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Paper 11
Date: August 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,
Petitioner,

v.

SPEYSIDE MEDICAL, LLC,
Patent Owner.

IPR2021-00243
Patent 9,445,897 B2

Before PATRICK R. SCANLON, JAMES J. MAYBERRY, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

SCANLON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, "Petitioner") filed a Corrected Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1–4, 6–10, 16–23, and 24 of U.S. Patent No. 9,445,897 B2 (Ex. 1001, "the '897 patent"). Speyside Medical, LLC ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp."). With our authorization, Petitioner filed a Preliminary Reply (Paper 9, "Prelim. Reply") and Patent Owner filed a Preliminary Sur-reply (Paper 10, "Prelim. Sur-reply").

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2020). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019) ("The Board will not institute on fewer than all claims or all challenges in a petition."), *available at* https://www.uspto.gov/TrialPracticeGuideConsolidated ("TPG").

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies Medtronic CoreValve LLC and Medtronic, Inc. as the real parties in interest. Pet. 5. Petitioner adds that "[n]o other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition." *Id.*

Patent Owner identifies itself as the real party in interest. Paper 5, 2.

B. Related Matters

The '897 patent is the subject of litigation in the U.S. District Court for the District of Delaware, in a case styled *Speyside Medical, LLC v. Medtronic CoreValve LLC,* No. 20-cv-00361-LPS (filed March 13, 2020). Pet. 5; Paper 5, 2. Both parties identify the following *inter partes* review proceedings as related to the '897 patent: IPR2021-00239 (challenging U.S. Patent No. 8,377,118); IPR2021-00240, IPR2021-00241, and IPR2021-00310 (each challenging U.S. Patent No. 9,510,941); IPR2021-00242 (challenging U.S. Patent No. 10,449,040); and IPR2021-00244 (challenging U.S. Patent No. 9,603,708). Pet. 5; Paper 5, 2.

C. The '897 Patent

The '897 patent, titled "Prosthetic Implant Delivery Device with Introducer Catheter," issued September 20, 2016, with claims 1–24. Ex. 1001, code (54), code (45), 33:19–34:59. The '897 patent is directed "to medical methods and devices . . . for percutaneously implanting a valve." *Id.* at 1:18–20. We reproduce Figure 5B of the '897 patent below.

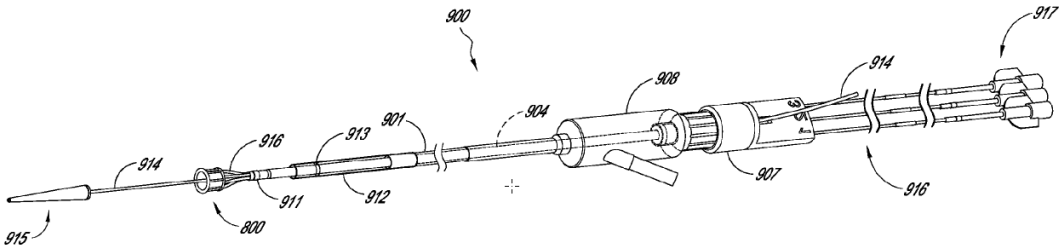

FIG. 5B

Figure 5B is a side perspective view of deployment catheter 900 with implant 800. *Id.* at 4:30–32, 18:64–66. Catheter 900 includes outer tubular member 901 having proximal end 902 and distal end 903, and inner tubular member 904 extending through outer tubular member 901. *Id.* at 19:53–58. Distal end 903 of outer tubular member 901 includes sheath jacket 912 that houses implant 800. *Id.* at 19:61–66. Inner tubular member 904 can comprise multiple lumens, one of which can accommodate guidewire tubing 914. *Id.* at 20:46–49. Guidewire tubing 914 is coupled to guidewire tip 915. *Id.* at 20:64–67. Guidewire tip 915 can have a tapered shape for direct insertion into an access vessel to dilate the access vessel for accommodating an introducer catheter. *Id.* at 21:45–51.

We reproduce Figure 8A of the ’897 patent below.

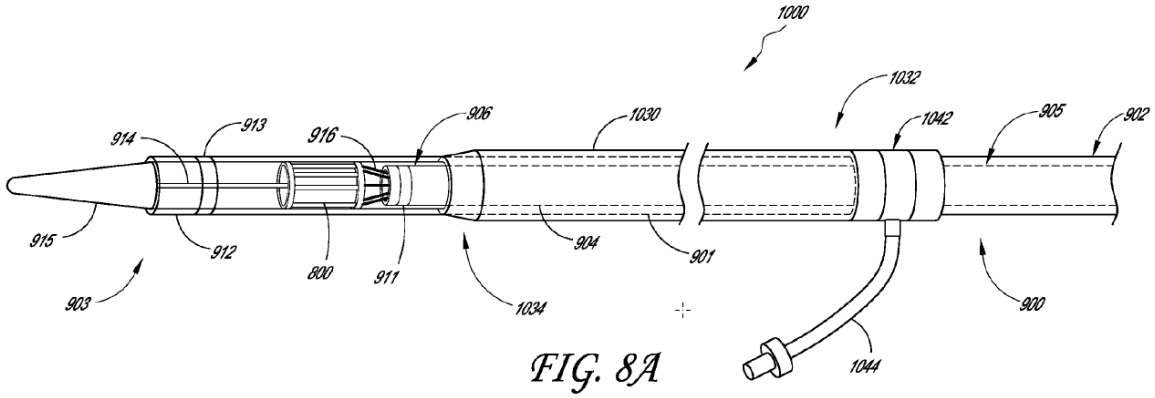

FIG. 8A

Figure 8A illustrates combined delivery system 1000 for delivering implant 800. Ex. 1001, 23:66–24:1. Combined delivery system 1000 includes

