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.

IPR2020-00126
Patent 8,048,032 B2

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

PAULRAJ, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

On November 12, 2019, Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–20 and 22 of U.S. Patent No. 8,048,032 ("the '032 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response. Papers 8 (confidential version), 9 (redacted version) ("Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply addressing Petitioner's burden on those issues. Paper 12 ("1st Reply"); Paper 14 ("1st Sur-Reply"). Also pursuant to our authorization, Petitioner filed another Reply and Patent Owner filed another Sur-Reply addressing the factors for discretionary denial under 35 U.S.C. § 314(a). Paper 19 ("2nd Reply"); Paper 20 ("2nd Sur-Reply").

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. §42.4(a) (2019). We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the arguments and evidence of record, we institute *inter partes* review of claims 1–20 and 22 of the '032 patent.

B. Real Parties-in-Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc., as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S. À.R.L., Vascular Solutions

LLC, Arrow International, Inc., and Teleflex LLC and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2.

C. Related Matters

Patent Owner is asserting the '032 patent against Petitioner in the United States District Court for the District of Minnesota in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 ("*Medtronic*"). Pet. 5; Paper 4, 2. The '032 patent is also the subject of a declaratory judgement action filed by another party, *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 ("*QXM*"), which has been currently stayed pending our institution decision. Paper 19; Paper 20. The '032 patent was also previously the subject of litigation in the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and the subject of previous *inter partes* reviews in IPR2014-00760 and IPR2014-00761 filed by Boston Scientific Corp., which terminated based on settlement. Pet. 5.

Petitioner has also filed another petition challenging the'032 patent based on different prior art. IPR2020-00127.[1] In addition, Petitioner has filed concurrent petitions challenging related reissue patents: RE45,830 (IPR2020-00128; IPR2020-00129; IPR2020-00130; IPR2020-00131), RE 45,760 (IPR2020-00132; IPR2020-00133; IPR2020-00134), RE45,776

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

(IPR2020-00135; IPR2020-00136), and RE47,379 (IPR2020-00137; IPR2020-00138).

D. The '032 Patent

The '032 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on November 1, 2011, from a non-provisional application filed May 3, 2006. Ex. 1001, codes (45), (54), (22).

The '032 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1001, Abstract. According to the '032 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:15–17. In coronary artery disease, the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions in a phenomenon known as stenosis. *Id.* at 1:20–26. In treating the stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery, sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:30–36. However, crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated, which can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease. *Id.* at 1:36–40.

To solve this problem, the '032 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 2:53–56. The '032 patent teaches that the coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the

coronary artery, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 2:57–61. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '032 patent:

Fig. 1

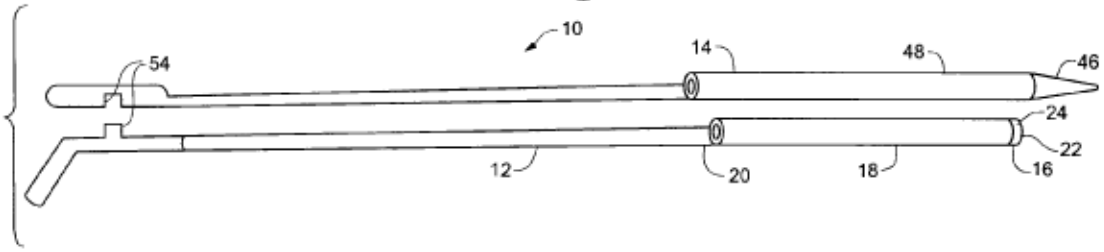

Fig. 2

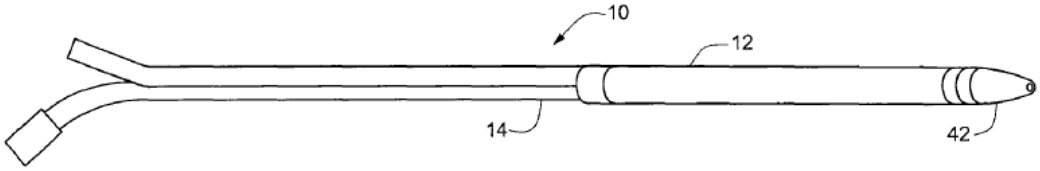

Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:15–21; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:6–8. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:9–10. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:13–14. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:14–15. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:19–20. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:59–60. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:60–61. Tapered inner catheter 14 may also include

clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 6:64–67.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:12–13. The coaxial guide catheter/ tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta, and advanced until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. *Id.* at 4:15–23. The tapered inner catheter may be removed once the coaxial guide catheter tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating. *Id.* at 4:23–26. Once the tapered inner catheter is removed, a cardiac treatment device, such as a guidewire, balloon, or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. *Id.* at 4:30–33. The presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter/guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion. *Id.* at 4:33–39.

E. Illustrative Claim

Among the challenged claims, independent claim 1 is representative and reproduced below:

> 1. A device for use with a standard guide catheter, the standard 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 a 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 lumen to the branch artery, the device comprising:

a flexible tip portion defining a tubular structure 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 and 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.

Ex. 1001, 10:21–54 (cl. 1).

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–20 and 22 would have been unpatentable based on the following grounds. Pet. 7.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–19, 22	102	Itou[2]

[2] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
3, 13, 14	103(a)	Itou, Ressemann,[3] and the knowledge of POSITA
20	103(a)	Itou, Berg,[4] and the knowledge of POSITA

Petitioner relies upon the Declarations of Dr. Stephen Brecker (Ex. 1005) and Dr. Richard Hillstead (Ex. 1042) in support of its Petition.

II. ANALYSIS

A. Priority Date of the '032 Patent

Petitioner argues that "[t]he '032 patent is subject to the AIA's first-to-file provisions because it contains at least one claim that lacks a written description, and therefore, pre-AIA priority." Pet. 14. Petitioner advances this argument to preclude Patent Owner from swearing behind the Itou reference based on a showing of prior invention, which could otherwise be done for a pre-AIA "first-to-invent" application. *Id.* We are not persuaded by Petitioner's argument.

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 effective filing date is "the actual filing date of the patent or the application for the patent containing a claim to the invention; or the filing date of the earliest application for which the patent or application is entitled." 35 U.S.C. § 100(i)(1). In the present case, the '032 patent issued from an application filed May 3, 2006, and does not claim the benefit of any other filing date. Ex. 1001, code (22). Thus, the only possible effective filing date

[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").

of the '032 patent is May 3, 2006, which thus qualifies it as a pre-AIA patent.[5]

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternatives for a person having ordinary skill in the art. First, Petitioner asserts that "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 14. Alternatively, Petitioner asserts that "if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* at 14–15. Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* at 15.

Patent Owner indicates that "[f]or purposes of this Preliminary Response only, Teleflex does not currently dispute Medtronic's proposed definition of a POSITA." Prelim. Resp. 16.

On this record, in determining whether the evidence of record supports institution, we apply both of Petitioner's definitions for a POSITA, as they are undisputed at this time and consistent with the level of skill

[5] Petitioner's priority date argument appear to be a back door attempt to have us address whether the '032 patent satisfies the written description requirement of 35 U.S.C. § 112. But this is a question we may not address in an IPR. *See* 35 U.S.C. § 311(b).

reflected in the prior art and the specification of the '032 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b)(2019). This standard requires that we construe claims "in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for the claim terms a "standard guide catheter," "placed in a branch artery," and "flexural modulus." Pet. 15–19. Patent Owner responds to Petitioner's proposed constructions by asserting that "no specific construction of these terms (or any other terms) is necessary for the Board to deny the Petition." Prelim. Resp. 19–20. Patent Owner also asserts that the '032 patent provides an express definition for the claim term "interventional cardiology devices." *Id.* at 16–19. In particular, Patent Owner contends that the recitation of a lumen "through which interventional cardiology devices are insertable" in claims 1 and 11 should be construed to require that "all four enumerated devices (guidewires, balloon catheters, stents, and stent catheters) be insertable into the lumen." *Id.* at 17.

