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Paper 22
Date: June 8, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

IPR2020-00132
Patent RE45,760 E

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

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 25–42, 44, and 47 of U.S. Patent No. RE45,760 E ("the '760 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Medical Devices S.A.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; Paper 14. 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).

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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) (2012). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) ("*SAS*"). 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, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted.

A. Real Parties in Interest

Petitioner identifies its real parties-in-interest as Medtronic, Inc. and Medtronic Vascular, Inc., and notes that "Medtronic plc is the ultimate

parent of both entities." Pet. 5. Patent Owner identifies its real parties-in-interest as Teleflex Medical Devices S.A.R.L.; Vascular Solutions LLC; Arrow International, Inc.; and Teleflex LLC. Paper 4, 2. Patent Owner also notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." *Id.*

B. Related Matters

Petitioner has filed two separate Petitions for *inter partes* review of the '760 patent as IPR2020-00133 and IPR2020-00134. The '760 patent is at issue in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 (D. Minn. filed July 2, 2019) ("*Medtronic*") and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("*QXM*"). Pet. 5–6; Paper 4, 2. The '760 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent). The '850 patent was the subject of two previous *inter partes* reviews: IPR2014-00762, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate, and IPR2014-00763, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate. Pet. 6; Paper 4, 2–3. The '850 patent was also at issue in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013). *Id.*

Petitioner has filed Petitions for *inter partes* review of related U.S. patents as follows: U.S. Patent No. 8,048,032 ("the '032 patent") in IPR2020-0126, IPR2020-0127; U.S. Patent No. RE45,380 ("the '380 patent") in IPR2020-00128, IPR2020-00129, IPR2020-00130, and IPR2020-00131; U.S. Patent No. RE45,776 ("the '776 patent") in IPR2020-00135 and

IPR2020-00136; and U.S. Patent No. RE47,379 ("the '379 patent") in IPR2020-00137 and IPR2020-00138.[1]

C. The '760 Patent

1. Specification

The subject matter claimed in the '760 patent is directed to a device for use with a standard guide catheter. Ex. 1001, 13:36–17:13. Figures 1 and 5 of the '760 patent, reproduced below, depict a coaxial guide catheter and a tapered inner catheter.

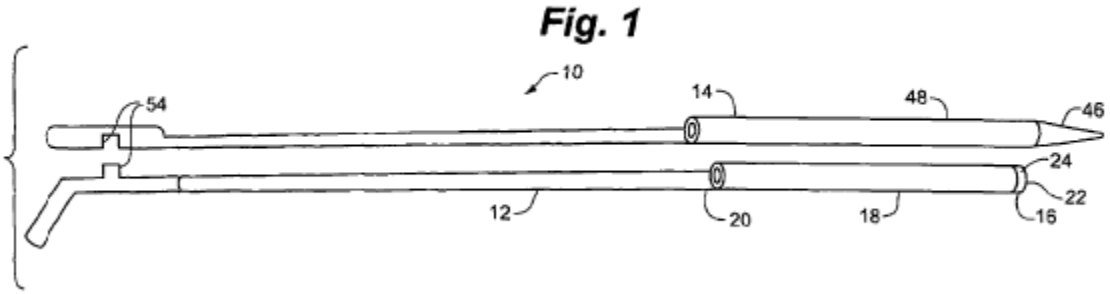

Figure 1 of the '760 patent

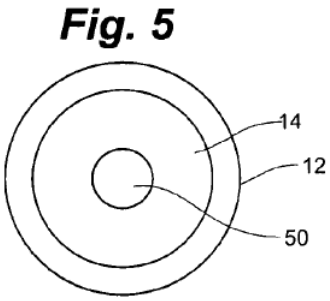

Figure 5 of the '760 patent

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

As shown in Figures 1 and 5, above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 generally includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:40–41. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:44–45. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:45–46. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:49–50. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:22–23. Both tapered portion 46 and straight portion 48 are pierced by lumen 50. *Id.* at 7:23–24. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:27–29. Thus, tapered inner catheter 14 is keyed to coaxial guide catheter 12. *Id.* at 7:29–30.

2. Illustrative Claim

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

25. A system, comprising:

> a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and
>
> a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable

through the hemostatic valve at the proximal end of the guide catheter,

the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending/or a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured *to receive one or more stents or balloon catheters* when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein a material forming the segment defining the side opening is more rigid than the tubular structure.

