Trials@uspto.gov
571-272-7822

Paper 11
Entered: March 10, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC COREVALVE LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

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IPR2020-01454
Patent 9,125,739 B2

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Before ERICA A. FRANKLIN, JAMES A. TARTAL, and ERIC C. JESCHKE, *Administrative Patent Judges.*

TARTAL, *Administrative Patent Judge*.

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

# I. INTRODUCTION

Medtronic CoreValve LLC ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–5 ("the Challenged Claims") of U.S. Patent No. 9,125,739 B2 (Ex. 1001, "the '739 patent"). Paper 2 ("Pet."). Colibri Heart Valve LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). With our prior authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 8, "Reply") to address Patent Owner's arguments about discretionary denial under § 314(a), and Patent Owner filed a Sur-reply (Paper 9, "Sur-reply).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the Challenged Claims. Accordingly, we authorize an *inter partes* review to be instituted as to the Challenged Claims of the '739 patent on the grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

## II. BACKGROUND

### *A. The '739 Patent*

The '739 patent, titled "Percutaneous Replacement Heart Valve and a Deliver and Implantation System," issued September 8, 2015, from Application No. 14/253,650 ("the '650 Application"), filed April 15, 2014. Ex. 1001, codes (21), (22), (45), (54). The replacement heart valve device described by the '739 patent "comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent." *Id.* at 4:64–5:1.

Figure 5 of the '739 patent is reproduced below.

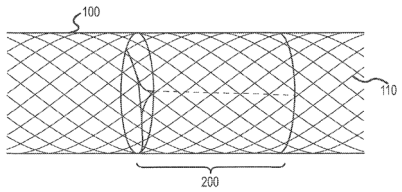


FIG.5

Figure 5 illustrates a side view of a replacement heart valve device mounted within a self-expanding stent in the expanded position. Ex. 1001, 6:31–34. "The replacement heart valve device comprises a stent member 100 and a flexible valve means 200." *Id.* at 6:55–57. "The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration." *Id.* at 7:32–33. The stent member may be a meshwork of nitinol wire formed into a tubular structure that "flares markedly at both ends in a trumpet-like configuration." *Id.* at 7:55–63. The "trumpet-like configuration" is not illustrated in Figure 5, or in any other figure of the '739 patent.

The valve means comprises "a generally tubular portion" and, "preferably, a peripheral upstanding cusp or leaflet portion." *Id.* at 6:61–64. The valve means is "flexible, compressible, host-compatible, and non-

thrombogenic." *Id.* at 8:27–28. It may be made from various materials, preferably mammal pericardium tissue. *Id.* at 8:28–35. The cusp or leaflet portion of the valve means is generally tubular in shape and comprises two to four leaflets. *Id.* at 7:5–8. The cusp or leaflet portion of the valve means is "formed by folding the pericardium material used to create the valve." *Id.* at 8:44–46. "The starting material is preferably a flat dry sheet, which can be rectangular or other shaped." *Id.* at 8:47–49. The cusps/leaflets "open in response to blood flow in one direction and close in response to blood flow in the opposite direction." *Id.* at 8:49–51.

Figure 8 of the '739 patent is reproduced below.

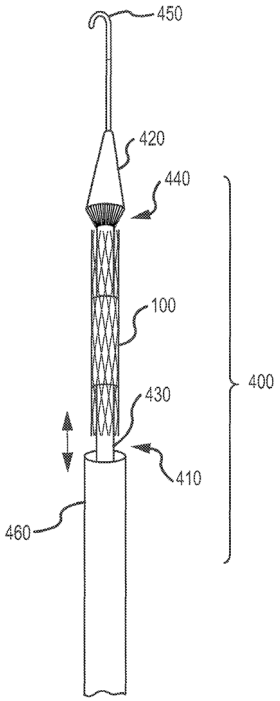


FIG.8

Figure 8 illustrates the "delivery and implantation system of the replacement artificial heart valve," including "flexible catheter 400 which may be

inserted into a vessel of the patient and moved within that vessel." *Id.* at 11:40–44. The '739 patent further explains as follows:

> The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand.

*Id.* at 11:44–62.

### *B. Illustrative Claim*

Petitioner challenges claims 1–5 of the '739 patent. Pet. 1. Claim 1 is independent and claims 2–5 depend from claim 1. Ex. 1001, 14:2–38. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

> 1. An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
>
> a prosthetic heart valve including:
>
> a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and
>
> a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides

entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

*Id.* at 14:2–29.

### *C. Asserted Grounds of Unpatentability*

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

| Claim(s) Challenged | 35 U.S.C. § | Reference(s)/Basis |
|---|---|---|
| 1–5 | 103 | Garrison[1] |
| 1–5 | 103 | Garrison, Leonhardt[2] |
| 1–5 | 103 | Garrison, Nguyen[3] |
| 1–5 | 103 | Garrison, Leonhardt, Nguyen |

[1] U.S. Patent No. 6,425,916 B1, issued July 30, 2002 (Ex. 1005, "Garrison").
[2] U.S. Patent No. 5,957,949, issued September 28, 1999 (Ex. 1006, "Leonhardt").
[3] U.S. Patent No. 5,961,549, issued October 5, 1999 (Ex. 1020, "Nguyen").

| Claim(s) Challenged | 35 U.S.C. § | Reference(s)/Basis |
|---|---|---|
| 1–3, 5 | 103 | Andersen,[4] Limon,[5] Gabbay[6] |
| 1–3, 5 | 103 | Andersen, Limon, Phelps[7] |
| 1–3, 5 | 103 | Andersen, Limon, Phelps, Nguyen |
| 4 | 103 | Andersen, Limon, Gabbay, Garrison |
| 4 | 103 | Andersen, Limon, Phelps, Garrison |
| 4 | 103 | Andersen, Limon, Phelps, Nguyen, Garrison |

Pet. 10–11. We refer to the grounds based on Garrison, alone or in combination with Leonhardt and/or Nguyen (i.e., the first four grounds in the table above) as the "Garrison Grounds," and the six grounds including Andersen and Limon as the "Andersen/Limon Grounds." Petitioner relies on the supporting Declaration of William J. Drasler, Ph. D., dated September 1, 2020. Ex. 1002.

*D. Related Proceedings*

The parties identify the '739 patent as a subject of *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847 (C.D. Cal., filed May 4, 2020) (the "CDCA Case"). Pet. 7; Paper 4, 1. In addition to the '739 patent, U.S. Patent No. 8,900,294 ("the '294 patent") is also a subject of the CDCA Case. The '739 patent and the '294 patent were each issued from applications that were continuations of U.S. Application No. 13/675,665, and have substantially the same specification. The '294

[4] U.S. Patent No. 5,840,081, issued November 24, 1998 (Ex. 1013, "Andersen").
[5] U.S. Patent No. 6,077,295, issued June 20, 2000 (Ex. 1008, "Limon").
[6] U.S. Patent No. 7,025,780 B2, issued April 11, 2006 (Ex. 1009, "Gabbay").
[7] WO 00/15147, published March 23, 2000 (Ex. 1010, "Phelps").

patent was challenged in a petition for *inter partes* review that was recently denied. *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, IPR2020-001453, Paper 11 (PTAB Mar. 5, 2021). The '739 patent is also challenged in *Edwards Lifesciences Corp. and Edwards Lifesciences LLC v. Colibri Heart Valve LLC*, IPR2020-01649 (filed Sept. 18, 2020) (decision on institution of petition pending). Paper 4, 1.

### *E. Real Parties in Interest*

Petitioner identifies itself and Medtronic Inc., as real parties in interest. Pet. 7. Patent Owner identifies no additional real parties in interest. Paper 4, 1

## III. ANALYSIS

### *A. Discretionary Denial of the Petition Under 35 U.S.C. § 314(a)*

Patent Owner argues we should exercise our discretion under § 314(a) to deny institution due to the common issues being litigated in the CDCA Case with respect to the '739 patent. Prelim. Resp. 15–28; Sur-reply 1–5. Petitioner argues discretionary denial of the Petition is not warranted. Pet. 22; Reply 1–5. For the reasons that follow, we decline to exercise our discretion to deny the Petition under § 314(a).