At this stage of the proceeding, we determine that it is only necessary to construe the term "interventional cardiology devices" to resolve the disputed issues for purposes of this institution decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding

that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy").

Independent claims 1 and 11 of the '032 patent recite a standard guide catheter having a continuous lumen sized "such that interventional cardiology devices are insertable into and through the lumen." Ex. 1001, 10:26–27, 11:34–35. 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 1:17–21.

Petitioner contends that, in the *QXM* litigation, 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. 15–16 (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* litigation. Ex. 1013 (Claim Construction Order).

Patent Owner contends that "interventional cardiology devices," as used in independent claims 1 and 11,

> 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, 2:53–64. 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 3:5–20. 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 5:9–12. 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 11, 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. 1001,7:36–40 ("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 . . . ."); *Id.* at 7:42–8:7; Figs. 7–8.

Furthermore, 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 7:36–40, 7:42–8:7, 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 5:9–12) and that the term "interventional cardiology devices" is not limited to guidewires, balloon catheters, stents and stent catheters (*id.* at 1:17–21). 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.

D. Ground 1: Anticipation of Claims 1–19 and 22 by Itou

Petitioner asserts that claims 1–19 and 22 are anticipated by Itou. Pet. 19. We focus our analysis on independent claim 1 for purposes of this decision. Before we turn to the merits of Petitioner's anticipation challenge, however, we first address Patent Owner's arguments regarding the prior art status of Itou.

1. 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. 19–20.

Patent Owner argues that Itou does not qualify as prior art based on an earlier invention date for the claimed invention of the '032 patent. Prelim. Resp. 21–24. In particular, Patent Owner contends that conception of the claimed invention occurred in "late 2004," and reduction to practice occurred "in the spring and summer of 2005." *Id.* at 22. As support for this contention, Patent Owner relies upon the declarations of inventor Howard

Root (Ex. 2001) and Deborah Schmalz (a former Vice President of Regulatory Affairs at Patent Owner's predecessor-in-interest) (Ex. 2039), along with certain notebook pages and other documents (Exs. 2002–2022, 2024) allegedly showing prior conception and reduction to practice. Patent Owner further contends that, despite having much of the evidence related to conception and reduction to practice, Petitioner does not address it in the Petition. *Id.* at 24.

The burden to show that Itou is prior art to the '032 patent rests with Petitioner. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). That said, because Petitioner has presented evidence that Itou was filed prior to the filing date of the '032 patent, thus qualifying as § 102(e) prior art, 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. Although Patent Owner's presents multiple pieces of evidence in the Preliminary Response in support of this contention, Petitioner has not had an opportunity to fully consider and address this evidence in this proceeding.[6]

[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

Based on the present record, we determine that genuine issues of material fact remain about the alleged invention date, and these factual issues are best resolved after the record is more fully developed. *See* 37 C.F.R. § 42.108(c) (stating "a genuine issue of material fact created by [Patent Owner's] testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review").

