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Paper 22
Date: June 8, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

IPR2020-00129
Patent RE45,380

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

TORNQUIST, *Administrative Patent Judge*.

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

INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 25–39 of U.S. Reissue Patent RE45,380 (Ex. 1201, "the '380 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response to the Petition (Paper 8, "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 12) addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply (Paper 14) addressing Petitioner's burden on those issues. Also pursuant to our authorization, Petitioner filed another Reply (Paper 19) and Patent Owner filed another Sur-Reply (Paper 20) addressing the factors for discretionary denial under 35 U.S.C. § 314(a).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2019). The standard for institution is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute an *inter partes* review of all challenged claims and all asserted grounds set forth in the Petition. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-

or-no institution choice respecting a petition, embracing all challenges included in the petition").

A. Related Matters

The parties indicate that the '380 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.) ("*Medtronic* case") and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn) ("*QXM* case"). Pet. 5; Paper 4, 2–3. The '380 patent is also at issue in IPR2020-00128, IPR2020-00130, and IPR2020-00131. Paper 4, 3; Pet. 5.

B. The '380 Patent

The '380 patent relates to catheters used in interventional cardiology procedures and, in particular, to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." Ex. 1201, 1:31–35.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or lesions." *Id.* at 1:44–46. This narrowing is referred to as stenosis. *Id.* at 1:48–49. To treat a stenosis, "it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery." *Id.* at 1:49–52. To achieve this result, a guide catheter is inserted through the aorta and into the ostium of the coronary artery where it is typically seated into the opening or ostium of the artery to be treated. *Id.* at 1:53–57. A guidewire or other instrument is then passed through the lumen of the guide catheter and inserted into the artery beyond the stenosis. *Id.* at 1:39–41, 1:57–59. Crossing the tough lesions, however, may create enough backwards force to dislodge the guide catheter from the ostium of the artery being treated,

making it difficult or impossible to treat certain forms of coronary artery disease. *Id.* at 1:59–63.

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

Fig. 1

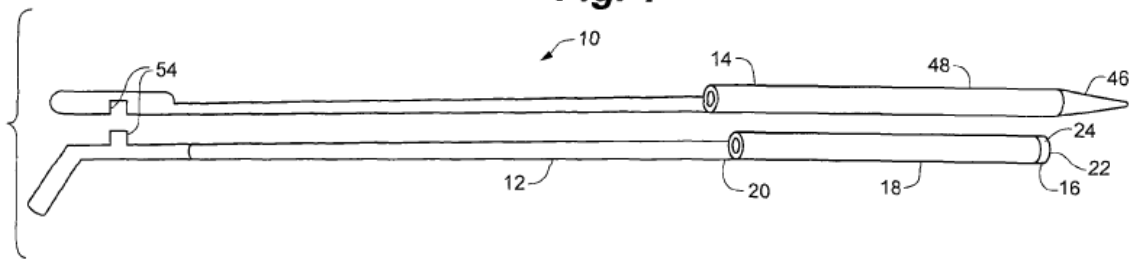

Fig. 2

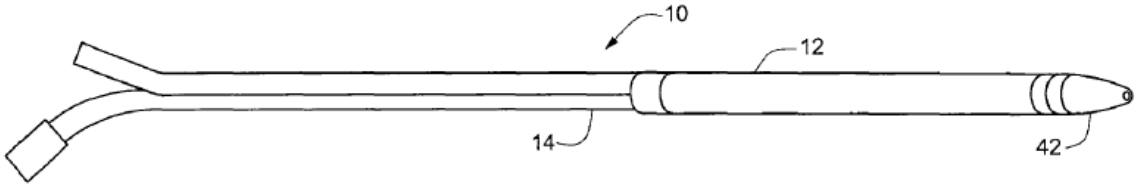

Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled together. *Id.* at 5:40–45. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:34–35. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48, both of which are pierced by lumen 50 (not labeled in Figure 1). *Id.* at 7:16–20. Clip 54 releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:21–23.

Figure 8 of the ’380 patent is reproduced below:

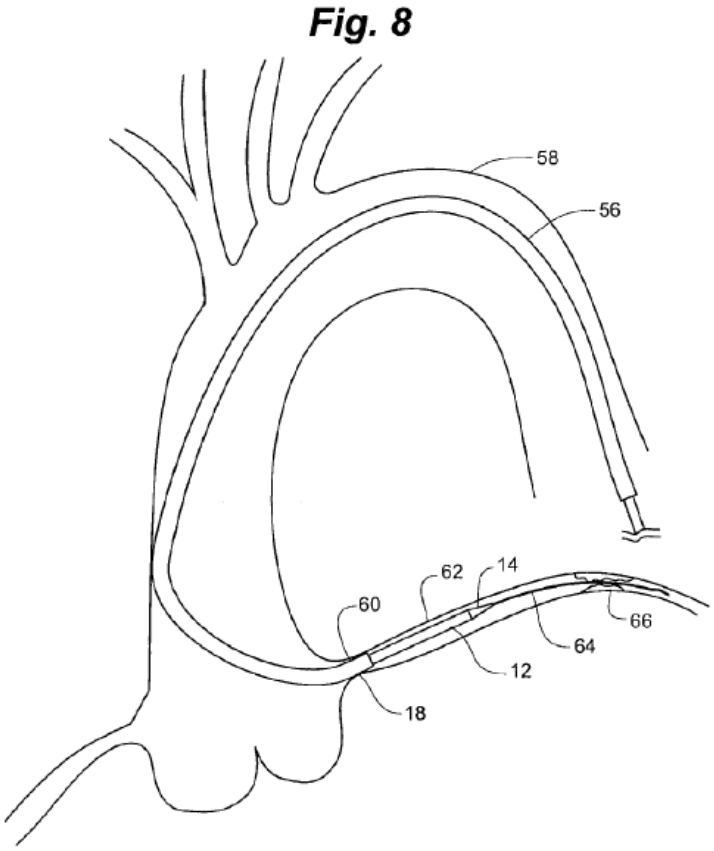

Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 5:61–64. In Figure 8, “coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62.” *Id.* at 8:6–10. According to the ’380 patent, “[c]oaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64.” *Id.* at 8:10–14. “Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.” *Id.* at 8:14–17. At this point, coaxial guide catheter 12 is ready to accept a treatment

catheter such as a stent or balloon catheter which may be advanced to the stenosis. *Id.* at 8:17–18, 8:30–32.

C. Illustrative Claim

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

> 25. A system comprising:
>
> means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and
>
> means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,
>
> the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,
>
> wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and

the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion.

Ex. 1201, 13:43–14:5.