introducer catheter 1030 positioned at least partially over delivery catheter 900. *Id.* at 24:2–4. The '897 patent explains that "it is advantageous to use the combined delivery system 1000 because the introducer catheter 1030 can have a smaller diameter than would possible if the introducer catheter 1030 and the delivery catheter 900 are separately introduced into the patient." *Id.* at 24:6–10. For example, the outer diameter of sheath jacket 912 can be larger than the inner diameter of introducer catheter 1030. *Id.* at 24:10–15.

D. Illustrative Claim

Of the challenged claims, claim 1 is the sole independent claim. Claim 1 is reproduced below:

> 1. A method of positioning a prosthetic implant within a heart, the method comprising:
>
> advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system, the delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter,
>
> wherein during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter, the introducer catheter comprising a hemostasis valve assembly at a proximal end of the introducer catheter;
>
> translumenally advancing the prosthetic valve to a position proximate a native valve of the heart, the prosthetic valve being at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter; and
>
> deploying the prosthetic valve.

Ex. 1001, 33:19–38.

E. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims would have been unpatentable on the following grounds:[1]

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6–10, 16, 17	103(a)	Lane[2]
1–4, 6–10, 16, 17	103(a)	Lane, Hartley[3]
3, 4	103(a)	Lane, Nguyen[4]
3, 4	103(a)	Lane, Hartley, Nguyen
16, 18–22, 24	103(a)	Lane, Thomas[5]
16, 18–22, 24	103(a)	Lane, Hartley, Thomas

Pet. 9. Petitioner supports its challenge with the Declaration of Dr. William J. Drasler (Ex. 1002).

III. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the effective filing date of the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the application from which the '897 patent issued has an effective filing date prior to March 16, 2013, we apply the pre-AIA version of § 103.
[2] US 2011/0319989 A1, published Dec. 29, 2011 (Ex. 1023).
[3] US 2007/0185558 A1, published Aug. 9, 2007 (Ex. 1015).
[4] US 2008/01400189 A1, published June 12, 2008 (Ex. 1026).
[5] WO 2012/023980 A1, published Feb. 23, 2012 (Ex. 1006).

encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

Petitioner submits that a person having ordinary skill in the art "would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor's degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants," and "[a]dditional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education." Pet. 18 (citing Ex. 1002 ¶¶ 31–34).

For the purposes of its Preliminary Response, Patent Owner applies, and does not dispute, Petitioner's proposed level of ordinary skill in the art. Prelim. Resp. 23.

Based on our review of the record before us, we find that Petitioner's stated level of ordinary skill in the art is reasonable because it is consistent with the evidence of record, including the asserted prior art. Accordingly, for the purposes of this Decision, we adopt Petitioner's definition.

B. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the district-court-type standard, as described in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) (2020). Under that standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1313–14. Although extrinsic evidence, when available, may also be useful

when construing claim terms under this standard, extrinsic evidence should be considered in the context of the intrinsic evidence. *See id.* at 1317–19.

Petitioner argues that "[a]ll claim terms should be construed according to their plain and ordinary meaning as would have been understood by a [person having ordinary skill in the art] in view of the specification." Pet. 19 (citing Ex. 1002 ¶ 56).

In response, Patent Owner argues that Petitioner has proposed constructions for the terms "vascular system," "access vessel," and "hemostasis valve assembly" in the parallel district court proceeding. Prelim. Resp. 24 (citing Ex. 2001, 7–8). Regarding the first two terms, Patent Owner argues that, to the extent any clarification is necessary, the Board should adopt the constructions Patent Owner proposed in the district court proceeding. *Id.* at 25–26 (citing Ex. 2003, 12–15). Patent Owner does not oppose applying the plain and ordinary meaning of "hemostasis valve assembly" "[f]or purposes of the instant Petition." *Id.* at 26.

We do not discern a need to construe explicitly any claim term because doing so would have no effect on the analysis below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (stating that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Patent Owner, however, also argues that we should deny institution because Petitioner fails to apply the construction for "hemostasis valve assembly" that it proposed in the parallel district court proceeding. Prelim. Resp. 32–33 (citing *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 at 10–11 (PTAB Mar. 1, 2019)). More specifically, Patent Owner

argues that, although Petitioner asserts that "hemostasis valve assembly" should be given its plain and ordinary meaning in this proceeding, "[i]n the parallel district court proceeding, . . . the term 'hemostasis valve assembly' was identified for construction and [Petitioner] asked the court to adopt a construction of 'a part that selectively controls the flow of blood.'" *Id.* at 33 (citing Ex. 2001; Ex. 2002). According to Patent Owner, Petitioner's "failure to advance its district-court construction—or to explain how the prior art allegedly satisfies that construction—prevents the Board from resolving the issues set forth in the Petition," and, as such, Petitioner fails to meet its burden under 37 C.F.R. § 42.104. *Id.* at 33–34 (citing *OrthoPediatrics*, Paper 9 at 10–11).