35 U.S.C. § 314(a) states that

> [t]he Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

The language of § 314(a) expressly provides the Director with discretion to deny institution of *inter partes* review. *See 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 v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding."); Consolidated Trial Practice Guide November 2019 ("TPG"),[8] 55.

In considering whether to exercise discretion to deny institution under § 314(a), we consider an early trial date in related litigation as part of an assessment of all relevant circumstances of the case, including the merits, in an effort to balance considerations such as system efficiency, fairness, and patent quality. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 5–6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"); *see also NHK Spring Co. v. Intri-Plex Techs., Inc*., IPR2018-00752, Paper 8, 19–20 (PTAB Sept. 12, 2018) (precedential) (denying institution relying, in part, on § 314(a) because the parallel district court proceeding was scheduled to finish before the Board reached a final decision) ("*NHK*"). In considering whether to institute trial when there is a parallel, co-pending district court case, the Board evaluates the following factors ("*Fintiv* 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;

[8] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

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.

*Fintiv*, 5–6. In evaluating these *Fintiv* factors, "the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at 6.

We have considered the circumstances and facts before us in view of the *Fintiv* factors and determine that the circumstances presented in this proceeding, in light of the CDCA Case, do not weigh in favor of exercising our discretion under § 314(a) to deny institution of *inter partes* review for the following reasons.

1. *Whether the Court Granted a Stay or Evidence Exists that a Stay may be Granted if a Proceeding is Instituted*

"If a court has denied a defendants' motion for a stay pending resolution of a PTAB proceeding, and has not indicated to the parties that it will consider a renewed motion or reconsider a motion to stay if a PTAB trial is instituted, this fact has sometimes weighed in favor of exercising authority to deny institution." *Fintiv*, 7–8. After the Petition was filed, the district court denied Petitioner's motion to stay the CDCA Case during a Status Conference held on November 17, 2020. *See* Ex. 2009 ¶ 6. Further, no evidence exists that a stay may be granted if we were to institute *inter partes* review. To the contrary, the undisputed evidence shows that the district court set a trial date of September 14, 2021, "which the [district court] indicated at the Status Conference would not move under any circumstances." Ex. 2004, 2.

Petitioner argues that the district court's denial was not in writing and that "the judge has contemporaneously continued other trial dates in light of

COVID" in other cases. Reply 1. In response, Patent Owner argues that whether the district court denial was in writing "is of no moment," because the court "denied the stay orally during the 11/17/20 conference, and subsequently entered a scheduling order 'maintaining the September 14, 2020 jury trial date,' which is consistent with his denial of the stay motion." Sur-reply 1 (citing Ex. 2009 ¶ 6; Ex. 2003, 2–4). We agree with Patent Owner that the evidence shows Petitioner's request for a stay was denied and that the absence of a written order does not suggest otherwise.

Patent Owner also argues that the circumstances in which a stay has been entered in other district court cases are distinguishable from the CDCA Case and that the Board has stated "when a district court has denied a motion to stay and has not indicated it would reconsider if an [IPR] is instituted, the facts underlying this factor weigh in favor of denying institution." Sur-reply 2 (quoting *Apple Inc. v. Pinn, Inc.*, IPR2020-00999, Paper 15, 8 (PTAB Dec. 8, 2020)). We agree with Patent Owner. The Board has explained, "[a] judge determines whether to grant a stay based on the facts of each specific case as presented in the briefs by the parties." *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, 12 (PTAB May 13, 2020) (informative) ("*Fintiv* DDI"). Accordingly, the Board has declined "to infer, based on actions taken in different cases with different facts," how the district court would rule on a requested stay. *Id.* In this proceeding there is no need to speculate on how the district court *would rule*, because the district court *has ruled* and has denied Petitioner's motion for a stay.

We agree with Patent Owner that the district court unambiguously denied Petitioner's motion for a stay, as confirmed by the subsequently entered scheduling order, which maintains the September 14, 2021 trial date. We do not accept Petitioner's invitation to speculate whether a stay will

eventually be entered in the CDCA Case. Indeed, as Patent Owner has shown, the district court conveyed in no uncertain terms that the September 2021 trial date "would not move under any circumstances." Ex. 2004, 2. We do not take it upon ourselves to question that statement. We find that the denial of Petitioner's motion to stay the CDCA Case and the district court's directive that the trial date "would not move under any circumstances" weighs in favor of exercising our discretion to deny institution under § 314(a).

2. *Proximity of the Court's Trial Date to the Board's Projected Statutory Deadline for a Final Written Decision*

As stated in *Fintiv*, "[i]f the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution." *Fintiv*, 9. There is no dispute that the trial in the CDCA Case is scheduled to begin on September 14, 2021, which is nearly six months before a Final Written Decision would be due in this proceeding. *See* Ex. 2004, 2.

Petitioner argues that the trial date is uncertain because "Petitioner is not aware of any C.D. Cal. trials since 3/23/2020—creating a backlog of 9+ months," and "the average time to trial for patent cases in the district is 2 years 8 months." Reply 2. In response, Patent Owner argues that the Board generally takes the district court schedule "at face value absent some strong evidence to the contrary," that the district court has indicated no intent to handle a backlog of cases by disrupting currently-scheduled cases, and that the CDCA Case has proceeded in accordance with the existing schedule with the appointment of a Technical Special Master to conduct a *Markman* hearing on February 1, 2021. Sur-reply 2–3 (quoting *Fintiv DDI*, 13).

The evidence shows that Petitioner's request for a stay of the CDCA Case was denied and that the parties were told that the trial date "would not move under any circumstances." Ex. 2004, 2. We find no persuasive evidence to suggest that the district court, in reaching its decision to deny the stay, was unaware of the backlog of cases caused by COVID or of the potential for additional trial delays due to future circumstances.

The evidence also shows that the trial date of the CDCA Case is scheduled to be earlier than the projected statutory deadline for a final written decision in this proceeding by nearly six months, and that there is persuasive evidence that the trial date will not be changed if *inter partes* review were to be granted, which are considerations that weigh in favor of exercising our discretion to deny institution under § 314(a). *See, e.g.*, *NHK*, 20 (finding that the advanced state of the district court case, which was set to go to trial approximately six months before the Board's final decision would be due, weighed in favor of denial); *GlobalFoundries Inc. v. UNM Rainforest Innovations*, IPR2020-00984, Paper 11, 11–16 (PTAB Dec. 9, 2020) (finding that a scheduled trial date four months before the statutory deadline for a final written decision was a factor weighing in favor of discretionary denial); *NanoCellect Biomedical, Inc. v. Cytonome/ST, LLC*, IPR2020-00551, Paper 19, 16 (PTAB Aug. 27, 2020) (same).

*3. Investment in the Parallel Proceeding by the Court and the Parties*

Under this factor we first consider Petitioner's timing in filing the Petition. If a petitioner, "faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition," that decision "may impose unfair costs to a patent owner." *Fintiv*, 11. On the other hand, "[i]f the evidence shows that the petitioner filed the petition expeditiously, such as promptly after becoming aware of

the claims being asserted, this fact has weighed against exercising the authority to deny institution." *Id.*

Petitioner contends that the "Petition was filed 4 months after the complaint was served (Ex. 1036, *4) and over 2 months before initial responses to both infringement and invalidity interrogatories were due." Reply 2. Patent Owner argues that the relevant date is not when the complaint was served, but when Petitioner was aware of the asserted claims, which Patent Owner contends occurred when it filed, but did not serve, its "original complaint" nine months prior to the date the Petition was filed. Sur-reply 4. Petitioner responds that even with respect to the date the unserved "original complaint" was filed, "the Petition still would have been over 3 months before the bar date." Reply 3.

We consider the date the "original complaint" was filed to suggest Petitioner was aware of claims that may be asserted, but find those claims were not "being asserted" until a complaint was served. We find no unreasonable delay in Petitioner's prompt filing of the Petition only four months after the complaint was served. *See Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15, 12–13 (PTAB Jan. 9, 2020) (finding petitioner was diligent in filing the petition within two months of patent owner narrowing the asserted claims in the district court proceeding); *Illumina, Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19, 8 (PTAB Dec. 18, 2019) (finding petitioner was diligent in filing the petition several months before the statutory deadline and in response to the patent being added to the litigation in an amended complaint). Accordingly, we find that Petitioner filed the Petition promptly after becoming aware of the claims being asserted, which is a consideration that weighs in favor of not exercising our discretion to deny the Petition.

