UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG,

*Petitioners*,

v.

BOSTON SCIENTIFIC SCIMED, INC.,

*Patent Owner*.

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Case IPR2017-00060
Patent 8,992,608

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Before the Honorable NEIL T. POWELL, JAMES A. TARTAL, and ROBERT L. KINDER, *Administrative Patent Judges.*

**PATENT OWNER'S NOTICE OF APPEAL**

***By Electronic Filing***
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

***By Hand Delivery***
Office of the General Counsel
U.S. Patent & Trademark Office
Madison Building East, 10B20
600 Dulany Street
Alexandria, Virginia 22314-5793

***By Electronic Filing***
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

To the Director of the United States Patent and Trademark Office:

Pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. § 90.2(a), Patent Owner Boston Scientific Scimed, Inc. ("Appellant") hereby provides this Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("PTAB") in IPR2017-00060, concerning the *inter partes* review of U.S. Patent No. 8,992,608 ("the '608 patent"), and from all underlying orders, decisions, rulings, and opinions. The issues on appeal include, without limitation, the following: (i) the PTAB's determination of unpatentability of claims 1-4 of the '608 patent under 35 U.S.C. § 103, (ii) whether the PTAB complied with Supreme Court precedent in

*SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), and (iii) whether the PTAB's determination of unpatentability of claims 1-4 of the '608 patent is constitutional and complies with the Administrative Procedure Act and other legislative and regulatory limits on the PTAB's authority. A copy of the PTAB's Final Written Decision is attached as Exhibit 1.

The PTAB issued its Final Written Decision on March 23, 2018. This notice is therefore timely filed within sixty-three (63) days of the PTAB's decision as prescribed by 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1).

Pursuant to 37 C.F.R. § 90.2(a)(1), a copy of this Notice of Appeal is being filed with the PTAB. Pursuant to Federal Circuit Rule 15(a)(1), a copy of this Notice of Appeal is also being filed with the Clerk of the United States Court of Appeals for the Federal Circuit, along with the necessary fees.

Appellant does not believe that any fees are due to the United States Patent and Trademark Office with this Notice of Appeal. However, if any such fees are due, the Director is authorized to charge the fees to Deposit Account No. 50-2387.

Dated: May 24, 2018

Respectfully submitted,

*/Jennifer A. Sklenar/*

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*Attorney for Patent Owner Boston Scientific Scimed, Inc.*

## CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing PATENT OWNER'S NOTICE OF APPEAL was served on May 24, 2018 to the following Counsel for Petitioner via e-mail:

| | |
|---|---|
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*Attorneys for Petitioners Edwards LifeSciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG*

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# Exhibit 1

Trials@uspto.gov
571.272.7822

Paper No. 64
March 23, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

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Case IPR2017-00060
Patent 8,992,608 B2

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Before NEIL T. POWELL, JAMES A. TARTAL, and ROBERT L. KINDER, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

# FINAL WRITTEN DECISION
*Inter Partes* Review
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

# I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, claims 1–4 of U.S. Patent No. 8,992,608 B2 (Ex. 1001, "the '608 patent") were shown to be unpatentable by a preponderance of the evidence.

## A. PROCEDURAL HISTORY

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1–4 of the '608 patent. Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Pursuant to 35 U.S.C. § 314(a), we determined the Petition showed a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of claims 1–4 and instituted *inter partes* review of the '608 patent. Paper 7 ("Inst. Dec."). After institution, Patent Owner filed a Patent Owner Response. Paper 21; Paper 22 (publicly available redacted version of the Patent Owner Response) ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 33; Paper 34 (publicly available redacted version of Petitioner's Reply to Patent Owner's Response) ("Pet. Reply").

Patent Owner also filed a Motion to Exclude expert testimony (Paper 41, "PO Mot."), to which Petitioner provided a Response in opposition (Paper 45, "Pet. Resp."), further to which Patent Owner provided a reply in support (Paper 49 (publicly available redacted version of Patent Owner's Reply to Petitioner's Response); Paper 50 ("PO Reply"); and further to which Petitioner provided a Surreply (Paper 51, "Pet. Surreply").

Oral argument was held before the Board on December 19, 2017. Paper 55 ("Tr.").[1] We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Having considered the record before us, we determine Petitioner has shown by a preponderance of the evidence that claims 1–4 of the '608 patent are unpatentable. *See* 35 U.S.C. § 316(e). We also deny Patent Owner's Motion to Exclude.

### B. RELATED MATTERS

According to the parties the '608 patent is a subject of a case captioned *Boston Scientific Corp. et al. v. Edwards Lifesciences Corp.*, Case No. 1:16-cv-00275 (D. Del.). Pet. 25; Paper 4, 2. Petitioner also states that "there is at least one pending U.S. patent application, serial number 14/873,462, that claims priority to the '608 patent." *Id.* at 26.

### C. REAL PARTIES IN INTEREST

Petitioner identifies Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG as real parties in interest. Pet. 25. Patent Owner identifies Boston Scientific Scimed, Inc. and Boston Scientific Corp. as real parties in interest. Paper 4, 2.

[1] Prior to the oral argument, Patent Owner filed Objections (Paper 53) to the demonstratives filed by Petitioner and Petitioner filed Objections (Paper 52; *see also* Paper 58 (corrected objections)) to the demonstratives filed by Patent Owner. The objections of the Parties generally relate to allegations that a demonstrative slide misstates the record or is improper new evidence or argument. *See id.* Demonstrative exhibits are not evidence. In this Final Written Decision, we rely directly on the arguments presented properly in the briefs of the Parties and the evidence of record, not on demonstrative slides; therefore, the objections of the Parties are overruled.

## II. BACKGROUND

The ’608 patent, titled “Everting Heart Valve,” issued March 31, 2015, from U.S. Application No. 12/492,512, filed June 26, 2009. Ex. 1001, (21), (22), (45), (54). As background information, below we provide a summary of the ’608 patent, along with an illustrative claim from the ’608 patent, and we identify the instituted grounds of unpatentability and the proffered expert testimony. We also address our reasons for denying the Motion to Exclude.

### A. SUMMARY OF THE ’608 PATENT

The ’608 patent generally relates to “methods and apparatus for endovascularly replacing a patient’s heart valve.” Ex. 1001, Abstract. “Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates.” *Id.* at 1:29–31. Petitioner further explains that the ’608 patent “is directed to a collapsible and expandable prosthetic heart valve delivered via a catheter (‘transcatheter heart valve’ or ‘THV’).” Pet. 1.

Figures 3A and 3B of the ’608 patent are reproduced below.

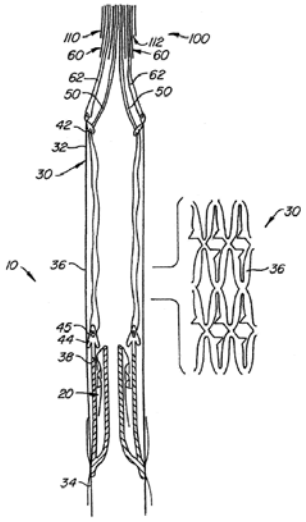


FIG. 3A

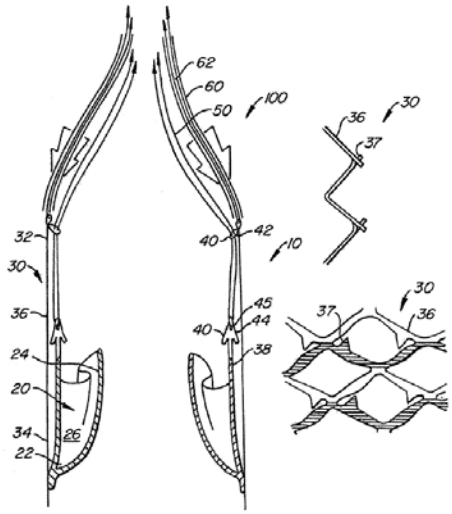


FIG. 3B

Illustrated in Figure 3A is the delivery and in Figure 3B the deployment of a replacement heart valve and anchor. Ex. 1001, 3:36–38. Apparatus 10 may be deployed from lumen 112 by retracting sheath 110, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. *Id.* at 7:30–39. "Control wires 50 then are retracted relative to apparatus 10 and tubes 60 to impose foreshortening upon anchor 30." *Id.* at 7:39–41.

The '608 patent also states that "[a]nnular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to and supported by posts 38." *Id.* at 5:60–63. "Replacement valve 20 is preferably made from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues or human cadaver tissue." *Id.* at 5:51–53.

According to the '608 patent, one of the obstacles to replacing a patient's heart valve is the risk of paravalvular leakage ("PVL") around the replacement valve, as illustrated in Figure 13, reproduced below.[2]

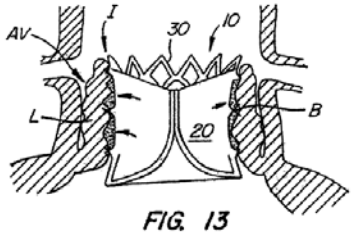

FIG. 13

[2] Paravalvular leakage is also referred to as paravalvular aortic regurgitation ("PAR"). PO Resp. 7 (further describing PVL / PAR as "the tendency for blood to leak around the outside of the prosthetic frame during diastole, the phase of the cardiac cycle when the aortic valve must prevent blood from reentering the heart through the aorta") (citing Ex. 2004, 307). Additionally, the Parties do not distinguish "perivalvular" leakage from "paravalvular" leakage, therefore, our understanding is that the two terms are used in the art interchangeably. *See, e.g.*, Ex. 1059, 12 (describing the use of a cuff to prevent "perivalvular leak around the valve").

Figure 13 illustrates paravalvular leaking around a replacement heart valve and anchor. *Id.* at 3:60–61. Diseased aortic valve AV includes native valve leaflets L with an irregular surface. *Id.* at 12:19–23. "[I]nterface I between leaflets L and anchor 30 may comprise gaps where blood B may seep through," posing "a risk of blood clot formation or insufficient blood flow." *Id.* at 12:23–27.

The '608 patent describes "optional elements for reducing regurgitation or leakage" including sacs arranged in a variety of ways, as well as seals that "expand over time to seal the interface between the anchor and valve and the patient's tissue." *Id.* at 12:28–42, 14:11–19; Figs. 14, 15A, 15B, 15C, 15D, 15E, 27, 28, 29, 30, 31. Further, the '608 patent states that "[a]nother way to seal the replacement valve against leakage" is illustrated in Figures 32, 33, and 34 as utilizing a fabric seal. *Id.* at 14:21–23.

Figures 32, 33, and 34 are reproduced below.

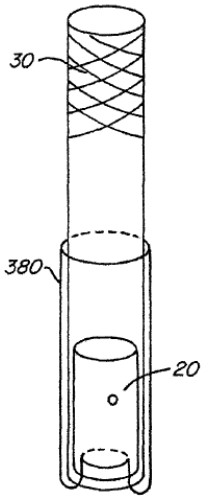


FIG. 32

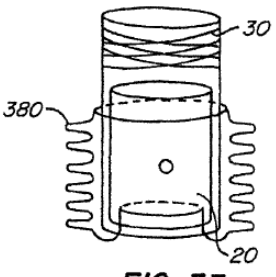


FIG. 33

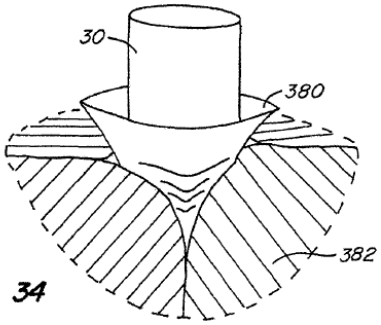


FIG. 34

An embodiment of the replacement heart valve and anchor is illustrated in Figure 32 in an undeployed configuration and in Figure 33 in a deployed

configuration. Ex. 1001, 4:38–42. Figure 34 illustrates the replacement heart valve deployed in a patient's heart valve. *Id.* at 4:43–44. The '608 patent explains:

> A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in FIGS. 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

*Id.* at 14:21–29. The '608 patent contains no additional description of fabric seal 380 or of the "flaps and pockets" it creates. As explained by Petitioner, the disclosure of the '608 patent focuses "primarily on self-expanding THV technology," not on the various sealing features briefly mentioned in the '608 patent. Pet. 27–28; *see also* Ex. 1001, 2:40–3:12 (in the '608 patent the "Summary of the Invention" does not expressly address "fabric seal," "flaps," or "pockets"); 1:63–64, 2:10–11 (addressing deficiencies in the prior art and stating that the "[s]tandard self-expanding systems have very poor accuracy in deployment" and that "[a]nother drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength").

With regard to the prosecution history of the '608 patent, Petitioner identifies June 16, 2004, as the priority date. Pet. 1; *see also* PO Resp. 6 n.2 (Patent Owner does not dispute the priority date identified by Petitioner). Petitioner explains that during prosecution the Examiner found that "[a]n implantable fabric having pleats and pockets is well known in the art" and that it "would have been obvious to one of ordinary skill in the art to modify the seal [of a reference disclosing an artificial valve] to include pleats as an obvious alternative design choice." Pet. 37 (quoting Ex. 1002, 353)

(emphasis omitted). The application claims were then amended by the applicant to require a fabric seal such that "when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue." *Id.* at 38 (quoting Ex. 1002, 358) (emphasis omitted). The Examiner allowed the amended claims without explanation. *Id.* at 39 (citing Ex. 1002, 373).

### B. ILLUSTRATIVE CLAIM

Claim 1 is the sole independent claim challenged, from which challenged claims 2–4 depend. Claim 1 is illustrative of the claimed subject matter and is reproduced below:

> 1. A system for replacing a heart valve, comprising:
> [1.1] an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;
> [1.2] a replacement valve commissure support element attached to the expandable anchor;
> [1.3] a commissure portion of a replacement valve leaflet attached to the commissure support element; and
> [1.4] a fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, [1.5] the fabric seal having an undeployed state and a deployed state, [1.6] wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets;
> [1.7] wherein a distal end of the replacement valve leaflet is attached to the fabric seal and when the expandable anchor is in the collapsed delivery configuration, [1.8] the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, [1.9] the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue.

Ex. 1001, 22:22–42 (additional numbering of claim elements corresponding to Pet. 77 (Appendix of "Element-By-Element" breakdown of claim 1)).

### C. INSTITUTED GROUNDS OF UNPATENTABILITY

We instituted *inter partes* review of claims 1–4 of the '608 patent on the following grounds of unpatentability asserted in the Petition:

| Reference(s) | Basis | Claims challenged |
|---|---|---|
| Spenser[3] and Elliot[4] | § 103 | 1–4 |
| Spenser and Thornton[5] | § 103 | 1–4 |
| Spenser and Cook[6] | § 103 | 1–4 |

Inst. Dec. 24.

### D. PROFFERED EXPERT DECLARATIONS

Petitioner supports its challenge with the Declaration of Nigel P. Buller, M.D., dated October 10, 2016 (Ex. 1007); the Supplemental Declaration of Nigel P. Buller, M.D., dated April 25, 2017 (Ex. 1035); and the Reply Declaration of Nigel P. Buller, M.D., dated September 22, 2017 (Ex. 1045). Dr. Buller is a retired Consultant Cardiologist and formerly, the "Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham and the Lead Clinician for the Cardiac Catheterization Laboratories." Ex. 1007 ¶ 6. Petitioner also supports its challenge with the Declaration of Larry Wood, dated September 21, 2017 (Ex. 1046).

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[3] WO 03/047468 A1, published June 12, 2003 (Ex. 1004, "Spenser") (citations to Spenser are to the original pagination).
[4] U.S. Patent App. Pub. No. 2003/0236567 A1, published December 25, 2003 (Ex. 1005, "Elliot").
[5] U.S. Patent No. 6,015,431, issued January 18, 2000 (Ex. 1019, "Thornton").
[6] U.S. Patent App. Pub. No. 2004/0082989 A1, published April 29, 2004 (Ex. 1006, "Cook").

Mr. Wood is currently "the Corporate Vice President, Transcatheter Heart Valves, at Edwards Lifesciences." Ex. 1046 ¶ 5.