In *OrthoPediatrics*, the petitioner advocated in a related district court proceeding that certain claim limitations were subject to means-plus-function claim construction, but asserted to the Board that no claim terms required construction for purposes of the petition. *OrthoPediatrics*, Paper 9 at 6; *see also id.* at 10 ("Petitioner also takes conflicting positions between this proceeding and the related district court litigation."). In view of "the unique circumstances," including where the petitioner advocated for a different claim construction in the related district court proceeding, the Board determined that the petition failed to comply with 37 C.F.R. § 42.104(b)(3) because of the petitioner's failure to provide an explicit claim construction. *Id.* at 10–11. The Board's determination, however, was limited to the situation in which construction of the disputed claim limitations was at issue because of arguments raised in the preliminary response. *Id.* at 9 (comparing the proceeding to prior related Board proceedings in which claim constructions for similar limitations were not in controversy).

The construction of "hemostasis valve assembly" is not in controversy in this proceeding. As noted above, Patent Owner indicates it does not oppose applying the plain and ordinary meaning of "hemostasis valve assembly" "[f]or purposes of the instant Petition." Prelim. Resp. 26. In addition, Patent Owner does not argue that the asserted prior art fails to disclose the hemostasis valve assembly as claimed. *Id.* at 27–32. Accordingly, we are not persuaded that *OrthoPediatrics* is applicable in this case. Thus, for purposes of this Decision, we determine that Petitioner's position with respect to claim construction complies with 37 C.F.R. § 42.204(b)(3). *See, e.g.*, *Samsung Elecs. Co. v. Cellect, LLC*, IPR2020-00476, Paper 14 at 12 (PTAB. July 31, 2020) ("It is not a requirement of 37 C.F.R. § 42.104(b)(3) that for every term for which Petitioner has proposed an express construction in related district court litigation, Petitioner must propose the same construction in the Petition."); *10X Genomics, Inc. v. Bio-Rad Labs., Inc.*, IPR2020-00086, Paper 8 at 17–22 (PTAB Apr. 27, 2020) (providing a comprehensive analysis of the issue).

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

Patent Owner argues that we should exercise discretion to deny institution under 35 U.S.C. § 314(a) in view of the parallel district court proceeding. Prelim. Resp. 39–44; *see* Prelim. Sur-reply. Petitioner disagrees. Pet. 17–18; Prelim. Reply.

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS*, 138 S. Ct. at 1356 ("[Section] 314(a) invests the

Director with discretion on the question whether to institute review . . . ." (emphasis omitted)); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d at1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

We consider an advanced state of a parallel district court proceeding as a "factor that weighs in favor of denying the Petition under § 314(a)." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential) ("*NHK*"). Specifically, we consider an early trial date as part of a "balanced assessment of all relevant circumstances of the case, including the merits." TPG 58. As part of this balanced assessment, we consider the following factors:

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

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). We address each factor below.

1. *Factor 1: whether the court granted a stay or evidence exists that one may be granted if this proceeding is instituted*

Petitioner states that it intends to seek a stay of the district court proceeding pending the outcome of this Petition and other related petitions.

Pet. 17. Patent Owner argues that Petitioner has presented no evidence that a stay would be granted in the district court proceeding and judges in Delaware courts routinely deny motions to stay filed prior to the institution of an IPR. Prelim. Resp. 41. Petitioner responds that the district court has denied Petitioner's motion to stay without prejudice to refile following this Decision and that the district court is likely to stay if we institute some or all of the petitions challenging the patents asserted in the district court proceeding. Prelim. Reply 1.

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

2. Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

Petitioner argues that trial in the district court proceeding is scheduled for October 2022, and this date is about two months after the date that a Final Written Decision would issue for this proceeding. Pet. 17 (citing Ex. 1008); Prelim. Reply 1. Patent Owner asserts that Petitioner twice sought to delay the district court proceeding by moving to dismiss Patent Owner's Complaint and Amended Complaint, opposed a motion to file a second Amended Complaint, and objected to setting a case schedule until its motion to dismiss was resolved. Prelim. Resp. 42 (citing Ex. 2010; Ex. 2011; Ex. 2012; Ex. 2013); Prelim. Sur-reply 2.

The record at this stage indicates a trial date of October 11, 2022, for the district court proceeding, which would occur about two months after the statutory deadline for our final written decision. Ex. 1008, 14. Patent Owner's arguments that Petitioner's motions in the district court proceeding

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

3. Factor 3: investment in the parallel proceeding by the court and the parties

Petitioner asserts that the district court "has not issued any substantive orders related to [the] '897 [patent]" and that although Patent Owner has served infringement contentions, Petitioner has not served invalidity contentions (as of the Petition's filing date), "depositions have not begun, and claim construction briefing has not yet begun." Pet. 17–18 (citing Ex. 1008).

