Trials@uspto.gov
571-272-7822

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.

IPR2020-00128
Patent RE45,380

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 1–4, 6–10, 12–21, and 23 of U.S. Reissue Patent RE45,380 (Ex. 1001, "the '380 patent"). Teleflex Innovations S.À.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

The parties indicate that the '380 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. 5–6; Paper 4, 2. The '380 patent is also at issue in IPR2020-00129, IPR2020-00130, and IPR2020-00131.[1] Paper 4, 2–3; Pet. 6.

B. The '380 Patent

The '380 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, 1:31–35.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions." *Id.* at 1:44–46. This narrowing is referred to as stenosis. *Id.* at 1:48–49. To 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 1:49–52. In this method, a guide catheter is inserted through the aorta and into the

[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 '380 patent, we need not and do not address Patent Owner's argument for denial based on multiple petitions.

ostium of the coronary artery where it is typically seated into the opening or ostium of the artery to be treated. *Id.* at 1:53–57. 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 1:39–41, 1:57–59. Crossing the 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 1:59–63.

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

Fig. 1

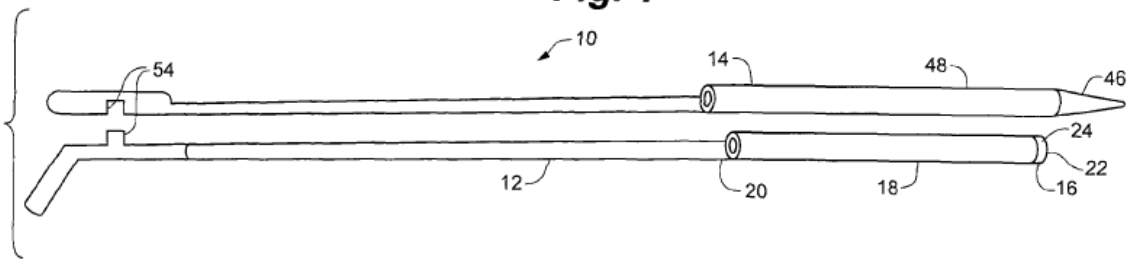

Fig. 2

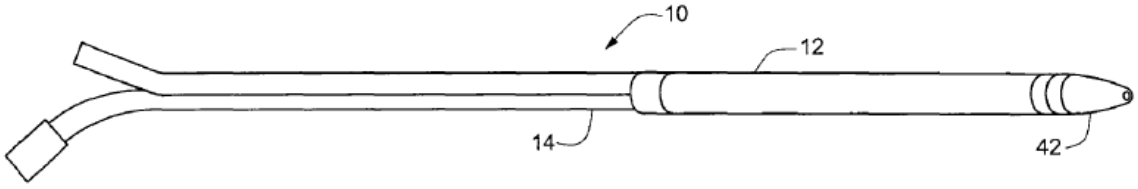

Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled together. *Id.* at 5:40–45. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:34–35. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:16–17. Clip 54

releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:21–23.

Figure 8 of the '380 patent is reproduced below:

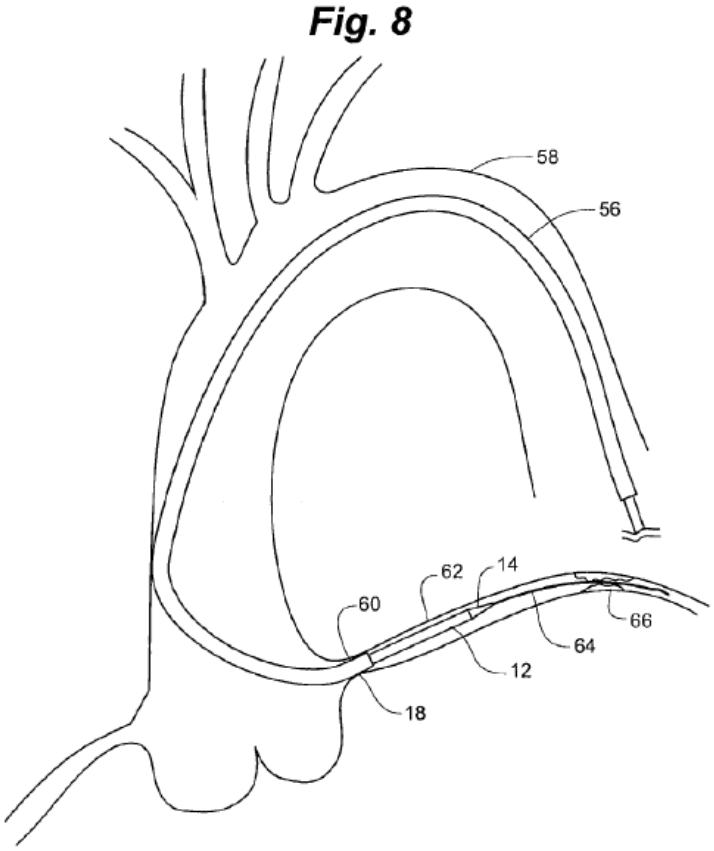

Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 5:61–64. In Figure 8, "coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guidewire has been placed in the ostium 60 of coronary artery 62." *Id.* at 8:6–10. The '380 patent explains that "[c]oaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64." *Id.* at 8:10–14. "Once coaxial guide catheter 12 is in place, tapered inner catheter

14 is removed from the inside of coaxial guide catheter 12." *Id.* at 8:14–17. At this point, coaxial guide catheter 12 is ready to accept a treatment catheter such as a stent or balloon catheter. *Id.* at 8:18–19. The '380 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 8:23–30.

C. Illustrative Claim

Independent claim 1 is illustrative of the challenged claims and is reproduced below.

> 1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and
>
> a device adapted for use with the guide catheter, including:
>
> a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis

than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

Ex. 1001, 10:47–11:24 (limitations added by reissue in italics).

D. Prior Art and Asserted Grounds

Petitioner contends claims 1–4, 6–10, 12–21, and 23 of the '380 patent would have been unpatentable on the following grounds (Pet. 8):

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6–10, 12–20, 23	102	Itou[2]
3, 14, 15	103	Itou, Ressemann[3]
21	103	Itou, Berg[4]

[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] Berg, US 5,911,715, issued June 15, 1999 (Ex. 1051) ("Berg").

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

For purposes of this decision, only the term "interventional cardiology devices" requires construction. *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.")).

Claims 1 and 12 require a flexible tip portion (claim 1) or a tubular portion (claim 12) that defines "a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable." Ex. 1001, 10:58–67, 12:17–28. To that point, the Specification expressly defines the claim term "interventional cardiology devices" as follows:

> For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be

> limited to guidewires, balloon catheters, stents and stent catheters.

Id. at 1:41–44.

Petitioner contends that, in the *QXM* case, Patent Owner stipulated that the term "interventional cardiology device(s)" means "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." Pet. 16 (citing Ex. 1012, 21; Ex. 1064 1 n.1). The district court, however, did not construe the term "interventional cardiology device(s)" in the *QXM* case. Ex. 1013 (Claim Construction Order).

Patent Owner contends that "interventional cardiology devices," as used in independent claims 1 and 12,

> requires that at least ***all four enumerated devices*** (guidewires, balloon catheters, stents, and stent catheters) be insertable into the lumen. This construction is based on the plain language of the claims ("interventional cardiology device**s**"), as well as the definition's use of the inclusive conjunction "and."

Prelim. Resp. 17. Patent Owner further contends as follows:

> This construction is . . . consistent with the specification. The Summary of the Invention describes the invention as a "coaxial guide catheter," i.e., a structure that serves the same basic function (delivering interventional cardiology devices) as the guide catheter in which it is placed. Exhibit 1001, 3:9–20. The coaxial guide catheter is contrasted from the tapered inner catheter that is placed within it – among other things, the tapered inner catheter "runs over a standard 0.014 inch coronary guidewire," while the coaxial guide catheter is "typically five to eight French" and has an inner lumen that is preferably only about one French size smaller than the guide catheter. *Id*.; *see also id.* at 3:28–43. The Summary notes that the "invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel." *Id*. at 5:33–36. Merely being sized to receive a guidewire is not enough; the claim language requires that guidewires, stents, stent catheters

> and balloon catheters be insertable through the claimed coaxial lumen.