Patent Owner's opposition relies on the Declaration of Dr. Andrew J. Manganaro, (Ex. 2079) and the Declaration of Stephen J. D. Brecker (Ex. 2080), both of which are dated June 23, 2017. Dr. Manganaro is a "board-certified cardiac, thoracic, and vascular surgeon with more than 25 years of experience." Ex. 2079 ¶ 5. Dr. Brecker is an interventional cardiologist with over twenty-five years of medical experience. Ex. 2080 ¶ 2.

In our consideration of the expert testimony, Patent Owner argues that Dr. Buller's declaration is "entitled to little or no weight because he lacks experience in the relevant technologies." PO Resp. 15–19. Patent Owner states that Dr. Buller has never performed a valve replacement procedure and has never implanted stent grafts. *Id.* at 16. In comparison, Patent Owner asserts that its experts are surgeons and that "to the extent that there is any disagreement between Dr. Buller and Patent Owner's experts, the Board should give less or no weight to Dr. Buller's opinions." *Id.* at 17.

Indeed, Dr. Buller is a cardiologist, not a surgeon. Ex. 2028, 37:17–19. Patent Owner, however, fails to provide a persuasive justification for why the fact that Dr. Buller has never performed a valve replacement procedure and has never implanted stent grafts matters, such that Dr. Buller's testimony should be given "little or no weight." Patent Owner also has not persuasively explained why we should find the opinion of surgeons more credible than Dr. Buller's opinion as a cardiologist. Further. Patent Owner has not shown that Dr. Buller lacks credibility because he is not a surgeon or that Dr. Buller's opinions are not based on relevant evidence.

We, therefore, determine that Patent Owner has not shown that Dr. Buller's opinions are entitled to little or no weight.

Next, Patent Owner argues that Dr. Buller is not a person of ordinary skill in the art because there is "no indication that Dr. Buller had a working knowledge of heart valve designs in 2004." PO Resp. 16. During oral argument, Patent Owner suggested Dr. Buller was "barely" a person of ordinary skill in the art. Tr. 31:3–10. Patent Owner has not moved to exclude Dr. Buller's testimony on the grounds that he is unqualified. Regardless, to testify as an expert under Federal Rule of Evidence 702, a person need only be "qualified in the pertinent art by knowledge, skill, experience, training, or education." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008). Thus, the issue is not whether Dr. Buller had a "working knowledge of heart valve designs in 2004," as Patent Owner argues. *See* PO Resp. 16. We have considered Dr. Buller's qualifications and are persuaded that he is so qualified at the time he offered his opinions in this matter. *See* Ex. 1007 ¶¶ 6–26.

Patent Owner also argues that Dr. Buller's declaration is entitled to little or no weight because he "repeatedly relies on unsupported, conclusory assertions, rather than credible evidence." PO Resp. 18. We have considered the opinions expressed by each of the experts in this case and accord the appropriate weight to each of their opinions based on whether the opinion is credible and whether it is supported by credible evidence.

### E. MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude the Declaration of Nigel P. Buller, M.D. (Ex. 1007) and the Reply Declaration of Nigel P. Buller, M.D. (Ex. 1045) on the basis that Dr. Buller failed to consider "evidence of

objective indicia or secondary considerations of nonobviousness." PO Mot. 1. A motion to exclude deals with the admissibility of evidence under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.62 (applying the Federal Rules of Evidence to *inter partes* reviews), 42.64; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,758 (August 14, 2012) ("Admissibility of evidence is generally governed by the Federal Rules of Evidence."). As stated in the Office Patent Trial Practice Guide, the parties may submit motions to exclude regarding evidence "believed to be inadmissible." Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,758. Further, a motion to exclude "must explain why the evidence is not admissible (e.g., relevance or hearsay)." *Id.* at 48,767.

Patent Owner reasons that:

> Dr. Buller's opinions should be excluded under Rule 702 because—absent consideration of objective indicia—they will not "help the trier of fact to understand the evidence or to determine a fact in issue," are not "based on sufficient facts," and are not "the product of reliable principles and methods . . . reliably applied . . . to the facts of the case."

PO Mot. 4 (quoting Fed. R. Evid. 702). According to Patent Owner, the "Federal Circuit has criticized obviousness experts for failing to consider the objective indicia." *Id.* at 3 (citing *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012); *InTouch Techs., Inc. v. VGO Commc'ns., Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)). Patent Owner proceeds to argue at length that Petitioner "fails to show lack of nexus," an issue outside the scope of a proper motion to exclude. PO Mot. 5–7 (emphasis omitted).

In response, Petitioner asserts that Dr. Buller was not required to anticipate and address in his initial declaration objective evidence of

nonobviousness that had not yet been raised by Patent Owner in this case. Pet. Resp. 3–4 (citations omitted). Petitioner further contends that, in his Reply Declaration, Dr. Buller addressed Patent Owner's objective evidence of nonobviousness, including allegations of copying, and reached the opinion that Patent Owner failed to establish the required nexus between the asserted evidence and the product ("Petitioner's S3 THV") relied on by Patent Owner. *Id.* at 2 (citing Ex. 1045 ¶¶ 9–27), 7. Petitioner also contends that "[o]nce Dr. Buller determined that there was no nexus between Petitioners' S3 THV and the Challenged Claims, there was no need for him to further address specific evidence of secondary considerations." *Id.* at 6; *see also id.* at 2 (noting that "other than the nexus issue, neither of [Patent Owner]'s experts addressed any of the secondary considerations"). Petitioner also notes that it provided a declaration from Mr. Wood further addressing objective evidence of nonobviousness. *Id.* at 2–3. Petitioner further argues that the issues raised by Patent Owner go to the weight accorded Dr. Buller's testimony, not to its admissibility. *Id.* at 8–9.

In reply, Patent Owner asserts that it is seeking to exclude Dr. Buller's declarations, not a ruling on the weight that should be afforded his testimony. PO Reply 5 (emphasis omitted). Patent Owner further argues that "[b]ecause Dr. Buller's analysis of nexus is incorrect, he is not relieved of the need to consider the objective evidence of nonobviousness," after which Patent Owner improperly argues at length that it has "demonstrated nexus." *Id.* at 2–5. As with its Motion, Patent Owner's substantive nexus arguments in its Reply disputing Dr. Buller's opinions are misplaced. The issue properly raised by the Motion to Exclude is the admissibility, not the correctness, of Dr. Buller's opinions. In its Surreply, Petitioner argues that

the new arguments and evidence relied on by Patent Owner in its Reply to purportedly show nexus are improper and should be disregarded. Pet. Surreply 1–2.

Rule 702 precludes expert testimony when it is not "based on sufficient facts or data" or is not "the product of reliable principles and methods." Fed. R. Evid. 702(b)–(c). Expert opinion that is not "sufficiently tied to the facts of the case" is "not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993). Rule 702(d) further limits expert testimony to situations where "the expert has reliably applied the principles and methods to the facts of the case." Rule 702 thus serves "a 'gatekeeping role,' the objective of which is to ensure that expert testimony admitted into evidence is both reliable and relevant." *Sundance*, 550 F.3d at 1360. The policy considerations for excluding expert testimony, such as those implemented by the gatekeeping framework established by the Supreme Court in *Daubert*, are less compelling in bench proceedings, such as *inter partes* reviews, than in jury trials. *See, e.g.*, *Volk v. United States*, 57 F. Supp. 2d 888, 896 n.5 (N.D. Cal. 1999).

We agree with prior panels of the Board, which have determined under similar circumstances that an expert's declaration in support of a Petition is not properly the subject of a motion to exclude on the basis that the expert did not consider objective evidence of nonobviousness that is not yet in evidence in the proceeding. *See Activision Blizzard, Inc. v. Acceleration Bay, LLC*, IPR2016-00724, slip op. at 30 n.13, 57 (PTAB Sept. 15, 2017) (Paper 53); *Activision Blizzard, Inc. v. Acceleration Bay, LLC*, IPR2015-01953, slip op. at 36 n.15, 57 (PTAB Apr. 19, 2017) (Paper

107). Patent Owner does not contend, and has not shown, that there was objective evidence of nonobviousness in this proceeding that Dr. Buller failed to address when he provided a declaration in support of the Petition. We also agree with Petitioner that Dr. Buller addressed objective evidence of nonobviousness in his Reply Declaration. Ex. 1045 ¶¶ 9–27. That Dr. Buller purportedly did not address objective evidence of nonobviousness in his reply to the satisfaction of Patent Owner does not support exclusion of Dr. Buller's declaration.

Nor does Patent Owner direct us to any authority to support the contention that an expert's declaration should be excluded for failure to address objective evidence of nonobviousness. Patent Owner's effort to exclude Dr. Buller's declarations are not persuasively supported by the cases upon which Patent Owner relies. *See Kinetic Concepts*, 688 F.3d at 1342 (does not exclude an expert's testimony based on an alleged failure to address objective evidence of nonobviousness); *InTouch Techs.*, 751 F.3d at 1327 (same). *Intri-Plex Tech.*, also relied on by Patent Owner, merely states the unremarkable proposition that "[e]vidence of secondary considerations of non-obviousness, when present, must always be considered en route to a determination of obviousness." *Intri-Plex Tech., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, IPR2014-00309, slip op. at 35–36 (PTAB Mar. 23, 2014) (Paper 83) (further explaining that "fact finders must withhold judgment on an obviousness challenge until it considers all relevant evidence, including that relating to the objective considerations") (citations omitted).

The Board, not Dr. Buller, is the "fact finder" in this proceeding, and we are obligated to consider all relevant evidence, including the declarations

of Dr. Buller, as well as objective evidence of nonobviousness provided by Patent Owner. For the foregoing reasons, Patent Owner's Motion to Exclude Dr. Buller's declarations is denied. Moreover, to the extent Patent Owner has improperly disputed the merits of Dr. Buller's opinions under the pretext of the Motion to Exclude, those arguments will not be given consideration beyond the extent to which they were properly raised in Patent Owner's Response to the Petition.

## III. ANALYSIS

In our analysis of whether Petitioner has sufficiently shown that the challenged claims of the '608 patent would have been obvious over the asserted prior art, we next address the applicable principals of law; the construction of the claim terms "flaps" and "pockets;" the scope and content of the asserted prior art of Spenser, Elliot, Thornton, and Cook; the differences between the claimed subject matter and the asserted prior art; the level of ordinary skill in the art; the objective evidence of nonobviousness; and, finally, the reasons supporting obviousness.

### A. PRINCIPLES OF LAW

To prevail in its challenge to the patentability of claims 1–4 of the '608 patent, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). In an *inter partes* review, "[a] claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and

customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

A patent claim is unpatentable as obvious under 35 U.S.C. § 103(a) if "the differences between" the claimed subject matter "and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

An obviousness determination "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

### B. CLAIM CONSTRUCTION

Claim 1 recites "the fabric seal comprises flaps." Ex. 1001, 22:34. Claim 2 depends from claim 1 and further recites "the fabric seal defines a plurality of pockets." *Id.* at 22:43–44. Petitioner contends that "flaps" should be construed to mean "circumferentially oriented folds or unattached ends." Pet. 43. Petitioner further contends that "pockets" should be construed to mean "open spaces or cavities formed by flaps of the fabric seal." *Id.* at 45.

Patent Owner argues that Petitioner's proposed constructions are not the broadest reasonable interpretation, but proposes no alternative. PO Resp. 20 (noting that the district court, with respect to the '608 patent, construed "flaps" to mean "fabric projecting from the anchor" and "pockets" to mean "cavities formed by the fabric seal") (citing Ex. 2032, 3). Patent Owner further asserts that "Petitioner cannot meet its burden of proving that claims 1–4 are unpatentable even under its own proposed constructions." *Id.* Patent Owner, therefore, does not dispute that the meaning of "flaps" and "pockets" is at least as broad as Petitioner's proposed construction.

In the absence of any dispute between the parties, we determine no express construction of "flaps" or "pockets" is necessary. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

### C. SCOPE AND CONTENT OF THE PRIOR ART

Petitioner relies on Spenser, Elliot, Thornton, and Cook with respect to its contentions that claims 1–4 of the '608 patent would have been

obvious under the instituted grounds. Pet. 66–73. Patent Owner does not dispute the prior art status of any of the asserted references.

*1. Spenser (Ex. 1004)*

Spenser, titled "Implantable Prosthetic Valve," describes a prosthetic valve comprised of a support stent and valve assembly. Ex. 1004, Abstract. Figure 1 of Spenser is reproduced below.

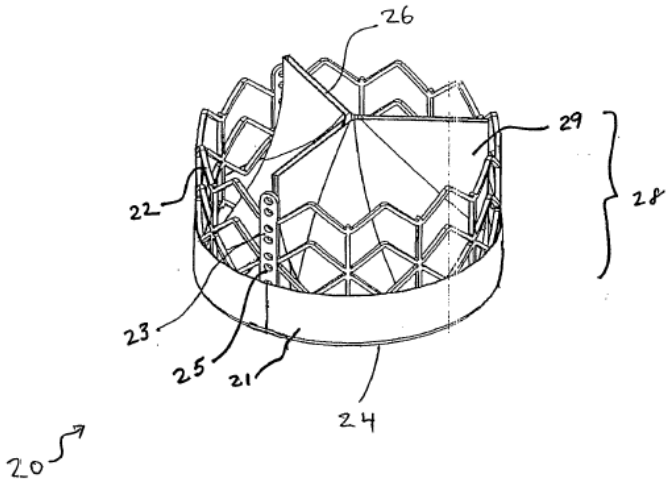



Figure 1 illustrates an implantable prosthetic tricuspid valve suitable for deployment by a stent. Ex. 1004, 14. Tricuspid implantable prosthetic valve 20 includes valve assembly 28, with inlet 24, outlet 26, and outer walls consisting of collapsible pliant material 29. *Id.* at 22. Valve assembly 28 is attached to annular support stent 22 at bores 25 on support beams 23. *Id.* "[C]uff portion 21 of the valve assembly 28 is wrapped around support stent 22 at inlet 24 to enhance the stability." *Id.* "Preferably cuff portion 21 of valve material 28 is attached to support beams 23." *Id.* Spenser describes as an "important feature" the constant length of the support beams 23 such that "there is no need for slack material as the attachment points (25) remain at constant distances regardless of the position of the valve device (crimped or deployed)." *Id.* at 23. Spenser explains that with support beams of constant

length, "there is no relative movement between the valve assembly and the support beams," resulting in "greater stability, enhanced safety, better sealing and consequently longer lifespan." *Id.* While the support beams remain a constant length, "the entire support stent may longitudinally or laterally extended." *Id.* at 22.

Figures 3 and 4 of Spenser are reproduced below.