Patent Owner argues that the parties have spent significant time and resources in the district court proceeding because Petitioner filed multiple motions to dismiss, opposed Patent Owner's motion to file an Amended Complaint, and unsuccessfully sought to compel certain discovery that the district court found to be irrelevant. Prelim. Resp. 42. Patent Owner contends that the parties are in the midst of claim construction briefing and a *Markman* hearing is scheduled for August 11, 2021. *Id.* (citing Ex. 1042; Ex. 2018).[6] Patent Owner further asserts that the parties served initial discovery requests, produced hundreds of thousands of pages of documents in fact discovery, served initial infringement and invalidity contentions, and will complete expert discovery and dispositive motions by the deadline for a Final Written Decision. *Id.* at 42–43.

Petitioner responds that the parties will not have held the *Markman* hearing, served final invalidity contentions, or completed fact discovery by

[6] Patent Owner's citation to Exhibit 1042 appears to be a typographical error. It appears that the intended citation may be Exhibit 1008.

this Decision. Prelim. Reply 1 (citing Ex. 1008; Ex. 1058; Ex. 1060 (rescheduling *Markman* hearing to October 12, 2021)).

Patent Owner does not cite evidence to support its arguments regarding the stage of fact and expert discovery and initial infringement and invalidity contentions. Conversely, the record at this stage indicates that the court has rescheduled the *Markman* hearing to October 12, 2021, which will occur after this Decision. Ex. 1008; Ex. 1058; Ex. 1060. Further, the record does not indicate that the parties or district court have made more than minimal investments on invalidity issues at this time. Finally, Patent Owner's arguments about investments that will occur *after* this Decision, but prior to any Final Written Decision for this proceeding, are unpersuasive because we consider the investment "at the time of the institution decision" not at some later date. *Fintiv*, Paper 11, 9–10.

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

4. Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Petitioner contends that "[t]he same grounds, arguments and evidence could not be presented in litigation after the earlier-expected final written decision," and "the Petition challenges at least one claim not at issue in the litigation." Pet. 18. Patent Owner argues that Petitioner's initial invalidity contentions in the district court proceeding include the same prior art cited in the Petition. Prelim. Resp. 43 (citing Ex. 2014, 16–20; Ex. 2015; Ex. 2016; Ex. 2017; Ex. 2019). Patent Owner also argues that Petitioner's challenge of claim 16, the only non-asserted claim challenged in the Petition, is without merit. *Id.*

Petitioner responds that it "recently stipulated that if the Board institutes, Petitioners will not pursue the IPR grounds in the district court litigation." Prelim. Reply 1 (citing Ex. 1059). Patent Owner contends that Petitioner's stipulation is meaningless because it is not as broad as the scope of estoppel under 35 U.S.C. § 315 and it leaves the same concerns about duplicative proceedings and inconsistent rulings. Prelim. Sur-reply 1 (citing *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 12 (PTAB June 16, 2020) (informative)).

The record indicates that the references Petitioner asserts in its grounds here are also asserted in the district court proceeding, with the exception of Hartley and Nguyen. Ex. 2014, 16–20. Petitioner, however, stipulates in the district court proceeding that "[i]f the PTAB grants institution of IPR2021-00243, Medtronic will not pursue the same grounds against the patent at issue in that IPR in the corresponding district court litigation." Ex. 1059. Although Petitioner's stipulation is not as broad as the stipulation discussed in *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential), it "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions."[7] *See Sand Revolution II, LLC*, Paper 24 at 12.

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

[7] In any event, overlap between this proceeding and the district court proceeding may result in greater efficiency because the statutory date for our final written decision falls before the October 2022 trial date in the district court proceeding. Thus, Petitioner will be estopped from raising in the district court proceeding any prior art that it raised or reasonably could have raised in this IPR. 35 U.S.C. § 315(e)(2).

5. Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Petitioner concedes that the parties for this proceeding and the district court proceeding are the same. Pet. 18. Because the statutory date for our final written decision falls before the October 2022 trial date in the district court proceeding, we find this factor weighs against exercising discretion to deny institution.

6. Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Petitioner argues that the asserted grounds challenging the claims of the '897 patent are particularly strong. Pet. 18; Prelim. Reply 1–2. Patent Owner in turn argues that Petitioner fails to account for the Office previously analyzing the same or substantially the same prior art and finding that it did not teach all elements of the claims, which undercuts Petitioner's arguments that the asserted grounds are strong. Prelim. Sur-reply 1. Patent Owner also asserts that Petitioner's arguments in the Reply exceed the scope of our authorization because they include claim construction arguments. *Id.* at 2.

For the reasons discussed below regarding Petitioner's obviousness challenges, we find Petitioner's grounds to be strong. For example, the current record shows that Lane teaches or suggests each limitation of challenged claim 1. *See infra* §§ III.E. Further, as we explain below, *see infra* § III.D, we do not exercise our discretion to deny institution under 35 U.S.C. § 325(d), so we are not persuaded that § 325(d) undercuts the strength of the merits.

