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Paper 9
Date: August 18, 2021

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 MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

ANKENBRAND, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 21 and 22 of U.S. Patent No. 9,603,708 B2 (Ex. 1001, "the '708 patent"). Paper 2 ("Pet."). Speyside Medical, LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). With our approval, Petitioner filed a Reply to the Preliminary Response (Paper 7, "Reply") and Patent Owner filed a Sur-Reply to Petitioner's Reply (Paper 8, "Sur-reply").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2020). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition."

For the reasons set forth below, we determine the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we institute an *inter partes* review.

II. BACKGROUND

A. Related Matters

The parties identify the district court proceeding *Speyside Medical, LLC v. Medtronic CoreValve LLC*, No. 1:20-cv-361-LPS (D. Del.) ("the district court proceeding") as a proceeding involving the '708 patent. 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.*

B. Overview of the '708 Patent

The '708 patent, titled "Low Crossing Profile Delivery Catheter for Cardiovascular Prosthetic Implant," issued on March 28, 2017. Ex. 1001, at [45], [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.

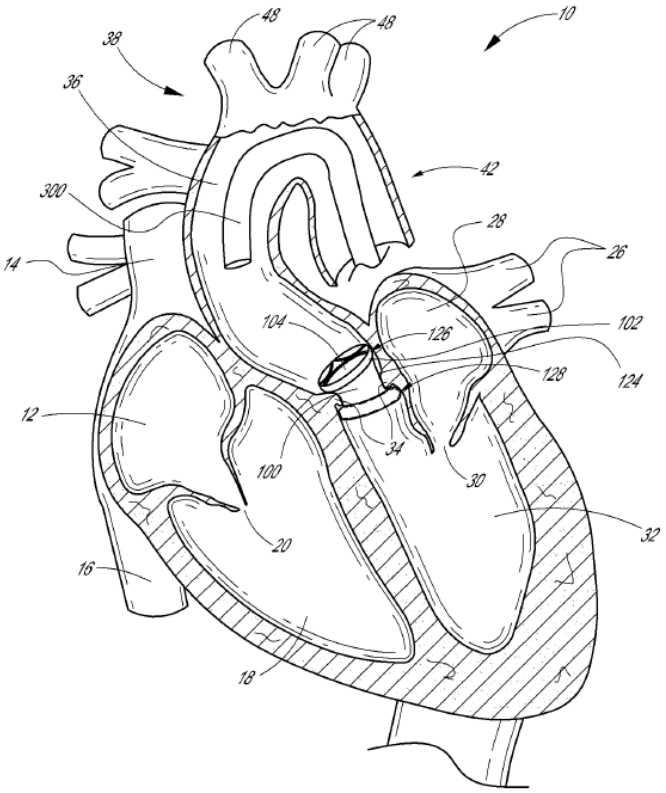


FIG. 2A

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.

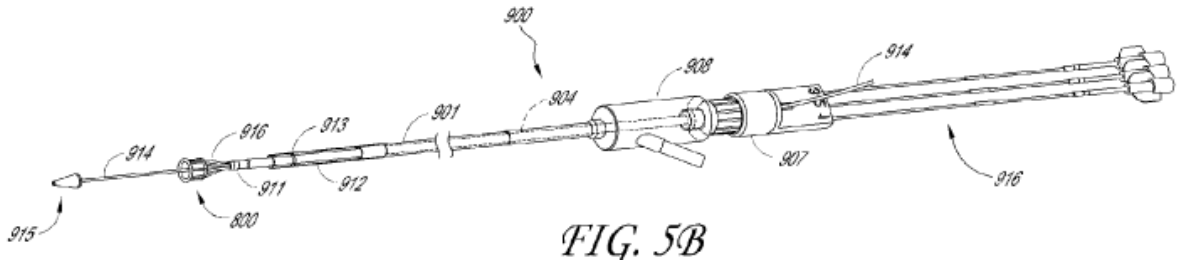


FIG. 5B

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.

C. Illustrative Claim

Petitioner challenges claims 21 and 22 of the '708 patent (collectively, "the challenged claims"). Independent claim 21 is illustrative of the claimed subject matter, and recites:

> 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.

D. Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §	References/Basis
21, 22	103(a)[1]	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

Pet. 13–14. Petitioner relies on the Declaration of Dr. William J. Drasler (Ex. 1002) to support its asserted grounds of unpatentability. Patent Owner disputes that Petitioner's asserted grounds render any of the challenged claims unpatentable. *See generally* Prelim. Resp.

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 103. Because the '708 patent has an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103.
[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).

III. DISCUSSION

A. Level of Ordinary Skill in the Art

Petitioner asserts that:

> 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). Patent Owner applies Petitioner's asserted level of ordinary skill in the art, but reserves the right to present arguments and evidence concerning the level of ordinary skill in the art if we institute a trial. Prelim. Resp. 16 (citing Pet. 23).

We adopt Petitioner's level of ordinary skill in the art because it is consistent with the problems and solutions the '708 patent identifies and with the prior art.

B. Discretion Under 35 U.S.C. § 314(a) Due to Parallel Proceeding

Patent Owner argues that we should exercise discretion to deny institution under 35 U.S.C. § 314(a) in view of the parallel district court proceeding. Prelim. Resp. 4, 39–44. For the reasons stated below, we do not exercise discretion to deny institution in view of the parallel proceeding.

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he

agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("[Section] 314(a) invests the Director with discretion on the question whether to institute review . . . ." (emphasis omitted)); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d at1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

When determining whether to exercise discretion to deny institution in view of a parallel litigation, we consider the following factors:

> 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
>
> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
>
> 3. investment in the parallel proceeding by the court and the parties;
>
> 4. overlap between issues raised in the petition and in the parallel proceeding;
>
> 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
>
> 6. other circumstances that impact the Board's exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). "These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding." *Id.* We address the *Fintiv* factors below and discuss in detail our reasons for not exercising discretion to deny institution based on § 314(a).

1. Likelihood of a stay

Petitioner states that it intends to seek a stay of the district court proceeding pending the outcome of this Petition and other related petitions. Pet. 22. Patent Owner argues, and Petitioner agrees, that the district court has denied Petitioner's motion to stay without prejudice to refile following this decision. Prelim. Resp. 41 (citing Ex. 2020); Reply 1. Petitioner argues, however, that the district court is likely to stay if we institute some or all of the petitions challenging the patents asserted in the district court proceeding. Reply 1.