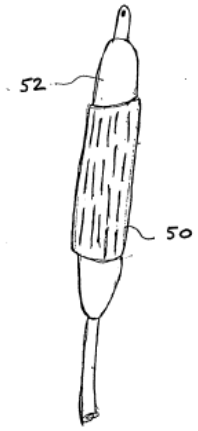



FIG. 3

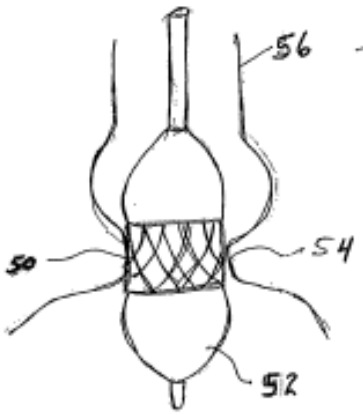
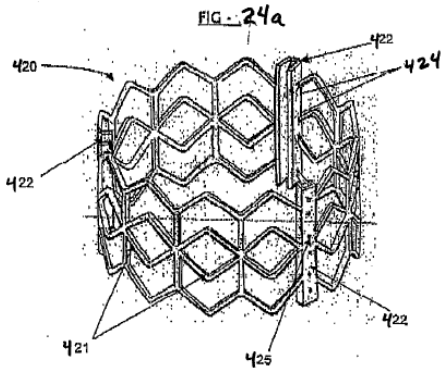



FIG. 4

Figure 3 illustrates "an implantable valve mounted to a stent 50 with an inflatable balloon 52, in a crimped position" that is "suitable for percutaneous catheterization and deployment." *Id.* at 24. Figure 4 illustrates support stent 50 expanded radially to take up its position at target location 54 in a body duct, such as aorta 56. *Id.*



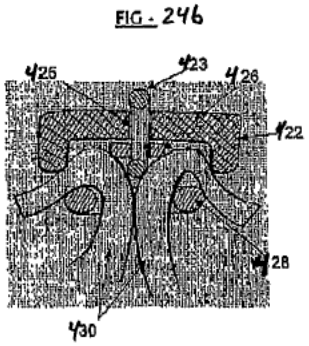




Figure 24a illustrates frame 420 of an implantable prosthetic valve suitable for crimping and expanding, including frame struts 421 and three support

beams 422 "designed to attach to a commissure of the valve structure." *Id.* at 33–34. Figure 24b illustrates means for mounting valve leafs 430 to support beam 422 using a U-shaped or forked holder 428. *Id.* at 34. "Bores 425 are designated for stitching the valve assembly by threads, wires, or other attaching means." *Id.*

*2. Elliot (Ex. 1005)*

Elliot, titled "Implantable Prosthesis with Displaceable Skirt," relates to "tubular prostheses, including, but not limited to, endovascular grafts and stent-grafts, for maintaining patency of blood vessels and treating aneurysms (e.g., aortic aneurysms), and tubular conduits for maintaining patency in other bodily passageways." Ex. 1005 ¶ 1. Elliot describes the use of "at least one skirt" that extends from a tubular body. *Id.* ¶ 24. The skirt has a peripheral edge that is free and displaceable to a greater diameter than the diameter of the tubular body, such that it "can be displaced to contact, and form a seal with a surrounding wall." *Id.* "Irregularities and/or wall displacement . . . can be responded to by the skirt [] in minimizing endoleaks about the prosthesis." *Id.*

Figures 7 and 8 of Elliot are reproduced below.

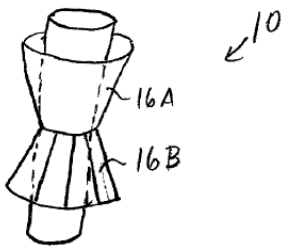



FIG. 7

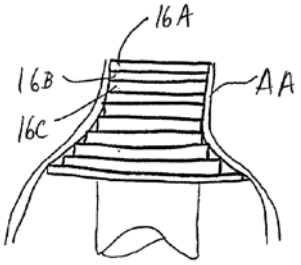



FIG. 8

Figure 7 illustrates prosthesis 10, including skirts 16a and 16b, and Figure 8 illustrates a plurality of skirts 16A, 16B, 16C. *Id.* ¶ 40.

*3. Thornton (Ex. 1019)*

Thornton, titled "Endolumenal Stent-Graft with Leak-Resistant Seal," relates to an implantable medical device, including a tubular member and one or more sealing members secured to an outer surface of the tubular member, which is expandable to engage an endolumenal wall. Ex. 1019, Abstract.

Figure 1 of Thornton is reproduced below:

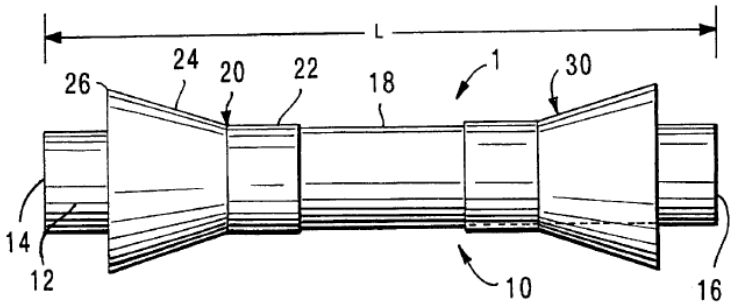



FIG.1

Figure 1 illustrates tubular member 10, including tubular wall 12 and seal members 20 and 30 on opposite ends. *Id.* at 7:14–20, 8:4–5. Thornton further explains:

> Seal member (20) is shown in FIG. l as an occlusive cuff, which has a first cuff end (22) secured to outer surface (18) of tubular wall (12), and which also has a second cuff end (24) at least a portion which is unsecured to form a flange (26). In this configuration, flange (26) forms a one-way valve that circumferentially surrounds tubular member (10) and occludes flow around tubular wall (12) in the direction from the first cuff end (22) to the second cuff end (24) when tubular member (10) is deployed with in a radially confining endolumenal space.

Ex. 1019, 7:20–29. The seal members may be made of Dacron fibers. *Id.* at 8:37–38. Thompson further explains that "there may also be a multiplicity of such seal members on a single end," and that they may be used in series "providing a redundancy of safety." *Id.* at 8:65–9:3.

*4. Cook (Ex. 1006)*

Cook, titled "Stent Graft with Improved Proximal End," relates to a stent graft prosthesis comprising a main body portion and a cuff that "comprises an external sealing zone that extends around the outer main body portion to help prevent leakage of fluids." Ex. 1006, Abstract.

Figures 2 and 6 of Cook are reproduced below.

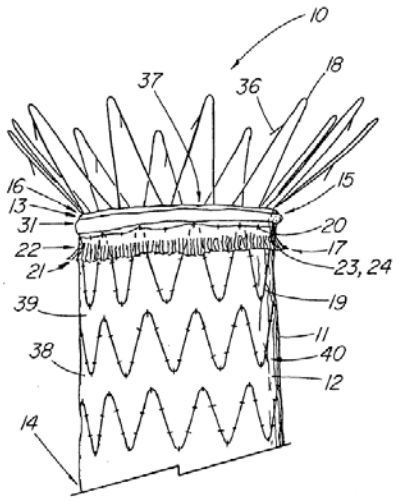


FIG. 2

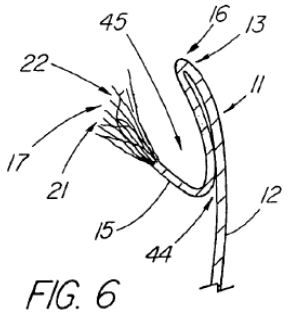


FIG. 6

Figure 2 illustrates graft prosthesis 10, including cuff portion 15 with frayed portion 22. Ex. 1006 ¶¶ 26, 30. As shown in Figure 6, according to Cook, sealing zone 21, including frayed portion 22, may be

> configured such that the free edge 17 of the cuff portion 15 is directed proximally (toward the first or folded edge 16), to produce a fold 44 that creates gutter-like pocket 45 that is able to collect any blood passing around the leading edge 16 of the graft 11 to prevent an endoleak and promote thrombus formation.

Ex. 1006 ¶ 36.

D. DIFFERENCES BETWEEN CLAIMED SUBJECT MATTER AND PRIOR ART

Petitioner has established, and Patent Owner does not dispute, that Spenser teaches every limitation of claims 1 and 4 other than "a fabric seal" that "in the deployed state . . . comprises flaps that extend into spaces

formed by native valve leaflets." [7] *See* Pet. 66–70; PO Resp. 3, 39–42. Further, our understanding is that "pockets," as recited by claims 2 and 3, cannot be formed without "flaps." *See* Ex. 1001, 14:21–29; *see also* Ex. 1007 ¶ 128 (defining "pockets" as "open spaces or cavities formed by flaps of the fabric seal"). Patent Owner disputes whether the asserted references teach "flaps," but does not separately argue that they fail to teach "pockets." Below, we address how Spenser teaches each of the limitations not in dispute, which applies to each of the asserted combinations of prior art, as well as how the additional prior art references, in combination with

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[7] During oral argument, after Petitioner completed its reply, Patent Owner requested additional time to "clarify" a response to an earlier question regarding what claimed elements Patent Owner contends were not disclosed by the asserted references. Counsel for Patent Owner stated:

> So I was asked what Patent Owner contends is missing from the three secondary references and we would -- I left out an element. I want to just be consistent with our briefing, the element that the seal be adapted to prevent blood from flowing between the fabric seal and heart tissue. The last element of claim 1 we also contend that is missing in the references.

Tr. 69:22–70:7. We have reviewed the Patent Owner Response and, contrary to Patent Owner's statement during oral argument, Patent Owner did not separately argue in its brief that the asserted references failed to disclose "the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue," as recited by claim 1. *See, e.g.*, PO Resp. 3, 38–47. Because the Patent Owner did not raise the argument in its Patent Owner Response, the argument was waived. *See* Paper 8, 6 (cautioning Patent Owner that "any arguments for patentability not raised in the response will be deemed waived"). Nonetheless, for the reasons provided, we determine Petitioner, bearing the burden, has shown by a preponderance of the evidence that Spenser, as well as the combinations of Spenser with Elliot, Thornton, or Cook, teach a fabric seal "adapted to prevent blood from flowing between the fabric seal and heart tissue," as claimed. *See, e.g.*, Ex. 1007 ¶¶ 178–180.

Spenser, teach the disputed limitations.[8] We determine that Petitioner has demonstrated by a preponderance of the evidence that the combinations of Spenser and Elliot, Spenser and Thornton, and Spenser and Cook each teach every limitation of claims 1–4 of the '608 patent.

*1. Spenser in Combination with Elliot*

Petitioner contends that claims 1–4 would have been obvious over Spenser and Elliot. Pet. 66–72.

*a. Claim 1*

Spenser teaches a tricuspid implantable prosthetic valve 20, corresponding to "a system for replacing a heart valve" recited in the preamble of claim 1 of the '608 patent. Ex. 1004, 14, 22, Fig. 1. Spenser teaches annular support stent 22 (similarly shown as stent 50 in Figures 3 and 4 and as frame 420 in Figures 24a and 24b) corresponding to the recited "expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end." *Id.* at 14, 22–24, 34; *see also* Ex. 1007 ¶ 115 n. 11 (explaining that the "distal end" is the end "farthest along the catheter from the surgeon (i.e., the inflow end of the valve")).

[8] Petitioner also asserted in the Petition under an anticipation ground that Spenser disclosed the recited "flaps" and "pockets" because "excess fabric would surround the prosthesis," forming longitudinal pleats if deployed short of its "maximum diameter," and because Spenser used a crimping device that would have caused pleats. Pet. 74–75. We denied institution of that anticipation ground because Petitioner did not sufficiently show that the recited flaps were necessarily present in the prosthetic described by Spenser. Inst. Dec. 9–10. Petitioner did not contend in the Petition that any of the challenged claims would have been obvious over Spenser, alone.

Corresponding to the claimed "commissure support element attached to the expandable anchor" Spenser teaches "[s]upport beams 23 are provided on annular support stent 22." Ex. 1004, 22. With regard to the recited "commissure portion of a replacement valve leaflet attached to the commissure support element," Spenser teaches that support beam 23 "provide anchorage to valve assembly 28." *Id.*; *see also* Figs 24a, 24b (illustrating pericardial leaflets attached to support elements of the frame).

Claim 1 also recites a "fabric seal." Spenser teaches this features as cuff portion 21 of valve assembly 28. *Id.* at 22. Cuff portion 21 may be made of fabric. *Id.* (valve assembly 28 comprises "outlet walls consisting of collapsible pliant material 29"); *see also id.* at 25, 33 (explaining a method of manufacturing the valve assembly using "fabric material" such as "PET").[9]

Cuff portion 21 is "adapted to prevent blood from flowing between the fabric seal and heart tissue," as recited by claim 1. The sealing ability of cuff portion 21 is taught by Spenser in regard to Figure 2, which illustrates an implantable valve 30 configured like implantable valve 20 of Figure 1. Spenser states with respect to Figure 2 that "[a] portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve, which enhances the sealing of the device at the valve inlet." Ex. 1004, 24. Dr. Buller further explains that when the valve assembly is anchored in place by expansion it is embedded in the surrounding tissue, causing the fabric seal (cuff portion 21) to conform to the

[9] Dr. Buller explains that PET fabric refers to polyethylene terephthalate, known commercially as Dacron. Ex. 1007 ¶¶ 157, 178; *see also* Ex. 1005 ¶ 21 (describing "a textile material (e.g., polyethylene terephthalate (PET)").

surrounding tissue, thereby demonstrating that cuff portion 21 is adapted to prevent blood from flowing between the fabric seal and heart tissue. Ex. 1007 ¶¶ 178–180.[10]

Cuff portion 21 has an "undeployed state" and a "deployed state," as recited by claim 1. Ex. 1004, 23 (stating that "the entire valve structure is adapted to be radially crimped and radially expanded"). Further, because Spenser teaches that "cuff portion 21 of the valve assembly 28 is wrapped around support stent 22 at inlet 24," and is adapted to be crimped and expanded, cuff portion 21 is "at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration" and "the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor," when "the expandable anchor is in the collapsed delivery configuration," as recited by claim 1. *Id.* at 22, Figs. 1–4.

Further, claim 1 recites that a "distal end of the replacement valve leaflet is attached to the fabric seal." Spenser teaches this feature,

[10] Although not raised in the Patent Owner Response, and therefore, waived as an argument, we nonetheless considered the testimony of Dr. Brecker that cuff portion 21 was adapted to prevent "through-the frame" leakage. Ex. 2080 ¶¶ 35–39, 55. We find Dr. Brecker's opinion not persuasive and credit the testimony of Dr. Buller, who explained in regard to leakage around a replacement valve that "blood flow occurs everywhere . . . [i]t would be trying to get anywhere there is potential to leak." Ex. 2028, 80:2–6. The notion that cuff portion 21 is adapted to prevent "through-the-frame" leakage, but not leakage between the fabric seal and heart tissue is insufficiently supported and unexplained by Patent Owner. Regardless, we also are persuaded, as explained below, that the combination of Spenser and Elliot teaches a fabric cuff "adapted to prevent blood from flowing between the fabric seal and heart tissue," as claimed.

explaining with regard to Figure 46b that the pericardium leaflet is pre-cut and assembled to a PET tube. *Id.* at 45–46.

Finally, claim 1 recites that "in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets." Spenser does not state whether cuff portion 21 necessarily creates "flaps" when deployed. Thus, Petitioner explains, and we agree, that Elliot discloses a fabric seal comprised of skirts 16A, 16B, 16C corresponding to the claimed "flaps." Pet. 71; Ex. 1005 ¶¶ 21–40 (stating, e.g., that "[o]ne or more of the skirts 16 may be provided to form seals along various points about the prosthesis 10").

Indeed, Figure 34 of the '608 patent illustrating fabric seal 380 and Figure 5b of Elliot illustrating skirt 16, reproduced side-by-side below, appear substantially identical with regard to teaching the recited "flaps."

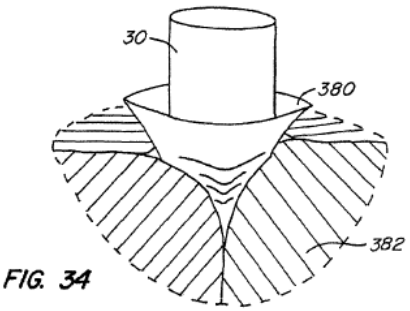

FIG. 34

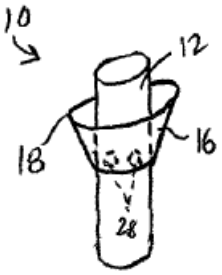

FIG. 5b

Figure 34 of the '608 patent illustrates that when anchor 30 is deployed "fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382." Ex. 1001, 14:21–27. Figure 5b of Elliot similarly illustrates prosthesis 10 with skirt 16 extending from tubular body 12. Although Elliot does not expressly address "spaces formed by native valve leaflets," Elliot teaches that the flaps extend into the surrounding tissue when the prosthetic is deployed:

> The skirt 16 terminates in a peripheral edge 18 that is spaced from a juncture between the skirt 16 and the tubular body 12. As described more fully below, the peripheral edge 18 is free and displaceable to a greater diameter than the diameter of the tubular body 12, particularly at its natural resting diameter. In this manner, portion(s) of the peripheral edge 18 can be displaced to contact, and form a seal with a surrounding wall. Irregularities and/or wall displacement (occurring such as from aneurysm neck expansion) can be responded to by the skirt 16 in minimizing endoleaks about the prosthesis 10.

