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Paper No. 11
Date: February 9, 2021

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.

IPR2020-01341
Patent 8,142,413 B2

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and CHRISTOPHER G. 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 1, 2, 4, 5, and 7–15 of U.S. Patent No. 8,142,413 ("the '413 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

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 "Medtronic plc is the ultimate parent of both entities." Pet. 4. Patent Owner identifies its real parties-in-interest as Teleflex Medical Devices S. À.R.L.; Vascular Solutions LLC; Arrow International, Inc.; and Teleflex LLC. Paper 7, 2. Patent Owner also notes "Teleflex Incorporated is the ultimate parent of the entities listed above." *Id.*

B. Related Matters

Petitioner filed a separate Petition for *inter partes* review of claims 1, 2, 4, 5, and 7–14 of the '413 patent as IPR2020-01342. Pet. 6; Paper 7, 3.

The parties indicate that the '413 patent is the subject of litigation 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. 4–5; Paper 7, 2. Patent Owner indicates that both of these district court proceedings are currently stayed. Paper 7, 2.

Petitioner also filed petitions challenging patents related to the '413 patent in the following proceedings: IPR2020-00126 (Patent 8,048,032 B2), IPR2020-00127 (Patent 8,048,032 B2), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00131 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00133 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,776), IPR2020-00136 (Patent RE45,776), IPR2020-00137 (Patent RE47,379), and IPR2020-00138 (Patent RE47,379).

The '413 patent was the subject of a previous *inter partes* review in IPR2014-00759 involving a distinct set of grounds, filed May 15, 2014, and terminated August 11, 2014, by way of joint motion to terminate. Paper 7, 2–3.

C. The '413 Patent

1. Specification

The '413 patent, titled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on March 27, 2012, from a non-provisional application filed June 28, 2010. Ex. 1001, codes (45), (54), (22).

The '413 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 '413 patent, interventional cardiology procedures often include inserting

guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:21–23. 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 1:26–31. 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 1:35–41. 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 1:41–45.

To solve this problem, the ’413 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 2:59–62. The ’413 patent teaches that the coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 2:62–67. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the ’413 patent:

Fig. 1

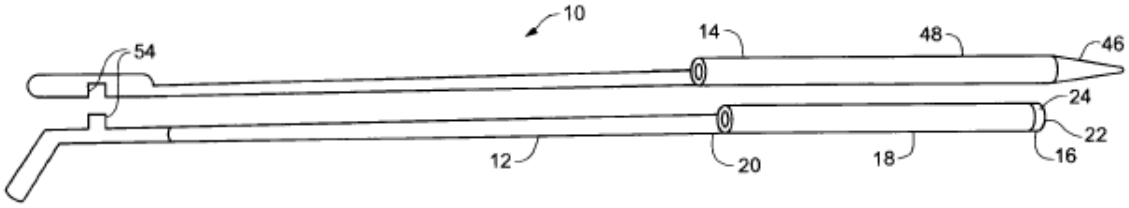

Fig. 2

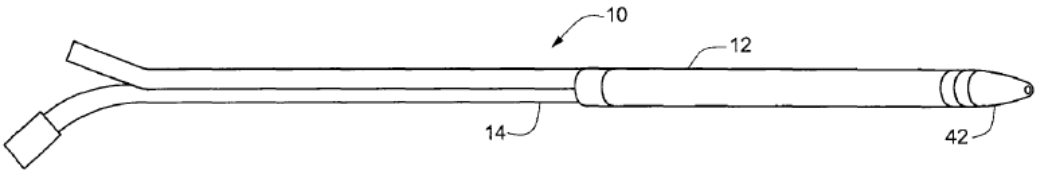

Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:22–27; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:12–14. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:15–16. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:20–21. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:21. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:25–26. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:65–66. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:65–67. 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 7:3–5.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:17–18. 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 4:21–28. 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 4:28–31. 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 4:35–38. 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 4:38–44.

2. Illustrative Claim

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

> 1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:
>
> inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,

further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;

advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.

