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Paper 20
Date: June 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX INNOVATIONS S.À.R.L.
Patent Owner.

IPR2020-00138
Patent RE47,379

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

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

INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 25, 26, 29–40, and 42–45 of U.S. Reissue Patent RE47,379 (Ex. 1201, "the '379 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response to the Petition (Paper 9, "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 14) addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply (Paper 15) addressing Petitioner's burden on those issues. Also pursuant to our authorization, Petitioner filed another Reply (Paper 17) and Patent Owner filed another Sur-Reply (Paper 18) addressing the factors for discretionary denial under 35 U.S.C. § 314(a).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2019). The standard for institution is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute an *inter partes* review of all challenged claims and all asserted grounds set forth in the Petition. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-

or-no institution choice respecting a petition, embracing all challenges included in the petition").

A. Related Matters

Petitioner indicates that the '379 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.) ("*Medtronic* case") and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn.) ("*QXM* case"). Pet. 4–5. Patent Owner identifies only the *Medtronic* case as a related matter involving the '379 patent. Paper 4, 2.

The '379 patent is also at issue in IPR2020-00137. Paper 4, 3; Pet. 5.

B. The '379 Patent

The '379 patent relates to catheters used in interventional cardiology procedures and, in particular, to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." Ex. 1201, 1:43–47.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or lesions." *Id.* at 1:57–59. This narrowing is referred to as stenosis. *Id.* at 1:61. To diagnose or treat aortic stenosis, "it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery." *Id.* at 1:61–65. In this method, a guide catheter is inserted through the aorta and into the ostium of the coronary artery where it is typically seated into the opening or ostium of the artery to be treated. *Id.* at 1:66–2:3. A guidewire or other instrument is then passed through the lumen of the guide catheter and inserted into the artery beyond the stenosis. *Id.* at 2:3–5. Crossing tough lesions, however, may create enough backwards force to dislodge the

guide catheter from the ostium of the artery being treated, making it difficult or impossible to treat certain forms of coronary artery disease. *Id.* at 2:6–10.

Figures 1 and 2 of the '380 patent are reproduced below:

Fig. 1

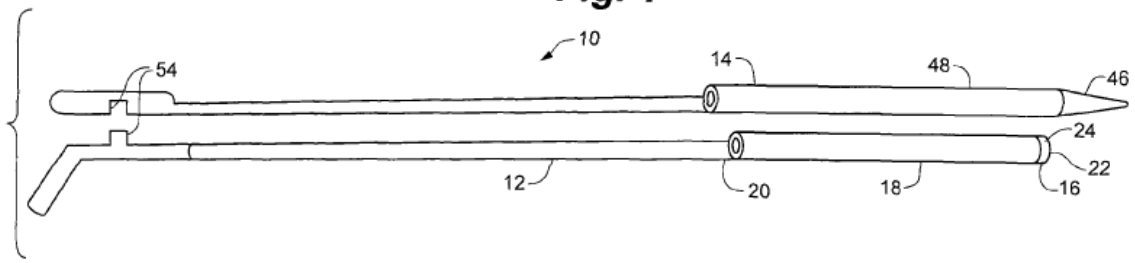

Fig. 2

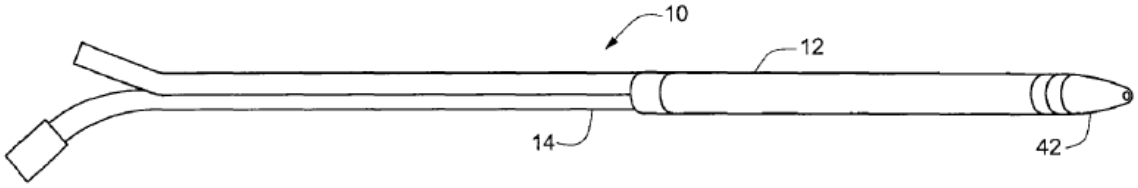

Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled. *Id.* at 5:57–62. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:50–51. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:36–37. Clip 54 releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:41–44.

Figure 8 of the ’380 patent is reproduced below:

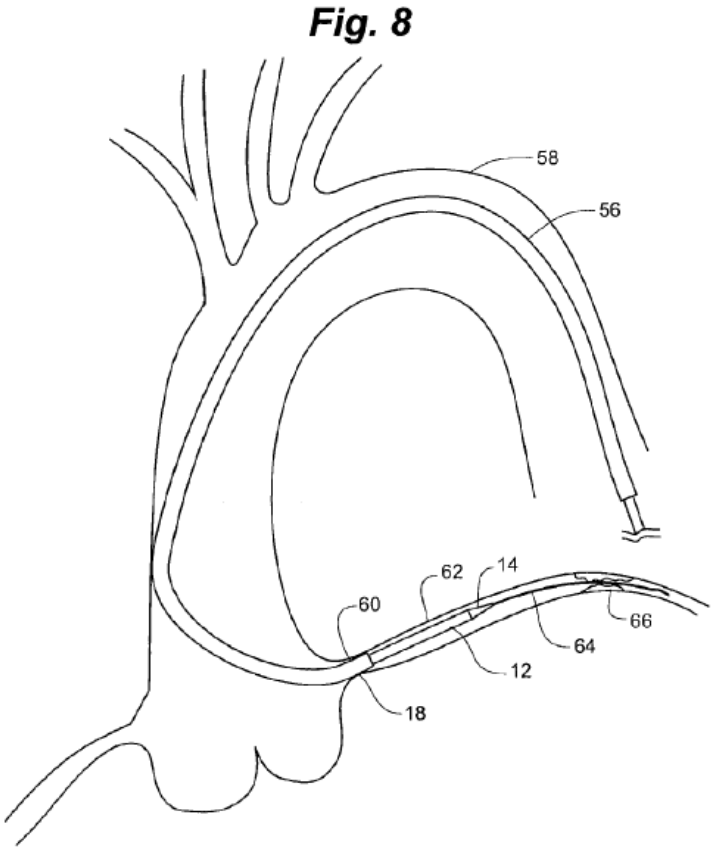

Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 6:11–14. In Figure 8, “coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62.” *Id.* at 8:26–32. “Coaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64.” *Id.* at 8:32–36. “Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.” *Id.* at 8:36–38. At this point, coaxial guide catheter 12 is ready to accept a treatment catheter such as a stent or balloon catheter. *Id.* at 8:39–40. The ’379 patent explains that coaxial guide

catheter 12 provides additional backup support to resist dislodging of guide catheter 56 from ostium 60 when force is applied to guidewire 64 to pass through stenotic lesion 66. *Id.* at 8:47–54.

C. Illustrative Claim

Independent claim 25 is illustrative of the challenged claims and is reproduced below.

25. A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:

providing a flexible tip segment having a lumen therethrough;

providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer, and extending from a proximal end portion to a distal end portion;

providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment;

defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape;

eccentrically positioning the distal end portion of the substantially rigid segment relative to a longitudinal axis of the proximal end portion of the reinforced segment; and

coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment,

wherein providing the substantially rigid segment, the reinforced segment, and the flexible tip segment includes forming a device length that is longer than the predefined length of the continuous lumen of the guide catheter such that when a distal end portion of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid

segment extends proximally of a proximal end of the guide catheter.

Ex. 1201, 13:61–14:25.

D. Prior Art and Asserted Grounds

Petitioner contends claims 25, 26, 29–40, and 42–45 of the '379 patent would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
25, 26, 29–31, 36, 38–40, 42–45	102	Ressemann[1]
25, 26, 29–32, 35–40, 42–44	103	Ressemann
33, 34	103	Ressemann, Takahashi[2]
44	103	Ressemann, Kataishi[3]
44	103	Ressemann, Enger[4]

Petitioner also relies on the testimony of Dr. Stephen Jon David Brecker (Ex. 1205) and Dr. Richard A. Hillstead (Ex. 1242). Pet. 7 n.2.

ANALYSIS

A. Claim Construction

In this proceeding, the claims of the '379 patent are 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). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the

[1] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1208) ("Ressemann").
[2] Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63:452–456 (2004) (Ex. 1210) ("Takahashi").
[3] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1225) ("Kataishi").
[4] Enger, US 5,980,486, issued November 9, 1999 (Ex. 1250) ("Enger").

entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner provides proposed constructions for the terms "standard guide catheter," "flexular modulus," and "concave track." Pet. 17–19. Patent Owner contends that "[a]t this stage, no specific construction of claim terms is necessary." Prelim. Resp. 14.

Upon review of the parties' arguments and supporting evidence, we determine that no terms of the '379 patent require construction for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *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.")).

B. § 314(a)

1. Multiple Petitions

Petitioner concurrently filed two petitions for *inter partes* review of the '379 patent: IPR2020-00137 and IPR2020-00138. In IPR2020-00137, Petitioner relies upon Itou (Ex. 1207) as the primary anticipating reference for most of the challenged claims. We recently instituted *inter partes* review based on that first petition. IPR2020-00137, Paper 22 (granting institution on June 8, 2020). In this proceeding, as discussed above, Petitioner relies upon Ressemann as the primary basis for its obviousness challenges. Petitioner ranks its petition for IPR2020-00137 as "Petition 1" and this current Petition as "Petition 2," and also provides an explanation of material differences between the petitions. Paper 3. Patent Owner contends we should exercise our discretion to deny institution on this second Petition

challenging the same claims of the '379 patent. Prelim. Resp. 19–23; Paper 8.

