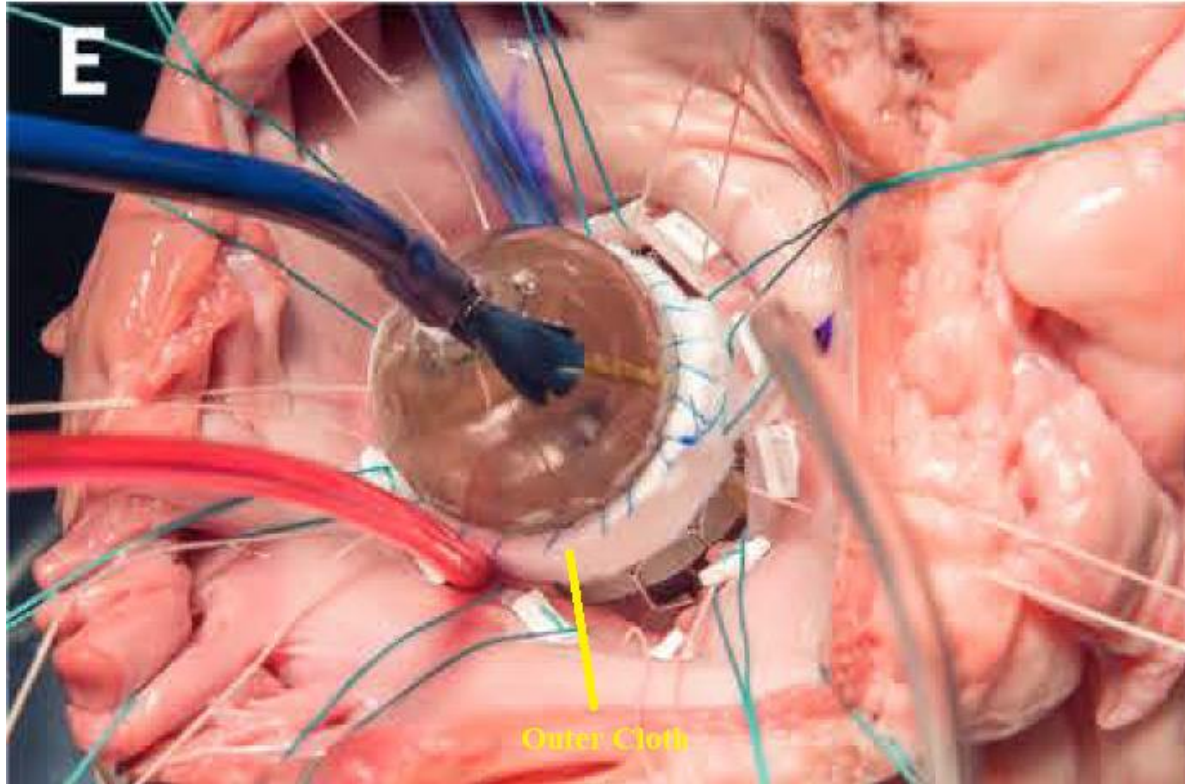


Ex. 2009, 5 (Fig. 2) (yellow annotations added).

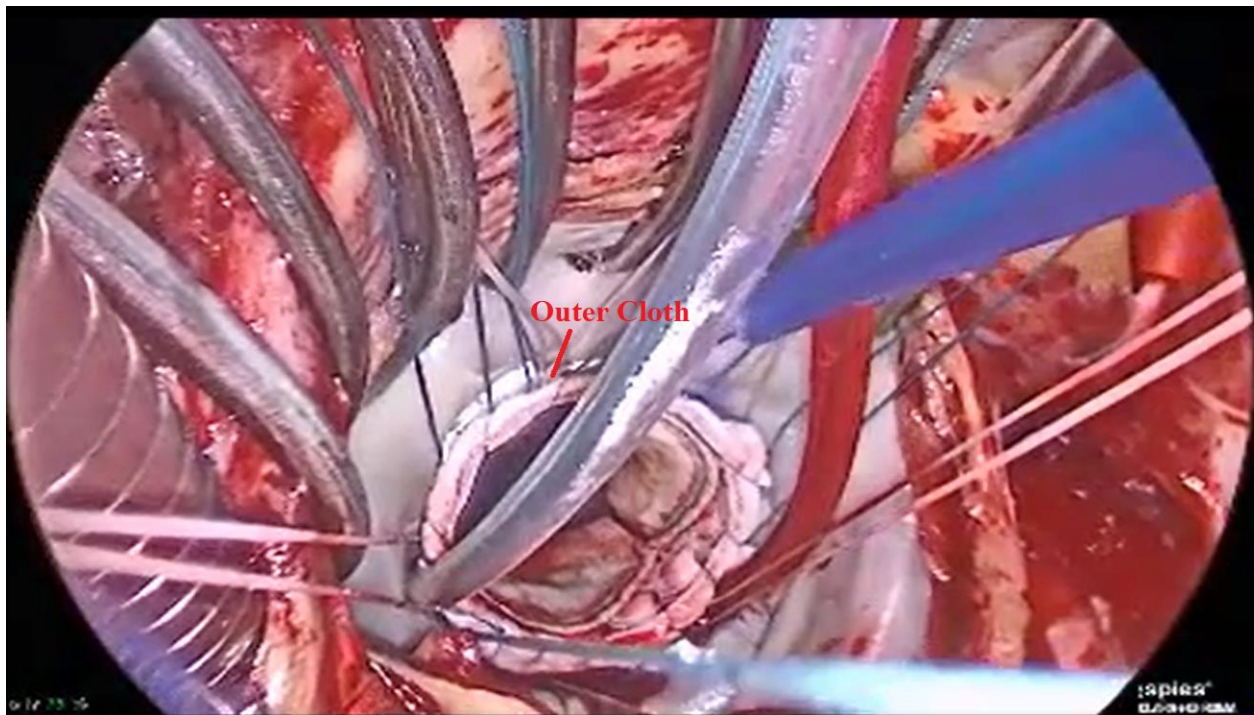
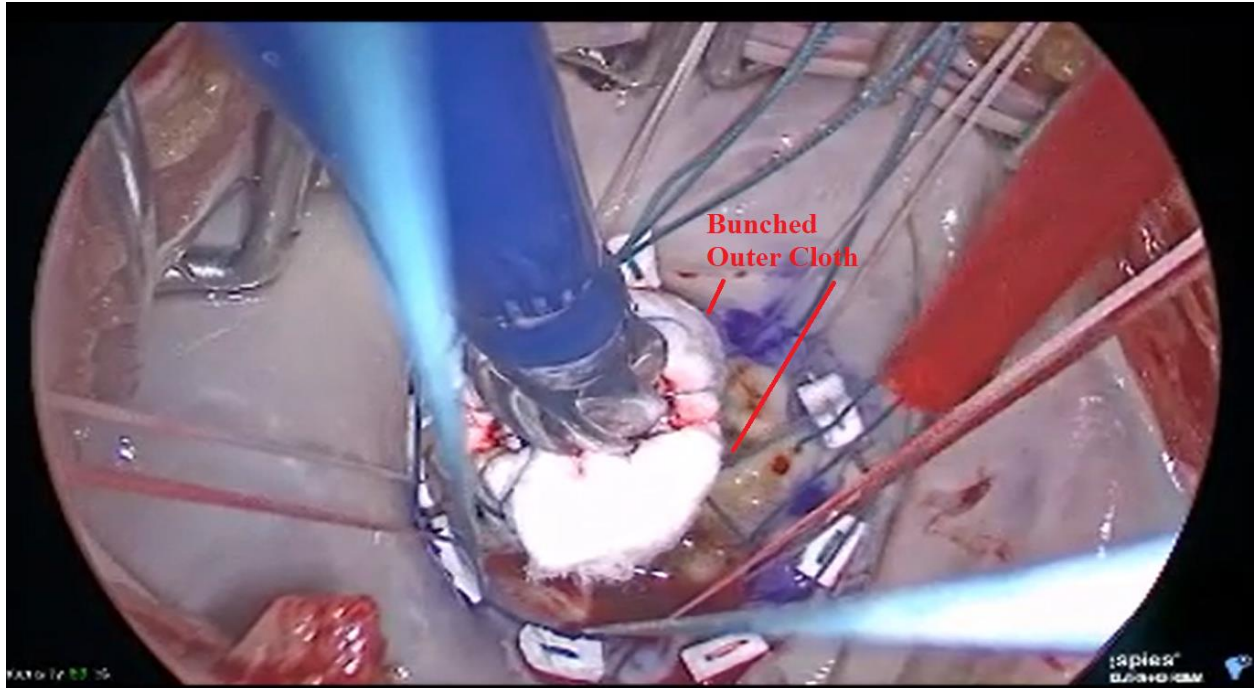


*Id.*; Ex. 1007 [Walther] 1121 (Fig. 1). When Russell's valve is crimped, its outer cloth is bunched and significantly thicker:





96. Such bunching is further shown in the video referenced in the Russell article which at 3:48-4:12 shows the crimped valve being positioned in the context of an open-heart surgery in the mitral valve and at 5:00-5:30 shows the expanded valve. Ex. 2010 [Russell-Video]. Bunching adds significantly increases the crimp profile:



*Id.*, 3:55, 5:20. A POSITA would know that a bunched up outer cloth as shown in Russell would prevent any valve from being crimped tightly enough to be delivered endovascularly.

97. As discussed in ¶63, *supra*, using certain assumptions, Spenser's valve with Spenser-II's outer cloth would have a diameter of at least 10.96 mm (when the valve is crimped and the cloth uncompressed)—similar to Walther's 11 mm delivery—over 36% too large for transfemoral delivery (Ex. 1010 [Spenser] 27:65-67) and endovascular delivery more generally. ...this is a rough conservative estimate that likely underestimates the effects of the bulging shown in Russell. This effect therefore will counteract the effect of compressibility.

98. The crimp profile of the valve without the cloth is 4mm. See Ex. 1010 [Spenser] 27:67-28:2; *see also* ¶63, *supra*. Therefore Spenser II's 1mm thick cloth (in the expanded state) would add approximately 6.96mm (10.96mm minus 4mm) to the crimped diameter. This calculation does not take into account for bunching, bulging, and compression.

99. Spenser-II's 1-5mm range is for the cloth in the expanded-state. Figure 22 is only shown in the expanded-state and its crimped-state is neither shown nor described:

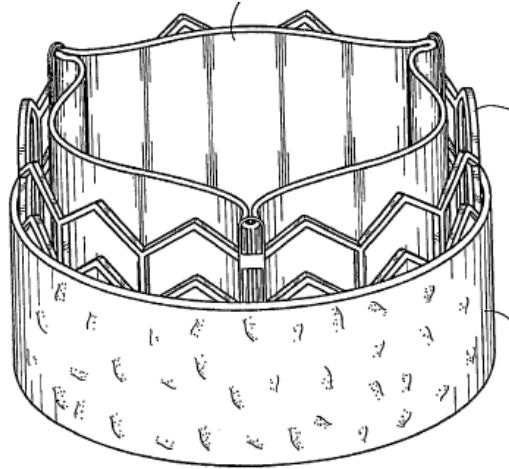


FIG. 22

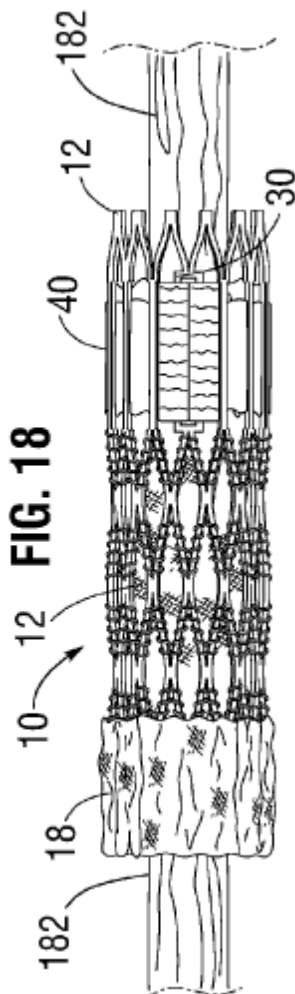
100. Thus, the 1-5mm range identifies the compressible material's thickness in the expanded-state. See Ex. 1011 [Spenser-II] ¶145. Dr. Buller agrees. Ex. 2052 [Buller-Depo.] 217:11-218:11; 218:4-6.

c. *Levi's Thin Outer Skirt Is Further Confirmation That Walther/Spenser-II Cannot Be Endovascularly Delivered.*

101. Levi teaches an endovascularly-deliverable TAVR with an outer skirt. To accommodate the added skirt, Levi's outer frame is narrowed at an inflow end where the skirt is attached. Ex. 1008 [Levi] 2:22-29, 8:43-51. Levi teaches that because of this, the crimped diameter with the outer skirt is "less than or equal to an outer diameter" where the skirt is not attached. *Id.*, 2:31-35. Levi further teaches that the crimped diameter can be 14F at the outflow end and 12F at the inflow end (where the skirt is attached). *Id.*, 8:56-59. Thus, there is just a 2F (.33mm) difference between the reduced and non-reduced portions. That means that the outer skirt could have, at most, a 1F **crimp** thickness (2F divided by 2). It

would be significantly thinner in the expanded-state. That Levi's cloth will crimp is confirmed both in Levi's Figure 18 and in Levi's commercial embodiment,

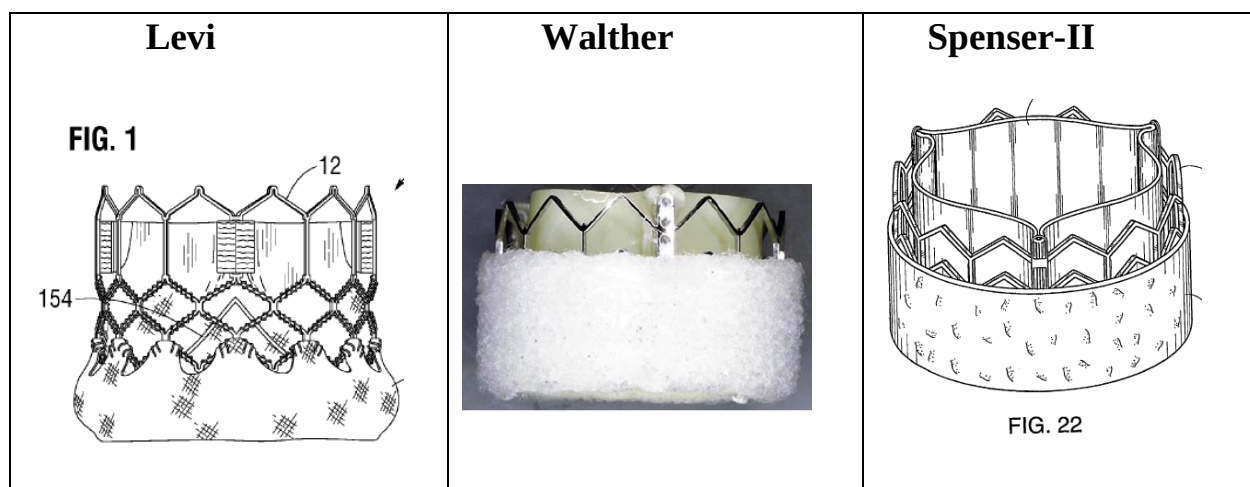
Sapient 3:

|                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Levi, FIG. 18</p> <p>The diagram shows a cross-sectional view of a medical device. It features a central shaft (10) with a series of crimped segments (12) and a distal end (182). A layer (18) is shown on the shaft, and a crimped segment (40) is shown in detail. A label 'FIG. 18' is placed vertically next to the diagram.</p> |  <p>Ex. 2050, Fig. 1(B).</p> <p>A photograph of a medical device, likely a catheter, showing a blue handle and a white, crimped segment. The device is shown against a blue background.</p> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

102. Levi's 1F crimp thickness is *far* thinner than Walther's and Spenser-II's cloths. Walther, per Dr. Buller, is 2mm thick in the expanded-state. Ex. 2052

[Buller-Depo.] 90:18-23. Spenser-II is 1-5mm thick in the expanded-state. In my mathematical calculation of Spenser-II's thickness, Spenser-II's 1mm-expanded-state cloth added ~6.96mm (10.96mm minus 4mm crimped valve = 6.96mm) to the crimped diameter. Thus, the 1mm thick cloth became roughly 3.48mm (10.44F) thick (6.96mm divided by 2 = 3.48) when crimped. Levi's outer skirt, by contrast is only ~1F thick when crimped. The thinnest range of Spenser-II's thick cloth would, thus, be roughly 10.44x thicker than Levi's skirt when crimped. The thickest range (5mm in the expanded-state) would be 5x that (*i.e.*, 52.2x thicker than Levi's skirt) when crimped. Walther, per Dr. Buller's estimate, is 2mm thick in the expanded-state. Using the same calculation, Walther's crimped cloth would be ~20.88x thicker than Levi's skirt. This is consistent with what is shown in Russell, where the crimped profile became much larger.

103. The difference in thickness is also reflected in the images themselves when showing the expanded-state:



104. Levi, thus, is able to be endovascularly-delivered not just because of its frame but because it uses a very thin outer skirt—one that is roughly 10.44-52.2x thinner than what is present in Spenser-II and roughly 20.88x thinner than what is present in Walther. Thus, while a specially designed TAVR adapted to Levi's thin skirt is endovascularly-deliverable, Levi only confirms why Walther's and Spenser-II's thick cloths would not be.

- d. *There Is No Evidence That A Device With Walther Or Spenser-II's Outer Cloth Could Be Delivered Via The Common Iliac.*

105. I do not believe a POSITA would be motivated to deliver TAVRs via the common iliac. The entire purpose of TAVR was to develop a percutaneous therapy to avoid a major surgery, particularly as many patients in need of TAVRs were elderly and inoperable. In my 1300 TAVR procedures, I have never once implanted a TAVR via the common iliac, nor do I know anyone who has to my knowledge and recollection.

- e. *There Is No Evidence To Support Dr. Buller And Petitioner's Unspecified Modifications Of Walther Or Spenser II's Outer Coverings.*

106. Petitioner and Dr. Buller suggest that Walther's or Spenser-II's outer coverings could be modified in some unspecified way and combined with some other frame or sheath so as to be endovascularly delivered. See IPR2022-00034-

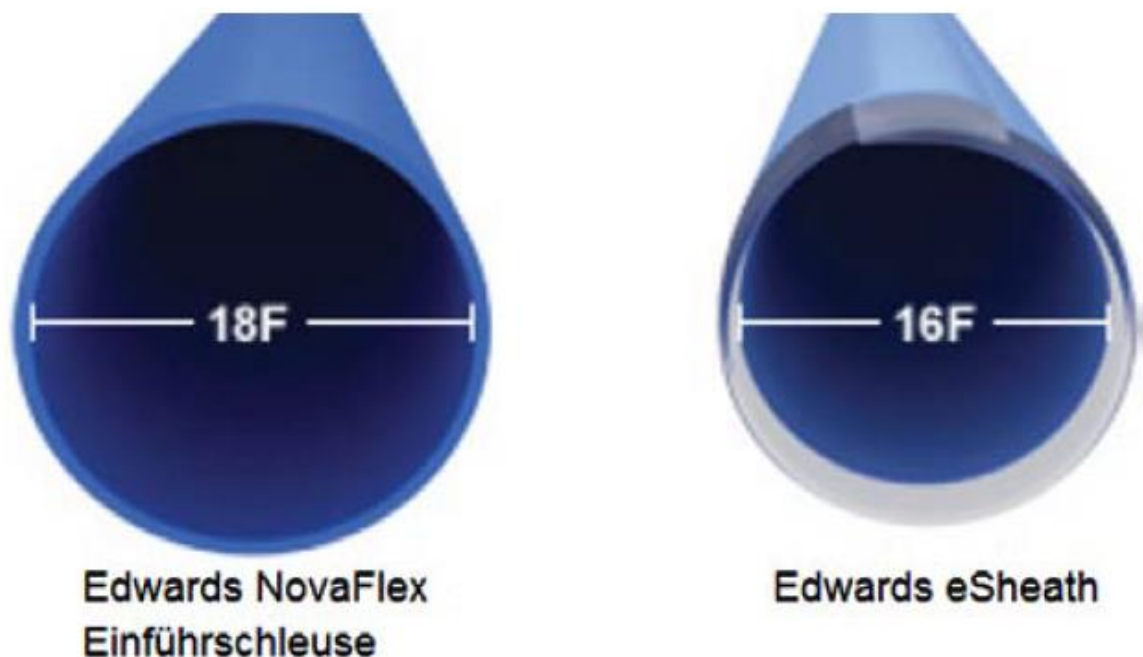
Pet., 40, 68; IPR2021-001527-Pet., 40-41; IPR2021-01584-Pet. 62; IPR2022-00193-Pet. 25-26, 58-59; IPR2022-00034-Ex. 1003 [Buller-Decl.] ¶153; IPR2021-001527- Ex. 1003 [Buller-Decl.] ¶130; IPR2021-01584-Ex. 1003, [Buller-Decl.] ¶¶166, 244; IPR2022-00193- Ex. 1003 [Buller-Decl.] ¶111. Petitioner and Dr. Buller do not tell us, however, precisely how it would modify Walther’s or Spenser-II’s outer cloth, which frame or sheath would be used, or precisely what the resulting modified combination would be. Petitioner and Dr. Buller say that there are many “suitable cloths having varying thicknesses and densities” and that an “appropriately dimensioned cloth” could be selected, but I cannot evaluate that statement without an identification of a particular cloth with a particular thickness or density. Nor could I evaluate whether it would satisfy other claim requirements, such as that the outer seal is “free of an outer graft covering” or has “radially/outwardly extending fibers.” I have, quite simply, no understanding of what specific combinations Petitioner has in mind or in what manner they would be modified to achieve the claimed invention. I further do not know why a POSITA would be motivated and able to make such unspecified combinations.

f. *A POSITA Would Not Be Motivated To Add Walther’s Or Spenser-II’s Thick Outer Cloths To A TAVR Meant For Endovascular Delivery*

107. Even if a TAVR with Walther’s or Spenser-II’s outer cloth could, somehow, be endovascularly delivered, I do not believe a POSITA would have

been motivated to make such a combination in 2012, as by any measure this would have significantly increased the crimp profile. The entire premise of TAVR was to make a percutaneous procedure that was minimally invasive and would provide a life-saving alternative for inoperable patients.

108. In 2012, POSITAs were interested in decreasing the crimp profile as much as possible, and a major thrust of design development was with this intention. Edwards' second-generation device, the SAPIEN XT (available in Europe in 2010) reduced the delivery profile from SAPIEN's 22-24F to 16-18F (interior diameter), as a large crimp profile was "one of the major concerns regarding vascular related complications."



Ex. 2049 [Blumenstein] 275; Ex. 2052 [Buller-Depo.] 17:9-18:7; 78:24-79:6. The

notion that a design development which substantially increased crimp profile (using Walther or Spenser II outer cloth, even if it could be at the limits of endovascular delivery), would gain traction, is fanciful.

109. Levi discloses a TAVR that is endovascularly-deliverable and with an outer skirt for addressing PVL. Levi's frame is modified so that *its* outer skirt could be added without increasing the crimp profile. Ex. 1008 [Levi] 2:23-35. Levi's outer skirt is also intended to address PVL. *Id.*, 14:7-9. Levi's outer skirt, as discussed, is far thinner than Walther's/Spenser-II's outer coverings, *e.g.*, on the order of 10-50x thinner.

110. Petitioner and Dr. Buller do not explain why a POSITA would add Walther or Spenser-II's bulky outer cloth to a TAVR meant to be endovascularly deliverable. Even if we assume these combinations were, somehow, endovascularly-deliverable, they would be just barely so and, if Petitioner's arguments are to be believed, may have to be made via an invasive common iliac surgery—the very thing TAVR sought to avoid. Petitioner, quite simply, does not explain why a POSITA would take this route. Petitioner does not argue that adding Walther's or Spenser-II's outer cloth would somehow improve the crimp profile or better reduce PVL over Levi's solution. I do not see why a POSITA would be motivated to do such a thing. As someone who was actively undertaking TAVR procedures in 2012, I can state as a fact that any new device which had a

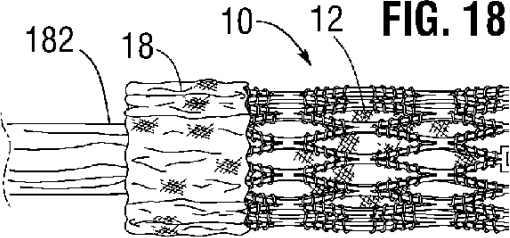
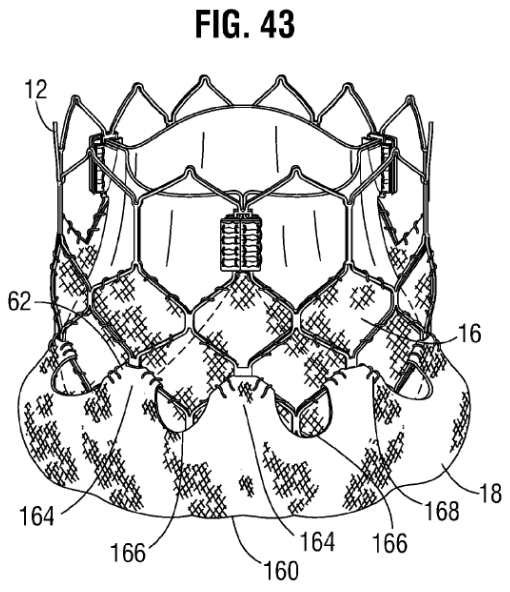
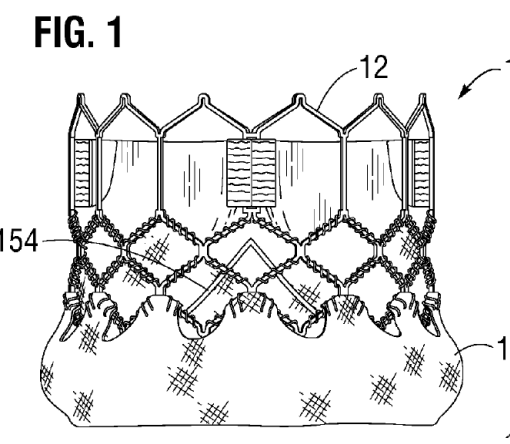
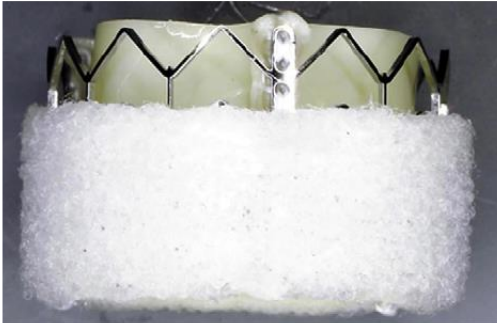
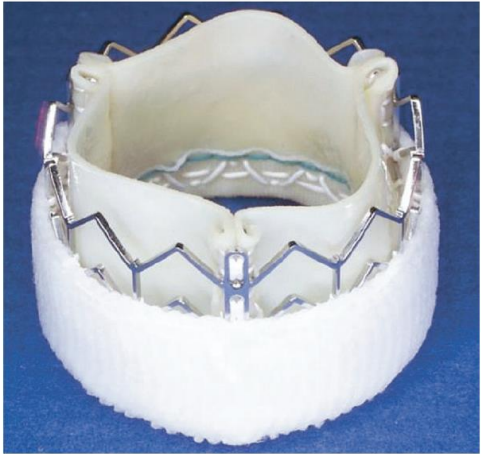
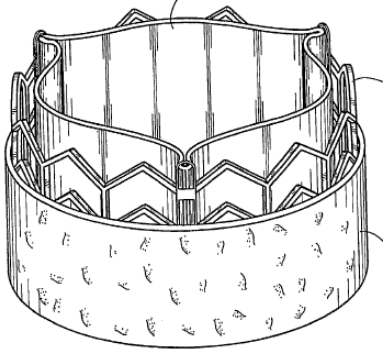
substantially increased profile, would be regarded negatively. The combinations seem driven by hindsight.