D. Prior Art and Asserted Grounds

Petitioner contends claims 25–39 of the '380 patent would have been unpatentable on the following grounds (Pet. 7–8):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
25–31, 34–37, 39	102	Ressemann[1]
27	103	Ressemann
27	103	Ressemann, Kataishi[2]
27	103	Ressemann, Enger[3]
32, 33	103	Ressemann, Takahashi[4]
38	103	Ressemann, Berg[5]
25, 26, 28–30, 32–37, 39	102	Itou[6]
31	103	Itou
27	103	Itou, Kataishi
38	103	Itou, Berg

Petitioner also relies on the testimony of Dr. Stephen JD Brecker (Ex. 1205) and Dr. Richard A. Hillstead (Ex. 1242). Pet. 7 n.2.

[1] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1208) ("Ressemann").
[2] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1225) ("Kataishi").
[3] Enger, US 5,980,486, issued November 9, 1999 (Ex. 1250) ("Enger").
[4] Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63:452–456 (2004) (Ex. 1210) ("Takahashi").
[5] Berg, US 5,911,715, issued June 15, 1999 (Ex. 1251) ("Berg").
[6] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1207) ("Itou").

ANALYSIS

A. § 314

1. Multiple Petitions

Petitioner filed four petitions for *inter partes* review of the '380 patent. IPR2020-00128 relies on Itou as the primary reference; IPR2020-00129—the present proceeding—relies on Ressemann as the primary reference; and IPR2020-00130 and IPR2020-00131 rely on Kontos as the primary reference. *See* Paper 3, 1–3. Petitioner labels IPR2020-00128 as "Petition 1A," IPR2020-00129 as "Petition 1B," IPR2020-00130 as "Petition 2A," and IPR2020-00131 as "Petition 2B." *Id.* at 1–2.

Petition 1A is directed to claims 1–4, 6–10, 12–21, and 23 of the '380 patent. *Id.* at 1. Petition 1B is directed to claims 25–39 of the '380 patent. *Id.* at 1–2. Petition 2A is directed to claims 1–4, 6–9, and 12–21 of the '380 patent. *Id.* at 2. Petition 2B is directed to claims 25–39 of the '380 patent.

Petitioner contends two petitions,[7] i.e., Petition 1A and Petition 1B, are necessary to address the claims of the '380 patent challenged by Petitioner "because of the length, type, and number of claims asserted by Patent Owner in district court." *Id.* at 4 (emphasis omitted). In particular, Petitioner contends the '380 patent has "42 lengthy claims," the simple recitation of which "takes up over 1,400 word—more than 10% of Petitioner[']s allotted word count." *Id.* Petitioner also contends that the

[7] In this Decision, we address only whether we should exercise our discretion to deny the present Petition, i.e., Petition 1B. We will address the parties' arguments regarding Petition 2A in our decision in IPR2020-00130 and the parties' arguments regarding Petition 2B in our decision in IPR2020-00131.

present Petition, Petition 1B, addresses means-plus-function limitations "requiring unique arguments." *Id.*

Patent Owner contends Petitioner's inability to "fit all arguments into a single petition is a problem it created itself." Paper 11, 4. According to Patent Owner, "[r]ather than judiciously selecting its strongest arguments, [Petitioner] chose, for example, to advance ***seven grounds*** against claim 27, and ***three*** separate grounds against independent claim 25." *Id.*

Claims 25–39 of the '380 patent, challenged in this Petition, were added by reissue and, in contrast to the claims challenged in Petition 1A, require analysis of potential means-plus-function claim terms. Ex. 1201, 13:44–46; Prelim. Resp. 16–21. Given the number and length of the challenged claims, and given the unique means-plus-function issues presented by the added reissue claims, we agree with Petitioner that analyzing claims 1–4, 6–10, 12–21, and 23 and claims 25–39 of the '380 patent in two different petitions is reasonable and justified under the circumstances.

Accordingly, we decline to exercise our discretion to deny the Petition under § 314(a).

2. Parallel District Court Cases

Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution due to the common issues being litigated in parallel district court cases. Prelim. Resp. 25–30. In particular, Patent Owner contends that the validity of at least some of the challenged claims of the '380 patent and other related patents is the subject of active litigation in two separate district court cases, the *QXM* case and the

Medtronic case, which are both currently pending in the District of Minnesota. *Id.* at 12.

In *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential, designated May 7, 2019) ("*NHK*"), the Board considered the fact that a parallel district court proceeding was scheduled to finish before the Board reached a final decision as a factor favoring denial of institution. In the more recently designated precedential decision *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 6 (PTAB Mar. 20, 2020) (precedential, designated May 5, 2020) ("*Fintiv*"), the Board set forth several other factors to consider under § 314(a) in determining whether to institute trial when there is parallel, co-pending litigation concerning the same patent: (1) whether a stay of the parallel litigation exists or is likely to be granted if a trial proceeding is instituted by the Board; (2) proximity of the court's trial date to the Board's projected statutory deadline; (3) the investment in the parallel proceeding by the court and parties; (4) the extent of overlap between issues raised in the petition and in the parallel litigation; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) and other circumstances that impact the Board's exercise of discretion, including the merits.

The parties address the *Fintiv* factors in supplemental briefing that we authorized. Paper 19; Paper 20. We have considered each of these factors and conclude that, on balance, the circumstances here do not favor discretionary denial under § 314(a).

As to whether a stay of the parallel litigation exists or is likely to be granted (*Fintiv* Factor 1), Petitioner contends that the presiding district court judge in the *Medtronic* and *QXM* cases "has granted every post-institution

request to stay litigation pending reexamination or IPR." Paper 19, 2 (citing Ex. 1293). Petitioner also points out that the *QXM* case, involving the '380 patent and other patents in this 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. 1294). Thus, Petitioner contends that the same judge will also entertain Petitioner's motion to stay the *Medtronic* case in the event of institution. *Id.* With respect to *Fintiv* Factor 1, Patent Owner contends that Petitioner has not sought a stay of the *Medtronic* litigation, and the Board has previously declined to infer how the district court would rule when neither party has requested a stay. Paper 20, 1. Patent Owner contends that the *QXM* case was stayed only because QXMedical agreed to exit the market and waived its obviousness/anticipation defenses, and that the district court has not granted stays involving direct competitors or allegations of irreparable harm. *Id.* Having considered the parties position, we determine that *Fintiv Factor* 1 favors institution, especially in view of the fact that a stay has already been granted in the related *QXM* case and the district court's prior history of granting stays pending resolution of related IPRs.

