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Paper 9
Entered: February 24, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner.

IPR2020-01343
Patent RE46,116 E

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

TARTAL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic, Inc., and Medtronic Vascular, Inc. ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 25–40, 42, 44–48, 52, and 53 ("the Challenged Claims") of U.S. Patent No. RE46,116 E (Ex. 1001, "the '116 patent"). Paper 1 ("Pet."). Teleflex Life Sciences Limited ("Patent Owner") filed a Preliminary Response. Paper 7 ("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 '116 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 '116 Patent

The '116 patent, titled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued August 23, 2016, from Application

No. 14/195,435, filed March 3, 2014. Ex. 1001, codes (21), (22), (45), (54). The '116 patent is a reissue of U.S. Patent No. 8,292,850 ("the '850 patent") from Application No. 13/359,059 filed on January 26, 2012, which the '116 patent states is a continuation of an application filed on November 1, 2013 (issued as U.S. Patent No. RE45,380), which is an application for the reissue of U.S. Patent No. 8,292,850, which is a division of an application filed on June 28, 2010 (issued as U.S. Patent No. 8,142,413), which is a division of an application filed on May 3, 2006 (issued as U.S. Patent No. 8,048,032). *Id.* codes (60), (64). The '116 patent is directed to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." *Id.* at 1:38–40.

The '116 patent explains, as background, that in "[i]nterventional cardiology procedures," guidewires or other instruments, such as balloon catheters and stents, are often inserted through guide catheters into coronary arteries that branch off from the aorta. *Id.* at 1:44–50. In coronary artery disease, "the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions" in a phenomenon known as stenosis. *Id.* at 1:50–54. In treating the stenosis, "a guide catheter is inserted through the aorta and into the ostium of the coronary artery," sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:59–65. However, according to the '116 patent, "[c]rossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated," which "can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease." *Id.* at 1:66–2:3.

The '116 patent discusses four categories of previous "attempts to provide support to the guiding catheter to prevent backward dislodgement

from the coronary ostium (referred to as 'backup support')." *Id.* at 2:4–7. One category of guiding catheters "are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed." *Id.* at 2:8–11. A second category are "guiding catheters that include a retractable appendage. *Id.* at 2:25–26. A third category are "guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium." *Id.* at 2:36–41. A fourth category, or "technique," of the prior attempts "includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents." *Id.* at 2:50–53. The '116 patent states this fourth technique was described in Takahashi,[1] which uses a guide catheter inserted "more deeply into the ostium of the coronary artery than typically has been done before." *Id.* at 2:53–62. The '116 patent states that such "deep seating" by this technique "creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery." *Id.* at 2:63–65.

The '116 patent purports to resolve issues identified with the prior procedures by using "a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter." Ex. 1001, 3:20–23. According to the '116 patent, the coaxial guide catheter "preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery," and

[1] Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, 63 CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS 452–456 (2004) (Ex. 1010, "Takahashi").

this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 3:23–28.

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '116 patent:

Fig. 1

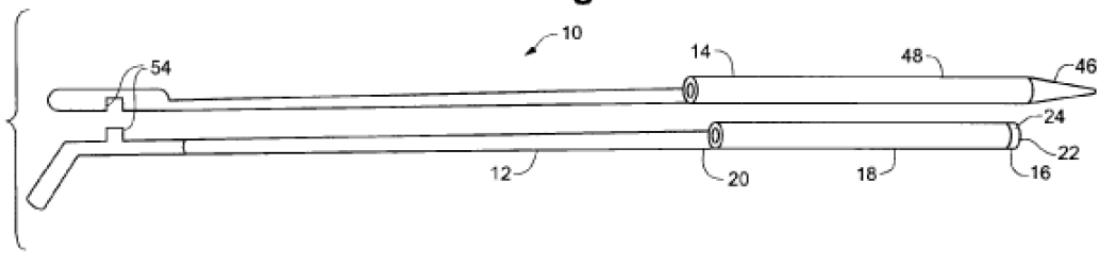

Fig. 2

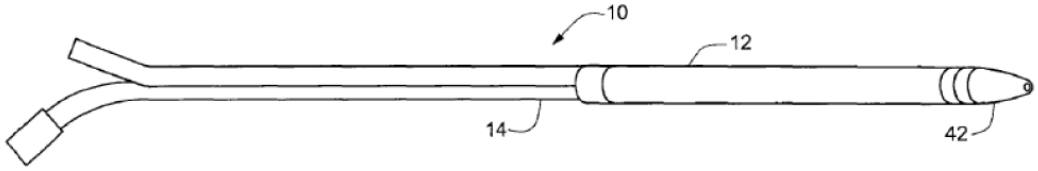

Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:51–56; Figs. 1 and 2. As shown above, "coaxial guide catheter assembly 10" includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:42–44. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:45–46. Tapered inner catheter 14 "includes tapered inner catheter tip 42." *Id.* at 7:26–27. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:30–31. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 7:31–32. "Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14