- g. *Adding Walther's Or Spenser-II's Outer Cloth To Levi Would Violate Levi's Principles Of Operation And For No Discernible Benefit.*

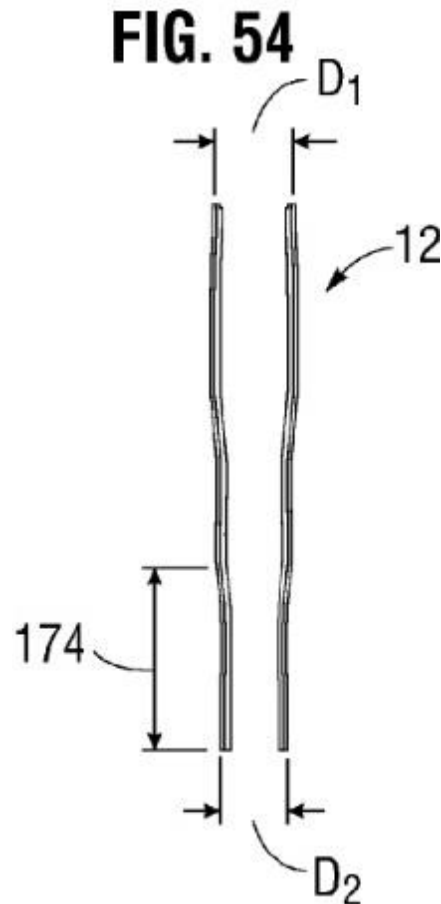
111. Levi's background of the invention teaches, "[a]n important design parameter" for TAVR design "is the diameter of the folded or crimped profile," which "is important" to "advance" the TAVR "through the femoral artery or vein," and "a smaller profile allows for treatment of a wider population of patients, with enhanced safety." Ex. 1008 [Levi] 2:1-7. Thus, Levi is interested in having a reduced crimp profile. *See also* Ex. 2052 [Buller-Depo.] 127:21-128:3. Walther/Spenser-II cloth is **far** thicker (*e.g.*, ~10-50x thicker) and would frustrate this guiding principle. *See* ¶¶101-104.

112. To accommodate its outer skirt, Levi makes the "outer diameter of the inflow end" of the frame "smaller than the outer diameter of the outflow end portion of the frame," and "[t]he reduced diameter at the inflow end portion can make room for an outer skirt positioned around the inflow end portion." *Id.*, 2:23-29. By reducing the diameter of the inflow area, the "outer skirt" could be "positioned around" the frame's inflow portion, such that the diameter of the inflow end with the outer skirt "**is still less than or equal to**" the outflow end's diameter. *Id.*, 2:31-35; 8:51-59; 14:30-35 (similar); 16:54-66; 17:12-18.

113. Levi includes a very thin outer skirt, one much thinner than what is seen in Walther, Cheung, and Spenser-II:

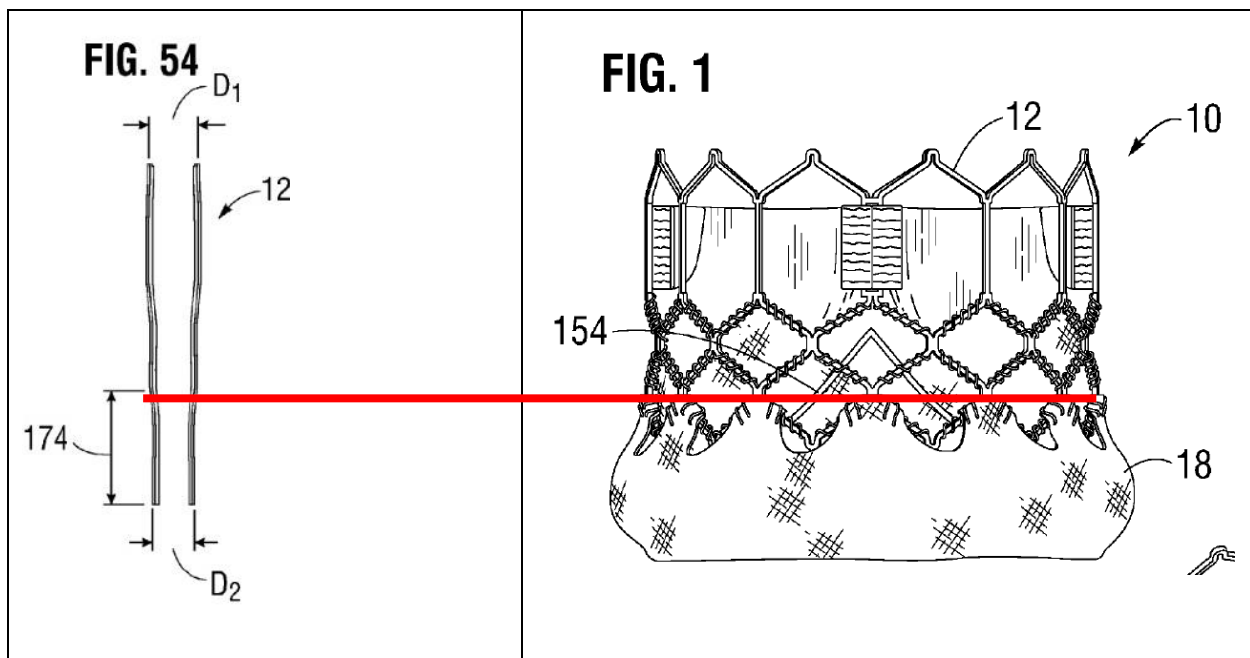
| Levi/Sapien 3                                                                                                                                                                                                                                                                                                                                                                                                                    | Walther/Cheung/Spenser-II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p data-bbox="240 289 747 525">  <b>FIG. 18</b> </p> <p data-bbox="240 609 747 1197"> <b>FIG. 43</b><br/>  </p> <p data-bbox="240 1239 747 1680"> <b>FIG. 1</b><br/>  </p> | <p data-bbox="873 289 1367 609">  </p> <p data-bbox="824 661 1218 703">       Ex. 1007 [Walther] Fig. 1.     </p> <p data-bbox="889 756 1367 1207">  </p> <p data-bbox="824 1260 1218 1302">       Ex. 1017 [Cheung] Fig. 2.     </p> <p data-bbox="938 1344 1318 1690">  </p> <p data-bbox="1084 1711 1172 1753"> <b>FIG. 22</b> </p> |

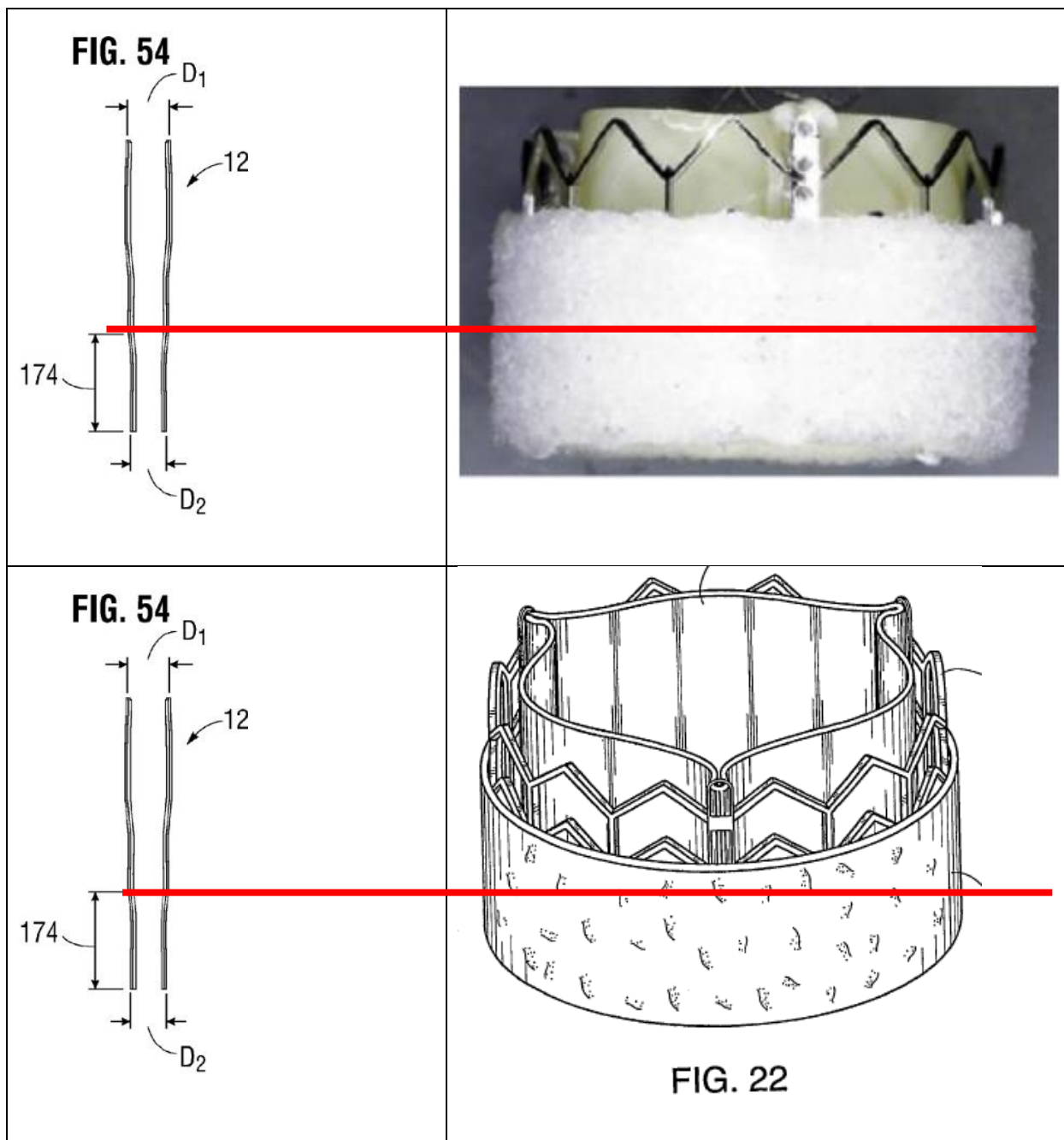
Levi states that the inflow end has a crimped profile of 12F compared to a 14F profile at the remainder of the valve (Ex. 1008 [Levi] 8:56-69):



114. Thus, this 2F reduced diameter portion would have only allowed for a fibrous network, sealing material, or an outer seal that was 0.33mm (1F) thick when crimped. This is far thinner than Walther's outer cloth and Spenser-II's which is 1-5mm when expanded and far greater in the crimped direction. By my estimates, Levi is on the order of 10-50x thinner. There is no reason to think Levi's frame could be reduced sufficiently further to accommodate a cloth that is many times thicker.

115. Additionally, whereas Levi's skirt lies lower on the reduced inflow end, Walther's and Spenser-II's outer coverings are far taller and extend much higher up the frame and would frustrate Levi's means of accommodating its very thin skirt. This comparison between Levi's figures and Levi with Walther and Spenser-II shows why Levi's approach works with Levi's skirt but would not work with Walther's and Spenser-II's much taller skirts:





116. Levi essentially reduces by 2F the portion of the frame where its skirt is attached. That would not work if Walther's or Spenser-II's much taller and *far* thicker outer covering is attached.

117. Levi's outer skirt is also designed to have "excess material or slack between the outer skirt's lower and upper edges..." *Id.*, 13:61-65. The outer skirt's slack "advantageous[ly]... allows the frame 12 to elongate axially during crimping without any resistance from the outer skirt and the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped condition." *Id.*, 14:8-14. Walther and Spenser-II's outer coverings, however, lack this quality. This is yet another conflict with Levi's design principles.

118. Additionally, Levi teaches against the use of "known fabric skirts" as taught, for instance, in Walther and Spenser-II. Ex. 1008 [Levi] 9:36-44 ("Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt... Unfortunately, ***a fabric skirt which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.***"). Thus, Levi indicates that a "known fabric skirt," like those taught in Walther and Spenser-II, have limited elasticity and "tends to deform the struts of the frame and prevents uniform crimping." I do not know why a POSITA would disregard this warning.

119. To be sure, Levi teaches a different type of fabric skirt, one that is "in contrast to known fabric skirts," is weaved at a 45-degree angle. Ex. 1008 [Levi]

9:52-10:4. This is still further reason a POSITA would not be motivated to abandon Levi's modified skirt in favor of a deficient "known fabric skirt."

120. Levi also teaches that the excess material in the outer skirt "causes the outer skirt to bulge outwardly... during radial expansion," that this excess material "can fill in gaps between the frame 12 and the surrounding native annulus" and that the "outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation..." Ex. 1008 [Levi] 13:62-14:9. This excess material and the symbiotic relationship between the inner and outer skirts would be lost if Levi's outer skirt were replaced with Walther's or Spenser-II's non-bulging outer cloth, which, in contrast to Levi's bulging skirt, lie flat against the frame.

121. Importantly, we are never told why these changes to Levi would make it better, whether in terms of crimp profile, reducing PVL, or anything else. Even if it could be done, we are not told *why* one would do it. Such a motivation is not self-evident. In sum, I see no reason why a POSITA would replace Levi's outer skirt with Walther's or Spenser-II's outer covering when doing so seems to serve no particular purpose and would have the effect of violating nearly all of Levi's design principles.

### **C. Radially/Outwardly Extending Fibers**

122. The '172 claims require “wherein the sealing material includes a plurality of radially extending fibers that extend outwardly of the outer frame.” The '011 claims require “wherein the sealing material includes a plurality of radially extending fibers that form a circumferential surface that extends outwardly of the outer frame.” The '846 claim requires “wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame.”

#### **1. Prior Testimony on Extending Fibers**

123. I have previously submitted declarations with respect to the “radially” or “outwardly” extending fibers limitation. My testimony from IPR2022-00034 is representative of my prior testimony in the other IPRs regarding this issue. To ensure this testimony is part of the post-institution record, I so testify again. *See* ¶¶124-127. This testimony applies equally to the “radially extending fibers” limitations found in the '172 and '011 patents. The following excerpts are from paragraphs 76-79 of my IPR2022-00034 declaration. *See also* IPR2021-01527-Ex. 2002, ¶¶76-79, IPR20221-01584-Ex. 2002, ¶¶73-76. The citations to the Petition and exhibits in this section of my declaration are to those in IPR2022-00034.

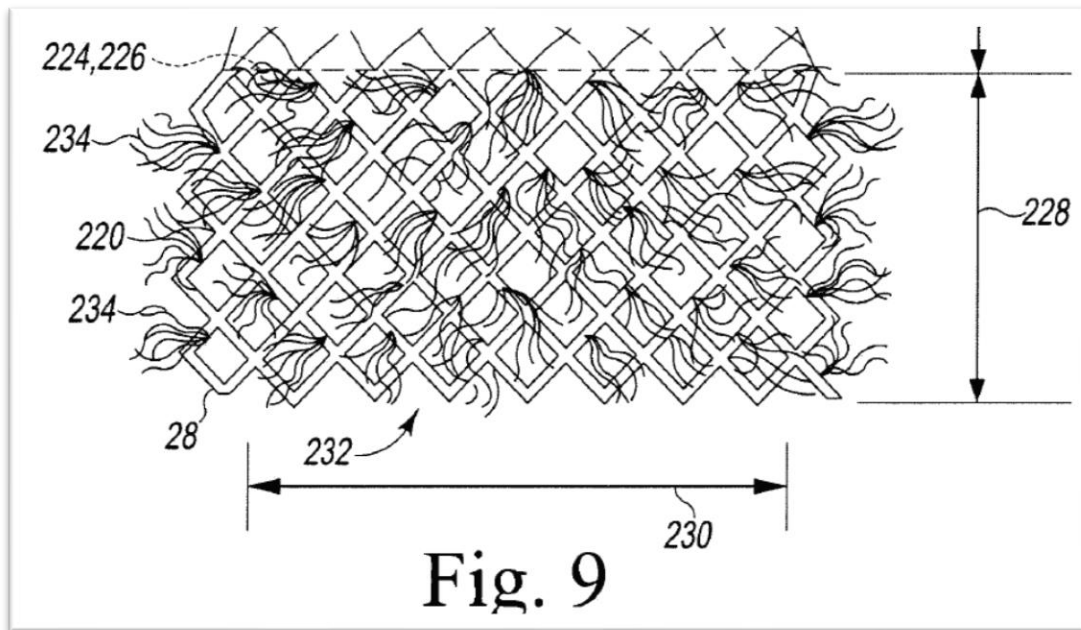
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124. Claim 6 requires an “outer seal” that “is formed of outwardly extending fibers positioned externally to the outer frame.” Ex. 1001 ['846]. The

'846 patent explains that these “radially extending fibers” are a significant aspect of the inventive structure and are intended to prevent paravalvular leak and migration of the proximal component within the aortic walls:

collagen fibers 234 are attached to the proximal section 220 to aid in ***preventing paravalvular leaks and migration of the proximal component*** 212 within the aortic walls. The fibers 234 extend outwardly from the proximal section 220 ...

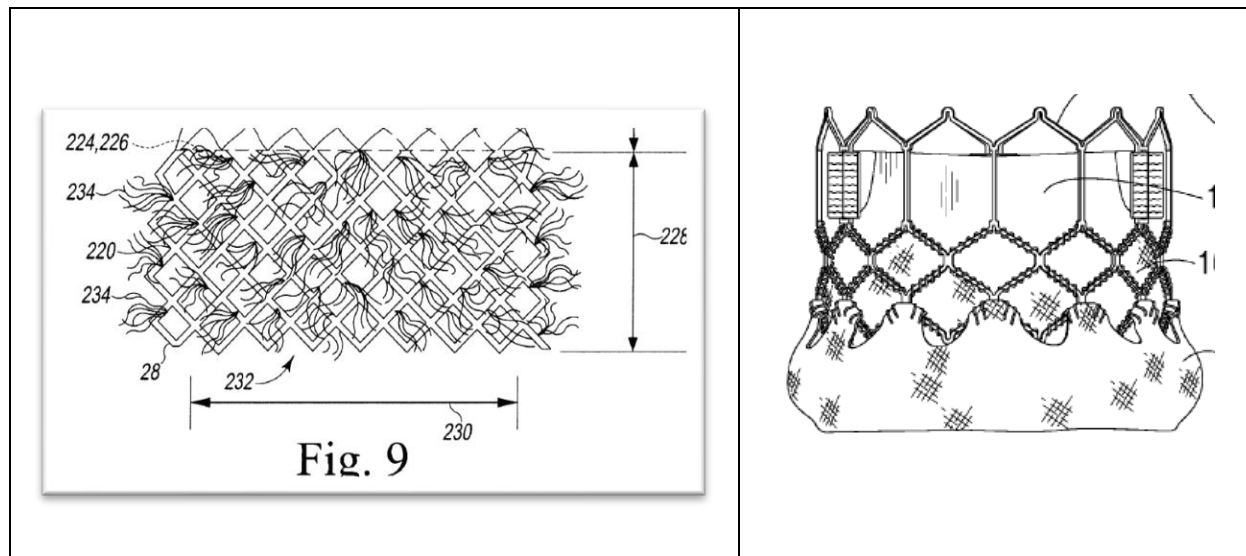
Ex. 1001 ['846] 12:43-47; *see also* 18:22-26. The radially extending fibers are readily apparent in the '846's figures and shown extending outwardly from the proximal section 220:



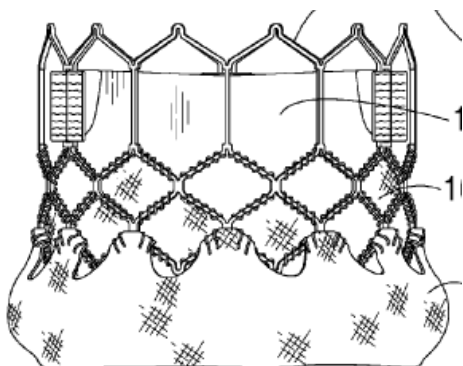
*Id.*, Fig. 9; *see also* Figs. 11, 12, 14.

125. I see that in Grounds 4 and 5, Petitioner is relying solely on the Levi reference. I see no disclosure in Levi, however of an “outer seal” including

“outwardly extending fibers,” nor do I see any reason for why this limitation would be obvious. To the contrary, Levi does not include any “outwardly extending fibers” that bear any remote resemblance to what is disclosed in the ’846 patent as this comparison below reveals:



126. Indeed, for Levi’s outer skirt, the alleged “outer seal”, appears to be very similar to the outer skirt on the SAPIEN 3 valve.



**Levi**



**SAPIEN 3 valve**

Ex. 1008 [Levi] Fig. 3; Ex. 2026 [Thomas Disclosure] 3.

127. I have significant experience handling and implanting the SAPIEN 3 valve. I could not see anything on the outer skirt of SAPIEN 3 that a POSITA would consider to be “outwardly extending fibers.”

#### **D. Outer Graft Covering**

128. Claim 6 of the '846 patent requires an “outer seal ... wherein the outer seal is free of an outer graft covering between the fibers and the outer frame.”

##### 1. Prior Testimony on Outer Graft Covering

129. I have previously submitted a declaration with respect to the “outer graft covering” limitation in IPR2022-00034. The following excerpts are from paragraphs 80-92 of my IPR2022-00034 declaration. See ¶¶130-142, *infra*. To ensure this testimony is part of the post-institution record, I so testify again. The citations to the Petition and exhibits in this section of my declaration are to the those in IPR2022-00034.

\*\*\*

130. Claim 6 requires an “outer frame” with an “outer seal” formed of “outwardly extending fibers” external to the frame “wherein the outer seal is ***free of an outer graft covering between the fibers and the outer frame.***” Ex. 1001 [’846] cl. 1. Claim 6 thus requires that there be no “outer graft covering between

the” “outwardly extending fibers” and the “outer frame.” Indeed, we can see such a structure in the ’846’s figures:

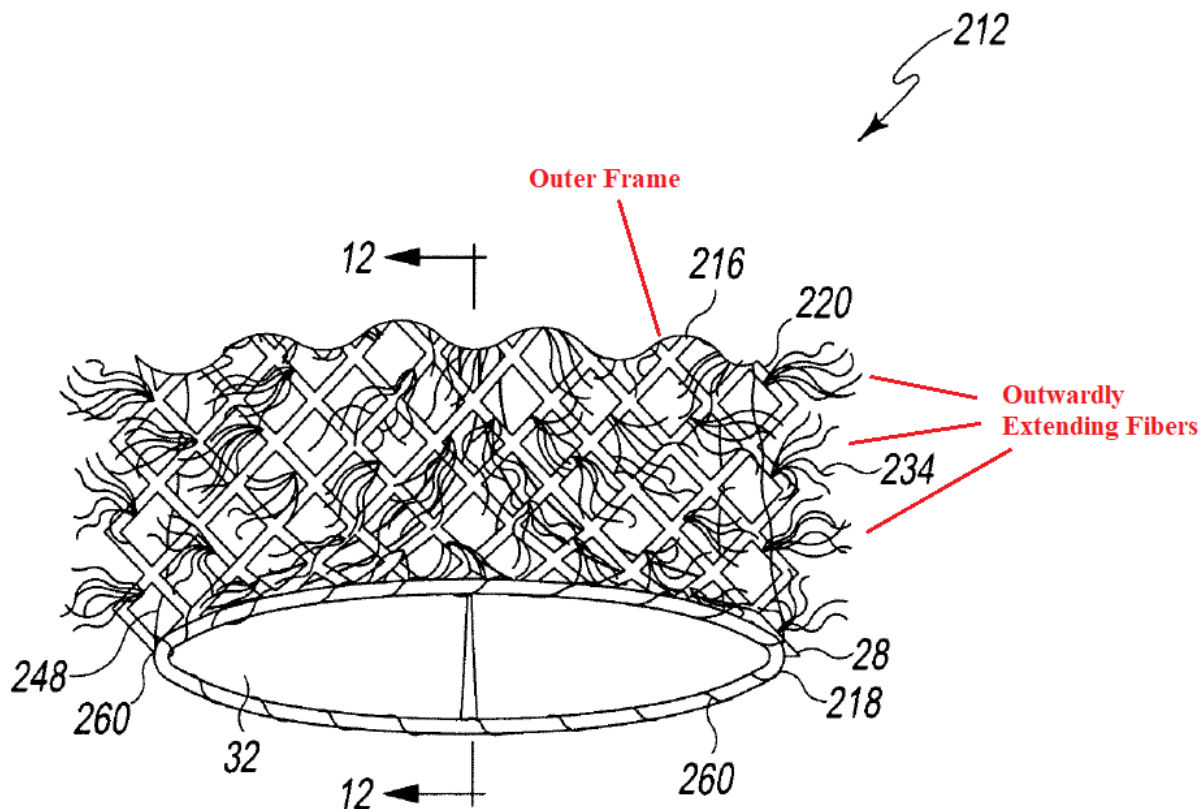


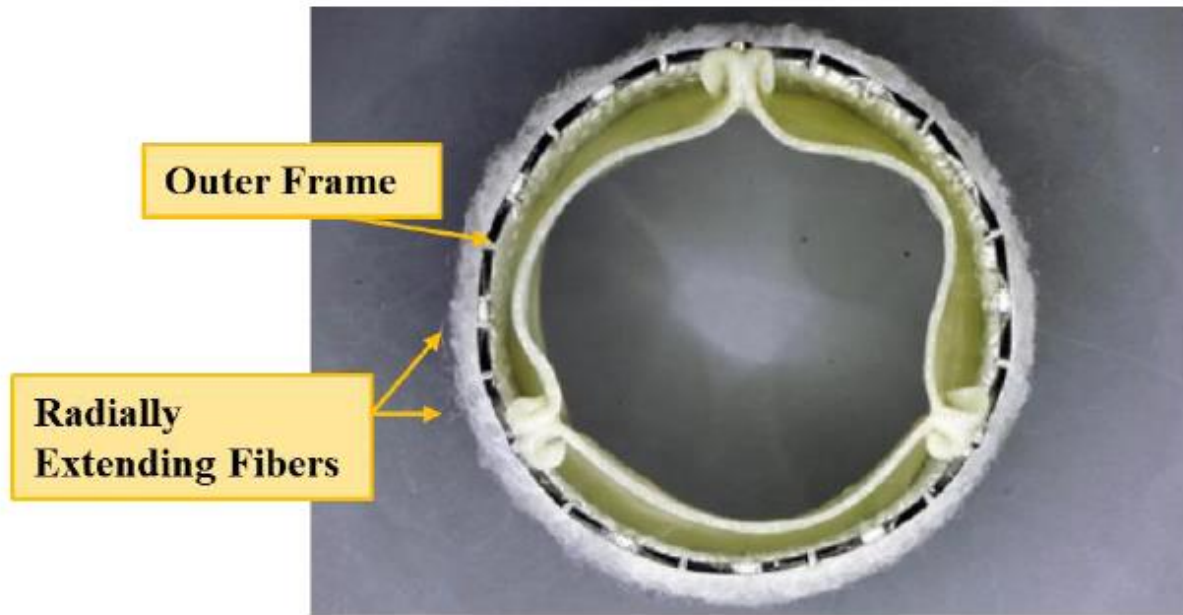
**Fig. 11**

Ex. 1001 [’846] Fig. 11 (annotated), Figs. 8-9, 13. I believe that a POSITA would appreciate that using an outer seal that was “free of an outer graft covering between the fibers and the outer frame,” would allow for a narrow delivery profile, and avoid the problematic bunching that would occur when tightly crimping a valve with the Walther or Spenser II outer cloths. See Section VI.2.

