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.

IPR2020-00135
Patent RE45,776 E

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. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 25–27, 29–33, 35–39, 41–49, and 52–56 of U.S. Patent No. RE45,776 ("the '776 patent," Ex. 1001). Paper 1 ("Pet."). Vascular Solutions, Inc. ("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 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 25–27, 29–33, 35–39, 41–49, and 52–56 of the '776 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 '776 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 '776 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. Petitioner further notes that the '776 patent is a reissue of U.S. Patent No. 8,292,850, which was the subject of a prior district court action and *inter partes* reviews in IPR2014-00762 and IPR2014-00763 filed by a different petitioner. Pet. 5.

Petitioner has also filed another petition challenging the '776 patent based on different prior art. IPR2020-00136.[1] In addition, Petitioner has filed concurrent petitions challenging other related patents: U.S. Patent No. 8,048,032 (IPR2020-00126; IPR2020-00127), RE45,830 (IPR2020-00128; IPR2020-00129; IPR2020-00130; IPR2020-00131), RE 45,760 (IPR2020-00132; IPR2020-00133; IPR2020-00134), and RE47,379 (IPR2020-00137; IPR2020-00138).

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

D. The '776 Patent

The '776 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on October 27, 2015, as a re-issue of U.S. Patent No. 8, 292,850 which itself issued from a non-provisional application filed January 26, 2012. Ex. 1001, codes (45), (64).

The '776 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 '776 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:45–47. 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 1:50–55. 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 1:59–65. 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 1:65–67.

To solve this problem, the '776 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 3:15–18. The '776 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 3:24–27. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '776 patent:

Fig. 1

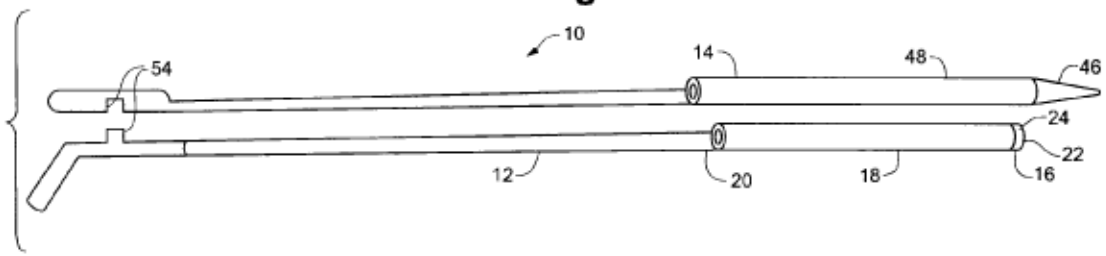


Fig. 2

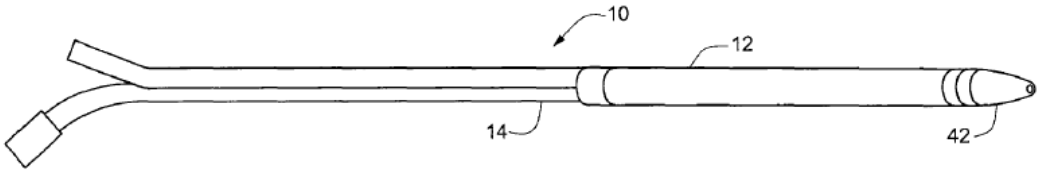


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:47–52; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 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 (not labeled in figures above). *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.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:43–44. 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 4:47–54. 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 4:54–57. 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 4:61–64. 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 4:64–5:3.

E. Illustrative Claims

Among the challenged claims, independent claim 25 is representative and reproduced below:

> 25. A guide extension catheter for use with a guide catheter, comprising:
>
> a substantially rigid segment;
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and

> a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,
>
> wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

Ex. 1001, 13:35–52 (cl. 25).

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 25–27, 29–33, 35–39, 41–49, and 52–56 would have been unpatentable based on the following grounds. Pet. 7.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
25–27, 29–33, 35–37, 41–45, 47–49	102	Itou
39, 46	103(a)	Itou and the knowledge of POSITA
36, 37, 52–56	103(a)	Itou, Kataishi, and the knowledge of POSITA
32, 36–38, 46, 52–56	103(a)	Itou, Ressemann, and the knowledge of POSITA
52–56	103(a)	Itou, Enger, and the knowledge of POSITA

Petitioner relies upon the expert declarations of Dr. Stephen Brecker (Ex. 1005) and Dr. Richard Hillstead (Ex. 1042) in support of its Petition. Patent Owner relies upon the expert declaration of Peter Keith (Ex. 2042) in support of its Preliminary Response.

II. ANALYSIS

A. Priority Date for the '776 Patent

Petitioner argues that "[t]he '776 patent is subject to the AIA's first-to-file provisions because (1) it contains claims that lack written description,

and therefore pre-AIA priority, and (2) it claims priority to RE45,380 ("the '380 patent"), which is subject to the AIA first-to-file provisions." Pet. 12. 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 effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2). As the "patent for which reissue was sought" in this case was issued October 23, 2012, we are not persuaded that AIA's first-to-file provisions apply to the '776 patent. Indeed, Petitioner provides no statutory or case law support for the proposition that a reissue patent may lose the filing date of the original patent for which reissue was sought.[2]

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. 13. Alternatively, Petitioner

[2] Petitioner's priority date argument appear to be a back door attempt to have us address whether the '776 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).