to coaxial guide catheter 12." *Id.* at 7:35–37. "The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French." *Id.* at 3:28–31. The coaxial guide catheter is made in at least three sizes corresponding to sizes commonly used in interventional cardiology procedures. *Id.* at 3:39–42.

Figure 4, reproduced below, shows a coaxial guide catheter in accordance with the invention described in the '116 patent:

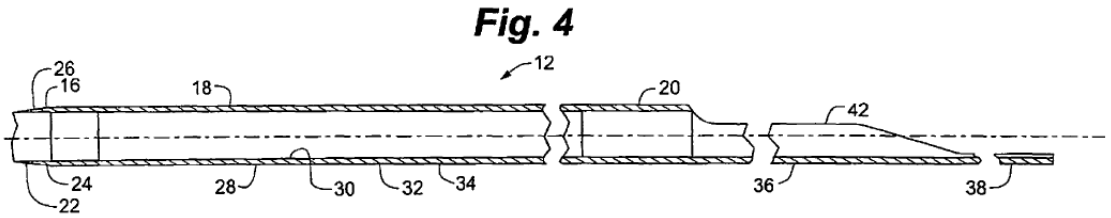

Figure 4 is a sectional view of the coaxial guide catheter with tip portion 16 depicted on the left side of the figure (rather than on the right side as shown in Figures 1 and 2). Ex. 1001, 5:60; Fig. 4. As shown above, coaxial guide catheter 12 has rigid portion 20 that "includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full circumference portion 40" (second full circumference portion 40 is shown in Figure 3). *Id.* at 7:7–10.

In operation, a guide catheter and a guidewire are used along with the coaxial guide catheter and the tapered inner catheter. Ex. 1001, 8:20–22. Figure 8, reproduced below, shows the operation of the coaxial guide

catheter assembly in accordance with the invention described in the '116 patent:

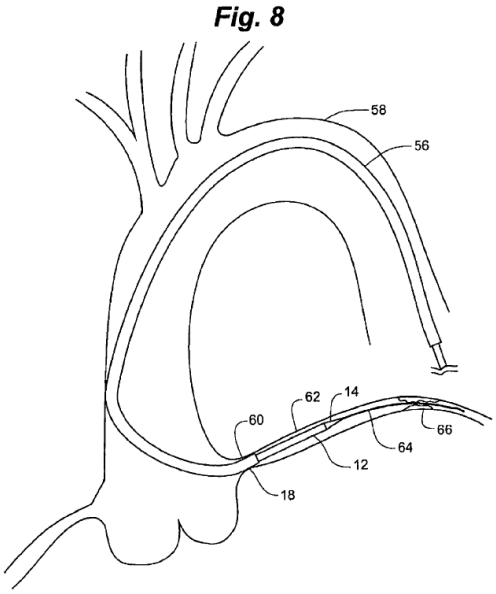

Figure 8 is a schematic view of a guide catheter and a guide wire in use with the coaxial guide catheter assembly within the aortic arch and coronary artery. *Id.* at 6:5–8; Fig. 8. First, guidewire 64 is inserted and passed through aortic arch 58 into ostium 60 of coronary artery 62. *Id.* at 7:65–66. Guide catheter 56 is then passed over guidewire 64 until the distal end of guide catheter 56 is seated in ostium 60. *Id*. at 8:4–6. Next, coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62. *Id.* at 8:22–24. The presence of coaxial guide catheter 12 within guide catheter 56 "provides stiffer back up support than guide catheter 56 alone." *Id.* at 8:38–40. "Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed." *Id.* at 4:58–62; *see also id.* at 8:30–32. Thereafter, coaxial guide catheter 12 can "accept a treatment

catheter such as a stent or a balloon catheter." *Id.* at 8:33–34. "[T]he presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion." *Id.* at 5:2–5:6. "[T]he invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters." *Id.* at 5:42–44.