Second, under this factor we also consider "the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision." *Fintiv*, 9. "Specifically, if, at the time of the institution decision, the district court has issued substantive orders related to the patent at issue in the petition, this fact favors denial." *Id.* at 9–10.

Patent Owner argues that the parties and court have devoted significant resources to the CDCA Case, including full briefing on a motion to dismiss certain counts, serving discovery requests, exchanging discovery, service of invalidity contentions, filing a joint claim construction chart, and the court's appointment of a Technical Special Master whose fees and expenses will be apportioned between the parties. Prelim. Resp. 21. Patent Owner further argues that before an institution decision is due, the parties will have completed claim construction, a *Markman* hearing and technology tutorial will have taken place, fact discovery will have closed, and the parties will have filed any discovery motions under the court's scheduling order. *Id.* at 21–22; *see also* Ex. 2005, 2–4 (CDCA Case order setting case schedule). Petitioner responds that "the district court case will be at most only half-way complete" when an institution decision is due. Reply 3.

We find that the parties and court have invested substantial time and resources, particularly with regard to the appointment of a Technical Special Master and the conduct of a *Markman* hearing, but also find no evidence that any substantive determinations on validity issues have been made in the CDCA Case. Further, according to the CDCA Case order, expert discovery has not yet started. Ex. 2005, 2. On balance, we find that the timeliness of the Petition and the level of investment of time and resources in the CDCA Case by the parties and the court, coupled with the absence of any

substantive determinations on validity issues by the court, suggests consideration of this factor is neutral with respect to our discretion to deny institution under § 314(a).

4. *Overlap Between Issues Raised in the Petition and in the Parallel Proceeding*

*Fintiv* states "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial [of institution]." *Fintiv*, 12. Patent Owner argues that Petitioner's grounds for review "rely on a subset of the same art at issue in" the CDCA Case. Prelim. Resp. 24–25 (citing Ex. 2009 ¶ 9).

Petitioner argues that it has proposed a stipulation that "mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions." Reply 3–4 (quoting *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 21 (PTAB Dec. 1, 2020) (precedential in relevant part)). Specifically, Petitioner's stipulation provides as follows:

> Medtronic stipulates that, if the Patent Trial and Appeal Board institutes inter partes review on IPR2020-01454, then Medtronic will not pursue in the corresponding district court case the specific grounds identified in the Petition in IPR2020-01454 in connection with the '739 patent claims challenged in the Petition, or on any other ground that was raised or could have been reasonably raised as to these claims in an IPR (i.e., any ground that was raised or could have been reasonably raised under Sections 102 or 103 on the basis of prior art patents or printed publications).

Ex. 1025, 1. In response Patent Owner argues that Petitioner's proposed stipulation "does nothing but reiterate the estoppel already prescribed by 35 U.S.C. §315(e)(2)," and "is toothless and nowhere promises it will

'cease asserting the prior art references relied upon in the petitions.'" Sur-reply 5.

We find that Petitioner has the better positon here. Petitioner unequivocally stipulates that it will "not pursue in the corresponding district court case the specific grounds identified in the Petition . . . or any other ground that was raised or could have been reasonably raised." Ex. 1025, 1. Considering that Petitioner has agreed to be bound by a stipulation that is substantively the same as the stipulation addressed in *Sotera*, we follow the *Sotera* precedent in finding that this factor weighs strongly against discretionary denial. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Exhibit 1038, 7–8.

5. *Whether Petitioner and the Defendant in the Parallel Proceeding are the Same Party*

According to *Fintiv*, "[i]f a petitioner is unrelated to a defendant in an earlier [district] court proceeding, the Board has weighed this fact against exercising discretion to deny institution." *Fintiv*, 13–14. There is no dispute that the parties to this proceeding and to the CDCA Case are the same. Pet. 22; Prelim. Resp. 26. Thus, this factor weighs in favor of exercising our discretion to deny institution under § 314(a).

6. *Other Circumstances that Impact the Board's Exercise of Discretion, Including the Merits*

The final *Fintiv* factor is a catch-all that takes into account any other relevant circumstances. A full merits analysis is not necessary as part of deciding whether to exercise discretion not to institute, but we consider particular "strengths or weaknesses" in deciding whether the merits tip the balance one way or another. *See Fintiv*, 15–16. Petitioner asserts that the Petition is "particularly strong," because the '739 patent admits "that the majority of the limitations were known in the art." Pet. 22. We fail to

discern why, even if accurate, a petition would be considered "particularly strong" merely because the challenged patent allegedly admits that "the majority" of the limitations were known in the art where unpatentability cannot be shown by establishing only that "the majority" of the limitations were known in the art.

Patent Owner argues that "the Petition suffers from numerous deficiencies warranting denial on the merits," and identifies claimed elements it contends are not shown in the prior art, as well as disputes the purported motivation to combine certain references. Prelim. Resp. 27–28. Patent Owner also argues that "Petitioner ignores that, during prosecution, the PTO considered Garrison and Leonhardt and rejected the crux of Petitioner's arguments." Sur-reply 5; *see also* Prelim. Resp. 29 (asserting that during prosecution of the '739 patent the Examiner rejected claims over Garrison and that "Leonhardt formed the basis of rejections in the '739 patent application's sister application" before the same Examiner).

Having considered Petitioner's and Patent Owner's arguments, and based on the limited record before us, we find that these "other" factors favor not exercising our discretion to deny institution. As discussed in detail *infra*, we determine, on this record, that Petitioner has demonstrated a likelihood of prevailing on its patentability challenges of at least one claim of the '739 patent. We find that the merits of the Petition are neither strong nor weak, and, accordingly, determine that this factor weighs neither in favor nor against exercising discretion to deny institution of *inter partes* review.

7. *Holistic Analysis of Fintiv Factors*

We undertake a holistic analysis of the *Fintiv* factors, considering "whether efficiency and integrity of the system are best served by denying or

instituting review." *Fintiv*, 6. We determine that the facts in this case that weigh against exercising discretion outweigh the facts that favor exercising discretion Accordingly, we determine that the circumstances presented weigh against denying institution under § 314(a).

*B. Discretionary Denial of the Petition Under 35 U.S.C. § 325(d)*

Patent Owner argues we should "deny Grounds 1–4 [the Garrison Grounds] under § 325(d)." Prelim. Resp. 28. Patent Owner also states that it "acknowledges that Grounds 5–10 [the Andersen/Limon Grounds] involve different art and arguments," but argues that Petitioner fails to show a reasonable likelihood of prevailing on the Andersen/Limon Grounds. *Id.* at 28 n.1. Petitioner concedes that Garrison was relied upon by the Examiner to reject claims during the prosecution of the '739 patent, but contends that its arguments concerning Garrison are based on an embodiment not considered by the Examiner and that the Examiner committed multiple errors material to patentability. Pet. 16–21. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 29–34.

In evaluating arguments under § 325(d), we use a 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). In applying the two-part framework, we consider the non-exclusive factors set forth in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)

(precedential in relevant part), which "provide useful insight into how to apply the framework" under § 325(d). *Advanced Bionics*, Paper 6 at 9. Those non-exclusive factors include:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

*Becton*, Paper 8 at 17–18. "If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office." *Advanced Bionics*, Paper 6 at 10.

Regarding the Garrison Grounds, Petitioner acknowledges that the Examiner rejected the claims over Garrison, and, therefore, Garrison was previously presented to the Office. Pet. 17–18. Petitioner argues that

Leonhardt was not previously presented to the Office during the prosecution of the '739 patent, whereas Patent Owner argues that Leonhardt was previously presented to the Office during the prosecution of the '739 patent's sister application. Prelim. Resp. 29. The record, however, is silent as to the similarity of the claimed subject matter in each application, and whether Leonhardt was before the Office in determining the patentability of the '739 patent claims. The parties do not present persuasive arguments as to whether Nguyen was previously presented to the Office. We determine that Garrison was previously presented to the Office, and the record is insufficiently developed to determine whether Leonhardt and Nguyen were previously presented to the Office. Accordingly, we proceed to the second part of the *Advanced Bionics* framework. *See Advanced Bionics*, Paper 6 at 10 ("[I]f the record of the Office's previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something").

