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Paper No. 20
Date: June 26, 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.

IPR2020-00127
Patent 8,048,032 B2

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, 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 1–9 and 11–20 of U.S. Patent No. 8,048,032 ("the '032 patent," Ex. 1401). Paper 3 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response. Paper 10 ("Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply addressing Petitioner's burden on those issues. Paper 14; Paper 15. Also pursuant to our authorization, Petitioner filed another Reply (Paper 17) and Patent Owner filed another Sur-Reply (Paper 18) addressing the factors for discretionary denial under 35 U.S.C. § 314(a).

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2012). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) ("*SAS*"). After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted.

A. Real Parties in Interest

Petitioner identifies its real parties-in-interest as Medtronic, Inc. and Medtronic Vascular, Inc., and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 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 4, 2. Patent Owner also notes that "Teleflex Incorporated is the ultimate parent of the entities listed above."

B. Related Matters

Petitioner has filed a separate Petition for *inter partes* review of claims 1–20 and 22 of the '032 patent as IPR2020-00126. We instituted *inter partes* review in IPR2020-00126 on June 9, 2020. IPR2020-00126, Paper 22.

The parties indicate that the '032 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 4, 2.

The '032 patent was the subject of two previous *inter partes* reviews: IPR2014-00760, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate, and IPR2014-00761, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate. Paper 4, 2–3.

C. The '032 Patent

1. Specification

The '032 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on November 1, 2011, from a non-provisional application filed May 3, 2006. Ex. 1401, codes (45), (54), (22).

The '032 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1401, Abstract. According to the

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

To solve this problem, the ’032 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 2:53–56. The ’032 patent teaches that the coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 2:57–61. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the ’032 patent:

Fig. 1

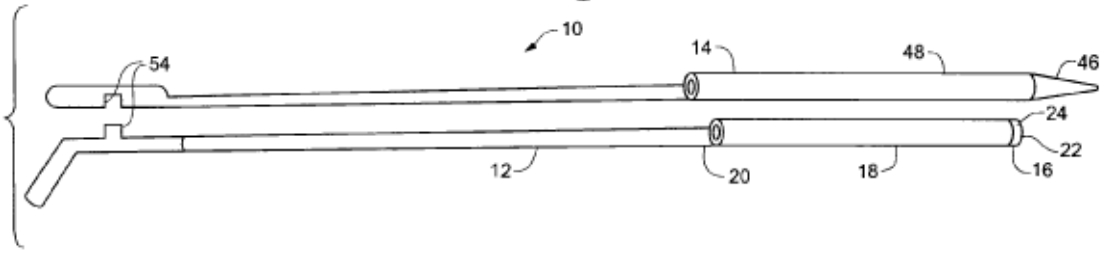


Fig. 2

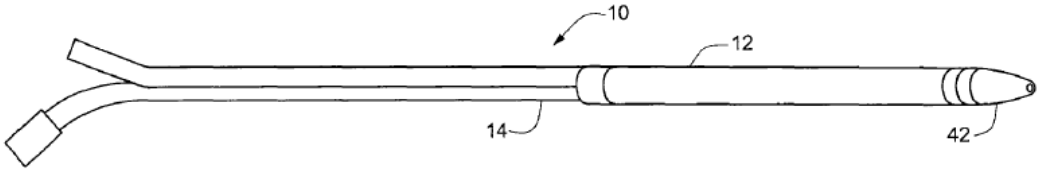


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:15–21; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:6–8. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:9–10. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:13–14. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:14–15. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:19–20. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:59–60. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:60–61. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 6:64–67.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:12–13. The coaxial guide catheter/

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

2. Illustrative Claims

Independent claims 1 and 11, reproduced below, are illustrative of the challenged claims.

> 1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:
>
> a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a

coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

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

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

11. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-

> sectional inner diameter through which interventional cardiology devices are insertable;
>
> a reinforced portion proximal to the flexible tip portion; and
>
> a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,
>
> such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

Ex. 1401, 10:21–54, 11:28–12:4.

D. Evidence

Petitioner relies upon the following prior art references.

Ex. 1409, S. B. Kontos, U.S. Patent No. 5,439,445 (issued Aug. 8, 1995) ("Kontos").

Ex. 1410, *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63: 452-456 (2004) ("Takahashi").

Ex. 1435, D. O. Adams et al., U.S. Patent Application Publication No. 2004/0010280 A1 (published Jan. 15, 2004) ("Adams").

Ex. 1451, T. A. Berg et al., U.S. Patent No. 5,911,715 (issued Jun. 15, 1999) ("Berg").

Petitioner relies upon the Declarations of Dr. Stephen Brecker (Ex. 1405) and Dr. Richard Hillstead (Ex. 1442) in support of its Petition.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–9 and 11–20 would have been unpatentable on the following grounds.

Ground	Claim(s)	35 U.S.C. §[1]	References/Basis
1	1–7, 9, 11–16, 18, 19	103(a)	Kontos, Adams, Knowledge of a POSITA
2	8, 17	103(a)	Kontos, Adams, Takahashi, Knowledge of a POSITA
3	20	103(a)	Kontos, Adams, Berg, Knowledge of a POSITA

II. ANALYSIS

A. 35 U.S.C. § 314

1. Multiple Petitions

Petitioner filed another petition for *inter partes* review of the '032 patent in IPR2020-00126 and, as noted above, we instituted review based on that petition. IPR2020-00126, Paper 22. The petition in IPR2020-

[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 '032 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.