B. Illustrative Claim

Petitioner challenges claims 25–40, 42, 44–48, 52, and 53 of the '116 patent. Pet. 1. Claims 25 and 52 are independent method claims. Ex. 1001, 13:62–14:25, 17:10–18:10. Claims 26–40, 42, and 44–48 depend from claim 25 and claim 53 depends from claim 52. *Id.* at 14:26–15:41, 15:47–50, 18:11–14. Claim 25 is illustrative of the claimed subject matter and is reproduced below.

> 25. A method, comprising:
>
> advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;
>
> advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

Id. at 13:62–14:25.

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. §	References/Basis
52, 53	102	Ressemann[2]
25–40, 42, 44–48, 52, 53	103	Itou,[3] Ressemann
45	103	Itou, Ressemann, Kataishi,[4]

Pet. 8–9. Petitioner relies on the supporting Declarations of Jon David Brecker, M.D., dated July 31, 2020 (Ex. 1005), and Richard A. Hillstead, Ph.D., dated July 30, 2020 (Ex. 1042).

D. Related Proceedings

The parties identify the '116 patent as a subject of: (1) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn.),

[2] U.S. Patent No. 7,604,612 B2, issued October 20, 2009 (Ex. 1008, "Ressemann").
[3] U.S. Patent No. 7,736,355 B2, issued June 15, 2010 (Ex. 1007, "Itou").
[4] US 2005/0015073 A1, published January 20, 2005 (Ex. 1025, "Kataishi").

and (2) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn.). Pet. 5–6; Paper 4, 2. Patent Owner states that both of these district court proceedings are currently stayed. Paper 4, 2. The parties further state that the '116 patent is a reissue of the '850 patent and that the '850 patent was a subject of: (1) *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn.), and (2) *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (PTAB, terminated). Pet. 6; Paper 4, 2–3.

Petitioner challenges claims 25–55 of the '116 patent in IPR2020-01344 through a second petition filed concurrently with the Petition in this case. Pet. 6. In accordance with our Trial Practice Guide, Petitioner provides an explanation of material differences between the two petitions and seeks consideration of the Petition in this case prior to the second petition filed in IPR2020-01344. Paper 3. Patent Owner does not address Petitioner's filing of multiple petitions challenging the '116 patent in its Preliminary Response. *See generally* Prelim. Resp. This Decision addresses only the first petition filed by Petitioner and, accordingly, we need not and do not address in this Decision whether a second petition is warranted.

Additionally, Petitioner identifies the following patents related to the '116 patent that are the subject of *inter partes* review proceedings initiated by Petitioner: U.S. Patent Nos. 8,048,032 (IPR2020-00126; IPR2020-00127), RE45,830 (IPR2020-00128; IPR2020-00129; IPR2020-00130), RE45,760 (IPR2020-00132; IPR2020-00134), RE45,776 (IPR2020-00135; IPR2020-00136), RE47,379 (IPR2020-00137; IPR2020-00138), and 8,142,413 (IPR2020-01341; IPR2020-01342). *Id.* at 6–7.

E. Real Parties in Interest

Petitioner identifies itself and Medtronic Vascular, Inc., as real parties in interest and notes "Medtronic plc is the ultimate parent of Medtronic, Inc." Pet. 5. Patent Owner identifies itself, Vascular Solutions LLC, Arrow International, Inc., and Teleflex LLC as real parties in interest. Paper 4, 2. Patent Owner also notes "Teleflex Incorporated is the ultimate parent of the entities listed above." *Id.*

III. ANALYSIS

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

Petitioner and Patent Owner present arguments about our discretion under 35 U.S.C. § 314(a). Pet. 15–16; Prelim. Resp. 5–7. Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("[Section] 314(a) invests the Director with discretion on the question whether to institute review." (emphasis omitted)); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

In determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a), the Board considers 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).

In considering whether to institute trial when there is a parallel, co-pending litigation concerning the same patent, 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.

Fintiv, 5–6. In evaluating these 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 here weigh against exercising discretion under § 314(a) to deny institution of *inter partes* review.

Relevant to *Fintiv* factors 1 and 2, the parties acknowledge that the parallel district court proceeding is stayed. Pet. 16; Prelim. Resp. 1; Paper 4, 2. The granting of a stay pending *inter partes* review has weighed strongly against exercising discretion to deny institution as it is a strong indication that the district court has a preference to wait for the Board's final resolution of the patentability issues raised in the petition before proceeding

with the parallel litigation. *See Fintiv* at 6–7. Accordingly, consideration of the first and second *Fintiv* factors weighs strongly against exercising discretion to deny institution.