Petitioner argues that the Examiner erred in a manner material to the patentability of the '739 claims by overlooking Garrison's teaching of the feature of "no reinforcing members reside within the inner channel of the stent member." Pet. 19–21. Petitioner specifically points to support structure 26 as a stent that does not have any reinforcing members within its inner chamber, and potentially having the same features of the valve displacer. *Id.* at 19. Petitioner further argues that Leonhardt discloses these same features. *Id.* at 20.

Patent Owner argues that the amendment to the claims to include the feature of "no reinforcing members reside within the inner channel of the stent member" is not the feature on which the Examiner allowed the claims. Prelim. Resp. 32. Patent Owner argues that the Examiner allowed the claims

based on the Examiner's suggested amendment that resulted in the limitation of "the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient." *Id.*

We are persuaded, on this preliminary record, that Garrison discloses both limitations. As discussed in more detail below, Garrison discloses that valve portion 38 resides within support structure 26 both when the replacement valve is collapsed and after it is deployed. Pet. 36–39, 42–43; *see infra* Section III.F.4. As such, we determine that the Examiner erred in a manner material to the patentability of the claims of the '739 patent by overlooking these disclosures of Garrison.

Regarding the Andersen/Limon Grounds, Patent Owner acknowledges these grounds "involve different art and arguments." Prelim. Resp. 28 n.1. Accordingly, because Petitioner has demonstrated that the Examiner erred in a manner material to the patentability of the claims with respect to the Garrison Grounds, and the Andersen/Limon Grounds do not present art or arguments that are the same or substantially the same as previously presented to the Office, we decline to exercise discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

### *C. Legal Standards of Obviousness*

A patent claim is unpatentable under 35 U.S.C. § 103[9] if the differences between the claimed subject matter and the prior art are such

[9] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '739 patent issued has an

that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103 that requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18; *KSR*, 550 U.S. at 407. At this stage of the proceeding, neither party presents evidence directed to secondary considerations. *See* Pet. 78; *see also generally* Prelim. Resp.

*D. Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art at the time of the invention 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 percutaneously, transluminally implantable cardiac prosthetic

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effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies.

> devices. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

Pet. 18 (citing Ex. 1002 ¶¶ 30–33.). Patent Owner does not dispute Petitioner's definition of a person of ordinary skill in the art in its Preliminary Response. Prelim. Resp. 3.

We adopt Petitioner's definition as we find it is consistent with the level of skill in the art at the time of the invention as reflected by the prior art and the '739 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

### *E. Claim Construction*

We apply the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317.

Petitioner asserts that all claim terms in the Challenged Claims should receive their plain and ordinary meanings. Pet. 23. Petitioner discusses three claim terms. *Id.* at 24–25. For the term "trumpet-like," Petitioner asserts only that the prior art discloses the limitation regardless of its exact metes and bounds. *Id.* at 24. Patent Owner notes the construction Petitioner proposed in district court, without taking a position on it. Prelim. Resp. 13.

Petitioner also argues that "valve means" and "controlled release mechanism" are not means-plus-function limitations. Pet. 24–25. Petitioner also identifies the structure it contends the '739 patent discloses that corresponds to these limitations. *Id.* Patent Owner does not contest Petitioner's construction in its Preliminary Response. Prelim. Resp. 13–14.

We find that an express construction of any claim term is not necessary for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed '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)).

### *F. The Garrison Grounds*

Petitioner asserts that claims 1–5 are rendered obvious by (a) Garrison alone; (b) Garrison in view of Leonhardt; (c) Garrison in view of Nguyen; and (d) Garrison in view of Leonhardt and Nguyen. Pet. 27–52. Patent Owner challenges each of those contentions. Prelim. Resp. 34–53, 62–66.

#### *1. Summary of Garrison*

Garrison is "directed to methods and devices for implanting replacement cardiac valves." Ex. 1005, 1:5–6. Garrison explains that "[a]n object of the present invention is to provide additional devices and methods which reduce the trauma associated with conventional open-chest methods

and devices for implanting cardiac valves." *Id.* at 1:49–52. Figures 1–12 of Garrison illustrate features of "a system for implanting a cardiac valve," while figures 13–15 illustrate features of "another system for implanting another cardiac valve." *Id.* at 2:60–3:22; *see also id.* at 3:23–4:6 (describing figures 16–22 as illustrating "another system for implanting a cardiac valve," figures 23–30 as illustrating "another system for implanting a cardiac valve," and figures 31 –38 as illustrating "another system for delivering a cardiac valve").

Figure 2 of Garrison is reproduced below.

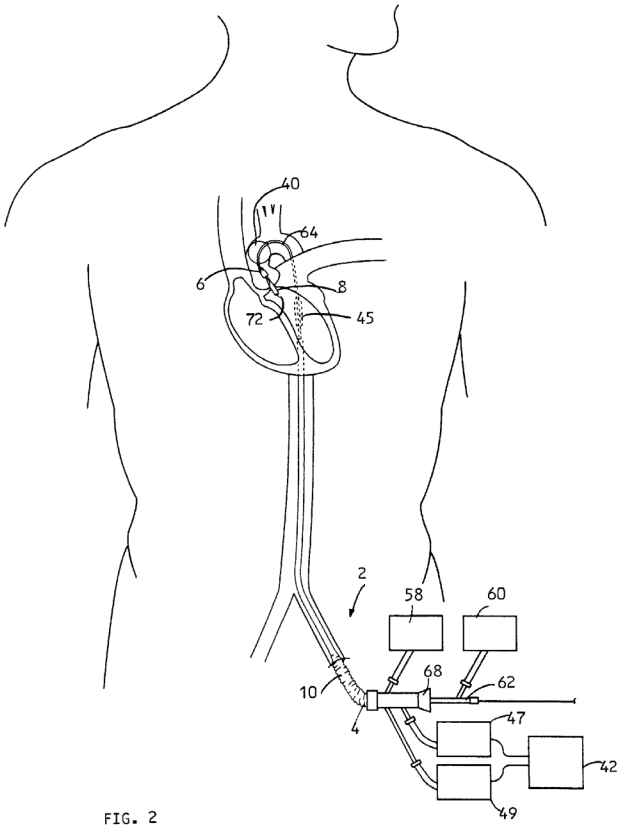


FIG. 2

Figure 2 illustrates "a system for implanting a cardiac valve," with a sheath retracted to expose the cardiac valve, a valve displacer and a temporary valve mechanism. According to Garrison, system 2 includes delivery catheter 4, cardiac valve 6, valve displacer 8, and protective sheath 10,

which "covers the delivery catheter 4, cardiac valve 6 and valve displacer 8 during introduction to prevent contact between the blood vessel and the cardiac valve 6 and valve displacer 8." *Id.* at 4:14–19. Garrison states "valve displacer 8 is expanded within the native valve to hold the native cardiac valve leaflets 6 open," but further provides that the native valve may be removed "rather than using the valve displacer 8." *Id.* at 4:46–52. Garrison further states "valve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately," and "[t]hus all features of any valve displacer described herein may also form part of any of the cardiac valves described herein." *Id.* at 4:52–54.

Figures 7 and 8 of Garrison are reproduced below.

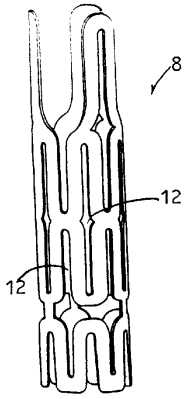


FIG. 7

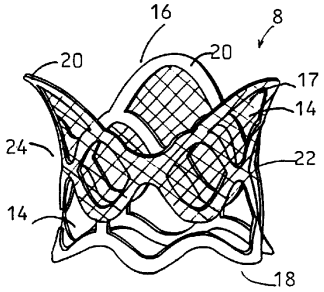


FIG. 8

Figures 7 and 8 illustrate valve displacer 8 in the collapsed condition and the expanded condition, respectively. *Id.* at 4:58–60. According to Garrison, "first and second ends 16, 18 of the valve displacer 8 flare outwardly to form a circumferential recess 24 at a central section 22," and provides that although the flare ends are preferred, "valve displacer 8 may have any other suitable shape which holds the leaflets open." *Id.* at 4:66–5:1, 5:11–14.