Ex. 1001, 13:36–14:7.

3. Relevant Prosecution History

The ’760 patent issued from U.S. Application Serial No. 14/195,385 (“the ’385 application,” Ex. 1003). The ’760 patent is a reissue of U.S. Pat. No. 8,292,850 (“the ’850 patent) (Ex. 1002).

D. Evidence

Petitioner relies upon the following prior art references.

Ex. 1007, T. Itou et al., U.S. Patent No. 7,736,355 B2 (issued June 15, 2010) (“Itou”).

Ex. 1008, T. V. Ressemann et al., U.S. Patent No. 7,604,612 B2 (issued Oct. 20, 2009) (“Ressemann”).

Ex. 1025, Y. Kataishi et al., U.S. Patent Application Publication No. 2005/0015073 A1 (published Jan. 20, 2005) ("Kataishi").

Ex. 1050, C. D. Enger et al., U.S. Patent No. 5,980,486 (issued Nov. 9, 1999) ("Enger").

Petitioner also relies upon the Declarations of Dr. Stephen Brecker (Ex. 1005) and Richard A. Hillstead (Ex. 1042) to support its contentions.

Petitioner also relies upon the Declarations of Peter T. Keith to support its contentions. Ex. 2042.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 25–42, 44, and 47 would have been unpatentable on the following grounds.

Ground	Claim(s)	35 U.S.C. §[2]	References/Basis
1	25–31, 33–38, 41, 42, 44, 47	102(e)	Itou
2	25, 30, 32, 39, 40	103(a)	Itou, Ressemann, Knowledge of a POSITA
3	32	103(a)	Itou, Kataishi, Knowledge of a POSITA
4	32	103(a)	Itou, Enger, Knowledge of a POSITA

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '760 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

The person having ordinary skill in the art is a hypothetical person who is presumed to be aware of all the relevant prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Kimberly-Clarke Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984). Moreover, the prior art itself is generally sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

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. 15. 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.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* Petitioner further asserts that "a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a one with an engineering degree might

have access to one with a medical degree" (citing Ex. 1005 ¶ 31; Ex. 1042 ¶¶ 18–19).

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

For the purposes of this decision, we apply Petitioner's definition of the level of ordinary skill in the art because it is undisputed at this time and consistent with the evidence of the record. *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).

The above definition is provisional and the parties are welcome to present further argument on this topic at trial.

B. 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). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for several claim terms, including the terms "concave track" and "flexural modulus." Pet. 15–19. Patent Owner responds to Petitioner's proposed constructions by asserting that "no specific construction of claim terms is necessary for the Board to deny the Petition in view of the deficiencies [Patent Owner] identifies in this Preliminary Response." Prelim. Resp. 16.

At this stage of the proceeding, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *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").

C. Prior Art Status of Itou (Ex. 1007)

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. 24–27. 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 24. 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. 2005–2022, 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.[3] 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.").

[3] 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. 24. 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.

D. Petitioner's Patentability Challenges

1. Ground 1: Anticipation by Itou

Petitioner asserts that claims 25–31, 33–38, 41, 42, 44, and 47 are anticipated by Itou. Pet. 19. For the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood that claim 25–31, 33–38, 41, 42, 44, and 47 are anticipated by Itou.

a) Summary 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:

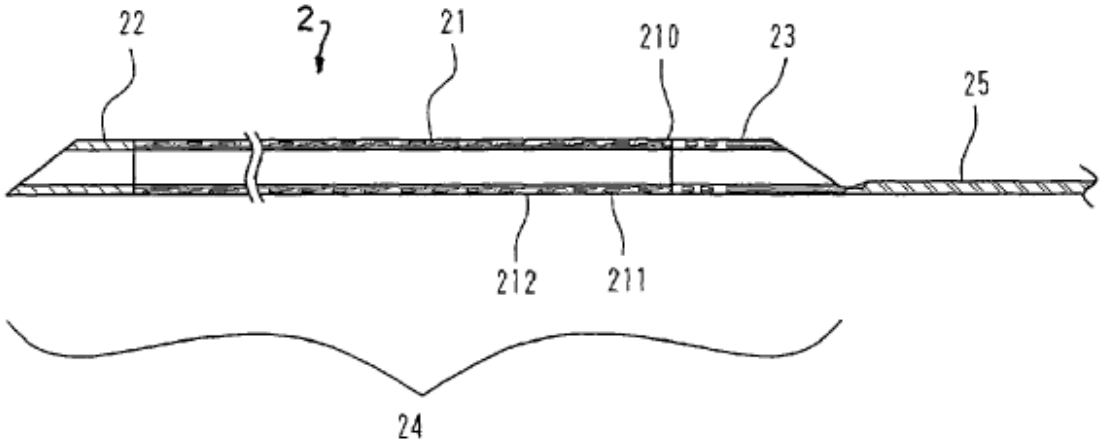

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion 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