The Board's Trial Practice Guide addresses the situation where there are parallel petitions challenging the same patent, as here, noting that "[t]wo 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." *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide ("Consolidated Practice Guide") (Nov. 2019)[5] 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 contends that this second Petition challenging the '379 patent is necessary because of the priority date dispute concerning Patent Owner's attempts to swear behind the Itou reference in IPR2020-00137. Paper 3, 1–2. Petitioner argues "[i]t would be manifestly unfair and prejudicial to Petitioner if the Board exercises its discretion under § 314(a) to deny Petition 2 and post-institution Patent Owner successfully swears behind Itou." *Id.* at 2. Petitioner also contends that two petitions are

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

necessary because of the length and number of claims asserted by Patent Owner in district court. *Id.* at 3–4.

Patent Owner responds that Petitioner's strategic choice to rely on a § 102(e) reference (Itou) does not justify multiple petitions. Paper 8, 1–2. Patent Owner argues that Itou's prior art status was at issue in the district court litigation, and Petitioner did not even try to address the invention date in its petitions, and thus this is not one of the "rare" cases in which two petitions are needed. *Id*. at 1. Patent Owner contends that Petitioner's choice to include excessive, duplicative challenges to the same claims does not justify institution on multiple petitions. *Id.* at 3–4. Patent Owner also contends that, if we are inclined to institute trial on one of the petitions, institution on only the Kontos-based petition would avoid at least some of the inefficiencies resulting from having to address duplicative issues before both the district court and the Board.[6] *Id*. at 4.

We have considered the parties' respective positions and determine that the circumstances here justify institution of this second Petition challenging the '379 patent. Contrary to Patent Owner's argument that it was a "strategic choice," Petitioner was entitled to rely upon Itou as § 102(e) prior art as a statutory basis for unpatentability. *See* 35 U.S.C. § 311(b) ("A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."). Given the possibility that we may determine that Itou does not qualify as prior art after fully considering Patent Owner's

[6] Contrary to Patent Owner's argument, IPR2020-00138 does not assert any grounds based on Kontos. Pet. 7–8.

priority date arguments, we determine that Petitioner provides a sufficient explanation as to why it was necessary to rely upon the anticipation and obviousness challenges presented here as an alternative basis for unpatentability.[7] 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 Ressemann and the motivation to combine the teachings of Ressemann and Takahashi, Kataishi, or Enger.

In light of the circumstances presented here, we decline to exercise our discretion under § 314(a) to deny institution based on the multiple petitions challenging the '379 patent. To the extent that conducting separate proceedings is burdensome on the Board, the Board may separately exercise its authority under 37 C.F.R. §§ 42.1(b), 42.122(a) to consolidate the trials.

2. Co-Pending District Court Litigation

Patent Owner argues that 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. 14–18. In particular, Patent Owner contends that the validity of at least some of the challenged claims of the '379 patent and other related patents is the subject of active

[7] Although Ressemann is also §102(e) prior art, Patent Owner has not sought to "swear behind" the Ressemann reference.

litigation in two separate district court cases, the *QXM* case and the Medtronic case, which are both currently pending in the District of Minnesota. *Id.* at 10–11.

In *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential, designated May 7, 2019) ("*NHK*"), the Board considered the fact that a parallel district court proceeding was scheduled to finish before the Board reached a final decision as a factor favoring denial of institution. In the more recently designated precedential decision *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential, designated May 5, 2020) ("*Fintiv*"), the Board set forth several other factors to consider under § 314(a) in determining whether to institute trial when there is parallel, co-pending litigation concerning the same patent: (1) whether a stay of the parallel litigation exists or is likely to be granted if a trial proceeding is instituted by the Board; (2) proximity of the court's trial date to the Board's projected statutory deadline; (3) the investment in the parallel proceeding by the court and parties; (4) the extent of overlap between issues raised in the petition and in the parallel litigation; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) and other circumstances that impact the Board's exercise of discretion, including the merits.

The parties address the *Fintiv* factors in supplemental briefing that we authorized. Paper 17; Paper 18. We have considered each of these factors and conclude that, on balance, the circumstances here do not favor discretionary denial under § 314(a).