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.*

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. 18.

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 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 "concave track" and "flexural modulus." Pet. 15–16. 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. 18.

At this stage of the proceeding, we do not perceive a need to construe any claim terms of the '776 patent for purposes of determining whether to institute trial. *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.").

D. Ground 1: Anticipation by Itou

Petitioner asserts that claims 25–27, 29–33, 35–37, 39, 41–43, 45, and 47–49 are anticipated by Itou. Pet. 7. We focus our analysis on independent claim 25 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. 16.

Patent Owner argues that Itou does not qualify as prior art based on an earlier invention date for the claimed invention of the '776 patent. Prelim. Resp. 26–29. 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 26. 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 26–27.

The burden to show that Itou is prior art to the '776 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 '776 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

[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. 27–28. 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.

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 (Ex. 1007)

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:

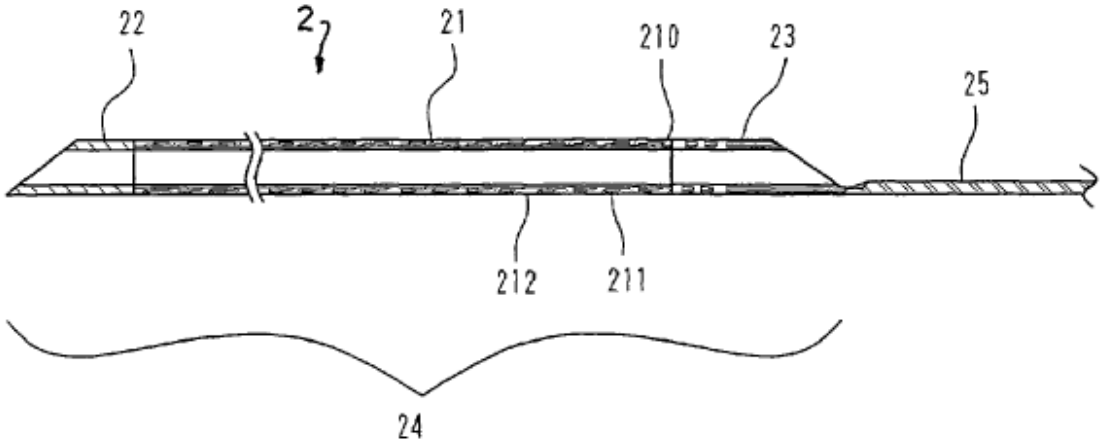


Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion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

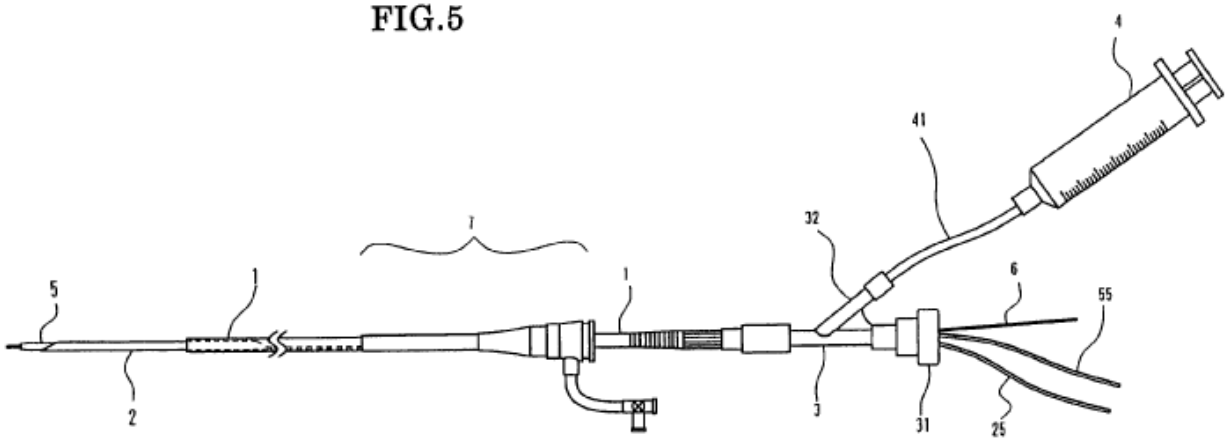


Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted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

