Trials@uspto.gov
571-272-7822

Paper 8
Date: March 26, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEARTVALVE LLC,
Patent Owner.

IPR2020-01649
Patent 9,125,739 B2

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

Edwards Lifesciences Corporation and Edwards Lifesciences 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.").

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 Delivery 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 '739 patent states that the '650 Application is a continuation of Application No. 13/675,665 (filed on November 13, 2012), which is a continuation of Application No. 10/887,688 (filed on July 10, 2004, and issued as U.S. Patent No. 8,308,797), which is a continuation-in-part of Application No. 10/037,266 (filed on January 4, 2002) ("the '266 Application").[1] *Id.* at code (63). 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.

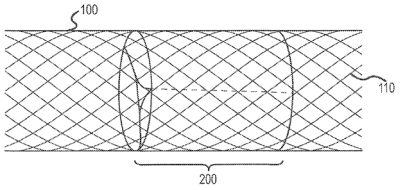


FIG.5

Figure 5 illustrates a side view of a replacement heart valve device mounted within a self-expanding stent in the expanded position. *Id.* at 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."

[1] Application No. 10/887,688 was published on May 26, 2005, as US2005/0113910 A1, and is the reference Petitioner identifies as "Paniagua" (Ex. 1015).

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.

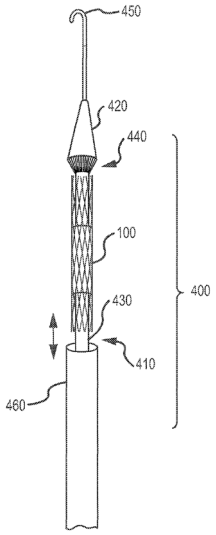


FIG.8

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	102	Paniagua[2]
1–5	103	Bessler,[3] Teitelbaum[4]
1–5	103	Bessler, Leonhardt[5]

[2] U.S. Patent App. No. 2005/0113910 A1, published May 26, 2005 (Ex. 1015, "Paniagua").
[3] U.S. Patent No. 5,855,601, issued January 5, 1999 (Ex. 1006, "Bessler").
[4] U.S. Patent No. 5,332,402, issued July 26, 1994 (Ex. 1007, "Teitelbaum").
[5] U.S. Patent No. 5,957,949, issued September 28, 1999 (Ex. 1012, "Leonhardt").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5	103	Bessler, Teitelbaum, Klint[6]
1–5	103	Bessler, Leonhardt, Klint

Pet. 26. We refer to the ground based on Paniagua as "the Paniagua Ground" and to the four grounds based on Bessler, in combination with other asserted art, collectively as the "Bessler Grounds." Petitioner relies on the supporting Declaration of Steven L. Goldberg, M.D., dated September 18, 2020. Ex. 1020.

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"), to which Petitioner is not a party. Pet. 24–25; Paper 4, 1. Additionally, an *inter partes* review has been instituted for claims 1–5 of the '739 patent in *Medtronic CoreValve LLC v. Colibri Heart Valve LLC*, IPR2020-01454 ("the Medtronic IPR") based on a petition filed by the defendant to the CDCA Case that asserts combinations of art not asserted in this proceeding. Medtronic IPR, Paper 11 (PTAB Mar. 10, 2021).

E. Real Parties in Interest

Petitioner identifies only itself as a real party in interest. Pet. 24. Patent Owner identifies only itself as a real party in interest. Paper 4, 1.

[6] U.S. Patent App. No. 2001/0044633 A1, published November 22, 2001 (Ex. 1019, "Klint").

III. ANALYSIS

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

Petitioner asserts in the Petition that discretionary denial under § 314(a) is not warranted, noting that it is "not a party to the co-pending district court litigation [i.e. the CDCA Case]." Pet. 70–73. Patent Owner argues that discretionary denial under § 314(a) does not require that Petitioner be a party to the co-pending district court case and that we should exercise our discretion due to the common issues being litigated in the CDCA Case with respect to the '739 patent. Prelim. Resp. 21–36. 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 Inc. 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"),[7] 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;
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.

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

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 information presented concerning 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. Petitioner notes a motion to stay was filed in the CDCA Case; however, Patent Owner explains that the district court denied the motion to stay the CDCA Case during a Status Conference held on November 17, 2020. Pet. 72; Prelim. Resp. 23 (citing 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 a status conference "would not move under any circumstances." Prelim. Resp. 23 (quoting Ex. 2004, 2). Although Petitioner is not a party to the district court proceeding, we find that the denial of the motion to stay the CDCA Case and the district court's directive that the trial date "would not move under any circumstances"

weigh 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 over six months before a final written decision would be due in this proceeding. Pet. 72; Ex. 2004, 2.

Petitioner argues that although the "trial date is earlier than a final written decision would be expected in this case," the defendant in the CDCA Case "has filed two motions that may alter that date—a motion to dismiss, as well as the previously noted motion to stay." Pet. 72. As discussed above, the evidence provided by Patent Owner shows the motion to stay the CDCA Case that Petitioner refers to was denied. *See* Ex. 2004, 2; Ex. 2009 ¶ 6. Petitioner does not otherwise explain why any pending motion to dismiss the CDCA Case supports the notion that the trial date may be altered, particularly in light of the indication by the district court that the trial date would not move under any circumstances. *See* Ex. 2004, 2.

Thus, the evidence 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 over six months, and persuasive evidence suggests that the trial date will not be changed if *inter partes* review were to be granted in this proceeding, 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 at 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 at 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.* Here, Petitioner is not a party to the CDCA Case and is not "faced with the prospect of a looming trial date." Because Petitioner was not served with a complaint, there is no information in the record to measure precisely the promptness of Petitioner's filing of the Petition. In the Medtronic IPR we found that the petitioner in that case promptly filed its petition only four months after the complaint against it was served. In this case, Petitioner filed the Petition less than three weeks after the Petition was filed in the Medtronic IPR. We find no unreasonable delay in Petitioner's filing, and Patent Owner does not argue otherwise. *See generally* Prelim. Resp.

Second, under this factor we 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.