As to the proximity of the court's trial dates to our statutory deadlines (*Fintiv* Factor 2), the parties agree that the district court has indicated that the *Medtronic* case must be "Ready for Trial" by August 1, 2021, which would be a few weeks *after* our statutory deadline for a final written decision in this proceeding and the related IPRs. 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. 1289). Petitioner points out that the district court already extended the original "Ready for Trial" date by two months in the *Medtronic* case, and that a trial date in the *QXM* case was finally set for February 24, 2020—more than ten months after the original "Ready for Trial" set by the court—before that case was stayed pending our institution decision. We determine that *Fintiv Factor* 2 also favors institution, especially given that the trials in the district court cases are not scheduled to take place until after we issue our final written decisions in these proceedings. Notably, in both the *NHK* and *Fintiv* cases, the trial dates in the parallel litigations were scheduled to occur before the final written decision deadlines. *See NHK*, IPR2018-00752, Paper 8 at 19 (noting trial date of March 25, 2019, where Board's institution decision was issued September 12, 2019); *Fintiv*, IPR2020-00019, Paper 15 at 10 (noting trial date of March 18, 2021 where Board's institution decision was due May 15, 2021).

As to the amount of investment by the parties and the court in the parallel proceeding (*Fintiv* Factor 3), Patent Owner contends that the district court is already deeply invested and has familiarity with the challenged patents in light of the relatively advanced stage of the *QXM* case. Paper 20, 1–2. But as noted above, the district court has indicated a preference to wait for the Board's institution decision before proceeding in the *QXM* case. With respect to the *Medtronic* case, Patent Owner contends that the parties have already exchanged infringement contentions, conducted extensive fact discovery (set to close September 1, 2020), and addressed the issues in a preliminary injunction motion. *Id.*; *see also* Prelim. Resp. 13. Although we

agree that the parties have invested some time and effort in the related litigation, we are not persuaded that those cases are in such an advanced stage that would favor 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. 1288, 9–14. However, the district court has not issued a claim construction order or any other substantive order. *See Fintiv*, Paper 11 at 10 (noting that if "the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*"). We, therefore, determine that resolution of those common issues by the Board may be beneficial to the resolution of the district court proceedings. Patent Owner also contends that Petitioner delayed bringing these challenges. Paper 20, 2. Petitioner, however, points out that it filed its IPR petitions roughly four months after the district court complaint in the *Medtronic* case, and before Patent Owner's infringement contentions were served in that case. Paper 19, 2; *see Fintiv*, Paper 11 at 11 (noting that "it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding"). We find that Petitioner did not unduly delay filing its IPR Petitions and that Factor 3 weighs against discretionary denial.

We have also considered the remaining *Fintiv* factors and determine, on balance, that they do not outweigh the foregoing factors in favor of institution. *Fintiv*, Paper 11 at 6 (explaining that when various factors weigh both in favor and against exercising discretion under § 314(a), we take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review"). With respect to *Fintiv Factor* 4

(overlap of issues), Patent Owner responds that there is complete overlap of the issues raised in the parallel proceedings, including the same invalidity prior art and arguments raised in the Petitions. Paper 20, 2. With respect to *Fintiv Factor* 5 (whether the same parties are involved), Patent Owner also points out that the Petitioner is the defendant in the *Medtronic* case. *Id.* In contrast to *NHK* and *Fintiv*, however, in this case the trial date is *after* the due date for our final written decision and, although there is an overlap of issues and parties between the *Medtronic* case and this proceeding, in this case any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court may stay the parallel litigation, and thus not reach the merits of Petitioner's invalidity defenses, before we issue our final written decision.

Finally, under *Fintiv Factor* 6, we have taken into account the merits of Petitioner's challenges and find that this favors institution.

In sum, based on our consideration of the foregoing factors, we decline to exercise our discretion under § 314(a) to deny institution.

B. Claim Construction

In this proceeding, the claims of the '380 patent are construed "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b)." 37 C.F.R. § 42.100(b). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

For purposes of this Decision, we address two terms of the '380 patent: "means for guiding" and "means for receiving . . . and guiding."

1. Means for Guiding

Claim 25 requires a "means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel." Ex. 1201, 13:44–46. Both parties agree that this "means for guiding" is a means-plus-function claim term and that the corresponding structure is a guide catheter. Pet. 15–16; Prelim. Resp. 16. We agree and adopt this construction for purposes of this decision. Ex. 1201, 3:9–12 ("The present invention is a coaxial guide catheter that is deliverable through standard guide catheters . . . .").

2. Means for Receiving and Guiding

Claims 25 also requires a

> *means for receiving* the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel *and guiding the interventional device deeper into the branch vessel*,
>
> *the means for receiving* the interventional device *and guiding the interventional device deeper into the branch vesse*l including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,

> wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and
>
> the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion.

Ex. 1201, 13:47–14:5 (emphases added). The parties dispute whether the "means for receiving the interventional device . . . and guiding the interventional device deeper into the branch vessel" is a means-plus-function limitation and, if so, what structure described in the Specification corresponds to this claim limitation. Pet. 16–17; Prelim. Resp. 16–21.

"Section 112, paragraph 6, allows a patentee to express a claim limitation by reciting a function to be performed rather than by reciting structure or materials for performing that function." *Northrop Grumman Corp. v. Intel Corp*., 325 F.3d 1346, 1350 (Fed. Cir. 2003). A term written in means-plus-function form is construed to cover "the corresponding structure, materials, or acts described in the specification and equivalents thereof" for performing the recited functions. 35 U.S.C. § 112, para. 6.

Use of the term "means" creates a rebuttable presumption that a claim term is a means-plus-function limitation. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). This presumption may be rebutted if the claim recites structure sufficient to perform the described functions in their entirety. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate

understanding of the structure." *Id.* at 1259–60; *see Inventio AG v. ThyssenKrupp Elevator Ams. Corp.*, 649 F.3d 1350, 1357 (Fed. Cir. 2011) (noting that one may still consider the written description to "inform the analysis of whether the claim recites sufficiently definite structure to overcome the presumption that § 112, ¶ 6 governs the construction of the claim") (*overruled on other grounds by Williamson*, 792 F.3d at 1339).

Petitioner contends claim 25 recites the basic components of the coaxial guide catheter that are described in the specification of the '380 patent, including "a tip portion, a reinforced portion, a side opening, and a substantially rigid portion." Pet. 16. Petitioner also contends claim 25 specifies the length (longer than the guide catheter), the size (configured to be passed through the lumen of the guide catheter), and properties of the device (having a more rigid side opening and substantially rigid portion than the tip portion). *Id.* (citing Ex. 1201, 13:55–14:5; Ex. 1205 ¶¶ 147–149). According to Petitioner, the detailed recitation of structure in claim 25 describing the "means for receiving" overcomes the presumption that claim 25 is a means-plus-function limitation. *Id.*

Patent Owner contends the structure recited in claim 25 is not sufficient to perform the recited function of receiving an interventional device and guiding it deeper into the branch vessel. Prelim. Resp. 17–18. In particular, Patent Owner contends claim 25 does not recite a tubular structure with a lumen into which an interventional device can be received and be guided "deeper into the branch vessel," which is necessary to achieve the recited functions of claim 25. *Id.* at 17.