131. Petitioner’s proposed combinations in Grounds 1-3 and 6-7 point to one Walther or Spenser II’s PET cloth as the “outer seal.” Pet., 28-30, 52-58. The arguments for these combinations, however, do not show that any of these “outer seals” are “free of an outer graft covering” as claimed. See Sections VI.C.1-2. Petitioner’s Grounds 4-5 rely on Levi’s outer PET skirt as the “outer seal,” but do not explain how this is “free of an outer graft covering” when Levi’s outer PET skirt is, in its entirety, an outer graft covering. See Section VI.C.3.

a. *Walther*

132. For Grounds 1-2, and 6, the Petition points to Walther’s outer PET cloth as the “outer seal.” Pet., 28-30, 52-55, 86-88; Ex. 1007 [Walther] 2 (describing “[a]n added poly(ethylene terephthalate) (PET) cloth”). Petitioner argues that “Walther’s outer cloth is formed of outwardly extending fibers positioned externally to SAPIEN’s outer frame,” per Petitioner’s annotated figure:



Pet., 29-30 (Citing Ex. 1007 [Walther] 2, Fig. 1; Ex. 1003 [Buller Decl.] ¶¶117-119).

133. I see that Dr. Buller contends that Walther’s PET cloth is made of woven fibers and has a “fibrous exterior” or “fibrous finish” that meets the outwardly extending fibers limitation. Ex. 1003 [Buller-Decl.] ¶¶118-119. Dr. Buller states that “PET can have a range of finishes” such as “Walther’s PET outer cloth” (PET with a fibrous finish) and Cribier’s (SAPIEN’s) “PET fabric cuff” (PET with no fibrous finish). *Id.*, 119. Indeed, the difference between PET cloth with a fibrous finish (on the left) and PET cloth without a finish (on the right) is readily apparent in Petitioner’s side-by-side comparison of Walther’s PET outer cloth (outside of the frame) and Cribier’s inner PET fabric cuff (inside the frame):



Pet., 29 (Walther, Fig. 1; Cribier, Fig. 1) (annotations added).

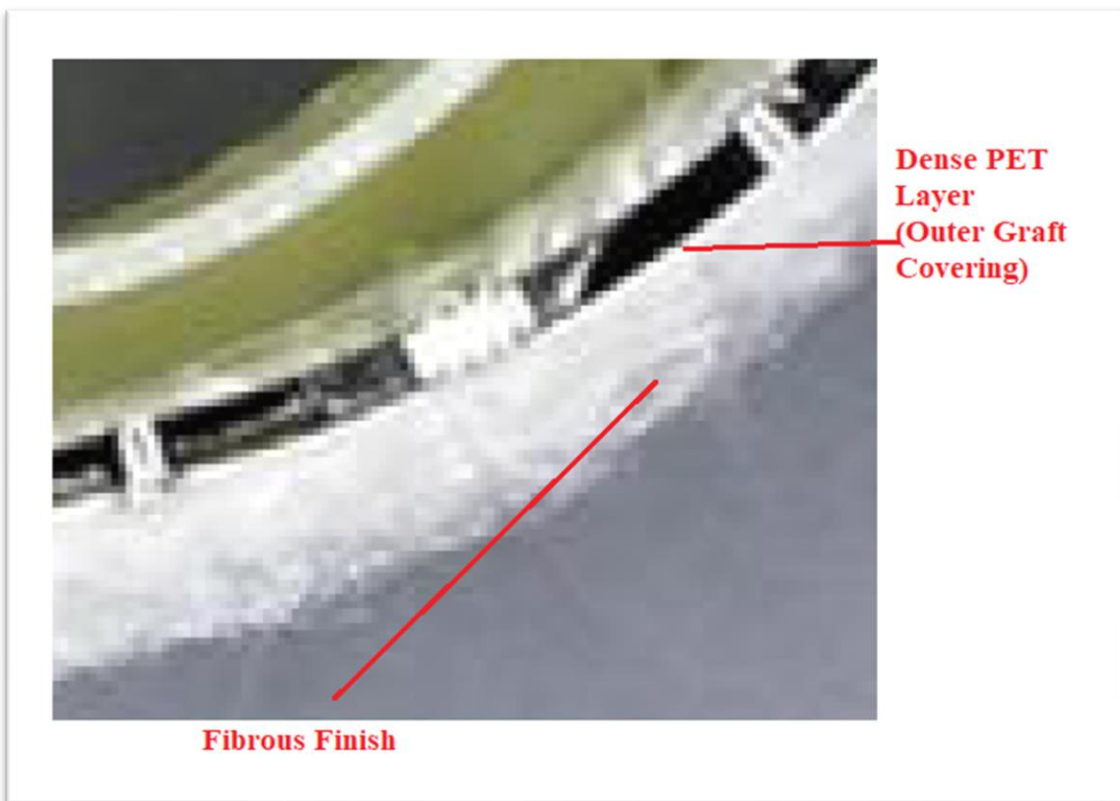
134. A POSITA would know, however, that Petitioner's Walther combinations do not teach the claimed invention because Walther is not "free of an outer graft covering" between the exterior "fibrous finish" and the valve's "outer frame." Petitioner's arguments does not account for Walther's PET cloth (specifically, the PET underneath the "fibrous finish") is itself being a "graft covering" that would be between the exterior "fibrous finish" (alleged "outwardly extending fibers") and the "outer frame" of the valve. I note that Petitioner relies on PET cloths/skirts/layers as the claimed "inner graft covering." Indeed, Petitioner relies on Cribier's "PET fabric cuff" (shown above) as the alleged "inner

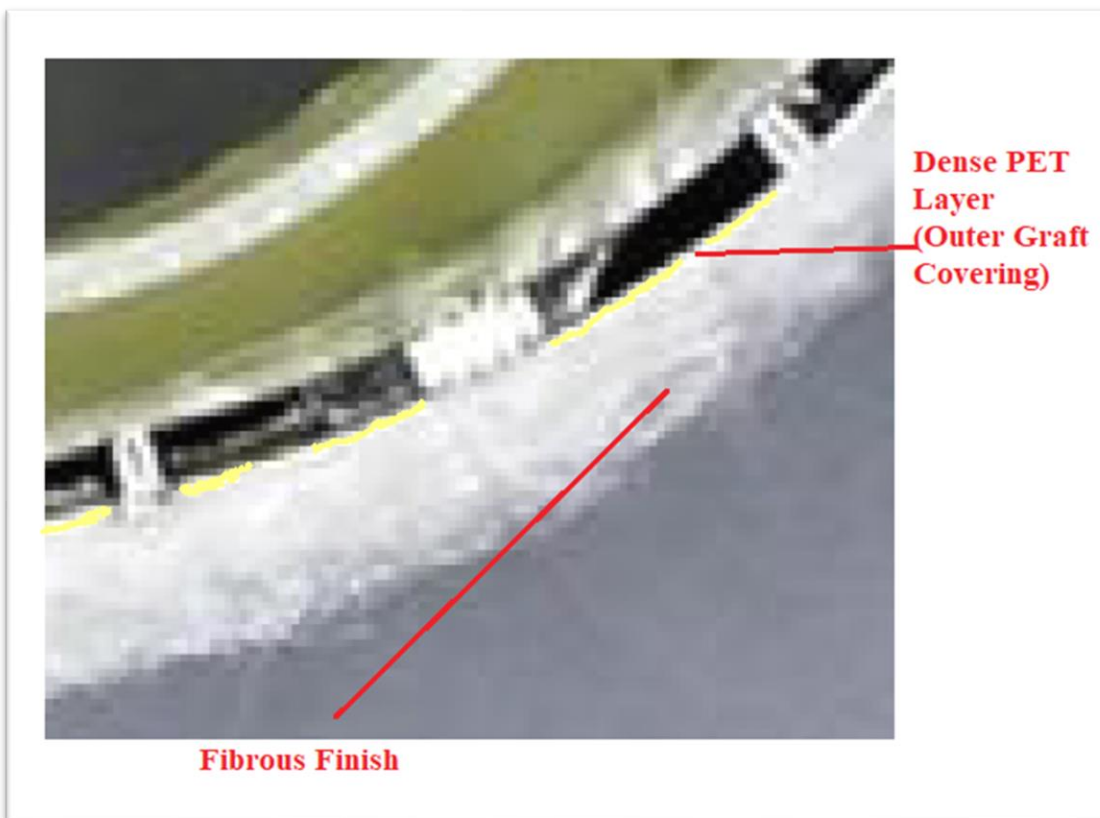
***graft covering***” in Ground 1. Pet., 26 (“Cribier discloses that SAPIEN includes an inner ‘(PET) fabric cuff,’ which is a graft covering”). Petitioner similarly relies on Spenser’s “PET layer 571” and Levi’s PET “inner skirt” as the “inner graft covering[s]” for Ground 2-7. Pet., 49-51, 79. Petitioner provides no explanation for why a POSITA would understand Cribier’s “PET fabric cuff” to be an “inner graft covering,” but would not also understand Walther’s “PET outer cloth” (the PET under the “fibrous finish”) to be an “outer graft covering.”

135. Consistent with what I believe Dr. Buller is saying in his declaration (Ex. 1003, ¶119), a POSITA would understand Walther’s “outer seal” to be a PET cloth with a fibrous finish presumably built-up on top of a denser PET layer, Ex. 1007 [Walther] Fig. 1, like icing on top of a cake, or the base of a pile carpet.



136. Indeed, if we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the second image) beneath the fibrous finish.





*Id.* (excerpted, magnified, annotated) (yellow highlighting added). I note that Petitioner repeatedly relies on a dense PET layer/cloth/skirt as the claimed “inner graft covering.” Pet., 26, 49-51, 79. Accordingly, a POSITA would understand that the dense PET layer underneath Walther’s fibrous finish would be an “outer graft covering” between the fibrous finish and the valve’s outer frame.

137. Petitioner’s argument that the “free of an outer graft covering” limitation is met seems to be that “Walther’s fibers directly contact the frame without any visible intervening graft covering and Walther never mentions an ‘outer graft covering.’” Pet., 30. I see no explanation or evidence that the alleged

“outwardly extending fibers” of Walther’s fibrous *finish* “directly contact the frame.” *Id.*

b. *Spenser II*

138. In Grounds 3 and 7 Petitioner relies on Spenser II’s PET “compressible material [that] may resemble a cloth or fabric” as the “outer seal,” and points to Spenser II’s “fibers extending from *the surface of the material*” as the “outwardly extending fibers.” Pet., 55-56 (quoting Spenser II, ¶145); *see also* Ex. 1011 [Spenser II] ¶145 (“In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET)”). I note that Patent Owner explained in prosecution that:

the seal of Spenser [II] appears to be relatively thick in construction, including *a graft covering* or sleeve with fibers extending from the sleeve.

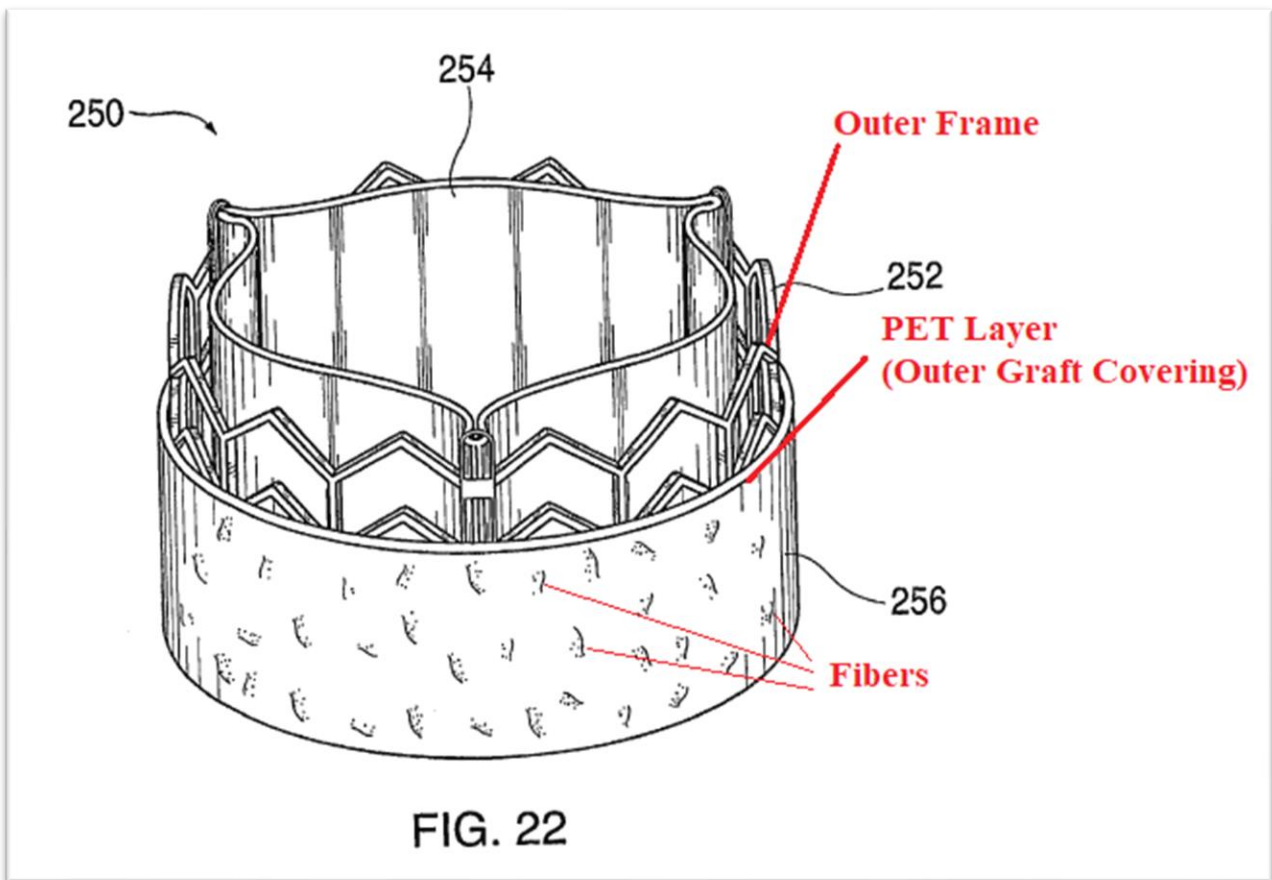
...

Spenser [II] appears to include *an outer graft covering between the fibers and the outer frame* ... [and] is *not modifiable to be free of an outer graft covering*, as such modification would have no structure for the fibers to attach to since the fibers emanate from compressible material 256.

Ex. 1002 [Pros.-Hist.] 147.

139. Spenser II’s disclosure has the same issue discussed above with regards to Walther. Similar to Walther, a POSITA would understand Spenser II’s

“outer seal” to be a PET cloth with fibers on top of the denser PET layer. Indeed, Spenser II describes its cloth as “extend[ing] entirely around the stent structure, such as in the form of a *sleeve*,” and shows the dense PET layer/sleeve as being distinct from the fibers on top of it.



Pet., 55 (Petitioner annotated Spenser II Fig. 22) (Additional annotations in **red**).

140. Petitioner’s argument that the “free of an outer graft covering” limitation is met seems to be that “Spenser II never pictures or mentions an ‘outer graft covering’ between *the compressible material* and frame.” Pet., 58.

Petitioner is essentially arguing that in Spenser II there is no “outer graft covering”

between Spenser II's "**outer seal**" and the "outer frame" of the valve. *Id.* It is important to note that claim 6, however, requires the "outer seal" itself to be "free of an outer graft covering between the **fibers**" (*i.e.*, the "outwardly extending fibers") and the "outer frame." Petitioner does not even contend that Spenser II's alleged "outer seal" is "free of an outer graft covering between" Spenser II's alleged "**fibers**" and the "outer frame." Indeed, Spenser II clearly shows the opposite, a sleeve/cloth (outer graft covering) between the fibers and the valve's frame. Ex. 1011 [Spenser II] ¶145.

c. *Levi*

141. In Grounds 4-5, Petitioner contends that Levi's "outer skirt of woven PET fabric" meets the claimed "outer seal." Pet., 81. As discussed, Levi's PET skirt does not appear to contain any "outwardly extending fibers," as required. Moreover, Petitioner fails to explain how Levi's outer PET skirt is "free of an outer graft covering," when it is itself an "outer graft covering." Indeed, Petitioner relies on Levi's woven PET inner skirt as the claimed "inner graft covering." Pet., 79-80 ("Levi discloses an inner skirt 16 ... constructed of ... PET." and "PET is a 'graft covering.'"); Levi 9:53-54 ("the skirt 16 desirably is **woven** from a first set of fibers ... and a second set of fibers"). Petitioner, however, gives no reason why Levi's woven PET outer skirt would not likewise be an "outer graft covering."

142. I see that Petitioner contends that “Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt” and “Levi does not include any ‘outer graft covering’ on the exterior of the outer frame.” Again, Petitioner fails to recognize that Levi’s outer skirt *is* an “outer graft covering.” For at least these reasons, Levi fails to teach this limitation.

2. Dr. Buller And Petitioner Fails to Demonstrate That Their Grounds Disclose or Render Obvious an “Outer Seal” “Free Of An Outer Graft Covering”

143. As I stated in my prior declaration, a POSITA would appreciate that a valve assembly ‘free of an outer graft covering between the first portion of fibers and the outer frame,’ would allow for a narrow delivery profile and minimize bunching.

a. *PET Fabric Or Cloth Can Be A “Graft Covering.”*

144. A “graft covering” may be formed from PET and PTFE, depending upon its density/porosity. Numerous references refer to a “graft covering” made of PET or PTFE. *See, e.g.*, Ex. 2059 [Brown] ¶32; Ex. 2060 [Shaw] ¶64; Ex. 2061 [Zhang] ¶196; Ex. 2062 [Xue] 472; Ex. 2063 [Van-Oepon] 1:41-46. Such materials may be low porosity.

b. *Walther’s PET Outer Cloth Include An “Outer Graft Covering.”*

145. I do not claim to be an expert in the field of cloth, textiles or fabrics but I am familiar with how these materials are used in the medical setting and have

reviewed literature, including the references cited below, detailing the structure of medical cloth, textiles, and fabrics.

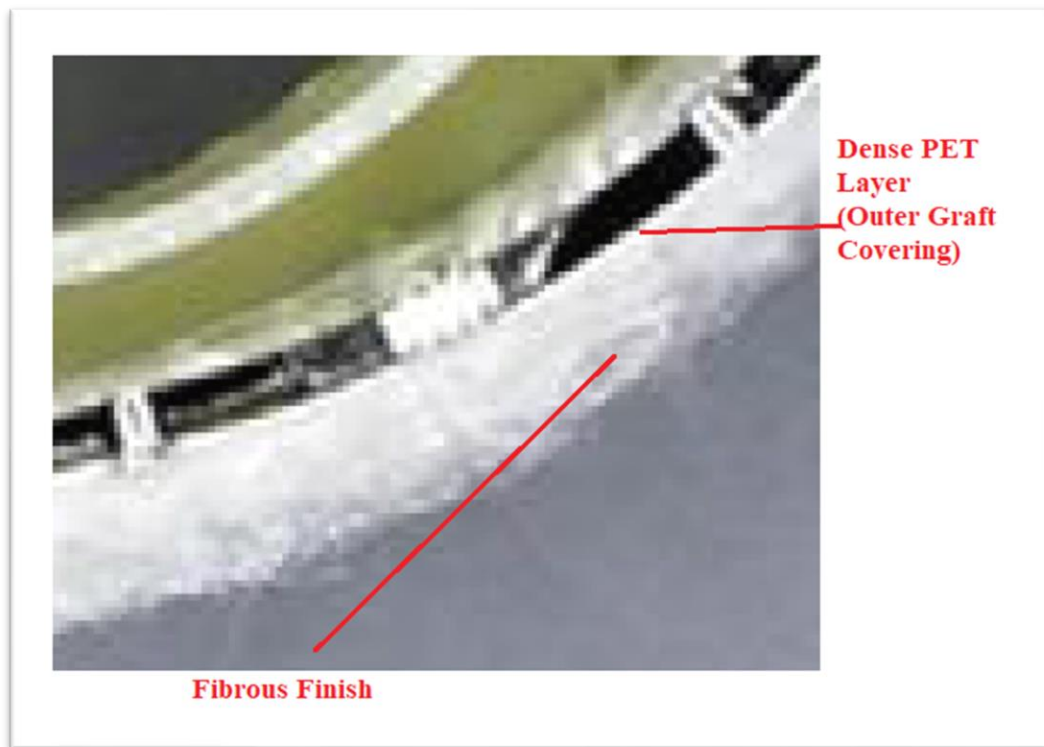
146. Dr. Buller describes Walther’s outer cloth as a “velour-like woven PET cloth.” Ex. 2008 [-193-Buller-Decl.] ¶305. A velour-like woven PET cloth may be analogized to a pile carpet.

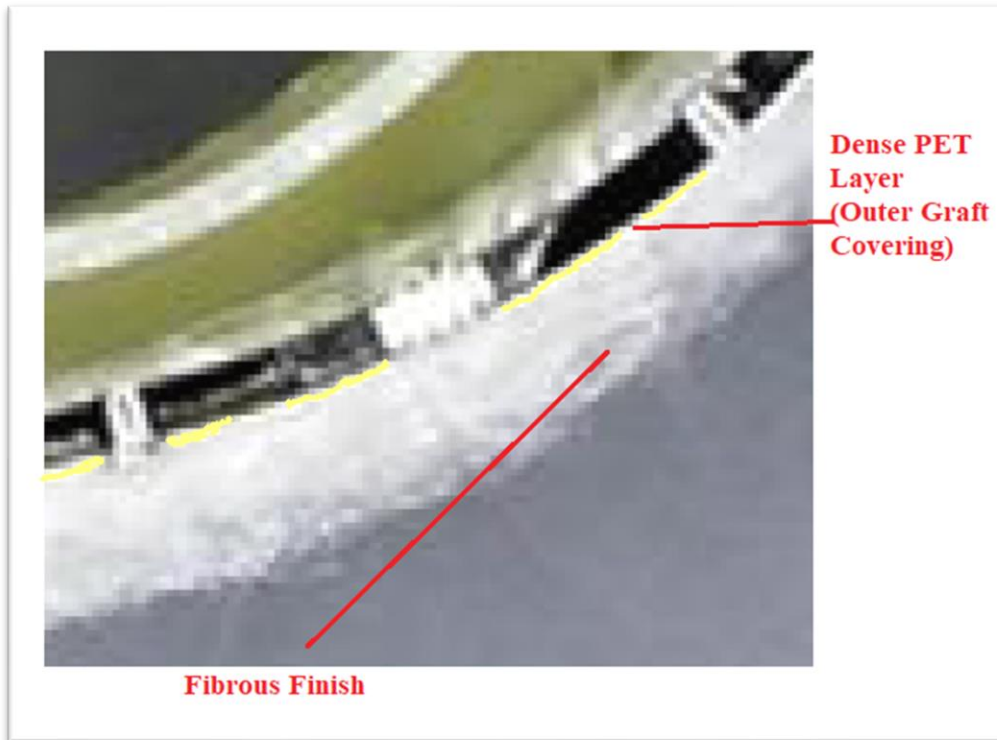


Like all woven fabric, Walther’s PET outer cloth appears to be formed by “an over-and-under pattern” of yarns, each composed of a bundle of fibers. See Ex. 2062 [Xue] 472; Ex. 2052 [Buller-Depo.] 94:6-7. This woven fabric is analogous to a pile carpet’s base. Woven velour has an additional “floating portion” of yarn

that “produce three-dimensional loose surface structures.” Ex. 2057 [Chu] 4. This is analogous to a pile carpet’s pile fabric.

147. Indeed, if we magnify Walther’s Figure 1, we can identify what appears to be the dense woven PET base layer (highlighted in yellow in the second image) beneath the fibrous finish.





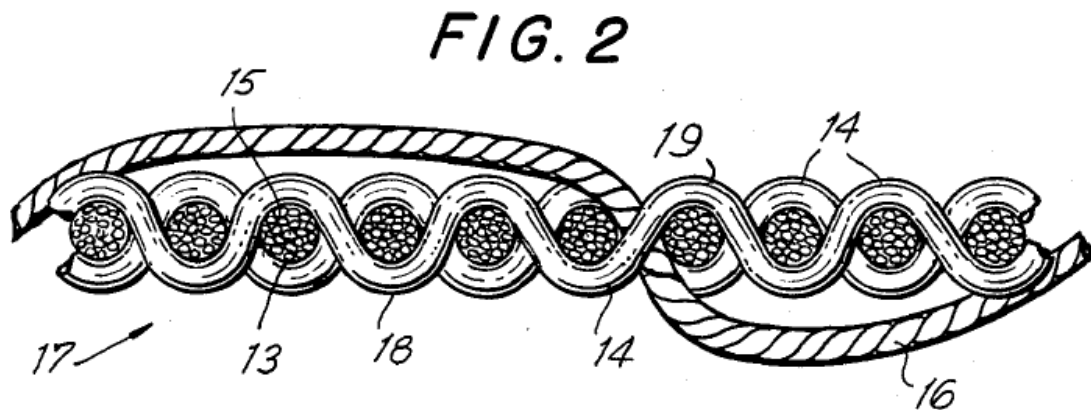
*Id.* (excerpted, magnified, annotated) (yellow highlighting added).

148. This image is consistent with Walther’s PET outer cloth being a woven velour. I note that Petitioner repeatedly relies on a dense, low porosity PET layer/cloth/skirt as the claimed “inner graft covering.” IPR2022-00034-Pet., 26, 49-51, 79. Accordingly, a POSITA would understand that the dense woven PET layer would be an “outer graft covering” between the fibers and the valve’s outer frame. In a “velour-like woven PET” cloth the woven base, but not the outwardly extending fibers would contact the frame.

149. I understand that velour may have an over-under pattern of a woven fabric but also incorporates “*floating portions* of ... yarn” that form “three-

dimensional loose surface structures,” “that conventional woven fabrics do not have.” Ex. 2057 [Chu] 4; *see also* Ex. 2062 [Xue] 472; Ex. 2056 [Hartley] ¶35.

150. I understand that this structure is, for example, illustrated in Liebig, in which “fill yarns 13” that run vertically and “warp yarns 14” that run horizontally form a woven structure separate from “loop yarns 16” that create the “three-dimensional loose surface structures” described in Chu.