As to whether a stay of the parallel litigation exists or is likely to be granted (*Fintiv* Factor 1), Petitioner contends that the presiding district court

judge "has granted every post-institution request to stay litigation pending reexamination or IPR." Paper 17, 2 (citing Ex. 1293). Petitioner also points out that the *QXM* case, involving the same family of patents challenged here, has already been stayed pending our institution decisions, and the court indicated that if we institute trial "the Court will invite the parties to brief whether the stay should extend through the conclusion of the review process." *Id.* (citing Ex. 1294). Thus, Petitioner contends that the same judge will also entertain Petitioner's motion to stay the *Medtronic* case in the event of institution. *Id.* With respect to *Fintiv* Factor 1, Patent Owner contends that Petitioner has not sought a stay of the *Medtronic* litigation, and the Board has previously declined to infer how the district court would rule when neither party has requested a stay. Paper 18, 1. Patent Owner contends that the *QXM* case was stayed only because QXMedical agreed to exit the market and waived its obviousness/anticipation defenses, and the district court has not granted stays involving direct competitors or allegations of irreparable harm. *Id.* Having considered the parties position, we determine that *Fintiv* Factor 1 favors institution, especially in view of the fact that a stay has already been granted in the related *QXM* case and the district court's prior history of granting stays pending resolution of related IPRs.

As to the proximity of the court's trial dates to our statutory deadlines (*Fintiv* Factor 2), the parties agree that the district court has indicated that the *Medtronic* case must be "Ready for Trial" by August 1, 2021, which would be a few weeks *after* our statutory deadline for a Final Written Decision in this proceeding and the related IPRs. Prelim. Resp. 11; Paper 17, 1. Petitioner asserts the date for an actual trial will likely be extended

even further, noting that district court's final "Ready for Trial" date in patent proceedings is, on average, over eight months after the originally scheduled date. Paper 17, 1 (citing Ex. 1289). Petitioner points out that the district court already extended the original "Ready for Trial" date by two months in the *Medtronic* case, and that a trial date in the *QXM* case was finally set for February 24, 2020—more than ten months after the original "Ready for Trial" set by the court—before that case was stayed pending our institution decision. *Id.* We determine that *Fintiv* Factor 2 also favors institution, especially given that the trials in the district court cases will not likely take place until after we issue our Final Written Decisions in these proceedings. Notably, in both the *NHK* and *Fintiv* cases, the trial dates in the parallel litigations were scheduled either before or only a few months after the Board's institution deadlines and before the final written decision deadlines. *See NHK*, IPR2018-00752, Paper 8 at 19 (noting trial date of March 25, 2019, where Board's institution decision was issued September 12, 2018); *Fintiv*, IPR2020-00019, Paper 15 at 10 (noting trial date of March 8, 2021 where Board's institution decision was due May 15, 2021).

As to the amount of investment by the parties and the court in the parallel proceeding (*Fintiv* Factor 3), Patent Owner contends that the district court is already deeply invested and has familiarity with the challenged patents in light of the relatively advanced stage of the *QXM* case. Paper 18, 1–2. But as noted above, the district court has indicated a preference to wait for the Board's institution decision before proceeding in the *QXM* case. With respect to the *Medtronic* case, Patent Owner contends that the parties have already exchanged infringement contentions, conducted extensive fact discovery (set to close September 1, 2020), and addressed the issues in a

preliminary injunction motion. *Id.*; *see also* Prelim. Resp. 11–12. Although we agree that the parties have invested some time and effort in the related litigation, we are not persuaded that those cases are in such an advanced stage that would favor denial of institution. The district court recently denied the preliminary injunction motion filed by Patent Owner, noting that there are substantial questions with respect to the validity of the asserted claims. Ex. 1288, 9–14. However, the district court has not issued a claim construction order or any other substantive order. *See Fintiv*, Paper 11 at 10 (noting that if "the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*"). We, therefore, determine that resolution of those common issues by the Board would be beneficial to the district court. Patent Owner also contends that Petitioner delayed bringing these challenges. Paper 18, 2. Petitioner, however, points out that it filed its IPR petitions roughly four months after the district court complaint in the *Medtronic* case, and before Patent Owner's infringement contentions were served in that case. Paper 17, 2; *see Fintiv*, Paper 11 at 11 (noting that "it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding"). We find that Petitioner did not unduly delay filing its IPR Petitions.

We have also considered the remaining *Fintiv* factors and determine, on balance, that they do not outweigh the foregoing factors in favor of institution. *Fintiv*, Paper 11 at 6 (explaining that when various factors weigh both in favor and against exercising discretion under § 314(a), we take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review"). With respect to *Fintiv Factor* 4

(overlap of issues), Patent Owner responds that there is complete overlap of the issues raised in the parallel proceedings, including the same invalidity prior art and arguments raised in the Petitions. Paper 18, 2. With respect to *Fintiv Factor* 5 (whether the same parties are involved), Patent Owner also points out that the Petitioner is the defendant in the *Medtronic* case. *Id.* In contrast to *NHK* and *Fintiv*, however, in this case the trial date is *after* the due date for our final written decision and, although there is an overlap of issues and parties between the *Medtronic* case and this proceeding, in this case any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court may stay the parallel litigation, and thus not reach the merits of Petitioner's invalidity defenses, before we issue our final written decision.