Petitioner asserts that it has "not and will not invest resources" in the parallel district court proceeding, because it is not a party to the CDCA Case. Pet. 72 (further stating that "it does not appear that the parties or the court have invested substantial resources" in the CDCA Case).

Patent Owner argues that the parties to the CDCA Case and the 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. 26–27. Patent Owner further argues that before an institution decision is due in this proceeding, the parties in the CDCA Case 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 27–28; *see also* Ex. 2005 (CDCA Case order setting case schedule).

We find that the parties to the CDCA Case and the 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 in the record that any substantive determinations on validity issues have been made in the CDCA Case.

Further, according to the scheduling order in the CDCA Case, expert discovery has not yet started. Ex. 2005, 3. On balance, we find the timeliness of the Petition and the level of investment of time and resources in the CDCA Case by the parties to the CDCA Case 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. *Fintiv* also provides as follows:

> Even when a petitioner is unrelated to a defendant, however, if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution." An unrelated petitioner should, therefore, address any other district court or Federal Circuit proceedings involving the challenged patent to discuss why addressing the same or substantially the same issues would not be duplicative of the prior case even if the petition is brought by a different party."

Id. at 14.

Petitioner argues that the "co-pending district court litigation is currently in its early stages and as a non-party, Petitioners have no control over or insight into what art and arguments may be raised in that case." Pet. 73.

Patent Owner argues that Petitioner fails "to address the fact that the issues in this Petition 'are the same as, or substantially similar to, those

already about to be litigated.'" Prelim. Resp. 31. According to Patent Owner, the grounds Petitioner asserts "rely on a subset of the same art at issue in" the CDCA Case and the invalidity arguments raised by the defendant in the CDCA Case "reflect each and every one of the five grounds at issue" in the Petition. *Id.* at 32 (citing Ex. 2009 ¶ 9; Exs. 2012–2016). Patent Owner further states that "while the CDCA Defendant has provided Patent Owner with a stipulation [Ex. 2017] that if the Board institutes IPR on the Petitions filed by the CDCA Defendant (IPR2020-01453 and -01454 [i.e., the Medtronic IPR]), the CDCA Defendant has not provided such a stipulation with respect to the current Petition."[8] *Id.* at 32–33 (citing Ex. 2017, 1).

The stipulation in the Medtronic IPR that Patent Owner refers to provides, in relevant part, as follows:

> Medtronic [i.e., the CDCA Defendant] 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. 2017 (the "Stipulation"). As noted above, the petition in IPR2020-01454 (the Medtronic IPR) was instituted. In accordance with the

[8] Patent Owner also argues that Petitioner "has made no promise that it would not seek to join in this Petition if instituted." Prelim. Resp. 32. Patent Owner does not explain how that argument is relevant to whether there is overlap between the issues in this proceeding and the issues raised in the district court proceeding for purposes of discretionary denial under § 314(a).

Stipulation, the CDCA Defendant will not pursue in the corresponding district court case the specific grounds raised in the Medtronic IPR, as well as "any other ground that was raised or could have been reasonably raised as to these claims in an IPR." *Id.* Accordingly, Patent Owner's argument that "the CDCA Defendant has not provided such a stipulation with respect to the current Petition" does not address whether the grounds raised in the Petition may be grounds that "could have been reasonably raised as to these claims in an IPR," and thus fall within the Stipulation's provision that the CDCA Defendant will not pursue such grounds in district court. To be clear, we do not speculate on whether the grounds raised in the Petition fall within the Stipulation; however, we recognize that if they do, this factor would seem to weigh against exercising discretion to deny institution of *inter partes* review. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 19 (PTAB Dec. 1, 2020) (precedential in relevant part)). Because we cannot determine on the record in this proceeding whether the Stipulation applies to the grounds asserted in this proceeding, we find, on balance, this factor is neutral.

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 Petitioner is not a party to the CDCA Case. Pet. 71; Prelim. Resp. 31. Thus, this factor weighs against 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 it relies on the publication of the '739 patent's "own grandparent prior art," Paniagua, to show anticipation and because the '739 patent "is based on the applicants' copying of portions of two pieces of prior art nearly word-for-word into the specification and then, twelve years later, filing a continuation application with claims that covered the copied references." Pet. 73.

Patent Owner argues that the Petition suffers from "numerous deficiencies," including that Paniagua is not prior art and that under the Bessler Grounds Petitioner fails "to show that the prior art discloses that 'the prosthetic heart valve is collapsed onto the pusher member,' as claim 1 requires." Prelim. Resp. 36. As explained below, we are persuaded on the current record that Petitioner has sufficiently shown how Klint teaches that limitation of claim 1, which Patent Owner does not yet substantively dispute. *See id.* at 52–54 (arguing a lack of reason to combine the asserted references, not that Klint fails to teach the feature it is relied upon by Petitioner).

Having considered Petitioner's and Patent Owner's arguments, and based on the limited record before us, we find that these "other" factors do not favor 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.

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)

Petitioner asserts in the Petition that discretionary denial under § 325(d) is not warranted. Pet. 73–75. Patent Owner argues we should deny the Paniagua Ground under § 325(d). Prelim. Resp. 36. Patent Owner also states that it "acknowledges that Grounds 2–4 involve different art (other than Leonhardt) and arguments than those presented to the PTO," and argues that Petitioner fails to show a reasonable likelihood of prevailing on those grounds. *Id.* at 36 n.1.

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 Paniagua Ground, Patent Owner argues that "Petitioner relies upon the very priority application that the USPTO plainly considered

during prosecution—the '739 patent's grandparent application." Prelim. Resp. 37 (citing Ex. 1002, 6, 19–63, 72, 73). In particular, Patent Owner argues that "when Applicants submitted their Preliminary Amendment, they specifically provided 'information to assist the examiner with assessing support for the claims as presented herein,' which the Examiner was required to consider in evaluating Applicants' patent application that matured into the '739 patent." *Id.* at 38 (citing Ex. 1002, 72, 73; MPEP § 2163). According to Patent Owner, "[b]ecause Petitioners have not demonstrated—or even alleged—that the PTO did not, in fact, consider whether the '739 patent could claim priority to its grandparent patent application, Petitioners have failed to meet their burden of demonstrating that the Examiner materially erred in examining the '739 patent with respect to Petitioners' Ground 1 art." *Id.*

Petitioner argues that the Examiner "did not consider whether the '739 [p]atent could claim priority to January 4, 2002," and, therefore, presumably did not consider whether Paniagua was prior art. Pet. 74. Petitioner does not suggest that the Examiner erred, because there is no indication in the record that the Examiner considered, or was obligated to consider, the particular issues raised by Petitioner concerning priority based on Paniagua.