Id. at 18.

Having considered the parties' positions and evidence of record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents and stent catheters. In the context of independent claims 1 and 12, the lumen of the recited guide catheter must be sized to receive at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents and stent catheters. For example, the diameter of the guide catheter is sized to receive a guidewire and a stent or balloon. *See* Ex. 1001, 7:60–64 ("Once the guidewire 64 is pushed past stenotic lesion 66 or occlusive lesion . . . , a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion 66 or occlusive lesion . . . .").

Moreover, based on the current record, we do not construe the claims to require that more than one of guidewires, stents, stent catheters and balloon catheters be simultaneously insertable into and through the lumen; although we recognize that certain embodiments disclosed in the Specification show a preference for the use of a guidewire and a stent or balloon. *Id.* at 7:60–64, Figs. 7–8.

Finally, we recognize that the Specification discloses that "the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel" (*id.* at 5:33–36) and that the term "interventional cardiology devices" is not limited to guidewires, balloon catheters, stents and stent catheters (*id.* at 1:41–44). To the extent

further discussion of what additional devices may be encompassed by this term is required for the purposes of our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

B. Claims 1–4, 6–10, 12–20, and 23 in view of Itou

Petitioner contends Itou anticipates claims 1–4, 6–10, 12–20, and 23 of the '380 patent. Pet. 19–65.

1. Priority Date of the '380 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 application for reissue for the '380 patent was filed November 1, 2013 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 27 of the '380 patent, the '380 patent has an effective filing date after March 16, 2013. Pet. 14. Thus, according to Petitioner, the '380 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 '380 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.[5]

2. Prior Art Status of Itou

Itou was filed on September 23, 2005, published on March 30, 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. 19.

Patent Owner contends Itou is not prior art to the '380 patent because conception of the invention claimed in the '380 patent occurred in late 2004 and reduction to practice occurred "in the spring and summer of 2005." Prelim. Resp. 21–22 (citing Ex. 2001 ¶¶ 5–46 (Root Declaration); Exs. 2002–2022, 2024). Patent Owner further contends that, despite having much of the evidence related to conception and reduction to practice, Patent Owner does not address it in the Petition. *Id.* at 23–24.

The burden to show that Itou is prior art to the '380 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 '380 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

[5] 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).

this proceeding. Thus, we determine that genuine issues of material fact remain about the alleged invention date and that these questions are best resolved after trial and on a complete trial record.[6] *Id.* (noting that 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.

[6] 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 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.

Figure 3 of Itou is reproduced below:

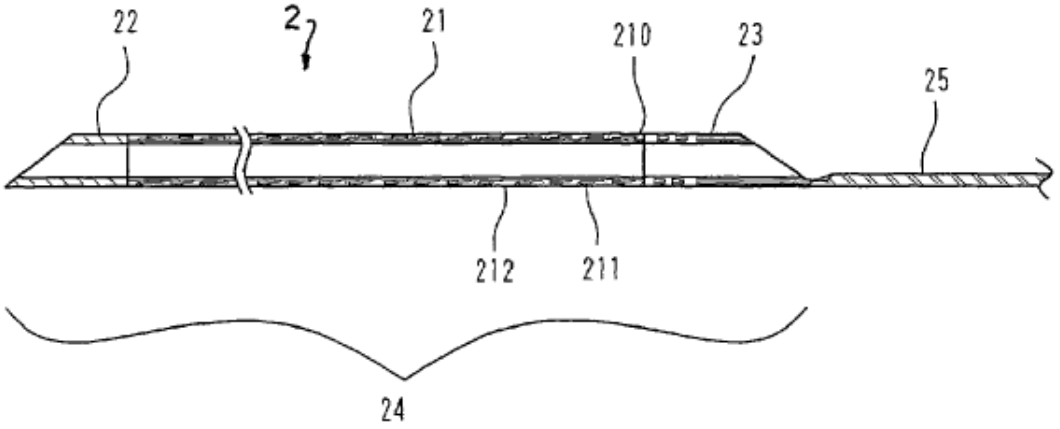

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion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