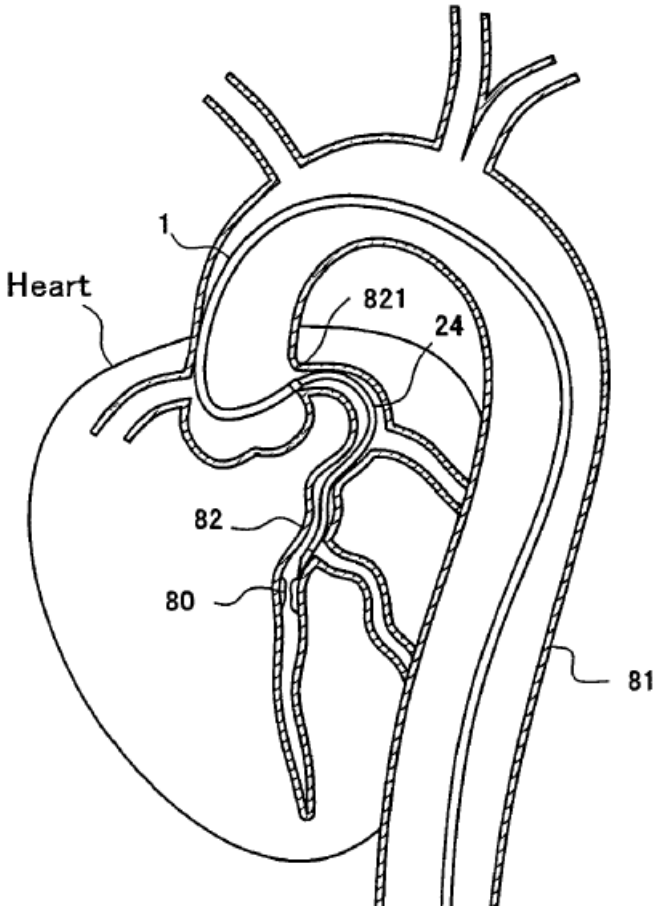


Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24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

3. Independent Claim 25

Petitioner contends that Itou teaches each of the limitations of independent claim 25 as follows:

With respect to the requirement for "[a] guide extension catheter for use with a guide catheter,"[4] Petitioner contends that, to the extent the preamble is limiting, Itou discloses this requirement by its combination of a guiding catheter 1 and suction catheter 2. Pet. 18–19 (citing Ex. 1007, 1:66–2:11, 7:1–23, 7:35–43, Abstract, Figs. 1B, 5–6, 8; Ex. 1005 ¶¶ 153–155).

With respect to the requirement for "a substantially rigid segment." Petitioner contends that Itou's wire-like portion 25 is a "substantially rigid" segment because it is used to advance suction catheter 2 through guiding catheter 1. *Id.* at 19–20 (citing Ex. 1007, 2:32–36, 5:35–46, Abstract, Figs. 5–6; Ex. 1005 ¶ 156).

With respect to the requirement for "a tubular structure defining a lumen and positioned distal to the substantially rigid segment," Petitioner identifies Itou's tubular body portion 21. *Id.* at 20 (citing Ex. 1007, Abstract, 3:47–58, 4:48–52, 5:14–15, Figs. 1B, 3, 4; Ex. 1005 ¶ 157).

With respect to the requirement for "the segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure," Petitioner contends that a partially cylindrical opening is positioned between a distal end of the wire-like portion 25 and a proximal end of the tubular structure 21. *Id.* at 21–22 (citing Ex-1007, Fig. 4, 3:47–48, 4:10–11, 4:27–30; Ex. 1005 ¶ 158).

[4] We need not determine at this time whether the preamble of claim 25 is limiting because Petitioner shows sufficiently for purposes of institution that the recitation in the preamble is disclosed in Itou.

With respect to the requirement for the "segment defining the partially cylindrical opening having an angled proximal end," Petitioner contends that Itou discloses that the opening is "inclined obliquely" and "formed by obliquely cutting one end of a metal pipe." *Id.* at 22 (citing Ex. 1007, 4:10–11, 4:27–32, Figs. 3–4; Ex. 1005 ¶ 159).

With respect to the requirement that the segment is "formed from a material more rigid than a material or material combination forming the tubular structure," Petitioner contends that Itou satisfies this requirement by disclosing that the partially cylindrical opening is "formed by obliquely cutting one end of a metal pipe" that is encased in resin layers, whereas the tubular structure 21 has "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211[.]" *Id*. at 22 (citing Ex. 1007, 3:45–58, 4:27–30 ("end 231"), 4:36–38, Figs. 3–4; Ex. 1005 ¶ 160; Ex. 1042 ¶¶ 66–73).

With respect to the requirement that the segment is "configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter," Petitioner contends that Itou discloses this requirement by teaching that suction catheter 2 is long enough so while its distal end is advanced to a target location—distal to the distal end of the guiding catheter 1—its proximal end remains in the guiding catheter. *Id.* at 24–25 (citing Ex-1007, 4:48–50, 5:15, 5:35-42, 6:30-35, Figs. 5-6; Ex-1005, ¶ 161). Petitioner also argues that the "configured to" language recites an intended use, to which no patentable weight should be given. *Id.* (citing *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

Finally, with respect to the requirement "wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure

defines a single lumen," Petitioner contends that Itou disclosed only a single lumen for the suction catheter 2, thereby satisfying this requirement. *Id.* at 25 (citing Ex. 1007, 4:48–50, 5:15, Fig. 3; Ex. 1005 ¶ 162).

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 25 of the '776 patent. We have considered, but are not persuaded by Patent Owner's arguments.