Paniagua is the grandparent application to the '739 patent. Ex. 1001, 1:8–15. As discussed below, on the current record we are not persuaded by Petitioner's argument that the '739 patent is not entitled to priority to Paniagua. *See infra* § III.G. Accordingly, as Paniagua and the '739 patent share the same priority date, we need not consider whether Paniagua was previously presented to the Office because it would not qualify as prior art.

Turning to the Bessler Grounds, Petitioner contends that "none of the references presented were substantively considered during prosecution" and

that Klint was not cited during prosecution. *Id.* at 73–74. Patent Owner does not dispute these contentions. Accordingly, we decline to exercise discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

C. Legal Standards of Anticipation and Obviousness

A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable for obviousness[9] if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness 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,

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

failure of others, etc." *Id.* at 17–18; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007). Neither party presents evidence directed to secondary considerations. *See generally* Prelim. Resp.; Pet. 70.

D. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

Petitioner contends that a person of ordinary skill in the art at the time of the invention "would have been an interventional cardiologist with a working knowledge of heart valve designs, expandable stents, and intravascular delivery systems for stents."[10] Pet. 41–42 (citing Ex. 1020 ¶ 27). Petitioner further states that such a person of ordinary skill "would, where necessary, work as a team in combination with a medical device engineer." *Id.* In its Preliminary Response, Patent Owner does not contest Petitioner's asserted level of ordinary skill in the art. 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

[10] Petitioner provides the same level of ordinary skill for both its anticipation ground based on Paniagua as for the Bessler Grounds; however, Petitioner identifies April 15, 2014, as the date of invention for anticipation based on Paniagua and January 4, 2002, for the Bessler Grounds, noting that a person of ordinary skill as of the latter date "would have had the additional knowledge of the important developments in the art in the intervening 12 years." Pet. 41–42.

(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). 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.

1. the prosthetic heart valve is collapsed onto the pusher member

Petitioner contends that "onto" means "in contact with," such that claim 1 of the '739 patent requires that the prosthetic heart valve is collapsed *in contact with* the pusher member. Pet. 37–41. Patent Owner disputes Petitioner's proposed construction and argues that "onto" means "around." Prelim. Resp. 13–19.

Petitioner reasons that the portion of the Specification of the '739 patent that discusses the "pusher member" "was copied nearly word-for-word from Bessler," and that "the 'pusher member' and the meaning of

mounting the replacement heart valve device 'onto' the 'pusher member' must be what Bessler teaches." Pet. 37–38. Bessler is cited on the face of the '739 patent. Ex. 1001, code (56). Petitioner does not suggest that the term "onto" appears anywhere in Bessler.

To purportedly support its argument that Bessler must define terms in the '739 patent, Petitioner turns to extrinsic evidence from a district court proceeding in which Patent Owner allegedly made arguments concerning a different patent from the '739 patent with the same specification to show that Patent Owner "argued that the only embodiment of a delivery system in the '739 Patent that describes using a pusher member to push out a prosthetic device is the one that was copied from Bessler." Pet. 38. Petitioner then turns to a figure from Bessler, which does not appear in the '739 patent, to allegedly show that Bessler teaches a replacement heart valve "in contact with" a pusher member. *Id.* at 38–39 (citing Ex. 1006, Fig. 14).

Petitioner's reasoning then turns to the prosecution history and argues that Patent Owner did not "correct" the Examiner in regard to statements by the Examiner concerning Gabbay that made clear that "'Gabbay . . . does not disclose the valve to be collapsed onto the pusher member' because 'Gabbay's pusher member 210 or 716 is a plunger member with lumen, ending proximally to the valve, which pushes out the valve from behind.'" *Id.* at 39 (quoting Ex. 1002, 238) (alteration in original). Petitioner then accuses Patent Owner of embracing "the Examiner's error" by failing to explain "to the Examiner that that the only description of a 'pusher member' in the specification describes the 'pusher member' as extending to a 'hollow section at the distal end [] of the catheter' where the replacement heart valve device is carried." *Id.* at 40 (citing Ex. 1001, 11:44–51) (alteration in original).

According to Petitioner, "the sole written description of a 'pusher member' in the '739 [p]atent *requires*" that "the pusher member 'terminates proximal' to the replacement heart valve device." *Id.* Petitioner relegates any discussion of Figure 8 of the '739 patent, which illustrates a prosthetic heart valve collapsed onto a pusher member, as claimed, to a footnote. *Id.* at 40 n.8. Petitioner states as follows:

> Figure 8 of the '739 [p]atent is not to the contrary. First, the description in the specification is inconsistent with what is illustrated in Figure 8, as a [person of ordinary skill in the art] would readily recognize. EX1020, ¶¶81–87. Additionally, to the extent Figure 8 is viewed in light of the specification, it identifies the "pusher member" as element 420, which is pictured as terminating adjacent to the stent 100. EX1001, Fig. 8; EX1020, ¶86, n.2.

Id. Dr. Goldberg testifies to the same thing, stating "[t]o the extent that Figure 8 in the '739 [p]atent is given any consideration, I note that it depicts the purported 'pusher member 420' as adjacent to the prosthetic heart valve device and not as passing through and surrounded by the interior of the prosthetic heart valve device." *See* Ex. 1001, Fig. 8; Ex. 1020 ¶ 87. Petitioner's argument and Dr. Goldberg's testimony in this regard are contrary to the express disclosure of the '739 patent. The '739 patent states that "[t]he 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*." Ex. 1001, 11:48–51 (emphasis added). Petitioner's argument, as supported by Dr. Goldberg, that pusher member 420 terminates adjacent to stent 100 and does not pass through the prosthetic heart valve device misrepresents what is illustrated and expressly disclosed in writing in the '739 patent. Thus, we do not find Petitioner's argument or Dr. Goldberg's testimony adequately supported.