Figure 5 of Itou is reproduced below:

FIG.5

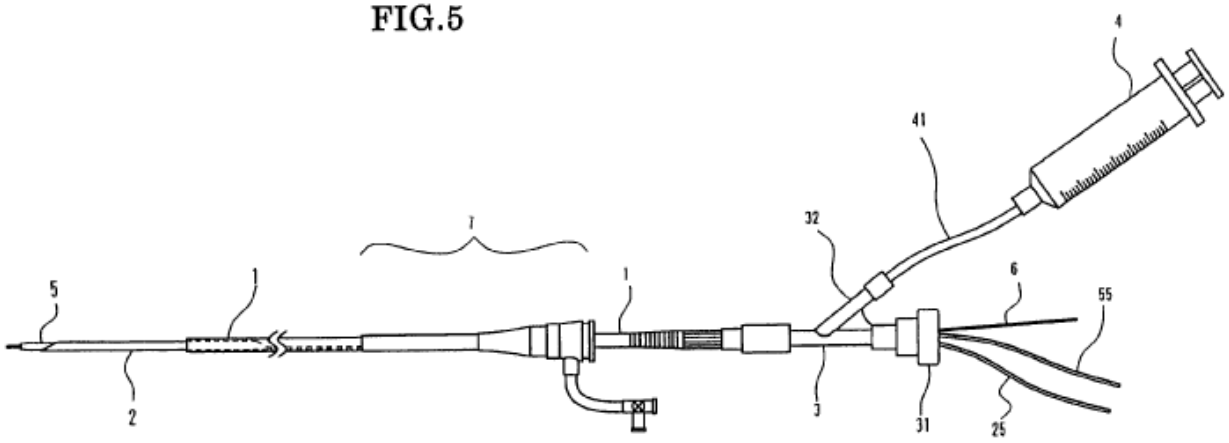

Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted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

A portion of Figure 6 of Itou is reproduced below:

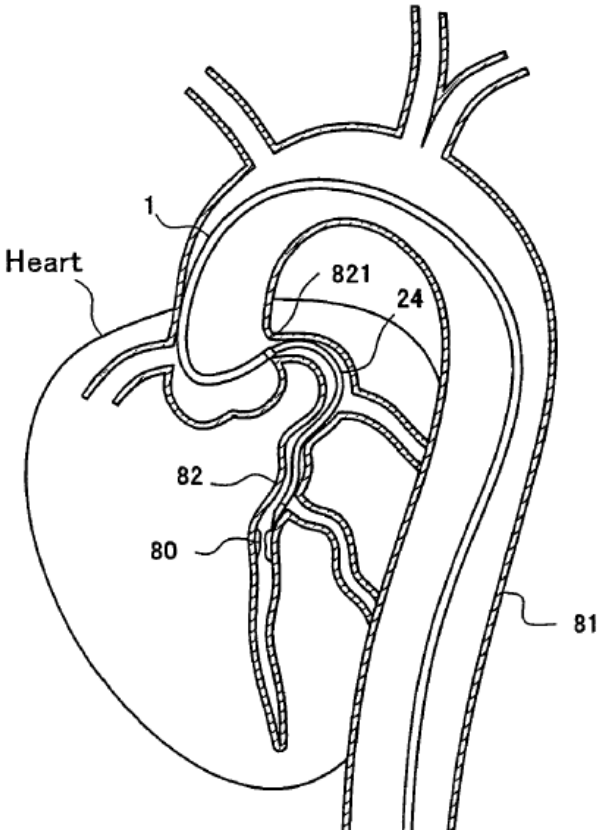

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24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