The "means for receiving" in claim 25 must perform two functions. First, it must be capable of receiving an interventional device from an

intermediate or distal portion of the means for guiding. Second, it must be capable of directing this interventional device deeper into the branch vessel. As noted by Petitioner, claim 25 provides an extensive recitation of structure for the "means for receiving." Pet. 16. Whether the structures identified in claim 25 are sufficient to perform the two recited functions of the means for receiving and guiding, however, is a disputed, material issue of fact that is addressed by both parties' experts. *See* Ex. 1205 ¶¶ 146–149; Ex. 2042 ¶ 21 (Keith Declaration). Accordingly, this issue is best resolved upon a full trial record. *See* 37 C.F.R. § 42.108(c) ("[A] genuine issue of material fact created by such 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.").

Because a claim must be construed in order to address questions of unpatentability, and in view of the presumption that use of the term "means" invokes § 112, ¶ 6, we preliminarily construe "the means for receiving . . . and guiding" recited in claim 25 as a means-plus-function claim term.

Construction of means-plus-function claim terms is a two-step processes. *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). First, we determine the claimed function. *Id.* Second, "we identify the corresponding structure in the written description of the patent that performs the function." *Id.*; *see Williamson*, 792 F.3d at 1351. "Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim." *Williamson*, 792 F.3d at 1352. In conducting this analysis, we may not incorporate structure from the written description beyond that which is necessary to perform the claimed function(s). *See*

Micro Chemical, Inc. v. Great Plains Chemical Co., 194 F.3d 1250, 1258 (Fed. Cir. 1999).

To the extent the "means for receiving . . . and guiding" is construed as a means-plus-function claim limitation, Petitioner contends "[t]he corresponding structure for the claimed function of receiving and guiding an interventional device deeper into a branch vessel is simply a coaxial guide catheter." Pet. 17 (citing Ex. 1205 ¶¶ 144–145). Although Petitioner concedes that other structural elements of coaxial guide catheters are described in the various embodiments of the '380 patent, Petitioner contends these structures may not be construed as corresponding structure because the Specification merely indicates that these structures "may" be used, i.e., that they are not necessary to perform the recited functions. *Id.*

Patent Owner contends the relevant corresponding structure is a "coaxial guide catheter having a tubular portion with a single lumen that is circular in cross-section, which is attached and coaxially aligned at its distal end to a tip having a lumen with a circular cross-section, and attached at its proximal end to a substantially rigid pushrod structure." Prelim. Resp. 20–21 (citing Ex. 1201, 3:9–12, 3:50–55, 6:31–37, 10:1–20; Ex. 2042 ¶ 21).

Upon review of the claims and the Specification, we agree with both parties that the means for receiving and guiding in claim 25 is a coaxial guide catheter. On this record, however, we are not persuaded that the additional structural limitations for the coaxial guide catheter asserted by Patent Owner are necessary to perform the recited functions. In particular, Patent Owner does not explain sufficiently why the Specification requires a single lumen or a lumen that is circular in cross-section. Nor do the portions of the '380 Specification cited by Patent Owner clearly indicate that these

structural limitations are required to perform the functions set forth in claim 25. Thus, insofar as we have preliminarily construed the "means for receiving . . . and guiding" in claim 25 as a means-plus-function claim limitation, we determine that the corresponding structure for this claim limitation would be understood to be a "coaxial guide catheter" and equivalents thereof.

C. Claims 25–31, 34–37, and 39 in view of Ressemann

Petitioner contends Ressemann anticipates claims 25–31, 34–37, and 39 of the '380 patent. Pet. 19–45.

1. Ressemann

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

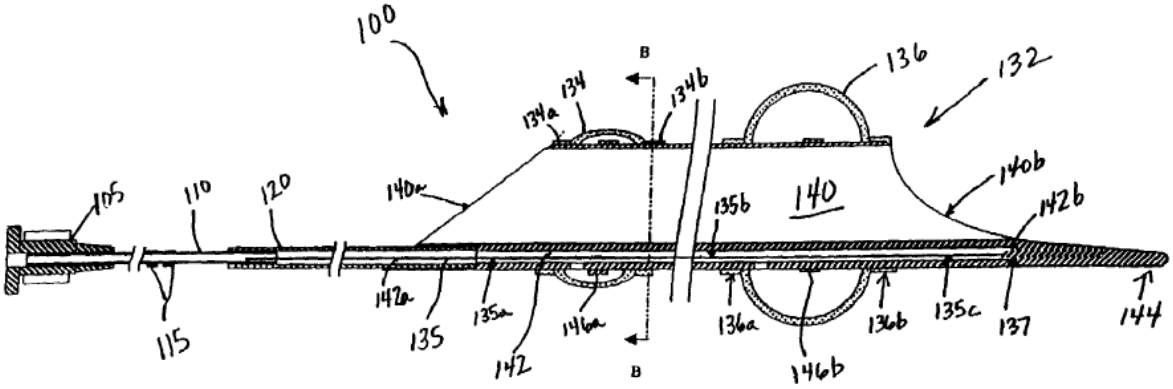

FIG. 1A

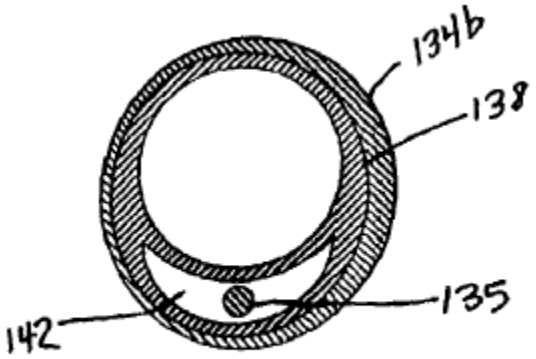

FIG. 1B

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

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

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

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

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

Figure 6D of Ressemann is reproduced below:

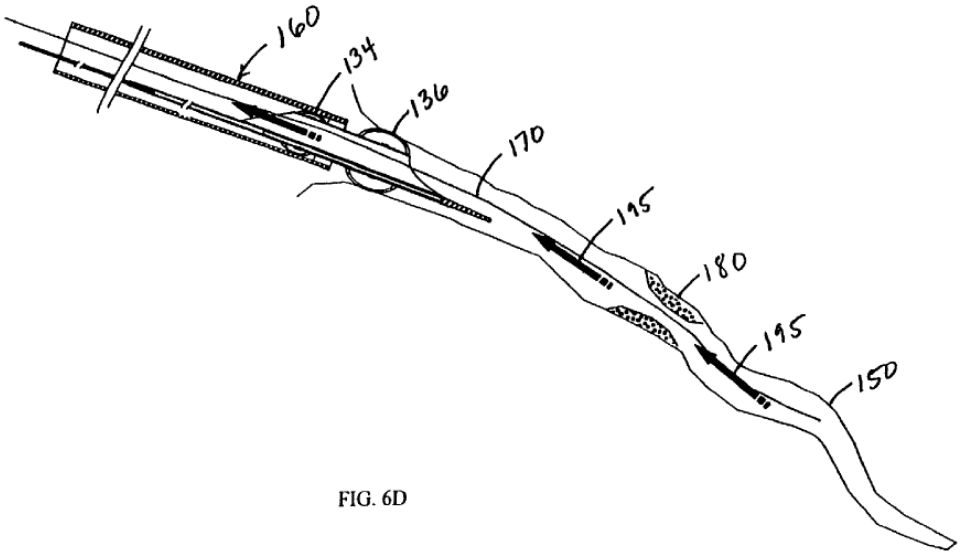

FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. 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 25

Petitioner contends Ressemann discloses every limitation of independent claim 25, including (1) a means for guiding (the guiding catheter) an interventional device from a location outside a subject to a location near an ostium of a branch vessel (Pet. 22–23 (citing Ex. 1208, 6:18–24, 10:17–21, 12:9–30, Figs. 6A–6I)); (2) a means for receiving (evacuation assembly 100) the interventional device from an intermediate or distal portion of the guide catheter and guiding the interventional device deeper into the branch vessel (*id.* at 23–25 (citing Ex. 1208, 12:9–14:10, 27:22–36, 27:51–53, 28:33–46, Figs. 6A–6F; Ex. 1205 ¶ 181)); (3) the means for receiving including a tip portion, a reinforced portion, a side opening, and a substantially rigid portion (*id.* at 25–28 (citing Ex. 1208, 6:19–24, 6:42–53, 6:66–7:18, 11:20–25, 11:29–35, 23:8–20, 24:20–32, 28:46–49, Figs. 1C, 6A–6F; Ex. 1205 ¶ 182; Ex. 1242 ¶¶ 77–78)); (4) the means for receiving having a length such that when it is extended distally of the means for guiding, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for

guiding (*id.* at 28–29 (citing Ex. 1208, 12:45–49, 22:31–37, 22:49–52, 27:22–36, 28:46–55, Fig. 5A; Ex. 1205 ¶ 183)); (5) wherein the tip portion, reinforced portion, side opening, and substantially rigid portion of the means for receiving are configured to be passed, at least in part, into the lumen of the guide catheter (means for guiding) to the location near the ostium of the branch vessel (*id.* at 29–30 (citing Ex. 1208, 6:18–24, 28:46–49, Fig. 6B; Ex. 1205 ¶ 184)); and (6) wherein the side opening and substantially rigid portion of the means for receiving are configured to be more rigid along a length thereof than the tip portion (*id.* at 30–32 (citing Ex. 1208, 6:19–24, 11:20–25, 22:33–37, 22:54–58, 24:20–32, 24:47–67; Ex. 1205 ¶ 185; Ex. 1242 ¶ 83)).

Patent Owner contends Petitioner's anticipation ground based on Ressemann fails for two reasons. Prelim. Resp. 34–39. First, Patent Owner contends Petitioner fails to demonstrate that Ressemann discloses structure that is the same as, or equivalent to, the structure disclosed in the '380 patent Specification for performing the claimed functions of "receiving the interventional device from an intermediate or distal portion of the means for guiding" and "guiding the interventional device deeper into the branch vessel." *Id.* at 34. According to Patent Owner, "failure to provide this analysis, which is necessary under the proper claim construction, is fatal to [Petitioner's] IPR petition." *Id.*

On this record, we are not persuaded by Patent Owner's argument because Petitioner identifies corresponding structure for the identified claim terms. Pet. 24. In particular, to the extent this claim term is construed to be a means-plus-function term, Petitioner identifies the corresponding structure as a "coaxial guide catheter" and asserts that Ressemann's evacuation

assembly 100 is a "coaxial guide catheter" that performs the functions recited in claim 25. *Id.* at 17, 24–25.

Second, Patent Owner contends Ressemann's evacuation assembly does not satisfy the "means for receiving" limitation because it does not have a tubular portion with a single lumen that is coaxial with the lumen of the guide catheter. Prelim. Resp. 35–38. According to Patent Owner, evacuation assembly 100 is not an equivalent structure because a single lumen tubular portion that is coaxial with the guide catheter "allows for maximizing the cross-sectional size of the lumen, thereby maintaining as much room as possible for receiving and guiding stent and balloon catheters to a location deep inside coronary anatomy." *Id.* at 38.

To the extent the term "coaxial guide catheter" requires a coaxial lumen, Petitioner presents evidence that Ressemann's evacuation sheath assembly with a non-coaxial lumen performs the same function ("receiving" and "guiding"), in substantially the same way (receiving an interventional cardiology device and guiding it through this lumen), to achieve substantially the same result (receiving and guiding an interventional cardiology device deeper into a blood vessel). Although Patent Owner contends it does not do so in the optimal fashion, this is not required to find structural equivalency. *See Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999) (explaining that structural equivalence under § 112 ¶ 6 is met when the allegedly equivalent structure "performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification"). In any event, Patent Owner's arguments raise a factual issue for trial, i.e.,

whether a guide catheter with a non-coaxial lumen is an equivalent of a guide catheter with a coaxial lumen.

In view of the foregoing, we determine that Petitioner has demonstrated a reasonable likelihood that claim 25 of the '380 patent is anticipated by Ressemann.

3. Claims 26–31, 34–37, and 39

Petitioner contends Ressemann also discloses every limitation of challenged claims 26–31, 34–37, and 39. Pet. 32–45. In support, Petitioner identifies where Ressemann discloses a side opening including at least two different inclined slopes (claims 26–27), a side opening having an arcuate cross-sectional shape that extends "less than 180º of a full circumference" (claim 28), a portion of a side opening having an arcuate cross-sectional shape that extends 25% to 40% of a full circumference (claim 29), a side opening that includes a portion having a hemicylindrical cross-sectional shape that is between the arcuate cross-sectional shape and the full circumference cross-sectional shape (claim 30), and a reinforced portion that has one or more braided elements embedded in a polymer (claim 31). *Id.* at 32–37. Petitioner also identifies where Ressemann discloses a "means for receiving" that has a concave track along a portion thereof (claim 34), a side opening that is incorporated with the distal end of the substantially rigid portion (claim 35) and the proximal end of the reinforced portion (claim 36), three different sections having a different structural modulus (claim 37), and a distal portion that is configured to anchor within the ostium and resist axial and shear forces (claim 39). *Id.* at 37–45.

