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Paper 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.

IPR2020-00130
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 1–4, 6–9, and 12–21 of U.S. Reissue Patent RE45,380 (Ex. 1401, "the '380 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response to the Petition (Paper 9, "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 14) addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply (Paper 15) addressing Petitioner's burden on those issues. 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).

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. 4–5; Paper 4, 2. The '380 patent is also at issue in IPR2020-00128, IPR2020-00129, and IPR2020-00131. Paper 4, 2–3; Pet. 5. We instituted *inter partes* review in IPR2020-00128 and IPR2020-00129 on June 8, 2020. IPR2020-00128, Paper 22; IPR2020-00129, Paper 22.

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. 1401, 1:31–35.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions." *Id.* at 1:44–46. This narrowing is referred to as stenosis. *Id.* at 1:48–49. To treat this 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. In this method, 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

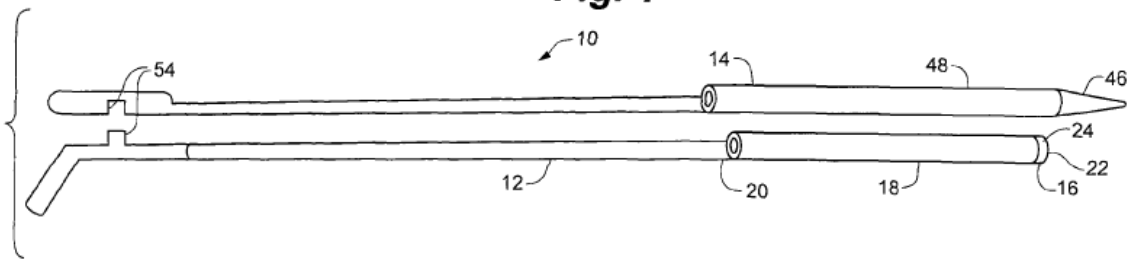


Fig. 2

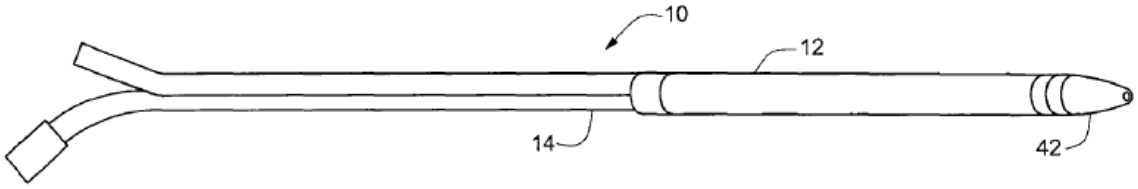


Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled. *Id.* at 5:40–45. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:34–35. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:16–17. 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:

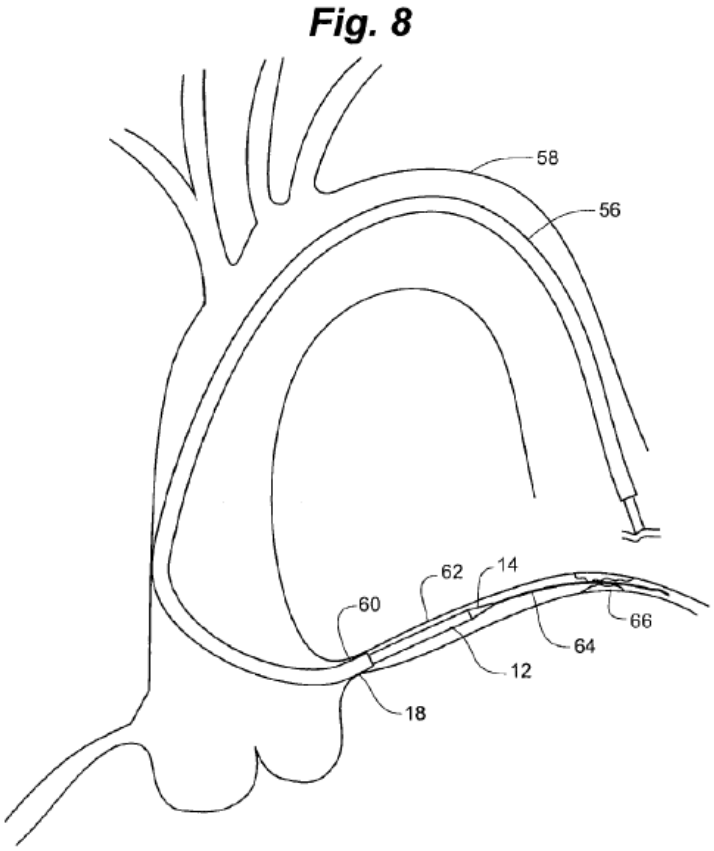


Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 5:61–64. In Figure 8, “coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 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. “Coaxial 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. *Id.* at 8:18–19. The '380 patent explains that coaxial guide catheter 12 provides additional backup support to resist dislodging of guide catheter 56 from ostium 60 when force is applied to guidewire 64 to pass through stenotic lesion 66. *Id.* at 8:23–30.

C. Illustrative Claim

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

> 1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a 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 the 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 continuous lumen of the guide catheter; and
>
> a device adapted for use with the guide catheter, including:
>
> a flexible tip portion defining a tubular structure and 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 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;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

Ex. 1401, 10:47–11:24 (limitations added by reissue in italics).

D. Prior Art and Asserted Grounds

Petitioner contends claims 1–4, 6–9, and 12–21 of the '380 patent would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6, 7, 9, 12–17, 19, 20	103	Kontos[1], Adams[2]
8, 18	103	Kontos, Adams, Takahashi[3]
21	103	Kontos, Adams, Berg[4]

[1] Kontos, US 5,439,445, issued August 8, 1995 (Ex. 1409) ("Kontos").
[2] Adams, US 2004/0010280 A1, published January 15, 2004 (Ex. 1435) ("Adams").
[3] 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. 1410) ("Takahashi").
[4] Berg, US 5,911,715, issued June 15, 1999 (Ex. 1451) ("Berg").

Petitioner also relies on the testimony of Dr. Stephen JD Brecker (Ex. 1405) and Richard A. Hillstead (Ex. 1442).

ANALYSIS

A. 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, only the term "interventional cardiology devices" requires construction. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

Claims 1 and 12 require a flexible tip portion that defines "a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable." Ex. 1401, 10:58–67, 12:17–28. 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 1:41–44.

Petitioner contends that, in the *QXM* case, 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).

Patent Owner contends that "interventional cardiology devices," as used in independent claims 1 and 12,

> 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. 15. 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, 3:9–20. 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 3:28–43. 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 5:33–36. 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 15–16.

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 12, 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. Ex. 1401, 7:60–64 ("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 . . . .").

Moreover, 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 7:60–64, Figs. 7–8.

B. 35 U.S.C. § 314

1. Multiple Petitions

Petitioner filed four petitions for *inter partes* review of the '380 patent:

IPR	Claims Challenged	Primary Reference	Petitioner's Ranking
IPR2020-00128	1–4, 6–10, 12–21, 23	Itou	Petition 1A
IPR2020-00129	25–39	Ressemann	Petition 1B

IPR	Claims Challenged	Primary Reference	Petitioner's Ranking
IPR2020-00130	1–4, 6–9, 12–21	Kontos	Petition 2A
IPR2020-00131	25–39	Kontos	Petition 2B

As indicated in the chart above, IPR2020-00128 relies on Itou as the primary reference; IPR2020-00129 relies on Ressemann as the primary reference; and IPR2020-00130 and IPR2020-00131 rely on Kontos as the primary reference. Paper 3, 1–2. Petitioner labels IPR2020-00128 as "Petition 1A," IPR2020-00129 as "Petition 1B," IPR2020-00130 as "Petition 2A," and IPR2020-00131 as "Petition 2B." *Id.* 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. Petitioner 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. *Id.* at 2–3.

