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Paper 22
Date: June 8, 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.

IPR2020-00137
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. 1001, "the '379 patent"). Teleflex Innovations S.A.R.L. ("Patent Owner") filed a Preliminary Response to the Petition (Paper 8, "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 12) addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply (Paper 14) addressing Petitioner's burden on those issues. Also pursuant to our authorization, Petitioner filed another Reply (Paper 19) and Patent Owner filed another Sur-Reply (Paper 20) 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 indicate 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. 5. Patent Owner identifies only the *Medtronic* case as a related district court matter. Paper 4, 2–3.

The '379 patent is also at issue in IPR2020-00138.[1] Paper 4, 3; Pet. 5–6.

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. 1001, 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 a 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] In accordance with our Trial Practice Guide, Petitioner provides an explanation of material differences and ranking for the multiple petitions directed to each challenged patent. Paper 3. Patent Owner responds that Petitioner has not justified institution on multiple petitions. Paper 11. Given that this is the first petition filed by Petitioner on which we are instituting trial for the '379 patent, we need not and do not address Patent Owner's argument for denial based on multiple petitions.

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 2:1–5. 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 ’379 patent are reproduced below:

Fig. 1

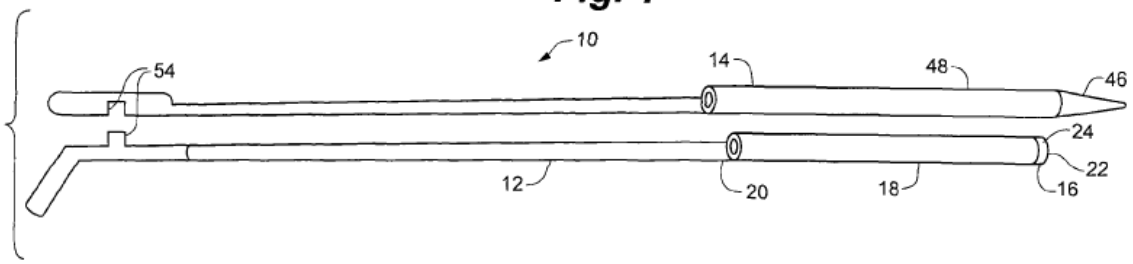


Fig. 2

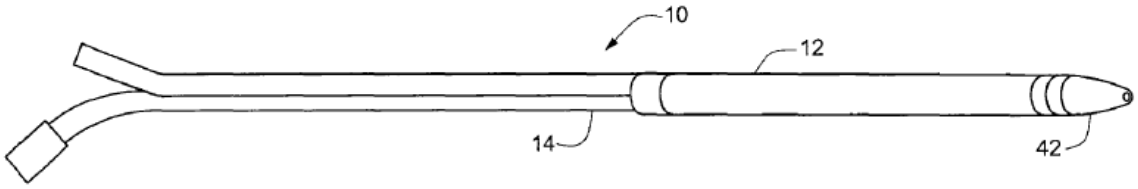
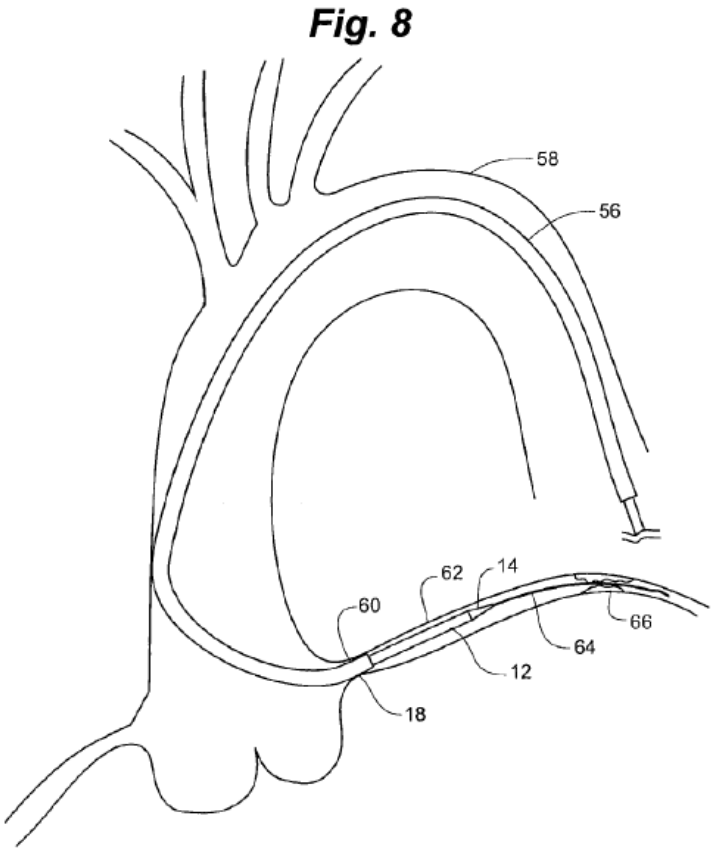


Figure 1 is a schematic depiction of the coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled. *Id.* at 5:57–62. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* 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 '379 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 after the guide catheter 56 has been placed in the ostium 60 of 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 the "combination of improved distal anchoring and stiffening of the guide catheter 56/coaxial guide catheter 12 combination 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 or another lesion." *Id.* at 8:47–52.