Patent Owner's arguments regarding the scope of Petitioner's arguments in the Preliminary Reply are also unpersuasive. Our

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

7. Conclusion

We have considered the circumstances and facts before us in view of the *Fintiv* factors. Because our analysis is fact-driven, no single factor is determinative of whether we exercise our discretion to deny institution under § 314(a). We take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when evaluating these factors. *Fintiv*, Paper 11, 6. Evaluating all of the factors on this record, we determine that the circumstances presented here do not support exercising our discretion under § 314(a) to deny institution of *inter partes* review.

D. Discretion Under 35 U.S.C. § 325(d)

Section 325(d) of Title 35 of the United States Code provides, in relevant part: "In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to

the Office." The Board uses a two-part framework for evaluating arguments under § 325(d):

> (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).

Petitioner argues that we should not exercise our discretion to deny institution under § 325(d) because the grounds raised in the Petition do not include the same or substantially the same prior art or arguments as were raised during prosecution of the '897 patent. Pet. 15–17. In particular, Petitioner argues that Lane, Zarbatany,[8] Hartley, Thomas,[9] and Nguyen were not considered during prosecution and are not cumulative. *Id.* at 16.

Patent Owner responds that the Petition relies on the same or substantially the same arguments previously presented to the Office. Prelim. Resp. 35–38. Specifically, Patent Owner asserts that "Petitioners' argument that Lane *does* teach an introducer catheter is substantially the same as (and thus cumulative of) the argument initially made by the Examiner concerning the Dwork prior art reference during prosecution, which was overcome by the Patent Owner."[10] *Id.* at 36. Patent Owner adds that, although indicating

[8] US 2004/0181238 A1, published Sept. 16, 2004 (Ex. 1005). Petitioner identifies Zarbatany as being incorporated by reference in Lane. Pet. 3.
[9] Petitioner concedes that Thomas was cited in an Information Disclosure Statement, but contends it was never cited in a rejection. Pet. 16 n.3.
[10] "Dwork" is U.S. Patent Application Publication US 2011/0257733 A1, published October 20, 2011 (Ex. 1021).

at one point during the prosecution that Dwork disclosed the claimed delivery and introducer catheters, the Examiner subsequently "concluded that Dwork fails to teach an introducer catheter that is 'preassembled' with the delivery catheter (and teaches away from doing so)." *Id.* at 36–37 (citing Ex. 1003, 2718, 2734). We provide a brief summary of the '897 patent's prosecution history and then address the parties' arguments.

1. Relevant Prosecution History of the '897 Patent

The '897 patent issued from Application No. 13/777,745 ("the '745 application"). Ex. 1001, code (21). The '745 application included original claim 19, which issued as claim 1. *See* Ex. 1003, 2744 (mapping original claim 19 to final claim 1). In a final office action, the Examiner rejected claim 19 (together with claims 20–24) under 35 U.S.C. § 102(b) as anticipated by Dwork. *Id.* at 2506–08.

The applicant subsequently submitted a Supplemental Response to the final office action, which proposed amending claim 19 to recite that the introducer catheter is preassembled over the delivery catheter. *Id.* at 2541. The Supplemental Response indicated that during a telephonic interview, the Supervisory Examiner "suggested that the Applicant amend Claim 19 to describe the pre-assembly step." *Id.* at 2544. The applicant argued that Dwork failed to disclose advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter because paragraph 54 of Dwork discloses that "'the introducer sheath 202 [is] inserted through the incision 206,' and '[t]he delivery device 40 is ***then*** inserted into the bodily lumen via the introducer device 200.'" *Id.* at 2545–46 (alterations in original). The applicant concluded that "the Final Office Action fails to establish that Dwork discloses the preassembly step recited in amended Claim 19." *Id.* at 2546.

The Examiner eventually allowed claim 19, after a minor Examiner's Amendment. *Id.* at 2730–32. The Examiner indicated that "Dwork teaches a method of positioning a prosthetic implant with a heart, but fails to teach a preassembled configuration and teaches away from preassembly because Dwork teaches deploying the introducer catheter first then deploying the delivery catheter within the introducer catheter." *Id.* at 2734.

2. Discussion

In view of the above, we determine that the Examiner's reasoning for allowing claim 19 over Dwork was based on the finding that Dwork did not teach a *preassembled* configuration. The Examiner did not indicate that Dwork failed to disclose an introducer catheter at all. This determination is bolstered by the fact that the applicant repeatedly argued that Dwork does not disclose preassembly. *See* Ex. 1003, 2546, 2722.

Here, Petitioner asserts that Lane discloses an introducer catheter that is preassembled over a delivery catheter.[11] Pet. 32–33 (citing Ex. 1023 ¶¶ 115, 122, 123, 138, Fig. 18; Ex. 1002 ¶¶ 87–88). We are not directed to any disclosure in Lane that is similar to the disclosure in paragraph 54 of Dwork suggesting that the delivery device is inserted *after* insertion of the introducer sheath. As such, we are not persuaded that arguments asserting that Lane discloses a preassembled introducer catheter are substantially the same as arguments asserting that Dwork discloses a preassembled introducer catheter. Accordingly, we determine that Petitioner's reliance on Lane does not involve the same or substantially the same arguments previously presented to the Office. Thus, we find that the same or substantially the same art or arguments were not previously presented and the first part of the

[11] We discuss this assertion in more detail in § III.E.2.a below.