Ex. 1001, 10:28–11:6.

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"); and

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

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

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 2, 4, 5 and 7–14 would have been unpatentable on the following grounds.

Ground	Claim(s)	35 U.S.C. §[1]	References/Basis
1	1, 2, 4, 7–14	102	Itou
2	1, 2, 4, 5, 7–14	103(a)	Itou, Knowledge of a POSITA
3	1, 2, 4, 5, 7–14	103(a)	Itou, Ressemann, Knowledge of a POSITA

II. ANALYSIS

A. 35 U.S.C. § 314: Parallel District Court Cases

Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS*, 138 S. Ct. at 1356. ("[Section] 314(a) invests the Director with discretion on the question whether to institute review." (emphasis omitted)); *Harmonic v. Avid Tech.,*

[1] 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 '413 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.

Inc., 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

In determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a), the Board considers an early trial date in related litigation as part of an assessment of all relevant circumstances of the case, including the merits, in an effort to balance considerations such as system efficiency, fairness, and patent quality. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 5–6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv* Order"); *see also NHK Spring Co. v. Intri-Plex Techs., Inc*., IPR2018-00752, Paper 8, 19–20 (PTAB Sept. 12, 2018) (precedential) (denying institution relying, in part, on § 314(a) because the parallel district court proceeding was scheduled to finish before the Board reached a final decision).

When considering an early trial date in related litigation, the Board evaluates the following factors ("*Fintiv* factors"):

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv Order 5–6. In evaluating these factors, "the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at 6.

1. Analysis

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. 5–7. We have considered the circumstances and facts before us in view of the *Fintiv* factors and determine that the circumstances presented here weigh heavily against exercising discretion under § 314(a) to deny institution of *inter partes* review.

Relevant to *Fintiv* factors 1 and 2, the parties acknowledge that the parallel district court proceeding is stayed. Pet. 16; Prelim. Resp. 1; Paper 7, 2. The granting of a stay pending *inter partes* review has weighed strongly against exercising discretion to deny institution under *NHK* as it is a strong indication that the district court has a preference to wait for the Board's final resolution of the patentability issues raised in the petition before proceeding with the parallel litigation. *See Fintiv* at 6–7. Accordingly, consideration of the first and second *Fintiv* factors weighs strongly against exercising discretion to deny institution.

The third *Fintiv* factor also provides that a petitioner's diligence or delay in filing a petition may be relevant. *See Fintiv* at 11–12. If the evidence shows that a petitioner filed its petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against denying institution. *See id.* at 11 (citing *Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15 at 12–13 (PTAB Jan. 9, 2020); *Illumina Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19 at 8 (PTAB Dec. 18, 2019)). If, however, the evidence shows that the petitioner did not file its petition expeditiously, such as at or around the same time that the patent owner responded to the petitioner's invalidity contentions, or even if a

petitioner cannot explain the delay in filing its petition, these facts have favored denial. *See Fintiv* at 11–12 (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019)).

Patent Owner contends that Petitioner's delay in filing the petition weighs in favor of denying institution under § 314(a). *See* Prelim. Resp. 5–6. In particular, Patent Owner contends that Petitioner unjustifiably delayed filing this Petition (and the Petition in IPR2020-01342) as compared to challenges against related patents brought 9 months earlier, which rely on similar art and arguments. *Id.*; *see* IPR2020-00126 (Itou and Ressemann), IPR2020-00128 (Itou and Ressemann), IPR2020-00129 (Itou and Ressemann), IPR2020-00132 (Itou and Ressemann), IPR2020-00133 (Ressemann), IPR2020-00134 (Itou and Ressemann), IPR2020-00135 (Itou and Ressemann), IPR2020-00137 (Itou and Ressemann), IPR2020-00138 (Ressemann). Patent Owner contends that Petitioner's "unjustified delay" in filing this petition prejudices Patent Owner. Prelim. Resp. 7. In particular, Patent Owner contends as follows:

> Petitioner has already relied on the present IPR petitions as a basis to seek an unprecedented extension of the one year statutory deadline in the eleven pending IPRs, even though it expressly and repeatedly relied on that one year deadline to convince the district court to stay the litigation. *See, e.g.*, IPR2020- 00126, Papers 56 and 61. If the present IPR petitions are granted, Petitioner will undoubtedly continue such delay tactics, such as by asking the district court to maintain the stay as to all patents in view of the present Petition.