00126 challenges claims 1–20 and 22 of the '032 patent (*id.*), while the current Petition challenges claims 1–9 and 11–20.

Petitioner relies on Itou[2] in every ground of unpatentability in IPR2020-00126, whereas the current Petition relies upon Kontos in every ground of unpatentability. IPR2020-00126, Paper 1, 8; Pet. 7. Petitioner contends the current Petition is needed to address challenged claims 1–9 and 11–20 of the '032 patent because Patent Owner asserts Itou is not prior art to the '032 patent under § 102(e), but does not dispute that Kontos is § 102(b) prior art. IPR2020-00126, Paper 3, 1–3.

The *Consolidated Trial Practice Guide* (November 2019)[3] explains that "there may be circumstances in which more than one petition may be necessary, including, for example, . . . when there is a dispute about priority date requiring arguments under multiple prior art references." Trial Practice Guide at 59. "In such cases two petitions by a petitioner may be needed, although this should be rare." *Id.* The Trial Practice Guide further instructs that "it is unlikely that circumstances will arise where three or more petitions by a petitioner with respect to a particular patent will be appropriate." *Id.*

Institution in this case would result in two concurrent *inter partes* review proceedings directed to the '032 patent. Thus, Petitioner must demonstrate that this is one of the "unlikely" and "rare" situations where two petitions against the same patent are justified. As noted above, the Trial Practice Guide instructs that "more than one petition may be necessary . . . when there is a dispute about priority date requiring arguments under multiple prior art references." *Id.* Here, IPR2020-00126 addresses grounds

[2] Ex. 1407, Itou, US 7,736,355 B2, issued June 15, 2010 ("Itou").

[3] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

based on Itou, a § 102(e) reference, and the current Petition addresses grounds based on Kontos, a § 102(b) reference. Given the possibility that we may determine that Itou does not qualify as prior art after fully considering Patent Owner's priority date arguments, this is precisely one of the circumstances recognized in our Trial Practice Guide "in which more than one petition may be necessary." Consolidated Practice Guide at 59. Moreover, the challenges presented in IPR2020-00126 and the current Petition do not significantly overlap with each other. For example, the obviousness challenges in the present Petition require an assessment of motivation to combine Kontos and Adams, which is not relevant to the anticipation and obviousness challenges presented in IPR2020-00126. Thus, we find that the current Petition presents a circumstance where a second petition against the same patent is justified.

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 '032 patent and other related patents is the subject of active litigation in two separate district court cases, the *QXM* case and the *Medtronic* case, which are both currently pending in the District of Minnesota. *Id.* at 12.

In *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential, designated May 7, 2019) ("*NHK*"), the Board considered the fact that a parallel district court proceeding was scheduled to finish before the Board reached a final decision as a factor favoring denial of institution. In the more recently designated precedential

decision *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential, designated May 5, 2020) ("*Fintiv*"), the Board set forth several other factors (the "*Fintiv* Factors") to consider under § 314(a) in determining whether to institute trial when there is parallel, co-pending litigation concerning the same patent: (1) whether a stay of the parallel litigation exists or is likely to be granted if a trial proceeding is instituted by the Board; (2) proximity of the court's trial date to the Board's projected statutory deadline; (3) the investment in the parallel proceeding by the court and parties; (4) the extent of overlap between issues raised in the petition and in the parallel litigation; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) and other circumstances that impact the Board's exercise of discretion, including the merits.

The parties address the *Fintiv* Factors in supplemental briefing that we authorized. Paper 17; Paper 18. 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 17, 2 (citing Ex. 1493). Petitioner also points out that the *QXM* case, involving the '032 patent and other patents in the same family, has already been stayed pending our institution decisions, and the court indicated that if we institute trial "the Court will invite the parties to brief whether the stay should extend through the conclusion of the review process." *Id.* (citing Ex. 1494). 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 18, 1. Patent Owner contends that the *QXM* case was stayed only because QXMédical agreed to exit the market and waived its obviousness/anticipation defenses, and that the district court has not granted stays involving direct competitors or allegations of irreparable harm. *Id.* Having considered the parties position, we determine that *Fintiv* Factor 1 favors institution, especially in view of the fact that a stay has already been granted in the related *QXM* case and the district court's prior history of granting stays pending resolution of related IPRs.

As to the proximity of the court's trial dates to our statutory deadlines (*Fintiv* Factor 2), the parties agree that the district court has indicated that the *Medtronic* case must be "Ready for Trial" by August 1, 2021, which would be a few weeks *after* our statutory deadline for a final written decision in this proceeding and the related IPRs. PO Resp. 23; Paper 17, 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 17, 1 (citing Ex. 1489). Petitioner points out that the district court already extended the original "Ready for Trial" date by two months in the *Medtronic* case, and that a trial date in the *QXM* case was finally set for February 24, 2020—more than ten months after the original "Ready for Trial" set by the court—before that case was stayed pending our institution decision. We determine that *Fintiv* Factor 2 also favors institution, especially given that the trials in the district court cases will not likely take place until after we issue our final written decisions in these proceedings.