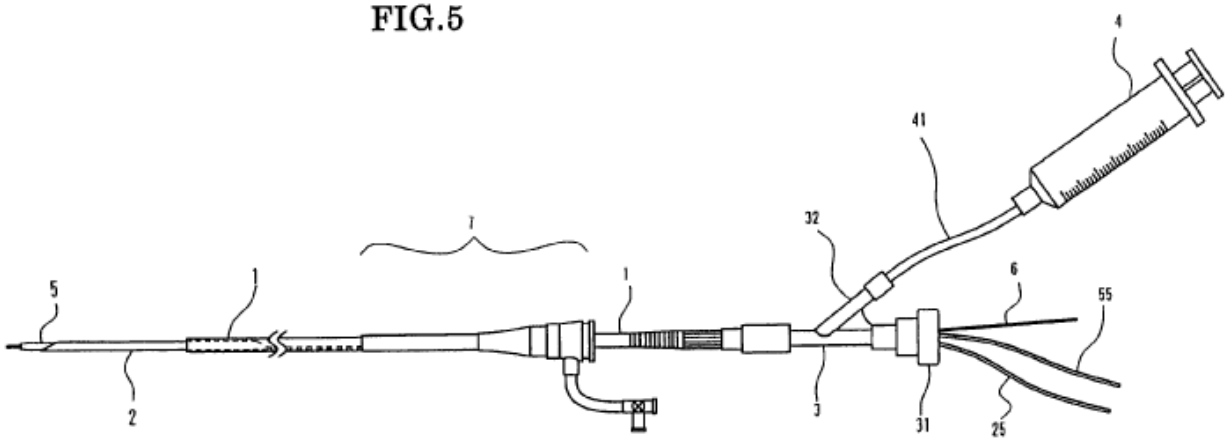

Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted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

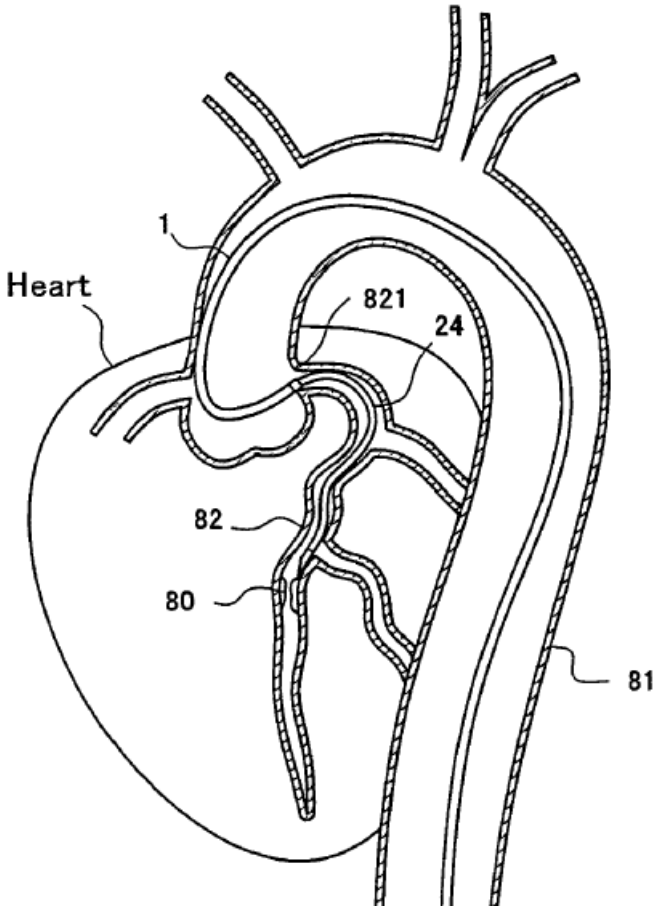

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24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