Patent Owner argues that Petitioner has not shown that Itou expressly or inherently discloses the limitation in the preamble of claim 25 reciting "[a] guide extension catheter for use with a guide catheter." Prelim. Resp. 35. Patent Owner contends the preamble is limiting and that Itou does not disclose that its suction catheter can be used as a guide extension catheter or that its suction catheter is configured to guide any interventional cardiology device. *Id.* at 36 (citing Ex. 2042 ¶ 48). We are not persuaded by this argument on the present record because Petitioner's expert Dr. Brecker has opined that Itou's "suction catheter 2 is insertable into guiding catheter 1 and may be used as a guide extension catheter." Ex. 1005 ¶ 154. Although Patent Owner's expert has opined that Itou's suction catheter is not a guide extension catheter (Ex. 2042 ¶ 48), we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

Patent Owner further argues that Petitioner has not shown that Itou expressly or inherently discloses the requirement that the guide catheter is "configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter." Prelim. Resp. 37–40. Patent Owner contends that "Itou teaches that the suction catheter 2 and distal end protective catheter 5 are assembled outside the body and inserted

into a delivery catheter together in the pre-assembled state," but this "is not the same as advancing an interventional cardiology device into an opening positioned within a guide catheter." *Id.* (citing Ex. 2042 ¶¶ 50–51). We recognize that the "configured to" language may not be purely functional and thus disregarded in the patentability analysis. *See Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) ("In common parlance, the phrase 'adapted to' is frequently used to mean 'made to,' 'designed to,' or 'configured to,' but it can also be used in a broader sense to mean 'capable of' or 'suitable for.'"). However, Patent Owner does not identify what particular structure is required by this claim that is lacking in Itou. To the extent that Patent Owner's expert opines that Itou's structure cannot meet this claim requirement (Ex. 2042 ¶¶ 50–51), we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

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 challenged claims and grounds contained in the Petition.

4. Claims 26, 27, 29–33, 35–37, 39, 41–45, and 47–49

Petitioner also contends that Itou anticipates claims 26, 27, 29–33, 35–37, 39, 41–45, and 47–49 of the '776 patent. Pet. 26–43.[5] In support of these arguments, Petitioner provides a detailed analysis of Itou and supporting testimony from Dr. Brecker identifying where each limitation of these claims is disclosed in Itou. *Id.* (citing *generally* Ex. 1005). Patent

[5] We note that the Petition's heading for ground 1 does not include claim 44 (Pet. 16), but the Petition nonetheless provides an analysis for why Itou anticipates claim 44. *Id.* at 36. Thus, we treat claim 44 as within the scope of the Petition's anticipation challenge.

Owner does not present separate arguments as to these claims in response to Petitioner's anticipation challenge.

Upon review of Petitioner's arguments and the supporting evidence, we determine that Petitioner has demonstrated a reasonable likelihood that claims 26, 27, 29–33, 35–37, 39, 41–45, and 47–49 are anticipated by Itou.

E. Ground 2: Obviousness in view of Itou and the Knowledge of a POSITA

Petitioner separately asserts that claims 39 and 46 would have been obvious in view of Itou and the knowledge of a POSITA. Pet. 43–46.

Claim 39 depends from claim 25 and recites "wherein the substantially rigid segment is formed from a section of stainless steel." Ex. 1001, 14:32–34. With respect to this requirement, Petitioner points out that Itou's proximal end portion 231 is formed by obliquely cutting one end of a metal pipe such as a pipe of stainless steel and a distal end portion 232, and contends a POSITA would have understood that stainless steel was commonly used for monorail style pushrods. Pet. 43–44 (citing Ex. 1007, 4:27–30, 4L33–34, 4:58–61; Ex. 1042 ¶ 78; Ex. 1050, 5:1–2). As discussed above, we determine that Petitioner presents sufficient evidence that Itou anticipates claim 39, and thus we need not address Petitioner's obviousness arguments for that claim based on Itou.

Claim 46 depends from claim 45, which in turn depends from claim 25, and recites "wherein a length of the reinforcing braid or coil is 20 to 30 cm." Ex. 1001, 14:62–63. With respect to this requirement, Petitioner contends that although the reinforcing braid or coil of Itou's tubular structure does not extend 20 to 30 cm, a POSITA would have motivation to lengthen the tubular structure "to accommodate reaching lesions located in

particularly tortuous vessels." Pet. 44–46 (citing Ex. 1005 ¶¶ 193–196; Ex. 1042 ¶¶ 131–135).

Patent Owner's only argument in response to ground 2 is that it fails for the same reason as ground 1. Prelim. Resp. 40–41. As discussed above, we determine that Petitioner has made a sufficient showing for ground 1. And upon review of Petitioner's arguments and the supporting evidence, we determine that Petitioner has demonstrated a reasonable likelihood that claims 39 and 46 would have been obvious based on Itou in view of the knowledge of a POSITA.

F. Ground 3: Obviousness in view of Itou, Kataishi, and the Knowledge of a POSITA

Petitioner asserts that claims 36, 37, and 52–56 would have been obvious in view of Itou, Kataishi, and the knowledge of a POSITA. *Id.* at 46–61. Petitioner relies upon Itou in the manner discussed above for similar claim limitations. Because we have determined that Itou discloses every limitation of claims 36 and 39, we only focus our analysis on claims 52–56 with respect to this ground.

