

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,
Petitioner,

v.

SPEYSIDE MEDICAL, LLC,
Patent Owner.

IPR2021-00244
Patent 9,603,708 B2

Before PATRICK R. SCANLON, JAMES J. MAYBERRY, and
KEVIN W. CHERRY, *Administrative Patent Judges*.

CHERRY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 21 and 22 (collectively, “the challenged claims”) of U.S. Patent No. 9,603,708 B2 (“the ’708 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner demonstrates, by a preponderance of the evidence, that claims 21 and 22 are unpatentable.

A. Procedural History

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, “Petitioner”) filed a Petition (Paper 2, “Petition” or “Pet.”) requesting an *inter partes* review under 35 U.S.C. § 311. Speyside Medical, LLC (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”). On August 18, 2021, we instituted an *inter partes* review of the challenged claims. Paper 9 (“Institution Decision” or “DI”).

Following institution, Patent Owner filed a Response (Paper 16, “Resp.”), Petitioner filed a Reply (Paper 20, “Reply”), Patent Owner filed a Sur-reply (Paper 25, “Sur-reply”), and Petitioner filed a Sur-sur-reply (Paper 26, “Sur-sur-reply”).

Petitioner relies on the Declaration of William J. Drasler, Ph.D. (Ex. 1002). Patent Owner relies on the Declaration of Ivan Vesely, Ph.D (Ex. 2023). Patent Owner took cross-examination testimony of Dr. Drasler via deposition and filed the transcript (Ex. 2030).

We heard oral argument on April 11, 2022, and the record includes a transcript of the argument. Paper 30 (“Tr.”).

B. Related Matters

The parties identify the following district court proceeding involving the '708 patent: *Speyside Medical, LLC v. Medtronic CoreValve LLC*, No. 1:20-cv-361-LPS (D. Del.). Pet. 8; Paper 4, 2. The parties also identify as related IPR2021-00239 (challenging U.S. Patent No. 8,377,118); IPR2021-00240, IPR2021-00241, and IPR2021-00310 (each challenging U.S. Patent No. 9,510,941); IPR2021-00242 (challenging U.S. Patent No. 10,449,040); and IPR2021-00243 (challenging U.S. Patent No. 9,445,897). *Id.* Subsequent to these filings, the Board granted institution in IPR2021-00239 and IPR2021-00243. The Board denied institution in IPR2021-00240, IPR2021-00241, IPR2021-00242, and IPR2021-00310.

C. The '708 Patent (Ex. 1001)

The '708 patent, titled “Low Crossing Profile Delivery Catheter for Cardiovascular Prosthetic Implant,” issued on March 28, 2017. Ex. 1001, code [45], code [54]. The '708 patent describes medical methods and a low crossing profile delivery catheter for percutaneously implanting a cardiovascular implant that has a formed-in-place support structure. *Id.* at 1:17–20.

The '708 patent explains that conventional methods for heart valve repair and replacement require a great deal of recovery time and have significant morbidity and mortality. *Id.* at 2:27–38, 2:51–54. As a result, the '708 patent recognizes a need for a less invasive method for heart valve replacement. *Id.* at 3:14–17. The '708 patent states that no stent based heart valve system had yet received regulatory approval, but a need remained for improvements over the basic concept of a stent based prosthetic valve. *Id.* at 3:39–41, 3:47–48.

We reproduce Figure 2A of the '708 patent below.

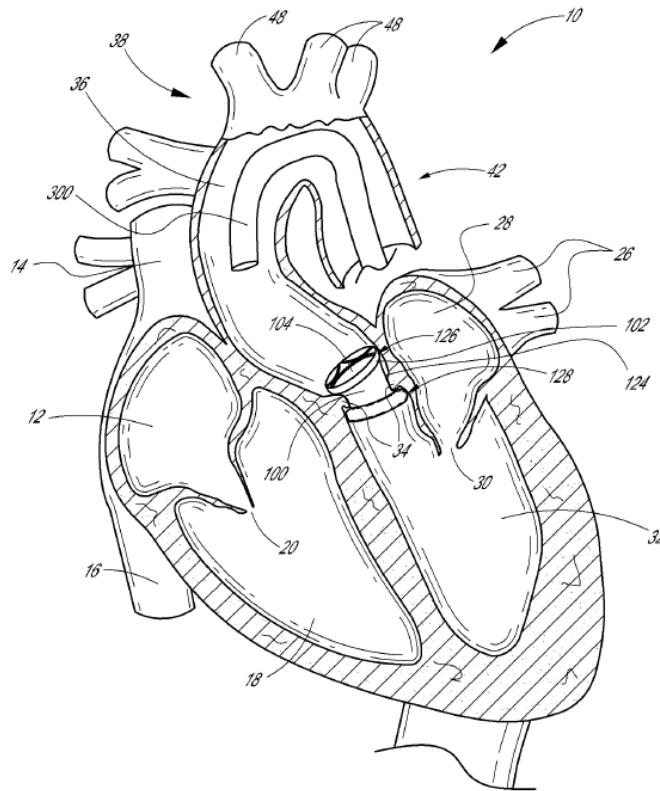


FIG. 2A

Figure 2A is a partial cut-away view of a left ventricle and aorta with a prosthetic aortic valve implant. *Id.* at 4:42–44. A cardiovascular prosthetic implant can be used to repair or replace a native abnormal or diseased aortic valve 34. *Id.* at 5:52–55, 5:61–63. The implant includes valve 104 mounted to a cuff or body. *Id.* at 6:27–28. The '708 patent discloses that “heart valve prostheses can be constructed with flexible tissue leaflets or polymer leaflets” and “[p]rosthetic tissue heart valves can be derived from, for

example, porcine heart valves or manufactured from other biological material, such as bovine or equine pericardium.” *Id.* at 15:24–28.

We reproduce Figure 5B of the ’708 patent below.

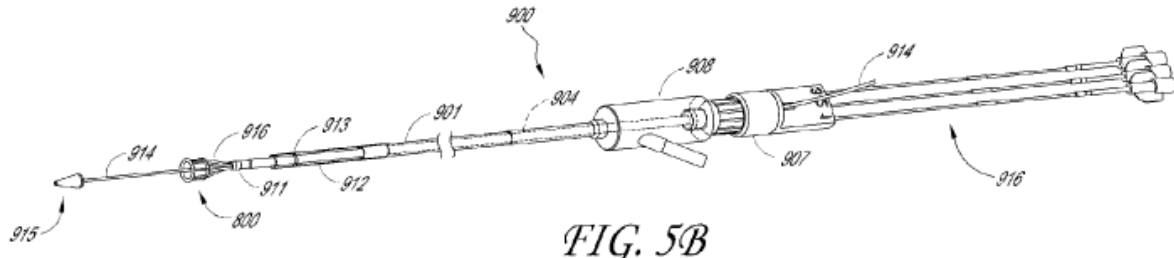


Figure 5B is a side perspective view of deployment catheter 900 with implant 800. *Id.* at 4:57–61, 19:7–9. Catheter 900 includes outer tubular member 801 having proximal end 902 and distal end 903. *Id.* at 19:57–59. The ’708 patent explains that “certain features of the implant 800 and delivery catheter 900 are particularly advantageous for facilitating delivering of cardiovascular prosthetic implant 800 . . . within a catheter body having outer diameter of about 18 French or less while still maintaining a tissue valve thickness equal to or greater than about 0.011 inches.” *Id.* at 19:17–23.

D. Illustrative Claim

Petitioner challenges claims 21 and 22 of the ’708 patent. Of the challenged claims, claim 21 is independent. Claim 21 is illustrative of the claimed subject matter and is reproduced below.

21. A delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure, wherein the delivery catheter comprises:

an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less; and

a cardiovascular prosthetic implant loaded within the distal end of the catheter body, wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure.

Ex. 1001, 30:1–12.

E. Asserted Unpatentability Challenges

We instituted an *inter partes* review of the challenged claims on the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §¹	References/Basis
21, 22	103(a)	Salahieh, ² Sands ³
21, 22	103(a)	Leonhardt, ⁴ Sands
21, 22	103(a)	Grube, ⁵ Nguyen ⁶
21, 22	103(a)	Salahieh, Nguyen

II. ANALYSIS

A. Legal Standards

To prevail in its challenge, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C.

¹ Because the claims at issue have an effective filing date before March 16, 2013, the effective date of the applicable provisions of the Leahy Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (“AIA”), we apply the pre-AIA version of 35 U.S.C. § 103 in this decision.

² U.S. Patent No. 7,381,219, issued June 3, 2008 (Ex. 1024).

³ Sands et al., *An Anatomical Comparison of Human, Pig, Calf, and Sheep Aortic Valves*, 8(5) Ann. Thorac. Surg. 407–414 (1969) (Ex. 1021).

⁴ U.S. Patent No. 5,957,949, issued Sept. 28, 1999 (Ex. 1020).