> Patent Owner persuasively explains as follows:
>
> > Petitioners' argument cannot be squared with "the well understood notion that claims of unrelated patents must be construed separately." *e.Digital Corp. v. Futurewei Techs., Inc.*, 772 F.3d 723, 727 (Fed. Cir. 2014). *See also Texas Digital Sys. Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1211 (Fed. Cir. 2002) (holding that a common inventor's representation of "matrix displays and seven-segment displays as two separate embodiments of the same invention" was irrelevant and "sheds no light" on whether "the claims in an unrelated patent are broad enough to encompass both a matrix and the familiar seven-segment pattern."); *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004) (noting that "this court's precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not."); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) (holding that statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent).

Prelim. Resp. 14. As Patent Owner explains, notwithstanding a similarity in language, the '739 patent and Bessler are describing different figures with Bessler illustrating a pusher member in contact with a prosthetic heart valve, "whereas the '739 patent is disclosing a prosthetic heart valve that is collapsed *around* its pusher member." *Id.* at 15. As Patent Owner explains, statements in the prosecution history of the '739 patent (which Petitioner addressed and seemed to dismiss as associated with some sort of Examiner error) make clear that the purported invention was distinguished over prior art that merely showed a pusher member in contact with a prosthetic heart valve. *Id.* at 18–19 (citing Ex. 1002, 238, 319). Patent Owner concludes as follows:

> Thus, in light of Applicants' repeated statements during prosecution that the prosthetic heart valve cannot be collapsed

> onto a pusher member that terminates proximally to the valve, Petitioners' proposed construction of "collapsed onto" to mean "collapsed in contact with"—which specifically includes "collapsed onto" a pusher member that terminates proximally to the valve as in Bessler—must fail.

Id. at 19.

We agree with Patent Owner and find for purposes of this Decision that Petitioner fails to show sufficiently that "onto" means "in contact with." For purposes of this Decision, as explained below, we need not expressly construe "onto" and decline to adopt Patent Owner's proposed construction of "onto" as meaning "around," which is an argument Patent Owner did not fully develop and support in its Preliminary Response.

2. valve means

Petitioner argues that "valve means" is not a means-plus-function limitation, and also identifies the structure it contends the '739 patent discloses that corresponds to this limitation. Pet. 24–25. Patent Owner does not contest Petitioner's construction of "valve means" in its Preliminary Response. Prelim. Resp. 20.

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. Alleged Obviousness Under the Bessler Grounds

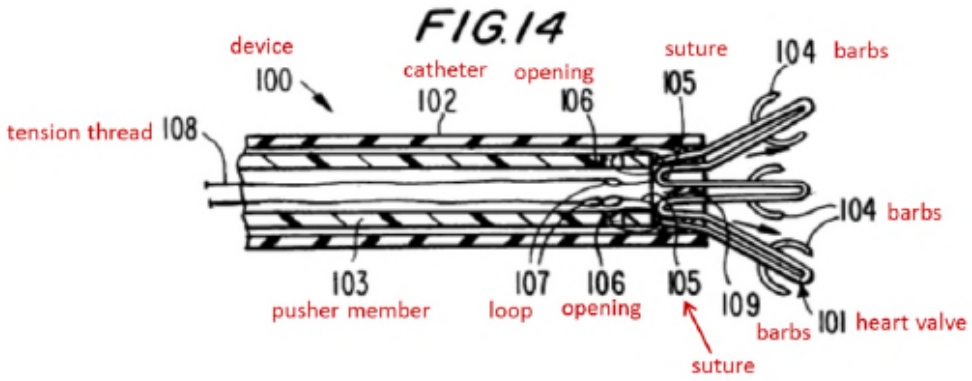
Petitioner contends the Challenged Claims would have been obvious over Bessler in various combinations with Teitelbaum, Leonhardt, and Klint. Pet. 26. According to Petitioner, the Specification of the '739 patent "copies

verbatim (or nearly so) over one hundred lines from Bessler . . . and Teitelbaum." *Id.* at 4–11. In summary, Petitioner argues that Bessler teaches "nearly all features" of the Challenged Claims other than that the stent member flares at both ends in a "trumpet-like configuration." *Id.* at 11–15. As to the "trumpet-like configuration," Petitioner contends the '739 patent copied its description nearly verbatim from Teitelbaum. *Id.* at 15–16 (comparing, e.g., Ex. 1001, 7:59–67 to Ex. 1007, 5:52–63). Petitioner also asserts that Leonhardt teaches a similarly flared stent. *Id.* at 20 (citing Ex. 1012, 4:60–65, 6:11, Fig. 2. Petitioner further contends that Klint teaches a delivery system for a prosthetic valve that is collapsed onto a pusher member, as recited by claim 1 of the '739 patent. *Id.* at 66–68. Below we briefly summarize the asserted references and further assess the sufficiency of the asserted combinations.

1. Summary of Bessler

Bessler, titled "Artificial Heart Valve and Method and Device for Implanting the Same," teaches a heart valve comprised of a self-expanding stent member and valve means that may be inserted percutaneously at the site of the removed heart valve "where it is released in a controlled fashion from the distal end of a catheter." Ex. 1006, code (54), 2:55–67.

Figure 14 of Bessler, as annotated by Petitioner, is reproduced below.



Pet. 38–39. Figure 14 illustrates a cross-sectional view of the distal end of device 100 for the percutaneous and transluminal implantation of a heart valve showing heart valve 101 in a partially ejected state. Ex. 1006, 3:28–30, 3:33–35, 28:33–35. According to Petitioner, heart valve 101 "is just distal to, and is *in contact with*," pusher member 103. Pet. 38. In regard to Figure 14, Bessler explains as follows:

> the catheter 102 has been brought to the appropriate site and the guide wire removed proximally. The pusher member 103 has been moved forward longitudinally of the catheter 102 to eject approximately one-half of the heart valve 101 from the distal end of the catheter 102. As seen in the drawing the distal end of the valve 101 is expanded and a slight pull of the entire unit will set the first circle of barbs 104 in the vessel wall. The heart valve 101 is held in place within the delivery catheter by a pair of threads or sutures 105. The sutures are looped through an opening 106 in the pusher member 103 and then passed about a portion of the heart valve 101 as shown. The other end of the suture 105 contains a loop 107. A tension thread 108 is passed through the suture loops and down through the center of the pusher member 103 to the proximal end of the catheter 102.