Figures 9 and 10 of Garrison are reproduced below.

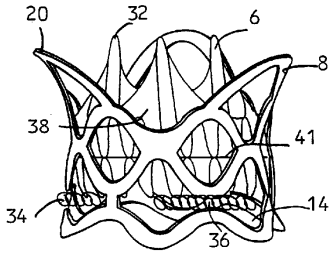


FIG. 9

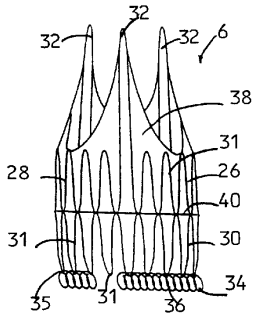


FIG. 10

Figures 9 and 10 illustrate cardiac valve 6 includes expandable support structure 26 with protrusions 34 in an expanded condition and a collapsed condition, respectively. *Id.* at 5:20–22, 30–32. "Protrusions 34 engage the openings 14 in the valve displacer 8 as shown in [Figure] 9 to secure the cardiac valve 6 to the valve displacer 8." *Id.* at 5:32–34. "[S]upport structure 26 may also have barbs to secure the cardiac valve 6 to the valve displacer 8 or to the blood vessel wall." *Id.* at 5:36–39. A delivery catheter with first and second expandable members is used to deploy valve displacer 8 and cardiac valve 6, respectively. *Id.* at 6:36–38; Figs. 3–6; *see also id.* at 7:49–8:9 (detailing that valve displacer 8 is placed between the valve leaflets and expanded to hold the native valve leaflets open, after which a "second catheter" is advanced until valve 6 is positioned adjacent valve displacer 8 where the second catheter is manipulated to until protrusions 34 of valve 6 engage openings 14 in displacer 8).

Figures 13 and 14 of Garrison are reproduced below.

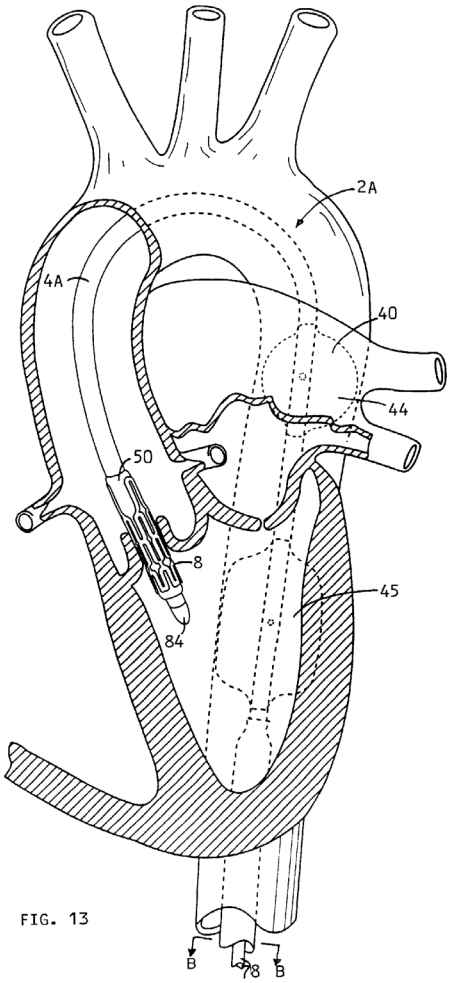


FIG. 13

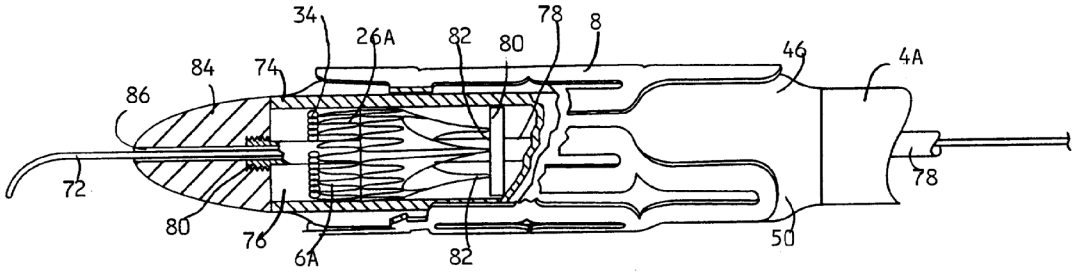


FIG. 14

Figure 13 illustrates "another system for implanting another cardiac valve," and Figure 14 illustrates a "partial cut-away view of the catheter" of Figure 13 "with the valve contained in a chamber." *Id.* at 3:16–19. Cardiac

valve 6A is similar to cardiac valve 6 described above; however, cardiac valve 6A "is self-expanding and, therefore, does not require an independent expansion mechanism." *Id.* at 8:13–16. "[C]atheter 4A has the expandable member 46, which is preferably the balloon 50, for expanding the valve displacer 8." *Id.* at 8:21–23. Garrison explains as follows:

> The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A. The cardiac valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by advancing a rod 78 having a pusher element 80 attached thereto. The pusher element 80 engages the posts 82 on the cardiac valve 6A to move the cardiac valve 6A out of the chamber 76. The rod 78 has threaded connections 80, 82 with a tip 84 and the pusher element 80 to facilitate assembling the delivery catheter 4A and loading the cardiac valve 6A in the chamber 76. The rod 78 has a guidewire lumen 86 for receiving the guidewire 72.

*Id.* at 8:24–34. "The cardiac valve 6A is implanted in substantially the same manner as the cardiac valve 6." *Id.* at 8:45–47; *see also id.* at 8:53–64 (describing how valve 6A is placed and secured after displacer 8 is expanded in place).

*2. Summary of Leonhardt*

Leonhardt, titled "Percutaneous Placement Valve Stent," describes an artificial valve, including "a tubular graft having radially compressible annular spring portions for biasing proximal and distal ends of the graft into conforming fixed engagement with the interior surface of a generally tubular passage." Ex. 1006, codes (54), (57).

Figures 2 and 4 of Leonhardt are reproduced below.

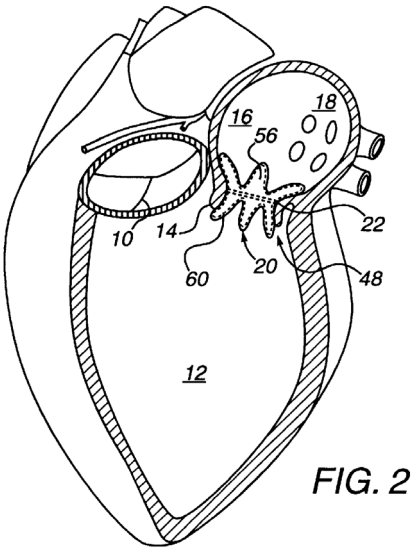


FIG. 2

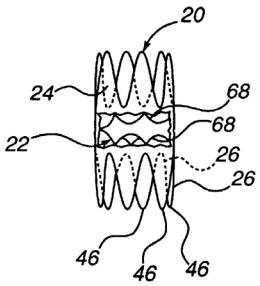


FIG. 4

Figure 2 illustrates a "valve stent fully deployed within the mitral valve," and figure 3 illustrates a sectional view of a "biological valve within the stent." *Id.* at 3:57–58, 61–62. As shown in Figure 4, valve stent 20 includes stent 26, biological valve 22, and graft material 24. *Id.* at 4:15–17. According to Leonhardt, as shown in Figure 2, "[s]tent 26 biases the proximal and distal ends of valve stent 20 into conforming and sealingly fixed engagement with the tissue of mitral valve 14," and the "deployed valve stent 20 creates a patent one way fluid passageway." *Id.* at 5:48–52.

*3. Summary of Nguyen*

Nguyen, titled "Multi-Leaflet Bioprosthetic Heart Valve," relates "to methods and apparatuses for selecting individual pericardial leaflets for a multi-leaflet hear valve prosthesis. Ex. 1020, code (54), 1:5–9. In relevant part, Nguyen teaches as follows:

> Bio-prosthetic valves may be formed from an intact, multi-leaflet porcine (pig) heart valve, or by shaping a plurality of individual leaflets out of bovine pericardial tissue and combining the leaflets to form the valve. The pericardium is a sac around the heart of vertebrate animals, and bovine (cow) pericardium is

> commonly used to make individual leaflets for prosthetic heart valves. The bovine pericardium is first harvested from the animal and then chemically fixed to crosslink collagen and elastin molecules in the tissue and increase the tissue durability, before being cut into leaflets. Various physical characteristics of the tissue may be examined before or after fixation.