b) Discussion

(1) Independent claim 25

Petitioner contends that Itou teaches each of the limitations of independent claim 25. To support its position, Petitioner directs our attention to the foregoing discourses of Itou and provides a detailed claim analysis addressing how each element of claim 25 is disclosed by Itou. Pet. 21–38 (citing Ex. 1005 ¶¶ 167–187). With respect to the requirement for a "guide extension catheter" including a "tubular structure" where "the side opening and the lumen of the tubular structure [are] configured to receive one or more stents or balloon catheters," Petitioner relies on the disclosure of Itou's suction catheter 2. *Id.* at 27–38 (citing Ex. 1005 ¶ 170); Ex. 1007, 2:12–15, 3:47–50, Fig. 1B, Fig. 3. Additionally, Petitioner contends that Itou describes a "distal end protective catheter" that is insertable through the suction catheter 2, which may be extended beyond the distal end of the guide catheter and into a coronary artery. Pet. 21 (citing Ex. 1007, Abstract, 2:29–38; Figs 5, 6; Ex. 1005 ¶¶ 95–98, 146–149; Ex. 1042 ¶¶ 20–27).

Patent Owner contends that Itou does not expressly or inherently disclose a "guide extension catheter" including a "tubular structure" where "the side opening and the lumen of the tubular structure [are] configured to receive one or more stents or balloon catheters" when the side opening and proximal end of the tubular structure are within the guide catheter and the distal end of the guide extension catheter extends beyond the guide catheter. Prelim. Resp. 35. In particular, Patent Owner contends that Itou does not expressly disclose "that its suction catheter can be used as a guide extension catheter, or that its suction catheter has a side opening and lumen configured

to receive one or more stents or balloon catheters (which happens in a proximal-to-distal direction)." *Id.* at 35–36. Patent Owner also contends that Petition has not established that "Itou's suction catheter is a guide extension catheter or has a side opening and lumen inherently (i.e. necessarily) configured to receive one or more stents or balloon catheters." *Id.* at 36 (citing Ex. 2042 ¶¶ 45, 48).

Patent Owner further contends that

> [the] Petition focuses solely on Itou's suction catheter diameter. Petition at 35–36. But that alone does not show that Itou's suction catheter is a guide extension catheter or has a side opening and lumen inherently (i.e. necessarily) configured to receive one or more stents or balloon catheters. *Id.* at 36 (citing Ex. 2042 ¶¶ 45, 48). . . . [The Petition] fails to show that the specific suction catheter structure of Itou would necessarily allow introduction of stents or balloon catheters. For example, Itou explains that its proximal tip 23 is formed by coating the inner and outer faces of metal body 231/232 with a "resin." Ex. 1007 at 4:27–38; Ex. 2042, ¶ 40. . . . This "resin" is used both to bond the proximal tip 23 to the middle body portion 21 by "fusion" and to form the inner surface of the proximal end of the tube 24 of the suction catheter. Ex. 1007 at 4:36-38; Ex. 2042, ¶ 40. Itou does not disclose any lubricious coating on the interior of its proximal or distal tips. The layer of a material such as PTFE with a "sliding property" provided for the middle "body portion 21" of Itou's suction catheter ends abruptly where the proximal tip 23 is joined. Ex. 1007 at 3:51-54, Fig. 3; Ex. 2042, ¶¶ 32, 42.

Id. at 36–39. Patent Owner further contends that "it was known that heat-'fused' resins could be sticky or tacky rather than lubricious." *Id.* at 39 (citing Ex. 2042 ¶ 40). Thus, according to Patent Owner, Petitioner has failed to establish that the disclosed resin "would necessarily work for proximal introduction of stents or balloon catheters." *Id.* at 39–40 (citing Ex. 2042 ¶¶ 40–41; Ex. 2055, 2).

Additionally, Patent Owner contends that Petitioner's reliance on Itou's protective catheter is misplaced because

> [a] protective catheter is not a stent or balloon catheter—they are different devices, with different structure, that serve different purposes, and are used differently. Protective catheters, for example, are inserted into the suction catheter outside the body. E.g., Ex. 1007 at 7:1–15 (explaining that a guide catheter is first put in place, and then a "combination" of the suction catheter and protective catheter is inserted into the guide catheter). . . . Further[more], unlike smooth protective catheters, balloon-expandable stents and balloon catheters have irregular exterior surfaces (caused by the struts of the stent and the folds of the balloon). Ex. 2042, ¶ 47. Thus, stents and balloon catheters are far more likely than a protective catheter to be impeded by non-lubricious surfaces and hung-up on protrusions, particularly when inserted into a reduced-diameter opening within a guide catheter.