Finally, under *Fintiv* Factor 6, we have taken into account the merits of Petitioner's challenges and find that this favors institution.

In sum, based on our consideration of the foregoing factors, we decline to exercise our discretion under § 314(a) to deny institution.

C. Claims 25, 26, 29–31, 36, 38–40, and 42–45 in view of Ressemann

Petitioner contends Ressemann anticipates claims 25, 26, 29–31, 36, 38–40, and 42–45 of the '379 patent. Pet. 19–58.

1. Ressemann

Ressemann 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. 1208, 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

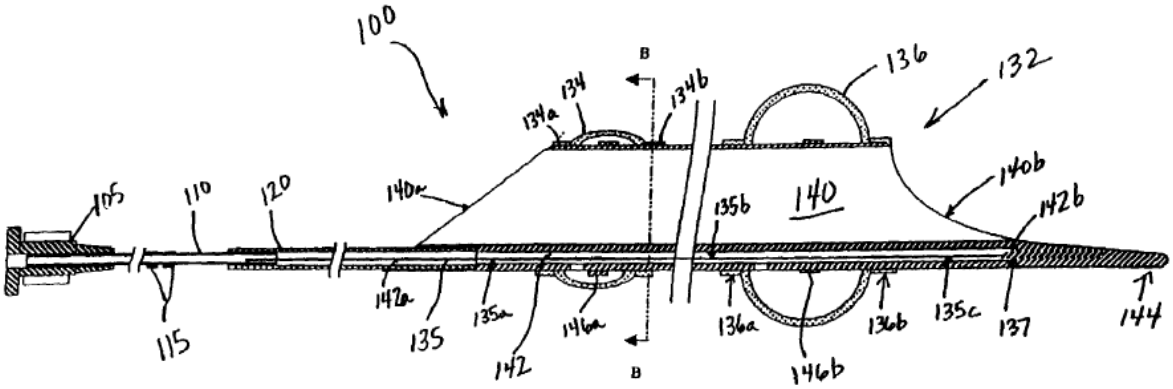

FIG. 1A

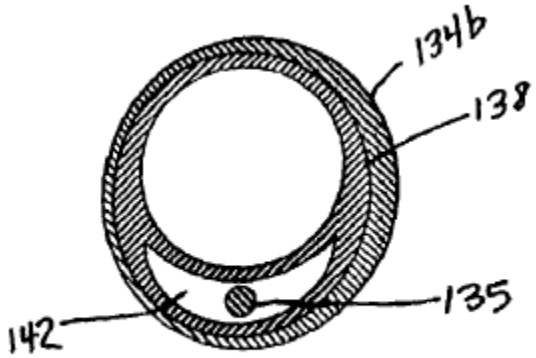

FIG. 1B

Figure 1A is a cross-sectional view of a partial length evacuation sheath. Ex. 1208, 3:16–18. Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B-1B. *Id.* at 3:19–20.

Figure 1A depicts evacuation sheath assembly 100, which "is sized to fit inside a guide catheter to advance a distal end of the evacuation sheath assembly into a blood vessel to treat a stenosis." *Id.* at 6:20–24, Fig. 5A. Evacuation head 132 includes multi-lumen tube 138, which preferably is made of a relatively flexible polymer, as well as evacuation lumen 140 and inflation lumen 142. *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. "The 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.

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. Evacuation sheath assembly 100 has a shaft that includes proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. 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. *Id.* at 11:30–39.

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. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel, and then evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:19–21, 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.

As shown in Figure 6D, reproduced below, the guidewire may then be advanced beyond a stenosis in the blood vessel.