*Id.* at 1:28–39.

*4. Alleged Obviousness over Garrison Alone*

Petitioner provides a claim chart identifying how Garrison allegedly teaches each limitation of claim 1 and its dependent claims 2–4. Pet. 26–46. Petitioner's contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 73–131. For the reasons discussed below we find Petitioner's contentions sufficiently show how Petitioner contends Garrison teaches each limitation of the Challenged Claims, and we direct our discussion to the arguments Patent Owner presents in opposition.

*a. Independent Claim 1*

> *An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:*

Petitioner contends, and Patent Owner does not yet dispute, that, to the extent the preamble of claim 1 is limiting, Garrison teaches "devices for implanting replacement cardiac valves," including a delivery catheter 4A with a guidewire lumen 86, corresponding to the preamble of claim 1. Pet. 32–33 (citing Ex. 1005, 1:5–6, 3:5–6, 4:11–22, 7:29–33, 8:25–34, Fig. 6; Ex. 1002 ¶¶ 89–91).

> *a prosthetic heart valve including:*
> *a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from a*

> *central portion that flares at both ends in a trumpet-like configuration; and*

Petitioner contends that support structure 26A of Garrison corresponds to the recited stent member. Pet. 32–36 (citing, e.g., Ex. 1005, 5:19–21, 8:10–18, Fig. 10; Ex. 1002 ¶¶ 92–95). With regard to the recited "trumpet-like configuration," Petitioner argues that Garrison teaches valve displacer 8 with flares at both ends in a trumpet-like configuration, and further teaches that the support structure may have all features of the valve displacer. Pet. 35–36 (citing Ex. 1005, 2:5–10, 4:52–65, Fig. 8; Ex. 1002 ¶¶ 96–99). Petitioner contends as follows:

> a [person of ordinary skill] would have understood, and at minimum found it obvious, that Garrison discloses a support structure that "flare[s] outwardly" in a similar manner in order to have the same features as the displacer and at minimum would have been motivated to use a support structure having this structure to advantageously conform the valve to the valve displacer or vessel walls in light of this disclosure." [Ex. 1005], 4:52–57, 4:66–5:1; [Ex. 1002] ¶¶ 98-99. Alternatively, a [person of ordinary skill] would have understood, and at minimum found it obvious, that Garrison also discloses an integrated valve displacer and cardiac valve such that the support structure "flare[s] outwardly," and the other discussions regarding the support structure in claim 1 similarly apply to the embodiment integrated with the valve displacer. [Ex. 1005], 2:5–10, 4:52–57; [Ex. 1002] ¶ 99.

Pet. 35.

Patent Owner argues that "the ends of Garrison's stent member flare like discrete tulip petals, rather than a tubular structure like a trumpet, and so do not disclose" a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration, as required by claim 1. Prelim. Resp. 62–63. Patent Owner notes that "Petitioner appears to contend that 'trumpet-like' means a tubular structure with ends that 'flare markedly,'" but

Patent Owner does not expressly dispute that construction or propose an express construction of its own. *Id.* at 13. For purposes of this Decision we are persuaded that Petitioner has sufficiently shown how Garrison teaches a structure with a "trumpet-like configuration." We note in this regard that Petitioner argues, with respect to other asserted grounds, that Gabbay teaches stent portion 14 that "will 'flare outwardly' at the ends in its expanded state" (Pet. 57–58 (citing Ex. 1009, Fig. 2)), and that Patent Owner has not yet disputed that Gabbay teaches a stent "that flares at both ends in a trumpet-like configuration" (Prelim. Resp. 62–66). On the current record we are not persuaded that the structure of Garrison is distinguishable from the structure of Gabbay given that Petitioner has shown both flare outwardly in a similar manner. The proper construction of "trumpet-like configuration" is an issue the parties may develop in support of their arguments during trial.

> *a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;*

Petitioner contends valve portion 38 of Garrison corresponds to the recited "valve means." Pet. 36–39 (citing, e.g., Ex. 1005, 5:42–50, Figs. 10, 11; Ex. 1002 ¶ 103). In particular, Petitioner asserts that Figures 10 and 11 of Garrison illustrate valve 38 residing entirely within the inner channel of the stent member. *Id.* at 38.

> *a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath,*

*wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and*

Corresponding to the recited "delivery system," Petitioner contends that Garrison teaches "delivery catheter 4A," including a pusher member (rod 78 with pusher element 80), a moveable sheath (the "outer wall" of catheter 4A), and a guidewire lumen (guidewire lumen 86). Pet. 39–42. Petitioner provide an annotated version of Figure 14 of Garrison to show how Garrison teaches the distal end of a "prosthetic heart valve" is located at the distal end of a moveable sheath. Pet. 41. In the annotated figure Petitioner colors green valve 6A and support structure 26A as corresponding to the recited "prosthetic heart valve." *Id.*

Patent Owner argues that Petitioner is improperly combining teachings from Figure 14 of Garrison, which pertains to a device to separately deploy the valve and the valve displacer, for this limitation while relying on teachings related to an integrated valve/valve displacer embodiment for other limitations. Prelim. Resp. 48–50. We reject this argument for the reasons discussed below, most notably, because it misrepresents Petitioner's contentions, which do not turn on an integrated valve/valve displacer embodiment of Garrison.

Patent Owner's second argument is even more dubious. Patent Owner argues that Petitioner "mislabeled the entire stent as the valve, in order to make it appear that the valve's distal end is at the distal end of the sheath." *Id.* at 50–53. Claim 1 recites "a prosthetic heart valve including: a stent member . . . and a valve means." Thus, where claim 1 recites "a distal end of the prosthetic heart valve" it includes, by the express language of claim 1, both a stent and valve means.

> *wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.*

Petitioner contends that valve portion 38 of Garrison resides within support structure 26 both when the replacement valve is collapsed and after it is deployed. Pet. 42–43 (citing, e.g., Ex. 1005, 3:53–56, 5:42–50, Figs. 10, 11).

Patent Owner first argues that an embodiment of Garrison illustrated in Figures 31–38 does not disclose valve means that reside entirely within the inner channel of the stent member in the collapsed configuration. Prelim. Resp. 34–39. Patent Owner's argument is misplaced as Petitioner does not rely on this embodiment or those figures, a fact Patent Owner concedes. *See* Prelim. Resp. 39 (stating that "Petitioner does not dispute the Examiner's characterization of Garrison's Figures 31 and 37, and instead points to Garrison's Figure 10 as meeting the claim 1 requirement").

Second, Patent Owner argues that Petitioner improperly relies on "the integrated valve/valve displacer embodiment" with regard to recited valve means residing within the stent member in the collapsed state. *Id.* at 39–44. Patent Owner, however, concedes that Petitioner's contentions do not turn on an "integrated valve/valve displacer embodiment." *Id.* at 42–43. Indeed, independent of the integrated valve/valve displacer embodiment, Petitioner makes clear that it contends a person of ordinary skill would have understood from Garrison that the support structure may have all features of the valve displacer, and would have been motivated "to use a support structure having this structure to advantageously conform the valve to the valve displacer or vessel walls." Pet. 35 (citing Ex. 1005, 2:5–10, 4:52–5:1,

Fig. 8; Ex. 1002 ¶¶ 98, 99). In response, Patent Owner argues that "Petitioner's proposed modification is unworkable" and provides a modified Figure 9 that Patent Owner uses to purportedly show that the support structure with flared ends would not be able to fit through the valve displacer. Prelim. Resp. 42–44. We have considered Patent Owner's arguments and self-modified figures, and find them speculative and insufficiently supported. Petitioner has sufficiently shown how Garrison teaches the recited valve means for purposes of institution on the current record.