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. 1001, 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, 33–40, 42, 43, 45	102	Itou[2]
26, 38–40, 43–45	103	Itou, Ressemann[3]
32	103	Itou
44	103	Itou, Kataishi[4]
44	103	Itou, Enger[5]

Petitioner also relies on the testimony of Dr. Stephen JD Brecker (Ex. 1005) and Dr. Richard A. Hillstead (Ex. 1042). Pet. 8 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).

[2] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").
[3] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1008) ("Ressemann").
[4] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1025) ("Kataishi").
[5] Enger, US 5,980,486, issued November 9, 1999 (Ex. 1050) ("Enger").

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

Petitioner provides express constructions for the terms "standard guide catheter," "flexural modulus," and "concave track."[6] Pet. 18–20. Patent Owner contends no claim terms require construction at this time. Prelim. Resp. 15.

Upon review of the parties arguments and supporting evidence, we determine that no claim terms of the '379 patent require express 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. Claims 25, 26, 29–31, 33–40, 42, 43, 45 in view of Itou

Petitioner contends Itou anticipates claims 25, 26, 29–31, 33–40, 42, 43, 45 of the '379 patent. Pet. 20–60.

1. Priority Date of the '379 Patent

The AIA's first-to-file provisions apply to patent applications "that contain[] or contained at any time a claim to a claimed invention that has an effective filing date" on or after March 16, 2013. AIA § 3(n)(1). The

[6] Petitioner also identifies constructions for claim terms that were stipulated to by Patent Owner and adopted by the district court in the *QXM* litigation. Pet. 17–18.

application for reissue for the '379 patent was filed December 30, 2015 and sought reissue of US Patent No. 8,292,850, which issued October 23, 2012 from an application filed January 26, 2012. Ex. 1001, codes (22), (64). Petitioner contends that because there is no written description support for the subject matter of at least claim 44 of the '379 patent, the '379 patent has an effective filing date after March 16, 2013. Pet. 15. Thus, according to Petitioner, the '379 patent is not supported by a pre-March 16, 2013 application making it subject to the AIA's first-to-file provisions. *Id.*

"The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2). As the "patent for which reissue was sought" in this case was issued October 23, 2012, we are not persuaded that AIA's first-to-file provisions apply to the '379 patent. Indeed, Petitioner provides no statutory or case law support for the proposition that a reissue patent may lose the filing date of the original patent for which reissue was sought.[7]

2. Prior Art Status of Itou

Itou was filed on September 23, 2005, published on March 20, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner contends Itou is therefore prior art under pre-AIA § 102(e). Pet. 20.

[7] To the extent the original patent for which reissue was sought does not contain written description support for a reissue claim, that claim may be invalid for lack of written description support. But this is a question we may not address in an IPR. *See* 35 U.S.C. § 311(b).

Patent Owner contends Itou is not prior art to the '379 patent because conception of the invention claimed in the '379 patent occurred in late 2004 and reduction to practice occurred "in the spring and summer of 2005." Prelim. Resp. 16–17 (citing Ex. 2001 ¶¶ 5–46 (Root Declaration); Exs. 2002–2022). Patent Owner further contends that, despite having much of the evidence related to conception and reduction to practice, Patent Owner does not address this evidence in the Petition. *Id.*

The burden to show that Itou is prior art to the '379 patent rests with Petitioner. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). That said, once Petitioner presents evidence that Itou was filed and/or issued prior to the filing date of the '379 patent, the burden of production shifts to Patent Owner to demonstrate that Itou is not prior art, for example, by presenting evidence of an earlier conception and reduction to practice. *Id.* at 1380. And, although Patent Owner's presents multiple pieces of evidence in the Preliminary Response to satisfy this burden, Petitioner has not had an opportunity to address this evidence in this proceeding. Thus, the question of conception and reduction to practice is best resolved after trial and on a complete trial record.[8] *Id.* (noting that

[8] As noted by Patent Owner, Petitioner was aware of some of Patent Owner's evidence of conception and reduction to practice before it filed the Petition. Prelim. Resp. 21. The district court, however, determined that Patent Owner's evidence was "unimpressive" and insufficient to demonstrate, at the preliminary injunction stage, an earlier conception and reduction to practice. Ex. 1088, 13–14. Petitioner also notes that Patent Owner did not provide detailed contentions regarding conception and reduction to practice until less than a week before its Petition was filed, and the relevant evidence that was previously produced to Petitioner was marked "attorneys eyes only' in the district court case and thus could not have been

the burden of production shifts back to Petitioner once sufficient evidence of conception and reduction to practice have been presented).