2. Overview of 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:

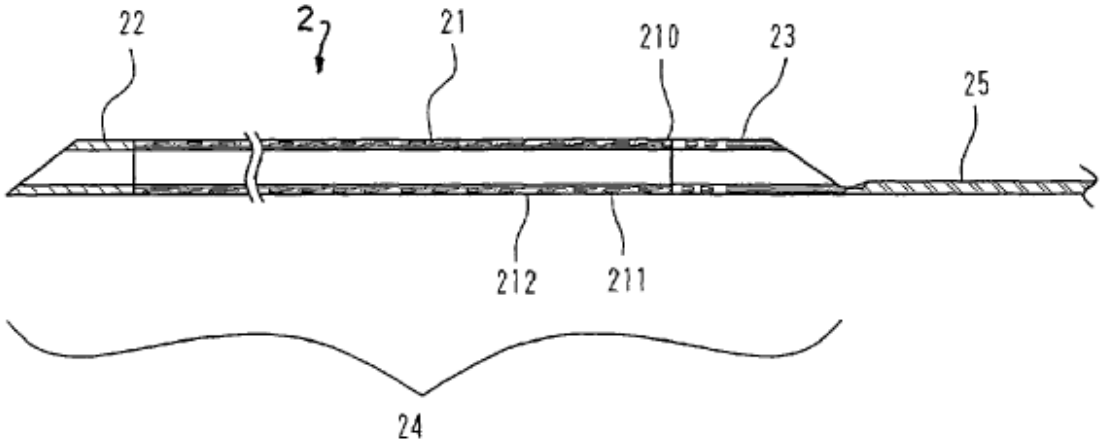

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an

determine Petitioner did not have an obligation to preemptively address Patent Owner's evidence in its Petition.

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

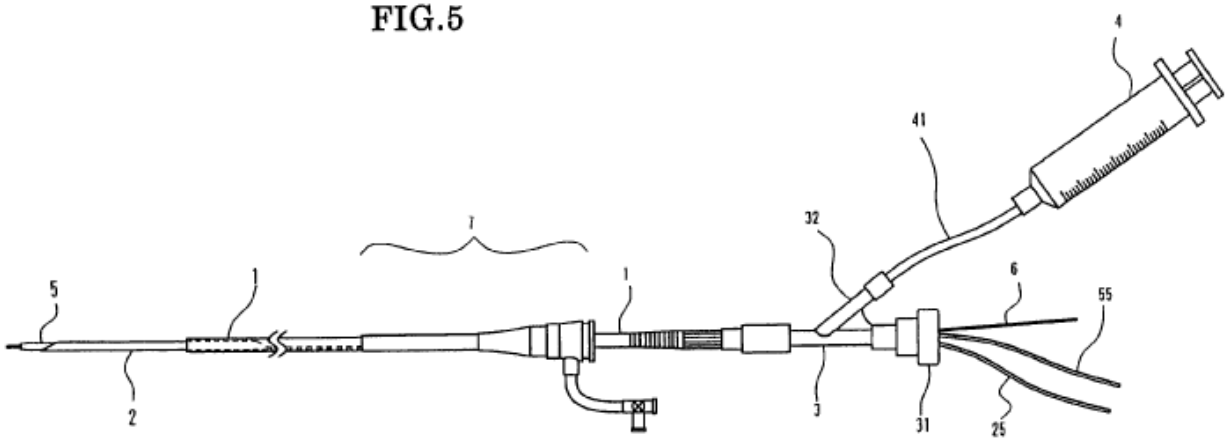

Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted 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:

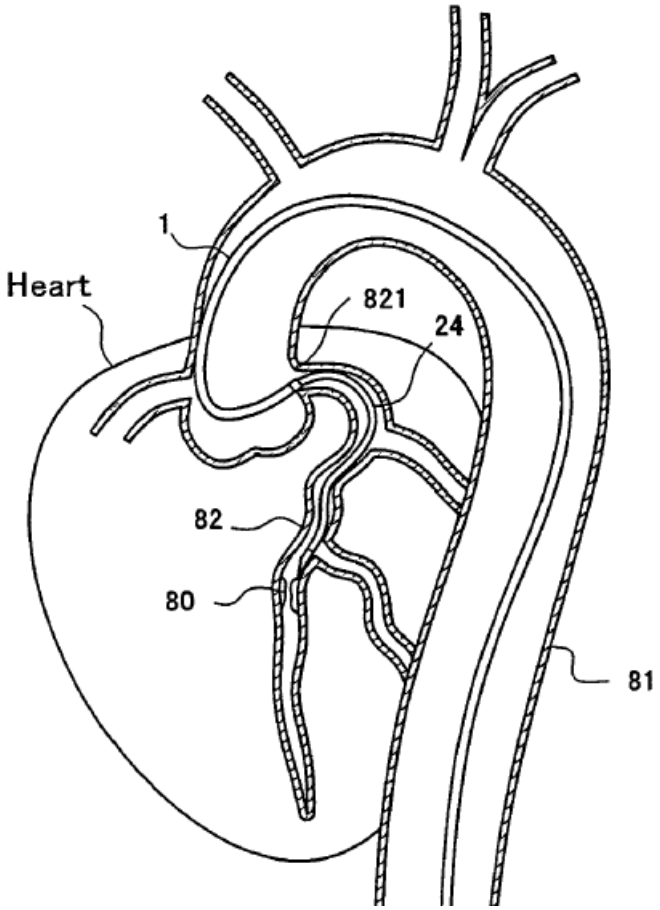

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24 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.