Ex. 2064 [Liebig] Figs. 1-2; *see also id.*, 4:22-25; 2:59-62. Liebig leaves loop yarn 16 intact but it is also possible to cut the loop yarn to form “cut pile” that exposes individual fibers, which may extend outwards. *See e.g.*, Ex. 2056 [Hartley] ¶35 (“the velour material may be of loop pile or **cut pile** form”). The “fibrous finish” described by Dr. Buller in Walther’s Fig. 1 appears consistent with woven base “graft covering” that incorporates cut piles such as those that would result if Liebig’s loop yarn 16 were cut. I understand that the cut piles would be similar to the cut yarns in the pile carpet shown here:



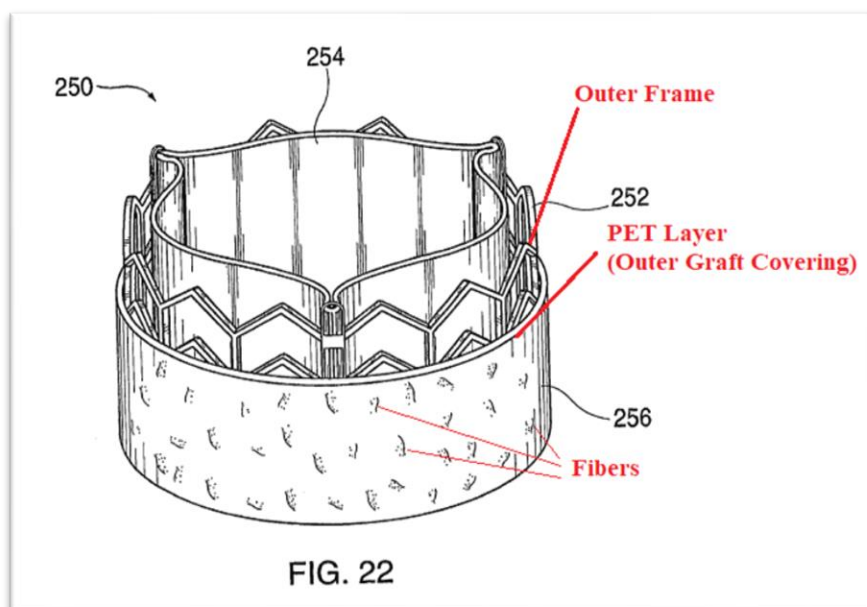
151. Again, Dr. Buller has identified Walther and Spenser-II as velour-like woven PET fabrics. This would seem to suggest Walther has woven base (a graft covering) from which the “outwardly extending fibers” emanate.

c. *Spenser-II’s Compressible Material Includes An “Outer Graft Covering.”*

152. As noted, Petitioner and Dr. Buller make clear that “woven PET” and a “velour-like woven PET,” particularly one with low porosity, is an outer graft covering. Thus, by Petitioner’s own admissions, Spenser-II’s compressible material *is* an outer graft covering from which “fibers extend[] from the surface.” Ex. 1011 [Spenser-II] ¶145. Consequently, Spenser-II includes an “outer graft

covering” (the compressible material) between its frame and the fibers (that extend from the surface of the compressible material).

153. Like Walther, a POSITA would understand Spenser-II’s “outer seal” to be a PET cloth with fibers on top of the denser PET layer. Indeed, Spenser-II describes its cloth as “extend[ing] entirely around the stent structure, such as in the form of a *sleeve*,” and shows the dense PET layer/sleeve as being distinct from the fibers on top of it. The “fibers extend[] from *the surface of the material*.” Ex. 1011 [Spenser-II] ¶145. The compressible material is meant to “reduce or prevent paravalvular leakage.” *Id.*



#### E. Two Rows Of Cells

154. The claims of the '538 patent require “a fibrous network positioned at least partially radially outwardly of the outer frame” of the valve “wherein the

fibrous network extends over at least two circumferentially extending rows of grids” of the frame.

1. Prior Testimony On Two Rows Of Cells

155. I have previously submitted a declaration with respect to the “two rows of cells” limitation in IPR2022-00193. The following excerpts are from paragraphs 76-93 of my IPR2022-00193 declaration. See ¶¶156-173. To ensure this testimony is part of the post-institution record, I so testify again. The citations to the Petition and exhibits in this section of my declaration are to the those in IPR2022-00193.

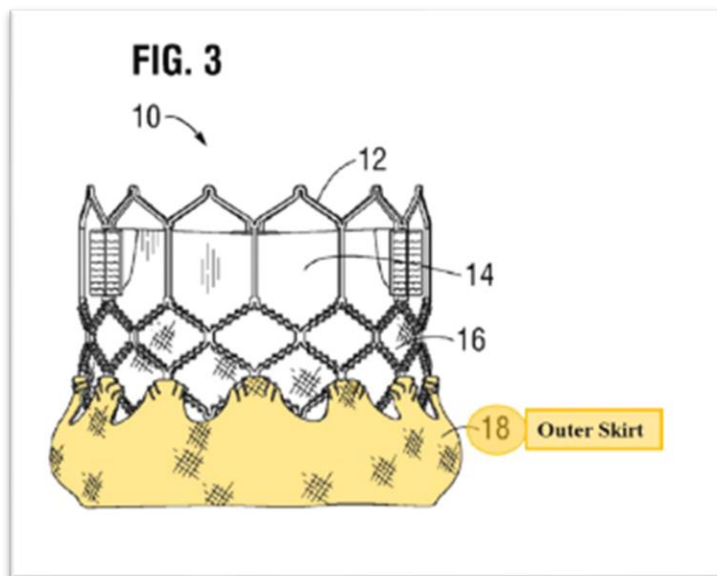
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156. The claims require a valve with “a fibrous network positioned at least partially radially outwardly of the outer frame” of the valve “wherein *the fibrous network extends over* at least *two circumferentially extending rows* of grids” of the frame. Ex. 1001 [’538] cls. 1, 11. In Grounds 5-6, Petitioner argues that “Levi’s outer skirt (fibrous network) extends over at least two ... rows of grids.” Pet., 98-99. This argument, however, is contradicted by Levi’s figures and specification which make clear that Levi’s outer skirt only extends over *one* row of grids. See Section VI.B.1. Petitioner’s argument seems to ignore these disclosures and relies solely on Levi’s Figure 42, a figure presenting Levi’s valve at a tilted angle. Levi’s Figures 1-3 and 43—which show the very same embodiment—make

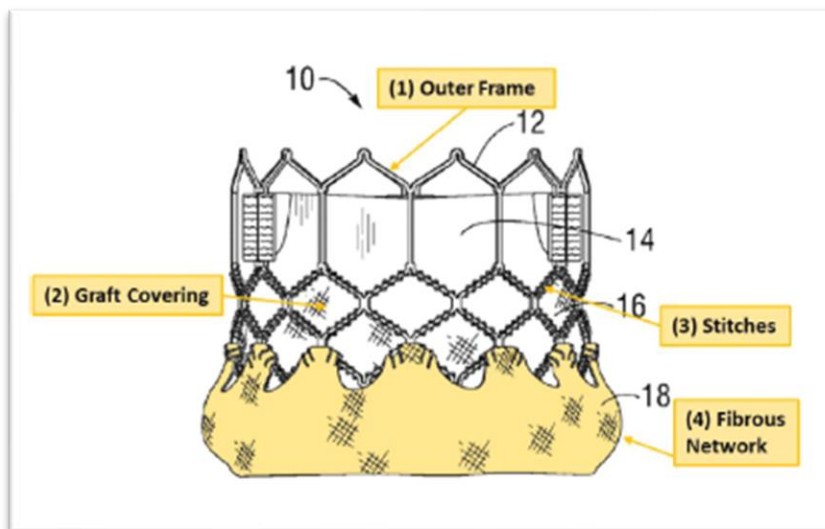
clear that Levi's skirt only covers one row, a fact that is further confirmed by Levi's commercial embodiment *which is Petitioner's own product*. See Section VI.B.2.

a. *Levi's Outer Skirt Only Extends Over One Row Of Grids.*

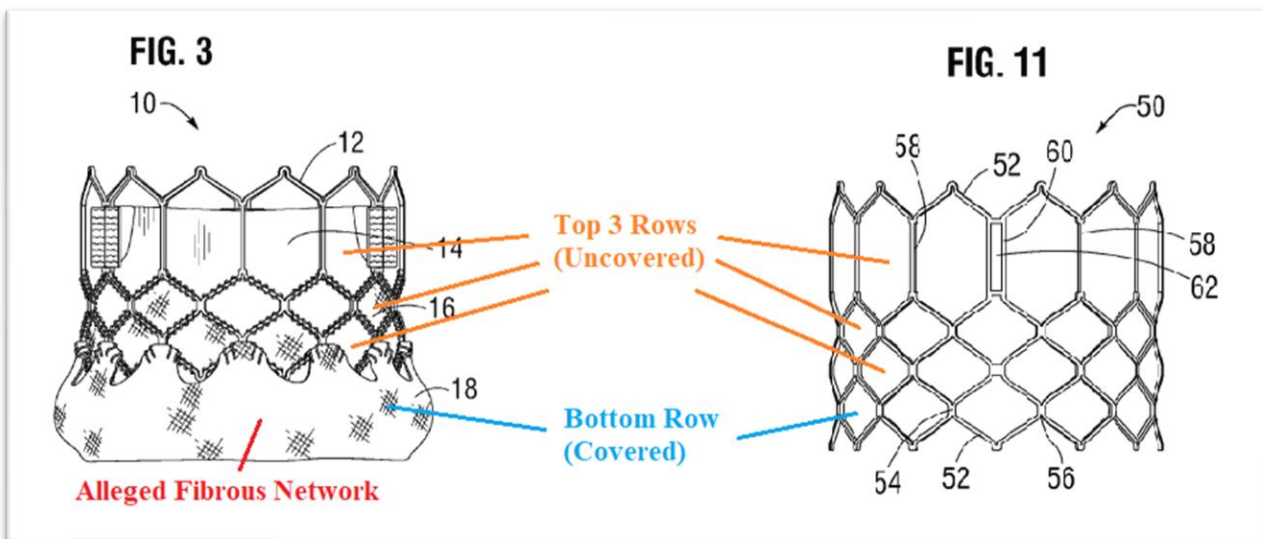
157. A POSITA would find it clear that Levi's outer skirt (alleged "fibrous network") only extends over one row of grids of Levi's frame. Indeed, numerous figures depicting Levi's "exemplary embodiment" confirm that Levi's outer skirt (18) only extends over (at most) the bottom row of grids, while the top three rows of grids are left uncovered. For example, Petitioner repeatedly relies on Levi's Figure 3 as showing Levi's outer skirt (alleged "fibrous network"):



Pet., 92 (annotations in Petition).

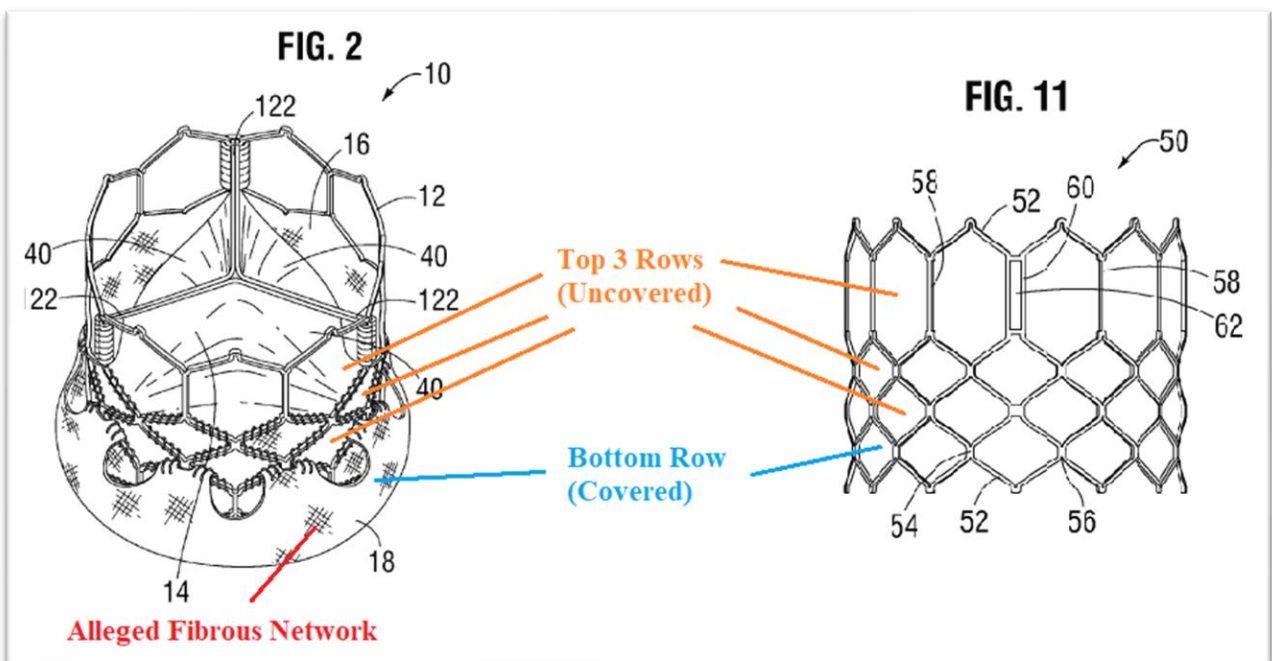
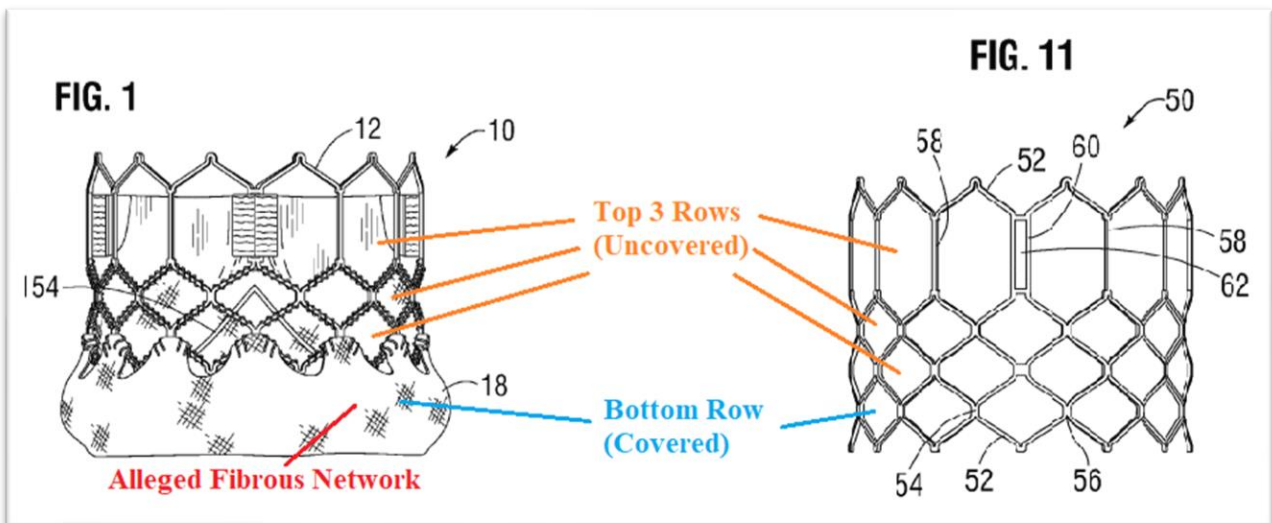


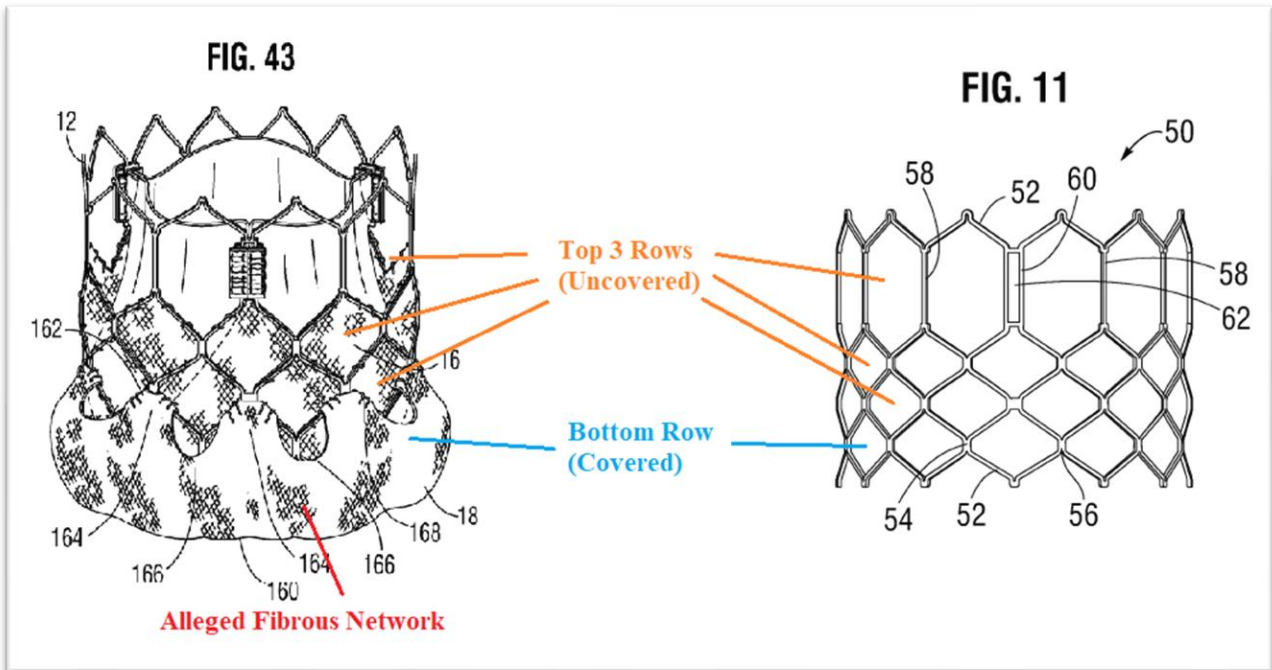
*Id.*, 15 (annotations in Petition); *see also id.*, 7, 84, 92, 106. When we compare Levi's Figure 3 to Levi's Figure 11 (showing the valve's frame), we can clearly see that Levi's outer skirt (alleged "fibrous network") only extends over, at most, one row of the gridded frame (the bottom row).



Ex. 1008 [Levi] Figs. 3, 11. Levi's Figures 1, 2, and 43 (below), depicting the

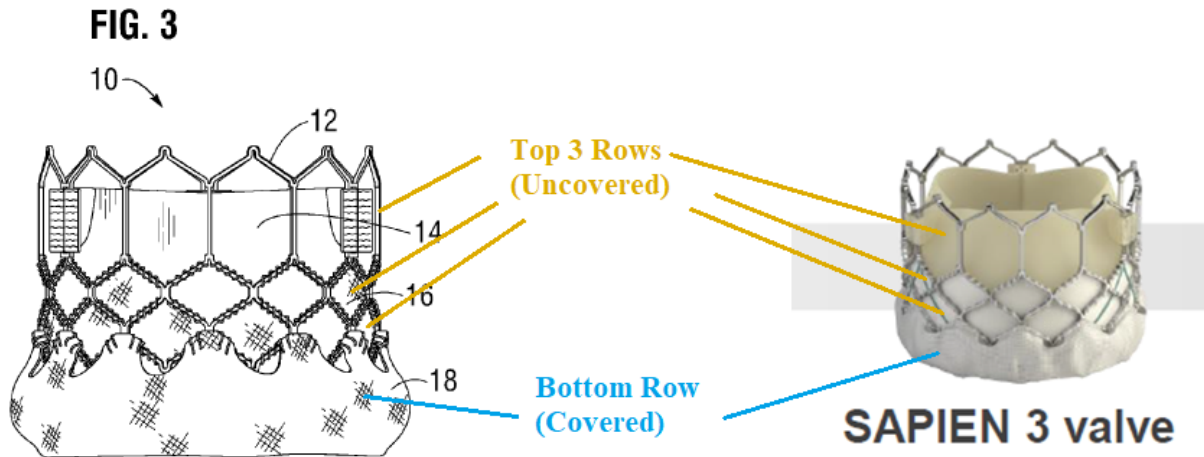
same embodiment as Figure 3, and likewise confirm that Levi's outer skirt only extends over, at most, one row of grids.





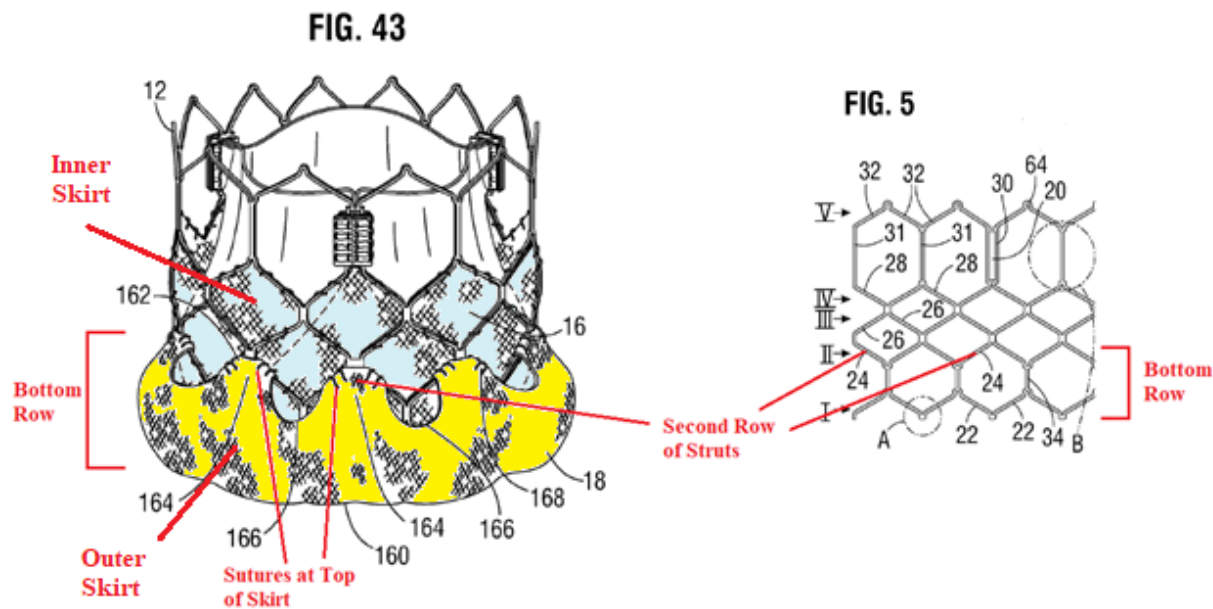
Ex. 1008 [Levi] FIGs 1-3, 43; *see also id.* 4:57-58 (“FIGS. 1-3 show an exemplary embodiment of a prosthetic heart valve.”), 5:14-15 (“FIGS. 42 and 43 show the exemplary prosthetic heart valve of FIG. 1.”).

158. I will also note that Petitioner’s SAPIEN 3 valve, which appears to be the commercial embodiment of Levi, shows the outer skirt only extending over one row of grids.



Ex. 1008 [Levi] Fig. 3; Ex. 2026 [Thomas] 3; *see also* Ex. 2022 [FDA-P200015] 26 (citing Levi as covering SAPIEN 3); Ex. 2023 [FDA-P140031S085d] 97, 219 (same); Ex. 2024 [FDA-P140031/S112] 131, 243 (same); Ex. 2025 [FDA-P140031-S125c] 143 (same).

159. Levi’s specification further confirms that its outer skirt only extends over, at most, one row of grids of the frame. Levi teaches that “projections 164” at the top of Levi’s outer skirt “can be sutured to the second rung II of struts 24 of the frame.” *Id.*, 13:58-61. Accordingly, the outer skirt only extends over one row of grids, as shown in the annotated figures below:



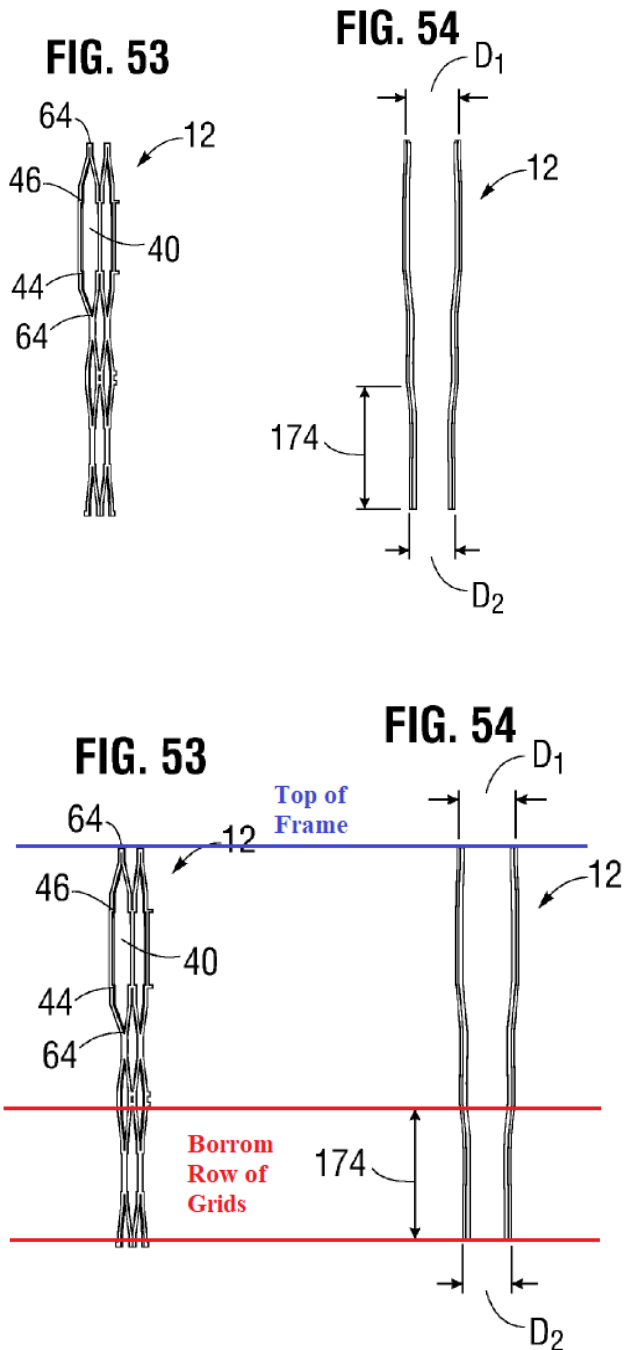
*Id.*, Figs. 43 (annotated, highlighted), 5 (excerpted, annotated).

160. It is my opinion that, based on the figures and the specification, a POSITA would have no doubt that the outer skirt in Levi’s “exemplary embodiment” only extends over, at most, one row of grids.

161. Finally, I will note that, as Petitioner points out, Levi’s “frame 12 has **a reduced diameter region** extending along a portion of the frame [174]... that generally corresponds to the region of the frame **covered by the outer skirt 18.**” Pet., 87 (citing Ex. 1008 [Levi] 8:46-54). This reduced diameter region 174 is shown as being just the bottom row of grids.