Ex. 1005 ¶ 24. Dr. Buller explains that Elliot discusses an exemplary stent graft device and that Elliot's teachings are directed more broadly to "tubular prosthesis" for "tubular conduits" in "bodily passageways" and, therefore, apply to a range of devices, including transcatheter heart valves. Ex. 1007 ¶ 65 n.2; *see also* Ex. 1005, Abstract ("[a]n implantable prosthesis is provided having a radially-expandable tubular body and at least one skirt extending therefrom."). In further support of his opinion that Elliot teaches "flaps," Dr. Buller relies on Elliot's disclosure that:

> [T]o limit Type I endoleaks [i.e., leaks between the vascular prosthesis and the vessel wall], an implantable prosthesis is provided having a radially-expandable tubular body and at least one skirt extending therefrom. The skirt terminates in a peripheral edge, wherein at least portions of the peripheral edge are free and displaceable to a greater diameter than the tubular body. . . . The skirt may actively inhibit Type I endoleaks by forming a physical barrier against flow between the tubular body and the aortic wall. In addition, the skirt may passively inhibit endoleak formation by sufficiently restricting blood flow to allow coagulation and clot formation, which would act as a barrier against endoleakage. Endothelial cell ingrowth into the skirt may also occur providing a cellular barrier against endoleakage.

Ex. 1007 ¶¶ 155–156 (quoting Ex. 1005 ¶ 9). Thus, Petitioner has shown that Elliot teaches a fabric seal with flaps and that the combination with

Spenser's fabric seal teaches a fabric seal "adapted to prevent blood from flowing between the fabric seal and heart tissue," as recited by claim 1.

Patent Owner argues that because Elliot "does not disclose a valve," Elliot "does not describe flaps that extend into the gaps formed by native valve leaflets," as recited by claim 1. PO Resp. 39. Patent Owner's argument is misplaced. Petitioner has shown that Spenser (not Elliot) discloses a replacement valve with a fabric seal and further relies on Elliot as showing a fabric seal with flaps which may be combined with the replacement valve of Spenser. Moreover, we agree with Petitioner that the teachings of Elliot are directed to an implantable prosthesis, which is broad enough to be applicable to a replacement heart valve, even if the example addressed by Elliot is a stent graft. Ex. 1007 ¶ 65 n.2. Thus, Patent Owner's argument that Elliot lacks an express disclosure of flaps "that extend into the gaps formed by native valve leaflets" does not refute Petitioner's demonstration based on the combination of Spenser and Elliot that all of the claimed elements are taught by the asserted prior art. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (nonobviousness cannot be established by attacking the references individually when obviousness is predicated upon a combination of prior art disclosures).

Patent Owner also argues that the conical seals shown in Elliott "show only a conical projection," not "flaps," and that "these conical seals would be compressed tightly between the anchor and the hard, calcified aortic annulus; crushed against the tubular stent." PO Resp. 39–43; *see also* Ex. 2079 ¶ 50 (Dr. Manganaro opining that "the skirt would be crushed against the support stent"); Ex. 2080 ¶ 62 (Dr. Brecker opining that "the conical seals would be crushed against the tubular stent"). First, contrary to

Patent Owner's argument, both the '608 patent and Elliot disclose virtually identical conical projections as fabric seals. *See* Ex. 1001, 14:22, Fig. 34; Ex. 1005 ¶¶ 21–22, Fig. 5b. Patent Owner fails to distinguish in any material way a difference between the structures of the conical seals of the '608 patent from the conical seals of Elliot to suggest that the first would form flaps when deployed, but the second would not.

Second, Patent Owner's argument is premised on the false notion that claim 1 is directed to an aortic replacement valve that may only be placed where there is a "hard, calcified aortic annulus." Claim 1 contains no such limitation, and the '608 patent makes clear that it is broadly directed to valve replacement "when there is a narrowing of the native heart valve, commonly referred to as stenosis, *or when the native valve leaks or regurgitates*." Ex. 1001, 1:29–31 (emphasis added); *see also* Ex. 1043, 90:6–9 (Dr. Brecker stating that in his opinion the system of claim 1 was not limited to aortic valves). Thus, no element of claim 1 limits the replacement valve to require placement where there is a "hard, calcified aortic annulus."

Third, even if there was such a requirement, Dr. Buller explains that Elliot describes a fabric seal that may be used at a location where the tissue is calcified, such as the "calcified topography of the lumen." Ex. 1045 ¶¶ 44–45 (quoting Ex. 1005 ¶ 4) (emphasis omitted).

Fourth, Patent Owner's conclusory argument that the conical seal of Elliot would be so "tightly compressed" as to not extend into spaces formed by native valve leaflets is not persuasive because it does not plausibly explain how a conical seal such as that taught by Elliot could be compressed without so much as forming a wrinkle. *See* PO Resp. 44. As Dr. Brecker explained *on behalf of Patent Owner*: (1) the '608 patent does not require

"that the flaps must project away from the anchor by a certain, required distance," (2) "a fabric seal that is not completely smooth must have portions that project away from the anchor," (3) "the vast majority of patients would have gaps [i.e., spaces formed by native valve leaflets] within the range of about 0.1 millimeters to about 5 millimeters," and (4) "gaps vary from patient to patient and there could be a patient in which the gaps were very small and only a 'wrinkle' in the fabric would suffice to extend into the gap." Ex. 1067 ¶¶ 21–24. Dr. Brecker's explanation strongly supports that applying the conical seal of Elliot to the replacement valve of Spenser would produce flaps that extend into gaps (or spaces) formed by native valve leaflets.

We further consider the declarations of Dr. Manganaro and Dr. Brecker on which Patent Owner relies in support of its contention that the combination of Spenser and Elliot fails to teach that "in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets," as claimed. PO Resp. 40 (citing Ex. 2079 ¶¶ 45–46; Ex. 2080 ¶¶ 61–62). Dr. Manganaro states that "[t]here is no suggestion in Elliot that any of its skirts would form 'flaps that extend into spaces formed by native valve leaflets' if deployed in a diseased and calcified native aortic valve." Ex. 2079 ¶ 45; *see also id.* ¶¶ 46–49 (attempting to distinguish the "landing zone" of the prosthesis of Elliot as applying only to a stent graft "landing zone" which is different from the "profile of a stenosed native aortic valve"). As noted above, claim 1 is not limited to "diseased and calcified native aortic valve" replacement, rendering Dr. Manganaro's opinion unpersuasive on the issue of whether Elliot teaches flaps. Similarly, Dr. Manganaro contends that "Elliot's skirts, when placed on Spenser's

valve and in the environment of a stenosed native aortic valve, would not comprise flaps that extend into spaces formed by native valve leaflets." Ex. 2079 ¶ 50. Again, Dr. Manganaro's opinion is not persuasive because claim 1 is not limited to the placement of a prosthesis "in the environment of a stenosed native aortic valve."

Dr. Manganaro also contends that, unlike the '608 patent, Elliott fails to disclose that the "fabric seal comprises bunched up flaps and pockets around its entire circumference, guaranteeing that a flap will be oriented in front of, and extending into when deployed, any space formed by native valve leaflets." *Id.* Claim 1 does not recite "bunched up flaps and pockets around its entire circumference," as Dr. Manganaro suggests. Further, contrary to Dr. Manganaro's testimony, Patent Owner argues that Petitioner's construction of "flaps" as requiring "circumferentially oriented folds or unattached ends" should be *rejected* as not the broadest reasonable, and instead directs us to the district court construction of flaps as "fabric projecting from the anchor." PO Resp. 20. We have considered Dr. Manganaro's declaration and determine it does not credibly refute Petitioner's evidence that the combination of Spenser and Elliot teach every limitation of claim 1. *See, e.g.*, Ex. 2079 ¶¶ 38–50.

Turning to Dr. Brecker's testimony, he asserts that Elliot describes a stent graft and that Elliot does not mention heart valves or any other valve. Ex. 2080 ¶ 56. Elliot, however, is not so narrow as Dr. Brecker implies, and more broadly states that the invention "relates to tubular prostheses, including, but not limited to endovascular grafts and stent-grafts, . . . and tubular conduits for maintaining patency in other bodily passageways." Ex. 1005 ¶ 1. Dr. Brecker further suggests that Elliot does not depict "flaps"

because Figures 3 and 5–8 of Elliot show "only a single, conical projection." Ex. 2080 ¶ 62. We disagree with Dr. Brecker's characterization of Elliot because, rather than a single projection, Figure 8 illustrates "a plurality of skirts serially arranged." Ex. 1005 ¶ 19. Moreover, Figure 7 of Elliot is also described as showing a first skirt and a second skirt that "provides a redundant seal to prevent endoleakage which may bypass" the first skirt. *Id.* ¶ 40.

Dr. Brecker further states that a person of ordinary skill would expect that the seals taught by Elliot would be "compressed tightly between a TAVR anchor and the hard, calcified aortic annulus." Ex. 2080 ¶ 62. As noted above, claim 1 of the '608 patent is not limited to a valve placed in a "hard, calcified aortic annulus." As further explained above with regard to Dr. Manganaro's virtually identical testimony, Dr. Brecker also identifies no support for the conclusory proposition that the conical seal of Elliot could be tightly compressed in some manner so as to avoid creating so much as a wrinkle that would correspond to the claimed flaps. We have considered Dr. Brecker's declaration and determine it does not credibly refute Petitioner's evidence that the combination of Spenser and Elliot teach every limitation of claim 1. *See, e.g.*, *id.* ¶¶ 49–62.

*b. Claims 2 and 3*

Claim 2, which depends from claim 1, further recites: "wherein, in the deployed state, the fabric seal defines a plurality of pockets." Ex. 1001, 22:43–44. Claim 3, which depends from claim 2, further recites: "wherein the pockets are adapted to fill with blood in response to backflow blood pressure." *Id.* at 22:45–46. Petitioner has shown that in the deployed state, the skirts taught by Elliot correspond to a fabric seal that defines both flaps

and a plurality of pockets adapted to fill with blood in response to backflow blood pressure. *See* Pet. 57–58, 71; *see also* Ex. 1005 ¶ 10 (stating that the "circumferential portion [of the skirt] may be trough-shaped such that force applied thereto by blood flow may be re-directed to define a radial force directed away from the prosthesis"), ¶ 37 ("expansion of the skirt 16 occurs under pressure of endoleakage"); Figs. 5b, 5c, 8; Ex. 1007 ¶ 156. Patent Owner disputes whether Elliot, in combination with Spenser, teaches "flaps," as discussed above with regard to claim 1, but Patent Owner does not separately argue that the combination fails to disclose "pockets." For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that the combination of Spenser and Elliot teach every limitation of claims 2 and 3.

*c. Claim 4*

Claim 4, which depends from claim 1, further recites: "wherein the expandable anchor is formed from stainless steel or nickel-titanium alloy." Ex. 1001, 22:47–48. Petitioner has shown, and Patent Owner does not dispute, that Spenser teaches an expandable anchor that may be formed from stainless steel or nickel-titanium alloy. Pet. 71 (citing Ex 1004, 21 (stating that "[t]he frame can be made from shape memory alloys such as nickel titanium . . ., or other biocompatible metals"). We note that Elliot also teaches that the radially expandable support member may be made of stainless steel or Nitinol (i.e. nickel-titanium). Ex. 1005 ¶ 22; *see also* Ex. 1001, 5:47 (stating "nickel-titanium ('Nitinol')"). For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that the combination of Spenser and Elliot teach every limitation of claim 4.

*2. Spenser in Combination with Thornton*

Petitioner contends that claims 1–4 would have been obvious over Spenser and Thornton. Pet. 66–72. Petitioner has shown, for the reasons provided above, that Spenser teaches every limitation of claims 1–4 other than the recited "flaps" and "pockets." Petitioner contends the teachings of Thornton and Elliot are substantially similar, and, indeed, a comparison of Figure 7 of Elliot to Figure 1 of Thornton shows that sealing members 23 and 30 of Thornton strongly resemble skirts 16A and 16B of Elliot. *See* Ex. 1007 ¶ 159; *see also* Ex. 2080 ¶ 63 ("Thornton's disclosure is similar to Elliot's."). In light of the similarity in the teachings, Petitioner's arguments regarding the combination of Spenser with Thornton are substantially the same as its arguments in support of the combination of Spenser with Elliot. Pet. 57–62. In particular, we agree with Petitioner that the sealing members of Thornton correspond to the claimed "flaps" and "pockets." *Id.* at 61 (quoting Ex. 1019, 4:6–13; citing *id.* at 4:6–13, 6:60–65, 7:20–42, 8:31–54, 8:65–67, Fig. 1). Dr. Buller further explains that Thornton:

> discloses a "tubular member-seal member combination . . . [that] has utility in the prevention of leakage flow around the outer surfaces of implantable endolumenal medical devices." Ex. 1019 at 7:5–9.[] "The seal member is secured to the outer surface and is adapted to occlude leakage flow externally around the tubular wall between the outer surface and the endolumenal wall when the tubular member is deployed within the endolumenal body space. In one mode of this variation, the seal member is an occlusive cuff that forms a flange as a one-way valve over the conduit tubing member's outer surface." *Id.* at 4:6–13. Thus, the seal member will conform to the irregular surface of the surrounding tissue. The device can include one or more sealing members and these sealing members can be formed with Dacron fabric, among other materials. *Id.* at 7:20–30, 8:31–54, 8:65–67.

Ex. 1007 ¶ 63. Dr. Buller also states that the prosthesis taught by Thornton was commercialized and "successfully implanted in patients with a low rate of reported endoleaks." *Id.* ¶ 64 (citing Ex. 1025, 1163; Ex. 1026). Thus, Petitioner has shown that Thornton teaches a fabric seal with flaps and that the combination with Spenser's fabric seal teaches a fabric seal "adapted to prevent blood from flowing between the fabric seal and heart tissue," as recited by claim 1, as well as "pockets" as recited by claims 2 and 3.

Further reflecting the similarity between Thornton and Elliot, Patent Owner argues that the asserted combination of Spenser and Thornton "fails for the same reason as Spenser in view of Elliot." PO Resp. 42. Likewise, we find Patent Owner's arguments not persuasive for the same reasons explained above in regard to the combination of Spenser and Elliot.

For example, Patent Owner argues that because Thornton "does not disclose a valve," Thornton "does not describe flaps that extend into the gaps formed by native valve leaflets." *Id.* at 42. Patent Owner's argument is misplaced. Petitioner has shown that Spenser (not Thornton) discloses a replacement valve with a fabric seal and further relies on Thornton as showing a fabric seal with flaps which may be combined with the replacement valve of Spenser. Moreover, we agree with Petitioner that the teachings of Thornton are directed to a "tubular member-seal member combination" for "the outer surfaces of implantable endolumenal medical devices," which is broad enough to be applicable to a replacement heart valve, even if the example addressed by Thornton is a stent graft. Ex. 1007 ¶ 63 n.1. Thus, Patent Owner's argument that Thornton lacks an express disclosure of flaps "that extend into the gaps formed by native valve leaflets" does not refute Petitioner's demonstration based on the combination

of Spenser and Thornton that all of the claimed elements are taught by the asserted prior art. *See In re Merck*, 800 F.2d at 1097.

Patent Owner also argues that the conical seals shown in Thornton "show only a conical projection," not "flaps," and that if used in a valve, Thornton's conical seal "would be tightly compressed between the anchor and the hard, calcified aortic annulus." PO Resp. at 43–44 (citing Ex. 2079 ¶¶ 53–56; Ex. 2080 ¶ 67). First, contrary to Patent Owner's argument, both the '608 patent and Thornton disclose virtually identical conical fabric seals. *See* Ex. 1001, 14:22, Fig. 34; Ex. 1019, 8:37–38, Fig. 1. Patent Owner fails to distinguish in any material way the structures of the conical seals of the '608 patent from the conical seals of Thornton to suggest that the first would form flaps when deployed, but the second would not.