3. Itou

Itou discloses "an intravascular foreign matter suction assembly" designed to suck, sample, and remove "foreign matter such as a thrombus or an embolus" from a blood vessel. Ex. 1007, 1:6–9, 1:47–49. This assembly includes a guiding catheter and a suction catheter configured to be inserted into the lumen of the guiding catheter. *Id.* at 1:49–65.

Figure 3 of Itou is reproduced below:

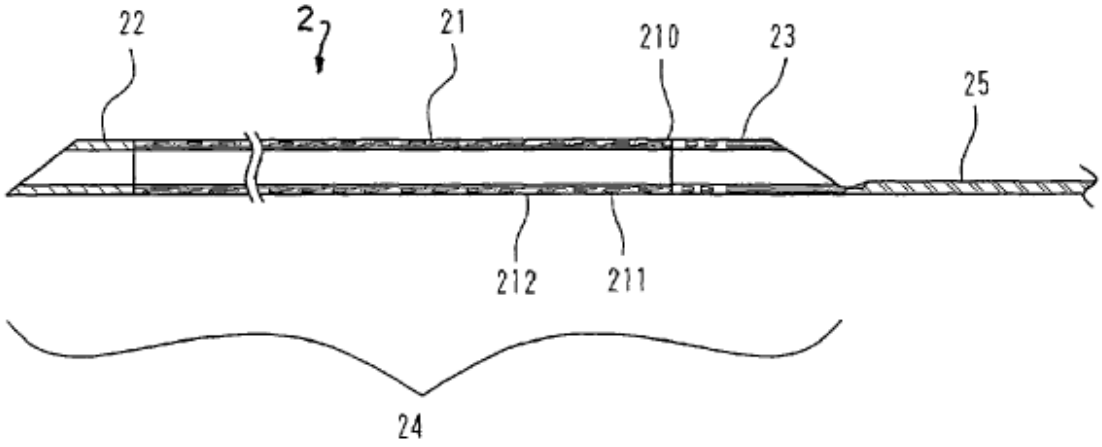


Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion 24 has an outer diameter that allows it to be inserted into the lumen of a guide

relied upon in the Petition. Paper 12, 2–5. Given that Patent Owner bears the burden of producing evidence to support its antedating contention, we determine Petitioner did not have an obligation to preemptively address Patent Owner's evidence in its Petition.

catheter and wire-like portion 25 has a sectional area smaller than the sectional area of the tube wall of tubular portion 24. *Id.* at 2:3:59–63. Tubular portion 24 has distal tip 22 that is flexible and reinforced tubular portion 21. *Id.* at 2:15–51, 3:50–58. Tubular portion 21 includes inner layer 210 made of resin material having a sliding property, "reinforcing layer 211 made of a metal wire made of stainless steel or the like," and outer layer 212 for covering the reinforcing layer. *Id.* at 3:50–56.

Figure 4 of Itou is reproduced below:

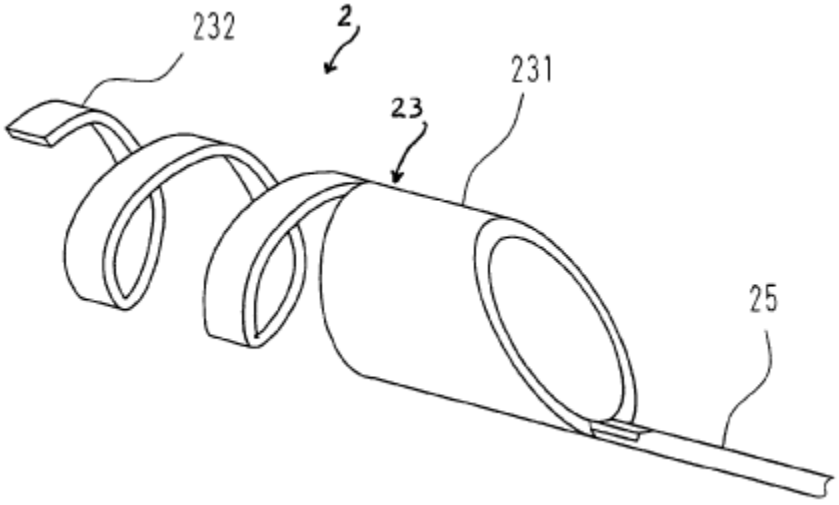


Figure 4 "is a view illustrating a joining method between a tubular portion and a wire-like portion of the suction catheter." *Id.* at 2:63–65. As shown in Figure 4, proximal tip 23 of the tubular portion includes a body "which in turn includes a proximal end portion 231 formed by obliquely cutting one end of a metal pipe." *Id.* at 4:27–29. Proximal end portion 231 is welded to the distal end of wire-like portion 25, which is "crushed into a form of a flat plate so that it may not be broken during use." *Id.* at 4:33–36.

Figure 5 of Itou is reproduced below:

FIG.5

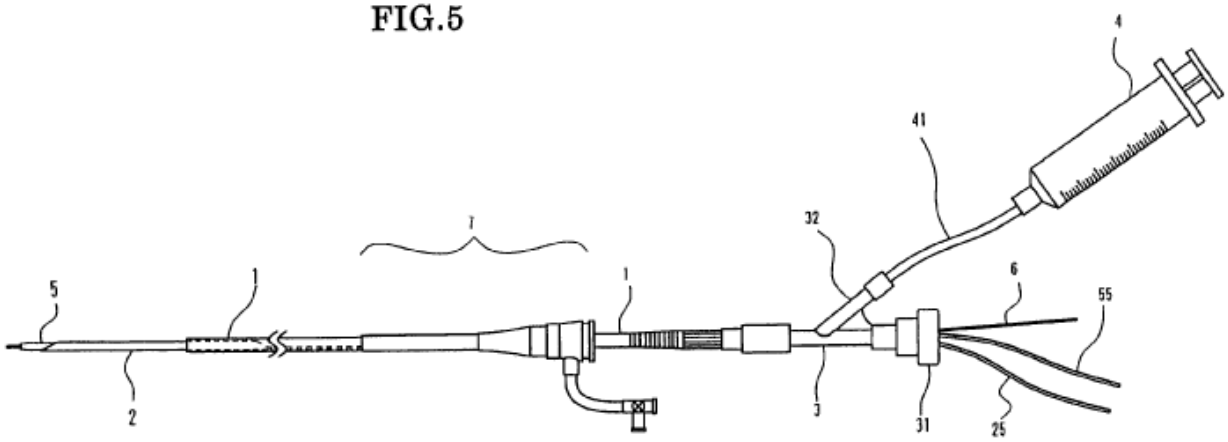


Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted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

A portion of Figure 6 of Itou is reproduced below:

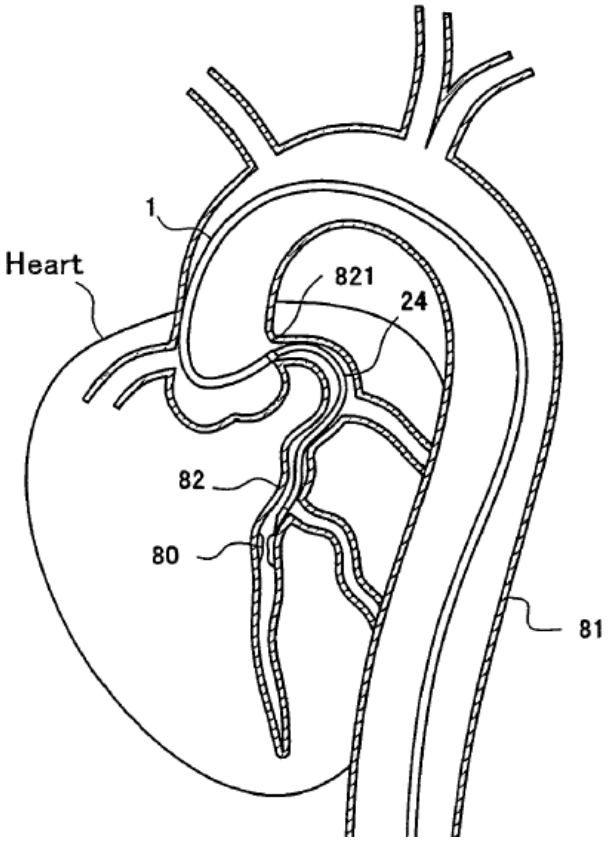


Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24 of suction catheter 2 is inserted into coronary artery 82 and is introduced along guide wire 6 to target location 80. *Id.* at 5:35–38.