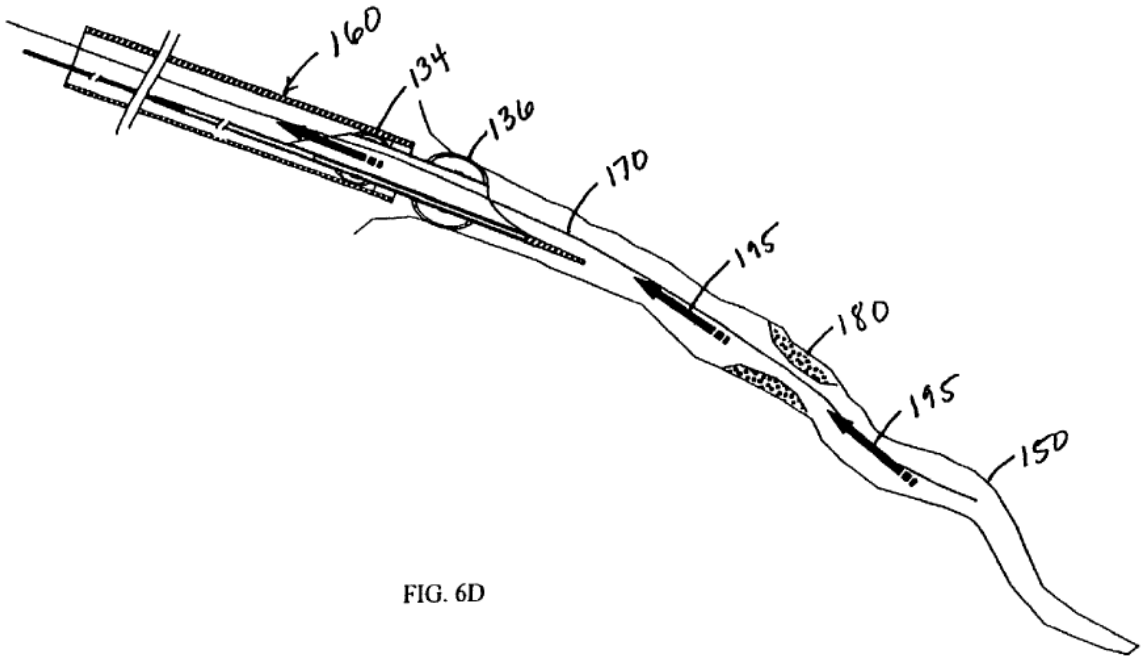

FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. As shown in Figure 6D, in this configuration the guide wire 170 may be advanced beyond stenosis 180 and then a therapeutic device, such as a stent, advanced over guide wire 170 and across stenosis 180. *Id.* at 13:15–20, 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.

2. Claim 25

Petitioner contends Ressemann discloses every limitation of independent claim 25, including (1) a method of forming a device for use with a standard guide catheter (evacuation sheath assembly 100) having a

continuous lumen extending for a predefined length[8] (Pet. 22–23 (citing Ex. 1208, 6:18–24, 12:9–30, 22:38–45, 28:26–36, 28:46–49, Fig. 16I, Abstract; Ex. 1205 ¶ 167)); (2) providing a flexible tip segment having a lumen therethrough (distal tip 140b and tip 144) (*id.* at 23–25 (citing Ex. 1205 ¶ 168; Ex. 1208, 6:36–60, 6:66–7:7, 10:20–21, 11:22–25, Figs. 1C, 1D)); (3) providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer, and extending from a proximal end portion to a distal end portion (stiffness transition member 135 and/or evacuation head 132 with coil 139) (*id.* at 25–27 (citing Ex. 1208, 6:44–60, 6:66–7:39, 11:29–35, 11:57–59, 23:50–60, Fig. 1C; Ex. 1205 ¶ 169; Ex. 1242 ¶¶ 60–66)); (4) providing a substantially rigid segment (substantially rigid segment formed of proximal and intermediate shaft portions 110 and 120) extending from a proximal end portion to a distal end portion, wherein this segment is more rigid along a longitudinal axis than the flexible tip segment (*id.* at 27–28 (citing Ex. 1208, 6:19–24, 6:36–39, 7:49–51, 10:47–11:14; Ex. 1205 ¶¶ 170–176; Ex. 1242 ¶¶ 67–70); (5) defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape (proximal opening to evacuation lumen 140 and hemicylindrical portion extending distally thereto) (*id.* at 29–30 (citing Ex. 1208, 6:52–60, 23:17–20, Figs. 1C, 1D; Ex. 1205 ¶ 177)); (6) eccentrically positioning the distal end portion of the substantially rigid segment relative to a longitudinal axis of the proximal end portion of the reinforced segment (*id.* at 30–31 (citing Ex.

[8] We need not determine whether the preamble of claim 25 is limiting because Petitioner shows sufficiently for purposes of institution that the recitation of the preamble is satisfied by the prior art.

1208, Figs. 1C, 1D; Ex. 1205 ¶ 178); (7) coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment (*id.* at 31–32 (citing Ex. 1208, Fig. 1C; Ex. 1205 ¶ 179)); and (8) wherein the various recited segments form a device length that is longer than the predefined length of the continuous lumen of the guide catheter such that when the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter (*id.* at 32–35 (citing Ex. 1208, 6:20–24, 12:19–14:10, Figs. 1C, 5A, 6A–6F; Ex. 1205 ¶ 180)).

Patent Owner does not address Petitioner's anticipation arguments based on Ressemann.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner sufficiently identifies where Ressemann discloses every limitation of independent claim 25. Accordingly, Petitioner has demonstrated a reasonable likelihood that claim 25 is anticipated by Ressemann.