162. Comparing Levi’s Figure 54 (showing the reduced diameter region 174 on the compressed frame) with Figure 53 (showing the grids on the frame in a

compressed state) we can see that the upper border of the reduced diameter region 174, for Levi's outer skirt, matches up with the apices of the bottom row of cells.



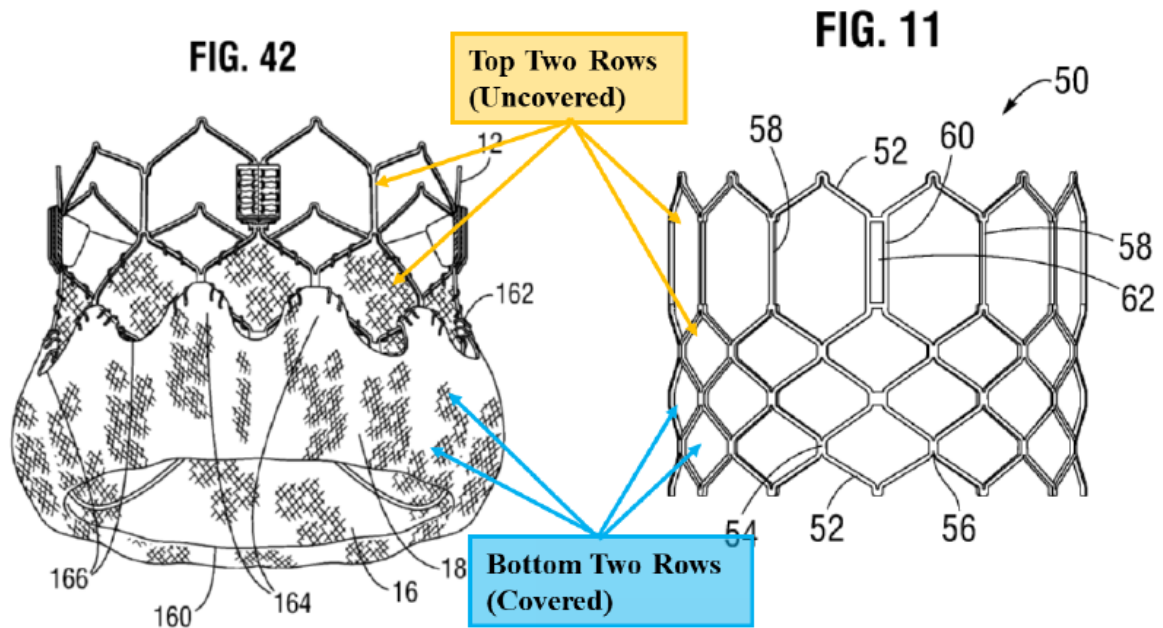
Ex. 1008 [Levi] Figs 53-54 (annotated). This teaching would further confirm a POSITAs understanding that Levi's outer skirt only extends over, at most, the bottom row of grids. Indeed, if one were to extend the outer skirt to cover two rows of grids, then the skirt would extend beyond the reduced diameter region 174, increasing the delivery profile of the device. This would defeat the purpose of having a reduced region (174) for the outer skirt "such that the outer skirt 18 does not increase the overall crimp profile of the valve." *Id.*, 8:51-54.

163. Accordingly, a POSITA would understand from Levi's figures and specification that Levi's outer skirt (the alleged "fibrous network") does not "extend[] over at least two circumferentially extending rows of grids" as required.

b. *Petitioner's Argument Relies Entirely On Figure 42, A Drafting Error That Is Inconsistent With Figures 1-3 And 43 Showing The Same Embodiment And The Specification.*

164. Petitioner seems to ignore Levi's clear teachings in the specification and Figures 1-3 and 43 that Levi's outer skirt only extends over, at most, one row of grids. Instead Petitioner bases its argument solely on what is, at best, a drafting error in Levi's Figure 42—showing Levi's valve at a tilted angle. Specifically, Petitioner's entire argument on this limitation is:

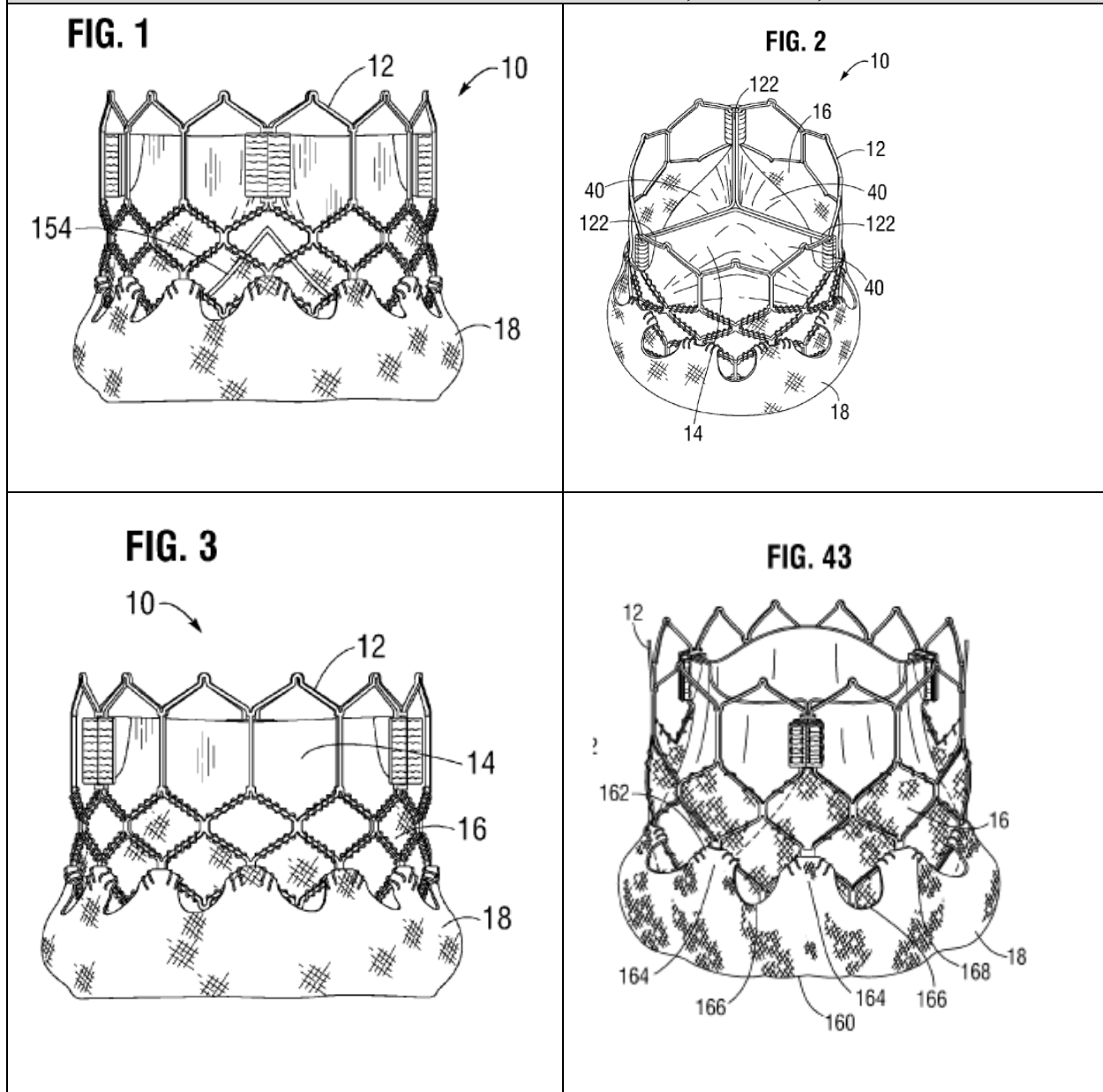
Levi's outer skirt (fibrous network) extends over at least two circumferentially extending rows of grids formed in the open cell configuration, as demonstrated by a comparison of Levi's Figures 42 and 11:



Pet., 98-99 (annotations in Petition). While Petitioner contends that Levi’s Figure 42 shows Levi’s skirt covering two rows of grids, Petitioner does not address Levi’s Figures 1-3, and 43, and Levi’s specification, all of which clearly show that Levi’s outer skirt (alleged “fibrous network”) only covers one row of grids (*see* Section VI.B.1).

165. It is important to note that Figure 42 is from the very same embodiment as Figures 1-3 and 43. *Id.* As Levi explains, “FIGS. 42 **and** 43 show **the** exemplary prosthetic heart valve of **FIG. 1.**” Ex. 1008 [Levi] 5:14-15; 4:57-58 (“FIGS. 1-3 show an exemplary embodiment of a prosthetic heart valve.”); 14:15 (“FIG. 56 shows the valve 10 of FIGS. 1-3 and 42-43 ...”). Again, as Figures 1-3, and 43 all confirm, Levi’s outer skirt extends over, at most, one row of grids:

**Levi's Figs. 1-3 and 43, Depicting the Same Embodiment as Fig. 42, All Confirm That Levi's Outer Skirt Extends Over, At Most, One Gridded Row**

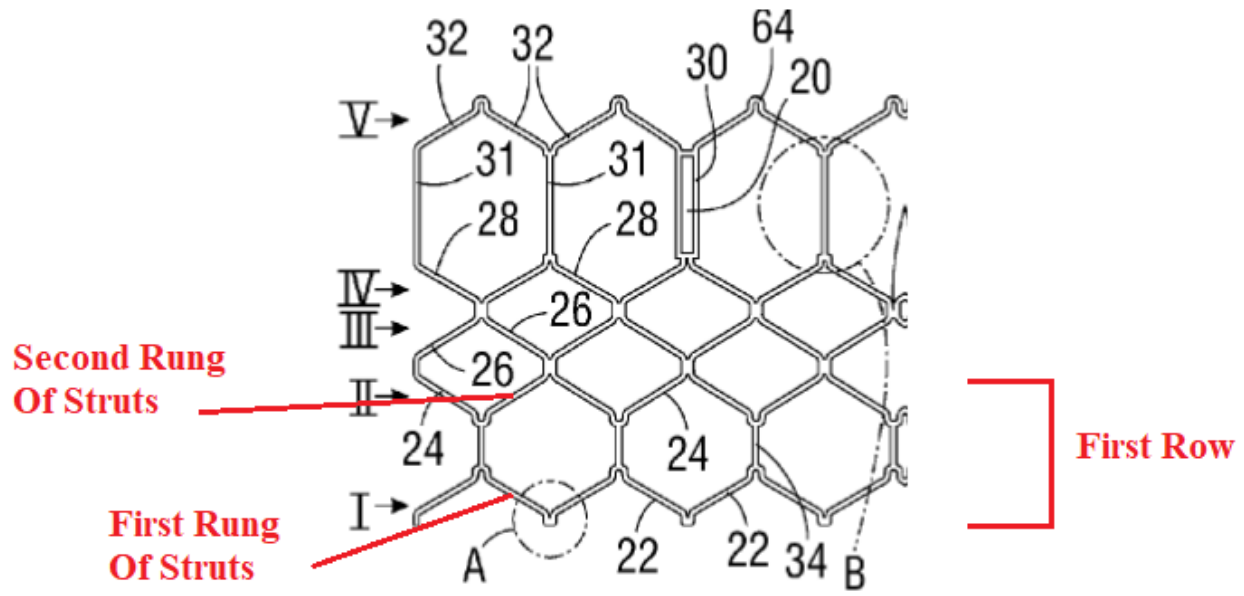


166. Levi's only discussion of Figure 42 similarly explains that Figures 42 and 43 show different aspects of the *same* embodiment with the *same* outer skirt. In particular, a POSITA would understand that Figure 42 is meant to show where the bottom of Levi's outer skirt is attached the rest of the valve, while Figure 43 is

meant to show where the projections 164 at the top of Levi's outer skirt are attached to the rest of the valve:

**The outer skirt 18** can have a substantially straight lower edge 160 and an upper edge 162 defining a plurality of alternating projections 164 and notches 166. **As best shown in FIG. 42**, 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. **As shown in FIG. 43**, each projection 164 can be sutured to the second rung II of struts 24 of the frame 12. The corners 162 of the projections 164 can be folded over respective struts of rung II and secured with sutures 168.

Ex. 1008 [Levi] 13:53-61. Thus, Figure 42 is intended to show where the bottom of the outer skirt is attached, not the top. Petitioner, however, relies upon Figure 42 to show where the stitching at the top is while ignoring Figure 43 which is actually intended to show where the top is sutured (*i.e.*, at the second rung II of struts 24). Thus, Figure 43 confirms both in the text and in its embedded reference to Figure 5 that only (at most) the first row of grids (between the first and second struts) is covered:



Ex. 1008 [Levi] Fig. 5 (annotated).

167. While Petitioner contends that Levi's Figure 42 shows the outer skirt covering two rows of grids, a POSITA would understand that this is, at best, a drafting error.

168. Levi confirms that Figures 1-3, 42, and 43 all depict the same embodiment. Ex. 1008 [Levi] 5:14-15, 4:57-58, 13:53-61, 14:15. Moreover, Figures 1-3 and 43 and Levi's specification all confirm that the outer skirt in this embodiment extends over, at most, one row of grids. *Id.*, Figs. 1-3, 43, 13:53-61. To the extent that Petitioner and Dr. Buller are arguing that Levi's Figure 42 shows a separate embodiment with a longer skirt, this premise is contradicted by Levi's specification. *Id.*

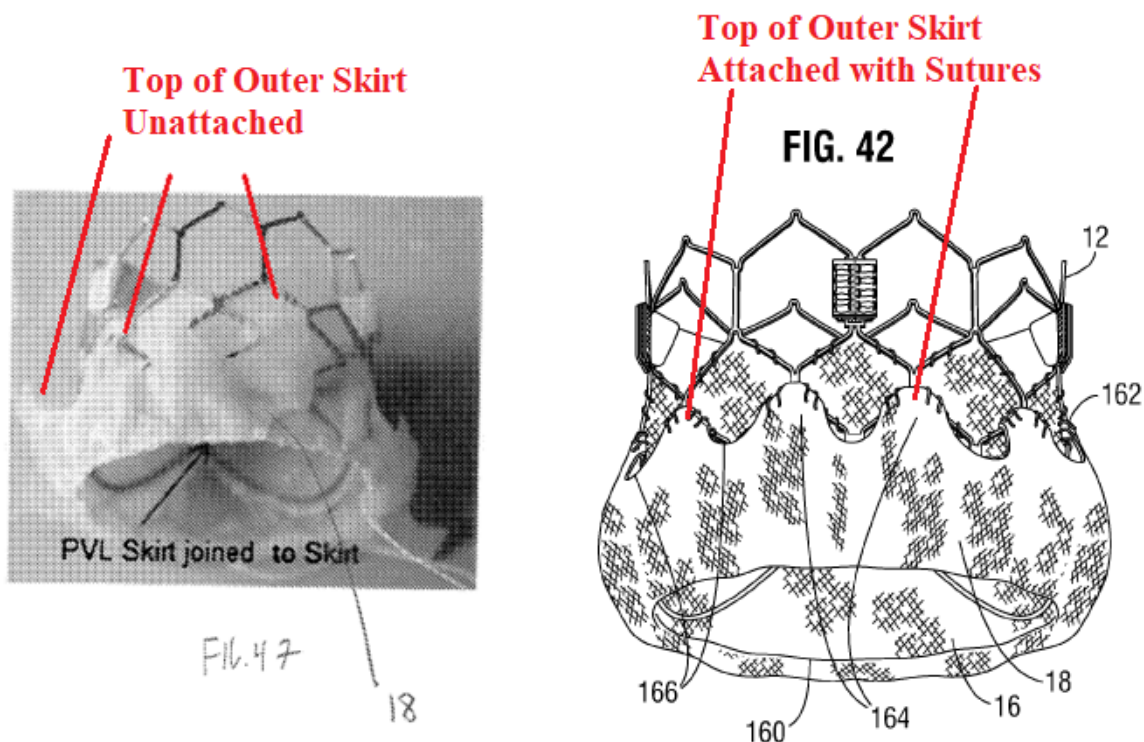
169. Furthermore, if Levi was to teach a separate embodiment with an outer skirt roughly twice as tall as the “exemplary embodiment,” a POSITA would expect there to be some explanation of the advantages/drawbacks of this taller skirt, and perhaps how the increased height of this skirt would affect delivery, placement, and general operation of the valve. At a bare minimum, a POSITA would expect a reference to at least mention that a particular figure was showing a separate embodiment. None of this is present in Levi. Quite the opposite, Levi is perfectly clear that Figures 1-3, 42 and 43 were all intended to show the **same embodiment** with the **same outer skirt**. *Id.*, 5:14-15, 4:57-58, 13:53-61, 14:15. As a result, a POSITA would understand that this is, at best, a drafting error in Levi’s Figure 42, perhaps a consequence of the tilted angle applied in Figure 42 but not in Figures 1-3 and 43. Indeed, a POSITA would understand that a taller skirt on Levi would add material, thus, increasing the delivery profile and making it more difficult to deliver.

170. This drafting error is further confirmed by analyzing Levi’s provisional application 61/508,513 (“Levi Provisional”), which Levi incorporates by reference, *id.*, 1:10-13. As shown below, the drawings in Levi’s Figures 42 and 43 appear to correspond respectively to Levi Provisional’s Figures 47 and 48, a pair of photographic images.



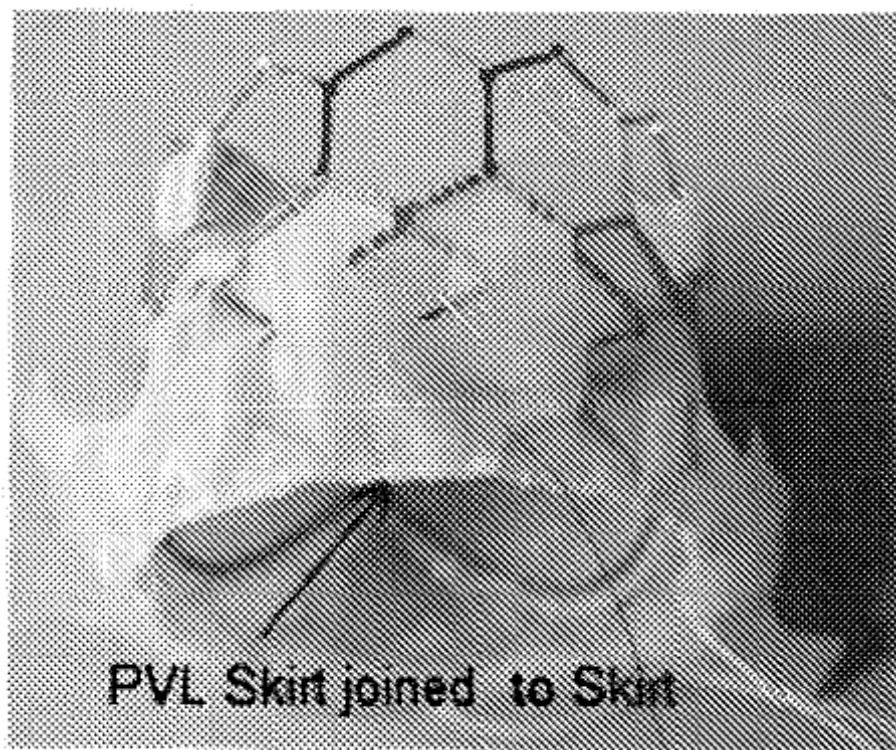
Levi's discussion of Figures 42 and 43. *Compare* Ex. 1008 [Levi] 13:53-61 with Ex. 2036 [Levi Provisional] ¶31.

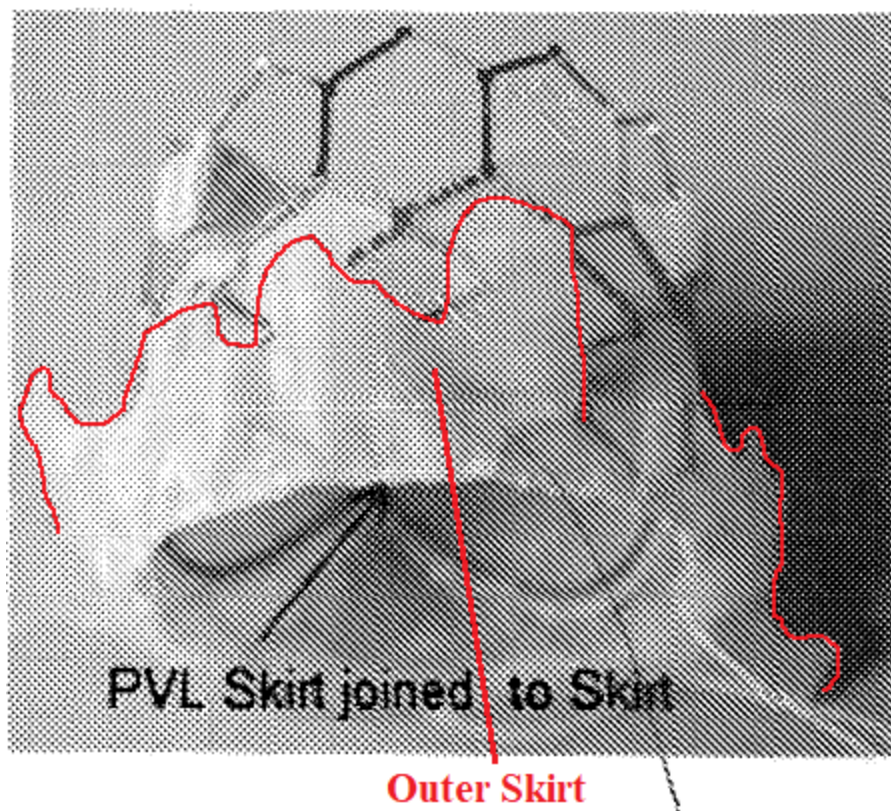
171. A major difference between the initial photograph image in Levi Provisional's Figure 47 and finalized drawing in Levi's Figure 42, however, is that in Levi Provisional's Figure 47, the top of the outer skirt is not attached to the frame, while Levi's Figure 42 shows the top of the skirt attached to the frame with sutures.



Ex. 1008 [Levi] Fig. 42 (annotated); Ex. 2036 [Levi Provisional] Fig. 47 (annotated). Because the top of the skirt in Levi Provisional's Figure 47 is not attached to the frame, the skirt hangs unevenly on the valve, covering the

first row of grids in parts, while seeming to be slightly higher on other parts, and even completely falling off of the valve frame in still other parts. This is illustrated by the following images, where the second image includes an added red line tracking the top of the outer skirt.





Ex. 2036 [Levi Provisional] Fig. 47. As the figure itself confirms via the text and arrow, it is intended to show where the outer skirt is joined at the bottom of the frame. *Id.* Accordingly, when the drafter was using the image Levi Provisional's figure 47 to make the drawing for Levi's Figure 42, he or she must have misinterpreted where the skirt would be attached at the top. Indeed, this is the only explanation for why the skirt in Levi's Figure 42 could appear taller than the same skirt in the same embodiment shown in Figures 1-3, and 43, and described in the specification.

172. In sum, it is my opinion that a POSITA would not understand Levi's Figure 42 to teach a taller skirt that covered two rows of grids. Instead, a POSITA

would understand that Levi's Figure 42, at best, contains a drafting error that is inconsistent with four other figures and Levi's specification. Further, Levi makes clear that Figure 42 is not intended to show where the top of the stitching is made, a job instead assigned to Figure 43 which confirms that Levi's outer skirt only extends over, at most, one row.

173. In sum, it is my opinion that a POSITA would understand that Levi's Figure 42 does not teach an outer skirt that "extends over at least two circumferentially extending rows of grids."

