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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 SCEINCES LIMITED,
Patent Owner.

IPR2020-01344
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 25–55 ("the Challenged Claims") of U.S. Patent No. RE46,116 E (Ex. 1401, "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. 1401, 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 ("the '059 application") 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, "[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. 1401, 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

[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. 1410, “Takahashi”).

guidewire to allow atraumatic placement within the coronary artery," and 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

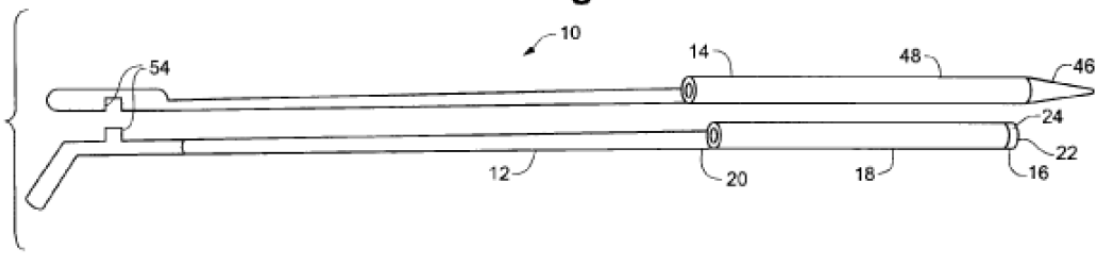


Fig. 2

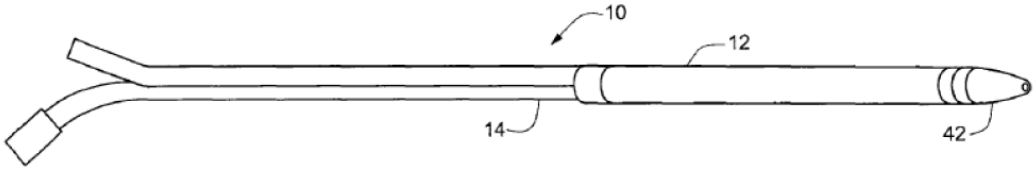


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:51–56; Figs. 1 and 2. As shown above, "coaxial guide catheter assembly 10" includes coaxial guide catheter 12 and tapered inner 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:

Fig. 4

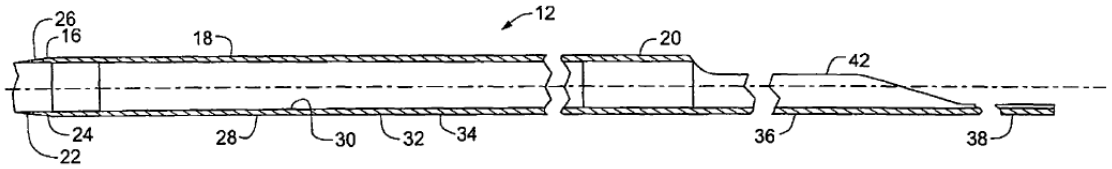


Figure 4 is a sectional view of the coaxial guide catheter with tip portion 16 depicted on the left side of the figure (rather than on the right side as shown in Figures 1 and 2). Ex. 1401, 5:60; Fig. 4. As shown above, coaxial guide catheter 12 has a rigid portion 20, which "includes first full circumference 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. 1401, 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:

Fig. 8

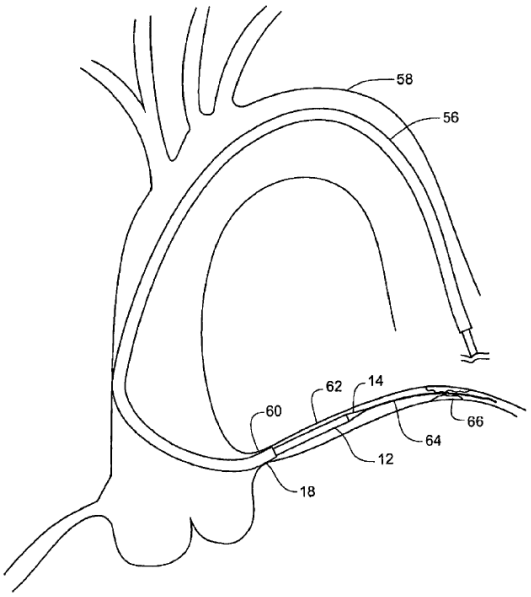


Figure 8 is a schematic view of a guide catheter and a guide wire in use with the coaxial guide catheter assembly within the aortic arch and coronary artery. *Id.* at 6:5–8; Fig. 8. First, guidewire 64 is inserted and passed through aortic arch 58 into ostium 60 of coronary artery 62. *Id.* at 7:65–66. 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 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 25–55 of the '116 patent. Pet. 1. Claims 25, 43, 51, and 52 are independent. Ex. 1401, 13:62–14:25, 15:51–16:15, 16:53–18:10. Claims 26–42 and 44–50 depend from claim 25, claim 46 depends from claim 43, and claims 53–55 depend from claim 52. *Id.* at 14:62–18:26. 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	103	Kontos,[2] Ressemann[3]
25–40, 42, 44–48	103	Kontos, Ressemann, Takahashi
45	103	Kontos, Ressemann, Takahashi, Kataishi[4]
25–55	103	Root[5]
45, 46	103	Kontos, Ressemann, Takahashi, Root

Pet. 8.

[2] U.S. Patent No. 5,439,445, issued August 8, 1995 (Ex. 1409, "Kontos").
[3] U.S. Patent No. 7,604,612 B2, issued October 20, 2009 (Ex. 1408, "Ressemann").
[4] US 2005/0015073 A1, published January 20, 2005 (Ex. 1425, "Kataishi").
[5] US 2007/0260219 A1, published November 8, 2007 (Ex. 1512, "Root") (publication of App. No. 11/416,629 (Ex. 1500), filed May 3, 2006, issued as U.S. Patent No. 8,048,032).

Petitioner relies on the supporting Declarations of Jon David Brecker, M.D., dated July 31, 2020 (Ex. 1405), and Richard A. Hillstead, Ph.D., dated July 30, 2020 (Ex. 1442).

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.), and (2) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn.). Pet. 5; 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 previously the 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. 5–6.

Petitioner challenges claims 25–40, 42, 44–48, 52, and 53 of the '116 patent in IPR2020-01343 through another petition filed concurrently with the Petition in this case, which we address further below. Pet. 6 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.*

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)

Patent Owner argues we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution due to the common issues being litigated in parallel district court cases. Prelim. Resp. 1–8. Patent Owner also argues we should exercise our discretion and deny institution because Petitioner has not justified multiple petitions challenging the '116 patent. *Id.* at 7.

1. Parallel Litigation

Petitioner and Patent Owner present arguments about our discretion under 35 U.S.C. § 314(a). Pet. 13–14; Prelim. Resp. 5–8. 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, 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. 13; 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 Kontos, Ressemann, Takahashi, and/or Kataishi are relied upon by Petitioner: IPR2020-00127 (Kontos and Takahashi), IPR2020-00129 (Ressemann, Takahashi, and Kataishi), IPR2020-00130 (Kontos and Takahashi), IPR2020-00131 (Kontos, Takahashi, and Kataishi), IPR2020-00133 (Ressemann, Takahashi, and Kataishi), IPR2020-00136 (Kontos, Ressemann, Takahashi, and Kataishi), IPR2020-00138 (Ressemann, Takahashi, 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, Paper Nos. 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. 7–8.

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 at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint asserting the '116 patent. Ex-1514. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline.

Pet. 14.

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. 6–7. 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.

2. Multiple Petitions

Petitioner challenges claims 25–40, 42, 44–48, 52, and 53 of the '116 patent in IPR2020-01343 through another 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 IPR2020-01343 prior to the Petition in this case. Paper 3. The petition in IPR2020-01343 relies on Ressemann, Itou,[6] and Kataishi as the asserted prior art. Concurrent with this Decision we enter a decision instituting *inter partes* review in IPR2020-01343.