Second, Patent Owner's argument is premised on the false notion that claim 1 is directed to an aortic replacement valve that may only be placed where there is a "hard, calcified aortic annulus." Claim 1 contains no such limitation, and the '608 patent makes clear that it is broadly directed to valve replacement "when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates." Ex. 1001, 1:29–31 (emphasis added); *see also* Ex. 1043, 90:6–9 (Dr. Brecker stating that in his opinion claim 1 was not limited to aortic valves). Thus, no element of claim 1 limits the replacement valve to require placement where there is a "hard, calcified aortic annulus."

Third, even if there was such a requirement, Dr. Buller explains that Thornton describes a fabric seal that may be used at a location where the tissue is calcified. Ex. 1045 ¶¶ 43, 45 (quoting Ex. 1019, 30:27–36).

Fourth, Patent Owner's conclusory argument that the conical seal of Thornton would be so "tightly compressed" as to not extend into spaces formed by native valve leaflets is not persuasive because it does not plausibly explain how a conical seal such as that taught by Thornton could be compressed without so much as forming a wrinkle. As stated above, Dr. Brecker explained *on behalf of Patent Owner*: (1) the '608 patent does not require "that the flaps must project away from the anchor by a certain, required distance," (2) "a fabric seal that is not completely smooth must have portions that project away from the anchor," (3) "the vast majority of patients would have gaps [i.e., spaces formed by native valve leaflets] within the range of about 0.1 millimeters to about 5 millimeters," and (4) "gaps vary from patient to patient and there could be a patient in which the gaps were very small and only a 'wrinkle' in the fabric would suffice to extend into the gap." Ex. 1067 ¶¶ 21–24. Dr. Brecker's explanation strongly supports that applying the conical seal of Thornton to the replacement valve of Spenser would produce flaps that extend into gaps (or spaces) formed by native valve leaflets.

We further consider the declarations of Dr. Manganaro and Dr. Brecker on which Patent Owner relies in support of its contention that the combination of Spenser and Thornton fails to teach that "in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets," as claimed. PO Resp. 44 (citing Ex. 2079 ¶¶ 53–56; Ex. 2080 ¶ 67). Dr. Manganaro states that "the conical seals shown in Figures 1 and 3 [of Thornton] comprise one attached end and one loose, unattached end, forming a single, conical projection—not the 'flaps' claimed in the '608." Ex. 2079 ¶ 51. Dr. Manganaro neglects to address Thornton's

statement that "there may also be a multiplicity of such seal members on a single end," and that they may be used in series "providing a redundancy of safety." Ex. 1019, 8:65–9:3. Dr. Manganaro further states that "[t]here is no suggestion in Thornton that any of its seals would form 'flaps that extend into spaces formed by native valve leaflets' if deployed in a diseased and calcified native aortic valve." Ex. 2079 ¶ 51; *see also id.* ¶¶ 52–55 (attempting to distinguish the "landing zone" of the prosthesis of Thornton as applying only to a stent graft "landing zone" which is purportedly different from the "profile of a stenosed native aortic valve"). As noted above, claim 1 is not limited to "diseased and calcified native aortic valve" replacement, rendering Dr. Manganaro's opinion unpersuasive on the issue of whether Thornton teaches flaps. Similarly, Dr. Manganaro contends that "Thornton's seals, when placed on Spenser's valve and in the environment of a stenosed native aortic valve, would not comprise flaps that extend into spaces formed by native valve leaflets." Ex. 2079 ¶ 56. Again, Dr. Manganaro's opinion is not persuasive because claim 1 is not limited to the placement of a prosthesis "in the environment of a stenosed native aortic valve."

Likewise, Dr. Manganaro contends that "[i]n contrast to Thornton's conical seals that do not bunch up, the [']608 patent's fabric seal comprises bunched up flaps and pockets around its entire circumference, guaranteeing that a flap will be oriented in front of, and extending into when deployed, any space formed by native valve leaflets" and that the "free-floating unattached ends" of Thornton's seals "would not have the structural integrity to extend into the narrow but deep chasms created by the displaced native valve leaflets." Ex. 2079 ¶ 56. Dr. Manganaro cites no underlying support

for his conclusory opinions. Moreover, claim 1 does not recite "bunched up flaps and pockets around its entire circumference," as Dr. Manganaro suggests. Further, contrary to Dr. Manganaro's testimony, Patent Owner argues that Petitioner's construction of "flaps" as requiring "circumferentially oriented folds or unattached ends" should be *rejected* as not the broadest reasonable, and instead directs us to the district court construction of flaps as "fabric projecting from the anchor." PO Resp. 20. Nor does Dr. Manganaro explain how the "deep chasms" he attributes to the displacement of native valve leaflets is consistent with Dr. Brecker's statement that "the vast majority of patients would have gaps within the range of about 0.1 millimeters to about 5 millimeters," and that "there could be a patient in which the gaps were very small and only a 'wrinkle' in the fabric would suffice to extend into the gap." Ex. 2079 ¶ 56; Ex. 1067 ¶¶ 21–24. We have considered Dr. Manganaro's declaration and determine it does not credibly refute Petitioner's evidence that the combination of Spenser and Thornton teach every limitation of claims 1–4. *See, e.g.*, Ex. 2079 ¶¶ 51–56.

Turning to Dr. Brecker's testimony, he asserts that Thornton describes a device that "preferably is adapted for delivery to an intravascular region of an aneurysm," and does not mention heart valves or any other valve. Ex. 2080 ¶ 63. Thornton, however, is not as narrow as Dr. Brecker implies, and more broadly states that the device is "an implantable medical device for providing an artificial conduit for physiological flow through an endolumenal body space that is defined by an endolumenal wall." Ex. 1019, 1:6–10. Dr. Brecker further suggests that Thornton does not depict "flaps" because Figures 1 and 3 of Thornton show "only a single, conical projection." Ex. 2080 ¶ 67. Dr. Brecker neglects to address Thornton's

statement that "there may also be a multiplicity of such seal members on a single end," and that they may be used in series "providing a redundancy of safety." Ex. 1019, 8:65–9:3.

Dr. Brecker further states that a person of ordinary skill would expect that the seals taught by Thornton would be "compressed tightly between a TAVR anchor and the hard, calcified aortic annulus." Ex. 2080 ¶ 67. As noted above, claim 1 of the '608 patent is not limited to a valve placed in a "hard, calcified aortic annulus." Dr. Brecker identifies no support for the conclusory proposition that the conical seal of Thornton could be tightly compressed in some manner so as to avoid creating so much as a wrinkle that corresponds to the claimed flaps. We have considered Dr. Brecker's declaration and determine it does not credibly refute Petitioner's evidence that the combination of Spenser and Thornton teaches every limitation of claims 1–4. *See, e.g.*, *id.* ¶¶ 63–67.

*3. Spenser in Combination with Cook*

Petitioner contends that claims 1–4 would have been obvious over Spenser and Cook. Pet. 72–73. Petitioner has shown, for the reasons provided above, that Spenser teaches every limitation of claims 1–4 other than the recited "flaps" and "pockets." Cook teaches a stent graft having a fabric cuff portion, formed of Dacron, providing "an external sealing zone that extends around the outer main body portion to help prevent leakage of fluids." Ex. 1006, Abstract; *see also id.* ¶ 26, Figs. 1, 6. As shown in Cook Figure 6, the cuff portion may be folded over "to produce a fold 44 that creates gutter-like pocket 45 that is able to collect any blood passing around the leading edge 16 of the graft 11 to prevent an endoleak and promote thrombus formation." *Id.* ¶ 36; *see also* Ex. 1007 ¶¶ 167–168. According to

Dr. Buller, although Cook describes an exemplary stent graft device, Cook's teachings are "not limited to stent grafts and instead applies to a range of devices, including THVs." Ex. 1007 ¶ 66 n.3 (citing Ex. 1006 ¶ 6 ("an illustrative intraluminal prosthesis, such as a stent graft"). Thus, Petitioner has shown that Cook teaches a fabric seal with flaps and that the combination with Spenser's fabric seal teaches a fabric seal "adapted to prevent blood from flowing between the fabric seal and heart tissue," as recited by claim 1, as well as "pockets" as recited by claims 2 and 3.

Further reflecting the similarity between Cook and both Elliot and Thornton, Patent Owner argues that the asserted combination of Spenser and Thornton fails for substantially the same reasons as Spenser in view of Elliot or Thornton. PO Resp. 44–47. Likewise, we find Patent Owner's arguments not persuasive for the same reasons explained above in regard to the combinations of Spenser with either Elliot or Thornton.

Patent Owner argues that because Cook does not disclose a valve, it does not describe flaps that extend into the gaps formed by native valve leaflets. PO Resp. 45–46 (arguing that Cook shows a cylindrical or conical cuff rolled over one end of a stent, not "flaps," and that Cook fails to suggest that, in the deployed state, the cuff "would form flaps that extend into the gaps formed by native valve leaflets"); Ex. 2079 ¶¶ 37, 57–62; Ex. 2080 ¶¶ 68–70. Patent Owner's argument is misplaced. Petitioner has shown that Spenser discloses a replacement valve with a fabric seal and further relies on Cook as showing a fabric seal with flaps, which may be combined with the replacement valve of Spenser. Moreover, we agree with Petitioner that the teachings of Cook are directed to an "intraluminal prosthesis" which is broad enough to include a replacement heart valve, even if the example addressed

by Cook is a stent graft. *See* Ex. 1006 ¶ 6; Ex. 1007 ¶ 66 n.3. Thus, Patent Owner's argument that Cook lacks an express disclosure of flaps "that extend into the gaps formed by native valve leaflets" does not refute Petitioner's demonstration based on the combination of Spenser and Cook that all of the claimed elements are taught by the asserted prior art. *See In re Merck*, 800 F.2d at 1097.

Patent Owner further asserts that if used in a valve, Cook's cuff "would be tightly compressed between the anchor and the hard, calcified aortic annulus." PO Resp. 46 (citing Ex. 2079 ¶¶ 59–62; Ex. 2080 ¶ 70). According to Patent Owner the "frayed ends" of the seal shown by Cook "would not have been understood to extend away from the stent to fill gaps formed by native valve leaflets," but instead "were meant to be pressed tightly against the smooth wall of the healthy aorta and promote the in-growth of tissue; it was this tissue ingrowth that would eventually provide a seal—not flaps extending into spaces formed by native valve leaflets." PO Resp. 46–47 (citing Ex. 1006 ¶¶ 9 ("[A] frayed region . . . facilitates sealing by encouraging thrombus formation and tissue ingrowth."), 30 ("The frayed portion 22 is particularly well adapted to make contact with the vessel and allow thrombocytes to collect and tissue to grow thereinto, thus improving the efficacy of the seal"); Ex. 2080 ¶ 70). First, Patent Owner fails to distinguish in any material way the structures of the conical seals of the '608 patent from the cuff of Cook to suggest that the first would form flaps when deployed, but the second would not.

Second, Patent Owner's argument is premised on the false notion that claim 1 is directed to an aortic replacement valve that may only be placed where there is a "hard, calcified aortic annulus." Claim 1 contains no such

limitation, and the ’608 patent makes clear that it is broadly directed to valve replacement “when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates.” Ex. 1001, 1:29–31 (emphasis added); *see also* Ex. 1043, 90:6–9 (Dr. Brecker stating that in his opinion claim 1 was not limited to aortic valves). Thus, no element of claim 1 limits the replacement valve to require placement where there is a “hard, calcified aortic annulus.”

Third, even if there was such a requirement, Dr. Buller explains that Cook describes a fabric seal that may be used at a location where the tissue is calcified. Ex. 1045 ¶¶ 43–47.

Fourth, Patent Owner’s conclusory argument that the cuff of Cook would be so “tightly compressed” as to not extend into spaces formed by native valve leaflets is not persuasive because it does not plausibly explain how a cuff such as that taught by Cook could be compressed without so much as forming a wrinkle. As stated above, Dr. Brecker explained *on behalf of Patent Owner*: (1) the ’608 patent does not require “that the flaps must project away from the anchor by a certain, required distance,” (2) “a fabric seal that is not completely smooth must have portions that project away from the anchor,” (3) “the vast majority of patients would have gaps [i.e., spaces formed by native valve leaflets] within the range of about 0.1 millimeters to about 5 millimeters,” and (4) “gaps vary from patient to patient and there could be a patient in which the gaps were very small and only a ‘wrinkle’ in the fabric would suffice to extend into the gap.” Ex. 1067 ¶¶ 21–24. Dr. Brecker’s explanation strongly supports that applying the seal of Cook to the replacement valve of Spenser would

produce flaps that extend into gaps (or spaces) formed by native valve leaflets.

We further consider the declarations of Dr. Manganaro and Dr. Brecker on which Patent Owner relies in support of its contention that the combination of Spenser and Cook fails to teach that "in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets," as claimed. PO Resp. 45 (citing Ex. 2079 ¶¶ 57–58, Ex. 2080 ¶¶ 68–70). That testimony is substantially similar to their testimony provided in regards to the asserted combinations of Spenser with Elliot or Thornton. *See* Ex. 2079 ¶¶ 57–62 (stating, for example, that Cook's cuff "is neither described nor depicted as extending into gaps or voids in its landing zone in the abdominal aorta," and that "[l]ike Elliot's skirts and Thornton's seals, Cook's cuffs are consistent with the typical stent graft seal design described above" and that the "profile of a stenosed native aortic valve is disparate to that of a stent graft's landing zone"); Ex. 2080 ¶¶ 68–70 (stating, for example, that "Cook does not mention heart valves," "Cook doesn't describe flaps that extend into the gaps formed by native valve leaflets," "the cuff would be pressed tightly between the frame and the tissue). We have considered the declarations of Dr. Manganaro and Dr. Buller and determine they do not credibly refute Petitioner's evidence that the combination of Spenser and Cook teaches every limitation of claims 1–4.

### E. LEVEL OF ORDINARY SKILL

The Supreme Court explained in *KSR* that

> Section 103(a) forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

> obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

550 U.S. at 405. Petitioner contends that a "person of ordinary skill in the art as of the priority date of the '608 patent would have been an interventional cardiologist with a working knowledge of heart valve designs and expandable stents, including stent-grafts." Pet. 45.

Dr. Buller supports Petitioner's definition, and further states that a person of ordinary skill "would, where necessary, work as a team in combination with a medical device engineer to experiment with or manufacture a device as claimed in the '608 patent." Ex. 1007 ¶ 36. Dr. Brecker states that he "agree[s] generally" with the definition provided by Dr. Buller, and further suggests that "a person of ordinary skill in the art could also include a cardiac surgeon with experience implanting aortic valve prostheses in the heart." Ex. 2080 ¶ 46. Dr. Buller also states, however, that only "a handful" aortic valve replacement procedures had been done by 2004, leaving a person of ordinary skill in the art with "little real world data." *Id.* ¶ 30. Dr. Manganaro states that a person of ordinary skill "would have been an interventional cardiologist with experience in transcatheter procedures or a cardiac and/or vascular surgeon with extensive knowledge of and experience with aortic valve replacement," as there is no evidence that any person had "extensive knowledge of and experience with aortic valve replacement" in 2004. Ex. 2079 ¶ 31.

Patent Owner does not contest Petitioner's assertion that a person of ordinary skill in the art would have been "an interventional cardiologist with a working knowledge of heart valve designs and expandable stents, including stent-grafts." Instead, Patent Owner asserts that "a cardiac or vascular surgeon with experience implanting surgical valves in 2004 was

also a [person of ordinary skill in the art]." PO Resp. 17 n.3. As noted above, however, only a "handful" aortic valve replacement procedures had been done by 2004.

Based on the evidence provided, including the prior art of record, we determine a person of ordinary skill in the art as of the priority date of the '608 patent would have been an interventional cardiologist or cardiac surgeon with a working knowledge of heart valve designs and expandable stents, including stent-grafts. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (noting that the prior art of record may reflect the level of ordinary skill in the art).