Ex. 1006, 7:46–61.

2. Summary of Teitelbaum

Teitelbaum, titled "Percutaneously-Inserted Cardiac Valve," teaches an expandable replacement cardiac valve "maintained in a collapsed form by cold temperature." Ex. 1007, codes (54), (57). In one design, the valve includes "a meshwork of nitinol wire," where "[a]way from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration." *Id.* at 2:20–27. According to Teitelbaum, the "flared ends of the stent maintain the position of this component across the native valve following deployment." *Id.* at 2:34–36. According to Teitelbaum, "[o]nce the stent has been pushed to the distal end of the sheath where it bridges the site of the dilated valve, the pusher will be held steady while the sheath is withdrawn, allowing the stent to come into contact with body temperature." *Id.* at 3:54–59.

3. 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. 1012, codes (54), (57).

Figures 2 and 4 of Leonhardt are reproduced below.

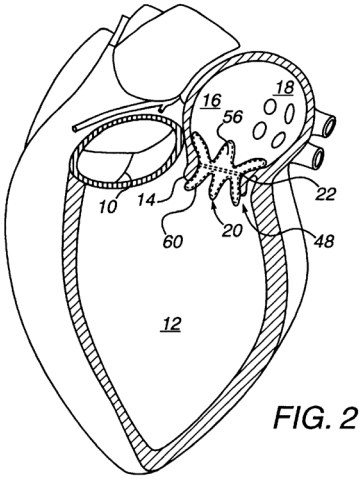


FIG. 2

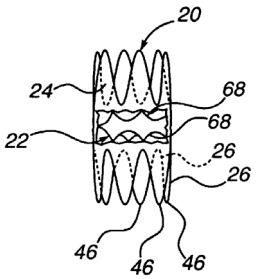


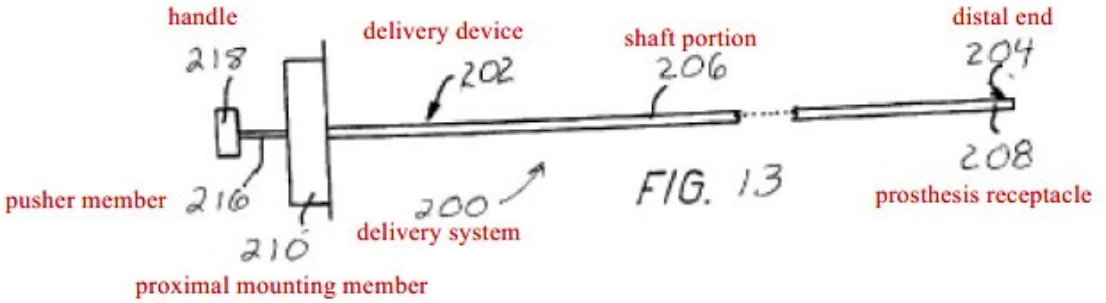
FIG. 4

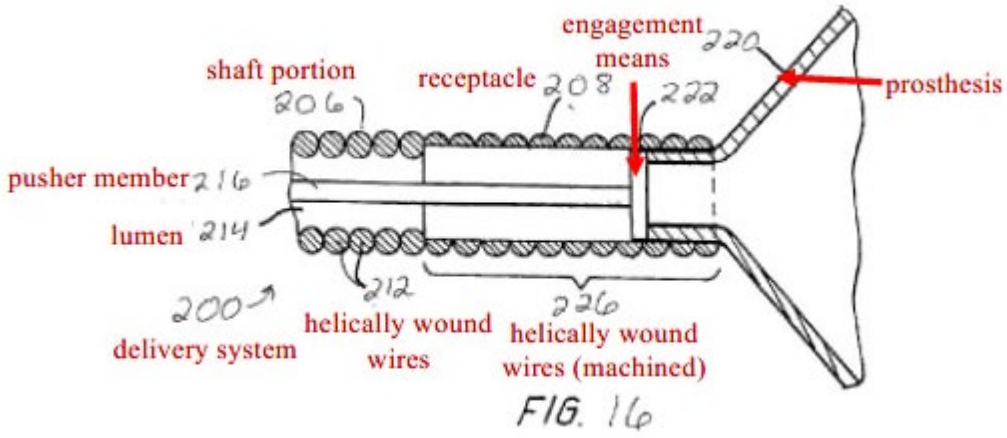
Figure 2 illustrates a "valve stent fully deployed within the mitral valve," and figure 4 illustrates a sectional view of a "biological valve within the stent." *Id.* at 3:57–58, 61–62. As shown in Figure 4, valve stent 20 includes stent 26, biological valve 22, and graft material 24. *Id.* at 4:15–17. 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.

4. Summary of Klint

Klint, titled "Endovascular Medical Device with Plurality of Wires," describes a "medical device for passage along the vasculature of a patient," which "may be a catheter or may be one or more components of a delivery system for endovascular devices, such as a central member within a catheter, for example, a pusher or delivery device for an embolization coil." Ex. 1019, code (54), ¶ 15.

Figures 13 and 16 of Klint are reproduced below, with annotations provided by Petitioner.