3. Independent Claim 38 and Dependent Claims 26, 29–31, 36, 39, 40, 42–45

Petitioner identifies where it contends every limitation of independent claim 38 and dependent claims 26, 29–31, 36, 39, 40, 42–45 is disclosed expressly or inherently in Ressemann. Pet. 35–58.

Patent Owner does not address Petitioner's anticipation arguments with respect to these claims.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner identifies sufficiently where every limitation of

challenged claims 26, 29–31, 36, 38–40, 42–45 is disclosed expressly or inherently in Ressemann. Accordingly, Petitioner has demonstrated a reasonable likelihood that these claims are anticipated by Ressemann.

D. Obviousness of Claims 25, 26, 29–32, 35–40, and 42–44 over Ressemann

1. Claims 25, 26, 29–32, 36, 38–40, and 42–44

To the extent that it is determined that: (1) claim 25 requires that "the ***entire*** flexible tip segment must have a lumen therethrough"; (2) Ressemann does not disclose one or more braided or coiled metallic elements covered with the polymer (claim 32); (3) claim 36's "atraumatic bumper" must have a lumen (claim 36); or (4) Resseman does not disclose the inclined wall limitations of claim 44, Petitioner contends these claims, and those that depend therefrom, would have been obvious over Ressemann in view of the common knowledge in the art. Pet. 58–63, 65–66, 68–69.

We need not address these arguments because Petitioner has demonstrated sufficiently for purposes of institution that Ressemann discloses the identified claim limitations.

2. Claim 35

Claim 35 depends from claim 25 and further requires "wherein providing one or both of the reinforced segment and the flexible tip segment includes lining the lumens thereof with polytetrafluoroethylene." Ex. 1201, 14:64–67.

Although Ressemann discloses that lumen 140 is a tube "preferably made of a relatively flexible polymer such as low-density polyethylene, polyurethane, or low durometer Pebax(R) material," it does not specify whether lumen 140 has a lining. Pet. 64 (citing Ex. 1208, 6:37–42).

Petitioner contends lumens for catheters for coronary interventions were commonly lined with polytetrafluoroethylene to reduce friction and asserts one of ordinary skill in the art would have ensured that lumen 140 of Ressemann included a polytetrafluoroethylene liner in order to reduce friction when deploying its balloon and stent catheter. *Id.* at 64 (citing Ex. 1215, 548 ("Yet the catheter must still incorporate a Teflon liner to reduce friction, . . . "); Ex. 1208, 12:19–13:60, Figs. 6B-6E; Ex. 1205 ¶ 225; Ex. 1242 ¶¶ 99–102).

Patent Owner contends Petitioner's obviousness grounds fail because Petitioner did not address known objective evidence of nonobviousness, including evidence of commercial success, licensing by competitors, copying, and long-felt need. Prelim. Resp. 23–36. We are not persuaded by these arguments.

First, the question of nexus is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). Thus, here, as in most cases, an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage.

Second, objective evidence of nonobviousness is relevant only if there is a nexus between this evidence and the claimed invention. *Id.*
A presumption of nexus applies if the asserted objective evidence "is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (quoting *Polaris Indus., Inc. v. Artic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). To the extent that a presumption of nexus does not apply, Patent Owner may still prove nexus "by showing that

the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)).

Patent Owner contends a presumption of nexus applies in this case because its "GuideLiner" product "embodies challenged claims and is coextensive with" them. Prelim. Resp. 28. In support, Patent Owner directs our attention to an expert report submitted in the QXM case that maps the claims to its GuideLiner product. *Id.* at 27 (citing Ex. 2056 ¶¶ 160–168 (which include App'x J (448–453), App'x K (495–502, App'x L (540–546))). Patent Owner provides no persuasive analysis, however, to explain why the claims of the '379 patent are *coextensive* with its GuideLiner product. *See Fox Factory*, 944 F.3d at 1373. Moreover, the expert report relied upon by Patent Owner indicates that Patent Owner's GuideLiner product embodies the claims of at least five other patents. Ex. 2056 ¶¶ 164–168. In this situation, a presumption of nexus is appropriate only if Patent Owner demonstrates that the claims of all five patents "generally cover the same invention." *Fox Factory*, 944 F.3d at 1377. Patent Owner does not attempt to demonstrate this fact. *See* Ex. 1288, 11–12 (noting the existence of two different versions of catheters: "over-the-wire" and "rapid-exchange"). Indeed, that Patent Owner separately sought patent protection for each of these six patents suggests that these patents do not generally cover the same invention.[9] *Fox Factory*, 944 F.3d at 1378. Thus, on this record, a presumption of nexus does not apply.

[9] Several identified patents are terminally disclaimed. *See* Ex. 1201, code (45). Patent Owner does not assert, however, that *all* of the identified patents are terminally disclaimed to the same patent.