Notably, in both the *NHK* and *Fintiv* cases, the trial dates in the parallel litigations were scheduled either before or only a few months after the Board's institution deadlines and before the final written decision deadlines. *See NHK*, IPR2018-00752, Paper 8 at 19 (noting trial date of March 25, 2019, where Board's institution decision was issued September 12, 2018); *Fintiv*, IPR2020-00019, Paper 11 at 1 (noting trial date of November 16, 2020 where Board's institution decision was due May 15, 2020).

As to the amount of investment by the parties and the court in the parallel proceeding (*Fintiv* Factor 3), Patent Owner contends that the district court is already deeply invested and has familiarity with the challenged patents in light of the relatively advanced stage of the *QXM* case. Paper 18, 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. 22. Although we agree that the parties have invested some time and effort in the related litigation, we are not persuaded that those cases are in such an advanced stage that would favor denial of institution. The district court recently denied the preliminary injunction motion filed by Patent Owner, noting that there are substantial questions with respect to the validity of the asserted claims. Ex. 1488, 9–14. However, the district court has not issued a claim construction order or any other substantive order in the *Medtronic* case. *See Fintiv*, Paper 11 at 10 (noting that if "the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*"). We, therefore,

determine that resolution of those common issues by the Board may be beneficial to the resolution of the district court proceedings. Patent Owner also contends that Petitioner delayed bringing these challenges. Paper 18, 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 17, 2; *see Fintiv*, Paper 11 at 11 (noting that "it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding"). We find that Petitioner did not unduly delay filing its IPR Petitions.

We have also considered the remaining *Fintiv* Factors and determine, on balance, that they do not outweigh the foregoing factors in favor of institution. *Fintiv*, Paper 11 at 6 (explaining that when various factors weigh both in favor and against exercising discretion under § 314(a), we take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review"). Petitioner contends that Patent Owner has only asserted a subset of the challenged claims in the *Medtronic* litigation. Paper 17, 1. With respect to *Fintiv* Factor 4 (overlap of issues), Patent Owner responds that there is complete overlap of the issues raised in the parallel proceedings, including the same invalidity prior art and arguments raised in the Petitions. Paper 18, 2. With respect to *Fintiv* Factor 5 (whether the same parties are involved), Patent Owner also points out that Petitioner is the defendant in the *Medtronic* case. *Id.* We find there is an overlap of issues and parties between the *Medtronic* case and this proceeding. In *Fintiv*, the Board noted that "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Fintiv*,

Paper 11 at 13. In this case, however, any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court may stay the parallel litigation and thus not reach the merits of Petitioner's invalidity defenses before we issue our final written decision. Finally, under *Fintiv* Factor 6, we have taken into account the merits of Petitioner's challenges, as discussed above, and find that this favors institution.

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

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 that "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 12. Alternatively, Petitioner asserts that "if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as

mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* Petitioner further asserts that "a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a POSITA with an engineering degree may have access to one with a medical degree." *Id.* at 12–13 (citing Ex. 1405 ¶ 27; Ex. 1442 ¶¶ 18–19).

Patent Owner indicates that "[f]or purposes of this Preliminary Response only, Teleflex does not currently dispute Medtronic's proposed definition of a POSITA." Prelim. Resp. 12.

On this record, in determining whether the evidence of record supports institution, we apply both of Petitioner's definitions for a POSITA, as they are undisputed at this time and consistent with the level of skill reflected in the prior art and the specification of the '032 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). 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 claimed terms, including "standard guide catheter," "placed in a branch artery," "flexural modulus," "interventional cardiology devices." Pet. 13–19. With the exception of "interventional cardiology devices," Patent Owner contends that "no specific construction of [any other term] is necessary for the Board to deny the Petition." Prelim. Resp. 18.

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

1. "interventional cardiology devices"

Independent claims 1 and 11 of the '032 patent recite a standard guide catheter having a continuous lumen sized "such that interventional cardiology devices are insertable into and through the lumen." Ex. 1401, 10:26–27, 11:34–35. To that point, the Specification expressly defines the claim term "interventional cardiology devices" as follows:

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

Id. at 1:17–21.

Petitioner contends that, in the *QXM* litigation, Patent Owner stipulated that the term "interventional cardiology device(s)" means "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." Pet. 13 (citing Ex. 1412, 21; Ex. 1464, 1 n.1). The district court,

however, did not construe the term "interventional cardiology device(s)" in the *QXM* litigation. Ex. 1413 (Claim Construction Order).

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

> requires that at least ***all four enumerated devices*** (guidewires, balloon catheters, stents, and stent catheters) be insertable into the lumen. This construction is based on the plain language of the claims ("interventional cardiology device**s**"), as well as the definition's use of the inclusive conjunction "and."