Id. at 41–42. Thus, according to Patent Owner, a person of ordinary skill in the art would not expect to be able to insert stents or balloon catheters into the proximal opening of a suction catheter like Itou when the opening is located inside a guide catheter. *Id.* at 42–43; Ex. 1008, 25:23–29; Ex. 2042 ¶¶ 49–53.

Having considered the parties positions and evidence of record, summarized above, we determine that Petitioner has offered sufficient evidence to institute trial. We have considered Patent Owner's argument and evidence in support of its position that Itou does not expressly or inherently disclose a "guide extension catheter" including a "tubular structure" where "the side opening and the lumen of the tubular structure [are] configured to receive one or more stents or balloon catheters," summarized above. However, for purposes of deciding whether to institute an *inter partes* review, we view a genuine issue of material fact in the light

most favorable to the petitioner. In this case, Petitioner and Drs. Brecker and Hillstead provide a reasoned analysis as to why those elements are disclosed by Itou and Patent Owner and Dr. Keith's counter testimony create a genuine issue of fact. 37 C.F.R. § 42.108(c). Thus, for purposes of this Decision, we resolve the parties' dispute in favor of Petitioner. That being said, we will evaluate both parties' arguments once the record is developed further during trial.

Having determined that Petitioner meets the threshold for review of claim 25 based on anticipation by Itou, we institute a review as to all of the challenged claims and grounds contained in the Petition.

(2) Dependent Claims 26–31, 33–38, 41, 42, 44, and 47

Petitioner also identifies where Itou discloses the limitations of dependent claims 26–42, 44, and 47 of the '760 patent. Pet. 40–48, 54–60. In support of these arguments, Petitioner directs our attention to the foregoing discourses of Itou and provides a detailed claim analysis addressing how each element of claim 25 is disclosed by Itou. Pet. 38–56.

Patent Owner does not address Petitioner's specific arguments with respect to dependent claims 26–42, 44, and 47.

Having considered the parties positions and evidence of record, we determine that Petitioner has identified sufficiently where Itou discloses every limitation of dependent claims 26–42, 44, and 47. Thus, Petitioner has demonstrated a reasonable likelihood that these claims are anticipated by Itou.

(3) Conclusion

Having considered the parties positions and evidence of record, summarized above, we determine that Petitioner has established a reasonable

likelihood of prevailing in demonstrating the unpatentability of claims 25–31, 33–38, 41, 42, and 44 with respect to Ground 1.

2. Ground 2: Obviousness in view of Itou, Ressemann, and the knowledge of POSITA

To the extent not anticipated by Itou, Petitioner contends the subject matter of claims 25, 30, 32, 39, and 40 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. 56–73.

a) Summary of the Ressemann

Ressemann is directed to an apparatus "used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels." Ex. 1208, 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