⁵ Grube et al., *Percutaneous Aortic Valve Replacement for Severe Aortic Stenosis in High-Risk Patients Using the Second- and Current Third-Generation Self-Expanding CoreValve Prosthesis*, 50(1) JACC 69–76 (2007) (Ex. 1011).

⁶ U.S. Patent Application Pub. No. 2006/0259136 A1, published Nov. 16, 2006 (Ex. 1010).

§ 316(e); 37 C.F.R. § 42.1(d) (2020). A claim is unpatentable 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 of the invention to a person having ordinary skill in the art. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). 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, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Subsumed within the *Graham* factors is the requirement that the skilled artisan would have had a reasonable expectation of success in combining the prior art references to achieve the claimed invention. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). “Obviousness does not require absolute predictability of success. . . . [A]ll that is required is a reasonable expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988).

Moreover, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

B. Level of Ordinary Skill in the Art

In the Institution Decision, we adopted Petitioner’s asserted level of ordinary skill in the art. DI 7. Petitioner’s asserted level of ordinary skill in the art is as follows:

A person of ordinary skill in the art (“POSITA”), at the time the ’708 or its parent applications were filed, would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor’s degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

Pet. 23 (citing Ex. 1002 ¶¶ 31–34).

For purposes of this Final Written Decision, we maintain our determination from the Institution Decision because neither party disputes that determination, and that level of ordinary skill is consistent with the record. *See* Resp. 11 (applying Petitioner’s level of ordinary skill).

C. *Claim Construction*

In an *inter partes* review, we construe claims “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). Furthermore, we expressly construe the claims only to the extent necessary to resolve the issues presented in this case. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

For purposes of this decision, the parties agree that we do not need to construe any claim terms to resolve their dispute. Resp. 12, 13 n.1; Reply 1 (“The Board need not construe any claim terms as the claims are

unpatentable under Grounds 1-2.”). Accordingly, we need not construe expressly any claim terms in this decision. *Nidec*, 868 F.3d at 1017.

D. Alleged Obviousness over Salahieh and Sands (claims 21 and 22)

Petitioner contends that the subject matter of claims 21 and 22 would have been obvious over Salahieh in view of Sands. Pet. 28–45. Petitioner directs us to portions of Salahieh and Sands that purportedly disclose each of the limitations in the challenged claims. *Id.* at 35–45. Petitioner also relies on Dr. Drasler’s testimony to support its arguments. *See id.* We provide a brief summary of Salahieh and Sands before turning to the parties’ arguments and our analysis. First, however, we address Patent Owner’s argument that Petitioner fails to show that Sands is a printed publication.

1. Whether Sands is a printed publication

Petitioner argues that “Sands was publicly accessible to [persons of ordinary skill in the art] and interested researchers both through the ANNALS OF THORACIC SURGERY as well as the University of Rochester Library well before 2010.” Pet. 12–13 (citing Ex. 1021; Ex. 1023, 5:52–59; Ex. 1002 ¶¶ 177–183; Ex. 1058; Ex. 1025). As to the former, Petitioner contends that “[i]ndicia of publication on Sands’ face, including its publishers, the Annals of Thoracic Surgery, which has been published regularly for more than fifty years, further indicate the public accessibility of Sands by 1969.” *Id.* at 13 (citing Ex. 1025, 1; Ex. 1063). As to the latter, Petitioner submitted a declaration from Jennifer McCarthy, an Acquisition Assistant in the Collections & Systems Division of the Institute for Innovative Education, Miner Libraries, explaining how the Miner Libraries of the University of Rochester School of Medicine & Dentistry catalogues serial materials it receives. *See* Ex. 1061.

Patent Owner does not address Petitioner’s arguments about Sands’ public accessibility in its Response, explaining that it intends to take Ms. McCarthy’s deposition (as discussed during a November 2021 teleconference with the Board) and reserving the right to submit arguments regarding the public accessibility of Sands. Resp. 17 n.3.⁷ In its Sur-reply, Patent Owner argues that Ms. McCarthy’s declaration “includes numerous deficiencies that preclude [Petitioner] from meeting its burden” to show that Sands is a printed publication. Sur-reply 23–24. Patent Owner also argues that none of Petitioner’s other evidence “establishes dissemination or meaningful indexing of the Sands reference.” *Id.* at 24.

In the Reply, Petitioner argues Patent Owner’s public accessibility arguments are waived because Patent Owner did not present them in the Response. Reply 25; *see* Sur-sur-reply 1. Petitioner further argues that Patent Owner provides no rebuttal to Dr. Drasler’s testimony or to its documentary evidence of Sands’ availability, and that Patent Owner’s expert “published extensively” in the *Annals of Thoracic Surgery*—the same journal that published Sands. *Id.* at 25–26.

“A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent . . . only on the basis of prior art consisting of patents or *printed publications*.” 35 U.S.C. § 311(b) (2018) (emphasis added). As such, whether an asserted, non-patent reference qualifies as a printed publication is a threshold issue in evaluating a

⁷ Patent Owner’s Response was due before it could depose Ms. McCarthy, and the parties agreed that Patent Owner could include public accessibility arguments based on Ms. McCarthy’s testimony in later briefing. Ex. 1069, 8–12.

petitioner's grounds of unpatentability. A petitioner bears the burden of proving that a non-patent reference qualifies as a printed publication. *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 772 (Fed. Cir. 2018) ("As petitioner, Blizzard had the burden to prove Lin is a printed publication."); *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 11 (PTAB Dec. 20, 2019) (precedential) ("To prevail in a final written decision in an *inter partes* review, the petitioner bears the burden of establishing by a preponderance of the evidence that a particular document is a printed publication.").

The determination of whether a reference is a "printed publication" "involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). Whether a document qualifies as a printed publication is a legal conclusion based on underlying factual determinations. *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380 (Fed. Cir. 2018).

We do not reach Patent Owner's arguments regarding the McCarthy declaration because we find Petitioner's other evidence and arguments demonstrate by a preponderance of the evidence that Sands was publicly available.⁸ Our analysis focuses on the indicia of availability on Sands and Dr. Drasler's testimony, as outlined below.

⁸ We disagree with Petitioner's argument that Patent Owner "waived the right to dispute [Sands'] public accessibility" by failing to address it in the Response. Reply 25. As Patent Owner notes, the parties agreed that Patent Owner could provide public accessibility arguments after Patent Owner scheduled Ms. McCarthy's deposition. Resp. 17 n.3; *see* Ex. 1069, 8–12.

First, we turn to the indicia on Sands' face, as that evidence is probative of public accessibility. *See Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1377 (Fed. Cir. 2018) ("Although the ABT Catalog's date is not dispositive of the date of public accessibility, its date is relevant evidence that supports the Board's finding of public accessibility at the March 2003 IDS Conference."). Sands' face includes the name of the journal it was published in—the Annals of Thoracic Surgery ("ATS")—as well as a publication date, volume, and issue number. Ex. 1021, 1–2.⁹ This provides evidence that Sands was published in the November 1969 ATS issue.

In addition, Dr. Drasler testifies that the Annals of Thoracic Surgery has been a well-known academic journal in the field of cardiology for decades. Ex. 1002 ¶ 178. Dr. Drasler explains that "ATS was known to publish broad coverage on advances in chest and cardiovascular surgery" and he "regularly read ATS from at least about 1986 to 2008." *Id.* Dr. Drasler further testifies that ATS is the official journal of The Society of Thoracic Surgeons, membership information for The Society of Thoracic Surgeons indicates that ATS issues were distributed to its members, and ATS had a circulation of 2733 people in 1969. *Id.* (citing Ex. 1025, 5, 17; Ex. 1063, 1). Dr. Drasler further states that "[a] person of ordinary skill in the art would have also known that the bibliographic information of all articles previously published by the ATS was indexed by issue on the ATS website, and also searchable, and thus would be able to easily identify the Sands article." *Id.* ¶ 180 (citing Ex. 1025, 6–7).

⁹ We cite to the page numbers that Petitioner added to Sands.

Certain exhibits support Dr. Drasler’s testimony. For example, Exhibit 1025, a declaration from the Records Request Processor at the Internet Archive, demonstrates that ATS was an official journal for the Society of Thoracic Surgeons, and that membership in the Society included a monthly subscription to ATS. Ex. 1025, 5, 17. Further, a 2015 Society of Thoracic Surgeons article provides a snapshot of ATS statistics from 1969, supporting Dr. Drasler’s testimony that ATS had a circulation of 2733 in 1969. Ex. 1063, 1 (Table 1, titled *Snapshot of The Annals’ Statistics from 1969–2014*). Therefore, although actual dissemination is not required to show public accessibility, *Acceleration Bay*, 908 F.3d at 772, Petitioner’s evidence indicates that Sands was published and disseminated to a significant number of members of the Society of Thoracic Surgeons in 1969.