The record indicates that no stay exists at present in the district court proceeding. We decline to speculate on the likelihood of a stay if Petitioner were to refile its motion in view of this Decision. Accordingly, this factor is neutral.

2. Proximity of trial date to projected statutory deadline

Petitioner argues that trial in the district court proceeding is scheduled for October 2022, and this date is about two months after the date that a Final Written Decision would issue for this proceeding. Pet. 22 (citing Ex. 1036); Reply 1. Patent Owner asserts that Petitioner twice sought to delay the district court proceeding by moving to dismiss Patent Owner's Complaint and Amended Complaint, opposed a motion to file a second Amended Complaint, and objected to setting a case schedule until its motion to dismiss was resolved. Prelim. Resp. 41 (citing Ex. 2010; Ex. 2011; Ex. 2012; Ex. 2013); Sur-reply 2.

The record at this stage indicates a trial date of October 11, 2022, for the district court proceeding, which would occur about two months after the statutory deadline for our final written decision. Ex. 1036, 14. Patent

Owner's arguments that Petitioner's motions in the district court proceeding were designed to delay the district court proceeding in favor of this proceeding are conclusory and not persuasive. Therefore, this factor weighs against exercising our discretion to deny institution.

3. Investment in the parallel proceeding

Petitioner asserts that the district court "has not issued any substantive orders related to the '708 [patent]" and that although Patent Owner has served infringement contentions, Petitioner has not served invalidity contentions (as of the Petition's filing date), "depositions have not begun, and claim construction briefing has not yet begun." Pet. 22 (citing Ex. 1036).

Patent Owner argues that the parties have spent significant time and resources in the district court proceeding because Petitioner filed multiple motions to dismiss, opposed Patent Owner's motion to file an Amended Complaint, and unsuccessfully sought to compel certain discovery that the district court found to be irrelevant. Prelim. Resp. 41–42. Patent Owner contends that the parties are in the midst of claim construction briefing and a *Markman* hearing is scheduled for September 24, 2021. *Id.* at 42 (citing Ex. 1042; Ex. 2018; Ex. 2020). Patent Owner further asserts that the parties served initial discovery requests, produced thousands of pages of documents in fact discovery, served initial infringement and invalidity contentions, and will complete expert discovery and dispositive motions by the deadline for a Final Written Decision. *Id.*

Petitioner responds that the parties will not have held the *Markman* hearing, served final invalidity contentions, or completed fact discovery by this Decision. Reply 1 (citing Ex. 1036).

Patent Owner does not cite evidence to support its arguments regarding the stage of fact and expert discovery and initial infringement and invalidity contentions. Conversely, the record at this stage indicates that the court has rescheduled the *Markman* hearing to October 12, 2021, which will occur after this Decision. Ex. 1068. Further, the record does not indicate that the parties or district court have made more than minimal investments on invalidity issues at this time. Finally, Patent Owner's arguments about investments that will occur *after* this Decision, but prior to any Final Written Decision for this proceeding, are unpersuasive because we consider the investment "at the time of the institution decision" not at some later date. *See Fintiv*, Paper 11, 9–10.

As a result, the parties and the district court have made relatively little investment in the district court proceeding at this time. Therefore, this factor weighs against exercising our discretion to deny institution.

4. Overlap of issues

Petitioner contends that "[t]he same grounds, arguments and evidence could not be presented in litigation after the earlier-expected final written decision." Pet. 22. Patent Owner argues that Petitioner's initial invalidity contentions in the district court proceeding include the same prior art cited in the Petition. Prelim. Resp. 42 (citing Ex. 2014, 25–29; Ex. 2015; Ex. 2016; Ex. 2017). Patent Owner asserts that the Petition does not challenge any claims that are not asserted in the district court proceeding. *Id.* In addition, Patent Owner argues that "the Petition raises claim construction issues that are currently pending before the district court" and "[t]here also is a risk of the district court and the Board reaching different results for the terms 'at

least about 0.011 inches' and the phrase 'a leaflets.'" *Id.* at 42–43 (citing Ex. 1042; Ex. 2018; Ex. 2020).

Petitioner responds that it "recently stipulated that if the Board institutes, Petitioners will not pursue the IPR grounds in the district court litigation." Reply 1 (citing Ex. 1067). Patent Owner contends that Petitioner's stipulation is meaningless because it is not as broad as the scope of estoppel under 35 U.S.C. § 315 and it leaves the same concerns about duplicative proceedings and inconsistent rulings. *Id.* (citing *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 (PTAB June 16, 2020) (informative)).

The record indicates that the references Petitioner asserts in its grounds here are also asserted in the district court proceeding. Ex. 2014, 26–28. Claims 21 and 22 are also asserted in the district court proceeding. Ex. 2015, 2–26. Petitioner, however, stipulates in the district court proceeding that "[i]f the PTAB grants institution of IPR2021-00244, Medtronic will not pursue the same grounds against the patent at issue in that IPR in the corresponding district court litigation." Ex. 1067. Although Petitioner's stipulation is not as broad as the stipulation discussed in *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential), it "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions."[7] *See Sand Revolution II, LLC*, Paper 24 at 12.

[7] In any event, overlap between this proceeding and the district court proceeding may result in greater efficiency because the statutory date for our final written decision falls before the October 2022 trial date in the district

Accordingly, we find this factor weighs against exercising our discretion to deny institution.

5. Identity of parties

Petitioner concedes that the parties for this proceeding and the district court proceeding are the same. Pet. 22. Because the statutory date for our final written decision falls before the October 2022 trial date in the district court proceeding, we find this factor weighs against exercising discretion to deny institution.

6. Other circumstances, including the merits

Petitioner argues that the asserted grounds challenging the claims of the '708 patent are particularly strong. Pet. 22; Reply 1–2. Patent Owner in turn argues that Petitioner fails to account for the Office previously analyzing the same or substantially the same prior art and finding that it did not teach all elements of the claims, which undercuts Petitioner's arguments that the asserted grounds are strong. Sur-reply 1. Patent Owner also asserts that Petitioner's arguments in the Reply exceed the scope of our authorization because they include claim construction arguments. *Id.* at 2.