Prelim. Resp. 14. Patent Owner further contends as follows:

> This construction is . . . consistent with the specification. The Summary of the Invention describes the invention as a "coaxial guide catheter," i.e., a structure that serves the same basic function (delivering interventional cardiology devices) as the guide catheter in which it is placed. Exhibit 1401, 2:53–64. The coaxial guide catheter is contrasted from the tapered inner catheter that is placed within it – among other things, the tapered inner catheter "runs over a standard 0.014 inch coronary guidewire," while the coaxial guide catheter is "typically five to eight French" and has an inner lumen that is preferably only about one French size smaller than the guide catheter. *Id*.; *see also id.* at 3:5–20. The Summary notes that the "invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel." *Id*. at 5:9–12. Merely being sized to receive a guidewire is not enough; the claim language requires that guidewires, stents, stent catheters and balloon catheters be insertable through the claimed coaxial lumen.

Id. at 15.

Having considered the parties' positions and evidence of record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. In the context of independent claims 1 and 11, the lumen of the recited guide

catheter must be sized to receive at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. For example, the diameter of the guide catheter is sized to receive a guidewire and a stent or balloon. *See* Ex. 1401, 7:36–40 ("Once the guidewire **64** is pushed past stenotic lesion 66 or occlusive lesion . . . , a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion . . . ."); *Id.* at 7:42–8:7, Figs. 7–8.

Furthermore, based on the current record, we do not construe the claims to require that more than one of guidewires, stents, stent catheters, and balloon catheters be simultaneously insertable into and through the lumen, although we recognize that certain embodiments disclosed in the Specification show a preference for the use of a guidewire and a stent or balloon. *Id.* at 7:36–40, 7:42–8:7, Figs. 7–8.

Finally, we recognize that the Specification discloses that "the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel" (*id.* at 5:9–12) and that the term "interventional cardiology devices" is not limited to guidewires, balloon catheters, stents and stent catheters (*id.* at 1:17–21). To the extent further discussion of what additional devices may be encompassed by this term is required for the purposes of our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

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. Petitioner's Patentability Challenges

1. Ground 1: Obviousness in view of Kontos, Adams, and the Knowledge of a POSITA

Petitioner asserts that claims 1–7, 9, 11–16, 18, and 19 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos, Adams, and the knowledge of a person of ordinary skill in the art. Pet. 7. For the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1–7, 9, 11–16, 18, and 19 would have been obvious over the combination of Kontos, Adams, and the knowledge of a person of ordinary skill in the art.

a) Summary of the References Relied Upon

(1) Kontos (Ex. 1409)

Kontos is directed to a support catheter assembly for facilitating medical procedures and, in particular, to a catheter assembly that has "particular utility in facilitating insertion of a PTCA[4] balloon into a lesion." Ex. 1409, 1:9–13.

Figure 1 of Kontos is reproduced below:

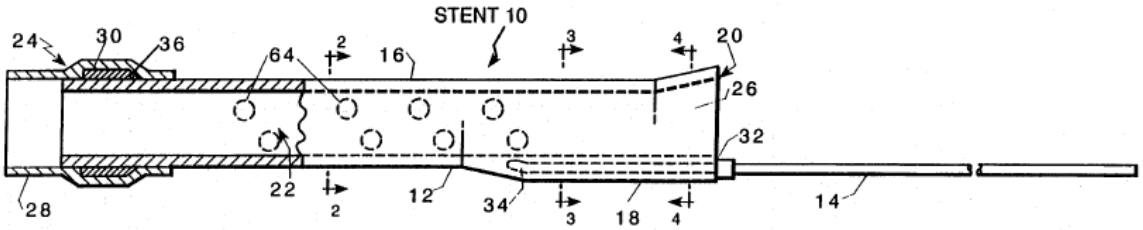


FIG. 1

Figure 1 is a side plan view of a support catheter, "cut-away in part to show in logitudinal cross-section a tubular body having a soft tip and radiopaque marker, and a manipulating wire." Ex. 1409, 2:51–54. As shown in

[4] PTCA stands for "percutaneous transluminal coronary angioplasty." Ex. 1405 ¶ 37.

Figure 1, support catheter assembly 10 is composed of two major elements, body 12 and insertion/manipulation wire 14. *Id.* at 3:45–46. Body 12, "which may be viewed as a mini guide catheter, includes tube 16 having a base portion 18 at its proximal end 20." *Id.* at 3:47–49. "Tube 16 has a continuous lumen 22 therethrough from proximal end 20 to distal end 24." *Id.* at 3:49–50. Body 12 also include a soft tip 28 disposed at distal end 24 and funnel portion 26 disposed at proximal end 20. *Id.* at 3:50–52. Wire 14 is attached to body 12 at base portion 18. *Id.* at 3:52–53. Support assembly 10 may also include distal marker band 30 and proximal marker band 32. *Id.* at 3:53–55.

Kontos explains that the size and shape of the various elements of support assembly 10 "may vary depending on the desired application," but in the applications depicted in Figure 1, tube 16 has a 0.055 inch outer diameter and lumen 22 has a 0.045 inch diameter. *Id.* at 4:46–50. According to Kontos, the sizes used in these embodiments "are generally suitable for existing PTCA catheters." *Id.* at 4:61–64.