### F. *OBJECTIVE EVIDENCE OF NONOBVIOUSNESS*

Evidence of objective indicia of nonobviousness, when present, must always be considered en route to a determination of obviousness. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075–76 (Fed. Cir. 2012). Patent Owner argues that "the objective indicia—including failure of others, long-felt need, copying, industry praise, unexpected results, and commercial success—all point strongly to the nonobviousness of the [']608 patent." PO Resp. 49. The testimony Patent Owner offers in support of its objective evidence of nonobviousness is limited to Dr. Brecker's opinion that Petitioner's Sapien 3 product embodies the elements of claims 1–3 of the '608 patent. Ex. 2080 ¶ 81. Petitioner disagrees with Patent Owner's arguments and maintains that any objective evidence of nonobviousness fails to overcome the strong demonstration of obviousness. Pet. Reply 17–27. For the reasons that follow we determine that Patent Owner has not shown the requisite nexus,

and that even if it had, the objective evidence it identifies provides little support for the nonobviousness of claims 1–4 of the ’608 patent.

*1. Nexus*

“All types of objective evidence of nonobviousness must be shown to have nexus.” *Gnosis S.p.A. v. S. Ala. Med. Sci. Found.*, IPR2013-00116, slip op. at 38 (PTAB June 20, 2014) (Paper 68). To show nexus Patent Owner must show “a legally and factually sufficient connection between the [objective evidence] and the patented invention.” *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Patent Owner concedes it currently has no product in the market that practices the claimed invention of the ’608 patent because “manufacturing caused problems and it’s currently in recall status.” Tr. 50:17–51:5; *see also* Ex. 1068 (“Class 1 Device Recall Lotus Valve System”). Instead, Patent Owner argues that Petitioner’s product (the “Sapien 3” or “S3”) practices each of the limitations of claim 1 of the ’608 patent. PO Resp. 50–57. Patent Owner relies on a claim chart provided by Dr. Brecker which purports to show how each element of claim 1 is present in the Sapien 3. Ex. 2080, App’x B.

We focus our discussion on one element of claim 1 of the ’608 patent that Petitioner contends Patent Owner failed to show to be present in the Sapien 3: “a replacement valve commissure support element attached to the expandable anchor.” Pet. Reply 21–22. Dr. Brecker provides an image of the Sapien 3 with arrows pointed to three portions of an expandable anchor which he labels “replacement valve commissure support element attached to the expandable anchor.” Ex. 2080, App’x B (p. 101); *see also* Ex. 2034, 6 (same figure). Dr. Brecker also states “identifying Sapien 3’s ‘commissure

attachments'" and cites to Exhibit 2077, but he does not identify which of the forty-eight pages of Exhibit 2077 he is relying on and does not explain what relevance it has to the claim language at issue, which does not recite "commissure attachments." *Id.* Patent Owner more precisely cites to page eleven of Exhibit 2077 in its response, but provides no further explanation. PO Resp. 51–52. The cursory arguments and citations provided by Patent Owner fail to adequately explain how the Sapien 3 practices each element of claim 1, most notably that a "support element" is attached to the "expandable anchor."

We further find persuasive Petitioner's argument that claim 1 of the '608 patent recites two distinct elements, "a replacement valve commissure support element" and an "expandable anchor," and that the first must be attached to the second. Pet. Reply 21. We agree with Petitioner that Patent Owner has not sufficiently shown how both of these elements are present in the Sapien 3 because Patent Owner merely circles a portion of the expandable anchor of the Sapien 3 as the "replacement valve commissure support element." Patent Owner offers no persuasive explanation for why the recited "support element" need not be a separate element from the recited "expandable anchor" or why the picture of the Sapien 3 shows a support element separate from the expandable anchor. Accordingly, we determine Patent Owner has not shown that the Sapien 3 practices claim 1 of the '608 patent. We, therefore, determine that Patent Owner has not provided sufficient evidence to rely on the Sapien 3 in support of objective evidence of nonobviousness of the '608 patent.

Notwithstanding our determination that the requisite nexus has not been shown, for completeness we further consider, below, the merit that

Patent Owner's objective evidence of nonobviousness would have had if nexus had been shown.

*2. Failure of Others*

Patent Owner contends that "Petitioner struggled unsuccessfully for years—before and after the priority date of the [']608 patent—to find a solution to PVL." PO Resp. 58–63 (quoting, e.g., *Mintz v. Dietz & Watson, Inc*., 679 F.3d 1372, 1379–80 (Fed. Cir. 2012) (quoting *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prod., Inc.*, 21 F.3d 1068, 1072 (Fed. Cir. 1994) ("the litigation argument that an innovation is really quite ordinary carries diminished weight when offered by those who had tried and failed to solve the same problem, and then promptly adopted the solution that they are now denigrating"). According to Patent Owner, Petitioner recognized that the need to avoid or reduce paravalvular leak was a major problem in 2003 and filed patent applications "proposing a variety of other solutions to PVL." *Id.* at 58 (citing Ex. 2039, 1; Ex. 2040, 36–38). Patent Owner alleges that Petitioner also acknowledged its first generation valve "lacked any solution to PVL" and pursued a project to prevent paravalvular leakage that was later abandoned due to associated risks with the solution being investigated. *Id.* at 59–60 (citing Ex. 2041, 6–7; Ex. 2042, 11–12; Ex. 2043, 23, 28; Ex. 2044, 12, 25. According to Patent Owner, Petitioner "did not include *any* PVL solution into either" the Sapien first sold in 2007 or the Sapien XT first sold in 2010. *Id.* at 60 (citing Ex. 2045, 4; Ex. 2046, 10).

Patent Owner also argues that practitioners proposed numerous solutions, "but not a fabric seal disposed around the exterior of the stent," and instead allegedly focused on the design of the stent, "valve positioning,

stent sizing, additional valves, and other strategies unrelated to a fabric seal." PO Resp. 60 (citing Ex. 1008, 702; Ex. 2004, 403–405; Ex. 2048, 1861; Ex. 2049, 1134; Ex. 2050, 1035–36). Patent Owner makes no showing that any of the alternative means for sealing that it contends were proposed actually failed to address PVL and neglects that the '608 patent, itself, discussed a number of different sealing features, but provided no indication any one worked better than the other. *See* Ex. 1001, 12:28–50 (describing "optional elements for reducing regurgitations or leakage" utilizing "Sacs filled with an appropriate material"), 14:21–29.

Moreover, although Patent Owner states that the purported "failure of others" was well documented, the information Patent Owner provides supports the opposite conclusion. Patent Owner states that "moderate to severe PVL was observed in 20.9% of patients receiving Petitioner's first generation Sapien device, which lacked a fabric seal." PO Resp. 61. Patent Owner, however, offers no explanation for why that device, which could also be described as not experiencing moderate to severe PVL in 79.1% of patients receiving the device, was a "failure." Patent Owner contends the second generation Sapien XT resulted in an increase in moderate to severe PVL to 29.2%. *Id.* Again, Patent Owner offers no explanation for why that device, which could also be described as not experiencing moderate to severe PVL in 70.8% of patients receiving the device, was a "failure." While efforts to reduce PVL through various means was clearly a priority for both Petitioner and practitioners generally based on the evidence identified by Patent Owner, there is no persuasive support for the broader argument that because PVL was not eliminated, prior efforts had failed.

Patent Owner also reasons, based largely on attorney argument alone, that because Petitioner's Sapien 3 used a fabric seal and virtually eliminated moderate to severe leakage around the valve, had such a seal been obvious, it would have been used in the prior generations of the device. *Id.* at 61–62. Patent Owner gives no consideration to what other factors influenced the effectiveness of the Sapien 3 in preventing paravalvular leakage, or whether improvements were made, for example, to other elements such as the anchor to enable the use of a fabric seal given the space limitations for deploying a transcatheter heart valve.

We further find persuasive Mr. Wood's explanation that early generations of the Sapien and Sapien XT were successful:

> prior to the U.S. approval of the Edwards SAPIEN device, U.S. patients who were considered by their physician to be inoperable for open-heart surgery aortic valve replacement had no options, and many of those patients would unfortunately go on to die. As a senior FDA administrator explained on the occasion of the approval of SAPIEN XT, prior to the introduction of transcatheter heart valve technology, up to fifty percent of patients suffering from aortic valve stenosis would not survive two years after the onset of symptoms without open-heart surgery, a procedure too risky for many of these patients to tolerate. (Ex. 1048 (Shuren, *Life-Saving, Smart Regulation on Behalf of Patients with Aortic Stenosis*, FDA Voice dated June 16, 2014).) After the approval of the SAPIEN valve, many of these patients could be saved, and go on to live for many additional years. Indeed, the success of the original SAPIEN device has widely been credited with helping to create the entire TAVR industry and with revolutionizing the treatment of patients with aortic stenosis. (*See, e.g.*, P.O. Ex. 2072 at 6-8.) Thus, the SAPIEN valve was an enormous success, not a failure as Patent Owner suggests (*cf.* P.O. Response at 61). The follow-up to the SAPIEN, the SAPIEN XT, continued to build on that success. (*See* P.O. Ex. 2021.) Many lives were saved because of these devices. *See, e.g.*, P.O. Ex. 2072 at 6-8; Ex. 1048.)

Ex. 1046 ¶ 20. Mr. Wood also demonstrates that Petitioner had developed transcatheter heart valves with fabric seals on the outside for sealing purposes prior to the priority date of the '608 patent. *Id.* ¶ 21–23. As noted above, it is apparent from the evidence that a reduction in PVL was an important consideration in the improvement of prosthetic valves, but that desire for marginal improvement does not demonstrate a failure of others. Accordingly, in consideration of all of the arguments and information, we find Patent Owner's evidence of the failure of others provides very little credible support in showing the nonobviousness of the challenged claims of the '608 patent.

*3. Long-Felt Need*

According to Patent Owner, "[t]he long felt need for a solution to PVL demonstrates that the invention of the '608 patent was not obvious." PO Resp. 64–64 (quoting, e.g., *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332 (Fed. Cir. 2016) ("Evidence of a long felt *but unresolved* need tends to show non-obviousness because it is reasonable to infer the need would not have persisted had the solution been obvious.") (emphasis added). In particular, Patent Owner asserts that after an article dated February 18, 2004, stated that "[l]arger maximal stent diameters and other improvements in stent design might decrease the incidence and severity of paravalvular aortic regurgitation in the future" (Ex. 1008, 5):

> numerous commentators highlighted the need for a solution to post-TAVR PVL. (*See*, *e.g.*, Ex. 2053 at I-245 (2007: "Future refinements of the sutureless devices should focus on further minimizing the risk for paravalvular leakage"); Ex. 2054 at 3 (2008: "The major concerns as regards to safety" include "long-term consequences of paravalvular leaks"); Ex. 2048 at 1862 (2009: "Paravalvular leak is expected to remain the major issue to be addressed in the next generation of TAVs, if TAV

> indications are expanded to younger and healthier patients."); Ex. 2049 at 1134 (2013: "The association of PVL after TAVR with mortality has made it the new 'in vogue' Achilles' heel of TAVR"); Ex. 2004 at 397, 405 (2013: "[PVL] is seen as a barrier to more widespread use of this promising technique. . . . As the use of TAVR expands to lower risk groups, the need to address PVL through . . . the development of THV technology is essential"); Ex. 2080 ¶ 33.) These publications demonstrate that the TAVR community recognized the need for a solution to PVL from 2004 until 2014, when Petitioner launched SAPIEN 3 with a fabric seal.

PO Resp. 63–64.

Thus, on one hand Patent Owner contends the '608 patent, with a priority date of June 16, 2004, "solved" the problem of paravalvular leakage. PO Resp. 6 n.2 (Patent Owner does not dispute the priority date identified by Petitioner), 22 ("the problem solved by the ['608 patent—PVL"). On the other hand, Patent Owner identifies a February 18, 2004, article as the starting point for the recognition by "the TAVR community" of the need for a solution to PVL. *Id.* at 64. If that were correct, then the span of time from recognition of the problem to resolution of the problem, by Patent Owner's admission, was less than four months (from February 18, 2004, until June 16, 2004). That the Sapien 3 was not launched until 2014, a date dependent upon government approval, is irrelevant to whether there was a long felt but unresolved need, particularly when Patent Owner contends it "solved" the problem in 2004. Similarly, Patent Owner contends its Lotus valve system practiced the claims of the '608 patent prior to 2014, yet provides no explanation for why the long-felt need was not resolved until the Sapien 3 was launched in 2014. *See id.* at 64–65. Nor does Patent Owner explain how it's contentions of long-felt need are consistent with Dr. Brecker's statement that the "idea that paravalvular leakage was going to be a major

drawback of some valve designs was not really appreciated until . . . the late 2000's," which would be after the '608 patent purportedly "solved" the problem. Ex. 2080 ¶ 3. In sum, Patent Owner has not presented a coherent argument based on credible evidence to establish that a long felt need was unresolved to support nonobviousness of the claimed invention.

We also credit the testimony of Mr. Wood, who explains why there was no long felt and unresolved need to address paravalvular leakage. Mr. Wood states that, prior to introduction of the Sapien 3, "close to 40% of patients who received either a SAPIEN or SAPIEN XT showed either no PVL or only trace PVL at 1 year [citing Ex. 2051 38] (SAPIEN = 38.2%, SAPIEN XT = 40.0%), and very few patients suffered severe paravalvular leakage." Ex. 1046 ¶ 29. Mr. Wood also explains multiple solutions were applied to reduce PVL, including proper sizing and placement of the prosthesis. *Id.* ¶¶ 30–33. Again, it is apparent from the evidence that a reduction in PVL was an important consideration in the improvement of prosthetic valves, but that desire for marginal improvement does not demonstrate a long-felt need, particularly when the purported "solution" of a fabric seal with flaps was practiced, as shown by the asserted prior art, before the priority date of the '608 patent. Accordingly, in consideration of all of the arguments and evidence, we find Patent Owner's evidence of long-felt need provides very little credible support for nonobviousness of the challenged claims of the '608 patent.

*4. Copying*

Patent Owner contends Petitioner performed a "competitive analysis" of the Patent Owner's Lotus valve system around November, 2008, noting the fabric seal, and that by 2010 Petitioner's next generation Sapien 3

included a fabric seal. PO Resp. 64–66. Thus, Patent Owner implies (but does not affirmatively state) that Petitioner's Sapien 3 copied the Patent Owner's Lotus valve system. *Id.* (quoting, e.g., *WBIP*, 829 F.3d at 1336 (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1000 (Fed. Cir. 1986)) ("copying the claimed invention, rather than one with public domain, is indicative of non-obviousness")). Patent Owner's argument is fundamentally flawed because Patent Owner fails to provide credible evidence that its Lotus valve system practices the '608 patent.

Dr. Manganaro, in his declaration states that "[t]he commercial embodiments of the [']608 patent are Scimed's Lotus Valve System and Lotus Edge Valve System—both TAVR devices." Ex. 2079 ¶ 30. Remarkably, Dr. Manganaro later explained that he did not prepare the first draft of paragraph thirty of his declaration, which instead was one of a number of portions of his declaration prepared by attorneys for Patent Owner that he subsequently adopted as his own opinion. Ex. 1044, 20:13–21:20, 23:6–16. More specifically, Dr. Manganaro admits he performed no analysis to compare the claims of the '608 patent to Patent Owner's Lotus valve system, and instead relied "upon the opinion of the attorney." *Id.* at 46:2–24. Patent Owner offers no explanation to suggest that Dr. Manganaro's reliance on counsel's opinion was reasonable in place of performing his own comparison of the Lotus valve system to the claims of the '608 patent. As for Dr. Brecker, he does not address the Lotus valve system. In the absence of any persuasive evidence that the elements of the challenged claims of the '608 patent are present in the Lotus valve system, Patent Owner has not shown that Petitioner copied claimed elements from the Lotus valve system for use in the Sapien 3.

Moreover, to the extent Patent Owner contends Petitioner performed a competitive analysis of the Lotus valve system around November, 2008, and noted the fabric seal, Patent Owner provides no persuasive evidence that the fabric seal of the Sapien 3 was copied from the Lotus valve system given that fabric seals were used on replacement valves prior to 2008. *See, e.g.*, Ex. 1004, Fig. 1. We also credit the testimony of Mr. Wood, who explains that Petitioner considered using a fabric skirt on the outside of a transcatheter heart valve prior to 2008. Ex. 1046 ¶¶ 34–35. Accordingly, we find Patent Owner's evidence of copying provides very little credible support for nonobviousness of the challenged claims of the '608 patent.