1. Overview of Kataishi (Ex. 1025)

Kataishi is a publication of a U.S. patent application that was filed on January 22, 2004, and published on January 20, 2005. Ex. 1025. Thus, on its face, Kataishi qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Kataishi teaches "a thrombus suction catheter with improved suction and crossing having a small pressure loss, which is a tube having a lumen passing through from a proximal end to a distal end, a distal end opening having an angled cut surface." Ex. 1025 ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

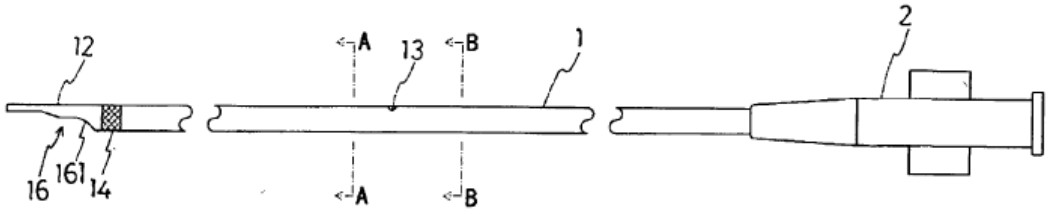


Fig. 1

As shown in Figure 1, a thrombus suction catheter includes a catheter body 1, a connector 2 provided at a proximal end of the catheter body 1, a distal end opening 12 formed by an angled cut surface, and a guide wire insertion port 13. *Id.* ¶¶ 27, 29.

2. Claims 52–56

Independent claim 52 recites a guide extension catheter similar to claim 25, except it requires that the segment is "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure," and further requires that "the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions." Ex. 1001, 15:15–34. Independent claim 53 also recites a similar device, except it further requires a "lumen 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." *Id.* at 15:35–16:18. Claims 54–56 depend from claim 53 and recite limitations similar to other dependent claims in the '776 patent. *Id.* at 16:19–37.

With respect to the limitation "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure" (claims 52), Petitioner relies upon the declaration testimony of Dr. Brecker and Dr. Hillstead to show that Itou's tubular structure 21 has a first flexular modulus, and that the segment defining the partially cylindrical opening is

formed by cutting a metal pipe and has a second flexural modulus. Pet. 54 (citing Ex. 1005 ¶ 216; Ex. 1042 ¶¶ 79–80).

With respect to the limitation "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions," Petitioner relies upon Kataishi's disclosure of a partially cylindrical opening with two inclined slopes. *Id.* at 54–55 (citing Ex. 1025, Figs. 2, 10; Ex. 1005 ¶ 219; Ex. 1042 ¶¶ 124–125). Petitioner contends that a POSITA had motivation to modify the partially cylindrical opening of Itou's suction catheter 2 to include an inclined region because "Kataishi teaches a suction catheter with a distal end designed to do two things: 1) improve crossability of the catheter; and 2) provide superior loading of matter (thrombus) into the distal end of the suction catheter," and "[t]hese advantages are accomplishment by the shape of Kataishi's distal end." Pet. 49, 55 (analysis of claim 36 incorporated for claim 52). Additionally, Petitioner contends that a POSITA would have been motivated to include a second, inclined slope to Itou's angled partially cylindrical opening because this modification "would increase the ease with which catheter (2) could receive a therapy catheter without impeding its ability to be maneuvered deeper into the coronary vasculature (compared to catheters with larger diameters)." *Id.* at 56–57 (citing Ex. 1005 ¶¶ 221–222; Ex. 1042 ¶¶ 121–123).

With respect to ground 3, Patent Owner additionally argues that the Petition fails to explain why a POSITA would have been motivated to modify Itou's proximal opening based on the shape of Kataishi's distal opening. Prelim. Resp. 42–47. According to Patent Owner, the distal end of Kataishi's suction catheter is designed to suction a thrombus from the side of the distal end by being flexible and shaped to conform about the thrombus

and against a vessel wall, and Petitioner has not shown how this relates to introducing interventional cardiology devices into the proximal end of a suction catheter. *Id.* at 43–44. On this record, we agree with Patent Owner 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. Petitioner's contentions with respect to claims 53–56 appear to be similarly deficient. Pet. 57–61. 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.

G. Ground 4: Obviousness in view of Itou, Ressemann, and the Knowledge of a POSITA

Petitioner asserts that claims 32, 36–38, 46, and 52–56 would have been obvious in view of Itou, Ressemann, and the knowledge of a POSITA. Pet. 61–76. Petitioner relies upon Itou in the manner discussed above for similar claim limitations. Because we have determined that Itou anticipates or renders obvious claims 32, 36 and 37, we only focus our analysis on the additional limitations of claims 38 and 52–56 with respect to this ground.