2. Dr. Buller and Petitioner Fail To Demonstrate That Levi Teaches Or Renders Obvious An Outer Skirt That "Extends Over At Least Two Circumferentially Extending Rows Of Grids"

174. Figures 1-3, and 43 all depict the embodiment as attaching the outer skirt extending over one row of cells.

**FIG. 1**

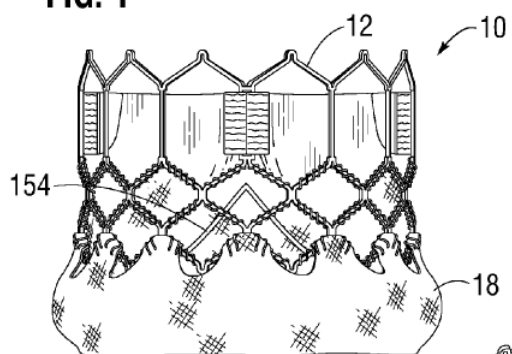


**FIG. 2**

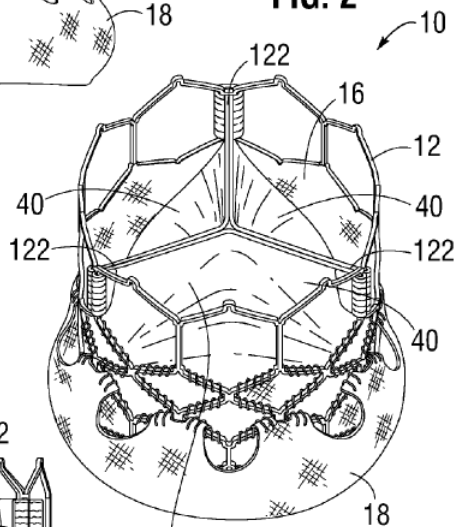


**FIG. 3**

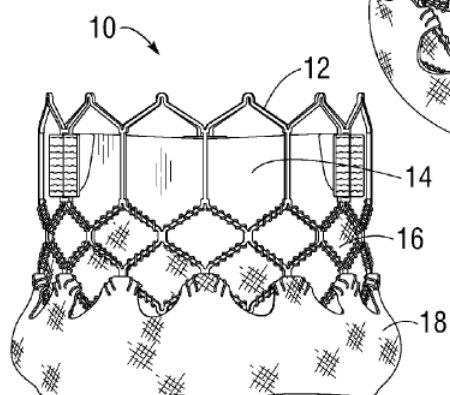
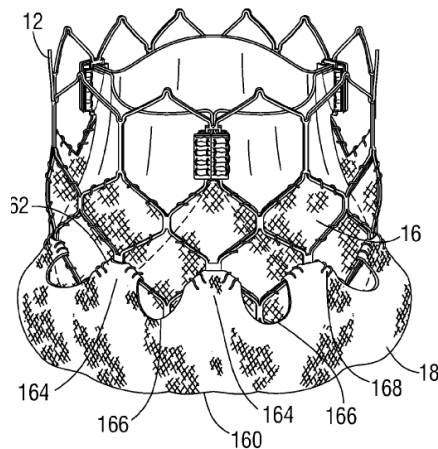
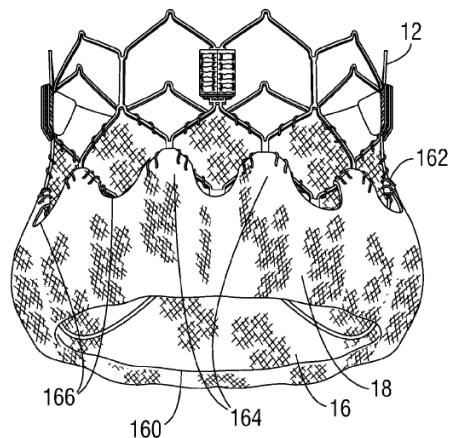


**FIG. 43**



175. Only one, Figure 42, appears to show the second row being covered.

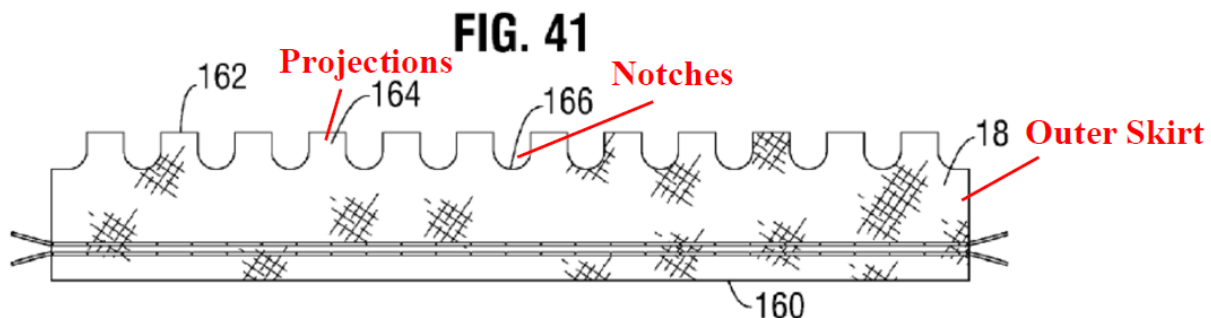
**FIG. 42**



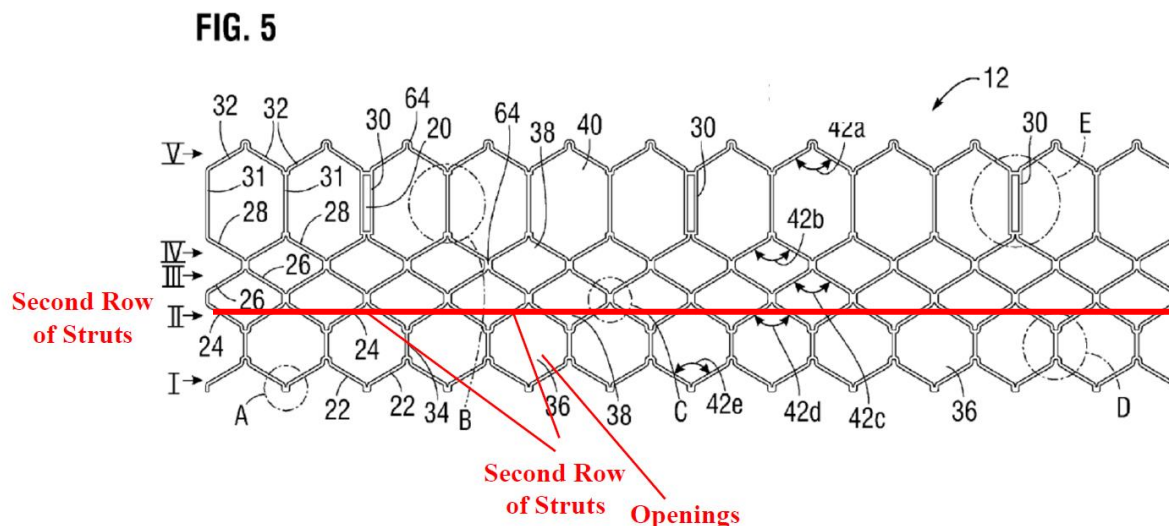
176. Figure 42 is, thus, inconsistent with the other five figures showing the same embodiment. Figure 42 is from a tilted angle and is intended to show how the outer skirt is sutured to the inner skirt. *Id.*, 13:55-57 (“***As best shown*** in FIG. 42, the lower edge 160 of the [outer] skirt 18 can be sutured to the lower edge of the inner skirt 16 at the inflow end of the valve.”). Thus, Figure 42 is meant to show how the outer skirt is attached to the inner skirt at the inflow end. Figure 42

is not intended to show an alternative arrangement where the outer skirt is attached higher on the skirt.

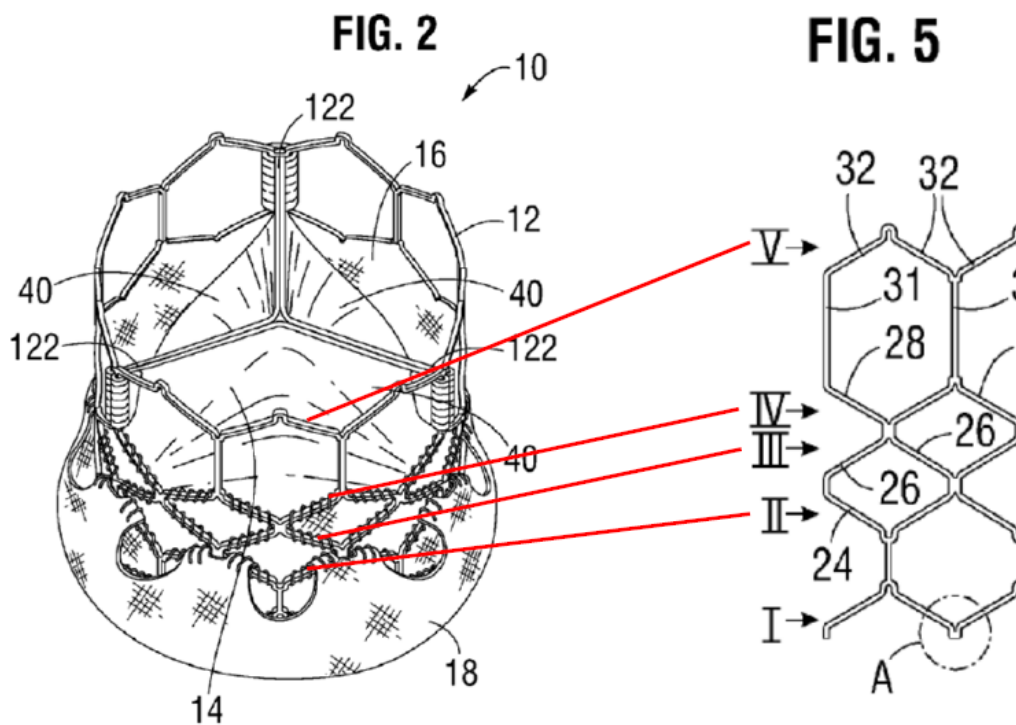
177. Notably, Figure 43, in contrast to Figure 42, *is* meant to show how the outer skirt is attached to the frame. *Id.*, 13:58-59 (“As shown in FIG. 43 each projection 164 can be sutured to the second rung II of struts 24 of the frame 12.”). Projections 164 may be seen, for instance, in Figure 41, and define the top of the outer skirt.



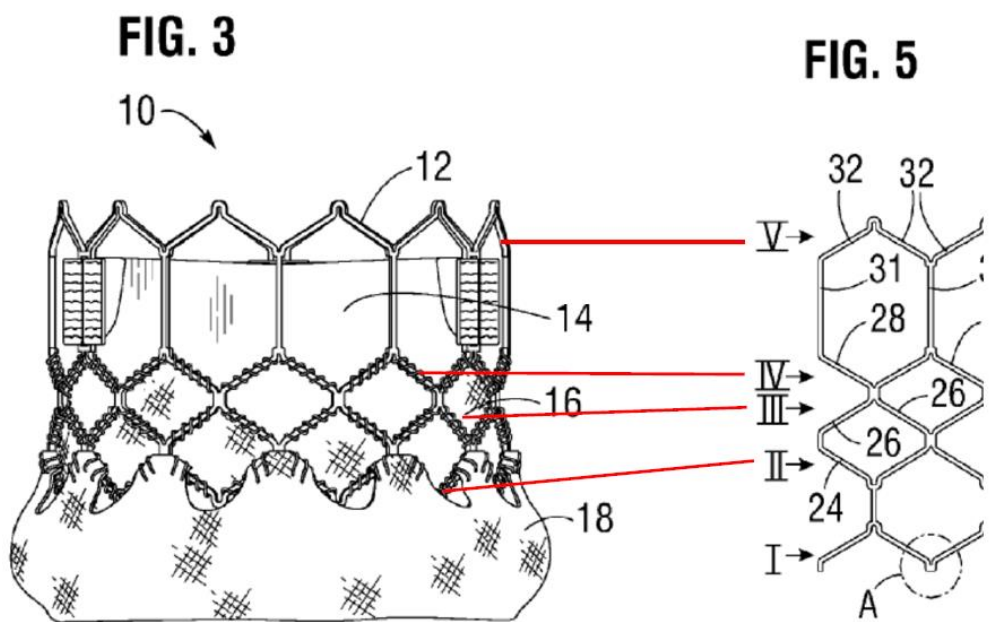
The projections, in turn, attach to second rung II (*i.e.*, the top of the first opening):



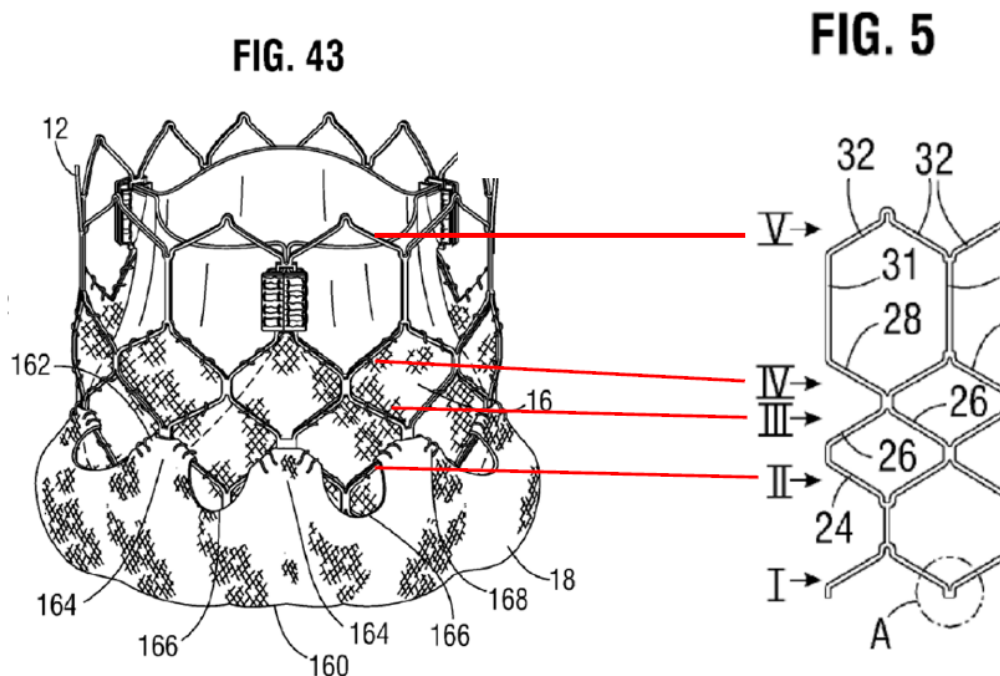




*Id.*, Fig. 2, 5 (excerpted and annotated).



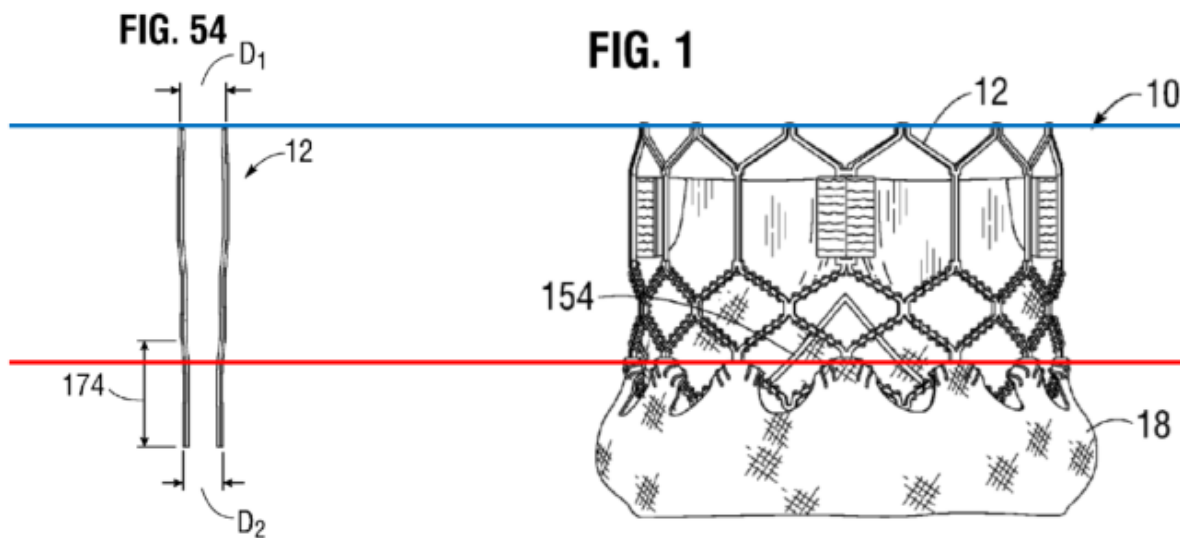
*Id.*, Fig. 3, 5 (excerpted and annotated).



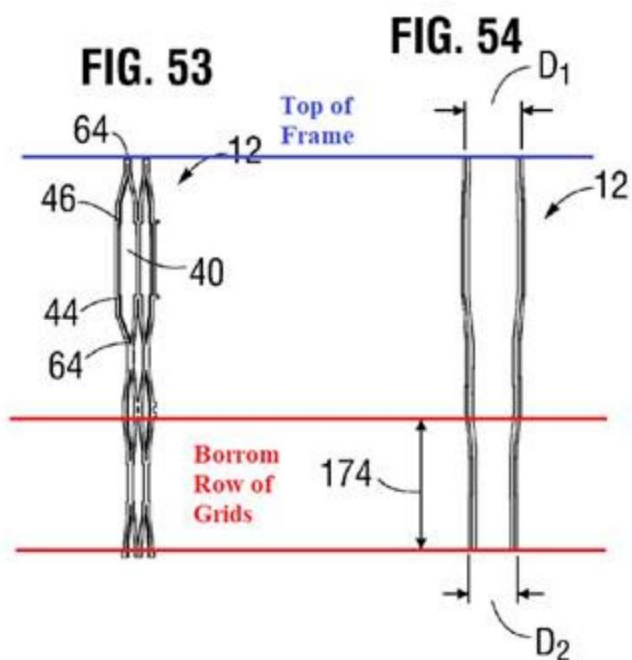
*Id.*, Fig. 43, 5 (excerpted and annotated).

179. Thus, Figures 1-3, 18 and 43 and the corresponding written description all demonstrate that the outer skirt covers one row of cells. Figure 42 is inconsistent.

180. Levi's design also requires its skirt to be attached at the bottom row. Levi has a "reduced diameter" region that "makes room" for the outer skirt such that the "outer diameter" of the inflow end "inclusive of the outer skirt, is still less than or equal to an outer diameter of an outflow end portion ..." *Id.*, 2:22-35, 8:46-54. The reduced diameter portion (D2) has, *e.g.*, a crimped diameter of 12F while the non-reduced diameter (D1) is 14F. *Id.*, 8:46-54. As can be seen, the reduced diameter lines up perfectly with the first row:



181. Likewise, a comparison of Figures 53 and 54 confirm that the reduced region corresponds perfectly to the first row of cells:

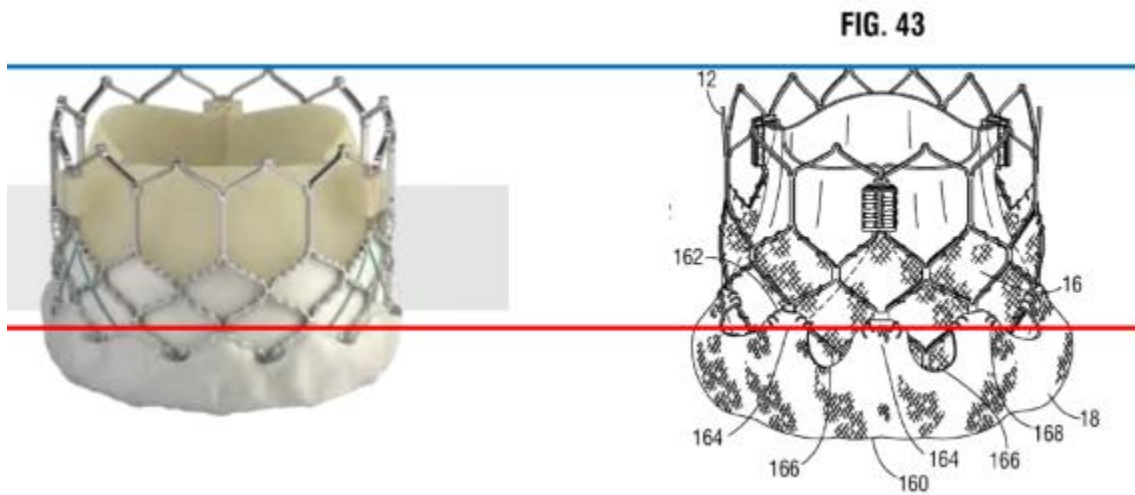


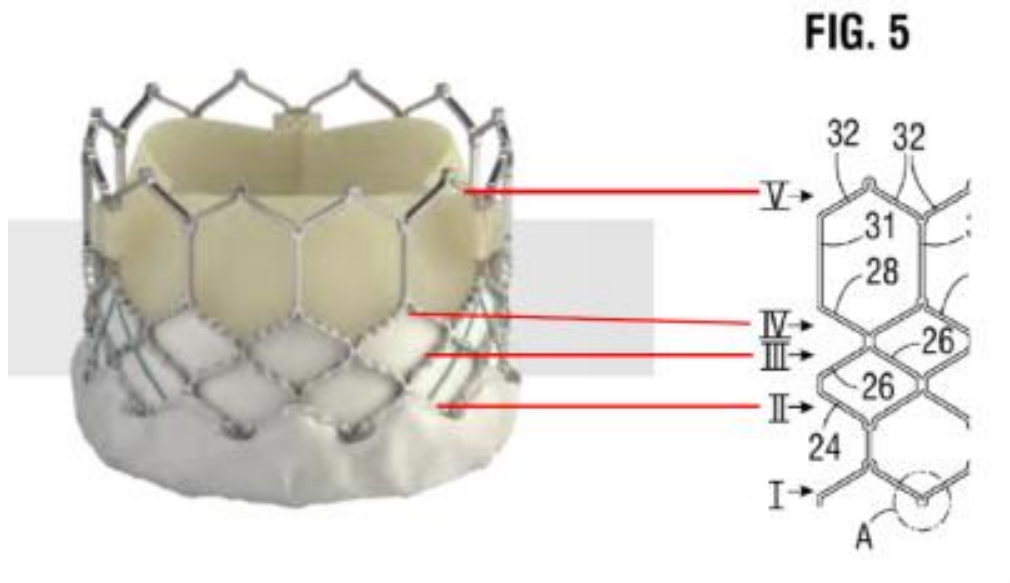
Ex. 1008 [Levi] Figs. 53-54 (annotated). As these comparisons show, the drawings are to scale. Similarly, Figs. 53 and 54 show portions of the frame of

Figure 4, an exemplary frame for the Fig. 1 embodiment (*id.*, 5:18-22), further underscoring this relationship.

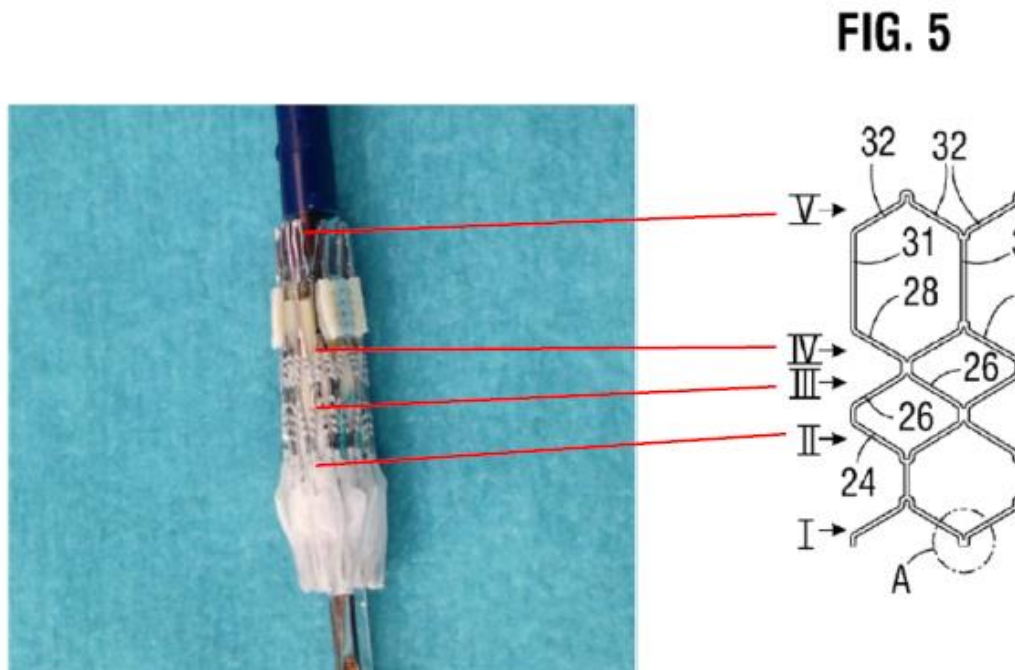
182. Fundamentally, if the skirt were attached to the frame's second row of openings—*i.e.*, in the non-reduced region—it would frustrate the reduced region's purpose of “making room” for the skirt and defy Levi's own design principles.

183. I have personally implanted large numbers of Sapien 3 valves. I am very familiar with it. I know that its skirt attaches only to the top of the first row of openings, as confirmed in numerous images:





184. A crimped view of Sapien 3 also corresponds to the first row:



Ex. 2050 [Schymik] Fig. 1(B) (cropped, rotated).

185. As Dr. Buller testified and I agree, there is a “direct relationship” between Levi’s figures and its commercial embodiment, the SAPIEN 3. Ex. 2051

[Buller-Depo.] 226:14-20. SAPIEN 3, consistent with Levi's Figures, and its disclosure and Levi's design principles, has a skirt attached to the top of the bottom row.

186. In sum, Figures 1-3, and 43 all show the skirt attached at the top of the bottom row. This is consistent with Levi's explanation of how the skirt is attached, Levi's means of accommodating the skirt, and Levi's commercial embodiment. Figure 42, however, is a clear error, inconsistent with five other figures showing the same embodiment, Levi's specification, Levi's design principles, and its commercial embodiment. Moreover, the Levi Provisional provides a clear indication of how the error was made. See ¶¶170-171, *supra*. It should be disregarded.

## **F. Overlapping Radial Alignment**

187. The claims of the '538 patent require a valve with "a fibrous network positioned at least partially radially outwardly of the outer frame" of the valve "wherein the fibrous network extends over at least two circumferentially extending rows of grids" of the frame.

### **1. Prior Testimony On Overlapping Radial Alignment**

188. I have previously submitted a declaration with respect to the "overlapping radial alignment" limitation in IPR2022-00193. The following excerpts are from paragraphs 94-119 of my IPR2022-00193 declaration. To ensure

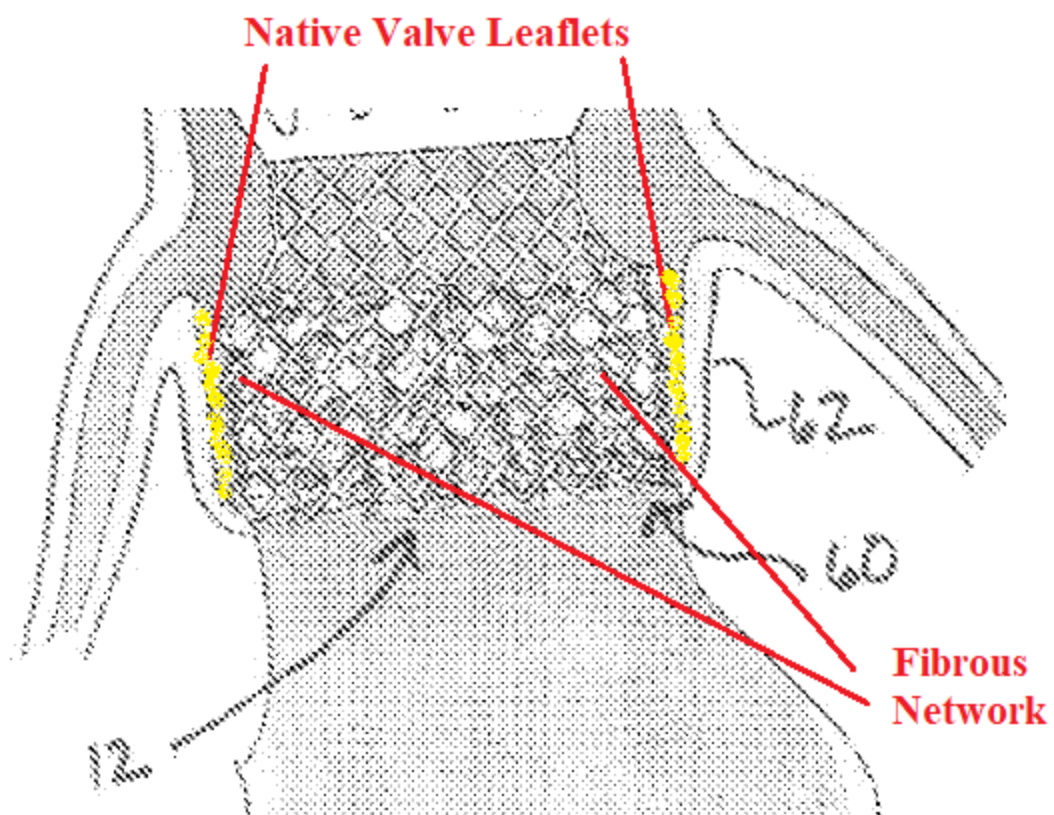
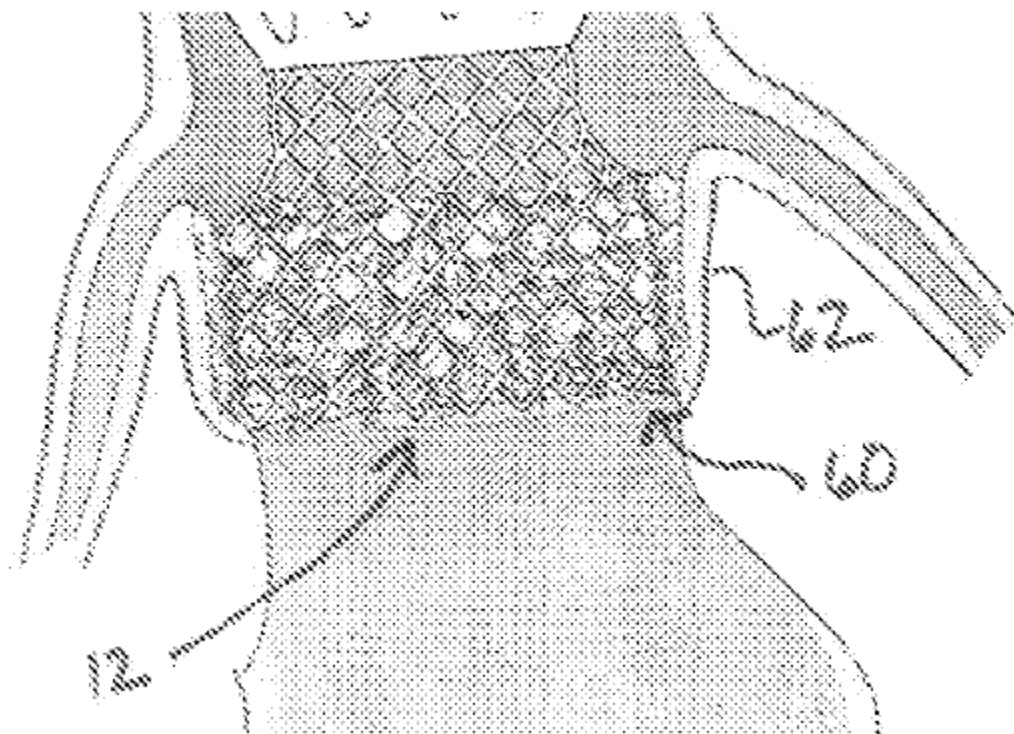
this testimony is part of the post-institution record, I so testify again. See ¶¶189-214. The citations to the Petition and exhibits in this section of my declaration are to the those in IPR2022-00193.