*5. Industry Praise*

Patent Owner states that "[t]he industry has widely praised the reduction in PVL achieved by" the Sapien 3. PO Resp. 66–69 (quoting, e.g., *Apple Inc. v. Samsung Elec. Co., Ltd.*, 839 F.3d 1034, 1053 ("if there is evidence of industry praise of the claimed invention in the record, it weighs in favor of the non-obviousness of the claimed invention"). Patent Owner provides examples of statements from practitioners collected by Petitioner after introduction of the Sapien 3 in Europe that Patent Owner describes as praising the reduction in PVL achieved by the Sapien 3, as well as statements from commentators in independent medical journals. PO Resp. 66–69; *see also* Ex. 2024, 4 ("lower rate of PVL and vascular complication in the S3 group seems to lead to the better outcome"); Ex. 2038, 2 ("[w]ith the Sapien 3 valve, PV leak can be even further prevented"); Ex. 2058, 1 (the Sapien 3 valves "have helped reduce" paravalvular regurgitation); Ex. 2059, 468, 470 ("the Sapien 3 THV appears to display significantly lower rates of PAR than the Sapien XT THV does");

Ex. 2018 ¶ 24 ("early experience utilizing the Sapien 3 valve suggests an excellent safety profile, with . . . very low rates of significant PVL"). According to Patent Owner, the Sapien 3 and the Lotus valve system both employ fabric seals and "have been favorably compared" to competing valves lacking an external fabric seal. PO Resp. 68 (citing Ex. 2060, 962; Ex. 2061; Ex. 2062, 9).

In reply, Mr. Wood acknowledges that the Sapien 3 has received significant praise, but also explains that the Sapien XT, without a fabric seal, and devices by other competitors have also received significant praise. Ex. 1046 ¶ 36 (citing Ex. 1049; Ex. 2072, 8). Mr. Wood states that the Sapien 3 received "significant praise for its reduced rate of vascular complications, an improvement over prior valves that has nothing to do with S3's outer skirt." *Id.*; *see also id.* ¶ 39 (discussing improvements of the Sapien 3). The evidence provided by Patent Owner demonstrates that the reduction in paravalvular leakage attributed to the external skirt was one, but not the only, feature of the Sapien 3 that received industry praise. Accordingly, we find Patent Owner's evidence of industry praise provides limited support for nonobviousness of the challenged claims of the '608 patent.

*6. Unexpected Results*

Patent Owner identifies no evidence of unexpected results beyond a line from a document dated May 8, 2016, that appears to propose video and audio for a promotional video concerning the Sapien 3. PO Resp. 69–70 (quoting, e.g. *WBIP*, 829 F.3d at 1335 ("Doubt or disbelief by skilled artisans regarding the likely success of a combination or solution weighs against the notion that one would combine elements in references to achieve

the claimed invention."). The document includes the statement that "what was surprising was the dramatic effect of the skirt on PV leak," which Patent Owner alleges is attributable to "developers." *Id.* (quoting Ex. 2063, 4). Patent Owner identifies no objective evidence of what constitutes a "surprising" or "dramatic" effect with respect to the statement relied upon to show unexpected results.

The same document Patent Owner relies upon also states that "[w]e knew from our early trials after SAPIEN XT that an outer cloth skirt would be effective in reducing perivalvular leak." Ex. 1046 ¶¶ 5–8, 37 (quoting Ex. 2063, 3). Although it is not clear what particular "early trials" were being referred to in Exhibit 2063, Mr. Wood further details how Petitioner utilized a skirt as a fabric seal in designs of prototype valve replacements for the purpose of preventing paravalvular leakage that predated the '608 patent. Ex. 1046 ¶¶ 21–25. Thus, Patent Owner has shown, at most, that in 2016 some persons viewed the Sapien 3's improved performance at reducing PVL to be attributable in some part to some aspect of the skirt that performed surprisingly well. As such, we find Patent Owner's evidence of unexpected results provides very little credible support for nonobviousness of the challenged claims of the '608 patent. *See* PO Resp. 69–70.

*7. Commercial Success*

Patent Owner argues the Sapien 3 "has enjoyed enormous commercial success." PO Resp. 70–72 (quoting, e.g. *WBIP*, 829 F.3d at 1337 ("Demonstrating that an invention has commercial value, that it is commercially successful, weighs in favor of its nonobviousness.") According to Patent Owner, the Sapien 3 "almost overnight" supplanted "the previously market-leading Sapien XT, which lacked a fabric skirt." *Id.*

at 70. Patent Owner's admission that the Sapien XT was the market leader without the fabric skirt strongly suggests that the commercial success of the Sapien 3 was attributable to something *other than* the fabric skirt. Further, as Mr. Wood explains, Patent Owner fails to address any of the other improvements of the Sapien 3 over the Sapien XT to support its contentions. Ex. 1046 ¶¶ 38–40. Mr. Wood also states that, for a period of time, Patent Owner's competing product featuring a fabric skirt was marketed in Europe alongside the Sapien XT, but that Patent Owner's product did not displace the competing products that lacked a fabric skirt. Moreover, the alleged "overnight" success of the Sapien 3 also was explained by Mr. Wood when he was asked what happened to Sapien XT sales after the launch of Sapien 3:

> Well, same thing that happened when we launched Sapien XT. What we do is we don't want customers to have dual inventory on their shelf. We don't want them switching back and forth between two platforms. There's a chance they could get confused. And the techniques are different from valve to valve, and the accessories are different from valve to valve.
>
> So what we do is we go in and we take back all of their old inventory and give them all new inventory of the new product. So we try to swap everybody out as fast as we can, and it's really just driven by how much capacity we have at any given point in time.
>
> So you'll see we switched almost all entirely from Sapien to Sapien XT, and then we switched almost entirely from XT to Sapien 3. And I've never done a price increase from one platform to the next. So the customer has every incentive to want the new product, not to keep the old product, because there's no advantage to them to have the old product.

Ex. 2096, 52:3–23.

Patent Owner also argues that "[t]he effectiveness of SAPIEN 3's fabric skirt in reducing PVL led directly to early approval of the device."

PO Resp. 70. Patent Owner offers no evidence supporting a direct connection between FDA approval and the addition of a fabric skirt. As Mr. Wood persuasively explains:

> It is true that S3 was approved in the U.S. earlier than expected, and it is true that in statements about the approval, both FDA and Edwards noted the addition of the outer skirt, but it is not fair to infer from those two facts that FDA approved S3 early because of the skirt alone. I am not aware that FDA has ever stated that it approved S3 early because of the addition of the outer skirt alone. Rather, it is my understanding that FDA approved S3 ahead of schedule due to the high quality of the 30 day clinical outcomes, where we were best in class. The improvements in mortality, stroke, and vascular complications seen with S3 were unrelated to PVL.

Ex. 1046 ¶ 42.

Patent Owner also argues that the market was expanded for Sapien 3 because of the reduction in paravalvular leakage from "patients at high risk" to include "patients at an intermediate risk for surgery." PO Resp. 71. Mr. Wood persuasively explains that Patent Owner's contentions are "simply not true." Ex. 1046 ¶¶ 43, 45 (citing Ex. 1055, which states that the Sapien XT was approved for "patients with intermediate surgical risk"). We have considered all of the evidence are argument Patent Owner provides and find that Patent Owner's evidence of commercial success provides limited support for nonobviousness of the challenged claims of the '608 patent. *See* PO Resp. 70–72.

### G. Reasons Supporting the Combinations of Prior Art

The Supreme Court instructs an expansive and flexible approach in determining whether a patented invention was obvious at the time it was made. *See KSR.*, 550 U.S. at 415. The existence of a reason for a person of ordinary skill in the art to modify a prior art reference is a question of fact.

*See In re Constr. Equip. Co.*, 665 F.3d 1254, 1255 (Fed. Cir. 2011). In an obviousness analysis, some kind of reason must be shown as to why a person of ordinary skill would have thought of combining or modifying the prior art to achieve the patented invention. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008). A reason to combine or modify the prior art may be found explicitly or implicitly in market forces; design incentives; the "interrelated teachings of multiple patents"; "any need or problem known in the field of endeavor at the time of invention and addressed by the patent"; and the background knowledge, creativity, and common sense of the person of ordinary skill. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009) (quoting *KSR*, 550 U.S. at 418–21).

As explained above, Spenser teaches nearly all of the features of the challenged claims, but does not expressly address whether its fabric seal includes "flaps" and "pockets," as claimed. Petitioner provides evidence that the fabric seal of Spenser would form "flaps" and "pockets" under certain circumstances. For example, Petitioner has shown that Spenser's fabric seal likely would form "flaps" and "pockets" if used to treat a patient with an annulus size short of the maximum expanded diameter of the device because excess fabric necessary to accommodate a larger annulus would surround the prosthesis and form longitudinally oriented pleats when not fully expanded. Pet. 74; *see also* Ex. 1004, 47 (explaining that the Spenser prosthesis "has the ability to change its diameter from about 4 mm to about 25 mm"); Ex. 1007 ¶¶ 60–61; Ex. 1029, 2 (stating that "Dacron grafts, most of which were larger in diameter than the native lumen, were longitudinally 'pleated' inside the vessel lumen."). Petitioner also has shown that when

Spenser's replacement valve is compressed for delivery, the crimping device used likely would form a pleated structure in the fabric seal that would remain after re-expansion, forming "flaps" and "pockets" when deployed, as supported by Patent Owner's allegations in foreign proceedings. Pet. 74–75; *see also* Ex. 1004, 32 (explaining that "an accessory crimping device that is adapted to crimp a valve device in the operating theater as part of the implantation procedure"); Ex. 1032, 46–48 (Patent Owner arguing in foreign proceeding that the external fabric seal of a prosthetic valve "has a pleated structure after re-expansion, because the outer part of the seal is compressed to a very small diameter on the balloon catheter," and that "[t]hereby, pleats are formed by applying external pressure").

Petitioner also has shown that the problem of paravalvular leakage was known before the priority date of the '608 patent and was addressed by replacement valves with varying degrees of success. *See, e.g.*, Ex. 1011, 1:37–46 (U.S. Patent No. 3,365,728, filed December 18, 1964, teaching a heart valve prosthesis "with a ring of compressible cushion material which will conform to irregularities in the bed in which the valve is placed whereby a good seal is established and leakage between the valve and the tissue is prevented"). As further shown by Petitioner, the Textbook of Interventional Cardiology, published in 1994, made clear that "perivalvular leak" was one of the known problems of prosthetic valves that "[t]he designer of any percutaneously placed valve will need to consider . . . during its design and development in order to minimize these problems." Pet. Reply 13; Ex. 1064, 1271. That some practitioners may have been surprised later at "how impactful" the problem of paravalvular leakage was does not rebut that it was a known risk from the outset of prosthesis design for both stent grafts

and replacement valves. *See* Ex. 2080 ¶ 33. Petitioner has shown that blood leakage between an implantable prosthesis and the native tissue was not unique to replacement valves, but was also a well-known problem with other implantable devices, such as stent grafts, well before the '608 patent priority date. Ex. 1007 ¶ 59; Ex. 1015, 277 ("Endoleaks resulting from an incomplete seal . . . were the primary technical complications seen with [certain graft] devices"), 279 ("The endoleak rate in early European trials with the tube graft was 38%"). Indeed, Elliot, Thornton, and Cook all seek to provide improved means for preventing such leakage, as detailed above. *See* Ex. 1007 ¶¶ 62–66.

Given the similarity in the relevant teachings of Elliot, Thornton, and Cook, Petitioner contends the same reasons support each of their combinations with Spenser.[11] Pet. 59–62, 64, 71–73. According to Petitioner, a person of ordinary skill would have been prompted to combine

[11] Petitioner asserted as separate grounds of unpatentability in the Petition that the challenged claims of the '608 patent would have been obvious over Cribier (WO 98/29057, published July 9, 1998 (Ex. 1003, "Cribier")), in combination with Elliot, Thornton, or Cook. Pet. 57–64. We did not institute review on the grounds dependent on Cribier based on the information Petitioner provided with regard to the teachings of Cribier. Inst. Dec. 23. Petitioner argued in the Petition that the same reasons support combing Cribier and either Elliot, Thornton or Cook. Pet. 59–60 (providing the rationale for the combination of Cribier and Elliot), 61–62 (contending the rationale for the combination of Cribier and Thornton is the same as the rationale for combining Cribier and Thornton), 64 (contending the rationale for the combination of Cribier and Cook is the same as the rationale for combining Cribier and Elliott or Thornton). Petitioner further argues in the Petition that the rationale supporting the combination of Spenser with Elliot, Thornton, or Cook is the same rationale Petitioner provided for the combination of Cribier and Elliot, Thornton, or Cook. Pet. 71–73.

the teachings of Spenser and Elliot, Thornton, or Cook: (1) "to further improve the sealing function of the fabric seal and further minimize the risk of paravalvular leaks;" (2) to use known techniques ("external skirts to prevent endoleaks") to improve similar devices (implantable valve prosthesis) in the same way yielding predictable results. *Id.* Petitioner's contentions are consistent with the Examiner's determination during the prosecution of the '608 patent that

> [a]n implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis [a reference disclosing a prosthetic aortic conduit[12]], and would have been obvious to one of ordinary skill in the art to modify the seal of Leonhardt et al. [a reference disclosing an artificial valve[13]] to include pleats as an obvious alternative design choice.

Pet. 37–38 (quoting Ex. 1002, 353) (emphasis omitted). In further support of its argument, Petitioner has shown that prior to the priority date of the '608 patent "the need for improved sealing function against paravalvular leaks" was known. Pet. 59 (citing Ex. 1008, 5 (stating that "[s]evere paravalvular aortic regurgitation might impair long-term clinical outcomes" after valve replacement, and that "[l]arger maximal stent diameters and other improvements in stent design might decrease the incidence and severity of paravalvular aortic regurgitation in the future.").

Petitioner also reasons, and we agree, that the teachings of Elliot, Thornton, and Cook are not limited to stent grafts. Pet. 61; *see also*

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[12] U.S. Patent No. 6,352,554 B2, issued March 5, 2002 (titled "Prosthetic Tubular Aortic Conduit and Method for Manufacturing the Same"). Ex. 1021.

[13] U.S. Patent No. 5,957,949, issued September 28, 1999 (titled "Percutaneous Placement Valve Stent"). Ex. 1027.

Ex. 1005, Abstract (Elliot broadly teaching "[a]n implantable prosthesis is provided having a radially-expandable tubular body and at least one skirt extending therefrom"); Ex. 1019, Abstract (Thornton broadly teaching "[a]n implantable medical device has a tubular member and a sealing member secured to an outer surface of the tubular member"); Ex. 1006, Abstract, ¶ 6 (Cook describing a stent graft prosthesis as an "illustrative intraluminal prosthesis" which includes "a leading edge portion having an external structure configured to prevent anchoring stent detachment and/or leakage of blood or fluids around the graft portion"). Thus, the teachings of Elliot, Thornton, and Cook are applicable to a range of prosthesis, including replacement valves.