For the reasons discussed below regarding Petitioner's obviousness challenges, we find Petitioner's grounds to be strong. For example, it is undisputed, on the current record, that the asserted references disclose each limitation of the challenged claims for the respective grounds. And the current record shows that one of ordinary skill in the art would have had a reason to modify Salahieh's or Leonhardt's device to use porcine valves

court proceeding. Thus, Petitioner will be estopped from raising in the district court proceeding any prior art that it raised or reasonably could have raised in this IPR. 35 U.S.C. § 315(e)(2).

with the thickness Sands describes and to modify Grube's or Salahieh's device to use pericardial tissue leaflets with the thickness Nguyen describes with a reasonable expectation of success. *See infra* §§ IIIF–G. Further, as we explain below, *see infra* § III.C., we do not exercise our discretion to deny institution under 35 U.S.C. § 325(d), so we are not persuaded that § 325(d) undercuts the strength of the merits.

Patent Owner's arguments regarding the scope of Petitioner's arguments in the Reply are also unpersuasive. Our authorization to file the Reply and the Sur-reply stated that the briefs should address the *Fintiv* arguments raised in Patent Owner's Preliminary Response. Ex. 2021. Petitioner's arguments in the Reply regard *Fintiv* factor 6, which includes the merits of the grounds raised in the Petition. *See Fintiv*, Paper 11 at 14. We do not view Petitioner's reply arguments addressing this factor, which generally disagree with Patent Owner's position in the Preliminary Response regarding Petitioner's ground, as rearguing the merits of its challenges or bolstering its proposed grounds. Nor do we view Petitioner's reply arguments as directed to claim construction, as Patent Owner argues. Accordingly, this factor weighs against exercising our discretion to deny institution.

7. Conclusion

We have considered the circumstances and facts before us in view of the *Fintiv* factors. Because our analysis is fact-driven, no single factor is determinative of whether we exercise our discretion to deny institution under § 314(a). We take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when evaluating these factors. *Fintiv*, Paper 11, 6. Evaluating all of the factors on this

record, we determine that the circumstances presented here do not support exercising our discretion under § 314(a) to deny institution of *inter partes* review.

C. Discretion under 35 U.S.C. § 325(d)

Petitioner argues that we should not exercise our discretion to deny institution under § 325(d) because the grounds raised in the Petition do not include the same or substantially the same prior art or arguments as were raised during prosecution of the '708 patent. Pet. 19–21. Petitioner argues that, even if the art and arguments are substantially the same, the examiner erred in a manner material to the patentability of the claims. *Id.* at 21. For this latter point, Petitioner contends:

> Specifically, to the extent the Examiner considered references teaching a delivery catheter sized 18 French or smaller ('708FH, 2069), the Examiner erred in failing to reject the claims over a combination of any of those references and art teaching tissue valve leaflets having a thickness of at least about 0.011 inches that were loaded in such catheters, including, for example, **Nguyen** and **Sands**.

Id. at 21–22.

Patent Owner responds that we should deny institution under § 325(d) because the examiner set forth the same obviousness theory during prosecution that Petitioner now asserts. Prelim. Resp. 22–24. Specifically, Patent Owner asserts that the examiner rejected the challenged claims over one reference that discloses an 18-French catheter and another reference that discloses a valve having a leaflet thickness of at least about 0.011 inches. *Id.* (citing Ex. 1003, 326–327, 2065–2067, 2101–2102, 2744–2746; Ex. 1024; Ex. 1020; Ex. 1011; Ex. 1034; Ex. 2005; Ex. 1021; Ex. 1010; Ex. 1007; Pet. 20, 34). Thus, Patent Owner asserts that we "would be analyzing the

same combination of teachings that the Examiner already considered and allowed the claims over." *Id.* at 23.

Patent Owner further contends that Petitioner fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims. *Id.* at 25. According to Patent Owner, Petitioner argues that the Examiner erred by not considering the references Petitioner asserts in the Petition, but Petitioner asserts these references in the same manner as the Examiner asserted the other references. *Id.* at 25–26 (citing Pet. 21–22).

> To evaluate whether to exercise discretion under 35 U.S.C. §325(d), the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

Here, even assuming that the references asserted in the Petition are substantially similar to references presented during prosecution, or that Petitioner's arguments are the same or substantially similar to those presented during prosecution, Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. In particular, we determine that the examiner erred in overlooking references that teach a natural tissue valve comprising leaflets with a thickness of at least about 0.011 inches, which Sands and Nguyen disclose. Thus, we focus our discussion on the second part of the *Advanced Bionics* framework.

Before doing so, we provide a brief summary of the '708 patent's prosecution history.

1. The '708 patent's prosecution history

The examiner rejected claim 21 under 35 U.S.C. § 103(a) over the combination of Osborne, Sarac, and Cai. Ex. 1003, 323–327. Of these references, the examiner relied upon Cai for disclosing a tissue valve having the thickness claim 21 requires. *Id.* at 327. In a second rejection over the combination of Allen, Sarac, and Cai, the Examiner again relied upon Cai for disclosing a tissue valve having the required thickness. *Id.* at 329–330.

In response to the rejections, the applicant argued that "[e]ach cited reference discloses only polymer valves or other biocompatible synthetic valves," not tissue valves. *Id.* at 354. The examiner repeated the § 103 rejections in a further office action. *Id.* at 600–606. In response, the applicant argued that Cai teaches away from using a tissue valve because Cai discloses polymer leaflets as "hav[ing] the potential to overcome the shortcomings of" tissue valve designs. *Id.* at 629. The applicant also argued that combining the asserted references would have led the ordinarily skilled artisan to a "valve with polymer leaflets (not tissue leaflets)" given Cai's disclosure. *Id.* at 629–630.

The Examiner subsequently rejected claim 21 as anticipated by Dobben and as obvious over the combination of Lashinski and Cai. *Id.* at 2063–66. In the latter rejection, the Examiner again relied on Cai for disclosing a tissue valve that had the required thickness. *Id.* at 2067. In response, the applicant argued that Dobben discloses a valve made from nylon disks and, again, argued that Cai teaches away from a tissue valve. *Id.* at 2087–88.

After another office action rejecting claim 21 over Dobben (anticipation) and Lashinski and Cai (obviousness), *id.* at 2095–99,[8] the applicant amended claim 21 to recite "a natural tissue valve comprising a leaflets," *id.* at 2123 (underlining indicates the language the applicant added to claim 21). The applicant also repeated the arguments that neither Dobben nor Cai discloses "natural" tissue leaflets. *Id.* at 2124–25. The applicant did not discuss Lashinski. The examiner subsequently allowed the claims, determining that the prior art failed to teach or render obvious a catheter having "a distal end with a diameter of 18 French or less, a cardiovascular implant with an inflatable cuff, and a natural valve leaflet with a thickness of at least about 0.11 inches, where the implant is loaded in the distal end of the catheter." *Id.* at 2740, 2744.