Patent Owner also asserts that it has sufficiently demonstrated nexus between its objective evidence and the claimed invention. Prelim. Resp. 28–29. But, as noted above, Patent Owner asserts a nexus exists for multiple patents. In this situation, "the patentee retains the burden of proving the degree to which evidence of secondary considerations tied to a product is attributable to a particular claimed invention." *Fox Factory*, 944 F.3d at 1378. Patent Owner has not done so on the record before us at this time.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner has explained sufficiently why one of ordinary skill in the art would have sought to line the lumens of the reinforced segment and flexible tip segment of Ressemann with polytetrafluoroethylene. Accordingly, Petitioner has demonstrated a reasonable likelihood that claim 35 would have been obvious over Ressemann.

3. Claim 37

Claim 37 depends indirectly from claim 25 and further requires "wherein providing the flexible tip segment includes covering a marker band with the polymer or the elastomeric material." Ex. 1201, 15:4–6. Petitioner contends that Ressemann discloses using a marker band and coating this band with polyurethane, which is the same material used to form the "atraumatic bumper" recited in claim 36. Pet. 66–67 (citing Ex. 1208. 23:55–24:23, Fig. 16F). To the extent any modification of Ressemann's distal tip were attempted, Petition contends one of ordinary skill in the art would have "retained the radiopaque marker band on the distal tip because those in the field appreciate that distal, radiopaque marker bands were necessary to allow detection of the distal end of a catheter via fluoroscopy." Pet. 67 (citing Ex. 1209, 4:16–19; Ex. 1205 ¶ 230).

Patent Owner does not directly address Petitioner's arguments with respect to claim 37.

On this record, Petitioner sufficiently explains why Ressemann generally discloses the subject matter of claim 37 and why one of ordinary skill in the art would have ensured that the flexible tip of Ressemann retained a marker band covered by polymer or elastomeric material. Accordingly, Petitioner has demonstrated a reasonable likelihood that claim 37 would have been obvious over Ressemann.

E. Claims 33 and 34 over Ressemann and Takahashi

Petitioner contends the subject matter of claims 33 and 34 would have been obvious over the combined disclosures of Ressemann and Takahashi. Pet. 69–74.

1. Takahashi

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. Ex. 1210, 452.[10] In this system, the inner lumen of the 5 French catheter is 0.059 inches and the inner lumen of the 6 French catheter is at least 0.071 inches. *Id.* 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 minimal damage "and then it can be inserted more deeply into the artery." *Id.*

[10] We cite to the pagination of the original document.

2. Claims 33 and 34

Claim 33 depends from claim 25 and further requires "wherein providing the reinforced segment includes forming or obtaining a reinforced segment including a lumen having a uniform inner diameter that is about one French smaller than an inner diameter of the continuous lumen of the guide catheter." Ex. 1201, 14:55–59. Claim 34 depends from claim 33 and further requires "wherein the lumen of the reinforced segment is greater than or equal to 0.056 inches and the continuous lumen of the guide catheter is greater than or equal to 0.070 inches." *Id.* at 14:60–63.

Petitioner concedes that there is greater than a one French differential between the inner diameter of evacuation lumen 140 and the inner lumen of the guiding catheter of Ressemann. Pet. 71. Petitioner contends, however, that one of ordinary skill in the art would have modified Ressemann to achieve a one French differential in view of Takahashi's disclosure that inserting a 5 French catheter into a 6 French guiding catheter increased backup support. *Id.* at 73. According to Petitioner, to achieve this goal one of ordinary skill in the art would have removed Ressemann's sealing balloons to decrease the outer diameter of assembly 100. *Id.* at 72.

Petitioner's proposed modifications require seemly extensive modification of Ressemann's system, including using a smaller guide catheter and removing Ressemann's sealing balloons, thereby eliminating the capability to act as an aspiration catheter. *Id.* at 72–73. The parties are encouraged to address whether these proposed modifications are relevant to Petitioner's obviousness arguments based on Resseman and Takahashi.

F. Claim 44 over Ressemann and Kataishi or Ressemann and Enger

Petitioner contends claim 44 would have been obvious over the combined disclosures of either Ressemann and Kataishi or Ressemann and Enger. Pet. 74–84.

Patent Owner does not address directly either obviousness ground.

Because we determine that a reasonable likelihood exists that claim 44 is anticipated by Ressemann, we need not address Petitioner's additional obviousness arguments related to this claim.

G. Appointments Clause

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." Prelim. Resp. 36–37 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338-39). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

CONCLUSION

In view of the foregoing, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one challenged claim of the '379 patent. Thus, we institute review of all challenged claims on all asserted grounds set forth in the Petition.

ORDER

It is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on all challenged claims of the '379 patent and on all asserted grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is hereby given of the institution of trial, which shall commence on the entry date of this decision.

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