Prelim. Resp. 7.

Petitioner explains the 9-month difference in its filing of the current Petitions by noting as follows:

> When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '413 patent. As a

> result, Petitioner did not file an IPR against the '413 patent at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint that asserted the '413 patent. Ex-1114. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline.

Pet. 16–17.

We find that the current record does not support a finding that the Petition was filed with delay. Rather, the filing of the Petition was in response to Patent Owner's Amended Complaint adding the '413 patent to the related litigation. Ex. 1114. We do not consider, based on the current record, the filing of the Petition within 6 months of the filing of the Amended Complaint that asserted the '413 patent to be unjustified.

With respect to *Fintiv* Factor 4 (overlap of issues) and *Fintiv* Factor 5 (whether the same parties are involved), we find there is an overlap of issues and parties between the *Medtronic* case and this proceeding. In *Fintiv*, the Board noted "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 12. In this case, however, any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court has stayed the parallel litigation and thus will not reach the merits of Petitioner's invalidity defenses before we issue our final written decision.

Furthermore, we note that the district court's stay of the litigation pending denial of institution or a final written decision allays concerns about inefficiency and duplication of efforts. *Id.* To the contrary, exercising our discretion to deny the Petition would force inefficiency and the possibility of conflicting decisions because the district court would then have to resolve

similar and overlapping issues presented in the context of only the '413 patent, one of several related patents being asserted by Patent Owner in the related litigation.

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.

Balancing all of the *Fintiv* factors, on this record, we determine that the circumstances presented here weigh against exercising discretion under § 314(a) to deny institution of *inter partes* review.

B. 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 "[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. 11. Alternatively, Petitioner asserts "if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical

engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* at 11–12. Additionally, Petitioner contends "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* at 12. Petitioner further asserts "a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a POSITA with an engineering degree may have access to one with a medical degree." *Id.* (citing Ex. 1005 ¶ 31; Ex. 1042 ¶¶ 18–19).

Patent Owner does not address the level of ordinary skill in its Preliminary Response.

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 '413 patent. *See Okajima*, 261 F.3d at 1355(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). 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.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the

extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner proposes construction for several claim terms, including "interventional cardiology devices," "standard guide catheter," and "placed in a branch artery" Pet. 13–16. Patent Owner does not address claim construction in its Preliminary Response, although Patent Owner previously addressed the term "interventional cardiology devices" in the related IPRs. *See e.g.* IPR2020-00126.

For the purpose of this Decision, we find it helpful to address the term "interventional cardiology devices."

1. "interventional cardiology device(s)"

Independent claim 1 of the '413 patent recites a standard guide catheter having a continuous lumen sized "such that interventional cardiology devices are insertable into and through the lumen." Ex. 1001, 10:36–37. To that point, the Specification states in regard to the claim term "interventional cardiology devices" as follows:

> For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.

Id. at 1:23–26.

Petitioner contends that, in the *QXM* litigation, Patent Owner stipulated that the term "interventional cardiology device(s)" means "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." Pet. 13 (citing Ex. 1012, 21; Ex. 1064, 1 n.1). The district court, however, did not construe the term "interventional cardiology device(s)" in the *QXM* litigation. Ex. 1013 (Claim Construction Order).

Based on the current record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. In the context of independent claim 1, the lumen of the recited guide catheter must be sized to receive at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. For example, the diameter of the guide catheter is sized to receive a guidewire and a stent or balloon. *See* Ex. 1001, 7:42–46 ("Once the guidewire **64** is pushed past stenotic lesion 66 or occlusive lesion . . . , a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion . . . ."); *id.* at 7:47–65, Figs. 7–8.