2. Error material to patentability

Here, Petitioner relies on references disclosing leaflets made from natural tissue (not polymer or synthetic leaflets) for the recited valve leaflet thickness. Petitioner asserts that Sands discloses a mean leaflet thickness of 0.80 mm and 0.70 mm for porcine valve leaflets and that Nguyen discloses a valve prosthesis constructed of porcine, bovine, or equine pericardium with a thickness between 0.012" and 0.014". Pet. 41–42, 58, 74–75, 78 (citing Ex. 1021, 6; Ex. 1010 ¶¶ 23, 49). As noted above, the examiner allowed claim 21 only after the applicant amended the claim to recite "a *natural* tissue valve comprising a leaflets" without a further rejection over prior art

[8] In responding to the applicant's arguments, the examiner found that Lashinski teaches that "the valve can comprise a natural tissue material or a synthetic . . . which would read on Cai's valve. Alternatively, Cai can just read on the given dimensions of a tissue valve" that Lashinski discloses. *Id.* at 2101–2102.

references disclosing a thickness for natural tissue valve leaflets. Ex. 1003, 2123, 2740–2747. The applicant's statements during prosecution further show that the applicant considered the prior art the examiner used to teach the claimed valve thickness in the rejections during prosecution to be directed to polymer and synthetic valves. *Id.* at 354 (distinguishing the applied references from the claims because the applied references disclose only *polymer valves* or other biocompatible *synthetic valves*, whereas the claims are directed to *tissue valves/leaflets*), 2087–88 (same); *see also* Prelim. Resp. 19 ("The record shows that the Applicant repeatedly distinguished the claimed [natural] tissue valves from ***polymer*** or ***synthetic*** valves disclosed in the prior art."). Therefore, Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims by failing to consider references like Sands and Nguyen that disclose natural tissue valves with the recited valve leaflet thickness.

Accordingly, we do not exercise our discretion under § 325(d) to deny institution in this proceeding.

D. Claim Construction

In an *inter partes* review, we construe claim terms according to the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b). Under that standard, 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." *Id.* Furthermore, we expressly construe the claims only to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 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))).

Petitioner discusses the preambles of claims 21 and 22, as well as the terms "at least about 0.011 inches" and "natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure." Pet. 24–26. Patent Owner does not address the preambles, but does discuss "at least about 0.011 inches" and "natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure." Prelim. Resp. 17–20. The parties agree that we need not construe the term "natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure" to resolve their dispute at this stage of the proceeding. Pet. 25; Prelim. Resp. 18 n.1. For purposes of this decision, we need only discuss the term "at least about 0.011 inches."

Petitioner argues that "[r]egardless of the exact metes and bounds of this term, the prior art discloses" leaflets having a thickness of "at least about 0.011 inches." Pet. 24.

Patent Owner responds that Petitioner's claim construction differs from its position in the parallel district court proceeding, where Petitioner asked the district court to find the term indefinite. Prelim. Resp. 17 (citing Ex. 2001; Ex. 2002; Ex. 2004). Patent Owner asserts that this creates a problem because "Petitioner fails to specify any 'metes and bounds' for the claim limitation" and Petitioner "has created the risk that the district court and Board will determine a different scope for the same claim limitation."

Id. Patent Owner argues this favors discretionary denial under § 314(a). *Id.* at 17–18.

Patent Owner's arguments are unpersuasive. A petitioner in an *inter partes* review cannot challenge a claim of a patent under 35 U.S.C. § 112. 35 U.S.C. § 311(b). Therefore, Petitioner is unable to assert here that the challenged claims of the '708 patent are indefinite. In any event, after reviewing the parties' arguments and evidence, we do not need to construe the exact metes and bounds of the limitation "at least about 0.011 inches" in order to resolve the parties' dispute at this stage of the proceeding. *See infra* §§ III.F–G. Thus, Patent Owner's argument that we may construe this claim term to have a different scope than the district court is unavailing, as is Patent Owner's argument that we should deny institution under § 314 for efficiency reasons.

E. Asserted References

Before turning to Petitioner's asserted grounds, we provide a brief summary of the asserted references.[9]

1. 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.

[9] We refer in our discussion to the page numbers Petitioner added to each reference.

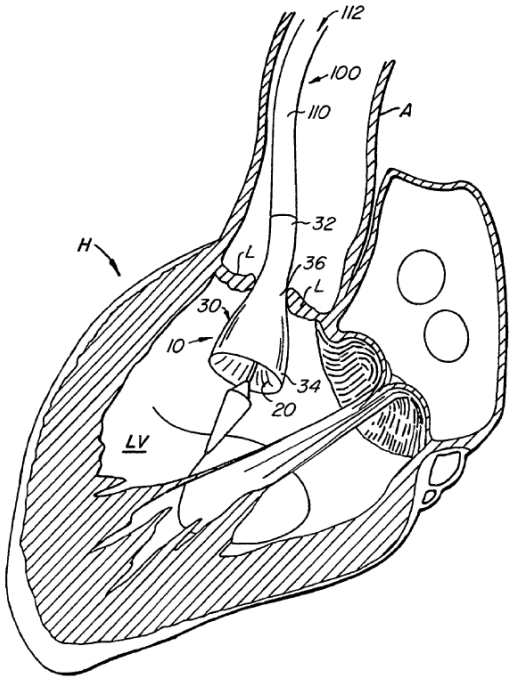


FIG. 5B

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 a 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.

2. 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.

3. Leonhardt (Ex. 1020)

Leonhardt is directed to "artificial valves . . . placed percutaneously by a catheter . . . [to] replace existing valves such as are in the heart." *Id.* at 1:4–7. We reproduce Leonhardt's Figure 4, below.

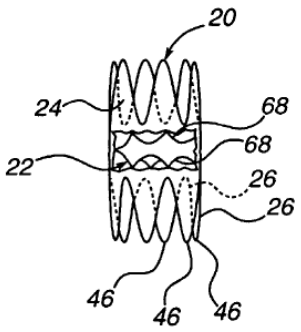


FIG. 4

Figure 4 depicts "a sectional view showing the biological valve within the stent." *Id.* at 3:61–62. "Valve stent 20 comprises a malleable graft material 24 enclosing deformable self-expanding stent 26 to which a biological valve 22 is attached. . . . The deployed valve stent 20 creates a patent one way fluid passageway." *Id.* at 5:45–51. Leonhardt explains that "[b]iological valve 22 is preferably a porcine valve treated and prepared for use in a human." *Id.* at 6:23–24.