1. Overview of Ressemann (Ex. 1008)

Ressemann is a U.S. patent that issued on October 20, 2009 from an application filed on August 9, 2002. Ex. 1008. Thus, on its face, Ressemann qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

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. 1008, 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

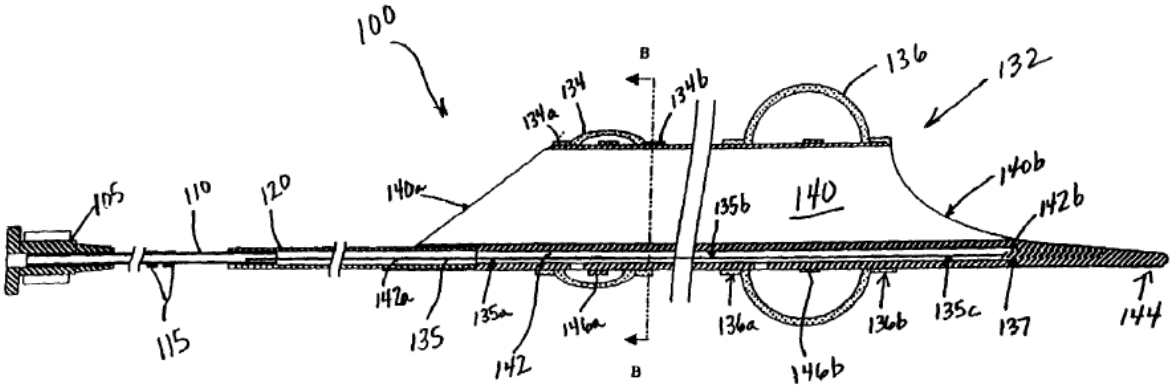


FIG. 1A

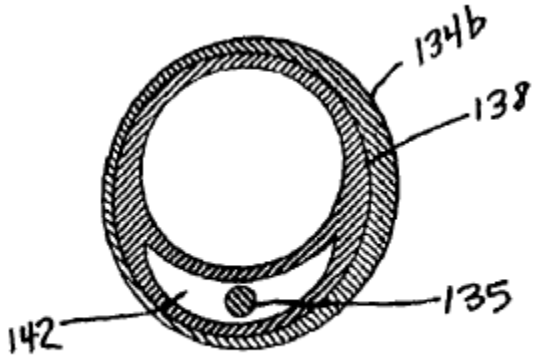


FIG. 1B

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:

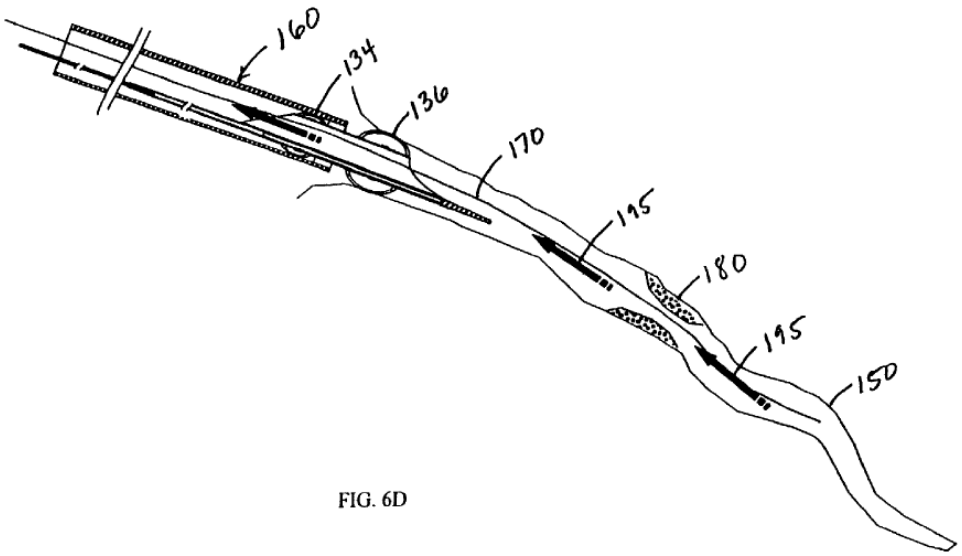


FIG. 6D

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. As shown in Figure 6D, 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.