4. Independent Claims 1 and 12

Petitioner contends Itou discloses every limitation of independent claim 1, including (1) a system for use with interventional cardiology devices (protective catheter 5 and guidewire 6), that is adapted to be inserted into a branch artery (Pet. 22 (citing Ex. 1007, 5:35–38, 43–46, 7:1–23, 7:35–42, Figs. 5, 6, 8; Ex. 1005 ¶¶ 160–166));[7] (2) a guide catheter (guiding catheter 1) that has a continuous lumen extending from its proximal end at a hemostative valve (the valve built into main connector 31) to a distal end adapted to be placed in the branch artery (*id.* at 22–25 (citing Ex. 1007, 1:66–2:5, 3:29–37, 5:11–23, 5:32–34, 5:65–67, 7:7–10, Figs. 1A, 5, 6; Ex. 1005 ¶ 167)); (3) a continuous lumen of the guide catheter that has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen (*id.* at 25–27 (citing Ex. 1007, 3:59–63, 4:43–52, 4:61–63, Fig. 5, Table 1;

[7] We need not determine at this time whether the preamble of claim 1 is limiting because Petitioner shows sufficiently for purposes of institution that the recitation in the preamble is disclosed in Itou.

Ex. 1005 ¶ 168)); (4) a device (suction catheter 2) that is adapted for use with guiding catheter 1 (*id.* at 27 (citing Ex. 1007, 2:5–11, 2:27–38, 5:12–17, 5:26–42, 7:7–23, Figs. 1A, 1B, 5, 6; Ex. 1005 ¶¶ 161–162)); (5) the device having a flexible tip portion defining a tubular structure (tip 22 and tubular portion 21) and having a circular cross-section and length that is shorter than the predefined length of the continuous lumen of the guide catheter, and a tubular structure that has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defines a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable (*id.* at 27–29 (citing Ex. 1007, 1:60–65, 2:12–26, 4:48–52, 7:1–23, Figs. 3, 5, Table 1; Ex. 1005 ¶ 170)); (6) a substantially rigid portion (solid wire-like portion 25) that is proximal of and operably connected to the flexible tip portion and, when combined with the length of flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter such that when the flexible tip portion is extended beyond the distal end at least a portion of the substantially rigid portion extends through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter (*id.* at 29–36 (citing, *inter alia*, Ex. 1007, Fig. 3 (depicting flexible tip 21, 22 operably connected to rigid wire-like portion 25), Fig. 5 (depicting distal portion of flexible tip 21, 22 extending beyond the distal end of guiding catheter 1 and depicting a portion of wire-like portion 25 extending beyond the valve in main connector 31)); and (7) a distal tip portion (tip 22) that is more flexible than a cylindrical distal reinforced portion of the tubular structure (tubular portion 21) (*id.* at

36–38 (citing Ex. 1007, Fig. 3; Ex. 1005 ¶¶ 174–177, 185; Ex. 1042 ¶¶ 21–24, 50, 53–58, 63)).

Petitioner also contends that Itou discloses every limitation of independent claim 12, citing to essentially the same disclosures of Itou set forth above. *Id.* at 52–59.

Patent Owner contends independent claims 1 and 12 are not anticipated by Itou because Petitioner has failed to demonstrate that the tubular structure of Itou has an inner diameter "through which interventional cardiology devices are insertable." Prelim. Resp. 33–39. According to Patent Owner, this claim phrase requires that *all* "interventional cardiology devices" identified in the '380 patent are insertable through the inner diameter of the tubular portion of a device, including "at least balloon catheters, stents, and stent catheters." *Id.* at 33–34 (emphases omitted).

Petitioner demonstrates that the tubular portion of Itou's device has an inner diameter through which both guide wire 6 and protective catheter 5 may be inserted. Pet. 26 (providing the inner diameters of suction catheter 2), 29 (citing Ex. 1007, Fig. 5). Patent Owner does not dispute this evidence, but contends a "protective catheter" and "guide wire" are not "balloon catheters, stents, and stent catheters." Prelim. Resp. 34–35. We do not find this argument persuasive because we do not construe the disputed claim phrase to require that all "interventional cardiology devices" be insertable through the lumen of a particular device.