Patent Owner argues the Petition in this case "is merely a 'backup'" that gives Petitioner "another bite at the apple," which compounds the "inefficiency and unfairness that will result if any of Petitioner's petitions are instituted." Prelim Resp. 7. Patent Owner further argues Petitioner "made a deliberate choice . . . to rely on a §102(e) reference that Petitioner knew was not prior art." *Id.*

The Board's Trial Practice Guide addresses the situation where there are parallel petitions challenging the same patent, as here, and notes "[t]wo

[6] U.S. Patent No. 7,736,355 B2, issued June 15, 2010 (Ex. 1407, "Itou").

or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns" and that "multiple petitions by a petitioner are not necessary in the vast majority of cases." Patent Trial and Appeal Board Consolidated Trial Practice Guide ("Consolidated Practice Guide") (Nov. 2019) 59; *see also* 84 Fed. Reg. 64,280 (Nov. 21, 2019). "Nonetheless, the Board recognizes that there may be circumstances in which more than one petition may be necessary, including, for example, when the patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date requiring arguments under multiple prior art references." *Id.*

Petitioner states that Itou is the primary reference in IPR2020-01343 and that "Petitioner[] anticipate[s] that Patent Owner may allege that the '116 Patent inventors conceived of and reduced to practice the underlying invention" prior to the priority date of Itou. Paper 3, 2. Petitioner argues the Board previously instituted *inter partes* review of a related patent in proceedings between the parties based on two petitions in IPR2020-00135 and IPR2020-00136 under the same circumstances presented in this proceeding. *Id.* at 2–3. Petitioner argues "two petitions are justified" for the same reasons here, including because of the length and number of claims asserted by Patent Owner in district court. *Id.* at 4–5.

We have considered the respective arguments of the parties and determine the circumstances in this case support declining to exercise our discretion under § 314(a) to deny the Petition for substantially the same reasons set forth in IPR2020-00136. In that case, the Board declined to deny institution of a second petition between the parties, explaining as follows:

> Given the possibility that we may determine that Itou does not qualify as prior art after fully considering Patent Owner's priority date arguments, we determine that Petitioner provides a sufficient explanation as to why it was necessary to rely upon the obviousness challenges presented here as an alternative basis for unpatentability. Indeed, this is precisely one of the circumstances recognized in our Trial Practice Guide "in which more than one petition may be necessary." Consolidated Practice Guide at 59.
>
> Moreover, we find that the challenges presented in the two petitions are not excessive or duplicative. Although Petitioner challenges the same claims in each petition, the prior art and issues to be decided do not significantly overlap with each other. For instance, the obviousness challenges presented here require an assessment of the motivation to combine the teachings of Kontos and Ressemann, reasonable expectation of success, and secondary considerations that are not relevant to the anticipation challenge presented in [the related case challenging the same patent]. And although there were also obviousness challenges presented in the first petition that relied upon Ressemann or Kataishi for certain additional claims, the manner in which those references are relied upon in combination with Kontos in this second Petition is different. Finally, given the number and length of the 26 challenged claims (including 3 independent claims), which are all potentially the basis for Patent Owner's infringement allegations in the parallel litigation, and the complexity of the arguments that have been raised by both parties for each challenge, we determine that it was appropriate for Petitioner to rely upon multiple petitions for its alternative challenges in light of the word count limits for each petition.

Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.À.R.L., IPR2020-00136, Paper 20, 39–40 (PTAB June 26, 2020).

Accordingly, for the same reasons, we decline to exercise our discretion under § 314(a) in this proceeding to deny institution based on the multiple petitions challenging the '116 patent.

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[7] 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; *KSR*, 550 U.S. at 407. At this stage of the proceeding, neither party presents

[7] 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 states 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).

evidence directed to secondary considerations. *See* Pet. 76–77; *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. 11. 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 12. 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) "side opening" needs no construction and should be given its plain and ordinary meaning, (2) "lumen" as "the cavity of a tube," and (3) "flexural modulus" as "[a] measure of resistance . . . to bending." Pet. 12–13 (quoting Ex. 1440, 722). 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 Kontos, Ressemann, Takahashi, Kataishi, and Root, each of which we briefly summarize in relevant part below.

1. Summary of Kontos

Kontos, titled "Support Catheter Assembly," is directed to a support catheter assembly for facilitating medical procedures and, in particular, to a catheter assembly that has "particular utility in facilitating insertion of a PTCA[8] balloon into a lesion." Ex. 1409, code (54), 1:9–13.