Petitioner and Dr. Drasler also direct us to patents and academic literature citing to Sands. Ex. 1002 ¶ 181; *see* Pet. 12–13 (citing Dr. Drasler’s testimony). Dr. Drasler testifies that Sands “was cited at least 48 times” prior to the ’708 patent’s priority date, including in a U.S. patent issued in 2000. Ex. 1002 ¶ 181 (citing Ex. 1058 (Google Scholar printout showing citations to Sands); Ex. 1023, 5:55–57 (U.S. Patent No. 6,129,758 citing to Sands to explain that “[i]t is known in the art that there is a range of dimensions for a particular valve”). This evidence demonstrates that Sands was available to those interested in its subject matter and persons of ordinary skill in the art.

Patent Owner’s public accessibility arguments, on the other hand, primarily focus on alleged deficiencies in Ms. McCarthy’s declaration. Sur-reply 22–24. Even if such deficiencies exist—a position we do not necessarily agree with—and we decided to give Ms. McCarthy’s testimony

little weight, Petitioner’s additional evidence amply demonstrates Sands’ public accessibility.

Patent Owner addresses this additional evidence by asserting that Petitioner “relies on the fact that Sands appeared in the ATS journal, but fails to demonstrate that the relevant volume—dated in 1969—was disseminated or indexed at that time or any other time before the priority date.” *Id.* at 24 (citing Ex. 1002 ¶ 179; Ex. 1025). Patent Owner further contends that Petitioner’s “reliance on citations to Sands in patents or academic papers is also deficient because it fails to establish that the reference was disseminated to the interested public or meaningfully indexed.” *Id.* (citing *Acceleration Bay*, 908 F.3d at 772–773).

We disagree. As the case law makes clear, neither dissemination nor indexing is required to show that a reference was publicly accessible. *See, e.g., Acceleration Bay*, 908 F.3d 765 at 772 (“A reference is considered publicly accessible if it was ‘disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.’” (quoting *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1355–56 (Fed. Cir. 2018))); *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009) (“While cataloging and indexing have played a significant role in our cases involving library references, we have explained that neither cataloging nor indexing is a necessary condition for a reference to be publicly accessible.”); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988) (“no requirement to show that particular members of the public actually received” a reference). In any event, Petitioner’s evidence shows not only that Sands was made available such that persons interested and ordinarily skilled in the

art could locate it, but also that Sands was disseminated. Accordingly, Petitioner establishes, by a preponderance of the evidence, that Sands is a printed publication.

2. *Salahieh (Ex. 1024)*

Salahieh relates to methods and apparatus for endovascularly replacing a heart valve. Ex. 1024, 1:6–7. We reproduce Salahieh’s Figure 5B below.

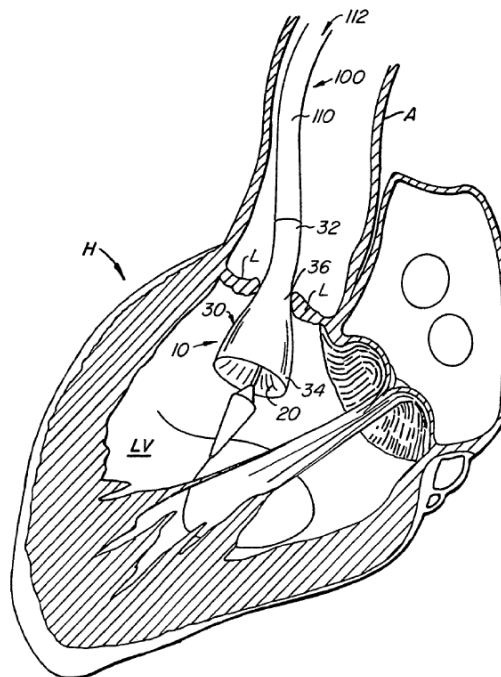


FIG. 5B

Figure 5B depicts Salahieh’s apparatus 10 replacing an aortic valve via Salahieh’s delivery system 100. *Id.* at 4:17–18, 9:10–12. Apparatus 10 includes replacement valve 20 disposed within and coupled to anchor 30. *Id.* at 6:11–12. Salahieh teaches that “[r]eplacement valve 20 is preferably from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues.” *Id.* at 6:29–35.

Salahieh's apparatus 10 includes sheath 110, which has lumen 112 and describes deploying apparatus 10 from lumen 112. *Id.* at 8:9–11, 9:21. Salahieh explains that its invention uses “a delivery catheter having a diameter of 21 french or less” and its apparatus 10 “may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a catheter having a diameter no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french.” *Id.* at 3:21–23, 6:51–55.

3. *Sands (Ex. 1021)*

Sands describes a study “of the comparative anatomies of human, pig, calf, and sheep aortic valves so as to facilitate the selection of the most favorable heterograft donor species.” Ex. 1021, 1. Sands obtained hearts for each of the various types of subjects, removed aorta portions from the samples, expanded the portions using air pressure, froze the portions with liquid nitrogen, and then sectioned the portions for study. *Id.* at 1–2. Sands explains that the aortic valves include leaflets. *Id.* at 1.

During the study, Sands found that the mean leaflet thickness measurement near a pig leaflet base was 0.80 mm and the mean leaflet thickness measurement near pig leaflet distal free edge was 0.70 mm. *Id.* at 6. Sands teaches:

Variations in leaflet thickness . . . may be important. Sterilized heterografts, utilized as dead tissue, must retain functional durability for prolonged periods of time in the absence of the normal systems by which supportive structures, such as collagen or elastic fibers, are maintained or regenerated.

Id. In view of this, “sheep valves should be eliminated from routine clinical use, since their extremely thin and fragile leaflets may not be structurally

strong enough to support heavy pressure loads for long periods of time” and “[t]he calf aortic wall is excessively thick for most clinical applications.” *Id.* Sands concludes that “[h]uman and pig valve noncoronary leaflets are the only leaflets in which annular and immediate subannular attachments are entirely of fibrous rather than muscular tissue” and “[t]he anatomical features considered in this study suggest that the pig provides more optimal aortic valve heterografts for clinical use than do calves or sheep.” *Id.* at 7.

4. *Analysis - claim 21*

Petitioner asserts that Salahieh discloses every limitation of claim 21 except a leaflet “thickness of at least about 0.011 inches.” Pet. 35–42 (citing Ex. 1024, 3:21–26, 6:6–16, 6:23–41, 6:49–55, 7:2–10, 8:8–14, 9:10–24, 11:7–9, Figs. 1A–2A, 4A, 5A–5C; Ex. 1002 ¶¶ 79–88).¹⁰ For that limitation, Petitioner contends that Sands discloses a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches because Sands discloses mean leaflet thickness measurements of 0.80 mm and 0.70 mm (0.0315 inches and 0.0275 inches) for porcine aortic valves. *Id.* at 41–42 (citing Ex. 1021, 2, 4, 6, Fig. 2; Ex. 1002 ¶¶ 73–78, 89–93), 58 (citing same).

Patent Owner does not contest Petitioner’s arguments or evidence that Salahieh and Sands teach or suggest each limitation of claim 21. Reply 2; *see generally* Resp.¹¹ Accordingly, on the complete record, we find

¹⁰ Petitioner points to Salahieh’s disclosure of using porcine tissue to form the replacement valve and leaflets as corresponding to the limitation “a natural tissue valve comprising a leaflets.” *See, e.g., id.* at 39.

¹¹ Patent Owner refers to our determination in the Institution Decision that “Sands demonstrates it was known that porcine valve leaflets had a thickness overlapping the claimed leaflet thickness range,” and that “overlapping

Petitioner persuasively establishes that Salahieh and Sands disclose each limitation of claim 21 for the reasons set forth in the Petition. Pet. 35–42 (and evidence cited therein).

The parties’ dispute in this case centers on whether Petitioner demonstrates: (1) that one of ordinary skill in the art would have had a reason to modify Salahieh’s heart valve to include leaflets having the thickness Sands discloses, and (2) whether the ordinary artisan would have reasonably expected success in achieving the claimed device. We address these issues in turn below.

a) Whether Petitioner demonstrates a reason to combine Salahieh and Sands

Petitioner contends that one of ordinary skill in the art would have applied Sands’ teachings regarding porcine valve leaflets to Salahieh’s porcine valve leaflets because “**Sands** teaches an optimization for replacement aortic valves (sourcing valve grafts from porcine aortic valves due to their particular characteristics including leaflet thickness), and **Salahieh** teaches a replacement aortic valve that uses porcine aortic valve leaflets.” Pet. 32 (citing Ex. 1002 ¶ 74). Similarly, Petitioner argues that a

ranges disclosed in the prior art create a presumption of obviousness.” Resp. 22 n.4 (citing DI 34). Patent Owner “respectfully submits that the question of overlapping ranges is not relevant here,” but “does not dispute that Sands teaches a valve leaflet thickness greater than 0.011 inches, or that Salahieh teaches a 17-French catheter” (i.e., a catheter with a distal end having an outer diameter of 18 French or less, as set forth in claim 21). *Id.* Thus, we treat Patent Owner’s argument as disputing whether Petitioner has met its burden of establishing that an ordinarily skilled artisan would have had a reason to combine the references’ teachings with reasonable expectation of success, not whether Salahieh and Sands collectively disclose the claim limitations.

heart valve formed from heterograft natural valve leaflets is a natural tissue valve and one of ordinary skill in the art would have “been motivated to apply Sands’ teachings of using porcine aortic valve leaflets of the indicated thickness—a thickness known to function in human patients—in implementing **Salahieh’s** natural tissue valve.” *Id.* at 32–33 (citing Ex. 1002 ¶ 74).