189. The claims require a valve that “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.” Ex. 1001 [’538] cls. 1, 11. As to this limitation, Petitioner relies on either the positioning of Levi’s valve as disclosed (Grounds 5-6), or on the hypothetical positioning of a combination of one of the valves in Cribier, Spenser, or Levi with one of the outer cloths in either of Walther or Spenser II (Grounds 1-4, 7-8). As discussed below, neither set of grounds demonstrates that the limitation is met.

a. *Levi’s Skirt Is Not “In Overlapping Radial Alignment With Native Valve Leaflets”*

190. The ’538 patent claims a valve that 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.” This positioning is demonstrated in the figures in the ’538’s provisional application, discussed below.

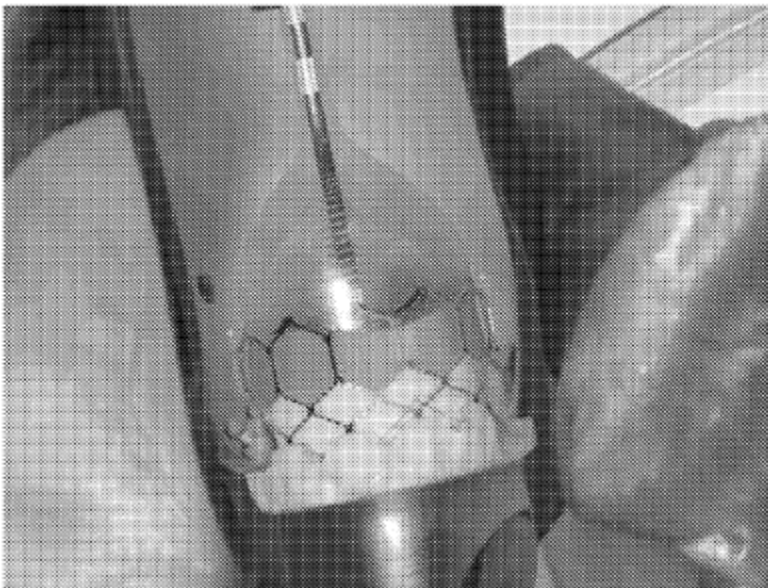
191. In the clean and annotated copies of figure 10 from the ’538’s provisional application (“’446 Provisional”), below, we can see the valve positioned so that the fibrous network is in overlapping radial alignment with the patient’s native valve leaflets:



Ex. 1006 ['446 Provisional] Fig. 10 (excerpted, annotated). This provisional is incorporated by reference into the '538. Ex. 1001 ['538] 1:37-42.

192. I will note that, during prosecution of the '538, Patent Owner seems to have differentiated the claimed invention from other valves, like Levi, with outer seals that were positioned below the native leaflets (*i.e.*, not in overlapping radial alignment). Specifically, Patent Owner explained:

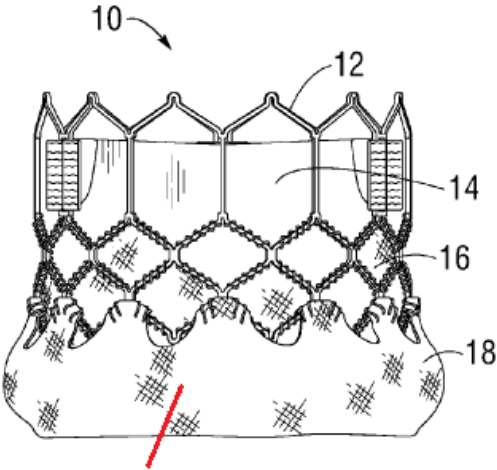
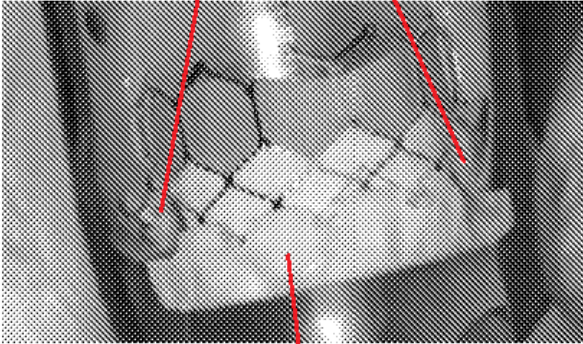
Much of the prior art teaches, when using an outer seal, ***to position the outer seal below the native leaflets***. For example, a valve embodied by the art of record Levi is shown in this image taken from online:



Applicant submits that sealing below the leaflets has been the preferred method for creating an outer seal for transcatheter aortic valve replacement because the triangulation shape created by the folded up native leaflets has proven challenging to seal against.

Ex. 1002 ['538-PH] 151-152. The Applicant distinguished Levi on this very same basis yet again in the prosecution of related patent 10,857,011. Ex. 2034 ['011 Prosecution-History] 117-118 (“In much of the prior art, for example, Applicant submits that the seal was made below the native leaflets in the patient, but not against the leaflets. See, for example, ... US Patent Publication No. 2012/0123529 to Levi, ... In order to seal against the leaflets, one would need a taller outer seal ...”).

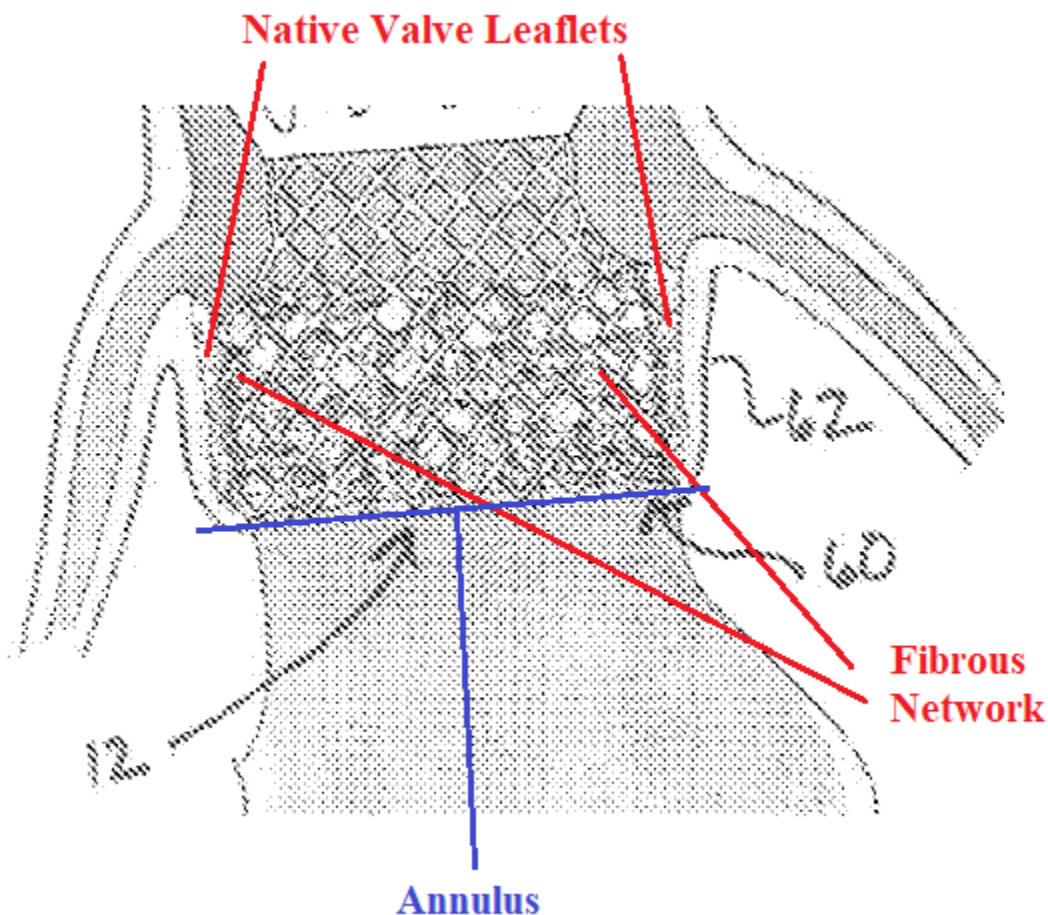
193. Therefore, as Patent Owner explained in prosecution, Levi’s commercial embodiment confirms that a POSITA would know that Levi’s valve is designed to be positioned such that its outer skirt (the alleged “fibrous network”) is **below** the leaflets. As can be seen in the annotated images below, the Levi valve discussed in prosecution is identical to the Levi reference’s valve.

| Levi<br>(Ex. 1008, Fig. 3)                                                                                                                                       | Levi's Commercial Embodiment<br>(Ex. 1002, 152)                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>FIG. 3</b></p>  <p><b>Outer Skirt<br/>(Alleged "Fibrous Network")</b></p> |  <p><b>Native Valve Leaflets</b></p> <p><b>Outer Skirt</b></p> |

194. Consistent with the Patent Owner's discussion during prosecution, the Levi reference likewise confirms that its valve is deployed such that the outer skirt is **below** the native leaflets. Indeed, I see that Petitioner acknowledges that Levi's valve is implanted such that the outer skirt is situated next to the annulus (*i.e.*, below the native leaflets). Pet., 96 (Levi "'is adapted to be implanted in the native aortic annulus' and that the outer skirt 'fill[s] in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus.'") (quoting Ex. 1008 [Levi] 5:52-54, 14:3-7) (quotation edits in Petition); *id.*, 36 (arguing that "fibers 'above the annulus' would

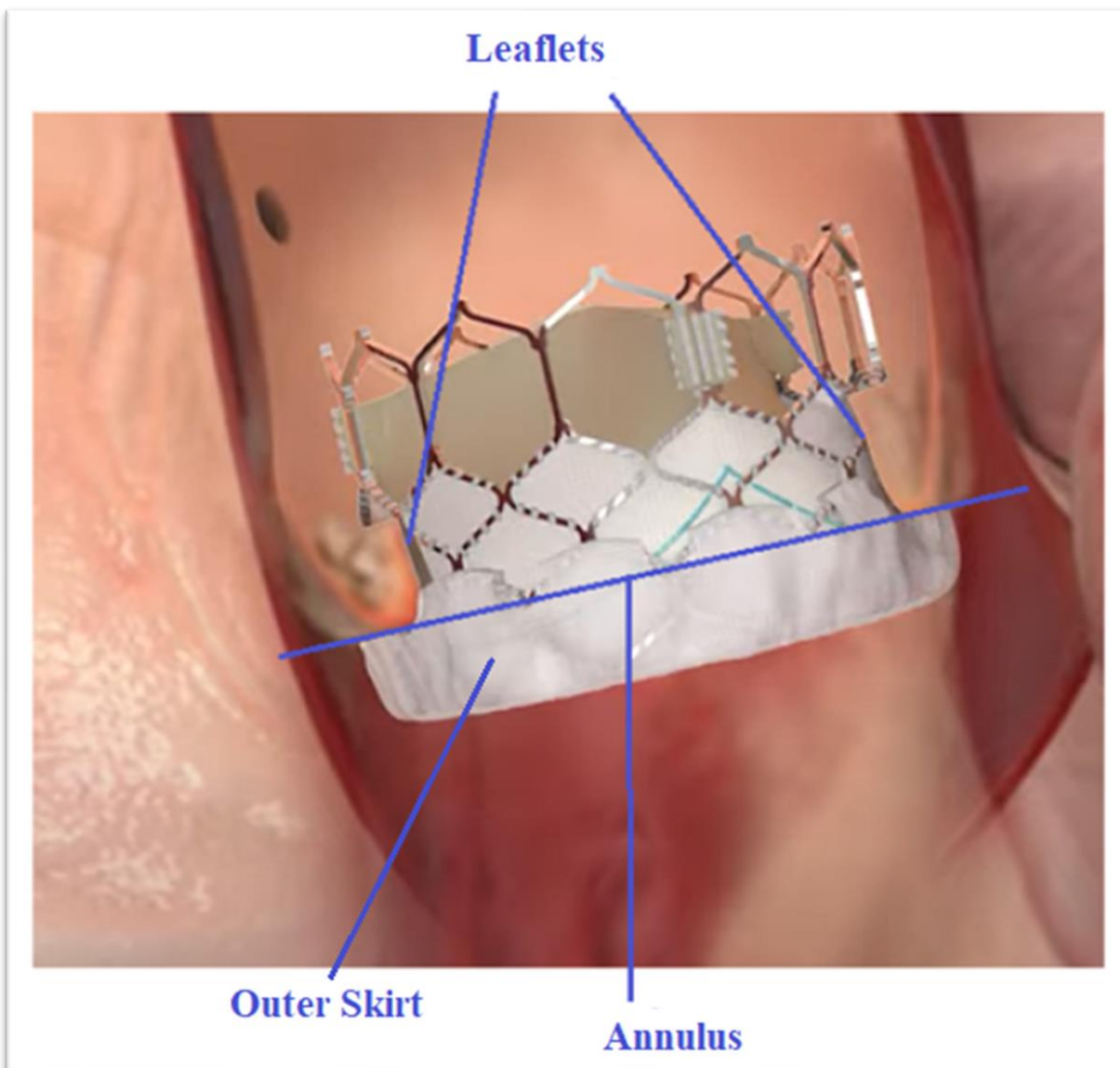
be in overlapping radial alignment with the leaflets”), 67 (“the patient’s aortic leaflets ... are attached to the annulus and extend distally therefrom”).

195. As Petitioner correctly points out, the annulus sits below the patient’s native valve leaflets. Pet., 67 (“the patient’s aortic leaflets ... are attached to the annulus and extend distally therefrom”). This positioning is illustrated in the annotated version of the ’446 provisional’s Figure 10 below.



Ex. 1006 [’446 Provisional] Fig. 10 (excerpted, annotated); *See also* Ex. 2037 [Hoffman] 6, Fig. 1 (showing location of annulus and native valve leaflets).

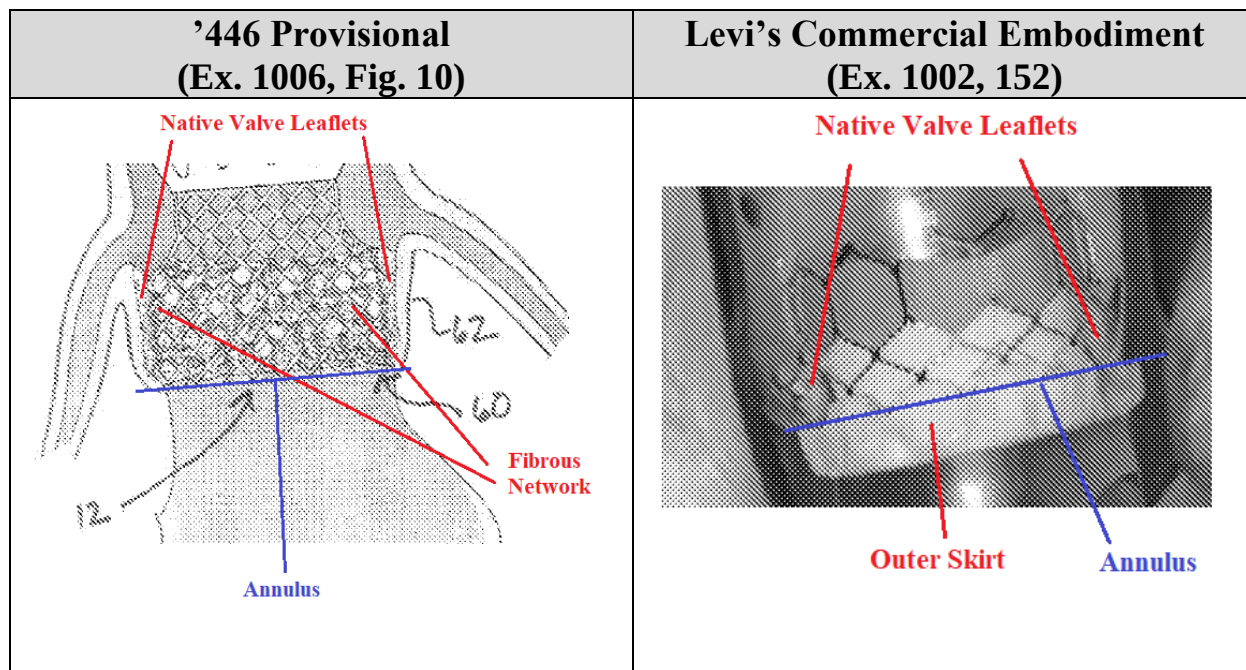
196. A POSITA would understand that Levi's disclosure that the outer skirt fills the gaps, and creates a seal, between the prosthetic valve and the native annulus, means that Levi's outer skirt is in overlapping radial alignment with at most the annulus, not the native leaflets. Ex. 1008 [Levi] 5:52-54, 14:3-7. Indeed, this positioning is clearly demonstrated by Petitioner Edward's own material regarding the commercial embodiment of Levi (SAPIEN 3) which shows the valve's outer skirt being positioned below the annulus, not in overlapping radial alignment with the native valve leaflets.



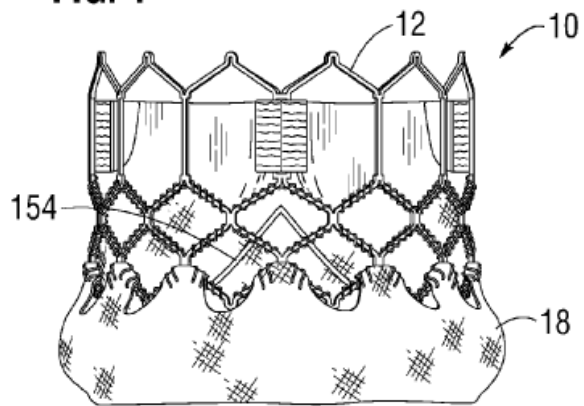
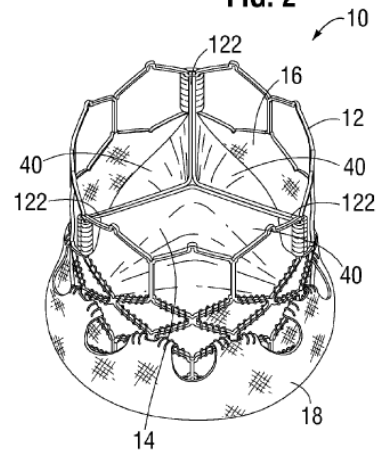
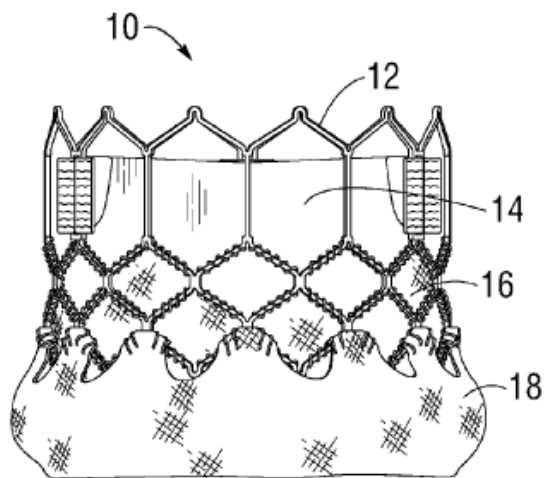
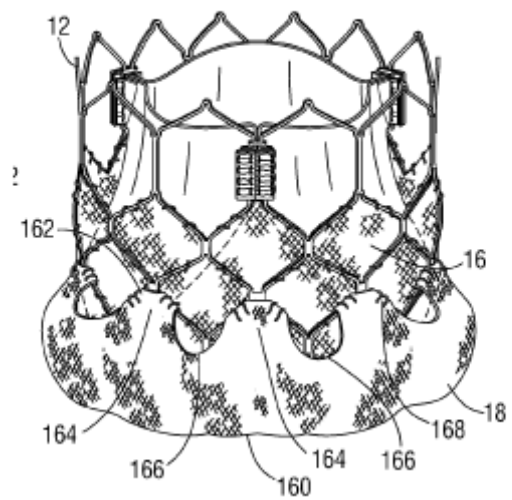
Ex. 2038 [SAPIEN 3 Video] 2:18.

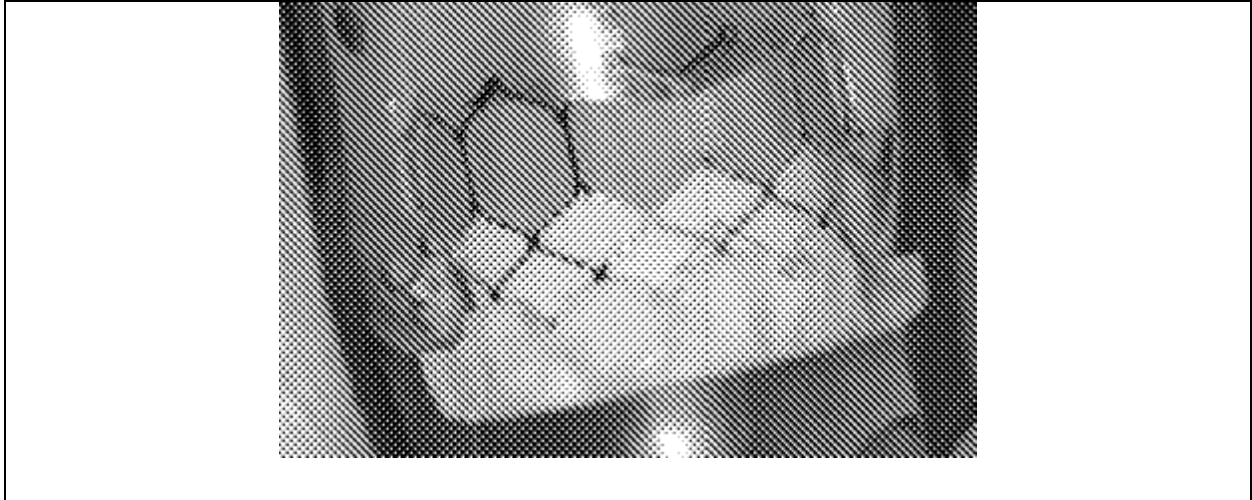
197. As I explain above, the '538's provisional application clearly shows a “fibrous network” “in overlapping radial alignment with native valve leaflets of the patient.” In fact, the difference between the claimed fibrous network’s positioning (in alignment with the leaflets) and Levi’s outer skirt positioning (below the

leaflets), as shown by Levi’s commercial embodiment, can be plainly seen in the annotated images below.