Figure 1 of Kontos is reproduced below:

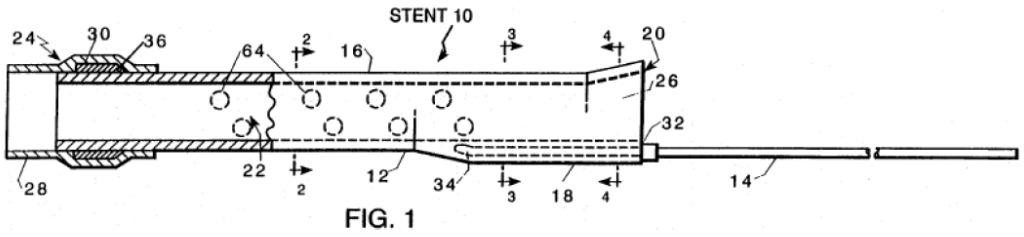


FIG. 1

Figure 1 is a side plan view of a support catheter, "cut-away in part to show in longitudinal cross-section a tubular body having a soft tip and radiopaque marker, and a manipulating wire." Ex. 1409, 2:51–54. As shown in Figure 1, support catheter assembly 10 is composed of two major elements, body 12 and insertion/manipulation wire 14. *Id.* at 3:45–46. Body 12, "which may be viewed as a mini guide catheter, includes a tube 16 having a base portion 18 at its proximal end 20." *Id.* at 3:47–49. "Tube 16 has a continuous lumen 22 there through from proximal end 20 to distal end 24." *Id.* at 3:49–50. Body 12 also includes a soft tip 28 disposed at distal end 24 and funnel portion 26 disposed at proximal end 20. *Id.* at 3:50–52. Wire 14 is attached to body 12 at base portion 18. *Id.* at 3:52–53. Support assembly 10 may also include distal marker band 30 and proximal marker band 32. *Id.* at 3:53–55.

[8] PTCA stands for "percutaneous transluminal coronary angioplasty." Ex. 1405 ¶ 37.

Kontos explains that the size and shape of the various elements of support assembly 10 "may vary depending on the desired application," but in the applications depicted in Figure 1, tube 16 has a 0.055 inch outer diameter and lumen 22 has a 0.045 inch diameter. Ex. 1409, 4:46–50. According to Kontos, the sizes used in these embodiments "generally are suitable for existing PTCA catheters." *Id.* at 4:61–64.

Figure 5 of Kontos is reproduced below:

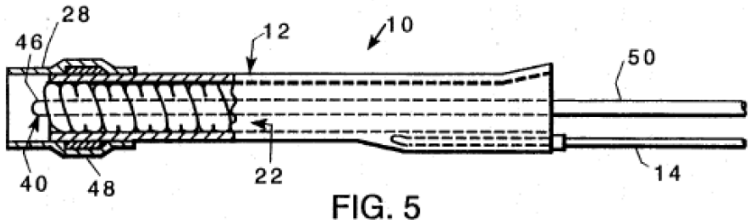
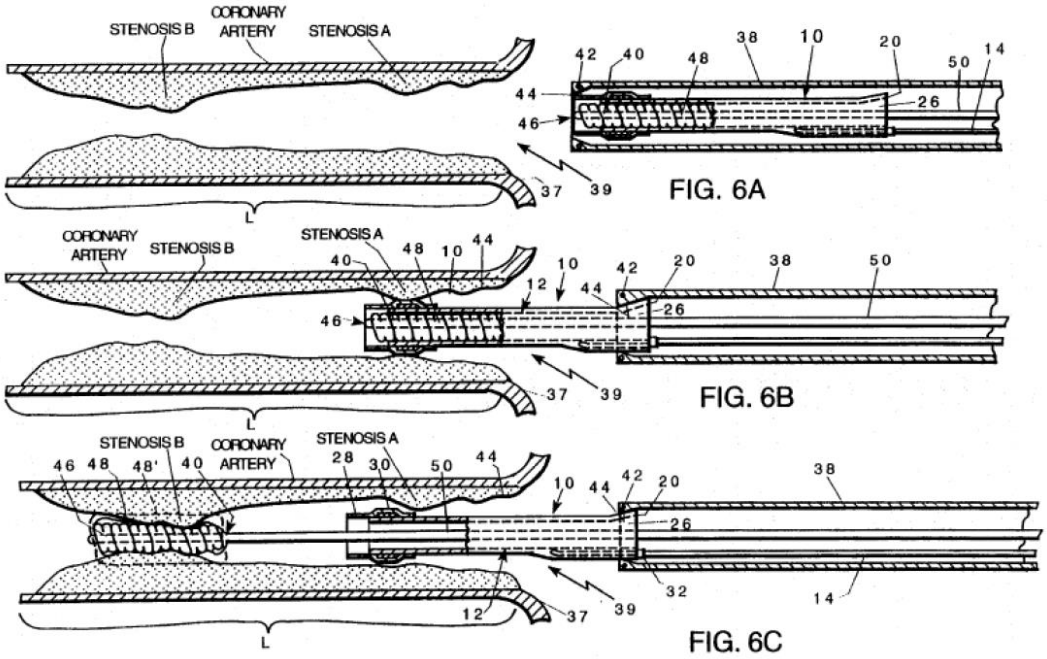