Petitioner does, however, argue in the alternative that "Garrison also discloses an integrated valve displacer and cardiac valve such that the support structure 'flare[s] outwardly,' and the other discussions regarding the support structure in claim 1 similarly apply to the embodiment integrated with the valve displacer." Pet. 35. To the extent Petitioner raises a separate contention based on a combination of different embodiments, an issue for trial is whether Petitioner has provided a sufficient reason supporting the combination. *See Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1077 (Fed. Cir. 2017) (affirming the Board's finding in an IPR that Microsoft improperly combined separate embodiments of the reference to argue the reference met a claim limitation).

*b. Dependent Claims 2–5*

Claim 2 further recites that "the stent member is self-expanding." Petitioner shows, and Patent Owner does not yet dispute, that Garrison teaches a self-expanding support structure, corresponding to the recited "stent member." Pet. 44 (citing Ex. 1005, 5:19–21, 8:13–22. 8:45–47; Ex. 1002 ¶¶ 120–122).

Claim 3 requires that "the stent member comprises nitinol." Petitioner shows, and Patent Owner does not yet dispute, that Garrison teaches support structure 26A may be made of nitinol, corresponding to the recited "stent member." Pet. 44 (citing Ex. 1005, 8:16–21; Ex. 1002 ¶¶ 123, 124).

Claim 4 recites that "the stent member includes two circles of barbs on an outer surface of the stent member." Petitioner shows, and Patent Owner does not yet dispute, that Garrison teaches that support structure 26 may have barbs and that a person of ordinary skill would have had reason to include such barbs "with a self-expanding stent with the predictable and advantageous result of more securely attaching the self-expanding stent to the valve displacer or vessel wall." Pet. 45–46 (citing, e.g., Ex. 1005, 5:26–41; Ex. 1002 ¶ 128).

Claim 5 recites that "the pusher member includes a controlled release mechanism." Petitioner shows, and Patent Owner does not yet dispute, that Garrison teaches "that the 'cardiac valve' is pushed using 'rod 78 having a pusher element 80 attached thereto,'" corresponding to this limitation. Pet. 47 (citing, e.g., Ex. 1005 8:25–44, 8:48–64; Ex. 1002 ¶¶ 129–133).

*5. Alleged Obviousness over Garrison and Leonhardt*

Petitioner contends the Challenged Claims would have been obvious over Garrison and Leonhardt. Pet. 47–52. Petitioner's contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 132–150.

Petitioner asserts that Leonhardt teaches a replacement stent device with biological valve 22 and stent 26, and that the deployed device includes ends of the stent that "flare out in a trumpet-like configuration to help it 'conform and seal' to the tissue." Pet. 48 (citing Ex. 1006, 6:17–22, Fig. 2). Petitioner further reasons that a person of ordinary skill "would have found it routine, straightforward and advantageous to apply Leonhardt's teachings

of a valve within a stent, and a trumpet-like configurations on the stent's ends, in implementing Garrison's cardiac valve and delivery method and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality." *Id.* at 49 (citing Ex. 1002 ¶ 138).

Petitioner also asserts that Leonhardt teaches a valve residing entirely within an inner channel of the stent member. *Id.* at 51 (citing Ex. 1006, 6:23–31, Figs. 2, 4; Ex. 1002 ¶¶ 146–150). Petitioner further reasons that a person of ordinary skill "would have been motivated to apply Leonhardt's teachings of placing the valve axially and radially inside the stent to Garrison's support structure 26A such that the valve portion 38 is advantageously protected by the support structure—avoiding valvular damage caused by the valve residing outside the stent's more protected inner channel and increasing the surface area over which the support structure presses and seals against the valve displacer to better secure the prosthesis." *Id.* at 51–52 (citing, e.g., Ex. 1005, 4:15–20; Ex, 1006, 7:10–20; Ex. 1002 ¶ 150).

Patent Owner argues that "Petitioner only alleges that Leonhardt 'teaches a valve residing entirely within an inner channel of the stent member,' without any mention of claim 1's specific requirement that the valve so reside both 'in [its] collapse configuration' and 'upon deployment in the patient.'" Prelim. Resp. 44–45 (citing Pet. 51–52). We find no ambiguity in Petitioner's assertion that "Leonhardt expressly teaches a valve residing entirely within an inner channel of the stent member (e.g., as shown in Fig. 4)," which we understand includes both the collapsed configuration and the deployed configuration. Patent Owner directs us to no contrary disclosure in Leonhardt. We also find on the current record Patent Owner's

argument that Petitioner's motivation for the asserted combination is insufficient because it only applies "upon deployment" to be misplaced. Prelim. Resp. 45–48. Where Petitioner has shown that Leonhardt teaches a valve within a stent member, and provides a reason a person of ordinary skill would have applied that teaching to Garrison, such reasoning need not extend to every possible benefit. In other words, on the current record we are persuaded that Petitioner provides a sufficient rationale even if it only concerns Leonhardt's valve and stent member in the deployed configuration where the same valve would be within the same stent member in the collapsed configuration. The mere fact that, according to Patent Owner, "Garrison teaches that its valve is protected by the trocar and/or sheath" does not show that a person of ordinary skill would have had no reason to apply the teachings of Leonhardt to Garrison where Petitioner shows a benefit of the combination in the deployed state.

Patent Owner also argues "the ends of Leonhardt's stent member flare like discrete tulip petals, rather than a tubular structure like a trumpet." Prelim. Resp. 63–64. Patent Owner notes that "Petitioner appears to contend that 'trumpet-like' means a tubular structure with ends that 'flare markedly,'" but Patent Owner does not expressly dispute that construction or propose an express construction of its own. *Id.* at 13. For purposes of this Decision, we are persuaded that Petitioner has sufficiently shown how Leonhardt teaches a structure with a "trumpet-like configuration," and further recognize it as an issue for further development at trial.

*6. Alleged Obviousness over Garrison and Nguyen or Garrison, Leonhardt, and Nguyen*

Petitioner contends that the Challenged Claims would have been obvious over Garrison and Nguyen or over Garrison, Leonhardt, and

Nguyen. Pet. 77–78. Petitioner's contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 151–153. Petitioner relies on Nguyen as further express disclosure of "leaflets made of fixed pericardial tissue." *Id.* at 77 (citing Ex. 1020, 1:28–39). Petitioner further reasons that a person of ordinary skill "would have been motivated to apply Nguyen's teachings of leaflets made of fixed pericardial tissue to Garrison's leaflets . . . to advantageously improve durability using a material well-known to be suited for replacement heart valves." *Id.* (citing Ex. 1020 1:28–39, 1:51–54; Ex. 1002 ¶153). At this stage of the proceeding, Patent Owner has not does not raise additional arguments with respect to Petitioner's contentions directed to Nguyen. *See generally* Prelim. Resp.

*7. Showing of a Reasonable Likelihood*

We have considered the evidence and argument presented by the parties and determine, for the reasons provided above, that the Petition provides the requisite showing, at this stage of the proceeding, that Garrison alone, Garrison in combination with Leonhardt, Garrison in combination with Nguyen, and Garrison in combination with Leonhardt and Nguyen teach or suggest the subject matter of the Challenged Claims. Petitioner also provides sufficient explanation for purposes of this Decision as to why one of ordinary skill in the art would have modified or combined the references of each ground to arrive at the claimed invention. We further determine, based on the current record, that the Petition shows a reasonable likelihood Petitioner would prevail in showing that the Challenged Claims would have been obvious over the asserted Garrison Grounds.

*G. The Andersen/Limon Grounds*

Petitioner also contends that the Challenged Claims are unpatentable as obvious over the Andersen/Limon Grounds. Pet. 52–78. Having already

found for the reasons provided above that Petitioner has shown a reasonable likelihood of prevailing on the Garrison Grounds, we focus our discussion of the Andersen/Limon Grounds on the arguments raised at this stage of the proceeding by Patent Owner.

In brief summary, Petitioner contends that Andersen teaches a valve prosthesis that uses a self-expandable stent corresponding to the recited "prosthetic heat valve," but does not teach a delivery system. Pet. 52–53 (citing, e.g., Ex. 1013, 1:21–33, 2:27–33, 2:44–58, 4:36–41; 6:62–63; Fig. 12). According to Petitioner, "Andersen also teaches that 'any prior art technique' can be used during implantation to 'supervise an accurate introduction and positioning of the valve prosthesis,' including the use of 'guide wires' and a 'catheter.'" *Id.* at 53 (citing Ex. 1013, 4:36–41; Ex. 1002 ¶¶ 155–157). Petitioner relies on Limon as teaching the recited "delivery system." *Id.* at 54–57 (citing, e.g., Ex. 1008, 2:32–40, 5:27–54, Figs. 8, 9).