We reproduce Leonhardt's Figure 9B below.

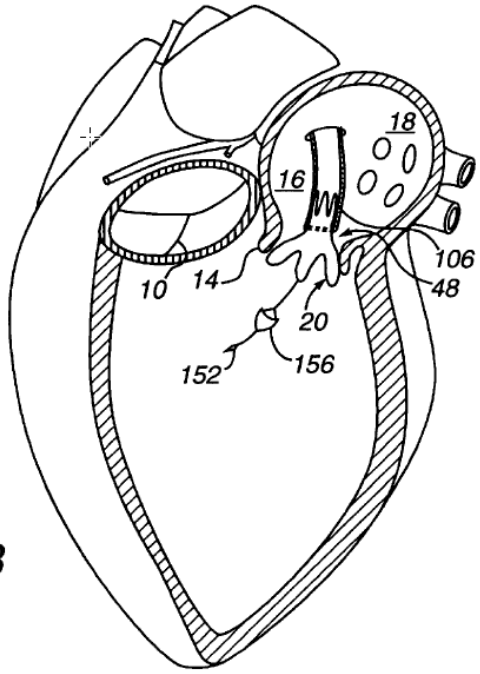


FIG. 9B

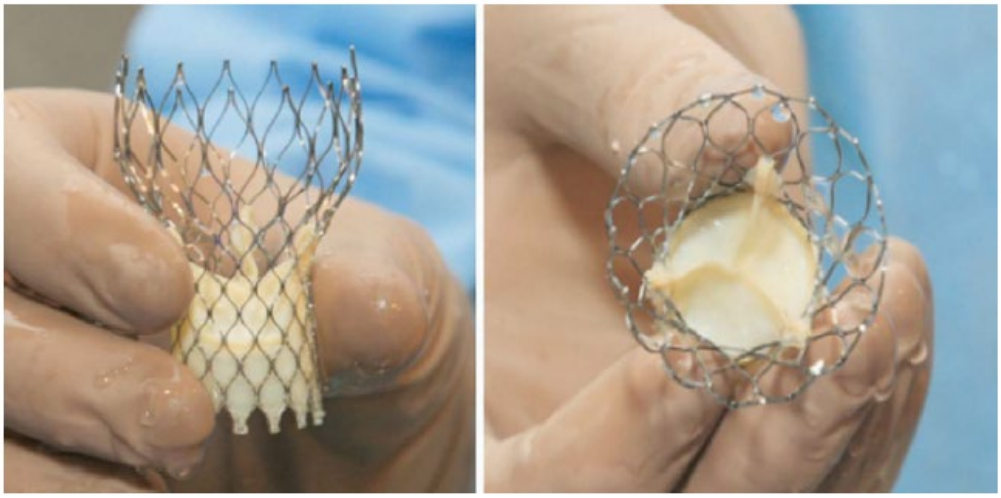
Figure 9B depicts "a method of deploying the valve stent in the mitral valve position." *Id.* at 4:8–10. Deployment catheter 100 (not labeled in Figure 9B), with outer sheath 106, enters the body through a femoral artery (for replacing the aortic valve) and is moved to the heart. *Id.* at 9:50–10:11. Once in position, the distal end of valve stent 20 is deployed by withdrawing outer sheath 106 to allow distensible fingers 46 to self-expand. *Id.* at 10:53–58, Fig. 9B. Leonhardt explains that "[t]he size of outer sheath 106 depends on the size of valve stent 20 to be implanted" but "[c]ommon sizes range from 12 [French] to 20 [French]." *Id.* at 6:55–57.

4. Grube (Ex. 1011)

Grube evaluates "the feasibility, safety, and clinical outcome of implantation of the 21-[French] and 18-[French] self-expanding CoreValve aortic valve prosthesis in high-risk patients with aortic valve disease (stenosis with or without regurgitation) using a retrograde percutaneous transvascular approach." Ex. 1011, 2. Grube explains that "[t]he innovation

of a more flexible delivery catheter for the retrograde approach recently improved the procedural outcome." *Id.* Grube's evaluation compares procedures using an 18-French sheath and procedures using a 21-French sheath. *Id.* at 5–6.

We reproduce Grube's Figure 1 below.



Grube's Figure 1 depicts "[t]he CoreValve aortic valve prosthesis consist[ing] of a trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent." *Id.* at 3 (referring to Fig. 1).

5. Nguyen (Ex. 1010)

Nguyen "relates to replacement valves for improving the cardiac function of a patient suffering from cardiac valve dysfunction, such as aortic valve regurgitation or aortic stenosis." Ex. 1010 ¶ 1. We reproduce Nguyen's Figure 1C below.

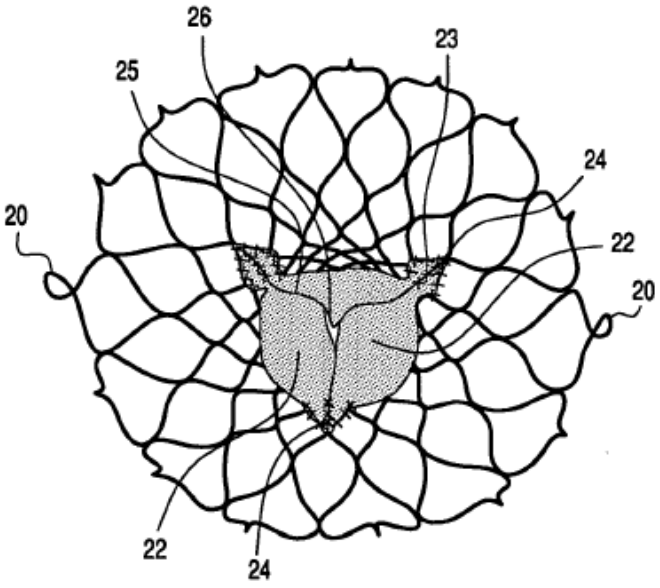


FIG.1C

Figure 1C is a top end view of valve prosthesis 10 that includes expandable frame 12 having valve body 14. *Id.* ¶¶ 31, 39. Valve body 14 includes individual leaflets 22. *Id.* ¶¶ 39, 46. Nguyen teaches that leaflet 22 is preferably "cut from a sheet of animal pericardial tissue, such as porcine pericardial tissue, or synthetic or polymeric material, either manually or using a die or laser cutting system." *Id.* ¶ 49. Nguyen further discloses that "leaflets **22** have a thickness of between 0.008" and 0.016", and more preferably between 0.012" and 0.014"." *Id.*

F. Grounds 1 and 2: Asserted Obviousness Based on Salahieh and Sands or Leonhardt and Sands

Petitioner contends that claims 21 and 22 are unpatentable under 35 U.S.C. § 103(a) because the subject matter of those claims would have been obvious over the combination of Salahieh and Sands or Leonhardt and Sands. Pet. 28–45, 45–61. Patent Owner opposes. Prelim. Resp. 26–39. Having considered the arguments and evidence before us, for the reasons set

forth below, we find that the record establishes a reasonable likelihood that Petitioner will prevail on its asserted grounds.