The third *Fintiv* factor provides that a petitioner's diligence or delay in filing a petition may be relevant. *See Fintiv* at 11–12. If the evidence shows that a petitioner filed its petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against denying institution. *See id.* at 11 (citing *Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15 at 12–13 (PTAB Jan. 9, 2020); *Illumina Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19 at 8 (PTAB Dec. 18, 2019)). If, however, the evidence shows that the petitioner did not file its petition expeditiously, such as at or around the same time that the patent owner responded to the petitioner's invalidity contentions, or even if a petitioner cannot explain the delay in filing its petition, these facts have favored denial. *See Fintiv* at 11–12 (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019)).

Patent Owner states that Petitioner had "knowledge of the '116 patent since at least February 2019" and that it "informed Petitioner of its plan to assert the '116 patent on January 24, 2020," three weeks before Patent Owner filed its Amended Complaint. Prelim. Resp. 5–7. Patent Owner argues that Petitioner unjustifiably delayed filing the Petition until nine months after Petitioner filed petitions challenging related patents on similar art and arguments. Prelim. Resp. 5–6 (identifying the following proceedings between the parties in which Itou, Ressemann, and/or Kataishi are relied upon by Petitioner: IPR2020-00126 (Itou and Ressemann), IPR2020-00128 (Itou and Ressemann), IPR2020-00129 (Itou, Ressemann, and Kataishi), IPR2020-00132 (Itou, Ressemann, and Kataishi), IPR2020-00133

(Ressemann and Kataishi), IPR2020-00134 (Itou and Ressemann), IPR2020-00135 (Itou, Ressemann, and Kataishi), IPR2020-00137 (Itou, Ressemann, and Kataishi), and IPR2020-00138 (Ressemann and Kataishi)). Patent Owner argues that Petitioner's "unjustified delay" in filing the Petition prejudices Patent Owner. Prelim. Resp. 7. In particular, Patent Owner contends as follows:

> Petitioner has already relied on the present IPR petitions as a basis to seek an unprecedented extension of the one year statutory deadline in the eleven pending IPRs, even though it expressly and repeatedly relied on that one year deadline to convince the district court to stay the litigation. *See, e.g.*, IPR20[20]-00126, Papers 56 and 61. If the present IPR petitions are granted, Petitioner will undoubtedly continue such delay tactics, such as by asking the district court to maintain the stay as to all patents in view of the present Petition.

Prelim. Resp. 7.

Petitioner explains the 9-month difference in its filing of the current Petition by noting as follows:

> When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '116 patent. As a result, Petitioner did not file an IPR against the '116 patent at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint that asserted the '116 patent. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly 5 months later and more than 7 months before the statutory deadline.

Pet. 16.

We determine the evidence does not support a finding that the Petition was filed with delay. Rather, the filing of the Petition was timely and in response to Patent Owner's Amended Complaint adding the '116 patent to the related litigation. We further find unsupported and not persuasive Patent Owner's argument that "because Petitioner buried Itou and the other prior art

it intended to rely on in its August 2019 discovery response," it was Petitioner's fault Patent Owner amended its complaint to add the '116 patent when it did. Prelim. Resp. 6. No persuasive evidence suggests Petitioner bears responsibility for Patent Owner's knowledge of relevant prior art or for Patent Owner's determination of whether and when to amend its complaint.

With respect to *Fintiv* Factor 4 (overlap of issues) and *Fintiv* Factor 5 (whether the same parties are involved), we find there is an overlap of issues and parties between the district court case and this proceeding. In *Fintiv*, the Board noted "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." *Fintiv*, 12. In this case, however, any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court has stayed the parallel litigation and thus will not reach the merits of Petitioner's invalidity defenses before we issue our final written decision.

Furthermore, the district court's stay of the litigation pending denial of institution or a final written decision allays concerns about inefficiency and duplication of efforts. *Id.* To the contrary, exercising our discretion to deny the Petition would force inefficiency and the possibility of conflicting decisions because the district court would then have to resolve similar and overlapping issues presented in the context of only the '116 patent, one of several related patents being asserted by Patent Owner in the related litigation.

Finally, under *Fintiv* Factor 6, we have taken into account the merits of Petitioner's challenges, as discussed below, and find this factor favors institution. Balancing all of the *Fintiv* factors, on this record, we determine

the circumstances presented here weigh against exercising discretion under § 314(a) to deny institution of *inter partes* review.