Advanced Bionics framework is not satisfied. Thus, we do not exercise our discretion under § 325(d) to deny institution in this proceeding.

E. Asserted Obviousness Based on Lane

Petitioner asserts that claims 1–4, 6–10, 16, and 17 are unpatentable under 35 U.S.C. § 103(a) based on Lane. Pet. 24–66. Patent Owner provides arguments addressing this asserted ground of unpatentability. Prelim. Resp. 27–32. We first summarize Lane and then address the parties' contentions.

1. Lane

Lane, titled "Transcatheter Mitral Valve Prosthesis," was published on December 29, 2011. Ex. 1023, codes (54), (43). Lane "relates to the treatment of valve insufficiency, such as mitral insufficiency, also referred to as mitral regurgitation." *Id.* ¶ 3. Lane explains that, although transcatheter devices and methods for the delivery of replacement valve assemblies have been developed, it would be desirable to provide improved transcatheter devices and methods for the treatment of mitral insufficiency. *Id.* ¶¶ 6–7.

We reproduce Figures 16 and 18 of Lane below.

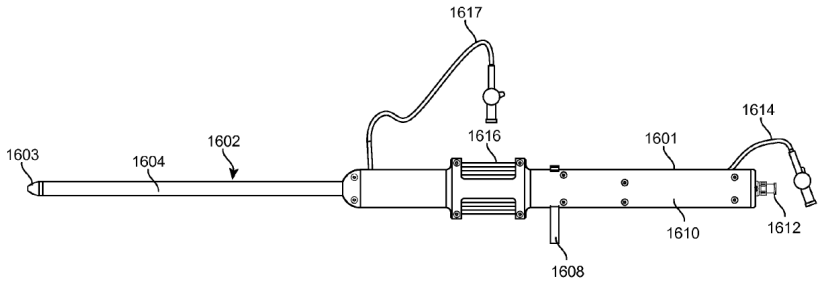

FIG. 16

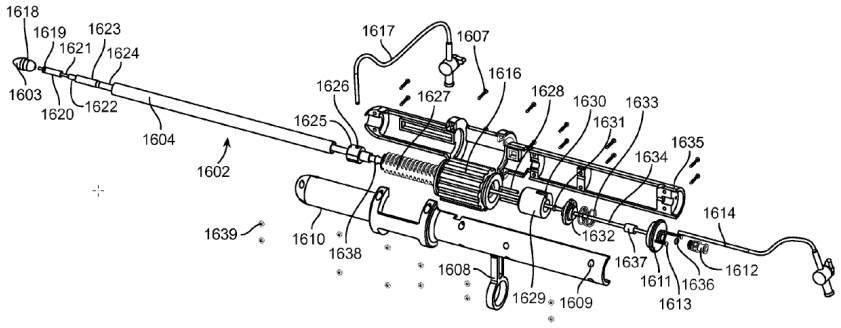

FIG. 18

Figure 16 is a side view of an exemplary embodiment of a delivery device for implanting a prosthetic heart valve transapically, and Figure 18 is an exploded view of the delivery device. Ex. 1023 ¶¶ 71, 73, 115.

The delivery device includes handle 1601, flexible sheath 1602 comprised of a plurality of concentric catheters, and tip 1603 for smoothly penetrating the apex of the heart. *Id.* ¶ 115. Handle 1601 includes thumbwheel 1616 for actuating sheath catheter 1604. *Id.* ¶ 117. The delivery device further includes first hemostasis tune 1617 and second hemostasis tune 1614. *Id.* ¶¶ 118–119.

Flexible sheath 1602 comprises four concentrically nested catheters. *Id.* ¶ 122. The innermost catheter is guide-wire catheter 1621 that is connected to tip 1603. *Id.* Next is hub catheter 1622, which is stationary and supports hub 1620. *Id.* The next catheter is bell catheter 1624, which houses hub 1620 and can be advanced and retracted axially with respect to hub 1620. *Id.* The outermost catheter is sheath catheter 1604, which houses a prosthetic mitral valve (not shown). *Id.* Sheath catheter 1604 "is able to penetrate the apex of the heart (not shown), by supporting and directing a tip 1603 and assisting in the dilation of an incision in the heart wall muscle." *Id.*

2. Independent Claim 1

Petitioner contends that Lane, when modified as proposed, discloses each limitation of independent claim 1. Pet. 31–47. To support its arguments, Petitioner identifies certain passages in the Lane and explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons that one of ordinary skill in the art would have allegedly modified Lane to dilate the access point of the access vessel. *Id.* at 38–39. Patent Owner argues that Petitioner has failed to show that Lane discloses a preassembled introducer catheter. Prelim. Resp. 27–32.