1. Claim limitations

Petitioner asserts that Salahieh (Ground 1) and Leonhardt (Ground 2) both disclose every limitation of claim 21 except that neither Salahieh nor Leonhardt teaches 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), 45–58 (citing Ex. 1020, 3:15–29, 3:32–37, 4:14–16, 5:41–42, 6:13–17, 6:23–31, 6:34–52, 6:55–61, 6:66–67, 7:11–20, 8:14–17, 9:50–55, 10:64–67, Figs. 4, 5, 9A; Ex. 1002 ¶¶ 106–124).[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).[11] Petitioner also asserts that Salahieh and Leonhardt both disclose the additional limitations of claim 22. *Id.* at 42–45 (citing 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 ¶¶ 94–96), 58–61 (citing Ex. 1020 at [57], 1:4–8, 3:15–29, 4:8–10, 9:64–67, 10:3–11, 10:44–45, 10:48–50, 10:53–11:32, 11:63–12:5, Figs. 9C–9D; Ex. 1002 ¶¶ 125–131).

[10] In these grounds, Petitioner points to Salahieh's and Leonhardt'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.*, Pet. 39 (discussing Salahieh), 57 (discussing Leonhardt).
[11] We cite to the page numbers that Petitioner added to Sands.

At this stage of the proceeding, Patent Owner does not contest Petitioner's arguments or evidence that Salahieh and Sands or Leonhardt and Sands teach or suggest each limitation of claim 21, and that Salahieh and Leonhardt teach the additional limitations of claim 22. *See generally* Prelim. Resp. On the current record, we find Petitioner shows sufficiently that Salahieh and Sands (Ground 1) and Leonhardt and Sands (Ground 2) disclose each limitation of the challenged claims.

2. Reason to modify and reasonable expectation of success

The nub of the parties' dispute centers on whether Petitioner shows sufficiently: (1) that one of ordinary skill in the art would have had a reason to modify Salahieh's or Leonhardt'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. Reason to modify Salahieh's or Leonhardt's device in view of Sands

Petitioner contends that one of ordinary skill in the art would have applied Sands's 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 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 makes similar arguments for the combination of Leonhardt and Sands. *Id.* at 48–52.

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 (citing 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 identified 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's valve leaflets in Leonhardt's replacement valve 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 "[t]he Petition fails to demonstrate that the prior art 'suggested the selection and combination'" of a delivery catheter having an outer diameter of 18 French or less and a natural tissue valve having a leaflet thickness of at least about 0.011 inches. Prelim. Resp. 26–27. Specifically, Patent Owner contends that Salahieh and Leonhardt are

silent regarding any desired dimensions for its replacement valve and do not indicate a desired thickness for its valve or leaflets. *Id.* at 27 (citing Ex. 1024, 6:29–41), 29 (citing Ex. 1020, 6:23–31). Patent Owner asserts that "at best," Salahieh and Leonhardt each contain "only a general motivation to use" a relatively narrow delivery catheter "without any consideration of prosthetic valve thicknesses that the catheter might be able to accommodate for a given French size." *Id.* at 27 (citing Ex. 1024, 6:29–41), 29 (citing Ex. 1020, 6:23–31).

Patent Owner further contends that Sands does not provide this missing teaching because "Sands provides a general survey comparing anatomical characteristics of human, pig, calf, and sheep valves," "Sands does not teach that the reported thickness values are desired or should be used instead of, for example, tissue valves with narrower dimensions," and "Sands does not suggest that all porcine valve leaflets will have the reported thickness values such that a general motivation to use porcine valves would necessarily lead a person of ordinary skill in the art to the claimed leaflet thickness." *Id.* at 28 (citing Ex. 1021, 1–2) (emphasis omitted). And Patent Owner argues that "Sands is not concerned with surgical delivery of the artificial valves, so it does not discuss or contemplate how variables like catheter size impact valve selection." *Id.* (citing Ex. 1021, 1).

The evidence of record supports Petitioner's argument that the ordinarily skilled artisan, seeking to improve upon Salahieh's or Leonhardt's replacement valve, would have had reason to use Sands's porcine valve leaflets as the leaflets of Salahieh's or Leonhardt's replacement valve. Salahieh and Leonhardt each disclose forming the replacement valve from porcine valve leaflets. Ex. 1024, 6:11–16, 6:29–30; Ex. 1020, 6:23–24.

Sands teaches porcine valve leaflets with a mean thickness of 0.80 mm (0.031 inches) and 0.70 mm (0.028 inches), i.e., "at least about 0.011 inches." 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, concluding 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's porcine valve leaflets in Salahieh's or Leonhardt'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. Thus, at this stage of the proceeding, Petitioner articulates a supported reason to combine.

b. 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). Petitioner makes similar arguments for the combination of Leonhardt and Sands. *Id.* at 51–52 (citing Ex. 1020, 6:23–24, 6:42–51, 6:55–57; Ex. 1021, 6; Ex. 1002 ¶ 110).

Patent Owner argues that Petitioner fails to establish a reasonable expectation of success in combining an 18-French delivery catheter with a 0.011-inch natural tissue valve. Prelim. Resp. 32–34; *see supra* § III.F.1.a. For example, Patent Owner asserts that Petitioner and Dr. Drasler provide no analysis of how Salahieh's catheter would have accommodated a tissue valve having the thickness Sands discloses, such as "testing or measurements of the catheter to show whether it could or could not accommodate a valve having the claimed thickness." *Id.* at 33–34 (citing Pet. 34; Ex. 1002 ¶¶ 76–78). Patent Owner further asserts that "[e]ach ground of the Petition suffers from the same lack of analysis and failure to address the claimed invention as a whole." *Id.* at 34. These arguments are unpersuasive because they attempt to engraft onto the obviousness analysis a level of success beyond what is required. "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).