B. Legal Standards

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 under 35 U.S.C. § 103[5] 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.*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103 that requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18;

[5] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), took effect on March 16, 2013. Because the application that issued as the '116 patent indicates that its priority application was filed before March 16, 2013, we apply the pre-AIA versions of these statutes. *See* 35 U.S.C. § 100(i).

KSR, 550 U.S. at 407. At this stage of the proceeding, neither party presents evidence directed to secondary considerations. *See* Pet. 78–80; *see also generally* Prelim. Resp.

C. 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 a person of ordinary skill in the art at the time of the invention would have "(a) a medical degree, (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 13. Petitioner, alternatively, contends a person of ordinary skill in the art at the time of the invention would have had "(a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* at 14. Petitioner further argues "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* Patent Owner does not dispute at this stage of the proceeding Petitioner's proposed level of ordinary skill. *See generally* Prelim. Resp.

For purposes of this Decision, we find the '116 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected in these references and the '116 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*,

261 F.3d 1350, 1355 (Fed. Cir. 2001). Accordingly, for purposes of this Decision, we adopt Petitioner's asserted level of ordinary skill in the art.

D. Claim Construction

"In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). That standard "includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Petitioner proposes the following constructions: (1) "substantially rigid" as "rigid enough to allow the device to be advanced within the guide catheter," (2) "side opening" needs no construction and should be given its plain and ordinary meaning, (3) "lumen" as "the cavity of a tube," and (4) "flexural modulus" as "[a] measure of resistance . . . to bending." Pet. 14–15 (quoting Ex. 1040, 772). Patent Owner does not dispute at this stage of the proceeding Petitioner's proposed construction of these terms. *See generally* Prelim. Resp. In view of the issues we address below, we determine it is not necessary to address the express interpretation of any claim term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

E. Scope and Content of the Prior Art

Petitioner relies on Ressemann, Itou, and Kataishi, each of which we briefly summarize in relevant part below.

1. Summary of Ressemann

Ressemann, titled "Emboli Protection Devices and Related Methods of Use," states that it is directed to an apparatus "used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels." Ex. 1008, code (54), 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

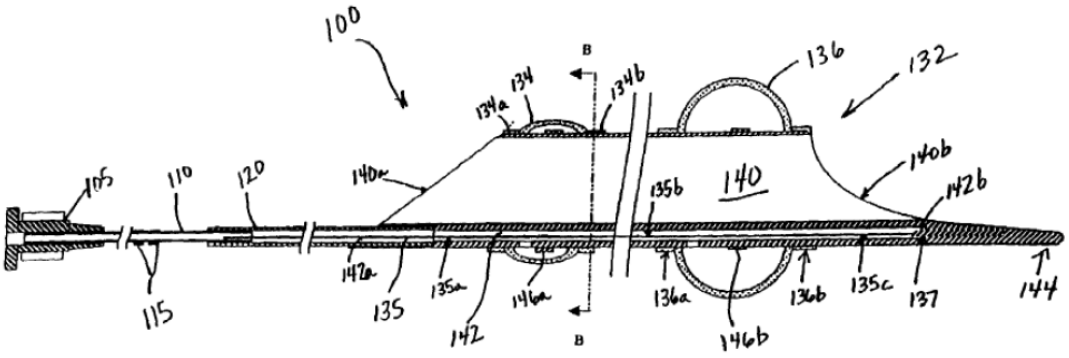

FIG. 1A

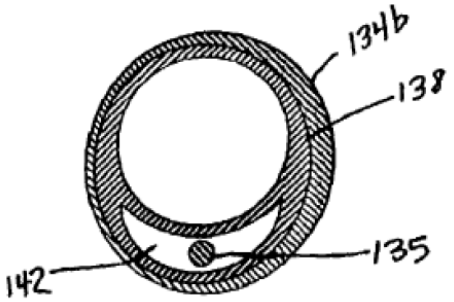

FIG. 1B

Figure 1A is a cross-sectional view of a partial length evacuation sheath. *Id.* at 3:16–18. Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B–1B of Figure 1A. *Id.* at 3:19–20.

Figure 1A depicts evacuation sheath assembly 100, which "is sized to fit inside a guide catheter" and be advanced "into a blood vessel to treat a stenosis." Ex. 1008, 6:18–24, Fig. 5A. Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. Evacuation head 132 includes multi-lumen tube 138, having evacuation lumen 140 and inflation lumen 142, and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and "is designed to allow for the passage of interventional devices such as, but not limited to[,] stent delivery systems and angioplasty catheters." *Id.* at 6:44–47. Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, "[t]he larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly." *Id.* at 6:58–60.

Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, "is located co-axially in the inflation lumen 142," and extends to soft tip 144. Ex. 1008, 11:30–39. Inflation lumen 142, having open proximal end 142a and closed distal end 142b, is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64.

In use, a guiding catheter is directed to a blood vessel, and then a coronary guide wire is advanced to a location just proximal to the distal tip of the guiding catheter. Ex. 1008, 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the

blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

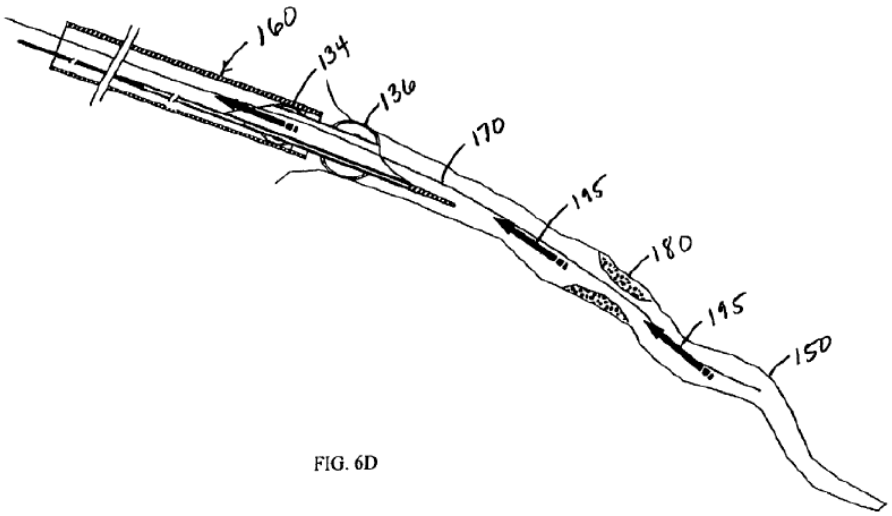

FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. Ex. 1008, 3:59–61. As shown in Figure 6D, guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, "[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber." *Id.* at 13:43–44. The assembly, which includes a guide catheter, "may be positioned within the ostium of the target vessel." *Id*. at 12:26–27.

2. Summary of Itou

Itou, titled "Intravascular Foreign Matter Suction Assembly," relates to an assembly designed to suck, sample, and remove "foreign matter such as a thrombus or an embolus" from a blood vessel. Ex. 1007, code (54), 1:6–9, 1:47–49. This assembly includes a guiding catheter and a suction catheter configured to be inserted into the lumen of the guiding catheter. *Id.* at 1:49–65.

Figure 3 of Itou is reproduced below:

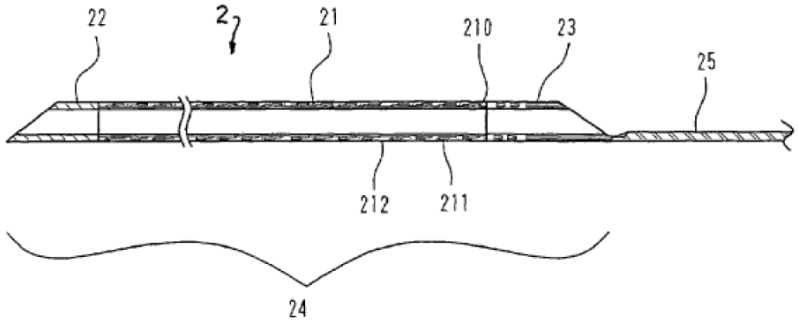

Figure 3 is a cross section of a distal end portion of suction catheter 2. Ex. 1007, 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion 24 has reinforced tubular portion 21 and flexible distal tip 22. *Id.* at 2:15–51, 3:50–58. Tubular portion 24 has an outer diameter that allows it to be inserted into the lumen of a guide catheter and wire-like portion 25 has a sectional area smaller than the sectional area of the tube wall of tubular portion 24. *Id.* at 3:59–63.