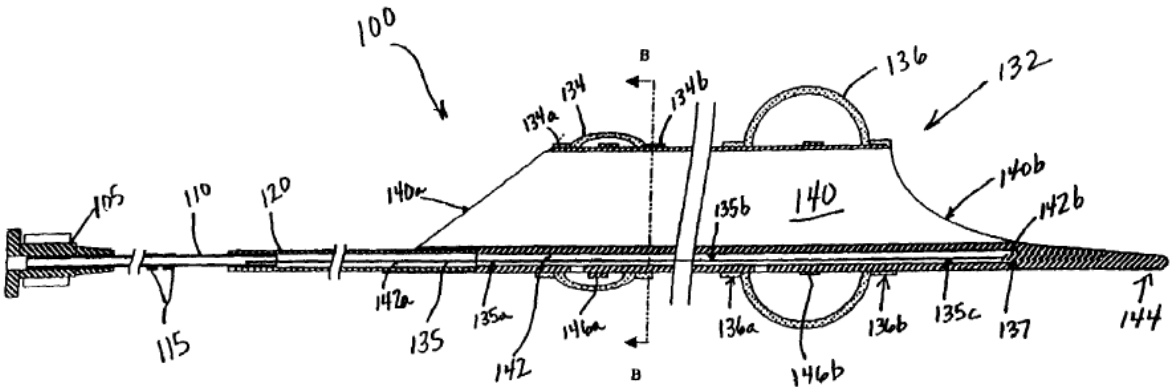

FIG. 1A

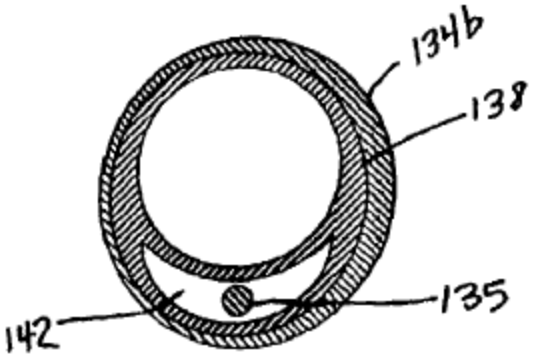

FIG. 1B

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

Figure 1A depicts evacuation sheath assembly 100, which "is sized to fit inside a guide catheter" and be advanced "into a blood vessel to treat a stenosis." *Id.* at 6:18–24, Fig. 5A. Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. Evacuation head 132 includes multi-lumen tube 138 having evacuation lumen 140 and inflation lumen 142 and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and "is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters." *Id.* at 6:44–47. Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, "[t]he larger area of

the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly." *Id.* at 6:58–60.

Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, "is located co-axially in the inflation lumen 142," and extends to soft tip 144. *Id.* at 11:30–39. Inflation lumen 142, having open proximal end 142a and closed distal end 142b, is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64.

In use, a guiding catheter is directed to a blood vessel and then a coronary guide wire is advanced to a location just proximal to the distal tip of the guiding catheter. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

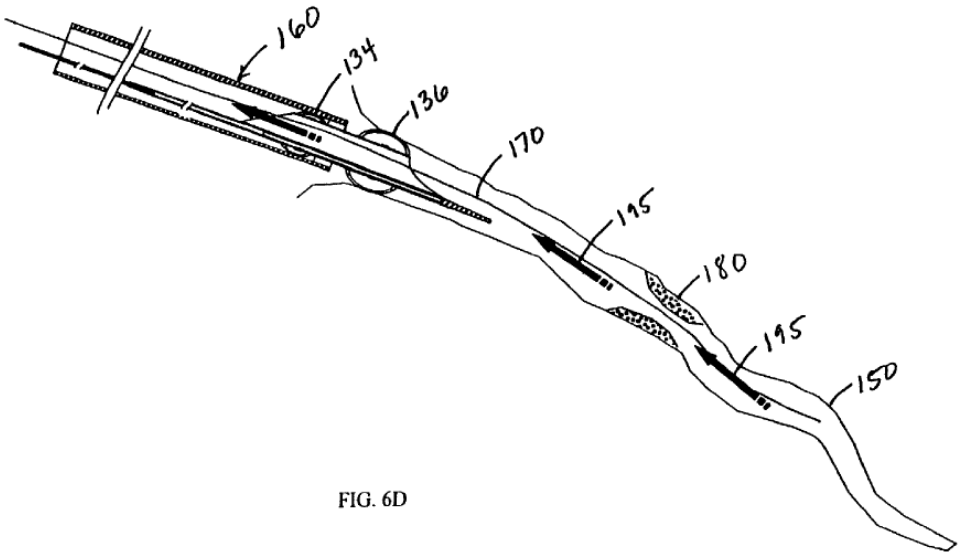

FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. Guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, "[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber." *Id.* at 13:43–44.

b) Discussion

Petitioner asserts that claims 25, 30, 32, 39 and 40 are unpatentable under 35 U.S.C. § 103(a) as obvious over Itou, Ressemann, and the knowledge of POSITA. Pet. 56–73. Petitioner provides a detailed claim analysis for claims 25, 30, 32, 39 and 40. *Id.*

Patent Owner contends that

> The Petition's obviousness arguments improperly focus exclusively on interior lumen diameter, while failing to explain why a POSITA would have been motivated to make the combination with a reasonable expectation of success and failing to address teaching away evidence regarding potential hang-up issues.

Prelim. Resp. 44.

Having determined that Petitioner presents sufficient evidence that Itou discloses every limitation of claims 25–42, 44, and 47, we need not address Petitioner's obviousness arguments based on the combination of Itou and Ressemann.