Pet. 67–68. Figure 13 illustrates delivery system 200 for delivery of a prosthesis such as a stent and Figure 16 illustrates an enlarged partial view of an embodiment of the delivery system of Figure 13. *Id.* ¶¶ 36, 37. Delivery system 200 includes "delivery device 202 having a distal end 204 and a shaft portion 206 extending between a prosthesis receptacle 208 at the distal end and a proximal mounting member 210 fixedly mounted to the shaft portion." *Id.* ¶ 92. Delivery system 200 also includes "pusher member 216 which can be inserted through the lumen 214," and handle or pin vise 218 "mounted on the pusher member for pushing it forwardly in the distal direction when a prosthesis 220 located in receptacle 208 is to be

released from the introducer device by being pushed out of receptacle 208." *Id.* ¶ 93. "At the distal end of the pusher member 216 an engagement means 222 can act on the prosthesis 220." *Id.* ¶ 94. Klint further states as follows:

> The engagement means can be for example a plate of a dimension fitting into receptacle 208 and abutting the proximal end of the prosthesis so that the plate pushes the prosthesis out of the receptacle when the pusher member is pushed forwardly. The engagement means can also be designed as an elongate member that extends coaxially inside the radially compressed prosthesis and engages the prosthesis at several locations along the length thereof so that the prostheses is partly pulled, partly pushed out of the receptacle. These engagement points or areas can be effected by radial projections, hooks, ridges, or another kind of engagement means such as a high friction material. This can be an advantage if the prosthesis has an extensive length, and in particular if it has a construction having a tendency to buckle when pushed upon.

Id.

5. 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, Bessler teaches "artificial heart valves," including a delivery system with guidewire 94. Pet. 48–49 (citing Ex. 1006, 1:7–11, 5:13–14, 7:35–38; Ex. 1020 ¶ 121).

> *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 Bessler teaches a prosthetic heart valve that is collapsible and expandable and that "may be implanted percutaneously and transluminally." Pet. 48–49 (citing Ex. 1006, 2:57–67, 3:52–55, 4:21–26, 5:44–51, 5:58–60; Ex, 1020 ¶ 122). With regard to the recited "trumpet-like configuration," Petitioner recognizes that Bessler does not explicitly teach a stent member "that flares at both ends in a trumpet-like fashion," and instead argues that this feature is taught by Teitelbaum, which Patent Owner does not yet dispute. *Id.* at 49–53 (citing, e.g., Ex. 1007, 2:21–29, 5:51–65, Fig. 2; Ex. 1020 ¶¶ 123, 124). Petitioner also reasons that both Bessler and Teitelbaum recognize the desirability of anchoring the expanded stent member at a desired site, and that Teitelbaum "explains that the purpose of the flared stent is to 'maintain the position of this component across the native valve following deployment.'" *Id.* at 50 (quoting Ex. 1007, 2:34–36, 5:63–65). Petitioner reasons, for example, that a person of ordinary skill "would have been motivated to modify Bessler's device by using a flared stent as taught by Teitelbaum in conjunction with, or as an alternative to, Bessler's optional barbs in order to better anchor the device in place and improve sealing, reducing leakage of blood around the valve device." *Id.* at 50–51 (citing Ex. 1020 ¶ 124).

Petitioner also contends that Leonhardt "[a]lternatively (or additionally)" teaches the "trumpet-like" flare of the stent. *Id.* at 51–52 (citing Ex. 1012, 4:60–65, 5:2–5, 6:10–11, 6:19–22, Fig. 2; Ex. 1020 ¶ 125).

Petitioner reasons that a person of ordinary skill "would have been motivated to combine Bessler's valve structure with the flared stent structure of Leonhardt because Leonhardt teaches that the advantage of its flared stent structure is that the "flair[s] . . . conform and seal to the tissue." *Id.* at 53 (citing Ex. 1012, 6:21–22) (alterations in original). Patent Owner has not yet disputed Petitioner's contentions with regard either to how both the combination of Bessler and Teitelbaum and the combination of Bessler and Leonhardt teach the features of this limitation or to the rationale for their combination. *See generally* Prelim. Resp.

> *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, and Patent Owner does not yet dispute, that Bessler teaches the recited valve means, including the recited leaflets. Pet. 54–56 (citing, e.g., Ex. 1006, 3:65–4:1, 5:21–24, Figs. 2, 3; Ex. 1020 ¶¶ 128–133, 135, 136).

> *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,*

Corresponding to the recited "delivery system," Petitioner contends that the '739 patent "copies its disclosure of the delivery system including a pusher member almost word-for-word from Bessler." Pet. 57 (citing Ex. 1006, 4:53–63 ("The system for implanting the above described artificial heart valve percutaneously and transluminally includes a flexible catheter," and the "catheter has a pusher member disposed within the catheter lumen"); Ex. 1020 ¶ 137). Petitioner also contends that the pusher member taught by

Bessler includes a guidewire lumen. *Id.* at 58 (citing Ex. 1006, 7:35–38 ("A guidewire 94 having a blunt end 95 is disposed through a lumen 97 of the pusher member 93 and is used to guide the distal end of the catheter 91 to the desired site")). Petitioner further contends that "Bessler's pusher member is disposed within a lumen of the moveable sheath (what Bessler refers to as a 'catheter')." *Id.* at 59 (citing Ex. 1006, 4:60–63 ("The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end of the catheter")). Patent Owner has not yet disputed Petitioner's contentions based on Bessler in regard to these recited features.

> *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,*

Petitioner contends, and Patent Owner does not yet dispute, that Klint teaches a delivery system for a valve member that provides for the engagement of the pusher member with the prosthesis such that the prosthesis "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," as shown in Figures 13 and 16 of

Klint.[11] Pet. 67–68 (citing Ex. 1019 ¶¶ 1, 91–103; Ex. 1020 ¶ 157–160). Petitioner also reasons that Klint expressly provides the reason and motivation for combining its teaching with a delivery system as taught by Bessler and Teitelbaum and Bessler and Leonhardt. *Id.* at 69–70. Specifically, Petitioner contends that a person of ordinary skill would have recognized "the advantage of this design, as explained by Klint (reducing the risk that the prosthesis will buckle or be damaged during delivery from having force applied to it by a pusher member located adjacent to the device)." *Id.* at 69 (citing Ex. 1019 ¶ 94; Ex. 1020 ¶ 162). Petitioner also asserts that a person of ordinary skill would have recognized "that collapsing the prosthesis onto the pusher member permits the operator to hold the apparatus steady, such as in the deployment method Teitelbaum describes (EX1007 at 5:15–19, 3:54–59), increasing the precision of device placement