Figure 5 of Itou is reproduced below:

FIG.5

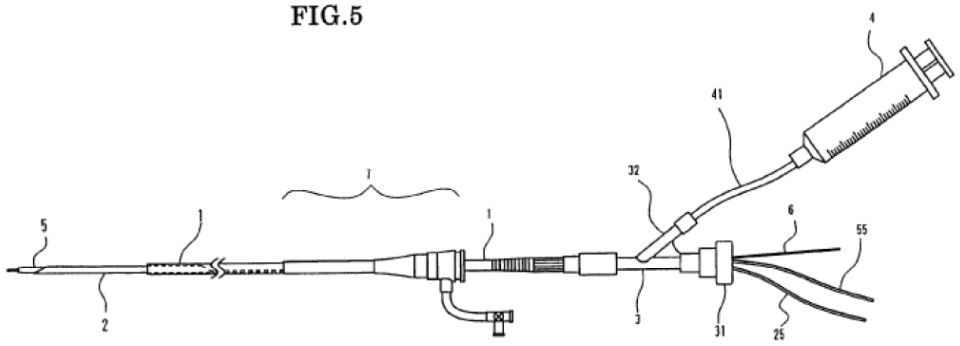

Figure 5 shows the suction assembly "in an assembled state." Ex. 1007, 2:66– 67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted into the lumen of the distal end protective catheter 5. *Id.* at 5:14–17. The proximal ends of suction catheter 2, distal end protective catheter 5, and guide wire 6 are "introduced to the outside through main connector portion 31 of Y-shaped connector 3." *Id.* at 5:17–20. A valve is built into main connector 31 and "can selectively clamp and fix" guide wire 6 and wire-like portions 25 or 55 "to prevent leakage of the blood." *Id.* at 5:20–23. In one embodiment, the inner diameter of the guiding catheter is 1.8 mm and the inner diameter of the suction catheter is 1.5 mm. *Id.* at 7:55–67 (Table 1).

A portion of Figure 6 of Itou is reproduced below:

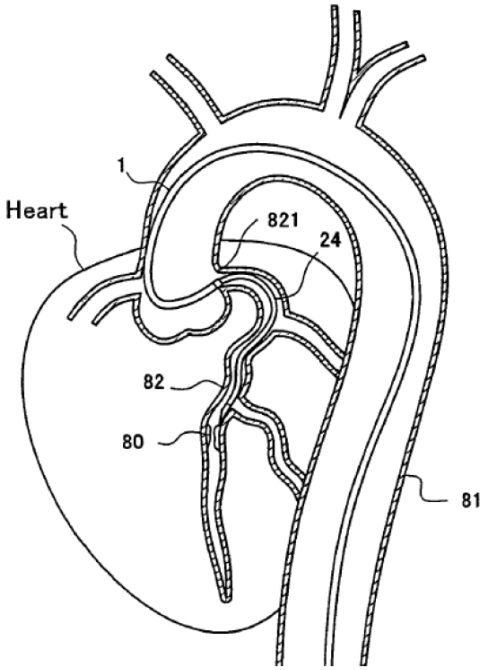

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. Ex. 1007, 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24 of suction catheter 2 is inserted into coronary artery 82 and is introduced along guide wire 6 to target location 80. *Id.* at 5:35–38. According to Itou, tubular portion 24 of suction catheter 2 has a "sufficient axial length so that the proximal end of the tubular portion 24 in an open state may not leap out from the distal end of the guiding catheter 1." *Id.* at 5:38–41.

3. Summary of Kataishi

Kataishi, titled "Thrombus Suction Catheter with Improved Suction and Crossing," teaches "a thrombus suction catheter with improved suction and crossing having a small pressure loss, which is a tube having a lumen passing through from a proximal end to a distal end, a distal end opening

having an angled cut surface." Ex. 1025, code (54), ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

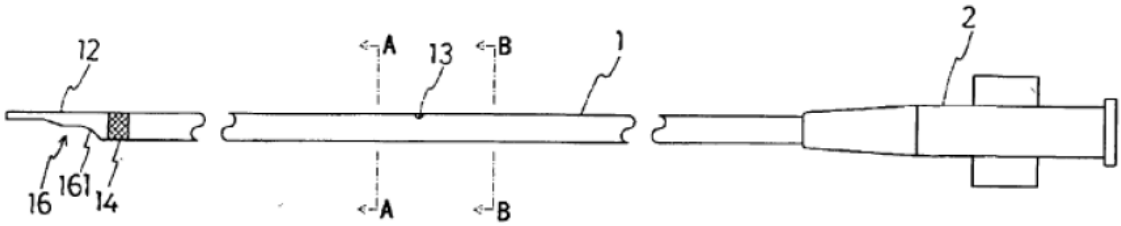

Fig. 1

As shown in Figure 1, a thrombus suction catheter includes a catheter body 1, a connector 2 provided at a proximal end of the catheter body 1, a distal end opening 12 formed by an angled cut surface, and a guide wire insertion port 13. *Id.* ¶¶ 27, 29.