3. Ground 3: Obviousness in view of Itou, Kataishi, and the knowledge of POSITA

Petitioner asserts that claim 32 would have been obvious over the combination of Itou, Kataishi and the common knowledge of a person of ordinary skill in the art.

a) Summary of Kataishi

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

Figure 2 of Kataishi is reproduced below:

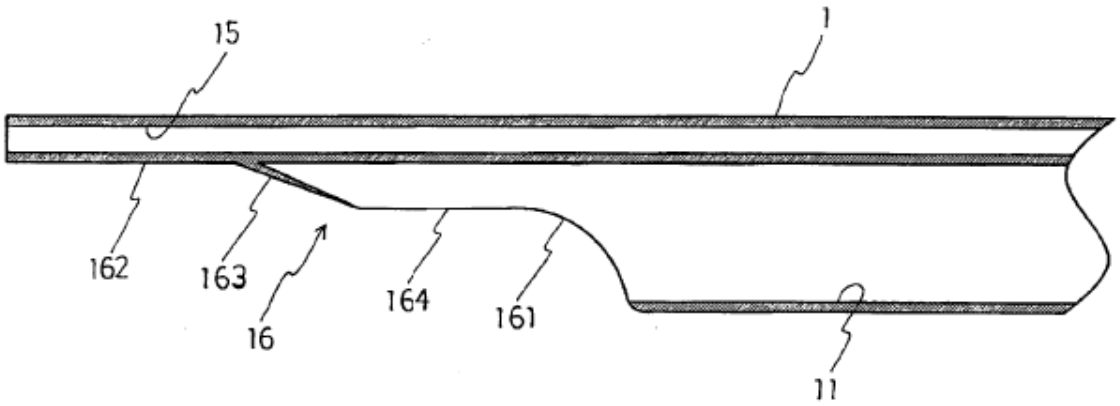

Fig. 2

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

end of ledge surface 164 and also angled with respect to the longitudinal surface. *Id.*

Figure 10 of Kataishi is reproduced below:

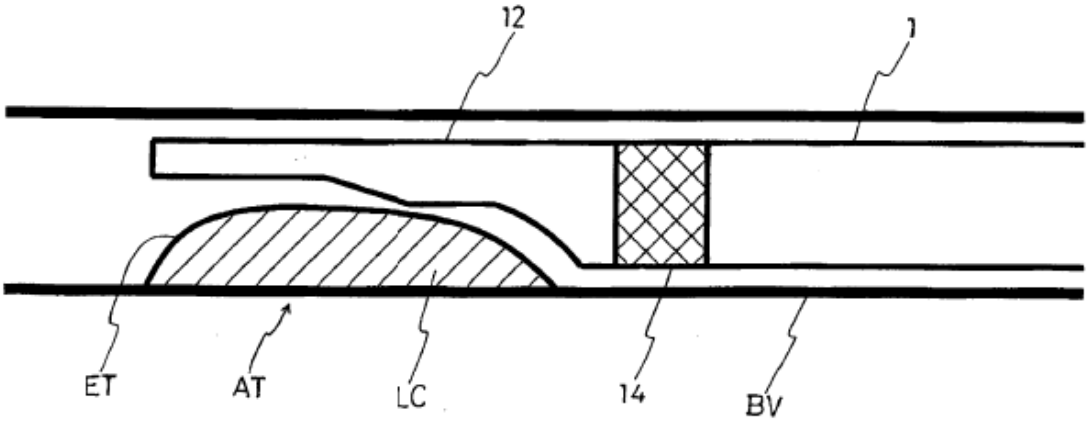

Fig. 10

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

b) Discussion

Petitioner asserts that claim 32 is unpatentable under 35 U.S.C. § 103(a) as obvious over Itou, Kataishi, and the knowledge of POSITA. Pet. 73–78. To support that assertion, Petitioner directs our attention to the foregoing discourses of Kataishi and provides a detailed claim analysis addressing how each element of claim 32 is disclosed by the combination of

Itou and Kataishi. Pet. 73–78. Petitioner contends that a person of ordinary skill in the art would have "had the motivation to modify the proximal opening of the tubular structure of Itou's suction catheter (2) so that it was configured to include two different inclined slopes, as disclosed in Kataishi." *Id.* at 77. Additionally, Petitioner contends that a person of ordinary skill in the art would have "had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because a POSITA would understand it was configured to receive a stent and balloon catheter" and that "by modifying the proximal opening of Itou's suction catheter with the teaching of Kataishi, a larger area for receiving a stent and balloon catheter would be achieved." *Id.* (citing Ex. 1042 ¶¶ 108–109; Ex. 1005 ¶¶ 287–289).