3. Independent Claim 1

Petitioner contends that Itou teaches each of the limitations of independent claim 1.

With respect to the requirement for "[a] device for use with a standard guide catheter," Petitioner contends that Itou teaches this limitation by "disclos[ing] a combination of guiding catheter 1 and suction catheter 2 (i.e. 'a device') and further disclos[ing] the system's use in delivering a protective catheter 5 and a guidewire 6 to the location of a coronary artery occlusion." Pet. 22 (citing Ex-1007, 5:35–38, 5:43–46, 7:1–23, 7:35–43, Figs. 5–6, 8).[7]

Petitioner further contends that the guiding catheter 1 taught by Itou satisfies the requirements for "the standard 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 a branch artery," and "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 lumen to the branch artery." *Id.* at 22–26. Petitioner points out that Itou teaches that guiding catheter 1 "preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation," with an inner diameter of 1.8 mm, and that protective catheter 5 and guidewire 6 are sized to be to be insertable into and through the lumen of the guiding catheter. *Id.* at 24–26.

With respect to the claim element reciting:

[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.

> a flexible tip portion defining a tubular structure 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[,]

Petitioner points to Itou's tubular portion 21 and tip 22 as satisfying the foregoing requirements for a "flexible tip portion." *Id.* at 26–28.

With respect to the claim element reciting:

> 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 and 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[,]

Petitioner points to the wire-like portion 25 of Itou's suction catheter 2, either fused to the proximal portion of an obliquely cut metal pipe 231 ("Mapping-1") or on its own ("Mapping-2"), as satisfying the foregoing requirements for a "substantially rigid portion." *Id.* at 28–35.

Based on the evidence and arguments of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least claim 1 of the '032 patent. We have considered, but are not persuaded by Patent Owner's arguments.

Patent Owner contends that the challenged claims 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. 30–36. According to Patent Owner, this claim phrase requires that *all* "interventional cardiology devices" identified in the '032 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 31–32.

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. 25–26 (providing the inner diameters of suction catheter 2) (citing Ex. 1007, Table 1, 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. 32. 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 '032 patent indicates that 8 French, 7 French, and 6 French guide catheters are "commonly used in interventional cardiology procedures." Ex. 1001, 3:5–8. For "a 5 French in 6 French" coaxial guide catheter, which appears to be the smallest diameter combination identified in the '032 patent, the '032 patent explains that the internal diameter of the coaxial guide catheter should be "greater than or equal to 0.056 inches." *Id.* at 3:14–20. 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. 25 (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 claim 1 is anticipated by Itou. Having determined that Petitioner meets the threshold for review of claim 1 based on anticipation by Itou, we institute a review as to all of the challenged claims and grounds contained in the Petition. Patent Owner does not present any separate arguments with respect to the prior art cited by Petitioner for the additional challenged claims or grounds presented in the Petition.

4. Claims 2–19 and 22

Petitioner also contends that Itou anticipates claims 2–19 and 22 of the '032 patent. Pet. 33–65. 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).

Upon review of Petitioner's arguments and Dr. Hillstead's supporting testimony, we determine that Petitioner has demonstrated a reasonable likelihood that claims 2–19 and 22 are anticipated by Itou.

E. Claims 3, 14, and 14 over Itou and Ressemann

To the extent not anticipated by Itou, Petitioner contends the subject matter of claims 3, 13, and 14 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.

Having determined that Petitioner presents sufficient evidence that Itou discloses every limitation of claims 3, 13, and 14, we need not address Petitioner's obviousness arguments based on the combination of Itou and Ressemann.