F. Alleged Anticipation by Ressemann

Petitioner contends that claims 52 and 53 are anticipated by Ressemann. Pet. 23–31. Petitioner provides a detailed explanation of how it contends Ressemann discloses each of the limitations of claims 52 and 53. *Id.* In particular, Petitioner explains how Ressemann's disclosures of the use of features including guide catheter 160, evacuation sheath assembly 100, intermediate shaft portion 120, and distal shaft portion 130, lumen 140, stent delivery system 194 correspond to the recited methods of claims 52 and 53. *Id.* Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1005 ¶¶ 164–174; Ex. 1042 ¶¶ 36–39, 58–62. At this stage of the proceeding, Patent Owner does not address in its Preliminary Response Petitioner's specific contentions with respect to anticipation by Ressemann. *See generally* Prelim. Resp.

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 Ressemann discloses each limitation of claims 52 and 53 of the '116 patent. We further determine, based on the current record, that the Petition shows that there is a reasonable likelihood that Petitioner would prevail in showing that claims 52 and 53 are anticipated by Ressemann.

G. Alleged Obviousness over Itou and Ressemann

Petitioner contends claims 25–40, 42, 44–48, 52, and 53 would have been obvious over the combination of Itou and Ressemann. Pet. 32–74. Petitioner provides a detailed explanation of how it contends each of the limitations of claims 25–40, 42, 44–48, 52, and 53 are taught or suggested by the combination of Itou and Ressemann. *Id.* For example, as to claim 25 Petitioner relies on teachings of Itou concerning guiding catheter 1 and suction catheter 2, and on Ressemann as providing the motivation for a person of ordinary skill in the art to perform the recited method using the structure taught be Itou. *See, e.g.,* Pet. 39. Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1005 ¶¶ 175–314; Ex. 1042 ¶¶ 63–112. At this stage of the proceeding, Patent Owner does not address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Itou and Ressemann. *See generally* Prelim. Resp.

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 Itou and Ressemann teaches or suggests the subject matter of claims 25–40, 42, 44–48, 52, and 53 of the '116 patent. Petitioner also provides sufficient explanation for purposes of this Decision as to why one of ordinary skill in the art would have combined the references to arrive at the claimed invention. *See*, *e.g.*, Pet. 42–46. We further determine, based

on the current record, that the Petition shows a reasonable likelihood Petitioner would prevail in showing that claims 25–40, 42, 44–48, 52, and 53 would have been obvious over Itou and Ressemann.

H. Alleged Obviousness over Itou, Ressemann, and Kataishi

Petitioner contends claim 45 would have been obvious over the combination of Itou, Ressemann, and Kataishi. Pet. 74–77. Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1005 ¶¶ 315–322; Ex. 1042 ¶¶ 113–121.

Claim 45 depends from claim 25 and further recites "wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a side-opening structure having at least two inclined slopes." Ex. 1001, 16:21–25. According to Petitioner, "Kataishi teaches a suction catheter with a distal end that provides superior loading of matter (thrombus) into the distal end of the suction catheter." Pet. 76 (citing Ex. 1005 ¶ 319; Ex. 1042 ¶ 114). Petitioner further reasons that "the ability to load something into a catheter opening," as taught by Kataishi, "applies equally to the proximal end of a catheter, especially a catheter such as Itou," because this "would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter." *Id.* (citing Ex. 1005 ¶ 320; Ex. 1042 ¶¶ 117–18).

At this stage of the proceeding, Patent Owner does not address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Itou, Ressemann, and Kataishi. *See generally* Prelim. Resp. Whether Petitioner has shown a sufficient rationale for applying the structure taught by Kataishi at the distal end of a suction catheter to the proximal side opening of Itou's suction catheter is an issue to be developed during trial.

I. Appointments Clause

Patent Owner argues "[t]he Petition should be denied because the manner in which administrative law judges are appointed is unconstitutional." Prelim. Resp. 8 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019), *cert. granted*).[6] Patent Owner further argues the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338–39).

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.

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 '116 patent are unpatentable over the asserted prior art. Accordingly, *inter partes* review shall proceed in this case on all of the grounds raised in the Petition. *See SAS*, 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v.*

[6] 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).

Iancu, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating the decision whether to institute *inter partes* review requires "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any 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 25–40, 42, 44–48, 52, and 53 of U.S. Patent No. RE46,116 E 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. RE46,116 E shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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