Patent Owner does not directly address Petitioner's arguments with respect to challenged claims 26–31, 34–37, and 39.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner has identified sufficiently where Ressemann discloses every limitation of challenged claims 26–31, 34–37, and 39. Accordingly, Petitioner has demonstrated a reasonable likelihood that claims 26–31, 34–37, and 39 are anticipated by Ressemann.

D. Claims 25, 26, 28–30, 32–37, and 39 in view of Itou

Petitioner contends Itou anticipates claims 25, 26, 28–30, 32–37, and 39 of the '380 patent. Pet. 63–81.

1. Itou

Itou discloses "an intravascular foreign matter suction assembly for sucking a foreign matter existing in a blood vessel." Ex. 1207, 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 1:53–65.

Figure 3 of Itou is reproduced below:

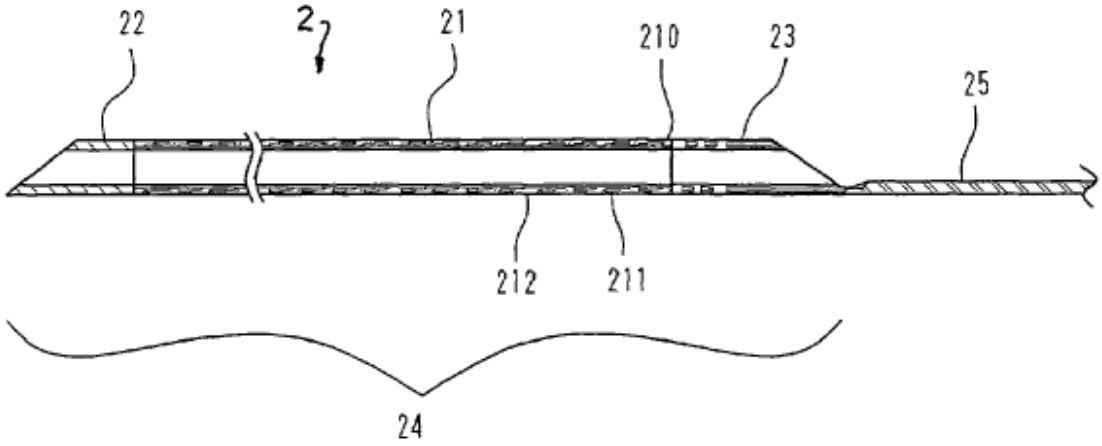

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, "formed from a solid metal wire and an outer layer such as a polymer coating." *Id.* at 3:46–50. Tubular portion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

has a distal tip 22 that is flexible and a reinforced tubular portion 21. *Id.* at 2:15–51, 3:50–58. The outer diameter of tubular portion 24 is selected to allow 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

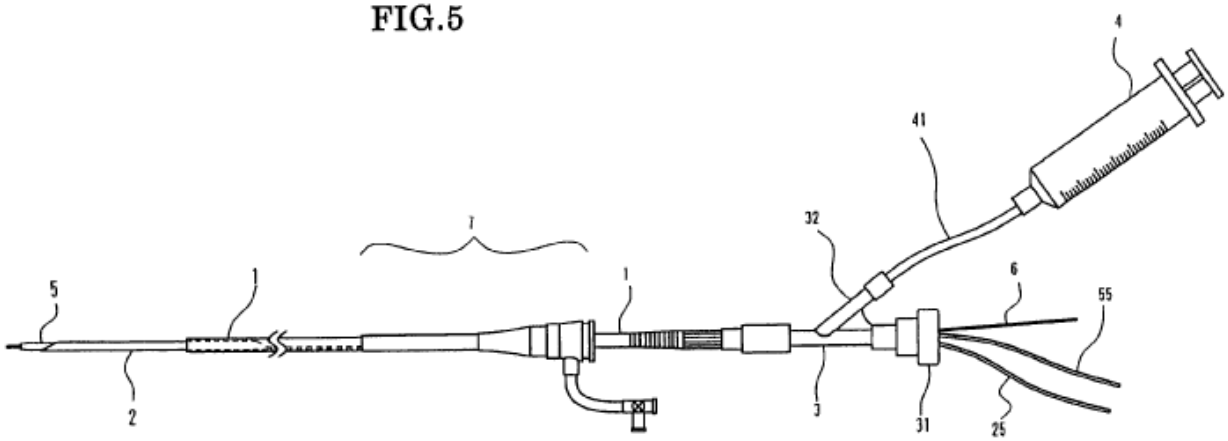

Figure 5 shows the suction assembly "in an assembled state." *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of distal end protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted in 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," which has a valve built therein. *Id.* at 5:17–20. 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:

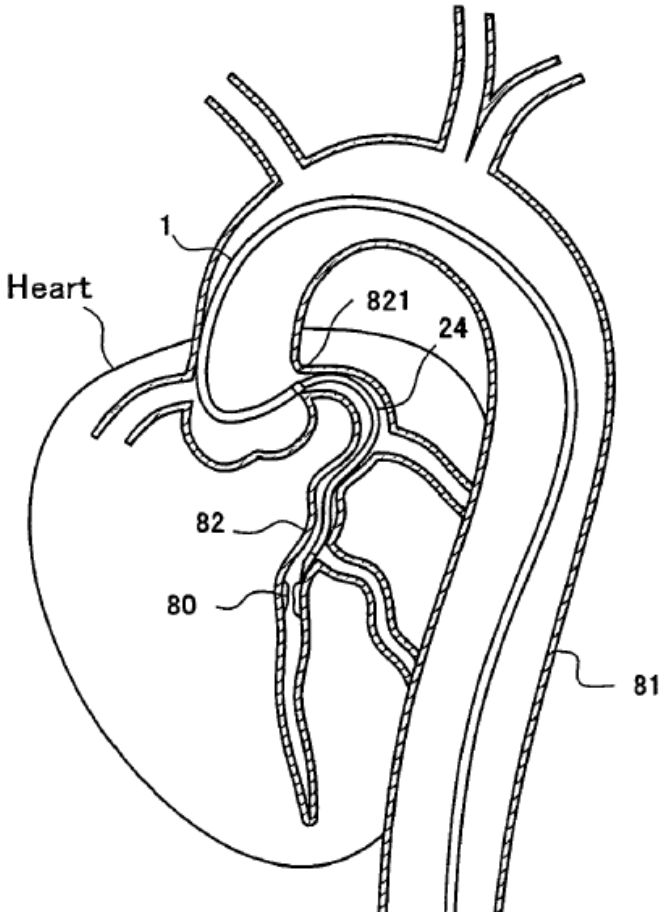

Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end "is secured in such a form that it is hooked at an ostium 821 of coronary artery 82." *Id.* at 5:29–34. Tubular portion 24 of suction catheter 2 is inserted into coronary artery 82 and introduced along guide wire 6 to target location 80 in coronary artery 82. *Id.* at 5:35–38.