F. Claims 20 over Itou and Berg

Claim 20 depends indirectly from claim 11 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 20 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. 76–79.

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:

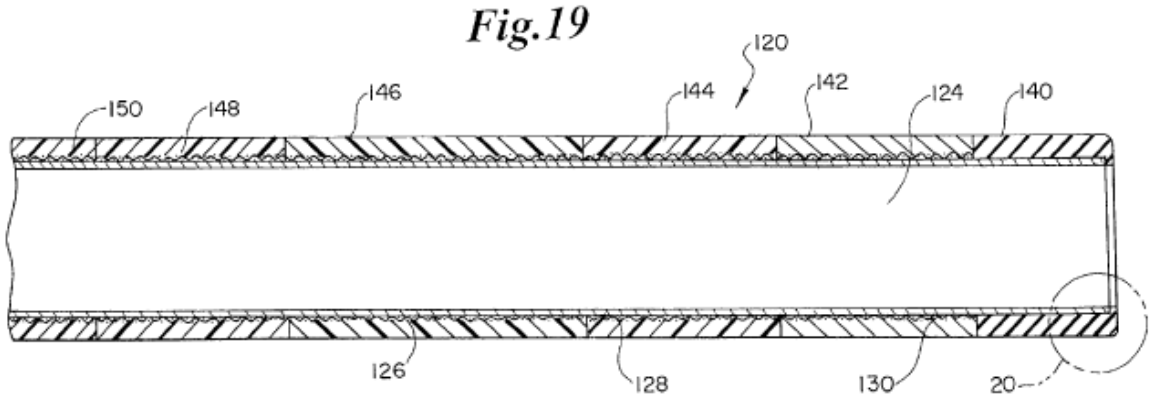

Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a plurality of discrete outer tubular member segments 140, 142, 144, 146, 148, and 150. *Id.* at 13:53–55. Soft tip zone 140 has a flexural modulus 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. 37–48. 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. 40. 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 38–39 (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 '032 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 separately sought patent protection for each of these six patents suggests that these patents do not generally cover the same invention. *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. 40–41. 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 20, 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 20 would have been obvious over the combined disclosures of Itou and Berg.

G. Discretionary Denial § 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 '032 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 (PTAB Mar. 20, 2020) (precedential, designated May 5, 2020) ("*Fintiv*"), the Board set forth several other factors (the "*Fintiv* 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 '032 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 *after* our statutory deadline for a final written decision in this proceeding and the related IPRs. PO 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 will not likely take place until after we issue our final written decisions in these proceedings. Notably, in both the *NHK* and *Fintiv* cases, the trial dates in the parallel litigations were scheduled only a few months after the Board's institution deadlines and before the final written decision deadlines. *See NHK*, IPR2018-00752, Paper 8 at 19 (noting trial date of March 25, 2019, where

Board's institution decision was issued September 12, 2018); *Fintiv*, IPR2020-00019, Paper 11 at 1 (noting trial date of November 16, 2020 where Board's institution decision was due May 15, 2020).

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 in the *Medtronic* case. *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.

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"). Petitioner contends that Patent Owner has only asserted a subset of the challenged claims in the *Medtronic* litigation. Paper 19, 1. 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 Petitioner is the defendant in the *Medtronic* case. *Id.* We find there is an overlap of issues and parties between the *Medtronic* case and this proceeding. In *Fintiv*, the Board noted that "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Fintiv*, Paper 11 at 13. In this case, however, 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, as discussed above, 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. 48 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019). Patent Owner further argues that the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338-39). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

III. CONCLUSION

Considering the information presented in the Petition and the evidence of the record, we determine that Petitioner has shown a reasonable likelihood that it will prevail in showing that at least one of the challenged claims of the '032 patent is unpatentable. Thus, we institute *inter partes* review of all challenged claims based on all of the grounds set forth in the Petition. Our findings and conclusions are not final and may change after considering the full record developed during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1–20 and 22 of the '032 patent based on the unpatentability challenges presented in the Petition.

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