We have reviewed Petitioner's contentions with respect to the limitations of claim 1, and for the reasons discussed below, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail in with respect to the contention that claim 1 would have been obvious based on Lane. *See* Pet. 31–47. We address Patent Owner's arguments below.

a) The "Advancing Together" Limitation

Claim 1 recites "advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system" ("the 'advancing together' limitation"). Ex. 1001, 33:21–23. In addressing this limitation, Petitioner argues that Lane's guide-wire catheter 1621, hub catheter1622, and bell catheter 1624 collectively correspond to the claimed delivery catheter. Pet. 32–33 (citing Ex. 1023 ¶¶ 115, 122, 138, Fig. 18). Petitioner also argues that Lane's sheath catheter 1604 corresponds to the claimed introducer catheter that is preassembled over the delivery catheter. *Id.* (citing Ex. 1023 ¶¶ 115, 122, 138, Fig. 18). According to Petitioner, "because [Lane's] distal tip 1603 cannot pass through and instead 'abut[s] against' the sheath catheter 1604's distal edge,

sheath catheter 1604 is preassembled over the other three catheters outside the patient." *Id.* at 32 (citing Ex. 1023 ¶ 123; Ex. 1002 ¶¶ 87–88) (second alteration in original).

Patent Owner presents several arguments asserting that Lane does not disclose a preassembled introducer catheter. Prelim. Resp. 27–32. First, Patent Owner argues that "Lane fails to teach *any* embodiment that uses an introducer catheter, much less a preassembled introducer catheter," and "[n]owhere in Lane is 'introducer' (or 'introducer catheter' or 'introducer sheath') ever mentioned." *Id.* at 28. It is well-settled, however, that "the [prior art] reference need not satisfy an *ipsissimis verbis* test," i.e., identity of terminology is not required, to disclose a claim limitation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). Although Lane does not refer explicitly to sheath catheter 1604 as an "introducer catheter," sheath catheter 1604 is the outermost of four concentrically arranged catheters. Ex. 1023 ¶ 122, Fig. 18. We are not directed to any evidence in the current record suggesting that the term "introducer" has any particular meaning in the art that would exclude sheath catheter 1604 from being considered an introducer catheter. Accordingly, we agree with Petitioner at this stage of the proceeding that Lane's sheath catheter 1604 is an "introducer catheter" as recited in claim 1.

Second, Patent Owner argues that "Lane's 'sheath catheter 1604' is more akin to the 'outer sheath 901' of the '897 Patent, not the '897 Patent's introducer catheter." Prelim. Resp. 28. This argument is not persuasive. Even if Lane's sheath catheter 1604 is "more akin" to outer sheath 901, this fact alone would not mean that catheter 1604 cannot satisfy the claimed introducer catheter. Claim 1 does not appear to recite structure corresponding to outer sheath 901. Claim 10 recites "an outer tubular

element" that appears to correspond to disclosed element 901. Ex. 1001, 34:8. Patent Owner does not dispute at this stage of the proceeding Petitioner's assertion that Lane's bell catheter 1624 corresponds to the outer tubular element of claim 10 . *See* Prelim. Resp. 27–32; Pet. 54–55.

Third, Patent Owner argues that "to the extent [Petitioner] is suggesting that the outermost sheath of a multi-lumen catheter must, by default, be an introducer catheter if no separate introducer catheter is used, such a proposition is belied by [Petitioner's] own cited prior art, including Thomas." Prelim. Resp. 29 (citing Ex. 1006). We do not find this argument persuasive because we do not view Petitioner's position as being that Lane's outermost sheath must be an introducer catheter *by default*. Instead, Petitioner explains, supported with Dr. Drasler's testimony, its assertion that Lane's sheath catheter 1604 corresponds to the claimed introducer catheter. Pet. 32–33; Ex. 1002 ¶ 87.

Last, Patent Owner argues that Lane ultimately issued as U.S. Patent No. 8,579,964 ("the '964 patent") to Neovasc Inc., and Neovasc touted the '964 patent as "the first patent covering the company's innovative Tiara™ transcatheter mitral valve replacement technology." Prelim. Resp. 31 (citing Ex. 2007; quoting Ex. 2004, 1–2). According to Patent Owner, "[i]t is widely recognized by persons of skill in the art that the delivery system for the Tiara device is delivered *without* an introducer catheter, which is consistent with Lane's disclosure and overall silence with respect to the use of an introducer." *Id.* at 31–32 (citing Ex. 2005, 3; Ex. 2006, 2).

Exhibit 2004 is a press release that states the '964 patent "protects key aspects of the Tiara mitral valve prosthesis." Ex. 2004, 1. There is no indication that the delivery system disclosed in the patent is a "key aspect." *Id.* at 1–3. Furthermore, neither of the exhibits Patent Owner cites reference

the '964 patent such that it is unclear whether Exhibits 2005 and 2006 refer to the delivery system disclosed in the '964 patent. Even assuming for the sake of argument that Exhibits 2005 and 2006 do refer to the delivery system disclosed in the '964 patent, stating that the valve is designed to be delivered without an introducer sheath does not necessarily mean that Lane's sheath catheter 1604 cannot be considered to be an "introducer catheter" as recited in claim 1. Therefore, Patent Owner's last argument is not persuasive.