Additionally, Petitioner has shown that even if Elliot, Thornton, and Cook only taught features of stent grafts, persons of ordinary skill in the art would have looked to vascular prosthesis such as stent grafts in selecting external covers for replacement valves. Pet. 61–62. Dr. Buller, explains that "from the earliest disclosures of transcatheter heart valves (i.e., Andersen and his colleagues [*see* Ex. 1018]), it was well known to look to stent graft technology in forming external covers on THVs." Ex. 1007 ¶¶ 73–74, 87, 169, 182–183 (citing Ex. 1018, 2:56–60, 4:3–17, 7:17–29, Figs. 11, 12 ("the stent may be made . . . with a cylinder surface which is closed by a suitable material," such that "a vascular prosthesis known per se is formed wherein the valve is mounted"); Ex. 1027, 5:53–59 (discussing graft material for THVs); Ex. 1009 ¶ 12 (teaching the use of Dacron and other materials as a "vascular occlusion device," as an "artificial valve," or to form "a stent graft"). Dr. Buller also notes that stent graft patents and publications are typically cited in THV patents, including the '608 patent. Ex. 1007 ¶ 87 n.6;

*see also* Ex. 1001, (56) (identifying U.S. Patent No 5,476,506 (Ex. 1034, 1:7–8, relating to "vascular grafts for repair of damaged or diseased sections of body vessels such as blood vessels")). Patent Owner's argument that Petitioner's contentions are "misplaced" because cited portions of Anderson and Leonhardt do not mention stent grafts, and that Pavcnik discusses artificial valves and stent grafts, but doesn't suggest that practitioners looked to stent grafts in selecting external covers for the valve embodiment is not persuasive because it fails to give consideration to what a person of ordinary skill in the art would have understood from the references asserted by Petitioner. PO Resp. 26 n.4. Moreover, Petitioner argues that the commercial success of stent grafts that used seals, such as the external skirt taught by Thornton, demonstrates a strong likelihood that applying seals as taught by Thornton, Elliot, or Cook to the prosthesis of Spenser would successfully improve the sealing function of Spenser. Pet. 62, 71–72 (citing Ex. 1025, Ex. 1026, Ex. 1007 ¶ 183). We agree with Petitioner that the proven capabilities of sealing suggested by the success of fabric seals in the stent graft context supports an expectation of success were the same features to be applied to replacement valves.

We have considered Patent Owner's numerous arguments in opposition to the obviousness of the combinations of Spenser with Elliot, Thornton, or Cook and find that they are insufficient for the following reasons to rebut the strong rationale articulated by Petitioner. *See* PO Resp. 21–38. Patent Owner argues that there was no motivation to combine Spenser with Elliot, Thornton, or Cook because they address different problems. PO Resp. 22–27 (Spenser and Elliot address "vastly different

problems"), 32–33, 35–36 (Spenser and Thornton or Cook address "very different problems").

With respect to Spenser, Patent Owner argues that it "does not address" paravalvular leakage, the problem purportedly "solved" by the '608 patent. PO Resp. 22 (citing Ex. 2030, 2:27–28 (indicating that a U.S. counterpart to Spenser does not "address leaks that can occur around the implanted valve")). Indeed, the term "paravalvular leakage" does not appear to be used in the specification of Spenser. *See* Ex. 1001; *see also* Ex. 2079 ¶ 64. That does not, however, demonstrate that the problem of paravalvular leakage was not addressed by Spenser's teaching of a prosthesis described as "suitable for implantation in body ducts." *See, e.g.*, Ex. 1004, Abstract; *see also id.* at 24 ("support stent 50 expands radially to take up its position"); 34 ("[a]fter final positioning of the valve, the valve is deployed"). The problem of blood leakage between a valve prosthesis and tissue was well known long prior to Spenser (*see, e.g.*, Ex. 1011, 1:37–46) and there is no explanation or evidence to suggest that the prosthesis of Spenser could function as a replacement valve without "addressing" paravalvular leakage by reducing or preventing the flow of blood between the device and heart tissue to some degree. We do not credit Dr. Manganaro's statement that paravalvular leakage "wasn't recognized by the prior art or known to the person of ordinary skill in the art," because it is conclusory, unsupported, and contrary to the evidence of replacement valves dating back well before the priority date of the '608 patent. Ex. 1007 ¶ 38; Ex. 1011; Ex. 1064, 1271; Ex. 2030, 2:29–33 (patent, filed June 30, 2004, issued October 2, 2007, stating with regard to prosthetic valves that "paravalvular leaks are a known side effect"); Ex. 1043, 77:18–79:16.

Moreover, there appears to be no dispute that the prosthetic valve of Spenser would "address" paravalvular leakage to some degree, though according to Dr. Brecker, there may have been concern it wouldn't "significantly reduce or prevent PVL." *See* Ex. 2080 ¶ 55. Dr. Brecker does not explain what he considers to be "significant" in that regard and he further concedes that prosthetic valves post-dating Spenser that he characterized as having "a tightly fitting external wrap" (Ex. 2080 ¶ 54) similar to Spenser were shown to have a "PVL rate" that is "significantly less" and, in particular, that the "tightly fitted external wrap," i.e. "skirt," was shown to result in a reduction of PVL. Ex. 1043, 94:20–95:24.

Similarly, Dr. Manganaro conceded that "[w]hether Spenser's cuff will prevent the flow of blood between the skirt and the heart tissue depends upon the degree of calcification," suggesting that Spenser "addresses" paravalvular leakage, regardless of whether it prevents all paravalvular leakage under all circumstances. Ex. 1044, 75:1–5. Thus, the evidence shows that one of ordinary skill would have understood from Spenser that a prosthetic valve with a fabric seal would reduce or prevent paravalvular leakage, but additional clinical data would be needed to understand how well it reduced or prevented such leakage.[14] The evidence fails to show that

[14] Dr. Brecker addressed the issue of what was known about paravalvular leakage in 1994 when asked about a textbook he confirmed was "highly regarded" in interventional cardiology. Ex. 1043, 71:10–72:15. Notwithstanding that the textbook expressly identified "paravalvular leak" under the heading "Design Problems of Percutaneous Valves," Dr. Brecker reasoned that in 1994 "there really was not necessarily any percutaneous valves that had been implanted in humans that enabled you to determine what the design problems were." *Id.* at 72:23–74:12. Dr. Brecker interpreted the textbook as identifying problems with "surgical valves" and that "any design features of percutaneous valves are going to have to bear

Spenser "does not address" paravalvular leakage or that the problem of paravalvular leakage was "unknown."

Patent Owner also argues that Elliot, Thornton, and Cook do not "disclose or even mention heart valves." PO Resp. 23, 32, 35. According to Patent Owner the abdominal aorta, where a stent graft is deployed, is "located far from the aortic valve," and "[*a*] *fortiori*, Elliot does not address the problem addressed by the [']608 patent–blood leaking around the outside of the valve through gaps created by the diseased and calcified native valve leaflets." *Id.* at 23. Patent Owner illustrates this argument with a figure that shows the aortic valve is near the heart, while the abdominal aorta is nearer the waist, though both are part of the same circulatory system. *Id.* Dr. Manganaro agrees that the abdominal aorta is "located far from the aortic valve." Ex. 2079 ¶ 65. Even were we to find these features are "far" from one another, Patent Owner's argument is not persuasive for numerous reasons, including because the teachings of Elliot are not limited to the abdominal aorta and the challenged claims of the '608 patent are not limited to the aortic valve. More broadly, Patent Owner has not shown by pointing to the distance between anatomical features that a person of ordinary skill in

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these in mind." *Id.* at 74:18–75:11. Although we find Dr. Brecker credible, we do not find the implicit logic persuasive that the known problem of paravalvular leakage with surgical replacement valves presented a design feature that would have to be kept in mind, but did not disclose a "known problem" because percutaneous valves had not yet been implanted in humans. There is no evidence or reasoning to support the notion that for a problem to be "known," it cannot merely be anticipated or predicted, but must be observed. Moreover, Dr. Brecker concedes paravalvular leakage was observed "in some of the very, very first [percutaneous] implants" and would have been known to those skilled in the art by June 2004. *Id.* 79:1–16.

the art would have viewed a prosthesis used to address a problem with blood leakage between the prosthesis and tissue in one location inapplicable to resolving a problem with leakage between a prosthesis and tissue at another location in the body "far" from the first.

Another thrust of Patent Owner's argument against the asserted combinations centers on the notion that the challenged claims of the '608 patent are directed to a problem with leakage around "diseased and calcified native valve leaflets" whereas Elliot, Thornton, and Cook are placed in locations with "healthy" tissue. For example, Patent Owner contends that Elliot addresses "leaks between the graft and *healthy* portions of the aorta." PO Resp. 24. Similarly, Patent Owner argues that Thornton teaches a device that engages "a healthy portion of the vascular wall," and a device that addresses leakage caused by wrinkles in the stent graft. *Id.* at 33. Cook, according to Patent Owner, instructs that sealing feature should be positioned "against the *healthy* aortic wall tissue." *Id.* at 35 (quoting Ex. 2079 ¶ 30). By contrast, according to Patent Owner, the "conditions inside the vessel where a transcatheter valve must be sealed—characterized by diseased and calcified native leaflets pushed aside by a stent—differ dramatically from the healthy portion of the aorta where a AAA stent graft must be sealed." PO Resp. 25–26; *see also id.* at 33, 35–36 (arguing that the prosthesis of Thornton and Cook are not shown to engage "the site of diseased and calcified native valve leaflets"); *see also* Ex. 2079 ¶ 59 (suggesting that in the context of abdominal aortic aneurysms, it is a "rare case" for the landing zone for a stent graft prosthesis to be calcified, and, when calcified, it is "minimal (erratic and modest in size)"); Ex. 2080 ¶ 80

(suggesting that in the descending aorta (including the abdominal aorta), the patient's tissue is "soft" and "non-calcified").

First, Patent Owner's argument is misplaced because the challenged claims of the '608 patent are not limited to aortic valves, or to valves placed over "diseased and calcified native valve leaflets." Second, Patent Owner's arguments are contrary to the disclosures of the asserted references, which make clear that even the stent graft examples disclosed may be placed where there is calcified tissue. Ex. 1045 ¶¶ 40–47 (citing, e.g., Ex. 1019, 30:27–36 ("calcified tissue" addressed at the location of the wall of the abdominal aortic artery); Ex. 1005 ¶ 4 (endoleaks may be caused by calcified topography of the lumen); Ex. 1060. Dr. Buller has persuasively shown that "the aorta, including the abdominal aorta, may be calcified, that this calcification is not uncommon and can vary from minimal to severe, and that stent graft sealing structures used in the aorta would account for the various, known degrees of calcification that may be present." *Id.* ¶ 47; *see also id.* ¶ 45 (explaining that "healthy" tissue in Thornton and Elliott refers to tissue that "is not part of the aneurysmal sac," not to tissue free of calcification).

Next, Patent Owner argues that the teachings of Spenser are inconsistent with Elliot, Thornton, and Cook. PO Resp. 27–31, 34, 37–38. Patent Owner identifies three objective of Spenser: 1) to avoid tearing and deformation of the valve assembly by attaching it to support beams of a constant length that avoid the need for slack material in the valve assembly, 2) to enhance the stability of the valve assembly by using a fabric cuff, and 3) to prevent migration of the valve assembly. PO Resp. 28–30. Patent Owner reasons that these objectives are inconsistent with the proposed addition of the skirt of Elliot to Spenser because it would "create slack in the

valve material and would render the cuff unable to enhance stability," and because "[d]isposing a loose-fitting fabric seal between the stent and the aortic annulus would have appeared to undermine" valve assembly migration prevention. *Id.* at 29.

We find Patent Owner's arguments not persuasive for numerous reasons. Most notable, the challenged claims of the '608 patent do not require "slack" material or a "loose-fitting" fabric seal, rendering Patent Owner's arguments inapplicable to the challenged claims. As Dr. Brecker explained *on behalf of Patent Owner*, the '608 patent does not require "that the flaps must project away from the anchor by a certain, required distance" and "only a 'wrinkle' in the fabric would suffice to extend into the gap." Ex. 1067 ¶¶ 21–24. Also, as Dr. Buller persuasively explains, Spenser eliminates the need for slack material in the valve assembly over the distance of the fixed length support member, but allows for slack material over other portions of the valve assembly to enable the entire support stent to be longitudinally extended. Ex. 1045 ¶¶ 31–39; Ex. 1004, 22 ("An important aspect of certain embodiments of the present invention is the provision of rigid support beams incorporated with the support stent that retains its longitudinal dimension while the entire support stent may be longitudinally or laterally extended"); 23 ("there is no relative movement between the valve assembly and the support beams"). Moreover, while Spenser suggests that the fabric seal (cuff portion 21) is "preferably" attached to the support beams, it doesn't require such attachment and would permit a skirt as taught by Elliot. Ex. 1004 at 22, 24.

Second, Elliot also does not require "slack" in the valve assembly or a "loose-fitting" seal. The skirts illustrated in Elliot merely show a portion of

conical fabric extending away from the tubular prosthesis with an unattached end, and Elliot does not require the skirt to be any minimum length. *See* Ex. 1005 Figs. 7, 8. There is no evidence to support Patent Owner's assertion that adding a protruding skirt, as taught by Elliott (a skirt that need extend as little as .1 mm to create the claimed "pockets" and "flaps") would alter the ability of cuff 21 of Spenser to provide the desired enhanced stability or would require that cuff 21 be loose fitting.

Third, with regard to the risk of migration, Patent Owner identifies no evidence to suggest that it would be increased with the use of a skirt as taught by Elliot in combination with the cuff of Spenser. Dr. Brecker suggests "a person of ordinary skill in the art would have had little real world data on which to base a prediction of the effect of such an outer seal on the potential for migration." Ex. 2080, ¶ 30. Dr. Brecker, however, does not address what one of ordinary skill would have known from the successful use of similar seals in other contexts, such as stent grafts. Contrary to Dr. Brecker's statements about the risk of migration, Dr. Buller explains that it would have been known that increasing the surface area of material in contact with tissue would help hold the device in place, not increase the risk of migration. Ex. 1045 ¶ 30 (citing Ex. 1059, 12 (explaining that cuff material wrapped around a support stent at the inlet "may enhance the stability of the stent" and "may also prevent migration of the valve as the friction between the valve device and the surrounding is increased). In sum, the evidence shows at most that persons of ordinary skill in the art would view the addition of the seal of Elliot to the prosthesis of Spenser as providing the potential for improved sealing, as Petitioner suggests, though more data would be required to evaluate the effectiveness

relative to known risks, such as valve migration. The evidence does not show that one of ordinary skill would have found that the addition of the seal of Elliot to Spenser would undermine Spenser's objectives of avoiding tearing and deformation of the valve assembly, enhancing the stability of the valve assembly, or preventing migration of the valve assembly.

Patent Owner makes the substantially the same arguments in opposition to the combination of Spenser and Thornton (PO Resp. 34) and the combination of Spenser and Cook (*Id.* at 37–38). We find these arguments unpersuasive for the same reasons explained above with respect to the combination of Spenser and Elliott.

H. COLLECTIVE CONSIDERATION OF THE GRAHAM FACTORS

Having considered each of the *Graham* factors individually, we now consider them collectively. The scope and content of the prior art, as well as the differences between the prior art and the challenged claims, heavily favor Petitioner's contention that claims 1–4 of the '608 patent would have been obvious over Spenser, in combination with either Elliot, Thornton, or Cook. Petitioner demonstrated that each of the claimed elements was taught in the prior art and that the differences between the prior art and the challenged claims were not significant. The level of ordinary skill in the art also heavily favors obviousness. The problem of paravalvular leakage was well known, and modifications to prevent such leakage would have been desirable while also taking into account other considerations, such as the compressed diameter of the prosthesis. Patent Owner has not shown the requisite nexus between the alleged objective indicia of nonobviousness and the challenged claims of the '608 patent. Moreover, even if nexus had been shown, the objective evidence of nonobviousness identified by Patent Owner

provides only either very little or limited support for nonobviousness of the challenged claims. Finally, Petitioner has persuasively shown that combining the teachings of Elliot, Thornton, or Cook with Spenser would have been the application of known techniques to improve similar devices in the same way that would have yielded predictable results, and that a person of ordinary skill would have been motivated to make such a modification to further improve the sealing function of the fabric seal and to further minimize the known risk of paravalvular leaks. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates by a preponderance of the evidence the obviousness of the subject matter of claims 1–4 of the '608 patent.

## IV. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 1–4 of the '608 patent would have been obvious over the combinations of: (i) Spenser and Elliot, (ii) Spenser and Thornton, and (iii) Spenser and Cook.

## V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude is *denied*;

ORDERED that claims 1–4 of U.S. Patent No. 8,992,608 B2 have been shown to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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