Furthermore, based on the current record, we do not construe the claims to require that more than one of guidewires, stents, stent catheters, and balloon catheters be simultaneously insertable into and through the lumen, although we recognize that certain embodiments disclosed in the Specification show a preference for the use of a guidewire and a stent or balloon. *Id.* at 7:36–65, Figs. 7–8.

Finally, we recognize that the Specification discloses that "the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel" (*id.* at 5:15–18) and that the term "interventional cardiology devices" is not limited to guidewires, balloon catheters, stents and stent catheters (*id.* at 1:24–26). To the extent further discussion of what additional devices may be encompassed by this term is required for the purposes of this Decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

2. Other Recited Claim Terms/Phrases

We determine that no express construction of any other claim term is necessary to determine whether to institute *inter partes* review.

D. 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. 17–19.

E. Petitioner's Patentability Challenges

1. Ground 1: Anticipation by Itou

Petitioner asserts that claims 1, 2, 4, and 7–14 are anticipated by Itou. Pet. 7. For the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1, 2, 4, and 7–14 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:

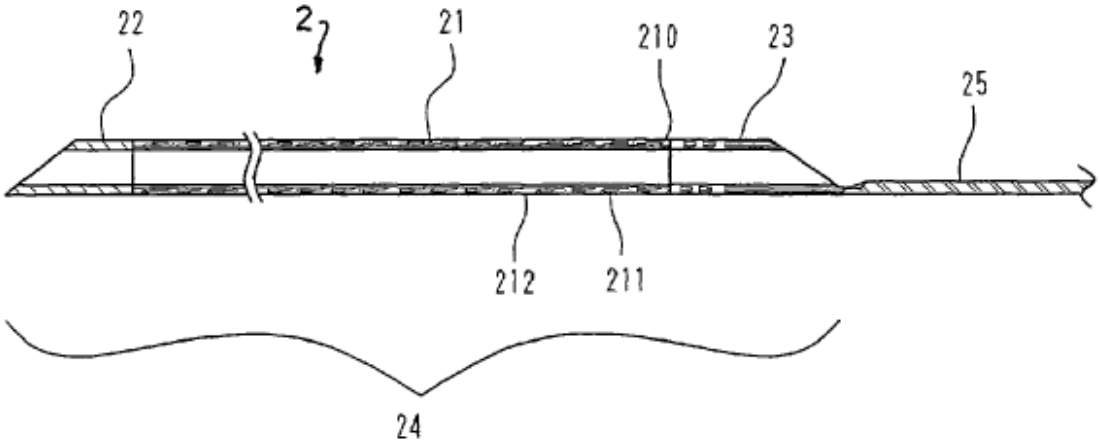

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion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

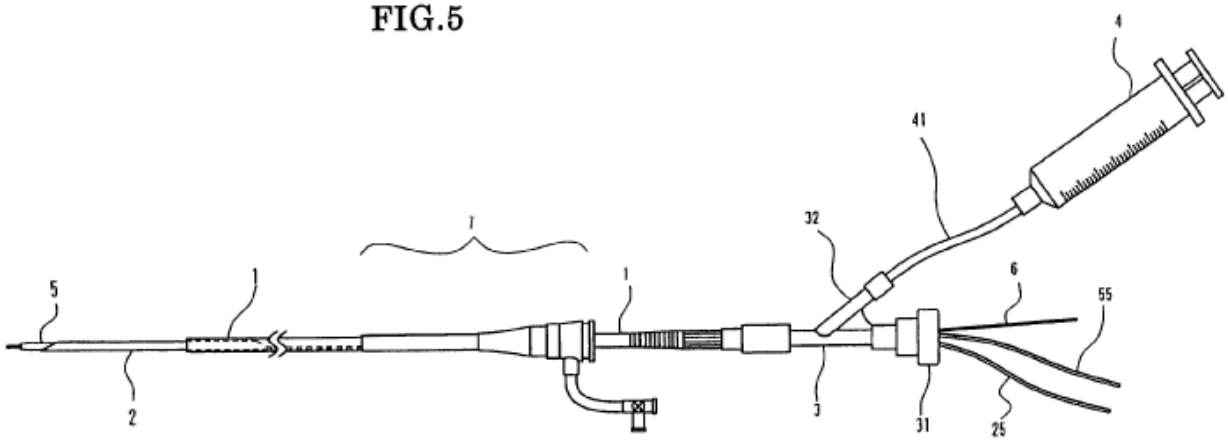

Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted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