Figure 5 of Kontos is reproduced below:

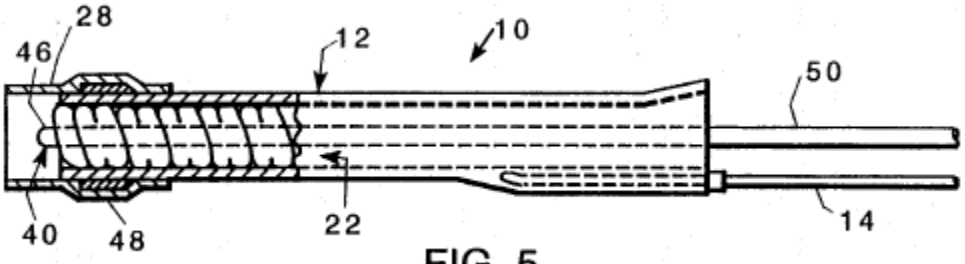
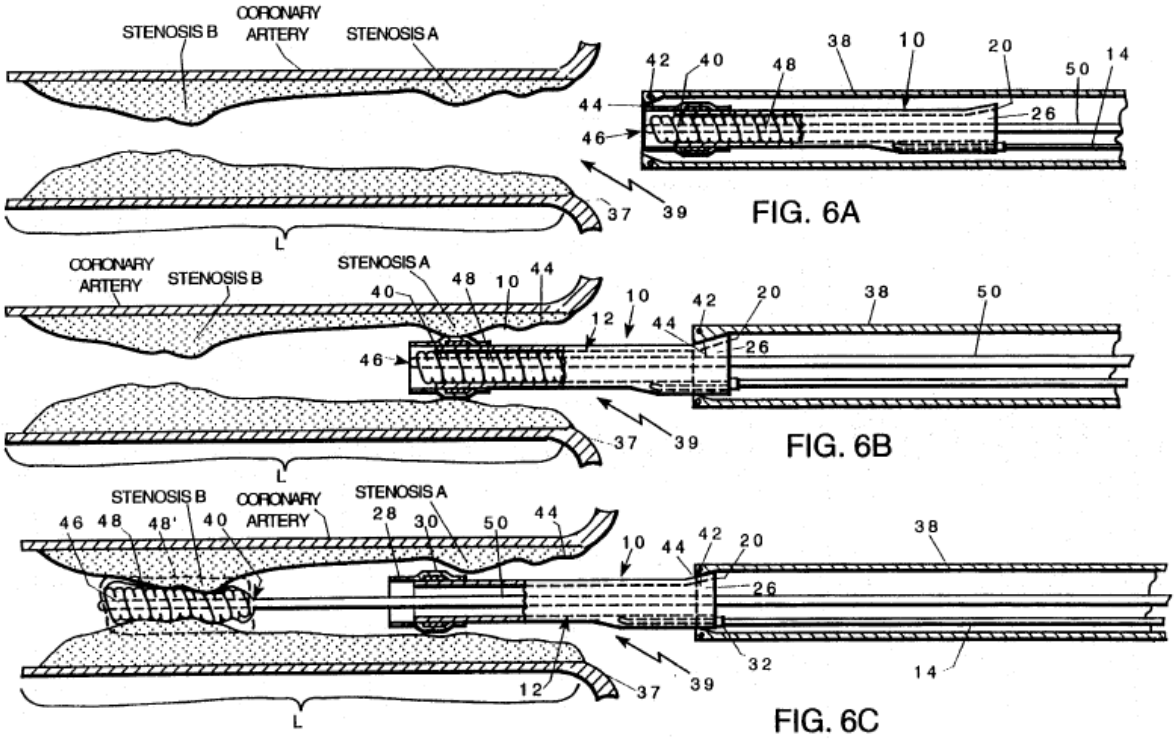


FIG. 5

Figure 5 is a side schematic view of a support catheter having a PTCA catheter disposed therein. *Id.* at 2:64–66. In this figure, PTCA catheter 40 and its deflated balloon 48 reside in lumen 22 of support assembly 10. *Id.* at 5:2–5.

Figures 6A–6C of Kontos are reproduced below:



Figures 6A–6C are cross-sectional views showing three stages in a process for guiding a PTCA catheter to a coronary artery lesion. *Id.* at 2:67–3:2. In Figure 6A, the PTCA catheter/support catheter assembly is fed into guide catheter 38 and advanced to the distal end of this catheter by simultaneously exerting axial force on wire 14 and catheter tube 50. *Id.* at 5:25–30.

In Figure 6B, when the PTCA catheter/support catheter assembly reaches the distal end of guide catheter 38, "it may be advanced as a unit out of the distal end of guide catheter 38 and into coronary ostia 39." *Id.* at 5:31–35. When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension protecting fragile balloon 48 and lessening "considerably the tendency of the PTCA catheter 40 to bend, buckle or kink." *Id.* at 5:49–56.

In Figure 6C, after body 12 has been positioned adjacent the restricted area, PTCA catheter 40 is advanced so that balloon 48 exits body 12 and is

advanced into the restricted area, e.g., stenosis B. *Id.* at 6:9–13. Balloon 48 is then inflated, as represented by dotted lines 48, "to effect a well-known angioplasty procedure." *Id.* at 6:13–15. Balloon 48 is then deflated and PTCA catheter 40, support catheter assembly 10, and guiding catheter 38 may be withdrawn. *Id.* at 6:15–18.