FIG. 5

Figure 5 is a side schematic view of a support catheter having a PTCA catheter disposed therein. Ex. 1409, 2:64–66. In this figure, PTCA catheter 40 and its deflated balloon 48 reside in lumen 22 of support assembly 10. *Id.* at 5:2–5.

Figures 6A–6C of Kontos are reproduced below:



Figures 6A–6C are cross-sectional views showing three stages in a process for guiding a PTCA catheter to a coronary artery lesion. Ex. 1409, 2:67–3:2. In Figure 6A, the PTCA catheter/support catheter assembly is fed into guide catheter 38 and advanced to the distal end of this catheter by exerting axial force on wire 14 and catheter tube 50 simultaneously. *Id.* at 5:25–30.

In Figure 6B, when the PTCA catheter/support catheter assembly reaches the distal end of guide catheter 38, "it may be advanced as a unit out of the distal end of guide catheter 38, into the coronary ostia 39." Ex. 1409, 5:31–35. When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension protecting fragile balloon 48 and lessening "considerably the tendency of the PTCA catheter 40 to bend, buckle or kink." *Id.* at 5:52–56.

In Figure 6C, after body 12 has been positioned adjacent the restricted area, PTCA catheter 40 is advanced so that balloon 48 exits body 12 and is advanced into the restricted area, e.g., stenosis B. Ex. 1409, 6:9–13. Balloon 48 is then inflated, as represented by dotted lines 48, "to effect a well known angioplasty procedure." *Id.* at 6:13–15. Balloon 48 is then deflated and PTCA catheter 40, support catheter assembly 10, and guiding catheter 38 may be withdrawn. *Id.* at 6:15–18.

2. 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. 1408,

code (54), 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

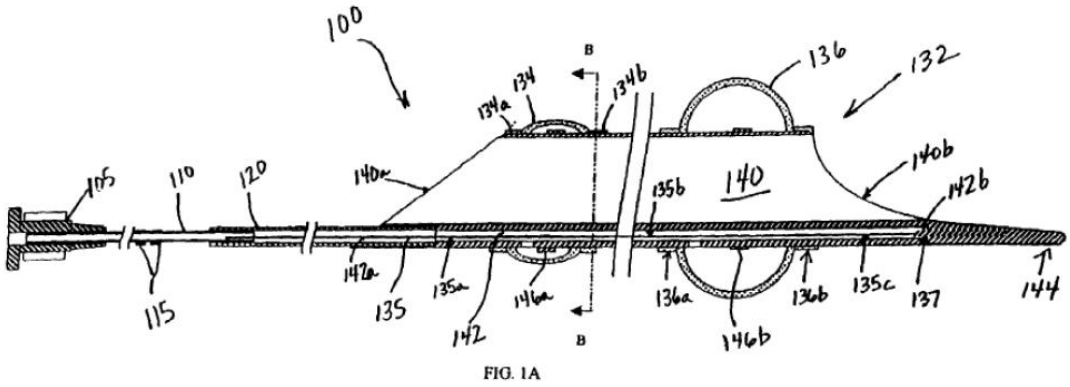


FIG. 1A

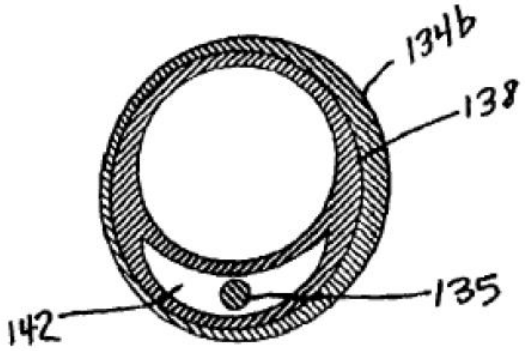


FIG. 1B

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. 1408, 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. 1408, 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. 1408, 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:

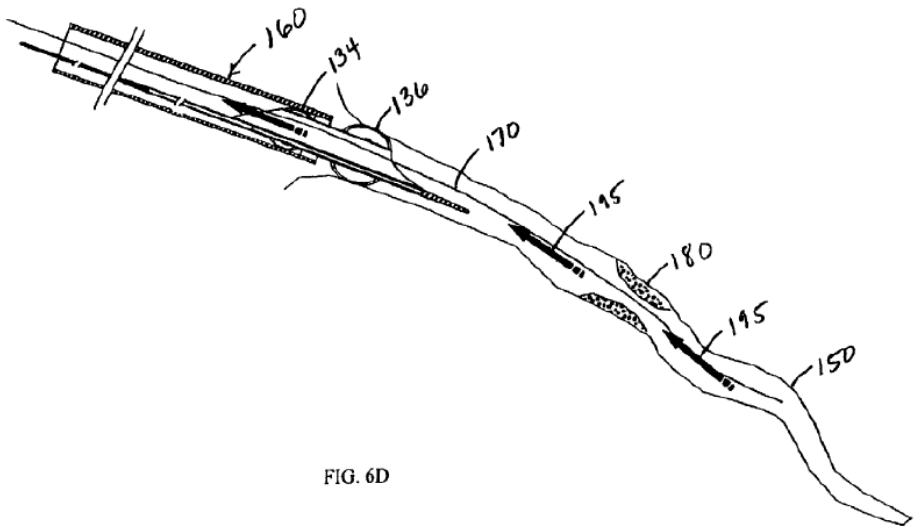


FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. Ex. 1408, 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.

3. Summary Takahashi

Takahashi, titled "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," discusses the use of a guiding catheter in percutaneous coronary intervention (PCI). *See generally* Ex. 1410. Takahashi discloses a "five-in-six" system wherein a 5 French guiding catheter is inserted into a 6 French guiding catheter to provide increased

backup support. *Id.* at 452. In this system, the 5 French catheter is 120 cm in length, whereas the 6 French catheter is 100 cm in length. *Id.* According to Takahashi, the soft end portion of the 5 French catheter "can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery." *Id.*

4. 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. 1425, code (54), ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

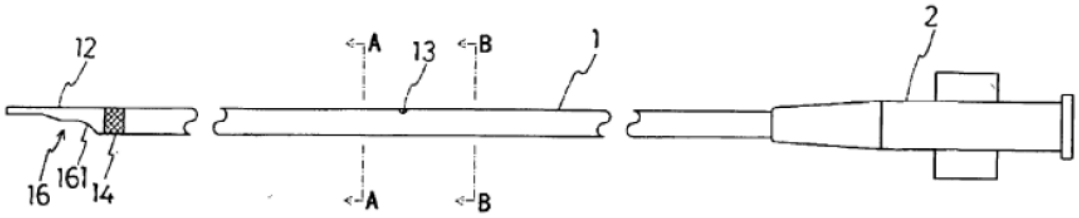


Fig. 1

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.

5. Summary of Root

The disclosure of Root, titled "Coaxial Guide Catheter for Interventional Cardiology Procedures," is substantially similar and related to the '116 patent. *Compare* Ex. 1512 *to* Ex. 1401. Root relates generally to a coaxial guide catheter for use with interventional cardiology devices that are

insertable into a branch artery that branches off from a main artery. Ex. 1512, code (54), Abstract.