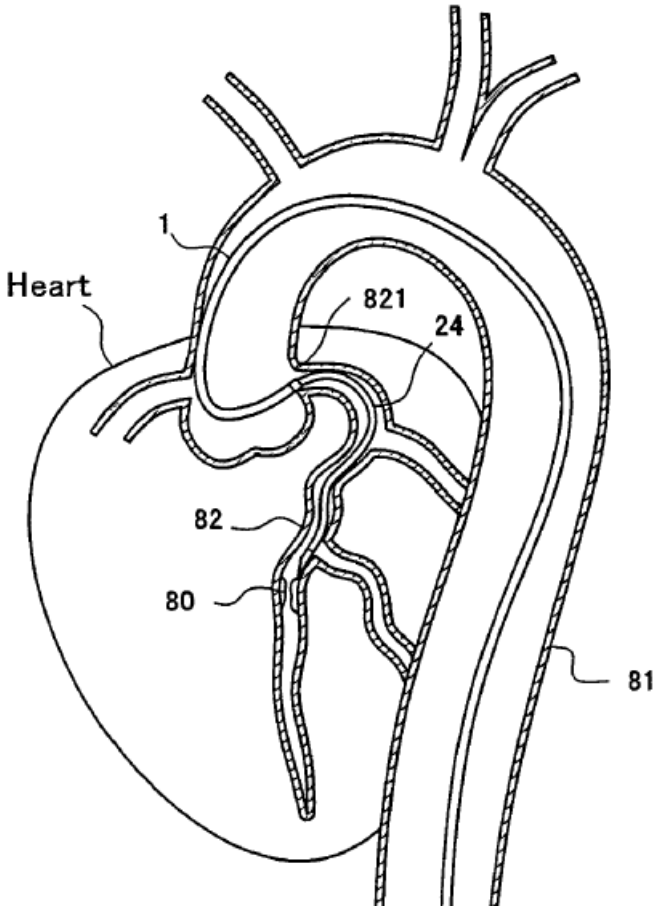

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of a coronary artery 82." *Id.* at 5:29–34. Tubular portion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

Petitioner contends that Itou teaches each of the limitations of independent claim 1. Pet. 21–51. 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 1 is disclosed by Itou. Pet. 21–51 (citing Ex. 1005 ¶¶ 160–225). To begin, Petitioner contends Itou discloses a method of providing backup support for an interventional cardiology device (protective catheter (5)) for use in the coronary vasculature (a catheter assembly that includes a guide catheter (GC) that is inserted into a coronary artery ostium). Pet. 23 (citing Ex. 1007, Abstract, 2:2–5, 2:29–38, 3:59–61. 5:32–34, 7:7–11, Figs. 1A–B, 5, 6).[2]

Petitioner further contends that Itou discloses an interventional cardiology device being adapted to be passed through a standard guide catheter, as required by claim 1. *Id.* at 24–26. Petitioner contends that Itou's guiding catheter (1) is a "standard guide catheter" and that Itou's "suction catheter (2) has a tubular portion (24) with an inner diameter 1.5 mm, sized to be insertable through the continuous lumen of the GC." *Id.* at 25 (citing Ex. 1007, Fig. 1A; Ex. 1005, ¶ 141, 179).

Petitioner further contends that Itou discloses a standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, as required by claim 1. *Id.* at 26–29. In particular, Petitioner contends that Itou discloses a guide catheter (GC 1) that has a continuous

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

lumen extending from its proximal end at a hemostative valve (the valve built into main connector 31) to a distal end adapted to be placed in the branch artery. *Id.* (citing Ex. 1007, 1:66–2:5, 3:29–37, 5:20–23, 5:32–34, 5:65–67, 7:7–10, 7:54–67, Figs. 1A, 5, 6; Ex. 1005 ¶ 181).