Patent Owner also contends that Petitioner's "reasonable expectation of success argument appears to rely on a theory that the thickness of ***any*** porcine valve leaflet is ***necessarily*** at least about 0.011 inches" and Petitioner "has not met the 'high standard' of showing that all porcine aortic valves are necessarily 0.011 inches thick or greater." Prelim. Resp. 35 (citing Pet. 35). Patent Owner continues that Sands's porcine valve measurements "were taken from a limited sample size of ten pigs" and

"[t]hus, Sands does not establish that all porcine valves necessarily have the reported thickness." *Id.* at 36 (citing Pet. 27–35; Ex. 1021, 1).

Patent Owner's arguments are unpersuasive because Sands discloses mean porcine leaflet thickness measurements of 0.80 mm and 0.70 mm. Ex. 1021, 6. In other words, Sands demonstrates it was known that porcine valve leaflets had a thickness overlapping the claimed leaflet thickness range. In the context of an *inter partes* review, overlapping ranges disclosed in the prior art create a presumption of obviousness, which a patent owner may rebut by showing that the claimed range is critical, i.e., it produces an unexpected result "different in kind and not merely in degree from the results of the prior art," that the prior art teaches away from the claimed range, or other relevant evidence of nonobviousness. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006, 1008 (Fed. Cir. 2018). At this stage of the proceeding, Patent Owner does not rebut the presumption.

In addition, Patent Owner appears to mischaracterize Petitioner's contentions as relying on an inherency theory. In any event, the inherency standard on which Patent Owner relies applies to whether a reference teaches or discloses certain subject matter, not to whether an ordinarily skilled artisan would have had a reasonable expectation of success in combining the teachings of the asserted references.

We further disagree with Patent Owner's contentions that Petitioner's arguments are conclusory. *See* Prelim. Resp. 36–37. As we explain above, Petitioner presents arguments addressing each limitation of the challenged claims and asserts reasons why one of ordinary skill in the art would have made the proposed combination with a reasonable expectation of success

with evidentiary support from Dr. Drasler and the asserted references. Pet. 35–41.

Accordingly, Petitioner establishes a reasonable likelihood that it would prevail in showing the unpatentability of claims 21 and 22 over the combined disclosures of Salahieh and Sands (Ground 1) and Leonhardt and Sands (Ground 2).[12]

G. Grounds 3 and 4: Asserted Obviousness Based on Grube and Nguyen or Salahieh and Nguyen

Petitioner contends that claims 21 and 22 are unpatentable under 35 U.S.C. § 103(a) because the subject matter of those claims would have been obvious over the combination of Grube and Nguyen (Ground 3) and Salahieh and Nguyen (Ground 4). Pet. 62–77, 77–80. Patent Owner opposes. Prelim. Resp. 26–39. Having considered the arguments and evidence before us, for the reasons set forth below, we find that the record establishes a reasonable likelihood that Petitioner will prevail on its asserted grounds.

[12] Patent Owner also asserts that Petitioner fails to meet its burden of explaining "how the challenged claims should be construed and how the construed claims are unpatentable" because Petitioner does not define the scope of the term "at least about 0.011 inches." Prelim. Resp. 37–39. As we explain in § III.D above, however, we do not need to construe the exact metes and bounds of that limitation in order to resolve the parties' dispute at this stage of the proceeding. Indeed, Patent Owner does not dispute Petitioner's assertion that 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 for porcine aortic valves. Pet. 41–42.

1. Claim limitations

Petitioner asserts that Grube (Ground 3) and Salahieh (Ground 4) both disclose every limitation of claim 21, except that neither Grube nor Salahieh teaches a leaflet "thickness of at least about 0.011 inches." Pet. 69–75 (citing Ex. 1011, 69–74, 76, Figs. 1, 2A; Ex. 1002 ¶¶ 146–154), 77–78 (referring back to Pet. §§ X.A.1, X.A.3, X.C.2–3 and evidence discussed therein).[13] To address that limitation, Petitioner contends that Nguyen teaches a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches because Nguyen discloses a valve prosthesis that includes individual leaflets having a thickness of preferably between 0.012 inches and 0.014 inches and preferably constructed of porcine, bovine, equine, or other mammalian tissue, such as pericardial tissue. *Id.* at 74–75 (citing Ex. 1010 ¶¶ 23, 39, 49, 56, Figs. 1C, 6; Ex. 1002 ¶¶ 139–145, 155–160). Petitioner also asserts that Grube and Salahieh both disclose the additional limitations of claim 22. *Id.* at 76–77 (citing Ex. 1011, 69–72, 74–76; Ex. 1002 ¶¶ 161–163), 77–78.

At this stage of the proceeding, Patent Owner does not contest Petitioner's arguments or evidence that Grube and Nguyen or Salahieh and Nguyen teach or suggest each limitation of claim 21, and that Grube and Salahieh teach the additional limitations of claim 22. *See generally* Prelim. Response. On the current record, we find Petitioner shows sufficiently that Grube and Nguyen (Ground 3) and Salahieh and Sands (Ground 4) disclose each limitation of the challenged claims.

[13] In these grounds, Petitioner points to Grube's and Salahieh's disclosure of using porcine pericardial tissue to form the replacement valve and leaflets as corresponding to the limitation "a natural tissue valve comprising a leaflets." Pet. 73–74 (discussing Grube), 78 (discussing Salahieh).

2. Reason to modify and reasonable expectation of success

Similar to Grounds 1 and 2, the parties' dispute centers on whether Petitioner shows sufficiently that one of ordinary skill in the art would have had a reason to modify Grube's or Salahieh's prosthesis to include leaflets having the thickness Nguyen discloses, and whether the ordinary artisan would have reasonably expected success in achieving the claimed device. We address those issues below.

a. Reason to Modify Grube's or Salahieh's Prosthesis in view of Nguyen

Petitioner's arguments are similar to those Petitioner presents as to Grounds 1 and 2. Specifically, Petitioner argues that one of ordinary skill in the art would have applied Nguyen's teachings regarding the thickness of leaflets formed from porcine pericardial tissue to Grube's or Salahieh's porcine pericardial tissue valve to yield the predictable benefit of a functional natural tissue valve that deliverable via Grube's or Salahieh's catheter. Pet. 66–67 (citing Ex. 1010 ¶ 56, Figs. 1C, 6; Ex. 1011, 69–70, Fig. 1; Ex. 1002 ¶¶ 140–143; Ex. 1009, 48; Ex. 1013), 79 (explaining that Nguyen provides additional detail for the thickness of porcine, bovine, or equine pericardial tissue).