Root discloses that interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id*. ¶ 2. 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.* 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.* ¶ 3. However, crossing 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.*

To solve this problem, Root describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. Ex. 1512 ¶ 11. Root teaches that 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 this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.*

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter:

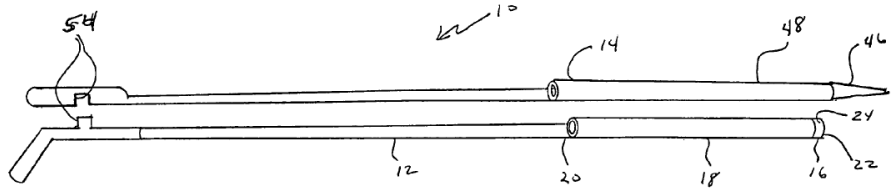


Fig. 1

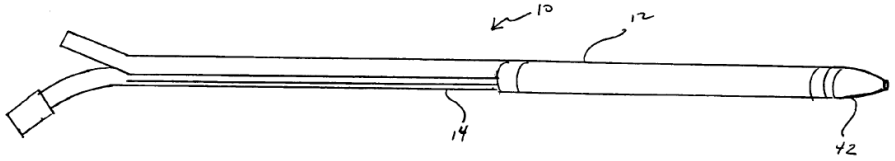


Fig. 2

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. Ex. 1512, ¶¶ 28–29; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* ¶ 50. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* ¶ 51. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* ¶ 52. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* ¶ 53. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* ¶ 62. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* 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.* ¶ 64.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. Ex. 1512, ¶ 22. The coaxial guide catheter/ tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta, and advanced until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. *Id.* The tapered inner catheter may be removed once the coaxial guide catheter tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating. *Id.* Once the tapered inner catheter is removed, a cardiac treatment device, such as a guidewire, balloon, or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. *Id.* ¶ 23. The 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.*

F. Alleged Obviousness over Kontos and Ressemann

Petitioner contends claims 52 and 53 would have been obvious over the combination of Kontos and Ressemann. Pet. 15–32. Petitioner provides a detailed explanation of how it contends each of the limitations of claims 52 and 53 are taught or suggested by the combination of Itou and Ressemann. *Id.* For example, as to claim 52, Petitioner relies on the teachings of Kontos concerning the use of guide catheter 38 and catheter assembly 10 as a guide extension. Pet. 15–17. Petitioner states "Kontos does not teach . . . a side opening proximal to the tubular structure," and relies on Ressemann as teaching "an evacuation assembly 100 (extension catheter) where the entry to the evacuation lumen 140a is 'preferably angled.'" *Id.* at 18 (citing Ex. 1508, 6:52–60). Petitioner also provides "multiple reasons" for

modifying Kontos to include a side opening as taught be Ressemann, including to "permit a reduction of the outer diameter of the catheter assembly without resulting in a commensurate reduction in the area of the point of entry of the extension catheters." *Id.* at 20. Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1405 ¶¶ 152–185; Ex. 1442 ¶¶ 120–143. At this stage of the proceeding, Patent Owner does not address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Kontos and Ressemann. *See generally* Prelim. Resp.

We have considered the evidence and argument presented by the parties and determine, for the reasons provided above, the Petition provides the requisite showing, at this stage of the proceeding, that the combination of Kontos and Ressemann teaches or suggests the subject matter of claims 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. 20–24. We further determine, based on the current record, that the Petition shows a reasonable likelihood Petitioner would prevail in showing claims 52 and 53 would have been obvious over Itou and Ressemann.

G. Alleged Obviousness over Kontos, Ressemann, and Takahashi

Petitioner contends independent claim 25 and claims 26–40, 42, and 44–48, which depend from claim 25, would have been obvious over Kontos, Ressemann, and Takahashi. Pet. 32–58. Petitioner provides a detailed explanation of how it contends each of the limitations of claims 25–40, 42, and 44–48 are taught or suggested by the combination of Kontos, Ressemann, and Takahashi. *Id.* For example, as to claim 25, Petitioner contends limitations similar to those recited in claim 52 are taught by Kontos

and Ressemann for substantially the same reasons provided by Petitioner with regard to claim 53. *Id.* at 32–34, 36. Petitioner further states Kontos "does not disclose the cross-sectional inner diameter of the guide catheter," and argues that Takahashi discloses this features by teaching "a 'five-in-six' system wherein the inner diameter of the 5 French catheter is not more than one French smaller than the cross–sectional inner diameter of the 6 French catheter." *Id.* at 34–35. Petitioner also reasons that a person of ordinary skill "would have been motivated to combine Takahashi with the Kontos-Ressemann combination, given the former teaches that the not-more-than-one French differential improved backup support of its catheter assembly." *Id.* at 35. Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1405 ¶¶ 186–235; Ex. 1442 ¶¶ 117, 118, 144–201. 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, the combination of Kontos, Ressemann, and Takahashi teaches or suggests the subject matter of claims 25–40, 42, and 44–48 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. 20–24. We further determine based on the current record, that the Petition shows a reasonable likelihood Petitioner would prevail in showing claims 25–40, 42, and 44–48 would have been obvious over Kontos, Ressemann, and Takahashi.