2. Claim 38

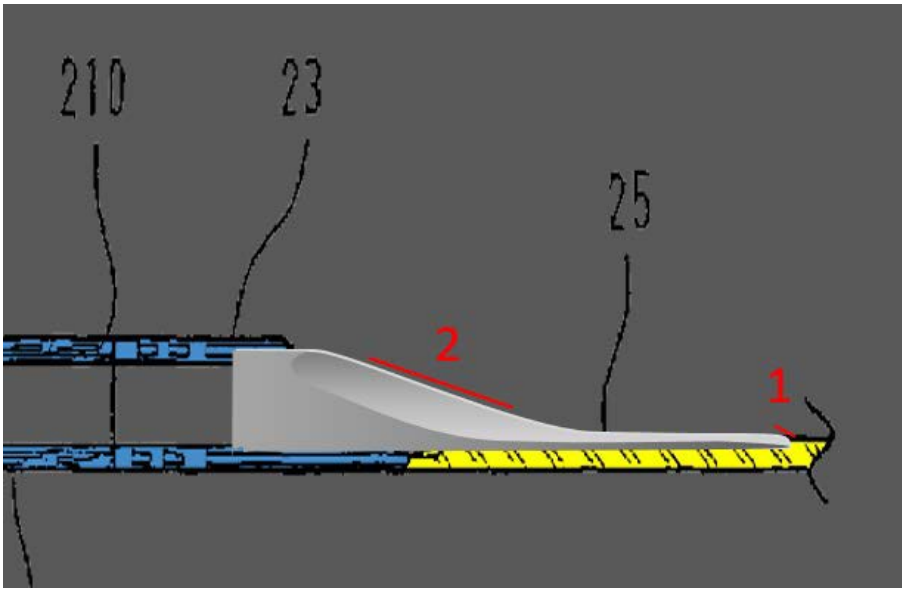
Claim 38 depends from claim 25 and recites "wherein the substantially rigid segment is formed from a hypotube." Ex. 1001, 14:30–31. Petitioner provides no analysis as to why the combination of Itou, Ressemann, and the knowledge of a POSITA renders claim 38 obvious. As such, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to that claim.

3. Claims 52–56

With respect to the limitation "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions" recited in claims 52–56, Petitioner's ground 4 relies upon the shape of Ressemmann's support collar 2141 as meeting this requirement. Pet. 72–74. Petitioner labels portions of Ressammann's Figure 16J as "incline #1" and "incline #2." *Id.* at 73 (citing Ex. 1008, Fig. 16J). Petitioner contends that:

> A POSITA would have had motivation to modify Itou's partially cylindrical opening with Ressemann's support collar for several reasons including: 1) such modification increases the area for receiving an interventional device, such as Itou's distal end protection device (5); 2) incline #1 provides an on-ramp to guide interventional devices into entry port at incline #2; 3) the tab portion provides a flexibility transition between the proximal end of tubular portion 24 and wire-like portion (25); and 4) the support collar reinforces the opening of the lumen.

Id. (citing Ex. 1042 ¶¶ 101, 113–116; Ex. 1005 ¶¶ 276–277). Petitioner provides the following representation of how Ressemann's collar would be incorporated into Itou's suction catheter 2:



Id. at 74. The annotated figure above shows a magnified version of Itou's Figure 3 with the wire-like portion 25 modified to include Ressemann's support collar leading into proximal tip 23. According to Petitioner, "[s]upport collar 2141 would be fit into the proximal opening of suction catheter (2) and tab portion 2141b would lie adjacent the exterior of wire-like portion (25)." *Id.*

With respect to ground 4, Patent Owner argues that:

> The Petition fails to address at least two fundamental problems with this analysis. One, Ressemann's support collar is buried inside and underneath other components of Ressemann's suction catheter. There is no reason why one skilled in the art would be motivated to extract Ressemann's support collar and use it (including the tab portion) to define the opening into Itou's suction catheter. Ex. 2024, ¶¶ 56–60. Two, even if it would have been obvious to apply "the teaching of Ressemann" to incorporate Ressemann's support collar into Itou's suction catheter, as the Petition proposes, the result would not look like the illustration in the Petition and would not meet the claim language. *Id.*, ¶¶ 61–62.

Prelim. Resp. 49.

Although we recognize that Patent Owner's expert has raised legitimate concerns about the combination of Ressamann and Itou, we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

H. Ground 5: Obviousness in view of Itou, Enger, and the Knowledge of a POSITA

Petitioner asserts that claims 52–56 would have been obvious in view of Itou, Enger, and the knowledge of a POSITA. *Id.* at 76–82. Petitioner relies upon Itou in the manner discussed above for similar claim limitations. We focus our analysis on the additional limitations of claims 52–56 with respect to this ground.

1. Overview of Enger (Ex. 1050)

Enger is a U.S. patent that issued on November 9, 1999. Ex. 1051. Thus, on its face, Enger qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Enger teaches a rapidly exchangeable catheter for use in the coronary arteries includes an elongate relatively stiff proximal segment that defines an inflation lumen, an intermediate, shorter segment formed from a more flexible plastic material and having two lumens, and a third, single lumen distal segment. Ex. 1050, Abstract. Figure 1 of Enger is reproduced below:

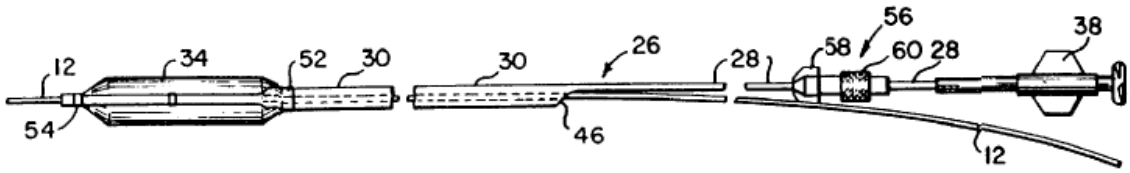


Fig. 1

Id. at 4:3. As shown above, catheter 26 includes an elongate proximal segment 28 which is formed from metallic hypodermic tubing, preferably stainless steel. *Id.* at 4:67–5:2. Catheter 26 also includes an intermediate segment 30 attached at its proximal end to the distal end of the metal tube 28 and being shorter in length than the metal tube 28. *Id.* at 5:5–8.