Petitioner further contends that Nguyen teaches that its device allows for a durable valve usable with a delivery sheath having a diameter less than 20–24 French and that its valve has a smaller delivery profile than that achievable with previous valves. *Id.* at 67–68 (citing Ex. 1010 ¶¶ 48–49, 65; Ex. 1002 ¶ 144), 79 (Nguyen teaches that its device permits a "smaller delivery profile than achievable with previously-known replacement valves"). In view of this, Petitioner argues that one of ordinary skill in the

art would have been led to use valve leaflets with the thickness Nguyen for teaches in Grube's valve and catheter. *Id.* at 68.

As to the combination of Grube and Nguyen, Patent Owner argues that Petitioner fails to establish a motivation to combine because Grube discusses CoreValve's efforts to reduce the diameter of a stent's delivery catheter, but "Grube is silent regarding any desired dimensions of the prosthetic valve" and "does not indicate a desired thickness for the valve or its leaflets." Prelim. Resp. 30–31 (citing Ex. 1011, 1–3; Pet. 63). Patent Owner further asserts that although "Nguyen describes tissue valves with a thickness between 0.008 and 0.016 inches," "[i]mportantly, however, Nguyen teaches that these valves are used with delivery catheters having a diameter of 20-24 French." *Id.* at 31 (citing Ex. 1010 ¶¶ 49, 65). Patent Owner contends that "both Grube and Nguyen are directed to the CoreValve prosthetic valve delivery system" but "it is clear that the state of CoreValve's technology prior to the invention of the '708 Patent relied on a larger 20-24 French delivery catheter to accommodate valve thicknesses between 0.008 and 0.016 inches." *Id.* (citing Pet. 62; Ex. 1010 ¶¶ 49, 65; Ex. 1011, 3).

As to the combination of Salahieh and Nguyen, Patent Owner argues that the references "at best" provide separate disclosures of individual elements, but "do not teach the 'selection and combination' of those elements as required to establish obviousness." *Id.* at 32 (citation omitted). Patent Owner also repeats its argument that although "Nguyen describes tissue valves with a thickness between 0.008 and 0.016 inches," it does so "only in connection with delivery catheters having a diameter of 20-24 French." *Id.* (citing Ex. 1010 ¶¶ 49, 65).

The evidence of record supports Petitioner's argument that the ordinarily skilled artisan would have had reason to use Nguyen's porcine pericardial tissue valve leaflets as the leaflets of Grube's or Salahieh's replacement valve. Both Grube and Salahieh disclose replacement valves made from porcine pericardial tissue, but do not disclose the thickness of the valve leaflets. Ex. 1011, 3; Ex. 1024, 6:29–32. Nguyen discloses a heart valve prosthesis (the same prosthesis as in Grube and a similar prosthesis to Salahieh) that includes a valve body skirt and leaflets preferably "constructed of porcine, bovine, equine or other mammalian tissue, such as pericardial tissue." Ex. 1010 ¶ 23. Nguyen teaches that the leaflets "have a thickness of between 0.008" and 0.016"." *Id.* ¶ 49. Nguyen also teaches that its prosthetic can be loaded into catheters "having a diameter of *less than* 20-24 French," not merely 20–24 French, as Patent Owner argues. Ex. 1010 ¶ 65 (emphasis added); Prelim. Resp. 31. And Nguyen explains that its device advantageously permits "a smaller delivery profile than achievable with previously-known replacement valves." Ex. 1010 ¶ 48. Nguyen, therefore, demonstrates that its device is suitable for Grube's and Salahieh's catheter sizes, i.e. those less than 20 French. Nguyen also expressly provides a reason for using its valve leaflets in Grube's and Salahieh's prostheses—to provide an improved delivery profile. Thus, at this stage of the proceeding, Petitioner articulates a supported reason to combine.

b. Reasonable Expectation of Success

Petitioner argues that applying Nguyen's teachings of CoreValve porcine pericardial leaflets to the CoreValve leaflets of Grube's prosthetic valve would have yielded "the predictable result of a functional natural tissue valve deliverable using **Grube**'s reduced profile catheter." Pet. 69.

Petitioner further explains that pericardial tissue thickness was well known. *Id.* (citing, e.g., Ex. 1002 ¶ 145). Petitioner makes similar arguments as to Salahieh and Nguyen. *Id.* at 78–80.

Specific to the Grube and Nguyen ground, Patent Owner argues that Nguyen "contradicts any argument that there would have been a reasonable expectation of success" because Nguyen discloses that the valve thickness ranging between 0.008 and 0.016 inches only works with a larger catheter diameter of 20–24 French. Prelim. Resp. 34. As we explain above, however, Nguyen teaches that its prosthetic can be loaded into catheters "having a diameter of *less than* 20-24 French." Thus, Patent Owner's argument is not persuasive.

Patent Owner's argument is also unpersuasive because Nguyen demonstrates it was known to use in a delivery catheter porcine pericardial tissue with leaflet having a thickness overlapping the claimed leaflet thickness range. Ex. 1010 ¶ 49; *see* Prelim. Resp. 31 (Patent Owner acknowledging, "both Grube and Nguyen are directed to the CoreValve prosthetic delivery system"). The overlapping thickness range creates a presumption of obviousness. *E.I. DuPont de Nemours*, 904 F.3d at 1006, 1008. At this stage of the proceeding, Patent Owner does not rebut the presumption.

Patent Owner does not present any arguments specific to the Salahieh and Nguyen ground that differ from the arguments it presents as to the Salahieh and Sands ground. *See* Prelim. Resp. 32–37. We find Patent Owner's arguments unpersuasive for the same reasons we provide in § III.F.2.a.

Accordingly, Petitioner establishes a reasonable likelihood that it would prevail in showing the unpatentability of claims 21 and 22 over the combined disclosures of Grube and Nguyen (Ground 3) and Salahieh and Nguyen (Ground 4).

IV. CONCLUSION

For the foregoing reasons, Petitioner demonstrates a reasonable likelihood that claims 21 and 22 of the '708 patent are unpatentable over the prior art of record. Accordingly, we institute an *inter partes* review of claims 21 and 22 on all grounds asserted in the Petition.

V. ORDER

It is hereby

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 21 and 22 of the '708 patent is instituted with respect to all grounds of unpatentability asserted in the Petition commencing on the entry date of this decision; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of trial.

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