Petitioner also asserts that “**Sands** teaches that ‘[v]ariations in leaflet thickness’ are important considerations for maintaining the ‘functional durability’ of the valve prosthesis ‘for prolonged periods of time’” and that sheep valves “may not be structurally strong enough to support heavy pressure loads for long periods of time.” *Id.* at 33 (quoting Ex. 1021, 6) (alteration in original). Petitioner contends that Sands teaches the thickness of porcine aortic valve leaflets and that one of ordinary skill in the art “would have been further motivated to apply **Sands’s** teachings to select porcine aortic valve leaflets . . . in implementing **Salahieh’s** valve constructed from porcine aortic leaflets.” *Id.* at 33–34 (citing Ex. 1002 ¶ 75); *see also id.* at 31 (explaining that Sands identifies the porcine valve as “the ‘more optimal aortic valve heterograft[.]’” (alteration in original)), 50–51 (asserting that an ordinarily skilled artisan would have used Sands’ valve leaflets because “[i]n contrast to other options,” Sands found porcine valve heterografts “to be optimal, in part because its leaflets were between 0.0276 and 0.0315 inches—providing enough support to retain functional durability for prolonged periods of time”).

Patent Owner argues that Petitioner “relies on Salahieh for its teaching of a delivery catheter with an outer diameter of 18 French or less.” Resp. 18 (citing Pet. 28–35). Patent Owner contends that Salahieh’s principal

embodiment includes a catheter with an outer diameter of 21 French or less and “Salahieh states, in a single passage, that the catheter has a ‘diameter of no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french.’” *Id.* (quoting Ex. 1024, 3:35–39, 6:51–55, 24:10–13).

Patent Owner asserts that Petitioner further “relies on Sands for its teaching of a tissue valve with the claimed leaflet thickness.” *Id.* (citing Pet. 30–31; Ex. 1021). Patent Owner acknowledges that Sands “provides a general survey comparing anatomical characteristics of human, pig, calf, and sheep valves,” which include size measures for leaflets, and that Sands teaches mean pig leaflet thickness measurements of 0.80 mm and 0.70 mm. *Id.* at 18–19 (citing Ex. 1021, 1–2, 6).

Patent Owner argues that Petitioner “fails to identify a teaching drawn from the references that would lead a person of ordinary skill in the art to the claimed invention as a whole.” *Id.* at 19 (citing Ex. 2023 ¶¶ 84–89). Patent Owner contends that “Salahieh does not provide any information concerning the suitable thickness for any particular material” and Salahieh does not “discuss a minimum catheter diameter that would be necessary to accommodate the thickness of a valve manufactured from any of the disclosed materials.” *Id.* at 20 (citing Ex. 2023 ¶ 85).

Patent Owner asserts that “[t]he additional teaching of Sands does not lead a person of ordinary skill in the art to the claimed invention.” *Id.* (citing Ex. 2023 ¶ 87); *see* Sur-reply 8–9 (citing Ex. 2023 ¶¶ 90, 94; Ex. 2031, 133). Patent Owner explains that “Sands says nothing . . . about catheter design” because it “was authored in 1969, decades before transcatheter aortic valve replacement (‘TAVR’) techniques were developed.” *Id.* at 21 (citing

Ex. 2023 ¶ 88). According to Patent Owner, “[a]t the time of Sands, the prevailing replacement techniques were invasive *surgical* aortic valve replacement (‘SAVR’) procedures that required opening the patient’s chest, arresting the heart, and using a heart-lung bypass machine to keep the patient alive.” *Id.* (citing Ex. 2023 ¶ 88). Patent Owner argues that the delivery profile of a replacement valve and leaflet thickness were not design constraints for SAVR as they are for TAVR. *Id.* (citing Ex. 2023 ¶ 88). In view of this, Patent Owner asserts the combination of Salahieh and Sands does not suggest the claimed invention and Petitioner resorts to hindsight. *Id.* at 21–22. Patent Owner also argues that, because Sands was directed to SAVR procedures, “[a] person of ordinary skill in the art would not have viewed Sands as an optimization to TAVR procedures, which involved different design considerations than those applicable to the invasive surgical techniques existing at the time of Sands.” *Id.* at 22 (citing Ex. 2023 ¶ 90).

Petitioner replies that it does not rely upon Sands for “a tissue valve with the claimed leaflet thickness,” but relies upon Sands to show the known “*thickness* of a porcine valve leaflet.” Reply 4 (citing Pet. 30–31).

Petitioner notes that it relies “on Salahieh’s teachings of endovascular delivery of a ‘porcine valve leaflet[]’ prosthesis via [17 French] catheter.” *Id.* (citing Ex. 1024, 6:11–16, 6:29–31; Pet. 4, 36–38; DI 31–33). Petitioner asserts that Patent Owner mischaracterizes Petitioner’s ground because Petitioner “applies Sands’s teachings of the *thickness* of a porcine valve leaflet (Pet. 30–31) and relies instead on *Salahieh’s* teachings that a porcine aortic valve works in a catheter with the claimed dimensions.” *Id.* at 4–5 (citing Ex. 1024, 6:29–31).

Petitioner further argues that Patent Owner does not point to “evidence that a [person of ordinary skill in the art] would have understood that porcine aortic leaflets of the thickness taught by Sands would not work for Salahieh’s porcine leaflets.” *Id.* at 5 (citing Ex. 1002 ¶¶ 91–98, 119, 120). Conversely, Petitioner contends that “[t]he art teaches porcine leaflets of known thickness would work, and Sands’ thickness is consistent with known porcine leaflet thicknesses.” *Id.* (citing Ex. 1024, 6:6–12, 6:29–31, 6:51–55; Ex. 1017, 330; Ex. 1018, 26; Ex. 1019, Table 3A; Pet. 34–35). According to Petitioner, the ground’s “primary reference discloses a valve material and the claimed catheter diameter while the secondary reference teaches the known characteristics of primary reference’s identified valve material.” *Id.* at 5–6 (citing Pet. 30–35).

Petitioner also contends that Patent Owner misapplies the law because Patent Owner “incorrectly asserts that because Salahieh discloses potential valve materials but not a minimum catheter diameter for each, a [person of ordinary skill in the art] would not know which catheter size to use with which material.” *Id.* at 6 (citing Resp. 19–20). Petitioner argues that “Salahieh teaches that **all** of its disclosed valve materials would work with a [17 French] catheter,” and Patent Owner has not attempted to show that Salahieh is non-enabling. *Id.* at 6–7 (citing Ex. 1024, 6:49–55). Petitioner asserts that Sands’ age does not undermine its teachings, which instead demonstrate that the thickness of porcine aortic leaflets was well known as of the ’708 patent’s priority date. *Id.* at 7.

Patent Owner responds by contending that Salahieh lists potential materials that could be used for its replacement valve and the various catheter sizes that might be used but “[t]here is no single embodiment that

describes a replacement valve made from porcine leaflets delivered through a 17-French catheter.” Sur-reply 2–3 (citing Ex. 1024, 6:6–15, 6:29–39, 6:51–55, 6:59–24:7, Figs. 1–4). Patent Owner argues that Petitioner cites a single passage in Salahieh describing a 17-French catheter “but that passage says nothing about whether a catheter that small can accommodate valves manufactured from each of the numerous materials identified separately in the specification, including porcine valve leaflets that were known to be thicker than pericardial and synthetic valves.” *Id.* at 3 (citing Pet. 37; Ex. 2023 ¶¶ 84–85). Patent Owner asserts that Salahieh’s passages regarding porcine valve leaflets also say nothing about catheter sizes. *Id.* (citing Pet. 39–41). In view of this, Patent Owner argues that Salahieh discloses a number of different valve materials and catheter sizes, which requires Petitioner to explain why one of ordinary skill in the art would have combined a specific valve material and catheter size. *Id.* at 4 (citing Ex. 2023 ¶ 85). Patent Owner contends that Petitioner does not provide any “particularized explanation of why a POSITA would select porcine valve leaflets and pair them with a 17-French catheter.” *Id.* (citing Pet. 29–34, 36–41). Patent Owner also disputes other rationales Petitioner provides for combining Salahieh and Sands. *Id.* at 9–10.