Patent Owner does not address Petitioner's arguments directed to the combination of Itou and Kataishi in its Preliminary Response specific to this proceeding. Prelim. Resp. 64.[4]

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

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

4. Ground 4: Obviousness in view of Itou, Enger, and the knowledge of POSITA

Petitioner asserts that claim 32 would have been obvious over the combination of Itou, Enger and the common knowledge of a person of ordinary skill in the art.

a) Summary of Enger

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

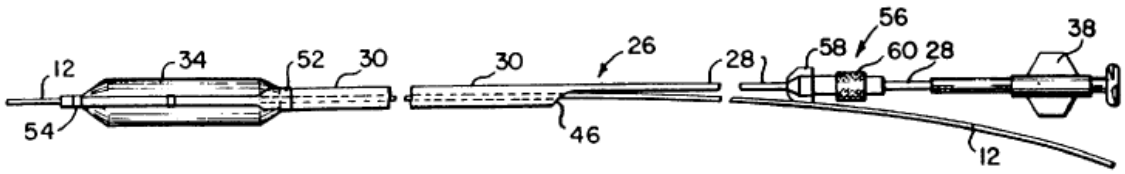

Fig. 1

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

Figure 7 of Enger is reproduced below:

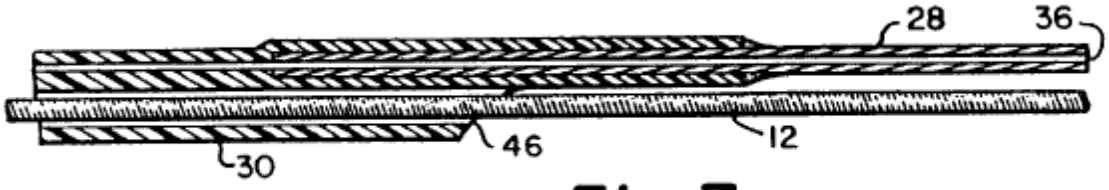

Fig. 7

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

b) Discussion

Petitioner asserts that claim 32 is unpatentable under 35 U.S.C. § 103(a) as obvious over Itou, Enger, and the knowledge of POSITA. Pet. 79–83. To support that assertion, Petitioner directs our attention to the foregoing discourses of Enger and provides a detailed claim analysis addressing how each element of claim 32 is disclosed by the combination of Itou and Enger. Pet. 73–83. With reference of Fig. 7 of Enger, shown above, Petitioner contends that a person of ordinary skill in the art would have been "motivated to provide a first incline to function as an 'on-ramp' to guide interventional devices such as distal end protective device or stent and balloon catheter (5) into the lumen of Itou's suction catheter (2)." *Id.* at 82–83 (citing Ex. 1005 ¶¶ 291–296).

Patent Owner does not address Petitioner's arguments directed to the combination of Itou and Enger in its Preliminary Response specific to this proceeding. Prelim. Resp. 64.[5]

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

5. Secondary Considerations

Patent Owner contends Petitioner's obviousness ground 2 fails because Petitioner did not address known objective evidence of nonobviousness, including evidence of commercial success, industry praise, licensing by competitors, copying, and long-felt need. Prelim. Resp. 53–64. Patent Owner contends a presumption of nexus applies in this case because its "GuideLiner" product "embodies challenged claims and is coextensive with them." Prelim. Resp. 56.

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

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

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). The question of nexus, however, is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Id.* at 944 F.3d 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.

III. 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. 27–32. In particular, Patent Owner contends that the validity of at least some of the challenged claims of the '760 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 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 '760 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. 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 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 of 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.

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 sub-set of the challenged claims in the district court litigation. Paper 19, 2. 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.* 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 are 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. Indeed, the overlap may actually favor institution here since the Board's earlier determination on the common patentability issues will either be dispositive at to the litigated issues, or at least provide sufficient guidance for the district court's resolution of similar issues. 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.

IV. 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. 64 (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.

V. CONCLUSION

On the present record, we find Petitioner shows sufficiently that the cited references would have taught or suggested each element of claims 25–42, 44, and 47, and set forth a sufficient rationale for why a person of ordinary skill would have been motivated to combine these teachings and suggestions to arrive at the invention recited in those claims. Accordingly,

Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 25–42, 44, and 47 would have been anticipated or obvious over the combinations of prior art set forth in the asserted grounds.

In this Decision, we address all issues raised by the parties in the pre-trial briefing. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), that an *inter partes* review of claims 25–42, 44, and 47 of the '760 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '760 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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