Moreover, the '380 patent indicates that 8 French, 7 French, and 6 French guide catheters are "commonly used in interventional cardiology procedures." Ex. 1001, 3:28–31. For "a 5 French in 6 French" coaxial guide catheter, which appears to be the smallest diameter combination

identified in the ’380 patent, the ’380 patent explains that the internal diameter of the coaxial guide catheter should be “greater than or equal to 0.056 inches.” *Id.* at 3:36–43. Petitioner presents evidence that in at least one embodiment of Itou the inner diameter of suction catheter 2 is 1.5 mm, or 0.059 inches. Pet. 26 (citing Ex. 1007, Table 1). This further supports Petitioner’s argument that the disputed claim limitation is disclosed in Itou.

Upon review of the parties’ arguments and supporting evidence, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1 and 12 are anticipated by Itou.

5. Dependent Claims 2–4, 6–10, 13–20 and 23

Petitioner also contends that Itou anticipates claims 2–4, 6–10, 13–20 and 23 of the ’380 patent. Pet. 38–51, 59–65. In support of these arguments, Petitioner provides a detailed analysis of Itou and supporting testimony from Dr. Hillstead identifying where each limitation of these claims is disclosed in Itou. *Id.* (citing *generally* Ex. 1042).

Patent Owner does not address Petitioner’s specific arguments with respect to claims 2–4, 6–10, 13–20 and 23.

Upon review of Petitioner’s arguments and Dr. Hillstead’s supporting testimony, we determine that Petitioner has demonstrated a reasonable likelihood that claims 2–4, 6–10, 13–20 and 23 are anticipated by Itou.

C. Claims 3, 14, and 15 over Itou and Ressemann

To the extent not anticipated by Itou, Petitioner contends the subject matter of claims 3, 14, and 15 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. 65–76.

Patent Owner does not directly address Petitioner's arguments with respect to claims 3, 14, and 15.

Having determined that Petitioner presents sufficient evidence that Itou discloses every limitation of claims 3, 14, and 15, we need not address Petitioner's obviousness arguments based on the combination of Itou and Ressemann.

D. Claim 21 over Itou and Berg

Claim 21 depends indirectly from claim 12 and further requires that "the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI." Ex. 1001, 13:29–33. Petitioner contends the subject matter of claim 21 would have been obvious over the combined disclosures of Itou and Berg, when considered in light of the knowledge of one of ordinary skill in the art. Pet. 76–80.

1. Berg

Berg discloses a "guiding catheter for use in coronary angioplasty and other cardiovascular interventions." Ex. 1051, Abstract. In particular, Berg discloses a guide catheter "having a transition zone with a different flexibility than adjacent portions of the catheter shaft for improved catheter performance." *Id.* at 1:21–25.

Berg notes that in order for a physician to place a catheter at the correct location in a blood vessel, the physician must apply longitudinal and rotational forces. *Id.* at 1:49–51. Thus, the catheter must be rigid enough to push through the blood vessel and torsionally rigid enough to transmit the applied torque, but flexible enough to navigate the bends in the blood vessel.

Id. at 1:49–56. Berg also notes that "it is preferable to have a soft tip or flexible section engage the ostium," thereby providing a less traumatic section to the blood vessel. *Id.* at 1:63–2:4. A problem that occurs, however, is that more flexible tips may increase the incidence of guide catheter back-out, when the guide disengages from its preferred positioning in the coronary ostium. *Id.* at 2:11–15.

Berg overcomes the deficiencies of the prior art "by providing a transition element in the material," which "allows for flexibility of a guiding catheter to be increased, while maintaining its ability to prevent catheter back-out." *Id.* at 2:35–39. Figure 19 of Berg is reproduced below:

Fig.19

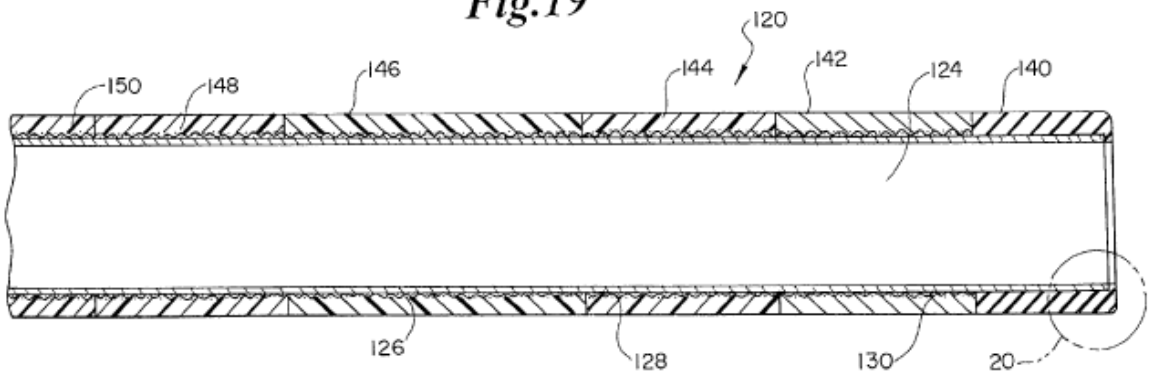

Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a plurality of discrete outer tubular member segments 140, 142, 144, 146, 148, and 150. *Id.* at 13:53–55. Soft tip zone 140 has a flexural modulus of "about 1 to about 15 Kpsi"; distal section zone outer tubular segment 142 has a flexural modulus of "between about 2 and about 49 Kpsi"; transition zone outer tubular segment 144 has a flexural modulus of "between about 13 and about 49 Kpsi"; secondary curve zone outer tubular segment 146 has a flexural modulus of "greater than 49 Kpsi"; mid-shaft zone outer tubular

segment 148 has a flexural modulus of "about 29 to about 67 Kpsi"; and proximal shaft zone outer tubular segment 150 has a flexural modulus of "greater than 49 Kpsi to provide maximum stiffness for push and control." *Id.* at 13:66–15:6.

2. Analysis

Petitioner contends that Berg discloses using a guide catheter having varying degrees of stiffness and that the flexural modulus for the first, second, and third portions of Berg's catheter overlap the ranges recited in claim 21. Pet. 78–79. Petitioner further contends that one of ordinary skill in the art would have used the flexural modulus disclosed in Berg for the catheter of Itou "because Itou explicitly teaches that suction catheter (2) was designed to reach 'deep location[s] in a coronary artery" and because Berg teaches that an increasingly rigid catheter is desirable to navigate vasculature. *Id.* at 79.

Patent Owner contends that 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. 40–51. 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).

Patent Owner contends that a presumption of nexus applies in this case because its "GuideLiner" product "embodies challenged claims and is coextensive with them." Prelim. Resp. 41, 43. 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 41–42 (citing Ex. 2056 ¶¶ 160–163, 166, 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 '380 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"). Indeed, that Patent Owner sought patent protection for each of these five patents suggests that these patents do not generally cover the same

invention.[8] *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. 41–42. But, as noted above, Patent Owner asserts that 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.

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.

3. Conclusion

Upon review of the parties' arguments and evidence, we determine that Petitioner has demonstrated sufficiently that Itou and Berg teach or suggest every limitation of claim 21, and that Petitioner explains sufficiently why one of ordinary skill in the art would have combined the disclosures of these references. Accordingly, Petitioner has demonstrated a reasonable likelihood that the subject matter of claim 21 would have been obvious over the combined disclosures of Itou and Berg.

[8] 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.

E. § 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 litigated in parallel district court cases. Prelim. Resp. 25–30. In particular, Patent Owner contends that the validity of at least some of the challenged claims of the '380 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 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 '380 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 QXMedical 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 *after* our statutory deadline for a final written decision in this proceeding and the related IPRs. Prelim. Resp. 13; 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*, IPR2018-00752, Paper 8 at 19 (noting trial date of March 25, 2019, where Board's institution decision was issued September 12, 2019); *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 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. 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 exercising 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.

F. 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. 51 (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 51–52 (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 '380 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 '380 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.

FOR PETITIONER:

Cyrus Morton
cmorton@robinskaplan.com

Sharon Roberg-Perez
sroberg-perez@robinskaplan.com

Christopher Pinahs
cpinahs@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
dvandenburgh@carlsoncaspers.com

Dennis Bremer
dbremer@carlsoncaspers.com