Petitioner further contends that Itou discloses continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, as required by claim 1. *Id.* at 29–31 (citing Ex. 1007, 3:59–63, 4:43–52, 4:61–63, 5:65-67, Fig. 5, Table 1; Ex. 1005 ¶¶ 182–190). In particular, Petitioner contends

> Distal end of protective catheter (5)—an "interventional cardiology device"—has a maximal outer diameter of 1.35 mm. Ex-1007, Table 1, 4:61-63. Protective catheter (5) has a lumen of "a size sufficient to receive" guidewire (6), which is also an "interventional cardiology device." Id. Both protective catheter (5) and guidewire (6) are sized to be insertable into and through the lumen of the GC (1). Id., 3:59-63, 4:43-52, Fig. 5; Ex-1005, ¶¶ 182-83.

Pet. 29–30.

Petitioner contends that Itou discloses inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end, as required by claim 1. *Id.* at 31–33. In particular, Petitioner contends "Itou's GC (1) is inserted over a guidewire (6) in addition to being over the suction catheter and distal end protective catheter." *Id.* at 31 (citing Ex. 1007, 1:66–2:5, 5:32–34, 7:7–10; Ex. 1005 ¶¶ 191);

Petitioner further contends that Itou discloses a method using a device having a flexible tip portion defining a tubular structure (tip 22 and tubular portion 21) having a circular cross-section and a length that is shorter than

the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. *Id.* at 34–38 (citing Ex. 1007, 2:12–26, 3:47-58, 4:48–52, 7:1–23, Figs. 3, 5, 6, Table 1; Ex. 1005 ¶ 194–195; Ex. 1042 ¶¶ 48–59).

Petitioner contends that Itou discloses that its method uses a device having a substantially rigid portion (solid wire-like portion 25) that is proximal of and operably connected to the flexible tip portion and, when combined with the length of flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter such that when the flexible tip portion is extended beyond the distal end at least a portion of the substantially rigid portion extends through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. *Id.* at 38–44 (citing, *inter alia*, Ex. 1007, 2, 5–9, 5:20–24, 5:43–46, Fig. 3 (depicting flexible tip 21, 22 operably connected to rigid wire-like portion 25), Fig. 5 (depicting distal portion of flexible tip 21, 22 extending beyond the distal end of guiding catheter 1 and depicting a portion of wire-like portion 25 extending beyond the valve in main connector 31), Fig. 6 (depicting Itou's suction catheter (2) with "flexible tip portion" extends through the lumen of the GC (1) into the coronary artery beyond the distal end of the GC); Ex. 1005 ¶ 196–200, 211–220; Ex. 1042 ¶¶ 48–59).

Finally, Petitioner contends that Itou discloses "inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second

artery," as required by claim 1. Pet. 49–51. In particular, Petitioner contends

> Itou discloses that "the distal end protective catheter 5" is advanced through and beyond a lumen of the flexible tip portion of Itou's suction catheter (2) into contact with a lesion in the second artery. "The distal end protective catheter 5 is inserted in the lumen of suction catheter 2 and projects from the distal end of suction catheter 2 such that it acts as a protective safety tip." Ex-1007, 4:48-52. Itou explains that "the distal end of the combination of the suction catheter 2 and the distal end protective catheter 5 is inserted *to the target location* 80." *Id*., 7:1-27 (emphasis added); Ex-1005, ¶ 223, 225. As shown in Figure 5, . . . the distal end protective catheter (5) extends beyond the lumen of the flexible tip portion of Itou's suction catheter (2).

Id. at 50.

Patent Owner does not address the merits of Petitioner's contentions at this stage of the proceeding. *See generally* Prelim. Resp.

Having considered the parties positions and evidence of record, we determine that Petitioner has identified sufficiently for purposes of this Decision where Itou discloses every limitation of claim 1. Thus, Petitioner has demonstrated a reasonable likelihood that claim 1 is anticipated by Itou.