2. Independent Claim 25

Independent claim 25 requires a "means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel." Ex. 1201, 13:47–50. Petitioner identifies Itou's guide

catheter as the means for guiding the interventional device to the location near the ostium of the branch vessel (Pet. 66), Itou's suction catheter as the means for receiving the interventional device (*id.* at 66–67), and Itou's end protective catheter as the interventional device (*id.* at 67–68).

As noted by Patent Owner, in Itou's disclosed embodiment, the suction catheter and interventional device (end protective catheter) are inserted into the guide catheter outside of the body and then the entire assembled structure is inserted into the patient. Prelim. Resp. 43–44 (citing Ex. 1207, 4:64–7:8; Ex. 2042 ¶ 37). Petitioner does not explain sufficiently why this disclosure teaches or suggests the limitations of claim 25. Nor does Petitioner persuasively explain why the suction catheter is inherently configured to receive the end protective catheter from an intermediate or distal portion of the guide catheter when it is disposed in a branch vessel. Ex. 1201, 13:47–51 (requiring receiving the interventional device from an intermediate or distal portion of the means for guiding and guiding the device "*deeper* into the branch vessel"). Accordingly, on this record, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that claim 25 is anticipated by Itou. Claims 26, 28–30, 32–37, and 39 of the '380 patent all depend, directly or indirectly, from claim 25. Because Petitioner's arguments do not resolve the issue noted above, Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to any of challenged claims 25, 26, 28–30, 32–37, and 39.[8]

[8] The parties dispute whether Itou is prior art to the '380 patent. *See* Pet. 12–13; Prelim. Resp. 39–46. We do not need to address this issue because we have determined that Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to its Itou-based grounds.

E. Claim 31 over Itou, Claim 27 over Itou and Kataishi, and Claim 38 over Itou and Berg

Petitioner contends that the subject matter of claims 27, 31, and 38 would have been obvious over the disclosures of Itou (claim 31), Itou and Kataishi (claim 27), and Itou and Berg (claim 38). Pet. 81–87. Petitioner's arguments with respect to these claims, however, do not resolve the deficiencies noted above for independent claim 25. Thus, for the reasons discussed above, Petitioner has not demonstrated a reasonable likelihood of prevailing on its obviousness grounds based on Itou.

F. Claim 27 over Ressemann, Ressemann and Kataishi, or Ressemann and Enger

Claim 27 depends from claim 26 and further requires "wherein the side opening includes at least two different inclined slopes." Ex. 1201, 14:8–9. Petitioner contends the subject matter of claim 27 is taught or suggested by (1) Ressemann, (2) Ressemann and Kataishi, and (3) Ressemann and Enger. Pet. 45–56.

Because Petitioner demonstrates a reasonable likelihood that claim 27 is anticipated by Ressemann, we need not address its additional obviousness grounds directed to this claim.

G. Claims 32 and 33 over Ressemann and Takahashi

Claim 32 depends from claim 25 and further requires that the inner diameter of the means for receiving and guiding is "not more than one French smaller than a second inner diameter of the lumen of the means for guiding." Ex. 1201, 14:25–31. Claim 33 depends from claim 32 and further requires that the lumen of the means for receiving and guiding "is configured to receive a stent and a balloon catheter." *Id.* at 14:32–35.

Petitioner contends the subject matter of claims 32 and 33 would have been obvious over the combined disclosures of Ressemann and Takahashi. Pet. 56–59.

1. Takahashi

Takahashi discloses a "five-in-six" system wherein a 5 French guiding catheter is inserted into a 6 French guiding catheter to provide increased backup support. Ex. 1210, 452.[9] In this system, the inner lumen of the 5 French catheter is 0.059 inches and the inner lumen of the 6 French catheter is 0.071 inches. *Id.* The 5 French catheter is 120 cm in length, whereas the 6 French catheter is 100 cm in length. *Id.* According to Takahashi, the 5 French catheter generates "stronger backup support" for the 6 French catheter and the soft end portion of the 5 French catheter "can easily negotiate the tortuous coronary artery with minimal damage" and be "inserted more deeply into the artery." *Id.*

2. Analysis

Petitioner concedes that Ressemann "does not teach the not-more-than-one-French differential" recited in claim 32, but asserts Takahashi discloses such a differential. Pet. 57. According to Petitioner, one of ordinary skill in the art would have sought to adopt this differential in Ressemann because Takahashi discloses that this differential provides "better back-up support for the guide catheter, and assists in deploying an angioplasty catheter across chronic total occlusions." *Id.* at 59 (citing Ex. 1210, 452, 454, 456; Ex. 1205 ¶¶ 220–221).

[9] Our citations to Takahashi are to the original page numbers of the document and not the page numbers added by Petitioner.

With respect to claim 33, Petitioner contends "Ressemann teaches using the lumen of evacuation assembly 100 to receive a stent and a balloon catheter." *Id.* (citing Ex. 1208, 13:55–14:19, 23:8–20, Figs. 6E–6G).

Patent Owner does not directly address Petitioner's arguments with respect to claims 32 and 33.

Petitioner's proposed combination would require multiple modifications to Ressemann's system, including using a smaller guide catheter, eliminating Ressemann's sealing balloons, and replacing the "inflation lumen with a solid pushrod or wire, such that Ressemann could be used as an extension catheter." Pet. 57–59. These modifications would extinguish the capability of the device to act as an aspiration catheter. *Id.* at 58. We question whether Petitioner has adequately supported such sweeping changes to Ressemann's system, and this is an issue the parties may address during trial.

H. Claim 38 over Ressemann and Berg

Claim 38 depends from claim 37 and further requires "wherein the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI." Ex. 1201, 14:53–57. Petitioner contends the subject matter of claim 38 would have been obvious over the combined disclosures of Ressemann and Berg. Pet. 60–63.

1. Berg

Berg discloses a "guiding catheter for use in coronary angioplasty and other cardiovascular interventions." Ex. 1251, Abstract. In particular, Berg discloses a guide catheter "having a transition zone with a different

flexibility than adjacent portions of the catheter shaft for improved catheter performance." *Id.* at 1:21–25.