For these reasons, at this stage of the proceeding and on the current record, we determine that Petitioner has made a sufficient showing that Lane discloses the "advancing together" limitation.

b) The Remaining Aspects of Petitioner's Contentions

Patent Owner does not offer any arguments specifically addressing the remaining limitations of claim 1. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions with respect to the remaining limitations of claim 1 and determine that the Petition provides a sufficient showing, at this stage of the proceeding, that Lane, when modified as proposed, satisfies each limitation. *See* Pet. 31–47.

c) Conclusion

For the above reasons, we determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 is unpatentable over Lane.

3. Dependent Claims 2–4, 6–10, 16, and 17

Because Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '897 patent is unpatentable, we institute on all grounds and all claims raised in the Petition. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64. Therefore, it is not necessary for us to assess every claim challenged by Petitioner. Nevertheless, we note that

Petitioner provides reasonable and detailed explanations, supported with the testimony of Dr. Drasler, indicating where Lane teaches or suggests the limitations of claims 2–4, 6–10, 16, and 17. Pet. 47–58. Further, Patent Owner offers no particular arguments with respect to claims 2–4, 6–10, 16, and 17 for us to consider at this stage of the proceeding. *See generally* Prelim. Resp. For these reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in its assertion that claims 2–4, 6–10, 16, and 17 are unpatentable over Lane.

F. Asserted Obviousness Based on Lane and Hartley

Petitioner also contends claims 1–4, 6–10, 16, and 17 are unpatentable under 35 U.S.C. § 103(a) based on Lane and Hartley. Pet. 58–61. In particular, Petitioner argues that

> [t]o the extent it is argued that further disclosure of "a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter" . . . is required, **Hartley** teaches inserting a nose cone dilator, with a tapered tip, connected to a catheter directly into an access vessel to dilate the vessel for the catheter—thus further rendering obvious claims 1-4, 6-10, 16-17 over **Lane** in view of **Hartley**.

Id. at 58–59 (citing Ex. 1002 ¶¶ 158–162). In addition, Petitioner provides reasons, supported with the testimony of Dr. Drasler, for why it would have been obvious to one of ordinary skill in the art to combine Lane and Hartley with a reasonable expectation of success. *Id.* at 60–61 (citing Ex. 1002 ¶¶ 160–162).

Patent Owner has not argued at this stage of the proceeding that Lane fails to disclose a distal tip that can be inserted directly into an access vessel to dilate the access vessel. Instead, Patent Owner argues only this ground fails in view of the alleged failure of Lane to disclose the preassembled

introducer catheter of claim 1. Prelim. Resp. 28. We do not agree that Lane fails to disclose a preassembled introducer catheter for the reasons discussed above. *See supra* § III.E.2.

In any event, because Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '897 patent is unpatentable (*see supra* §§ III.E), we include this ground in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

G. Remaining Grounds

Petitioner also challenges claims 3 and 4 as unpatentable under 35 U.S.C. § 103(a) based on the combination of Lane and Nguyen and the combination of Lane, Hartley, and Nguyen, and claims 16, 18–22, and 24 as unpatentable under 35 U.S.C. § 103(a) based on the combination of Lane and Thomas and the combination of Lane, Hartley, and Thomas. Pet. 61–82.

Petitioner relies on Nguyen as disclosing inserting a delivery device into a femoral artery and advancing a prosthesis through an aorta to the extent Patent Owner argues Lane fails to disclose these limitations. *Id.* at 61–62 (citing Ex. 1002 ¶¶ 163–167). Petitioner also provides reasons, supported with the testimony of Dr. Drasler, for why it would have been obvious to one of ordinary skill in the art to combine Nguyen with either Lane alone or Lane and Hartley with a reasonable expectation of success. *Id.* at 63–64 (citing Ex. 1002 ¶¶ 165–167).

Petitioner relies on Thomas as disclosing adjusting an angular position of the prosthesis, as recited in claim 16, to the extent Patent Owner argues Lane fails to disclose this limitation. *Id.* at 64 (citing Ex. 1002 ¶¶ 168–226). Petitioner also provides reasons, supported with the testimony of Dr. Drasler, for why it would have been obvious to one of ordinary skill in the art to combine Lane and Thomas with a reasonable expectation of

success. *Id.* at 68–69 (citing Ex. 1002 ¶¶ 176–180). Petitioner also provides explanations, supported with the testimony of Dr. Drasler, indicating how the combination of Lane and Thomas discloses the limitations of claims 18–22 and 24. *Id.* at 69–82 (citing Ex. 1002 ¶¶ 181–226).

Patent Owner does not argue at this stage of the proceeding that the various combinations Petitioner asserts fail to disclose the subject matter of claims 3, 4, 16, 18–22, and 24. Instead, Patent Owner argues only these grounds fail in view of the alleged failure of Lane to disclose the preassembled introducer catheter of claim 1. Prelim. Resp. 28. We do not agree that Lane fails to disclose a preassembled introducer catheter for the reasons discussed above. *See supra* § III.E.2.

In any event, because Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '897 patent is unpatentable (*see supra* § III.E), we include these grounds in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

IV. CONCLUSION

After considering the evidence and arguments of record, we determine that Petitioner has demonstrated a reasonable likelihood of success with respect to at least one of the challenged claims. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claims or any underlying factual or legal issues. The final determination will be based on the record as developed during the *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–4, 6–10, 16, and 17 of the '897 patent 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 the '897 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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