The evidence of record supports Petitioner’s argument that the ordinarily skilled artisan would have had reason to modify Salahieh’s replacement valve in view of Sands’ teachings. Salahieh discloses the use of “a delivery catheter having a diameter of 21 french of less” or “no more than 17 french” with its replacement valve. Ex. 1024, 3:21–26, 6:51–55. Salahieh further discloses that its replacement valve may be formed from porcine valve leaflets. *Id.* at 6:11–16, 6:29–30. In other words, Salahieh

itself suggests that a replacement valve made with porcine valve leaflets can be used with a catheter having a diameter of 21 French or less. Ex. 1024, 3:21–26, 6:29–30. Contrary to Patent Owner’s argument, these are not disclosures of different embodiments that would require a rationale to combine. Instead, Salahieh discloses what material its replacement valve may be made of and also teaches that its replacement valve may be used with catheters of a certain size.

Petitioner relies on Salahieh for disclosing a replacement valve having a natural tissue valve with porcine leaflets and a catheter having a distal end with an outer diameter of 18 French or less, as claim 21 recites. Pet. 28–30, 36–41 (citing Ex. 1024, 6:29–41, 6:49–55). Petitioner admits that Salahieh does not specifically disclose the thickness of a porcine valve leaflet. *Id.* at 33. Petitioner directs us to Sands, which discloses known thicknesses of a porcine valve leaflet. Reply 4; Pet. 30–31, 41–42 (citing Ex. 1021, 6). Sands discloses mean leaflet thickness measurements of 0.80 mm and 0.70 mm (0.0315 inches and 0.0275 inches) for porcine aortic valves. Ex. 1021, 6. Although Sands’ disclosure may be in the context of SAVR procedures, Salahieh itself demonstrates that porcine valve leaflets can be used with a catheter having the claimed diameter. Sands, in turn, demonstrates it was known at the time of the claimed invention that porcine leaflets, such as those Salahieh teaches, had a thickness within the claimed range.

Furthermore, Petitioner articulates a rationale to modify Salahieh and use Sands’ leaflet thickness. Pet. 33 (citing Ex. 1021, 6). Sands explains that “[v]ariations in leaflet thickness . . . may be important” and sheep valves, which are thinner than porcine valve leaflets, “may not be

structurally strong enough to support heavy pressure loads for long periods of time.” Ex. 1021, 6. Sands further expresses a preference for porcine valves, explaining that they “provide[] more optimal aortic valve heterografts for clinical use than do calves or sheep.” Ex. 1021, 7; *see also* Ex. 1002 ¶¶ 75, 108 (providing Dr. Drasler’s testimony as to why an ordinarily skilled artisan would have had a reason to use Sands’ porcine valve leaflets in Salahieh’s replacement valve). In other words, Sands explicitly teaches that thicker valve leaflets, i.e., porcine valve leaflets, may be more desirable for purposes of durability over prolonged periods. For these reasons, Petitioner has met its burden of establishing a reason to modify Salahieh in view of Sands.¹²

We do not agree with Patent Owner’s remaining arguments that Petitioner has not met its burden of articulating a sufficient rationale to modify Salahieh in view of Sands. For instance, Patent Owner argues that “a person of ordinary skill in the art would have recognized that it would have been unworkable to apply the porcine valves disclosed in Sands to the transcatheter delivery apparatus disclosed in Salahieh, as Dr. Drasler proposes” because “[i]n order to attach a porcine valve to the wire-mesh anchor disclosed in Salahieh, one would have to leave a certain amount of the native aortic root attached to the valve leaflets.” Resp. 23 (citing Ex. 1002 ¶ 75; Ex. 2023 ¶¶ 91–92); Sur-reply 5. According to Patent Owner,

¹² The parties also present arguments regarding whether Petitioner has demonstrated that it would have been “obvious to try” combining Salahieh’s catheter with Sands’ porcine valve. Resp. 26–28; Reply 9–10; Sur-reply 6–7. Because we find Petitioner’s other arguments have provided a sufficient reason to combine Salahieh and Sands, we do not reach this issue.

“[s]imply cutting away the leaflets and attaching them directly to the anchor would not provide strong enough structure to withstand the pressure accompanying normal blood flow.” Resp. 23 (citing Ex. 2023 ¶¶ 91–92). Patent Owner asserts that “Sands recognizes that concern, noting that ‘excision of the muscle mass compromises leaflet strength.’” *Id.* (citing Ex. 2023 ¶¶ 91–92; Ex. 1021, 7; Ex. 2031, 124).

Patent Owner also argues that including a portion of the aortic root would result in a bulkier replacement valve, which would have impacted the choice of catheter size and “would have led a person of ordinary skill in the art to use a catheter with a much larger diameter than 18-French in order to accommodate porcine valves as disclosed in Sands.” *Id.* at 23–24 (citing Ex. 2023 ¶ 93). To support its point, Patent Owner cites evidence about the JenaValve transcatheter device, which used a porcine root valve and a 32-French catheter for implantation through an incision in the chest; the Hancock II device, which used a porcine valve that was implanted directly into a chest cavity; and the CoreValve device, which used porcine pericardium tissue valves that Patent Owner argues “was known to be relatively thin, on the order of 0.0056 to 0.008 inches.” *Id.* at 24–25 (citing Ex. 2023 ¶¶ 42–43, 94–97; Ex. 2025, 1, 3, Fig. 5; Ex. 2026, 1; Ex. 2031, 134; Ex. 2027, 24). Patent Owner further argues in its Sur-reply that Dr. Vesely provided an explanation in his declaration but Petitioner chose not to depose Dr. Vesely, which leaves his testimony uncontested by cross-examination. Sur-reply 5 (citing Ex. 2023 ¶¶ 11, 93–97).

We decline to accept the conclusions offered in Dr. Vesely’s testimony merely because it is uncontested by cross-examination, but instead weigh that testimony based on the reasoning provided and corroborating

references cited. The Board has discretion to accord little weight to broad conclusory statements in expert testimony that the Board determines are unsupported by corroborating references. *In re American Acad. of Science Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) (citing *Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003)). Declarations that offer only opinion evidence have little value without factual support. *In re Beattie*, 974 F.2d 1309, 1313 (Fed. Cir. 1992). Patent Owner's arguments and Dr. Vesely's testimony lack sufficient support that one of ordinary skill in the art would have understood, at the time of the claimed invention, that a porcine valve leaflet required a portion of native aortic root in order to function.

Specifically, Patent Owner and Dr. Vesely both cite Exhibit 2031 for support. Resp. 23–24; Ex. 2023 ¶ 91. Exhibit 2031, however, has indicia indicating a date of 2011, which is after the '708 patent's earliest priority date. Ex. 2031, 1; Ex. 1001 at [60]. Patent Owner and Dr. Vesely also rely upon Exhibit 2025 and Exhibit 2027 to support their arguments. Resp. 24–25; Ex. 2023 ¶¶ 94–97. However, Exhibit 2025 is dated 2015 and Exhibit 2027 is dated 2017. Ex. 2025, 1; Ex. 2027, 1. Courts have recognized that, under certain narrow circumstances, later-issued patents and publications may be used to show the state of the art existing on the date of the application in question. *See In re Koller*, 613 F.2d 819, 824 (CCPA 1980); *see also id.* at n.5 (enumerating various circumstances). However, Patent Owner does not sufficiently explain how these references would have been relevant to the understanding of one of ordinary skill in the art at the time of the claimed invention and why we should give them significant weight in our analysis. *See* Sur-reply 10. For these reasons, Dr. Vesely's testimony on this issue is not supported by corroborating references demonstrating the

knowledge of one of ordinary skill in the art at the time of the invention. Therefore, Dr. Vesely's testimony regarding this issue is entitled to little weight.

We also do not agree with Patent Owner's argument that Sands recognizes this concern regarding the aortic root. Resp. 23 (citing Ex. 2023 ¶¶ 91–92; Ex. 1021, 7; Ex. 2031, 124). Sands teaches:

Furthermore, retention of the muscle mass at the base of animal valves will result in some stenosis if they are transplanted to the subcoronary position. Conversely, total excision of the muscle mass compromises leaflet strength; hence, some who have advocated debridement also apply a fabric support to the debrided area [2]. Unfortunately, fabric is notorious for its alteration and calcification, and it seems likely that the sutures required to hold the fabric to the leaflet may result in leaflet dysfunction or rupture.

Ex. 1021, 7. Thus, although Sands recognizes that total excision of muscle mass at the base of an animal valve comprises leaflet strength, Sands does not teach that such an embodiment would not function in a valve replacement device. In the absence of teaching away from such an embodiment or a suggestion it is non-functional, which we do not discern here, Sands' teaching of a concern for a valve without retained muscle mass at its base does not render use of that valve non-obvious. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (Something that is known or obvious does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.). Therefore, Sands also does not support Patent Owner's argument or Dr. Vesely's testimony that one of ordinary skill in the art would not have used a porcine valve without including aortic root tissue.