(2) Adams (Ex. 1435)

Adams discloses a device and method for treating vascular disease. Ex. 1435 ¶ 1. In particular, Adams discloses "a distal protection device which is deployed to filter or remove embolic debris" and "creates a seal to prevent the flow of blood during the treatment of vascular disease." *Id.* ¶ 11.

Figure 1A of Adams is reproduced below:

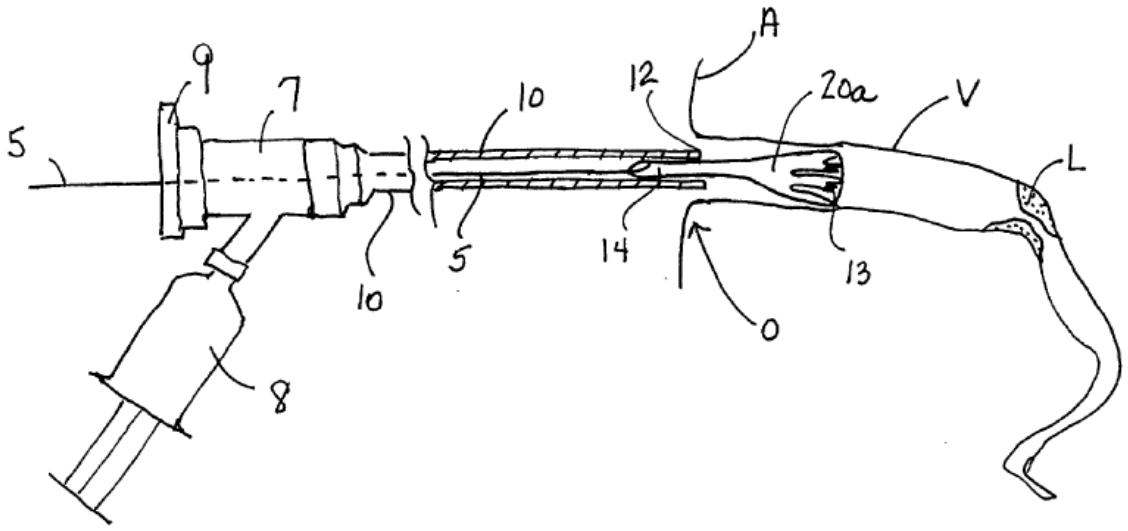


FIG. 1A

Figure 1A is a side view in partial cross-section of the device of Adams. *Id.* ¶ 28. In this figure, Y connector 7 is attached to the proximal end of guide catheter 10 and control wire 5 passes through Y connector 7. *Id.* ¶¶ 59–60. To reduce blood loss, Y connector 7 has hemostasis valve 9 at its proximal end. *Id.* ¶ 60. As shown in Figure 1A, distal end 12 of guide catheter 10 may be inserted into the ostium "O" of coronary vessel "V," which has a

lesion "L." *Id.* ¶ 59. Guide seal 20*a* is then deployed beyond the distal end of guide catheter 10. *Id.*

Adams explains that in practice, a physician advances a guidewire through the femoral artery into the aorta. *Id.* ¶ 61. "The guide catheter is then advanced over the guidewire until the distal tip of the guide catheter is in the ostium of the vessel." *Id.* The guide seal is then advanced beyond the distal tip of the guide catheter and, after some additional steps, an embolic protection device of choice may be advanced through the lumen of the guide seal and across the lesion to a point distal to the treatment site. *Id.*

b) Discussion

Petitioner asserts that claims 1–7, 9, 11–16, 18, and 19 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos, Adams, and the knowledge of a person of ordinary skill in the art. Pet. 7. For the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1–7, 9, 11–16, 18, and 19 would have been obvious over the combination of Kontos, Adams, and the knowledge of a person of ordinary skill in the art.

(1) Independent claims 1 and 11

Petitioner contends that the combination of Kontos and Adams teach each of the limitations of independent claims 1 and 11. Pet. 21–38 (citing Ex. 1405 ¶¶ 167–187).

With regard to the "coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable" limitation of claims 1 and 11, the Petition cites the balloon catheter 40 of the Kontos device:

> Moreover, an interventional cardiological device, such as a PTCA catheter 40 with balloon 48 is insertable through lumen

> 22 of tube 16, i.e., through the "cross-sectional inner diameter" of tube 16 and body 12. Ex-1405, ¶ 171; Ex-1409, 4:66–5:2, Figs. 6A-C.

Pet. 31; *see also id.* at 55–57; Ex. 1405 ¶ 227–228.

Patent Owner contends Petitioner's arguments with respect to independent claims 1 and 11 fail because "the claims require that at least these four interventional devices are insertable" and the Petition fails to show a prior art "structure through which stents and stent catheters are insertable, "which are two of the four 'interventional cardiology devices' required by independent claims 1 and 11." Prelim. Resp. 28. In particular, Patent Owner contends that the Petition relies solely on Kontos' disclosure of a balloon catheter, and that a balloon catheter is not a stent or stent catheter. *Id.* at 29–30 (citing Ex. 1409, 5:16–24 ("the balloon 48 of PTCA catheter 40 . . .")).