[11] Petitioner's contentions based on Klint are not premised on Petitioner's proposed construction of "onto" as meaning "in contact with," which is a construction we find insufficiently supported as explained above. *See supra* section II.E.1. Petitioner does also argue that Bessler teaches this limitation based on its proposed construction, which we find on the current record unconvincing for the same reasons. *See* Pet. 60–61; *see also* Prelim. Resp. 43–45 (arguing that "Bessler discloses a prosthetic heart valve that is collapsed near to, but certainly not 'onto', its pusher member"). Petitioner also argues if "onto" is "construed narrowly such that it requires the pusher member to pass through the interior of the prosthetic valve," then Leonhardt and Teitelbaum teach systems that "parallel" or are "similar" to what is recited in the limitation. Pet. 61–63. Patent Owner argues that Petitioner fails to show how either Leonhardt or Teitelbaum teach this limitation. Prelim. Resp. 45–51. Patent Owner presents arguments that appear to have merit in regard to Bessler, Leonhardt, and Teitelbaum and that would be better addressed on a full record developed at trial. For purposes of this Decision we rely on Petitioner's contention that Klint teaches this limitation, which Patent Owner does not yet dispute. *See generally* Prelim. Resp.

over pushing a device out of a catheter." *Id.* (citing Ex. 1020 ¶ 161); *see also id.* (arguing a reasonable expectation of success is supported by Klint which teaches the interchangeability of delivery systems with and without the prosthesis collapsed onto the pusher member).

On the current record, we disagree with Patent Owner's arguments that Petitioner's reason for combining the asserted references is insufficient for purposes of this Decision. Prelim. Resp. 52–54. First Patent Owner argues that Petitioner relies on the same motivation – allowing "the operator to hold the apparatus steady . . . increasing the precision of device placement" – as the motivation both to combine Teitelbaum or Leonhardt with Bessler and as motivation to add Klint to either of those combinations. *Id.* at 52. According to Patent Owner, a person of ordinary skill "would already believe that the combination of Bessler with Leonhardt/Teitelbaum accomplishes this goal, and so would not have any further motivation to modify the combined Bessler + Leonhardt/Teitelbaum device." *Id.* at 52–53. Patent Owner's argument is unsupported and we are not persuaded in this case that the same motivation fails to support modifications that promoted the same goal of improving the operability of the device.

Patent Owner also argues that "Klint places a condition on when" a delivery system "where the pusher member passes through the collapsed prosthesis" is advantageous, namely "*if* the prosthesis has an extensive length, and in particular if it has a construction having a tendency to buckle when pushed upon." *Id.* at 52–53 (quoting Ex. 1019 ¶ 94). Patent Owner further argues as follows:

> Here, Petitioners have not alleged that either of these conditions has been met. Namely, neither Petitioners nor their expert have alleged that a replacement heart valve for use in Bessler would have "an extensive length" or have "a construction having a

> tendency to buckle when pushed upon." (*See* Petition, 69-70, Ex. 1020, ¶160.) Thus, Petitioners have not alleged that a [person of ordinary skill in the art] reading Bessler and Leonhardt/Teitelbaum—which contain delivery systems similar to Klint's alternative (1)—would be motivated to substitute their delivery systems for Klint's alternative (2), since Petitioners have not alleged that the Bessler "artificial heart valve" may have "an extensive length," or that its "relatively rigid stent member" may have "a construction having a tendency to buckle when pushed upon." (*See* Ex. 1006, 3:48-51 ("The artificial heart valves of the invention…comprise (1) a relatively rigid stent member").)

Id. at 54 (second alteration in original). In addition to being unsupported, Patent Owner's arguments appear misplaced. Neither Bessler nor the Challenged Claims are confined to a prosthesis with any particular length or rigidity. Patent Owner does not suggest that applying the teachings of Klint in this regard render Bessler inoperable, and we are not convinced that Petitioner had an affirmative obligation to "allege" that the Bessler prosthesis "may have 'an extensive length,' or that its 'relatively rigid stent member' may have 'a construction having a tendency to buckle when pushed upon.'" To the contrary, Petitioner has sufficiently shown for purposes of this Decision that a person of ordinary skill would have recognized the benefits expressly disclosed by Klint and had reason to apply those teachings to Bessler to obtain the same benefit.

> *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.*

Petitioner contends, and Patent Owner does not yet dispute, that Bessler teaches a distal end of the prosthetic heart valve located at a distal

end of the moveable sheath, as well as valve means with the recited features, as illustrated in Figures 4 and 5 of Bessler. Pet. 63–64 (citing Ex. 1006, 3:65–4:1, 4:4–9, 4:63–66, 5:15–23, 7:30–33, 7:48–53; Ex. 1020 ¶¶ 130–133, 148, 149).

6. Dependent Claims 2–5

Claim 2 further recites that "the stent member is self-expanding." Ex. 1001, 14:30–31. Petitioner contends, and Patent Owner does not yet dispute, that Bessler teaches a self-expanding stent member. Pet. 64 (citing Ex. 1006, 2:60–62; Ex. 1020 ¶ 151).

Claim 3 requires that "the stent member comprises nitinol." Ex. 1001, 14:32–33. Petitioner contends, and Patent Owner does not yet dispute, that Bessler teaches a stent member that may be made from nitinol. Pet. 64 (citing Ex. 1006, 6:3–7; Ex. 1020 ¶ 152).

Claim 4 recites that "the stent member includes two circles of barbs on an outer surface of the stent member." Ex. 1001, 14:34–36. Petitioner contends, and Patent Owner does not yet dispute, that Bessler teaches a stent member with barbs that are "disposed in two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream direction." Pet. 65–66 (quoting Ex. 1006, 4:14–18).

Claim 5 recites that "the pusher member includes a controlled release mechanism." Ex. 1001, 14:37–38. Petitioner contends, and Patent Owner does not yet dispute, that Bessler such a controlled release delivery system, noting that the '739 patent description "was copied nearly word-for-word from Bessler's description." Pet. 66 (citing Ex. 1006, 4:63–5:3, 7:38–42, 7:53–67, Figs. 14, 15).

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 the combination of Bessler, Teitelbaum, and Klint, as well as the combination of Bessler, Leonhardt, and Klint, both 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 these references 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 combination of Bessler, Teitelbaum, and Klint, as well as the combination of Bessler, Leonhardt, and Klint.