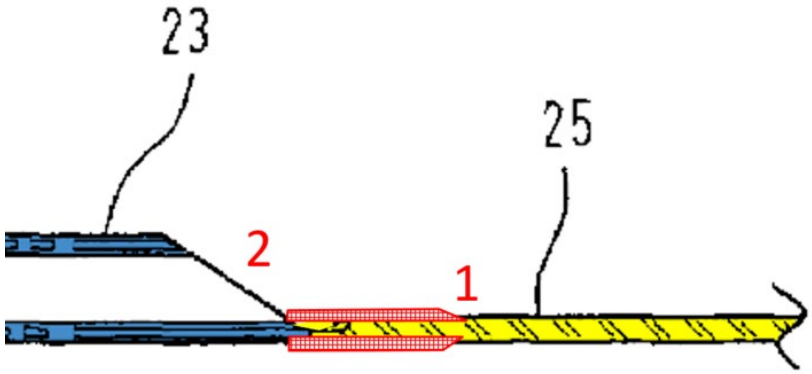
Figure 7 of Enger, reproduced below, is a sectional longitudinal illustration of the catheter in the region where the proximal metal tubular segment is joined to the intermediate more flexible plastic segment.

Fig. 7

Id. at 4:19–22. As shown above, metallic tubular proximal segment 28 defines a lumen 36 that extends fully through its length. *Id.* at 5:10–11. Flexible plastic intermediate segment 30 may be an extruded tube of suitable plastic such as high density polyethylene. *Id.* at 5:28–30.

2. Claims 52–56

With respect to the limitation "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions" recited in claims 52–56, Petitioner's ground 5 relies upon the shape of the proximal opening to Enger's guidewire lumen as meeting this requirement. Pet. 77–81. Petitioner labels portions of Enger's Figure 7 as "incline #1" and "incline #2." *Id.* at 79 (citing Ex. 1050, Fig. 7). Petitioner contends that "[a] POSITA had motivation 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 80 (citig Ex. 1042 ¶¶ 126–130; Ex. 1005 ¶ 307–308). Petitioner contends that the result of the combination would be a two-incline combination as shown below in the modified Figure 3 of Itou:



Id. The annotated figure above shows a magnified version Itou's Figure 3 with the wire-like portion 25 modified to include an additional incline leading into proximal tip 23.

With respect to ground 5, Patent Owner additionally argues that Enger does not disclose the claimed "at least two inclined regions," as its figures and specification shows the proximal opening of the guidewire lumen with only one inclined slope. Prelim. Resp. 56. Patent Owner contends that what the Petition calls "incline slope #1" is not part of the guidewire lumen's proximal opening at all. *Id.* at 57 (citing Ex. 2042 ¶¶ 43–44). Patent Owner further contends that Petitioner's purported motivations to add Enger's incline #1 to Itou's substantially rigid wire-like segment 25 fails for three reasons. *Id.* at 58. First, Patent Owner contends that the structure Petitioner relied upon does not serve to guide a guidewire into any lumen, but rather is the point where the guidewire *exits* the guidewire lumen. *Id.* at 59 (citing Ex. 1050, 6:42–44, 6:54–57; Ex. 2042 ¶¶ 45, 65–66). Second, Patent Owner contends that Petitioner's motivation is based on improper hindsight insofar Petitioner does not identify any reason to add a "collar" to Itou's device, in which the wire-like segment 25 is "welded" to the proximal end portion 231 of Itou's proximal tip 23. *Id.* at 59–60. Thus, Patent Owner contends that there would be negative consequences of the proposed modification because the addition of "incline slope #1" onto Itou's wire-like portion creates a "bump" proximal to the angled opening, thereby partially obstructing and decreasing the size of the opening. Id. at 60–61 (citing Ex. 2042 ¶ 67).

Although we recognize that Patent Owner's expert has raised legitimate concerns about the combination of Enger and Itou, we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

I. Objective Indicia

Patent Owner contends that Petitioner's obviousness grounds fail 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. 62–68. 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. 63. In support, Patent Owner directs our attention to an expert report submitted in the *QXM* case that maps the challenged claims to its GuideLiner product. *Id.* at 63 (citing Ex. 2056 ¶¶ 160–163, 168, App'x J (465–474), App'x K (515–518, App'x L (559–570)). Patent Owner provides no persuasive analysis, however, to explain why the claims of the '776 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.[6] *Fox Factory*, 944 F.3d at 1378. Thus, on this record, a presumption of nexus does not apply.

Because Patent Owner asserts that a nexus exists for multiple patents, it "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 case, 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.

J. 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. 29–33. In particular, Patent Owner contends that the validity of at least some of the challenged claims of

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

the '776 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 13.

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 '776 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 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 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 would be beneficial to the district court. 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 *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 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 will likely 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.

K. 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. 68–69 (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 '776 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 25–27, 29–33, 35–39, 41–49, and 52–56 of the '776 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