Berg notes that in order for a physician to place a catheter at the correct location in a blood vessel, the physician must apply longitudinal and rotational forces. *Id.* at 1:49–51. Thus, the catheter must be rigid enough to push through the blood vessel and torsionally rigid enough to transmit the applied torque, but flexible enough to navigate the bends in the blood vessel. *Id.* at 1:49–56. Berg also notes that "it is preferable to have a soft tip or flexible section engage the ostium," which "provides a less traumatic section to the blood vessel." *Id.* at 1:63–2:4. A problem that occurs, however, is that the use of more flexible tips may increase the incidence of guide catheter back-out, i.e., when the guide catheter disengages from its preferred positioning in the coronary ostium. *Id.* at 2:11–15.

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

Fig.19

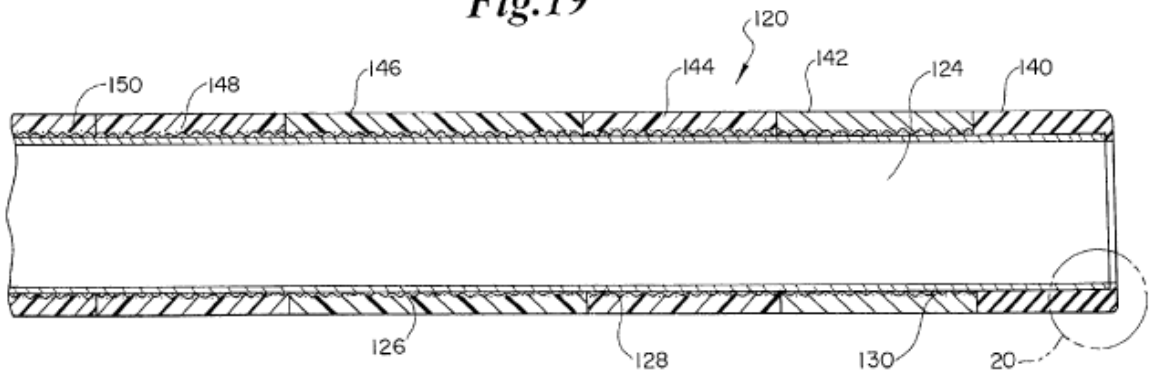

Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a

plurality of discrete outer tubular member segments 140, 142, 144, 146, 148, and 150. *Id.* at 13:53–55. Soft tip zone 140 has a flexural modulus of "about 1 to about 15 Kpsi"; distal section zone outer tubular segment 142 has a flexural modulus of "between about 2 and about 49 Kpsi"; transition zone outer tubular segment 144 has a flexural modulus of "between about 13 and about 49 Kpsi"; secondary curve zone outer tubular segment 146 has a flexural modulus of "greater than 49 Kpsi"; mid-shaft zone outer tubular segment 148 has a flexural modulus of "about 29 to about 67 Kpsi"; and proximal shaft zone outer tubular segment 150 has a flexural modulus of "greater than 49 Kpsi to provide maximum stiffness for push and control." *Id.* at 13:66–15:6.

2. Analysis

Petitioner contends Berg discloses a guide catheter with increasing rigidity in a distal to proximal direction and expressly discloses flexural moduli that overlap with the ranges recited in claim 38. Pet. 60–62. Petitioner further contends that one of ordinary skill in the art would have used the flexural moduli disclosed in Berg because Berg discloses that these flexural moduli allow for "flexiblity of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out." *Id.* at 62 (citing Ex. 1251, 2:37–39; Ex. 1244, 1:36–38).

Patent Owner does not directly address Petitioner's arguments with respect to claim 38, but contends the obviousness grounds should be denied in light of Petitioner's failure to address known objective evidence of non-obviousness. Prelim. Resp. 46. 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. 49. In support, Patent Owner directs our attention to an expert report submitted in the QXM case that maps the claims to its GuideLiner product. *Id.* at 48 (citing Ex. 2056 ¶¶ 160–163, 166 (referencing App'x J (448–453), App'x K (495–502, App'x L (540–546))). Patent Owner provides no persuasive analysis, however, to explain why the claims of the '380 patent are *coextensive* with its GuideLiner product. *See Fox Factory*, 944 F.3d at 1373. Moreover, the expert report relied upon by Patent Owner indicates that Patent Owner's GuideLiner product embodies the claims of at least five other patents. Ex. 2056 ¶¶ 164–168. In this situation, a presumption of nexus is appropriate only if Patent Owner demonstrates that the claims of all five patents "generally cover the same invention." *Fox Factory*, 944 F.3d at 1377. Patent Owner does not attempt to demonstrate this fact. *See* Ex. 1288, 11–12 (noting the existence of two different versions of catheters: "over-the-wire" and "rapid-exchange"). Indeed, that Patent Owner sought patent protection for each of these five

patents suggests that these patents do not generally cover the same invention.[10] *Fox Factory*, 944 F.3d at 1378. Thus, on this record, a presumption of nexus does not apply.

Patent Owner also asserts that it has sufficiently demonstrated nexus between its objective evidence and the claimed invention. Prelim. Resp. 49–50. But, as noted above, Patent Owner asserts that a nexus exists for multiple patents. In this situation, "the patentee retains the burden of proving the degree to which evidence of secondary considerations tied to a product is attributable to a particular claimed invention." *Fox Factory*, 944 F.3d at 1378. Patent Owner has not done so on the record before us at this time.

Moreover, the question of nexus is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Id.* at 1373. Thus, here, as in most cases, an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage.

Upon review of Petitioner's arguments and supporting evidence, we determine that Petitioner has sufficiently identified where Berg discloses flexular moduli that overlap those recited in claim 38 and has explained why one of ordinary skill in the art would have looked to Berg's moduli for use with Ressemann's catheter. Accordingly, Petitioner has demonstrated a reasonable likelihood that claim 38 would have been obvious over Ressemann and Berg. *See E.I. DuPont de Nemours & Co. v. Synvina C.V.*,

[10] Several identified patents are terminally disclaimed. *See* Ex. 1201, code (45). Patent Owner does not assert, however, that *all* of the identified patents are terminally disclaimed to the same patent.

904 F.3d 996, 1006 (Fed. Cir. 2018) (noting that a "presumption of obviousness" is created when the ranges of a claimed composition overlap the ranges disclosed in the prior art).

I. 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. 58 (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.

CONCLUSION

In view of the foregoing, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one challenged claim of the '380 patent. Thus, we institute review of all challenged claims on all asserted grounds set forth in the Petition.

ORDER

It is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on all challenged claims of the '380 patent and on all asserted grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is hereby given of the institution of trial, which shall commence on the entry date of this decision.

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