Patent Owner further contends that "[Petitioner]'s own evidence shows, stents are particularly bulky, stiff, and difficult to advance." *Id.* at 29 (citing Ex. 1415a, 96 ("Improvements in catheter design have enabled routine lumen diameters of 0.088 inches in 8F guiding catheters to facilitate passage of bulkier devices such as stents . . ."); *id.* at 98 ("[w]hen more shaft support is needed to help advance stiff device (e.g., a stent) around bend extra support wires are available . . .)). The Petition, however, provides no explanation or evidence "comparing a balloon catheter to a stent or a stent catheter, or any analysis of how the fact that a balloon catheter is insertable might mean that stents and stent catheters are also insertable." *Id.* at 29.

On this record, we do not find Patent Owner's arguments persuasive because we do not construe the relevant claim phrase to require evidence that all interventional cardiology devices discussed in the '032 patent are

insertable into the claimed lumen, and Petitioner provides ample evidence that the PTCA catheter and balloon of Kontos are insertable into the lumen of support catheter 10. Pet. 29–31 (citing Ex. 1409, 4:66–5:2, Figs. 6A–6C; Ex. 1405 ¶ 171).

Patent Owner also contends that Petitioner's obviousness grounds fail because Petitioner did not address known objective evidence of nonobviousness, including evidence of commercial success, licensing by competitors, copying, and long-felt need. Prelim. Resp. 30–42. We are not persuaded by these arguments.

First, the question of nexus is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). 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.

Second, objective evidence of nonobviousness is relevant only if there is a nexus between this evidence and the claimed invention. *Id.*
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. Arctic 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. 35–36. 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 33–34 (citing Ex. 2056 ¶¶ 160–163, 164, App'x J (483–489), App'x K (526–533, App'x L (579–585). Patent Owner provides no persuasive analysis, however, to explain why the claims of the '032 patent are *coextensive* with its GuideLiner product. *See Fox Factory*, 944 F.3d at 1373. Moreover, the expert report relied upon by Patent Owner indicates that Patent Owner's GuideLiner product embodies the claims of at least five other patents. Ex. 2056 ¶¶ 164–168. In this situation, a presumption of nexus is appropriate only if Patent Owner demonstrates that the claims of all five patents "generally cover the same invention." *Fox Factory*, 944 F.3d at 1377. Patent Owner does not attempt to demonstrate this fact. *See* Ex. 1488, 11–12 (noting the existence of two different versions of catheters: "over-the-wire" and "rapid-exchange"). Indeed, that Patent Owner separately sought patent protection for each of these five patents suggests that these patents do not generally cover the same invention.[5] *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. 35–36. 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

[5] Several identified patents are terminally disclaimed. *See* Ex. 1401, code (45). Patent Owner does not assert, however, that *all* of the identified patents are terminally disclaimed to the same patent.

F.3d at 1378. Patent Owner has not done so on the record before us at this time.

Upon review of the parties' arguments and the evidence of record, we determine that Petitioner identifies sufficiently where Kontos and Adams teach or suggest every limitation of independent claims 1 and 11. Petitioner also provides an explanation as to why one of ordinary skill in the art would have combined the disclosures of Kontos and Adams to arrive at the claimed invention. Accordingly, Petitioner demonstrates a reasonable likelihood that the subject matter of claims 1 and 11 would have been obvious over the combined disclosures of Kontos and Adams.

(2) Dependent Claims 2–7, 9, 12–16, 18, and 19

Petitioner identifies where it contends Kontos and Adams disclose every limitation of dependent claims 2–7, 9, 12–16, 18, and 19. Pet. 39–69. In support of these arguments, Petitioner provides a detailed analysis of the disclosures of Kontos and Adams, as well the supporting testimony of Dr. Brecker and Dr. Hillstead. *Id.* (citing *generally* Exs. 1405 and 1442).

Patent Owner does not address Petitioner's specific arguments with respect to claims 2–7, 9, 11–16, 18, and 19.

Upon review of Petitioner's arguments, as well as Dr. Brecker's and Dr. Hillstead's supporting testimony, we determine that Petitioner has sufficiently identified where each limitation of the challenged dependent claims are disclosed in Kontos and Adams. Accordingly, Petitioner has demonstrated a reasonable likelihood that claims 2–7, 9, 11–16, 18, and 19 would have been obvious over Kontos and Adams.

2. Ground 2: Obviousness in view of Kontos, Adams, Takahashi and the knowledge of POSITA

Claim 8 depends from claim 1 and claim 17 depends from claim 11. Ex. 1401, 11:54, 12:35. Both claims require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." *Id.* at 11:17–20, 12:35–38.