In addition, Patent Owner asserts that Petitioner’s reliance on impermissible hindsight “is further confirmed by the fact that the real-world embodiment of Salahieh’s device was not able to achieve the claimed invention.” Resp. 25–26 (citing Ex. 2023 ¶¶ 97); Sur-reply 6 (citing Ex. 2023 ¶¶ 42–43, 94–97). According to Patent Owner, Salahieh was originally assigned to a company, Sadra Medical, which offered a replacement valve assembly called the Lotus percutaneous aortic valve. Resp. 26 (citing Ex. 1024). Patent Owner contends the Lotus device used a pericardial tissue valve that was delivered via a 19-French catheter. *Id.* (citing Ex. 2024, 2870). According to Patent Owner, “[t]he design of the Lotus device demonstrates that those skilled in the art designing nitinol-frame transcatheter replacement-valve assemblies would have been motivated to use pericardial tissue, which was known to be relatively thin without sacrificing durability, rather than thicker porcine valves as disclosed in Sands.” *Id.* (citing Ex. 2023 ¶¶ 97–98).

Petitioner asserts that Patent Owner’s arguments regarding commercial embodiments are irrelevant because “[n]o commercial embodiment can change Salahieh’s express teaching of using ‘*preferably*’ a porcine aortic valve leaflet implant endovascularly-delivered via catheter ‘*more preferably*’ sized ‘*no more than 17 french*.’” Reply 7–8 (citing Ex. 1024, 6:23–41, 6:49–55; Pet. 37, 41). Petitioner further argues that “[n]early all of PO’s proffered evidence post-dates the ’708 priority date, and as such is irrelevant.” *Id.* at 8 (citing Ex. 2025; Ex. 2027; Ex. 2031). Petitioner contends that Patent Owner does not provide a logical relationship between the cited commercial embodiments and whether one of ordinary skill in the art “would have known Salahieh’s porcine valve would not fit in

Salahieh’s catheter sized [18 French] or less.” *Id.* (citing Resp. 24–35). In addition, Petitioner argues that the JenaValve device is delivered via a trocar, not a catheter, and is therefore irrelevant, Medtronic’s selection of pericardial leaflets is irrelevant to how one of ordinary skill in the art would understand Salahieh, and Patent Owner provides no evidence that the Lotus device is a commercial embodiment of Salahieh. *Id.* at 8–9 (citing Ex. 2025, Fig. 6).

Patent Owner responds to Petitioner’s arguments about the relevancy of later-dated exhibits by asserting that “[t]he first exhibit, Mieres, is relevant because it shows that even years after the invention, those skilled in the art still required large catheters to deliver porcine tissue valves” and “[i]t thus contradicts Medtronic’s argument that there would have been a motivation to select a smaller catheter years earlier, when the technology was less-developed.” Sur-reply 10 (citing Ex. 1025, 1; Ex. 2023 ¶ 94). According to Patent Owner, “[t]he other two references, Caballero and Helmus, are relevant because they describe known thickness values for pericardial tissue and design considerations for artificial heart valves.” *Id.* (citing Ex. 2017, 24; Ex. 2031, 124, 133; Ex. 2023 ¶¶ 42–43, 91).

We further do not agree with Patent Owner’s arguments regarding the cited commercial embodiments. Patent Owner does not direct us to any teaching by Salahieh or Sands that certain catheter sizes should be used with certain leaflet sizes, such as thicker leaflets being limited to larger catheters. As discussed above, Salahieh demonstrates it was known to use porcine valve leaflets with a catheter in the claimed range, Sands demonstrates that porcine valve leaflets were known to have a thickness in the claimed range, and Petitioner presents a sufficient reason to combine those teachings.

Furthermore, as discussed above, Patent Owner and Dr. Vesely do not sufficiently explain why Exhibit 2025 and Exhibit 2027, which are dated after the '708 patent's earliest priority date, are relevant to the understanding of one of ordinary skill in the art at the time of the claimed invention. Therefore, those references do not support Patent Owner's position. In view of the foregoing, we find Petitioner articulates a sufficient reason to modify Salahieh's heart valve to use Sands' leaflet thickness.

b) Whether Petitioner demonstrates a reasonable expectation of success

Petitioner asserts that one of ordinary skill in the art “would have had a reasonable expectation of success in applying **Sands**' teachings of known thicknesses of native porcine valve leaflets to **Salahieh**'s natural tissue valve” because “**Salahieh** teaches using ‘biologic tissues, e.g., porcine valve leaflets’ in a replacement heart valve apparatus for endovascular delivery in a catheter having a diameter ‘no more than 17 french’” and “the thickness of a suitable porcine aortic valve leaflet was well-known and a POSITA would have therefore found it obvious and straightforward to apply the teachings of a porcine valve comprising leaflets having a thickness of at least 0.011 inches to **Salahieh**.” Pet. 34–35 (citing Ex. 1021, 6; Ex. 1024, 6:6–12, 6:29–31, 6:51–55; Ex. 1002 ¶¶ 77–78, 184–190).

Patent Owner contends Petitioner's argument that the proposed combination would have been “obvious and straightforward” is conclusory and insufficient. Resp. 28–29 (citing Pet. 34; Ex. 1002 ¶ 78). Patent Owner argues that “a person of ordinary skill in the art would not have had a reasonable expectation of success in combining the 17-French catheter of Salahieh with the porcine valve leaflets of Sands.” *Id.* at 29 (citing Ex. 2023

¶¶ 101–110). Specifically, Patent Owner asserts that Petitioner “and Dr. Drasler ignore the fact that the replacement valves in Sands were being studied for the purpose of SAVR procedures, not TAVR procedures that were developed decades later.” *Id.* (citing Pet. 34–35; Ex. 1002 ¶ 78; Ex. 2023 ¶ 102). Patent Owner contends that the delivery profile of a replacement valve, and whether its leaflets could pass through a catheter, were not design constraints for such processes. *Id.* at 29–30 (citing Ex. 2023 ¶ 102). According to Patent Owner, “the fact that porcine donor valves had been used in SAVR procedures does not inform whether a person of ordinary skill in the art would have had a reasonable expectation of success delivering those same valves through an 18-French catheter in the context of TAVR procedures.” *Id.* at 30 (citing Ex. 2023).

Petitioner replies by asserting that one of ordinary skill in the art would have had a reasonable expectation of success in applying Sands’ thickness teachings to Salahieh’s porcine leaflets because “Salahieh already teaches using a [17 French] catheter to deliver a porcine leaflet replacement valve.” Reply 10–11 (citing Ex. 1002 ¶¶ 77–78, 184–190; Pet. 29, 34; Ex. 1024, 6:29–41). Petitioner states this point in another way: “Salahieh’s disclosure of delivering porcine leaflet implants via [17 French] catheter in TAVR procedures further demonstrates an expectation of success in applying Sands’ porcine-leaflet-thickness teachings.” *Id.* at 11 (citing Ex. 1024, 6:29–41).

Patent Owner contends that “the use of porcine valve leaflets for open-chest SAVR procedures as disclosed in Sands would tell a POSITA *nothing* about whether the same valves would work when delivered through the 17-French catheter of Salahieh.” Sur-reply 12 (citing Ex. 2023 ¶ 102).

Patent Owner argues that Petitioner cites Salahieh’s teachings but Salahieh “describes porcine leaflets as only one of numerous possible valve materials, and a 17-French catheter as one of several catheter sizes” and “Salahieh does not explain how a valve manufactured from porcine leaflets—with the thickness of Sands—could be incorporated into a 17-French catheter and delivered to a patient’s native valve site with a reasonable expectation of success.” *Id.* (citing Ex. 1024, 6:29–39; Ex. 2023 ¶¶ 106–109). According to Patent Owner, one of ordinary skill in the art would have expected the combination to fail. *Id.* (citing Ex. 2023 ¶¶ 106–109). Patent Owner also argues that Petitioner does not explain techniques Petitioner alleges as known in the art could have been applied to Salahieh and Sands or show that a resulting device would work with a reasonable expectation of success and meet claim 21’s requirements. *Id.* at 12–13 (citing Reply 5, 11–12).

We find that Petitioner sufficiently demonstrates that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Salahieh in view of Sands. As Petitioner argues, Salahieh suggests that a replacement valve including porcine valve leaflets can be used with a catheter having a diameter of “no more than 17 french.” Pet. 34–35 (citing Ex. 1024, 6:6–12, 6:29–31, 6:51–55; Ex. 1002 ¶¶ 77–78, 184–190); Reply 11. In other words, Salahieh itself shows that it was known to use a porcine valve with leaflets with a catheter in the claimed size range.

Petitioner cites Sands to demonstrate that porcine valve leaflets were known to have a thickness in the claimed range. Pet. 34–35 (citing Ex. 1021, 6). Modifying Salahieh in view of Sands therefore would have involved applying Sands’ teachings regarding porcine leaflet thickness to a

material that already Salahieh describes as suitable for its replacement valve (i.e., porcine valve leaflets) that can be used with a catheter size in the claimed range. Moreover, Petitioner cites other art teaching that a porcine valve was actually used with a catheter size in the claimed range (i.e., a 16-French sheath). Pet. 13 (citing Ex. 1031); Tr. 55:24–56:12 (discussing Ex. 1031); *see also* Ex. 1031, 645 (describing a porcine valve being used with a 16-French sheath). As a result, Petitioner not only demonstrates that one of ordinary skill in the art would have had a reasonable expectation of success in making the proposed combination at the time of the invention, which is all that is required under an obviousness analysis, but that actual success had been achieved for a porcine valve with a sheath in the claimed size range.