H. Alleged over Kontos, Ressemann, Takahashi, and Kataishi

Petitioner contends claim 45 would have been obvious over the combination of Kontos, Ressemann, Takahashi, and Kataishi. Pet. 58–61. Petitioner's contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1405 ¶¶ 236–243; Ex. 1442 ¶¶ 202–214.

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. 1401, 16:21–25. According to Petitioner, "Kataishi teaches a suction catheter with a distal end designed to . . . improve crossability of the catheter" and to "provide superior loading of matter (thrombus) into the distal end of the suction catheter." Pet. 60 (citing Ex. 1425 ¶ 10). Petitioner further reasons that "crossability and the ability to load matter into a catheter opening," as taught by Kataishi, "apply equally to the proximal end of a catheter." *Id.* (citing Ex. 1405 ¶ 240; Ex. 1442 ¶ 209).

At this stage of the proceeding, Patent Owner does not address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Kontos, Ressemann, Takahashi, 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 a catheter combining features of Kontos, Ressemann, and Takahashi is an issue to be developed during trial.

I. Alleged Obviousness over Root

Petitioner contends claims 25–55 would have been obvious over Root. Pet. 69–75. According to Petitioner, "Root is prior art under at least pre-AIA § 102(b)." Pet. 79. Specifically, Petitioner argues the effective filing

date of the Challenged Claims is no earlier than January 28, 2012, because "the priority applications provide no written description support for (i) a side opening outside of the substantially rigid segment or (ii) a side opening with "*at least two* inclined slopes." *Id.* at 62. In its Preliminary Response, Patent Owner asserts, without further explanation, that Root "is not prior art." Prelim. Resp. 6 n.2.

Petitioner provides a table identifying in the first column each Challenged Claim; in the second and third columns, citations from arguments presented by the applicant during prosecution of the '116 patent to show support from the '059 application; and, in the third column, citations purportedly corresponding to the disclosure in Root. 116. Pet. 70–75 (citing Ex. 1402 266–274, 745–755). Petitioner argues that the table shows "Root teaches nearly every limitation of the Challenged Claims." *Id.* (citing Ex. 1405 ¶ 247). Further, according to Petitioner, Root does not teach "placement of the side opening outside of the substantially rigid segment." *Id.* at 75. Petitioner reasons that a person of ordinary skill in the art "would have been motivated to construct the side opening of a material that was not rigid, as it was known that 'stents can get damaged entering [a] metal collar.'" *Id.* (quoting Ex. 1509, 10).

At this stage of the proceeding, Patent Owner does not otherwise address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Root. *See generally* Prelim. Resp. Whether Root is prior art is an issue for resolution on the full record developed during trial.

J. Alleged Obviousness over Kontos, Ressemann, Takahashi, and Root

Petitioner argues that "[t]o the extent" the combination of Kontos, Ressemann, Takahashi does not teach claims 45 and 46, these claims would

have been obvious over the combination of Kontos, Ressemann, Takahashi, and Root. Pet. 76. In particular, Petitioner argues a person of ordinary skill in the art "would replace Kontos's funnel 26 with the shape of the side opening in Root Figure 4." *Id.* Petitioner asserts a person of ordinary skill would have been motivated to replace Kontos's funnel with a side opening, but does not explain why. Instead, Petitioner cites "Section IX.A.3" of the Petition, which provides no explanation for a motivation. Pet. 33.

At this stage of the proceeding, Patent Owner does not otherwise address in its Preliminary Response Petitioner's specific contentions with respect to obviousness over Kontos, Ressemann, Takahashi, and Root. *See generally* Prelim. Resp. Whether Root is prior art and whether Petitioner has shown a motivation for the asserted combination are issues for resolution on the full record developed during trial.

K. 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*).[9] Patent Owner further argues the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* at 8–9 (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 &*

[9] 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).

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 Inst.*, 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating the decision whether to institute *inter partes* review requires "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any 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 25–55 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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