4. Independent Claims 25 and 38

Petitioner contends Itou discloses every limitation of independent claim 25, including a method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predetermined length (Pet. 23–25 (citing Ex. 1007, 1:60–65, Fig. 1A, Table

1, Abstract; Ex. 1005 ¶¶ 173–176));[9] the method comprising (1) providing a flexible tip segment having a lumen therethrough (*id.* at 25–26 (citing Ex. 1007, 2:15–17, 4:4–5, 4:48–51, Figs. 1B, 1E, 3, 5; Ex. 1005 ¶¶ 177–179)); (2) providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer ("reinforcing layer 211 made of a metal wire made of stainless steel or the like"), and extending from a proximal end portion to a distal end portion (*id.* at 26–27 (citing Ex. 1007, 3:51–56; Ex. 1005 ¶¶ 180–183; Ex. 1042 ¶¶ 30, 73–75)); (3) providing a substantially rigid segment ("wire-like portion 25" and proximal tip 23) 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 (*id.* at 28–34 (citing Ex. 1007, 1:60–63, 2:5–8, 2:32–37, 3:49–50, 4:27–36, 5:35–46, Figs. 1B, 3, 4; Ex. 1005 ¶¶ 184–197; Ex. 1042 ¶¶ 21–31, 27–38, 64–67); (4) defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape (*id.* at 34–36 (citing Ex. 1007, 7:19–20, 7:25–26, Figs. 3, 4); Ex. 1005 ¶¶ 198–200); (5) 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 36–37 (citing Ex. 1007, Figs. 3, 4; Ex. 1005 ¶ 201)); (6) coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment (*id.* at 38 (citing Ex. 1007, Fig. 3; Ex. 1005 ¶ 202)); (7) wherein the device length is

[9] 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.

longer than the predefined length of the continuous lumen of the guide catheter such that when the distal end is extended distally of the distal end of the guide catheter its proximal end extends proximally of the proximal end of the guide catheter (*id.* at 38–40 (citing Ex. 1007, 1:60–63, 2:5–8, 2:32–37, 5:35–46, Fig. 3, Table 1; Ex. 1005 ¶¶ 203–206)).

With respect to independent claim 38, Petitioner provides a similar analysis, while also accounting for the different limitations of that claim. *See Id.* at 50–53 (addressing the side opening limitations of claim 38).

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

On this record, Petitioner has identified sufficiently where Itou expressly or inherently discloses every limitation of independent claims 25 and 38. Accordingly, Petitioner has demonstrated a reasonable likelihood that these claims are anticipated by Itou.

5. Dependent Claims 26, 29–31, 33–37, 39, 40, 42, 43, and 45

Petitioner also identifies where Itou discloses the limitations of claims 26, 29–31, 33–37, 39, 40, 42, 43, and 45 of the '379 patent. Pet. 40–48, 54–60. In support of these arguments, Petitioner provides a detailed analysis of Itou, as well as supporting testimony from Dr. Brecker and Dr. Hillstead. *Id.* (citing *generally* Exs. 1005 and 1042).

Patent Owner does not address Petitioner's specific arguments with respect to dependent claims 26, 29–31, 33–37, 39, 40, 42, 43, and 45.

Upon review of Petitioner's arguments and Dr. Brecker's and Dr. Hillstead's supporting testimony, we determine that Petitioner has identified sufficiently where Itou discloses every limitation of dependent claims 26, 29–31, 33–37, 39, 40, 42, 43, and 45. Thus, Petitioner has

demonstrated a reasonable likelihood that these claims are anticipated by Itou.

C. Claims 26, 38–40, and 43–45 over Itou and Ressemann

Petitioner contends the subject matter of claims 26, 38–40, and 43–45 would have been obvious over the combined disclosures of Itou and Ressemann, when considered in light of the knowledge of one of ordinary skill in the art. Pet. 60–74. Petitioner relies upon this ground to the extent the Board determines that Itou does not disclose the "side opening" limitations of claim 26, a side opening that can "receive a balloon catheter and stent" as recited in claim 38, or the "concave track" limitation of claim 43. *Id.* at 62–63.

Having determined that Petitioner presents sufficient evidence that Itou discloses the identified structures, we need not address at this time Petitioner's arguments based on the combination of Itou and Ressemann.

D. Claim 32 over Itou

Claim 32 depends from claim 31 and further requires that the "length of the one or more braided or coiled metallic elements is in a range of 20 centimeters to 30 centimeters." Ex. 1001, 14:52–54. Petitioner concedes that the braided or coiled metallic elements of Itou do not extend between 20 to 30 centimeters, as "the entire length of the tubular portion of the catheter is only 150 mm (or 15 cm)." Pet. 74–75. Petitioner asserts, however, that the subject matter of claim 32 would have been obvious over the disclosures of Itou, when considered in light of the knowledge of one of ordinary skill in

the art.[10] *Id.* at 74–77. In particular, Petitioner asserts that one of ordinary skill in the art would have sought to increase the length of the tubular structure of the catheter, up to a total length of 30 cm, "to accommodate reaching lesions located in particularly tortuous vessels." *Id.* at 76 (citing Ex. 1005 ¶ 302; Ex. 1046, 1:39–44 (Dinh patent disclosing catheter braids); Ex. 1072, 2:24–25, 2:38–44).