Patent Owner's additional arguments and cited evidence are also insufficient to demonstrate that Petitioner has not sufficiently established a reasonable expectation of success. For instance, Patent Owner argues that one of ordinary skill in the art would have understood that a certain amount of native aortic root would be required for a valve leaflet, that Sands recognizes this concern, and Dr. Vesely explains that one of ordinary skill in the art would have concluded that the combination of Salahieh and Sands was unworkable and likely to fail. Resp. 31–32 (citing Ex. 2023 ¶¶ 103–106).

Paragraphs 103, 105 and 106 of Dr. Vesely's testimony do not cite any corroborating references and therefore only present Dr. Vesely's opinion. Declarations that offer only opinion evidence have little value without factual support. *In re Beattie*, 974 F.2d at 1313. Paragraph 104 cites Sands but, as discussed above in our analysis of Petitioner's reason to

combine, we accord this testimony little weight because Sands also recognizes that leaflets can be used without aortic root tissue without suggesting that the use of such leaflets would not have been obvious. Ex. 1021, 7. Paragraph 104 of Dr. Vesely’s testimony also cites Exhibit 2031 for support but, as discussed above in our reason to combine analysis, that exhibit is dated after the ’708 patent’s earliest priority date and Patent Owner does not adequately explain how that reference demonstrates what one of ordinary skill in the art would have expected or thought at the time of the claimed invention.

Patent Owner further argues that “the record evidence confirms that there would not have been a reasonable expectation of success” because Dr. Vesely explains there were commercial transcatheter devices that relied on porcine valve leaflets that required a much larger diameter than the claimed invention. Resp. 32 (citing Ex. 2023 ¶ 107). Specifically, Patent Owner cites the JenaValve device’s use of a porcine root valve with a 32-French catheter. *Id.* (citing Ex. 2025, 1, 3, Fig. 5; Ex. 2023 ¶ 107; Ex. 2030, 18:19–22). Patent Owner asserts that this “underscores that a person of ordinary skill in the art desiring to use porcine valve leaflets like those disclosed in Sands would not have had a reasonable expectation of success incorporating them into a catheter having a diameter that is much larger than 18-French.” *Id.* at 32–33 (citing Ex. 2023 ¶ 107).

Patent Owner also cites the Hancock II device, which used a porcine valve that was implanted directly into a patient’s chest, and the CoreValve device, which used porcine pericardial tissue valves, to support its argument that one of ordinary skill in the art “would not have had a reasonable expectation of success in combining Sands and Salahieh.” *Id.* at 33 (citing

Ex. 2023 ¶¶ 42–43, 108; Ex. 2026, 1; Ex. 2031, 134; Ex. 2027, 24). Patent Owner cites the Lotus device for this proposition, which is a commercial embodiment of Salahieh that used a pericardial tissue valve with a 19-French catheter. *Id.* at 34 (citing Ex. 2023 ¶ 109; Ex. 2024, 2870). Patent Owner argues that “[t]he Federal Circuit has explained that ‘contemporaneous evidence of what skilled artisans thought at the time of the invention can help inform our inquiry into whether the expectation of success was reasonable.’” *Id.* (quoting *NantKwest, Inc. v. Lee*, 686 Fed. Appx. 864, 875 (Fed. Cir. 2017)).

Petitioner responds to Patent Owner’s arguments about commercial embodiments by asserting that “the absence of a commercial product delivering a porcine leaflet implant via [17 French] catheter is irrelevant” and “[t]he law requires only a reasonable expectation of success, not an ‘absolute’ expectation.” Reply 12.

We agree with Petitioner’s reply because Patent Owner’s arguments about commercial embodiments appear to require actual proof that the combination would have succeeded.¹³ This, however, is not the proper test for an obviousness analysis. “Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988). As

¹³ Patent Owner’s argument that “Dr. Drasler explained that he was not aware of any commercial transfemoral devices that relied on a donor porcine valve passed through a catheter” exemplifies Patent Owner’s attempt to require actual proof of success. Resp. 32 (citing Ex. 2030, 78:25–79:14). The mere lack of awareness or knowledge that a combination had actually been done does not prove that one of ordinary skill in the art would have lacked a reasonable expectation of success based upon teachings of the prior art.

discussed above, Salahieh itself suggests that porcine valve leaflets can be used with a catheter size in the claimed range. Petitioner relies upon Sands to demonstrate that porcine valve leaflets, such as Salahieh's, have a thickness within the claimed range. This alone is sufficient to establish a reasonable expectation of success. Thus, to the extent Patent Owner would argue that one of ordinary skill in the art would not have had a reasonable expectation of success in using Salahieh's 17-French catheter with porcine valve leaflets, Salahieh's disclosure suggests otherwise. As noted above, Petitioner cites other art demonstrating it was known that a porcine valve could be used with a catheter size in the claimed range (i.e., a 16-French sheath). Pet. 13 (citing Ex. 1031). Thus, Salahieh's disclosures of using porcine valve leaflets and catheters in the claimed range do not stand alone as outliers within the prior art.

In its Sur-reply, Patent Owner cites Dr. Vesely's testimony, contends that Petitioner did not cross-examine Dr. Vesely or submit a reply declaration to rebut that testimony, and "[t]he Board should thus credit the testimony in deciding whether a POSITA would have had a reasonable expectation of success." Sur-reply 11 (citing Ex. 2023 ¶¶ 101–110). As noted above with regard in our analysis for whether Petitioner articulated a sufficient reason to combine Salahieh and Sands, we do not credit Dr. Vesely's testimony merely because Dr. Vesely was not cross-examined but determine whether Dr. Vesely's testimony is properly corroborated with supporting references. Also, as noted, above, we then accord that testimony its proper weight.

As discussed above in our section analyzing Petitioner's reason to combine, several of the references cited by Patent Owner and Dr. Vesely are

dated after the '708 patent's earliest priority date and Patent Owner does not adequately explain how those post-priority date references demonstrate what one of ordinary skill in the art would have expected at the time of the claimed invention and why we should give them significant weight in our analysis. *See* Exs. 2025, 2031, 2027. Furthermore, even if we were to consider the commercial embodiments that Patent Owner cites, the mere fact that certain devices did not practice the claimed invention does not demonstrate that one of ordinary skill in the art did not have an expectation that the claimed combination of catheter size and leaflet thickness was achievable. For instance, Patent Owner does not sufficiently explain with persuasive evidence why the valve materials and catheter sizes were selected for the cited commercial embodiments (e.g., because a particular valve material and catheter size would not work). Conversely, other evidence in the record, such as Salahieh's suggestion that porcine valve leaflets could have been used with a catheter in the claimed size range, without any reservation for what catheter sizes could be used with certain leaflet thicknesses, shows what one of ordinary skill in the art could have reasonably expected to achieve at the time of the invention. Therefore, we find that Petitioner shows by a preponderance of the evidence in the record that one of ordinary skill in the art would have had a reasonable expectation of success in making the proposed combination.

c) Objective Indicia

Patent Owner asserts that TAVR procedures were viewed as a less-invasive alternative to SAVR procedures when TAVR was first introduced but TAVR continued to suffer from complications as it progressed and was initially reserved for high-risk and inoperable patients that could not be

treated with SAVR procedures. Resp. 57 (citing Ex. 2023 ¶¶ 33–34, 44, 158, 159). Patent Owner argues that, in view of this, “there was a desire in the field to reduce complications and expand TAVR procedures to a broader patient base.” *Id.* (citing Ex. 2023 ¶ 160). Patent Owner further contends that “[t]o address that need, those in the field worked over the course of years to improve various aspects of replacement valves and related procedures” but, despite those efforts “those in the field did not achieve the claimed invention.” *Id.* at 58 (citing Ex. 2023 ¶ 160).

According to Patent Owner, “the evidence demonstrates that there was a long felt but unmet need to achieve a device and procedure that would meet the requirements of the claimed invention in the context of TAVR procedures.” *Id.* (citing Ex. 2023 ¶ 161). Patent Owner also argues that “a device that did meet the requirements of the claimed invention would have been unexpected given the prevailing belief that smaller catheter sizes would necessitate thinner valve leaflets.” *Id.* (citing Ex. 2023 ¶ 161).

Petitioner contends that Patent Owner “offers no nexus analysis and fails to show that any alleged ‘unique characteristic’/‘merits’ of claims 21–22 relative to the prior art met a purported need or achieved unexpected results, or that others failed.” Reply 26. Petitioner also argues that Dr. Vesely relies on a single study dated after the ’708 patent’s priority date that discusses “unspecified ‘engineering calculations’ and ‘newer’ commercial ‘delivery systems’” that are irrelevant, lacks specificity, and does not examine the closest prior art. *Id.* (citing Ex. 2023 ¶ 160). Patent Owner does not provide further arguments for objective indicia in its Sur-reply. *See generally* Sur-reply.

For objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). “[T]here is no nexus unless the evidence presented is ‘reasonably commensurate with the scope of the claims.’” *Id.* (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)). A patentee is entitled to a presumption of nexus “when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))).

We agree with Petitioner that Patent Owner does not address nexus for its asserted objective indicia. Therefore, we find that a presumption of nexus is inappropriate. However, “[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations.” *Fox Factory*, 944 F.3d at 1373. “To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). Patent Owner does not appear to attempt to prove a nexus through this alternative route. Thus, we find that Patent Owner has also failed to show that it should be afforded a nexus because the secondary considerations evidence is a direct result of the “unique characteristics of the claimed invention.”

Even if we were to find that Patent Owner has proven nexus because its evidence of objective indicia is the direct result of the unique characteristics of the claimed invention, we find that Patent Owner's evidence of objective indicia is entitled to little weight. As discussed above, Patent Owner argues its claimed invention satisfies a long-felt need. Resp. 57–58 (citing Ex. 2023 ¶¶ 157–161). “The existence of a long felt but unsolved need that is met by the claimed invention is further objective evidence of non-obviousness.” *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1369 (Fed. Cir. 2017). First, establishing long-felt need requires objective evidence that a recognized problem existed in the art for a long period without solution. *See Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983); *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). Second, another must not have satisfied the long-felt need before the invention of the challenged patent. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Third, the invention of the challenged patent must satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971); *see also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332–1333 (Fed. Cir. 2009) (articulating all three factors).

Here, even if we were to agree that Patent Owner has met the first two requirements, a position we do not agree with, we do not agree that Patent Owner has satisfied the third requirement. Patent Owner argues that the invention itself was the long-felt need and the invention satisfies that need. Resp. 58 (“Thus, the evidence demonstrates that there was a long felt but unmet need to achieve a device and procedure that would meet the requirements of the claimed invention in the context of TAVR procedures.);

Ex. 2023 ¶ 161 (“In my opinion, the foregoing evidence demonstrates that, after the introduction of TAVR procedures, there was a long felt but unmet need to achieve a device and procedure that would meet the requirements of the claimed invention.”). This circular reasoning is not a proper argument that a claimed invention satisfied a recognized, unfulfilled long-felt need because it would guarantee that a claimed invention cannot fail to meet the third requirement for long-felt need. Therefore, we find that Patent Owner’s evidence of long-felt need is entitled to little weight.

Patent Owner and Dr. Vesely also allege unexpected results but do not cite any particular evidence of unexpected results. Resp. 58; Ex. 2023 ¶ 161. As a result, we cannot evaluate evidence of unexpected results, such as to determine if the asserted evidence is commensurate in scope with the claims. *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005) (A showing of unexpected results generally must be commensurate in scope with a claimed range.). Therefore, we find that Patent Owner’s asserted evidence of unexpected results is entitled to marginal weight.

Having considered both the evidence in favor of obviousness and Patent Owner’s evidence for objective indicia, we determine that a preponderance of the evidence weighs in favor of unpatentability for claim 21. In addition, we emphasize that, although objective indicia must be taken into account, they do not necessarily control the obviousness conclusion. For instance, it has been determined in individual cases that objective evidence of nonobviousness did not overcome a strong prima facie case of obviousness. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010). *See Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir.

2009) (“evidence of unexpected results and other secondary considerations will not necessarily overcome a strong prima facie showing of obviousness.”); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008) (Objective indicia “including substantial evidence of commercial success, praise, and long-felt need, were inadequate to overcome a strong showing of primary considerations that rendered the claims at issue invalid.”); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) (“[T]his secondary consideration does not overcome the strong showing of obviousness in this case. Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion”).

Here, we determine that Petitioner has presented such a case because we find Petitioner’s evidence of obviousness for claim 21 over Salahieh and Sands to be strong. Specifically, Salahieh demonstrates that it was known to use a porcine valve with a catheter size in the claimed range, Sands demonstrates it was known that such a valve would have a leaflet thickness in the claimed range, and Petitioner articulates a sufficient reason to modify Salahieh in view of Sands and that one of ordinary skill in the art would have had a reasonable expectation of success of making the modification. Having considered Patent Owner’s evidence of objective indicia, we also find that it is unable to overcome Petitioner’s strong showing of obviousness. For this additional reason, a preponderance of the evidence weighs in favor of claim 21’s unpatentability.

d) Conclusion as to claim 21

For all of the foregoing reasons and in consideration of evidence favoring obviousness and evidence of nonobviousness, we are persuaded by

Petitioner’s arguments and evidence demonstrating that a person of ordinary skill in the art would have had reason to combine the teachings of Salahieh and Sands, with a reasonable expectation of success in arriving at the subject matter claim 21 recites. As noted above, we also agree with Petitioner’s arguments and evidence that Salahieh and Sands teach or suggest all of the limitations of claim 21. As a result, Petitioner establishes, by a preponderance of evidence, that claim 21 would have been obvious over the combination of Salahieh and Sands.

5. *Claim 22*

Petitioner also alleges that the combined teachings of Salahieh and Sands would have rendered obvious the subject matter of dependent claim 22. Pet. 43–45 (citing claim 21 arguments; Ex. 1024 at [57], 3:35–45, 6:51–56, 8:30–33, 8:50–9:9, 9:12–24, 9:38–41, 9:50–54, Figs. 5D, 5F; Ex. 1002 ¶¶ 97–100).

Patent Owner asserts:

[Petitioner] and Dr. Drasler fail to present any arguments or evidence about whether a person of ordinary skill in the art would have had a reasonable expectation of success combining the teachings of the prior art in order to perform the method of challenged claim 22, which requires translumenally advancing a catheter to a position proximate a native valve of a patient, deploying the cardiovascular prosthetic implant within the patient, and removing the catheter from the patient.

Resp. 35 (citing Pet. 34–35; Ex. 1002 ¶¶ 77–78). Patent Owner argues that, “[g]iven the state of the art discussed above, a person of ordinary skill in the art would not have reasonably expected to successfully deploy a device that relies on the porcine valve leaflets of Sands incorporated into the 17-French catheter of Salahieh.” *Id.* (citing Ex. 2023 ¶ 110).

Petitioner replies by contending that one of ordinary skill in the art “would have expected applying Sands’ teachings to Salahieh’s implant would work as expected, i.e. for endovascular delivery.” Reply 12–13 (citing Pet. 34–35; Ex. 1002 ¶¶ 77–78).

For the reasons discussed above with regard to claim 21, Petitioner establishes, by a preponderance of evidence, that one of ordinary skill in the art would have had a reason to modify Salahieh in view of Sands and that the proposed combination would have had a reasonable expectation of success. Furthermore, having reviewed the information Petitioner provides, including the relevant portions of Dr. Drasler’s declaration, we agree that the cited portions of Salahieh suggest a method of deploying a cardiovascular prosthetic implant that includes translumenally advancing a catheter to a position proximate to a patient’s native valve, deploying a cardiovascular implant within the patient, and removing the catheter from the patient, as claim 22 recites. *See* Ex. 1024, 3:35–45, 9:12–24, 9:38–41, 9:50–54. Furthermore, although Patent Owner argues a lack of reasonable expectation of success, it does not dispute that the cited disclosures teach or suggest claim 22’s limitations. Also, the limitations for the claim 21’s catheter, which claim 22 depends from, would have been obvious in view of Salahieh and Sands, as discussed above with regard to claim 21.

We, therefore, find Petitioner establishes, by a preponderance of the evidence, that claim 22 is unpatentable as obvious in view of the combined teachings of Salahieh and Sands.

E. Remaining Grounds

Having determined that Petitioner establishes by a preponderance of the evidence that claims 21 and 22 would have been obvious over Salahieh

and Sands, we do not address Petitioner’s additional grounds challenging claims 21 and 22. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (“We agree that the Board need not address [alternative grounds] that are not necessary to the resolution of the proceeding.”).

III. CONCLUSION¹⁴

After reviewing the complete record developed during the course of the trial, we conclude that Petitioner demonstrates, by a preponderance of the evidence, that claims 21 and 22 of the ’708 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner establishes by a preponderance of the evidence that claims 21 and 22 of the ’708 patent are 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.

In summary:

¹⁴ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	Reference(s)/Basis¹⁵	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
21, 22	103(a)	Salahieh, Sands	21, 22	
21, 22	103	Leonhardt, Sands		
21, 22	103	Grube, Nguyen		
21, 22	103	Salahieh, Nguyen		
Overall Outcome			21, 22	

¹⁵ In view of our determination that the subject matter of claims 21 and 22 would have been obvious over the combination of Salahieh and Sands, we do not reach Petitioner’s additional grounds challenging these claims.

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