(2) Dependent Claims 2, 4, and 7–14

Petitioner also identifies where Itou allegedly discloses the limitations of dependent claims 2, 4, and 7–14 of the '413 patent. Pet. 52–70. In support of these arguments, Petitioner directs our attention to the foregoing disclosures of Itou and provides a detailed claim analysis addressing how each element of claims 2, 4, and 7–14 is disclosed by Itou. *Id.*

Patent Owner does not address Petitioner's specific arguments with respect to dependent claims 2, 4, and 7–14. *See generally* Prelim. Resp.

Having considered the parties positions and evidence of record, we determine that Petitioner has identified sufficiently for purposes of this Decision where Itou discloses every limitation of dependent claims 2, 4, and 7–14. 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 1, 2, 4, and 7–14 as anticipated by Itou.

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

To the extent not anticipated by Itou, Petitioner contends the subject matter of claims 1, 2, 4, 5, and 7–14 would have been obvious over the disclosures of Itou when considered in light of the knowledge of one of ordinary skill in the art. Pet. 70–77.

Patent Owner does not address Petitioner's specific arguments with respect to dependent claims 2, 4, and 7–14. *See generally* Prelim. Resp.

We have reviewed Petitioner's contentions and are persuaded on the current record that Petitioner's arguments and evidence are sufficient to show a reasonable likelihood Petitioner would prevail in proving unpatentability of these claims.

3. Ground 3: 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 1, 2, 4, 5, and 7–14 would have been obvious over the

combined disclosures of Itou and Ressemann, when considered in light of the knowledge of one of ordinary skill in the art. Pet. 77–95.

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

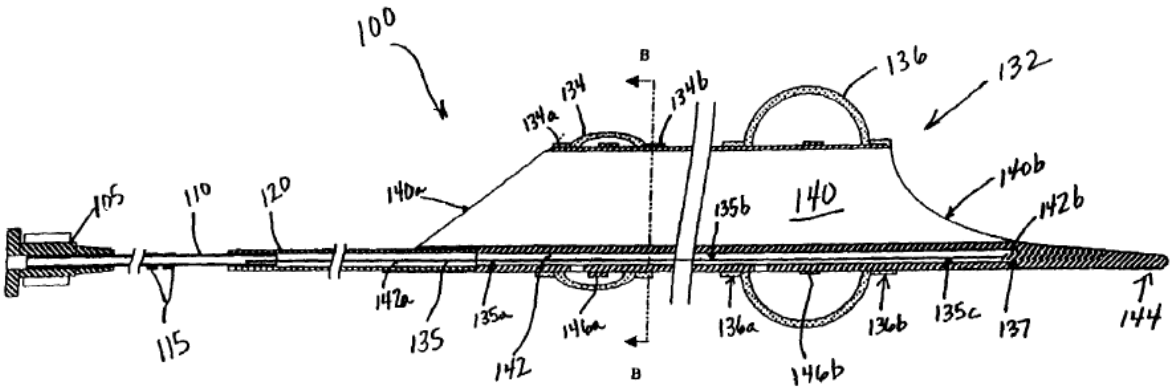

FIG. 1A

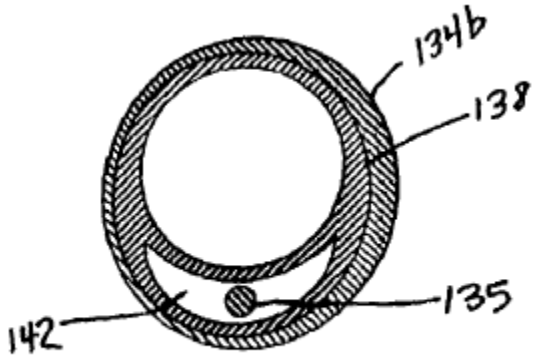

FIG. 1B

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:

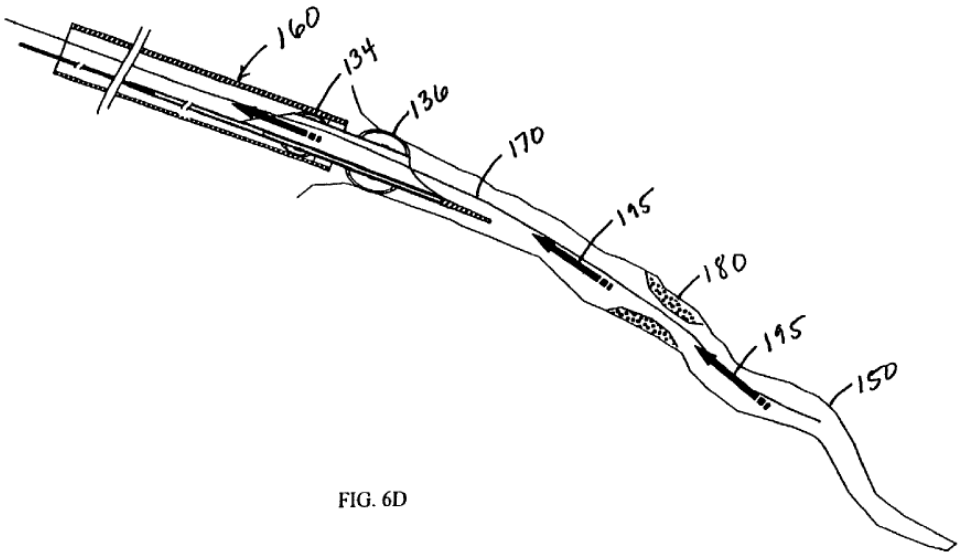

FIG. 6D

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. 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 1, 2, 4, 5, and 7–14 are unpatentable under 35 U.S.C. § 103(a) as obvious over Itou, Ressemann, and the knowledge of POSITA. Pet. 77–95. 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 1 is disclosed by the combination of Itou, Ressemann, and the knowledge of POSITA. *Id.* (citing Ex. 1005 ¶¶ 71–73, 160–73, 269–357; Ex. 1042 ¶¶ 54–59, 61–65, 71–73).

Patent Owner does not address Petitioner's specific arguments with respect to dependent claims 2, 4, and 7–14. *See generally* Prelim. Resp.

We have reviewed Petitioner's contentions as to this Ground and we are persuaded on the current record, that Petitioner's arguments and evidence are sufficient to show a reasonable likelihood Petitioner would prevail in showing the challenged claims would have been obvious over the asserted references. However, the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

III. 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. 8 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)[3]). Patent Owner further argues

[3] We note that the Supreme Court has accepted this case for review. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), *cert. granted sub nom. United States v. Arthrex, Inc.*, 2020 WL 6037206 (Oct. 13, 2020).

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).

This constitutional issue has been addressed by the Federal Circuit's decision in *Arthrex*, 941 F.3d at 1337 ("This as-applied severance . . . cures the constitutional violation."); *see also Arthrex, Inc. v. Smith & Nephew, Inc.*, 953 F.3d 760, 764 (Fed. Cir. 2020) (Moore, J., concurring in denial of rehearing) ("Because the APJs were constitutionally appointed as of the implementation of the severance, *inter partes* review decisions going forward were no longer rendered by unconstitutional panels."). Accordingly, we do not consider this issue any further for this Decision.

IV. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that at least one challenged claim of the '413 patent is unpatentable as anticipated and as obvious. In accordance with the Court's decision in *SAS*, 138 S. Ct. at 1359–60 and Office policy, we institute an *inter partes* review of all challenged claims of the '413 patent on all grounds alleged by Petitioner. *See* Guidance on the Impact of SAS on AIA Trial Proceedings (Apr. 26, 2018), https://www.uspto.gov/patents/ptab/trials/guidance-impact-sas-aia-trial ("If the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.").

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. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068

(Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing id. § 316(e)). 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.

V. 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 1, 2, 4, 5, and 7–14 of the '413 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 '413 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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