198. Petitioner makes three arguments with regards to this limitation. First, Petitioner argues that Levi’s “outer skirt covers at least two rows of the frame” and “[d]uring prosecution of a related patent, Patent Owner admitted that an outer seal covering two rows of the frame would press against, and thus radially overlap, the leaflets.” Pet., 96. As I have explained above, Levi’s outer seal only covers **one** row of the frame, and Petitioner’s argument to the contrary relies on what is, at best, a drafting error. See Section VI.B. Thus, a POSITA would understand that Levi’s outer skirt does not extend over two rows as confirmed by both Levi’s figures and its commercial embodiments:

**FIG. 1****FIG. 2****FIG. 3****FIG. 43**

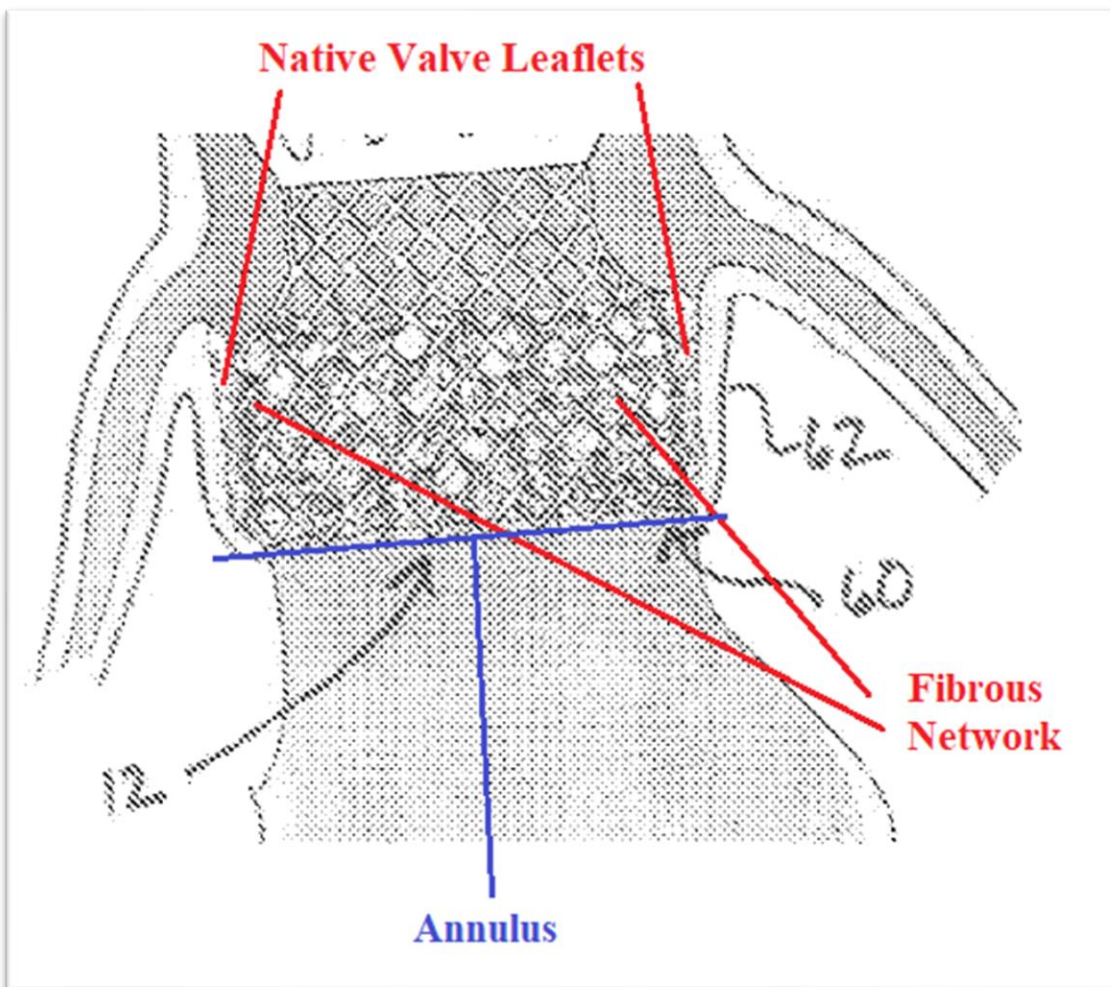


Ex. 1008 [Levi] Figs. 1-3, 43; Ex. 1002 [Prosecution-History] 152

199. Further, even if, counterfactually, Levi did have a skirt that covered two rows, I will point out that Patent Owner did not state that any valve with an outer seal covering two rows, deployed in any position in the aorta, will necessarily result in overlapping radial alignment with the leaflets. Instead, Patent Owner clearly explained that such a “heightened seal [] **allows** for sealing below the native leaflets and at the native leaflets.” Ex. 1046 [’253 Preliminary Amendment] 25. Levi’s disclosure is clear that its valve is to be positioned so its outer skirt **only** seals with the aortic annulus, **not** that it is in overlapping radial alignment with the native valve leaflets which lie above the annulus. Ex. 1008 [Levi] 5:52-54, 14:3-7

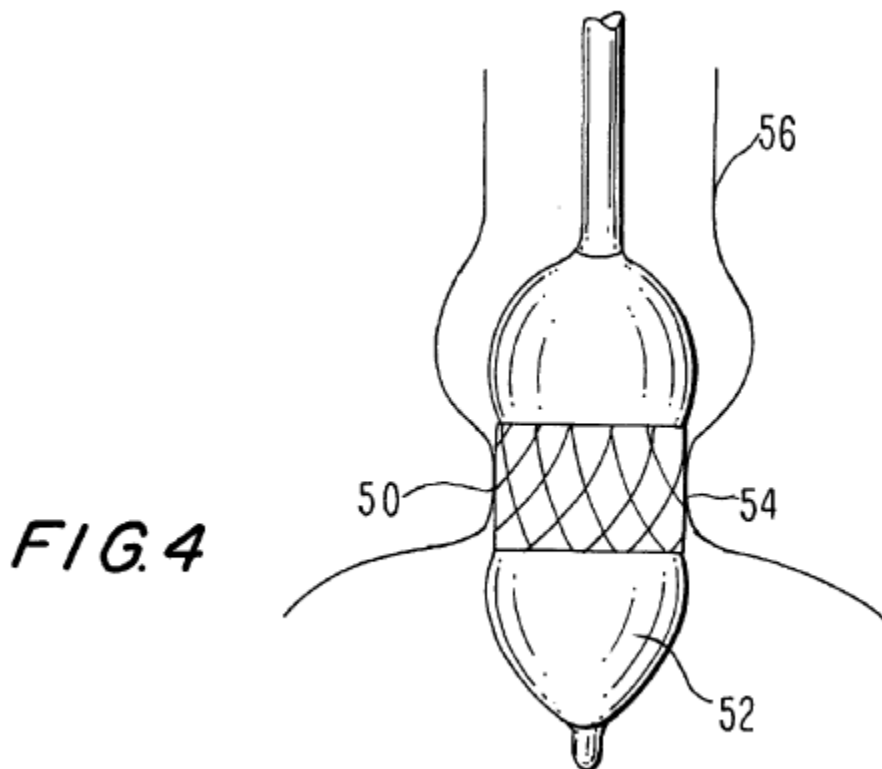
200. Next, I see that Petitioner argues that “some of [Levi’s] outer skirt’s fibers radially overlap the aortic leaflets, which extend from the annulus.” Pet., 96. Even if the very top of Levi’s outer skirt contacted the very bottom of the native valve leaflets, Petitioner does not explain how this would meet the claimed

“fibrous seal” that “is in overlapping radial alignment with native valve leaflets of the patient.” Petitioner has no explanation for how Levi’s skirt, which lies below the native leaflets, is in “overlapping radial alignment” with the patient’s native leaflets. Unlike Levi, the ’538’s provisional application shows a valve positioned so that the fibrous network is clearly in overlapping radial alignment with the patient’s native leaflet.



Ex. 1006 [’446 Provisional] Fig. 10 (annotated, excerpted).

201. Finally, Petitioner argues that “Levi also expressly incorporates the ’118 patent by reference, which discloses positioning the valve in overlapping radial alignment with the patient’s native aortic leaflets.” Pet., 96. Petitioner’s only cite to the ’118 patent is to its Figure 4 (below), but Petitioner does not explain how this shows overlapping radial alignment with the patient’s native aortic leaflets.



Ex. 1051 [’118 patent] Fig. 4. Moreover, Petitioner does not explain how the ’118 patent’s alleged alignment of the **valve** with the native leaflets would teach a **fibrous network** in overlapping radial alignment with the leaflets. The ’118’s Figure 4 does not even show a “fibrous network.” Indeed, the ’118 is Spenser’s

parent and Petitioner never contends that Spenser discloses a “fibrous network” or native leaflets for that matter. Moreover, and as discussed above, Levi is clear that its outer skirt fills the gaps between the frame and the annulus.

202. In sum, it is my opinion that a POSITA would understand that Levi does not disclose or suggest a “fibrous network” that “is in overlapping radial alignment with native valve leaflets of the patient” as claimed.

b. *Walther/Spenser II Combinations*

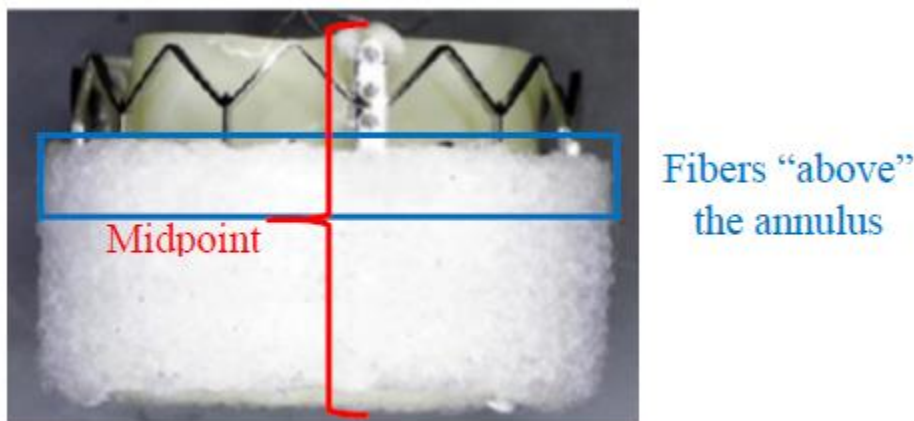
203. In Grounds 1-4 and 7-8, Petitioner adds Walther’s or Spenser II’s outer cloth (alleged “fibrous network”) to one of the valves in Cribier, Spenser, or Levi. Petitioner’s various combinations of valves and outer cloths are shown below.

| Ground(s) | Alleged<br>“Outer Frame” | Outer Cloth, Alleged<br>“Fibrous Network” |
|-----------|--------------------------|-------------------------------------------|
| 1-2       | Cribier                  | Walther                                   |
| 3         | Spenser                  | Walther                                   |
| 4         | Spenser                  | Spenser II                                |
| 7         | Levi                     | Walther                                   |
| 8         | Levi                     | Spenser II                                |

204. In Grounds 1-2, Petitioner takes Cribier’s uncovered valve, and attempts to add Walther’s outer cloth in order to meet the “fibrous network” limitation. Petitioner argues that this new proposed valve would be deployed with the exact same positioning Cribier employs for its valve which does not include a

“fibrous network.” Petitioner does not explain why a POSITA would be motivated to use this same positioning if a “fibrous network” were added.

205. In particular, I see that Petitioner contends that “Cribier instructs that ‘before deployment, **one third to half of the stented prosthesis needs to rest above the annulus** and the remainder in the LVOT [left ventricular outflow tract] in order to minimize [PVL] and avoid coronary occlusion’” and the part of the valve that is above the annulus “would be in overlapping radial alignment with the leaflets.” Pet., 34-36. Petitioner then argues that in its proposed modified version of Cribier, “Walther’s fibrous network covers approximately two-thirds of [the] frame” and therefore, “the fibers ‘above the annulus’ would be in overlapping radial alignment with the leaflets,” as Petitioner illustrates in the following annotated version of Walther’s figure 1:



*Id.*, 35-36.

206. Petitioner, however, does not explain why a POSITA would deploy the proposed modified Cribier valve such that half of the combined valve is above the annulus. More precisely, Petitioner does not explain why a POSITA would choose to position the proposed Cribier-Walther valve such that part of Walther's outer seal would be in contact with the native leaflets. *Id.* I will note that neither Cribier, nor Walther disclose an outer "fibrous network" in contact with the native leaflets. Cribier does not teach any outer "fibrous network," and Walther only discloses a device for "valve-in-valve implantation" where Walther's outer cloth (alleged "fibrous network") would be in contact with a previously implanted prosthetic valve, not the native leaflets of the patient. Ex. 1012 [Cribier], Ex. 1007 [Walther] 1, 3-6. In fact, as Walther describes implantation in a previous "surgical" valve, a POSITA would understand that the native valve leaflets would have been already removed during the implantation of the "surgical" valve. Ex. 1007 [Walther] 1-6. Further, there is no indication in Walther that a device with such a bulky outer cloth could even pass the diseased native leaflets. Ex. 1007 [Walther].

207. Moreover, such positioning of a cloth-covered valve would defy the conventional understanding of a POSITA in 2012 (the priority date asserted by Petitioner, *see* Pet., 21-23). As I noted earlier, a POSITA in 2012 would know to position a valve with an outer seal such that the outer seal was positioned at the

annulus, below the native valve leaflets. A POSITA at the time would have understood that the gaps between the bases of the leaflets could be difficult to seal against. Further, a POSITA would have understood that it is desirable to keep the part of the frame that is above the annulus **uncovered** for stability. As Petitioner's expert, Dr. Buller, testified in a separate matter, conventional thinking was that by pressing the bars of the frame into the leaflets "you could lock the device ... into the craggy, calcified, diseased native valve leaflets" and "help prevent migration" of the valve. Ex. 2035 [IPR2017-00060 Buller Tr.] 90:16-91:7; *see also id.*, 91:18-92:4 ("Q. ... do you recall testifying in the UK trial that the intermittent bars of the stent and the craggy, calcified valve can act to lock it together so that then it is fixed and is not likely to move .... A. It sounds proper and true").

208. I see no explanation in the Petition or Dr. Buller's declaration for why a POSITA would go against the conventional understanding and position the proposed modified Cribier such that part of the added outer seal would be above the annulus. Pet., 34-36; Ex. 1003 [Buller-Decl.] ¶¶137-139.

209. Indeed, a POSITA could have complied with the conventional approach by positioning the proposed valve such that the uncovered top one-third of the valve is above the annulus, *as Cribier teaches*, and the covered bottom two-thirds of the valve below the annulus (and below the native leaflets).

210. It is notable that a POSITA could have complied with the conventional approach by simply positioning the valve such that one-third of the valve was above the annulus, *as Cribier teaches*. Ex. 1012 [Cribier] 353. Cribier teaches that it is acceptable to position the valve such that one-third of the valve is above the annulus. *Id.* Petitioner’s proposed combination calls for Walther’s outer cloth to cover the bottom two-thirds of the frame. Pet., 35-36. If Walther’s outer cloth covered the **bottom** “two-thirds of [the] frame,” as Petitioner proposes, but only the **top** one third of the valve was above the annulus, then none of Walther’s outer cloth would be positioned next to the native valve leaflets.

211. Also, I note that Petitioner argues that “Patent Owner admitted during prosecution of a related patent that if an outer seal covers two rows of the frame, the seal presses against the leaflets.” Pet., 36 (citing Ex. 1046, 25). As discussed above, however, this is a mischaracterization of Patent Owner’s statements, which simply explained that the disclosed “heightened seal [] **allows** for sealing below the native leaflets and at the native leaflets.” Ex. 1046 [’253 Preliminary Amendment] 25.

212. For Grounds 3-4 and 7-8, Petitioner relies on its Ground 1 arguments contending that in the proposed combinations of Spenser or Levi with Walther or Spenser II “Walther’s outer cloth and Spenser II’s compressible material would be positioned in overlapping radial alignment with the patient’s aortic leaflets as

described in Ground 1.” Pet., 68; *id.*, 96-97 (similar). Petitioner’s arguments fail for the reasons discussed above.

213. Petitioner’s argument is further flawed in these grounds as its Ground 1 arguments rely on the valve positioning discussed in Cribier, which is not part of the combinations in Grounds 3-4 or 7-8. Pet., 19. Petitioner does not explain how it can rely on an argument based on Cribier’s teachings, when Cribier is not part of the Grounds 3-4 or 7-8 combinations. *Id.*, 68, 96-97.

214. In sum, Petitioner does not demonstrate that any of its proposed grounds disclose or render obvious a valve with a “fibrous network” that is “positioned so that the fibrous network ... is in overlapping radial alignment with native leaflets of the patient.”

## **VII. CONCLUSION**

215. Although my complete opinions are set forth above, for convenience I summarize several points of my opinions in conclusion. For the foregoing reasons, based on my expertise and experience and the record of this case that I have reviewed, it is my opinion that Petitioner and Dr. Buller fail to prove that:

- Its combinations including Walther or Spenser II’s outer covering could be “delivered endovascularly” or “endovascularly position[ed]” or that a POSITA would be motivated to make these combinations.

- Levi does not disclose or render obvious “a plurality of radially extending fibers that extend outwardly of the outer frame” as required by the ’172 patent or “a plurality of radially extending fibers that form a circumferential surface that extends outwardly of the outer frame” as required by the ’011 patent or an “outer seal is formed of outwardly extending fibers positioned externally to the outer frame” as required by the ’846 patent.
- The proposed combinations disclose or render obvious that “the outer seal is free of an outer graft covering between the fibers and the outer frame” as required by the ’846 patent.
- Levi does disclose or render obvious that a “fibrous network extends over at least two circumferentially extending rows of grids formed in the open cell configuration” as required by the ’538 patent.
- The proposed combinations disclose or render obvious that “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” as required by the ’538 patent.

216. I understand that my opinions discussed above support a legal conclusion that the claims are not obvious.

In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

I hereby declare that all statements made herein of my own knowledge are true and all statements made herein on information and belief were and are believed by me to be true, and that all statements herein were and are 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 and that any such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

A handwritten signature in black ink that reads "Stephen Brecker". The signature is written in a cursive style and is underlined with a single horizontal stroke.

Dated: July 11, 2022

---

Stephen J.D. Brecker, M.D.

## **EXHIBIT A**

# CURRICULUM VITAE

## STEPHEN JON DAVID BRECKER

ADDRESS : St. George's Hospital, Blackshaw Road, London SW17 0QT  
Telephone : +44-(0)20-8725-3556  
email : sbrecker@sgul.ac.uk  
NATIONALITY : British  
DATE OF BIRTH : 30th April 1960

### GENERAL EDUCATION

1973-1978 University College School, London NW3  
9 GCE 'O' Levels  
3 GCE 'A' Levels & 1 GCE 'S' Level with Distinction

### UNDERGRADUATE EDUCATION

1978-1984 St. Thomas' Hospital Medical School  
University of London

### QUALIFICATIONS

1981 BSc (Hons 2,i) Pharmacology and Basic Medical Sciences  
1984 MB, BS with Distinction  
1987 MRCP (UK)  
1993 MD  
1999 FESC  
1999 FACC  
2000 FRCP

**M.D. THESIS** Systolic and Diastolic Interactions in Ventricular Disease  
University of London : 1993

**APPOINTMENTS** 1996 - Present  
**Consultant Cardiologist,**  
**St. George's Hospital, London**  
  
2015 - 2020  
**Chief of Cardiology**  
**St. George's University Hospitals NHS Foundation Trust**  
**St. George's University of London**  
  
2016 - Present  
**Professor of Cardiology**  
**St. George's, University of London**

### APPOINTMENTS

2005-2006 : Clinical Lead, South West London Cardiac Network  
 2005-2010 : Director of Cardiac Catheterisation Laboratories  
 2006-2010 : Care Group Lead - Cardiology  
 1998-2020 : Recognised Teacher of the University of London

## **HONOURS, AWARDS AND PRIZES**

|      |                                                                                                                     |
|------|---------------------------------------------------------------------------------------------------------------------|
| 1980 | Grainger Testimonial Prize in Pharmacology                                                                          |
| 1981 | Medical Research Council BSc Scholarship                                                                            |
| 1982 | Lord Riddell Surgical Prize - Proxime accessit                                                                      |
| 1983 | Second Charles Box Medical Prize (Clinical Medicine)                                                                |
| 1983 | Gladstone, Stansfield, Stewart Memorial Bursary                                                                     |
| 1984 | Distinction in Pathology (London Part IV MB,BS)                                                                     |
| 1990 | British Heart Foundation Junior Research Fellowship                                                                 |
| 1991 | E. Merck Travelling Scholarship                                                                                     |
| 1992 | 1st Runner Up, Rhône-Poulenc Rorer / Junior Cardiac Club Travelling Scholarship - Investigators Awards              |
| 2000 | South Thames Department of Postgraduate Medical & Dental Education, University of London<br>Certificate in Teaching |

## **PREVIOUS APPOINTMENTS**

|                                 |                                                                                                                                                                                                                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| April 1994 -<br>April 1996      | <b>Clinical Lecturer and Honorary Senior Registrar in Cardiology<br/>The London Chest Hospital, The Royal Hospitals NHS Trust,<br/>London.</b>                                                                       |
| April 1993 -<br>April 1994      | <b>Waring Lecturer and Honorary Senior Registrar in Cardiology<br/>The Royal Brompton National Heart and Lung Hospital &amp; The National<br/>Heart and Lung Institute, London.</b>                                  |
| October 1990 -<br>April 1993    | <b>British Heart Foundation Junior Research Fellow,<br/>&amp; Honorary Registrar in Cardiology,<br/>The Royal Brompton National Heart and Lung Hospital &amp; The<br/>National Heart and Lung Institute, London.</b> |
| May 1989 -<br>October 1990      | <b>Registrar in Cardiology,<br/>The London Chest Hospital, London.</b>                                                                                                                                               |
| November 1988 -<br>May 1989     | <b>Registrar in General Medicine and Cardiology,<br/>St. Thomas' Hospital, London.</b>                                                                                                                               |
| November 1987 -<br>October 1988 | <b>Registrar in General Medicine,<br/>Kingston Hospital, Surrey.</b>                                                                                                                                                 |
| May 1987 -<br>October 1987      | <b>Senior House Officer in Neurology,<br/>The National Hospital for Nervous Diseases, Queen Square, London.</b>                                                                                                      |
| August 1986 -<br>February 1987  | <b>Senior House Officer in Cardiology,<br/>Brompton Hospital, London.</b>                                                                                                                                            |
| February 1986 -<br>July 1986    | <b>Senior House Officer, Intensive Therapy Unit,<br/>St. Thomas's Hospital, London.</b>                                                                                                                              |
| August 1985 -<br>January 1986   | <b>Senior House Officer,<br/>Department of Renal Medicine and Immunology,<br/>Hammersmith Hospital and Royal Postgraduate Medical School,<br/>London.</b>                                                            |
| February 1985 -<br>July 1985    | <b>House Physician to The Medical Unit,<br/>St. Thomas's Hospital, London.</b>                                                                                                                                       |
| August 1984 -<br>January 1985   | <b>House Surgeon,<br/>Kingston Hospital, Surrey.</b>                                                                                                                                                                 |

## **COURSES ORGANISED**

**Annual Transoesophageal Echocardiography Course**  
1995 – 1996    **The London Chest Hospital, London**  
1997 – 2016    **St. George's Hospital, London**

## **REVIEWER FOR JOURNALS**

Circulation, Journal of the American College of Cardiology, Heart, European Heart Journal, Lancet, Nature Clinical Practice Cardiovascular Medicine, American Journal of Cardiology, EuroIntervention, European Heart Journal Cardiovascular Imaging, Clinical Cardiology, International Journal of Cardiology, Catheterization and Cardiovascular Interventions, Drug & Therapeutics Bulletin, European Journal of Cardiac Pacing and Electrophysiology, Journal of Cardiovascular Risk, Intensive Care Medicine and Thorax.

## **SCIENTIFIC SESSION ABSRACT GRADER**

European Society of Cardiology, American College of Cardiology, Transcatheter Cardiovascular Therapeutics, British Cardiovascular Society.

## **FELLOWSHIP & MEMBERSHIP OF SOCIETIES**

Fellow of the Royal College of Physicians

Fellow of the European Society of Cardiology

Fellow of the American College of Cardiology

British Cardiovascular Society

British Cardiovascular Intervention Society

## **PATENT APPLICATIONS**

|          |                         |                    |
|----------|-------------------------|--------------------|
| 25.09.13 | Replacement Heart Valve | GB 2500432         |
| 25.09.13 | Replacement Heart Valve | EP 2 641 570 A1    |
| 26.09.13 | Replacement Heart Valve | US 2013/0253642 A1 |

## **AWARDED PATENTS**

|          |                        |                 |
|----------|------------------------|-----------------|
| 10.02.16 | Percutaneous Guidewire | EP 2 396 067 B1 |
| 15.05.18 | Percutaneous Guidewire | US 9 968 761 B2 |

## GRANTS

|          |                                 |        |
|----------|---------------------------------|--------|
| 01.06.16 | MEDTRONIC RESEARCH FELLOW AWARD | £96000 |
| 01.06.16 | MCS SMALL GRANTS AWARD          | £5600  |
| 01.06.17 | MCS SMALL GRANTS AWARD          | £5600  |
| 01.06.18 | MCS SMALL GRANTS AWARD          | £5750  |

## **PUBLICATIONS**

### **Books**

A Timmis, **S Brecker**. *Diagnosis in Color. Cardiology*. London. Mosby-Wolfe. 1997.

**S J Brecker**, R H Anderson. *The Adult Heart*. London. Imperial College Press. 2000.

**S J D Brecker**. *Percutaneous Device Closure of the Atrial Septum*. Abingdon. Informa Healthcare. 2006.

**S Brecker**, M Rothman. *Clinical Guide to Primary Angioplasty*. London. Informa Healthcare. 2010

### **Videotape and accompanying book**

**S J Brecker**, R H Anderson. *Echo-morphologic correlates: The adult heart*. London. Imperial College Press. 2000.

## Book Chapters

**S J D Brecker**, P J Oldershaw. Echocardiography. In : A Martin, A J Camm (eds). *Geriatric Cardiology. Principles and Practice*. Chichester. John Wiley & Sons Ltd. 1994, 91-129.

**S J D Brecker**. Transoesophageal echocardiography. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 17-27.

**S J D Brecker**. Atrial septal defect. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 103-110.

**S J D Brecker**. Ventricular septal defect. In : A Redington, D Shore, P Oldershaw (eds). *Congenital Heart Disease in Adults: A Practical Guide*. London. W. B. Saunders Company Ltd. 1994, 111-117.

**S J D Brecker**. Atrial septal defect. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 52-53.

**S J D Brecker**. Eisenmenger complex. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 124-126.

**S J D Brecker**. Heart block. In : R Pounder, M Hamilton (eds). *Handbook of Current Diagnosis & Treatment*. London. Current Medicine Inc., Churchill Livingstone. 1995, 176-178.

**S J D Brecker**, M T Rothman. Implant complications and management. In : U Sigwart (ed). *Endoluminal Stenting*. London. W. B. Saunders Company Ltd. 1996, 296-305.

**S J D Brecker**, M T Rothman. 1997. The Cordis coronary stent. In : P W Serruys (ed). *Handbook of Coronary Stents*. London. Martin Dunitz Ltd. 1997, 63-69.

R Sharma, **S J Brecker**. Echocardiography. In : H Purcell, A Kalra (eds). *Cardiology*. Edinburgh. Elsevier Mosby Ltd. 2005, 51-57.

M Hickman, **S Brecker**. Tips and tricks of atrial septal defect closure. In : M Sabate (ed). *Percutaneous Cardiac Interventions. Tips and Tricks of New Techniques Beyond Stenting*. Toulouse. PCR Publishing. 2010, 157-164.

J-C Laborde, **S J D Brecker**. Implantation of the CoreValve aortic valve. In : J D Carroll, J G Webb (eds). *Manual of Adult Structural Heart Disease Interventions*. Philadelphia. Lippincott Williams & Wilkins. 2012, 267-285.

W H Gaasch, **S J D Brecker**, G S Aldea. Transcatheter aortic valve replacement. *UpToDate*. Wolters Kluwer Health 2012-4. [www.uptodate.com](http://www.uptodate.com).

P S Douglas, G S Bloomfield. **S J D Brecker (Ed)**. Imaging for transcatheter aortic valve replacement. *UpToDate*. Wolters Kluwer Health 2014-6. [www.uptodate.com](http://www.uptodate.com).

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**S J D Brecker**, W H Gaasch, G S Aldea. Transcatheter aortic valve replacement: Indications. *UpToDate*. Wolters Kluwer Health 2016. [www.uptodate.com](http://www.uptodate.com).

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S Messé, **S J D Brecker**. Treatment of patent foramen ovale (PFO) for secondary stroke prevention. *UpToDate*. Wolters Kluwer Health 2019-2022. [www.uptodate.com](http://www.uptodate.com).

## Peer Review Editorials and Reviews

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Diagnosis, effects and treatment of subendocardial failure.

*Primary Cardiology* 1994; **20**:19-25.

J N Shephard, **S J Brecker**, T W Evans.

Bedside assessment of myocardial performance in the critically ill.

*Intensive Care Medicine* 1994; **20**:513-521.

**S J D Brecker**.

Myocardial infarction in patients with normal coronary arteries.

*Annals of Medicine* 1994; **26**:383-384.

**S J D Brecker**.

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*British Journal of Hospital Medicine* 1996; **55**:415-418.

**S J D Brecker**, D G Gibson.

What is the role of pacing in dilated cardiomyopathy ?

*European Heart Journal* 1996; **17**:819-824.

**S J D Brecker**, D G Gibson.

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*Heart* 1996; **76**:386-387.

T Treasure, **S J D Brecker**.

The role of echocardiography in the diagnosis of aortic dissection.

*The Journal of Heart Valve Disease* 1996; **5**:623-629.

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Initial experience of the Medtronic 34mm Evolut R Valve: The UK & Ireland Implanters' Registry..

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Presented at TCT Connect October 2020. *Journal of the American College of Cardiology*. 2020; **76**(17)(Suppl B):B53.

## **EXHIBIT B**

**Professor Stephen Brecker : Patent Expert Witness**

2009 AGA v Occlutech UK – Trial

2012 Edwards v CoreValve UK – Advice & Statement only

2014 AGA v Occlutech UK - Trial

2018 Boston v Edwards USA – IPR **and** Trial

2018 Abbott v Edwards UK – Advice & Statement only

2020 Edwards v Meril UK - Trial

2020 Medtronic v Teleflex USA – IPR

2021 Medtronic v Teleflex USA – IPR