G. Alleged Anticipation by Paniagua

Petitioner argues that claims 1–5 of the '739 patent are anticipated by Paniagua, that publication of the '688 Application (the grandparent application to the application that issued as the '739 patent). Pet. 42–47. In summary, Petitioner argues that "the [S]pecification of the '739 [p]atent fails to provide written description support for a valve means with two to four individual leaflets made from multiple separate pieces of valve material as claimed in each of the claims," that "[a]s a result, [Paniagua] is prior art under 35 U.S.C. §102(b)," and that "[b]ecause the specification of Paniagua is identical to the '739 [p]atent's, it anticipates each and every limitation of Claims 1–5." *Id.* at 42–43. Petitioner's arguments turn on whether Petitioner has shown sufficiently that Paniagua is prior art.

Claim 1 of the '739 patent recites "a valve means including two to four individual leaflets made of fixed pericardial tissue." Ex. 1001, 14:11–12. Petitioner argues that this claim language is "not limited to a single-piece valve design, but broadly covers "*both* valve means where the leaflets are made from a single piece of tissue *and* valve means where the leaflets are constructed from multiple, separate pieces of tissue material." Pet. 34. According to Petitioner, the '739 patent "draws a real distinction between [transcatheter heart valves] where the valve leaflets are made from a single piece of tissue material and [transcatheter heart valves] where the leaflets are formed by cutting and suturing multiple separate pieces of tissue together." *Id.* Because of this "real distinction" between one piece leaflets and multiple piece leaflets, Petitioner contends the '739 patent "claims a broader scope of invention than the '266 Application supports," such that the '739 patent has priority only to the '650 Application, which included the claim language at issue. *Id.* at 34–37.

Patent Owner argues that the claims of the '739 patent are directed to a product, not to a method of making that product or to a product-by-process, and that "the '739 patent's single claim term 'leaflets' is not limited as Petitioners allege because the scope of the claims—and the disclosure—includes leaflets in general, along with a host of other claim limitations relating to overall assembly." *Id.* at 42. Indeed, Petitioner cites no case law to support the notion that the "real distinction" Petitioner recognizes is described in writing in the '739 patent concerning how many pieces are used to make an element of a claimed apparatus equates to a lack of written description support for the apparatus. Petitioner's reliance on the Board's nonprecedential decision in *Dr. Reddy's Labs. S.A. v. Indivior UK Ltd.*, is misplaced. *Id.* at 2, 35 (citing IPR2019-00329, Paper 49 at 82–86 (PTAB

June 2, 2020). In *Dr. Reddy's* the Board found in regard to a composition claim that "the disputed ranges and ratios in [the challenged claims] place limits on the amount of polymer in the claimed films but that no such limits are disclosed in the [priority application] sufficient to provide written description support for those limitations." IPR2019-00329, Paper 49 at 79. The claims at issue in this case are not composition claims with recited ranges and do not recite any limit on the number of pieces used to make the recited leaflets.

Moreover, turning to the Specification of the '739 patent, which Petitioner concedes is the same as its parent and grandparent, we find ample written disclosure of one piece leaflets and multiple piece leaflets. *See, e.g.,* Ex. 1001, 3:36–4:32, 4:51–59; *see also* Prelim. Resp. 39–40 (describing how the '739 patent discloses sewing valves to a stent). For example, the '739 patent states "one prior replacement heart valve requires each sculpted leaflet to be trimmed in a way that forms an extended flap," that the "tip of each pericardial tissue strand is sutured directly to a papillary muscle," and that "[e]ach strand extends from the center of a leaflet in the valve, and each strand is sutured directly to either an anterior and posterior papillary muscle." Ex. 1001, 3:55–64.

The '739 patent also discusses a "preferred embodiment," stating as follows:

> The present invention is a replacement heart valve device and method of making same. The replacement heart valve device, in a preferred embodiment, 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. The cusp or leaflet portion of the valve means is formed by folding of the pericardium material preferably used to create the valve without cutting of slits to form

> leaflets or suturing or otherwise affixing of separate leaflet portions. Other forms of tissue and suitable synthetic materials can also be used for the valve, formed in a sheet of starting material. The folded design provides a number of advantages over prior designs, including improved resistance to tearing at suture lines. The cusps/leaflets open in response to blood flow in one direction and close in response to blood flow in the opposite direction. Preferably the tubular portion of the valve means contains the same number of cusps as the native valve being replaced, in substantially the same size and configuration. The outer surface of the valve means is attached to the stent member.

Id. at 4:63–5:15.

Patent Owner argues that "although the '739 patent's specification discloses that its preferred embodiment comprises a single piece of 'valve material to create the valve body and a leaflet-forming portion,' the invention is not limited to preferred embodiments," and that "[t]o find otherwise would be in direct contravention of black letter law preventing claims from being limited to preferred embodiments." Prelim. Resp. 40 (citing *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) (cautioning against limiting the claimed invention to preferred embodiments or specific examples in the specification)).

We find for purposes of this Decision that Petitioner's contentions fail to sufficiently support that the '739 patent is not entitled to priority to the '266 Application. The Specification of the '739 patent provides a written description of one piece leaflets and multiple piece leaflets, as explained above, and the claims of the '739 patent are not limited to a preferred embodiment.

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. 55. Patent Owner further argues "the remedy 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*).[12]

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

[12] 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).

> 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.

Prelim. Resp. 56. 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").[13] 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 combination of Bessler, Teitelbaum, and Klint, as well as the combination of Bessler, Leonhardt, and Klint. 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);

[13] Counsel is strongly cautioned against any additional misrepresentation of precedent. *See* 37 C.F.R. § 42.11(a).

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"); TPG, 64.

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

Brian P. Egan
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
began@mnat.com

Gregory S. Cordrey
JEFFER MANGELS BUTLER & MITCHELL, LLP
gxc@jmbm.com

PATENT OWNER:

Sarah E. Spires
Paul J. Skiermont
SKIERMONT DERBY LLP
sspires@skiermontderby.com
pskiermont@skiermontderby.com