Petitioner further reasons as follows:

> A [person of ordinary skill] would have been motivated to apply Limon's advantageous delivery system teachings to Andersen's transcatheter stented valve devices. [Ex. 1002] ¶163. For example, Limon's teachings advantageously allow a user to "recapture" and "reposition" a partially deployed stent ([Ex. 1008], 2:64-3:1), and better control the axial position of the stent throughout the procedure ([Ex. 1008], 1:53-57). A [person of ordinary skill] would have had a reasonable expectation of success because Andersen teaches that "any prior art technique" can be used during implantation for "accurate introduction and positioning of the valve prosthesis," and "it is possible to modify the valve prosthesis [or the catheter used in implantation] depending on the desired use" (4:36-41, 6:49-52), and Limon provides an example of such a delivery system. [Ex. 1002] ¶163. While it is not necessary to apply Limon's teachings of using attachment projections 30, as illustrated in Figure 9, to control

> the stent because the tension between the collapsed stented valve and the inner and outer members allows for controlled delivery, a [person of ordinary skill] would have also been motivated to apply the attachment projections teachings as they provide sufficient grip to maintain attachment to a valve/stent, even if mostly deployed, and can be formed of a material that is "soft by design"/"relatively soft" to cushion the stented valve of Andersen and hold it in place. [Ex. 1008], 4:52-5:26, 5:41-54; Ex. 1002 ¶164. Collapsing the valve onto the "soft" attachment projections further helps protect the valve and would have worked as expected—indeed, it was well-known to collapse valves onto expansion balloons. Ex. 1002 ¶164; e.g., Ex. 1005, 8:3-8, 6:35-40, Figs. 3-6; *see also KSR*, 550 U.S. at 417.

Pet. 56–57.

Patent Owner argues that a person of ordinary skill would not have been motivated to combine Andersen and Limon as suggested by Petitioner because "it would render Limon's delivery system inoperable." Prelim. Resp. 53–59. As an initial matter, we agree with Patent Owner that Petitioner's suggestion that Limon "provides an example" of what Andersen refers to as a "prior art technique" is inaccurate because Limon has a priority date many years after Andersen and could not have been an example of the prior art Andersen was referring to. *See* Prelim. Resp. 56.

Patent Owner also argues as follows:

> Andersen cannot be combined with Limon because Limon explicitly requires use with a stent 'that has an open lattice structure 29,' so that the 'outer surface 33 of inner member 24 … will partially fill the open lattice structure 29 of stent 28 to form attachment projections 30 so that the stent cannot move in an axial direction along outer surface 33 of inner member 24.' ([Ex. 1008], 4:41, 55–59.) Andersen, by contrast, does not disclose a stent "that has an open lattice structure" as Limon requires. (Ex. 1013, 4:66-5:17 (describing a stent made of wires folded into loops).) Moreover, Andersen is incapable of placing a stent with an open lattice structure (as in Limon) in contact with the outer

> surface 33 of inner member 24 for attachment projections to form between the stent and inner member because Andersen's replacement heart valve must contain a valve between its stent and the inner member. (Petition, 64 ("Andersen discloses that the 'valve 6 is mounted in a central position in the tubular means 24' (the stent member).") (quoting Ex. 1013, 6:64-7:8).) Thus, if Andersen utilizes a stent with an open lattice structure as in Limon (which Andersen does not disclose), then the valve will block the outer surface 33 of inner member 24 from … partially fill[ing] the open lattice structure 29 of stent 28 to form attachment projections 30" and would be inoperable. ([Ex. 1008], 4:55–58.)

Prelim. Resp. 56–58. Patent Owner, however, acknowledges that Petitioner contends "it is not necessary to apply Limon's teachings of using attachment projections 30." *Id.* at 57–60 (quoting Pet. 56). On the current record, we find Patent Owner's arguments to be unsupported, however, we recognize the sufficiency of Petitioner's purported rationale is an issue for further development at trial.

Patent Owner also argues that Andersen in view of Limon fails to teach "a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath." Prelim. Resp. 59–62. Patent Owner's argument lacks merit because Patent Owner again attempts to exclude the recited "stent member" from the recited "prosthetic heart valve," contrary to the express language of claim 1, which makes clear that "a prosthetic heart valve" includes "a stent member" and a "valve means."

### *H. Appointments Clause*

Patent Owner argues "this proceeding should be dismissed as unconstitutional because APJs are not appointed by the President and confirmed by the Senate, and therefore not empowered to institute IPR or render final written decisions revoking the rights of patent owners." Prelim.

Resp. 67. Patent Owner further argues "the remedy imposed in *Arthrex* . . . does not properly cure the Appointments Clause defect." *Id.* (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019), *cert. granted*).[10]

This constitutional issue was addressed by the Federal Circuit's decision in *Arthrex*, 941 F.3d at 1337 ("This as-applied severance . . . cures the constitutional violation."); *see also Arthrex, Inc. v. Smith & Nephew, Inc.*, 953 F.3d 760, 764 (Fed. Cir. 2020) (Moore, J., concurring in denial of rehearing) ("Because the APJs were constitutionally appointed as of the implementation of the severance, *inter partes* review decisions going forward were no longer rendered by unconstitutional panels."). Accordingly, we do not consider this issue any further for this Decision.

*I. Due Process Clause*

Patent Owner argues as follows:

> A finding of unpatentability by the unconstitutionally appointed APJs would violate the APA and the Due Process Clause and constitutes an unconstitutional taking. Additionally, subjecting a patent effectively filed before September 16, 2012 (when the relevant provisions of the Leahy-Smith America Invents Act went into effect) to IPR is also an impermissibly retroactive, unconstitutional taking. Subjecting a pre-AIA patent to IPR "unfairly interferes with its reasonable investment-backed expectations without just compensation." *Celgene Corp. v. Peter*, 931 F.3d 1342, 1358 (Fed. Cir. 2019). Further, subjecting a pre-AIA patent to IPR violates the Due Process Clause of the Fifth Amendment by eviscerating the Patent Owner's substantive vested rights.

[10] The Supreme Court accepted this case for review. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), *cert. granted sub nom. United States v. Arthrex, Inc.*, 141 S.Ct. 549 (Oct. 13, 2020).

Prelim. Resp. 68. Patent Owner's quotation and citation to *Celgene* improperly suggests the Federal Circuit made a determination when, in fact, the court was merely summarizing the argument of a party. *Celgene*, 931 F.3d at 1358 (stating "[s]pecifically, Celgene advances a regulatory takings theory and argues that subjecting its pre-AIA patents to IPR, a procedure that did not exist at the time its patents issued, unfairly interferes with its reasonable investment-backed expectations without just compensation").[11] We decline to consider Patent Owner's constitutional challenge as the Federal Circuit addressed this issue in *Celgene*, stating "we hold that the retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment." *Id.* at 1362–63.

## IV. CONCLUSION

Based on the evidence before us, we determine Petitioner demonstrates a reasonable likelihood of prevailing in its assertions that the Challenged Claims of the '739 patent are unpatentable over the asserted prior art. Accordingly, *inter partes* review shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst.,* 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating the decision whether to institute *inter partes* review requires "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any

[11] Counsel is strongly cautioned against any additional misrepresentation of precedent. *See* 37 C.F.R. § 42.1(c).

claim term and, thus, leaves undecided any remaining fact issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing *id.* § 316(e)).

## IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–5 of U.S. Patent No. 9,125,739 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 9,125,739 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

PETITIONER:

James L. Davis, Jr.
Scott A. McKeown
Cassandra Roth
ROPES & GRAY LLP
james.l.davis@ropesgray.com
scott.mckeown@ropesgray.com
cassandra.roth@ropesgray.com
Medtronic-Colibri-IPRService@ropesgray.com

PATENT OWNER:

Sarah E. Spires
SKIERMONT DERBY LLP
sspires@skiermontderby.com