Patent Owner does not address Petitioner's obviousness arguments directed to claim 32, but contends all of Petitioner's obviousness arguments fail because Petitioner failed to address Patent Owner's objective evidence of nonobviousness. Prelim. Resp. 26–38. We are not persuaded by these arguments.

Objective evidence of nonobviousness is relevant only if there is a nexus between this evidence and the claimed invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). 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)).

[10] Petitioner also identifies disclosure in U.S. Patent No. 5,704,926 (Sutton) of using a braided section that is "at least, e.g., about 5 cm, and preferably about 15–30 cm." *See* Pet. 76 (citing Ex. 1072, 2:38–44 (discussing one of two different braided sections of the catheter)).

Patent Owner contends that a presumption of nexus applies in this case because its "GuideLiner" product "embodies" the challenged claims and is "coextensive" with them. Prelim. Resp. 28, 30–31. 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 29 (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. 1088, 11–12 (noting the existence of two different versions of catheters: "over-the-wire" and "rapid-exchange"); Prelim. Resp. 29. Indeed, that Patent Owner sought patent protection for each of these patents suggests that these patents do not generally cover the same invention.[11] *Fox Factory*, 944 F.3d at 1378. Thus, on this record, a presumption of nexus does not apply.

Patent Owner also asserts that it has sufficiently demonstrated nexus between its objective evidence and the claimed invention. Prelim. Resp. 31–32. But, as noted above, Patent Owner asserts that a nexus exists for

[11] Several identified patents are terminally disclaimed. *See* Ex. 1001, code (45). Patent Owner does not assert, however, that *all* of the identified patents are terminally disclaimed to the same patent.

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.

Moreover, the question of nexus is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Id.* at 1373. 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.

Upon review of the parties arguments and evidence, we determine that Petitioner has demonstrated sufficiently that Itou, coupled with the knowledge of one of ordinary skill in the art, teaches or suggests every limitation of claim 32. Petitioner also sufficiently explains why one of ordinary skill in the art would have extended the length of the tubular portion of the catheter up to 30 cm, i.e., to reach lesions in small, tortuous arteries. Accordingly, Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 32 would have been obvious over Itou and the knowledge of one of ordinary skill in the art.

E. Claim 44 over Itou and Kataishi

Claim 44 depends from claim 38 and further requires "wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region."
Ex. 1001, 16:24–28. Petitioner contends Itou in combination with Kataishi renders this claim limitation obvious. Pet. 77–82.

1. Kataishi

Kataishi discloses "a thrombus suction catheter for removing a thrombus from coronary arteries" that has "remarkably improved suction and crossing (reaching ability and smooth passage to a subject site)." Ex. 1025 ¶ 1.

Figure 2 of Kataishi is reproduced below:

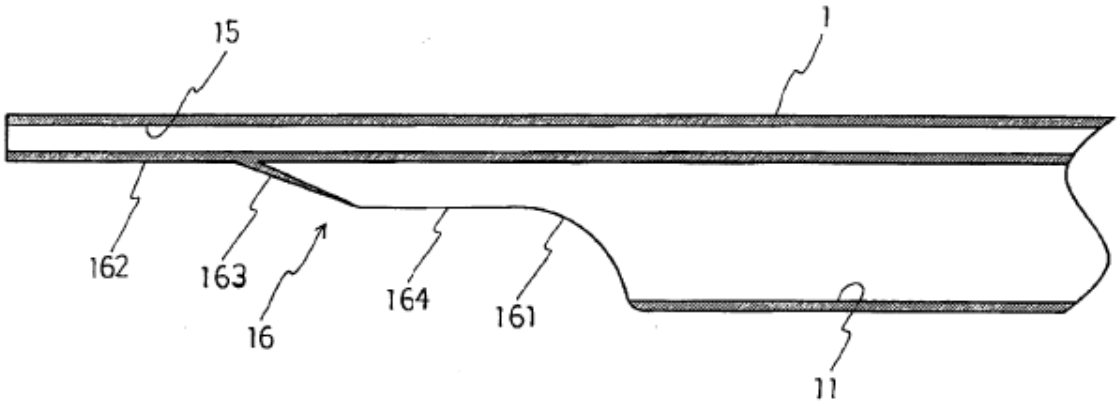


Fig. 2

Figure 2 of Kataishi is a cross-sectional view showing an enlarged portion of the disclosed thrombus suction catheter. *Id.* ¶ 14. The thrombus suction catheter includes catheter body 1 having a lumen 11. *Id.* ¶ 27. The distal end of the catheter is provided with cut surface 16 having on its proximal end side a first cut surface 163 defining an angle with the longitudinal axis of the catheter and a second concave cut surface 161 beginning at the trailing end of ledge surface 164 and also angled with respect to the longitudinal surface. *Id.*