Petitioner asserts that claims 8 and 17 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos, Adams, Takahashi and the knowledge of POSITA. Pet. 69–72.

a) Summary of Takahashi

Takahashi is a journal article entitled "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter." Ex. 1410. It bears a copyright date of 2004. *Id.* at 5. 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. *Id.* at 452. In this system, the 5 French catheter is 120 cm in length, whereas the 6 French catheter is 100 cm in length. *Id.* According to Takahashi, the soft end portion of the 5 French catheter "can easily negotiate the tortuous coronary artery with minimal damage and then it can be inserted more deeply into the artery." *Id.*

b) Discussion

Petitioner contends one of ordinary skill in the art would have sought to implement Takahashi's five-in-six system in the device of Kontos and Adams because of the increased support provided by the "not-more-than-one-French differential" taught by Takahashi. Pet. 71–72. Petitioner concedes that this modification would increase the diameter of Kontos's

body, but contends this modification was well within the skill in the art, "as appropriately sized catheters were ubiquitous in the art." *Id.* at 72 (citing Ex. 1442 ¶¶ 109–110; Ex. 1409, 4:64–65 (Kontos noting that "[o]f course, other sizes may be used for other applications"); Ex. 1410, 452).

Patent Owner does not address Petitioner's arguments with respect to claims 8 and 17.

On this record, Petitioner has demonstrated sufficiently that Kontos, Adams, and Takahashi teach of suggest every limitation of claims 8 and 17. Petitioner also provides sufficient explanation as to why one of ordinary skill in the art would have combined the three references to arrive at the claimed invention. Thus, Petitioner has demonstrated a reasonable likelihood that claims 8 and 17 would have been obvious over Kontos, Adams, and Takahashi.

3. Ground 3: Obviousness in view of Kontos, Adams, Berg and the knowledge of POSITA

Claim 20 depends from claim 19 and further requires that "the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI." Ex. 1401, 12:50–54. Petitioner contends the subject matter of claim 20 would have been obvious over the combined disclosures of Kontos, Adams, and Berg. Pet. 73–75.

a) Summary of Berg

Berg discloses a "guiding catheter for use in coronary angioplasty and other cardiovascular interventions." Ex. 1451, 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 more flexible tips may increase the incidence of guide catheter back-out, when the guide disengages from its preferred positioning in the coronary ostium. *Id.* at 2:11–15.

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

Fig.19

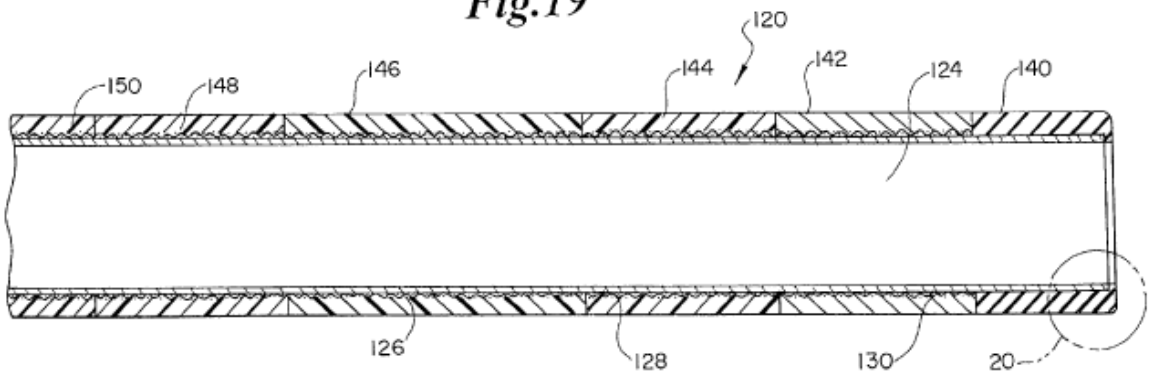


Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a plurality of discrete outer tubular member segments 140, 142, 144,

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.

b) Discussion

Petitioner contends Berg discloses using a guide catheter having varying degrees of stiffness and that the flexural modulus for the first, second, and third portions of Berg's catheter overlap the ranges recited in claim 20. Pet. 73–75. Petitioner further contends that one of ordinary skill in the art would have used the flexural moduli disclosed in Berg for the catheter of Kontos because Berg instructs that the disclosed combination of flexibilities allows the "flexibility of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out." *Id.* at 74–75 (quoting Ex. 1444, 1:36–38; Ex. 1451, 2:37–39; Ex. 1442 ¶ 118).

Patent Owner does not directly address Petitioner's arguments based on the combination of Kontos, Adams, and Berg.

Upon review of Petitioner's arguments and evidence, we determine that Petitioner has demonstrated sufficiently that Itou and Berg teach or suggest every limitation of claim 20, and that Petitioner explains sufficiently why one of ordinary skill in the art would have combined the disclosures of these references. Accordingly, Petitioner has demonstrated a reasonable

likelihood that the subject matter of claim 20 would have been obvious over the combined disclosures of Kontos, Adams, and Berg.

E. 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. 43 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019). Patent Owner further argues that the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338-39). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

III. CONCLUSION

On the present record, we find Petitioner shows sufficiently that the cited references would have taught or suggested each element of claims 1–9 and 11–20, and sets forth a sufficient rationale for why a person of ordinary skill would have been motivated to combine these teachings and suggestions to arrive at the invention recited in those claims. Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 1–9 and 11–20 would have been obvious over the combinations of prior art set forth in the asserted grounds.

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

reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

IV. 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 1–9 and 11–20 of the '032 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 '032 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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