Figure 10 of Kataishi is reproduced below:

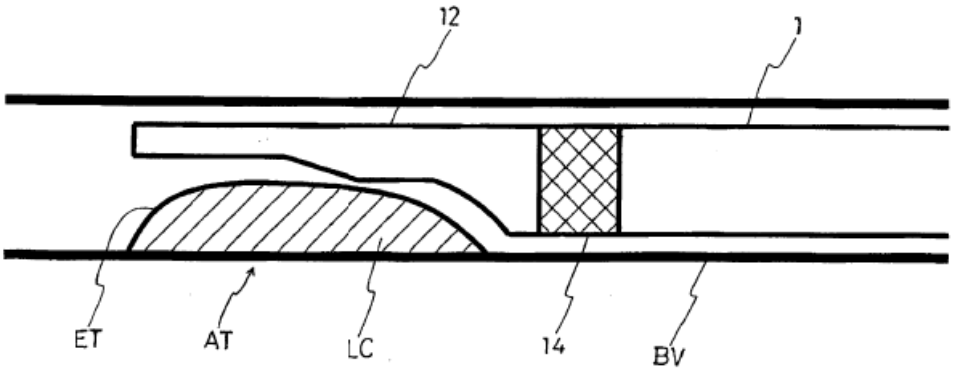


Fig. 10

Figure 10 shows the thrombus suction catheter of Kataishi covering an atheroma (AT), consisting of a lipid core (LC) beneath the vascular endothelium (ET), that is in a blood vessel (BV). *Id.* ¶¶ 22, 27. As shown in Figure 10, cut surface 161 (labelled in Figure 2) forms a concave portion that, according to Kataishi, improves the flexibility of the catheter distal end and enables cut surface 16 to absorb an expanded atheroma by suction. *Id.* Kataishi explains that the angled shape of a portion of distal end opening 12 "remarkably enhances suction" and enables the lipid core in the vascular endothelium to be removed by suction. *Id.*

2. Analysis

Petitioner contends one of ordinary skill in the art would have sought to configure the proximal opening of Itou's suction catheter to include two different inclined slopes separated by a non-inclined region in view of Kataishi. Pet. 80–81. In particular, Petitioner contends it was understood in the art that it was beneficial to size an aspiration catheter with a distal lumen of sufficient diameter to deliver an interventional cardiology device in order to remove fragments of plaque that may break free during angiolplasty or

stent delivery. *Id.* 81 (citing Pet. 66–67). And because the inclined regions of Kataishi's catheter allow for a larger area for receiving an element into the lumen of the catheter, Petitioner contends one of ordinary skill in the art would have understood that using the two different inclined shapes of Kataishi in Itou would increase the area of entry for a stent or balloon, just as it increased the area of entry for a thrombus. *Id.* at 81–82.

Patent Owner does not address Petitioner's arguments directed to the combination of Itou and Kataishi in its Preliminary Response specific to this proceeding.[12] We note, however, that Petitioner does not explain sufficiently why the inclined shape of Kataishi's distal opening would have been applicable to the angled partially cylindrical opening at the proximal end of Itou's suction catheter 2. Nonetheless, because we are instituting trial in this proceeding, the parties may further develop the record with respect to this issue before we reach our final determination as to this ground.

F. Claim 44 over Itou and Enger

Petitioner contends the subject matter of claim 44 also would have been obvious over the combined disclosures of Itou and Enger. Pet. 82–87.

1. Enger

Enger discloses a "rapidly exchangeable catheter for use in the coronary arteries." Ex. 1050, Abstract. Figure 1 of Enger is reproduced below:

[12] We note that Patent Owner raised concerns about the combination of Itou and Kataishi as applied to another related patent. *See* IPR2020-00135, Paper 8, 41–47.

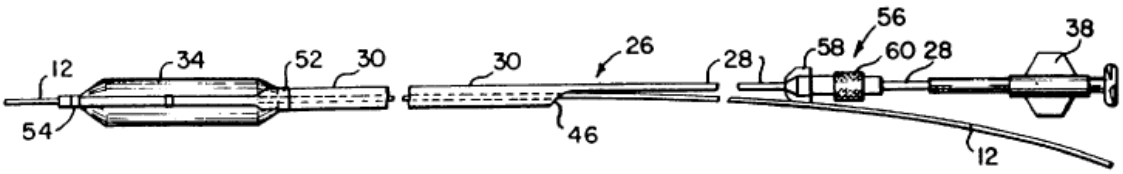


Fig. 1

Figure 1 is a fragmented illustration of the catheter of Enger. *Id.* at 4:3. Catheter 26 includes elongate proximal segment 28 formed from metallic hypodermic tubing, intermediate segment 30 made of a flexible plastic, and distal segment 32 (not labeled in Figure 1) having dilation balloon 34 mounted thereon. *Id.* at 4:67–5:10, 5:28. Intermediate segment 30 has both an inflation lumen and a lumen adapted to receive guidewire 12. *Id.* at 5:33–37.

Figure 7 of Enger is reproduced below:

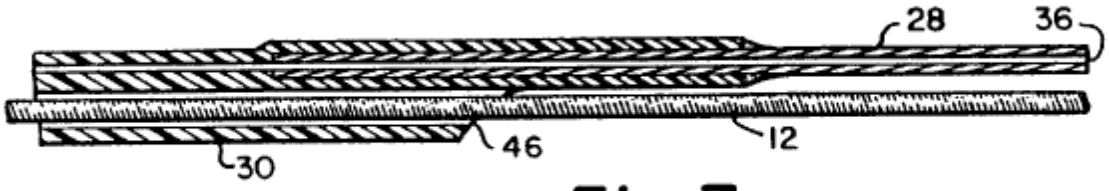


Fig. 7

Figure 7 "is a sectional longitudinal illustration of the catheter in the region where the proximal metal tubular segment is joined to the intermediate more flexible plastic segment." *Id.* at 4:19–22. As shown in Figure 7, the guidewire lumen terminates at proximal opening 46, such "that the guidewire is exposed proximally of the intermediate segment 30." *Id.* at 5:38–40.

2. Analysis

Petitioner contends proximal opening 46 of Enger has at least two inclined slopes, with the first incline functioning "as a start of an incline to the entry port located at" the second incline. Pet. 85–86. Petitioner contends one of ordinary skill in the art would have sought to provide Enger's first incline in Itou's device in order to function as an "on-ramp" to guide interventional devices into the lumen of Itou's suction catheter. *Id.* at 86.

Patent Owner does not directly address Petitioner's arguments with respect to Itou and Enger in its Preliminary Response specific to this proceeding.[13]

We note that Enger does not appear to use its angled incline to guide a guidewire into the lumen of a catheter. Instead, the guidewire is either assembled with the balloon catheter *before* the entire assembly is inserted through the guide catheter or the guidewire is inserted *first* and guided to the desired branch of the coronary arteries to be treated. Ex. 1050, 6:38–49. The parties are encouraged to further develop the record during trial as to whether this difference and any other concerns about the Itou/Enger combination raised in the other related proceedings are relevant to Petitioner's proposed combination in this proceeding.

G. § 314(a)

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

[13] We note that Patent Owner raised concerns about the combination of Itou and Enger as applied to another related patent. *See* IPR2020-00135, Paper 8, 55–62.

litigated in parallel district court cases. Prelim. Resp. 19–24. 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 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 11–12.

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, 6 (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 19; Paper 20. 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 in the *Medtronic* and *QXM* cases "has granted every post-institution request to stay litigation pending reexamination or IPR." Paper 19, 2 (citing Ex. 1093). Petitioner also points out that the *QXM* case, involving the '379 patent and other patents in the same family, 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. 1094). 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 20, 1. Patent Owner contends that the *QXM* case was stayed only because QXMédical agreed to exit the market and waived its obviousness/anticipation defenses, and that 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 *afte*r our statutory deadline for a final written decision in this proceeding and the related IPRs. Prelim. Resp. 12; Paper 19, 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 19, 1 (citing Ex. 1089). 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. We determine that *Fintiv* Factor 2 also favors institution, especially given that the trials in the district court cases are not scheduled to 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 to occur before the final written decision deadlines. *See NHK*, Paper 8 at 19 (noting trial date of March 25, 2019, where Board's institution decision was issued September 12, 2019); *Fintiv*, Paper 15 at 10 (noting trial date of March 16, 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 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 20, 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. 12–13. 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. 1088, 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 may be beneficial to the resolution of the district court proceedings. Patent Owner also contends that Petitioner delayed bringing these challenges. Paper 20, 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 19, 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 and that Factor 3 weighs against applying our discretion under § 314.

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 20, 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.

H. 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. 39 (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.* at 39–40 (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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