As noted above, we instituted review in both IPR2020-00128 and IPR2020-00129 because we determined that the second petition against the '380 patent in IPR2020-00129 was justified in view of the number and length of the challenged claims and in view of the unique claim construction issues presented in that case. IPR2020-00129, Paper 22 at 8–9.

IPR2020-00128 and IPR2020-00130 are both directed to claims 1–4, 6–9, and 12–21 of the '380 patent. IPR2020-00128, Paper 1 at 8 (also addressing claims 10 and 23 of the '380 patent); Pet. 7. Petitioner relies on Itou in every ground of unpatentability in IPR2020-00128, whereas the current Petition relies upon Kontos in every ground of unpatentability. IPR2020-00128, Paper 1, 8; Pet. 7. Petitioner contends the present third petition, or Petition 2A, is needed to address challenged claims 1–4, 6–9,

and 12–21 of the ’380 patent because Patent Owner asserts Itou is not prior art to the ’380 patent under § 102(e), but does not dispute that Kontos is § 102(b) prior art. Paper 3, 1–3.

The Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Trial Practice Guide”) (Nov. 2019)[5] 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 three concurrent *inter partes* review proceedings directed to the ’380 patent. Thus, Petitioner must demonstrate that this is one of the “unlikely” and “rare” situations where three 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, IPR2020-00128 addresses grounds 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

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

than one petition may be necessary." Consolidated Practice Guide at 59. Moreover, the challenges presented in IPR2020-00128 (Petition 1A) and IPR2020-00130 (Petition 2A and the present 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 IPR2020-00128. Thus, we find that the current Petition presents one of those "rare" and "unlikely" situations where a third 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. 22–25. 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 11–12.

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 at 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 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 '380 patent and other patents in this 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 *afte*r our statutory deadline for a final written decision in this proceeding and the related IPRs. Prelim. Resp. 12; 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 15 at 10 (noting trial date of March 8, 2021 where Board's institution decision was due May 15, 2021).

As to the amount of investment by the parties and the court in the parallel proceeding (*Fintiv* Factor 3), Patent Owner contends that that the district court is already deeply invested and has familiarity with the challenged patents in light of the relatively advanced stage of the *QXM* case. Paper 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. 12. 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. *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"). 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 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.

C. Claims 1–4, 6, 7, 9, 12–17, 19, and 20 over Kontos and Adams

Petitioner contends the subject matter of claims 1–4, 6, 7, 9, 12–17, 19, and 20 would have been obvious over the combined disclosures of Kontos and Adams. Pet. 17–71.

1. Kontos

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[6] balloon into a lesion." Ex. 1409, 1:9–13.

Figure 1 of Kontos is reproduced below:

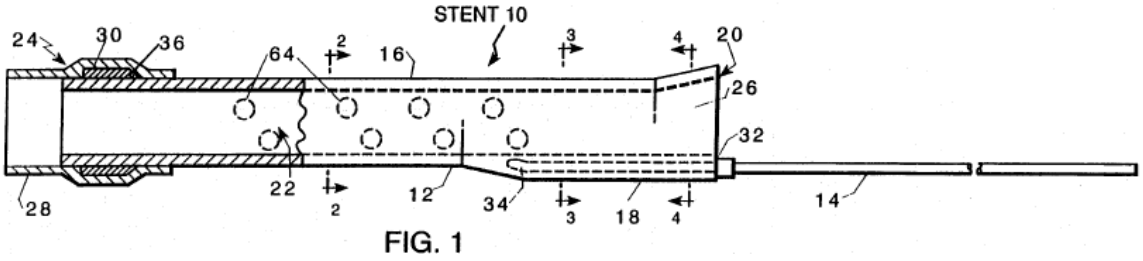


FIG. 1

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

[6] PTCA stands for "percutaneous transluminal coronary angioplasty." Ex. 1405 ¶ 41.

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 "generally are suitable for existing PTCA catheters." *Id.* at 4:61–64.

Figure 5 of Kontos is reproduced below:

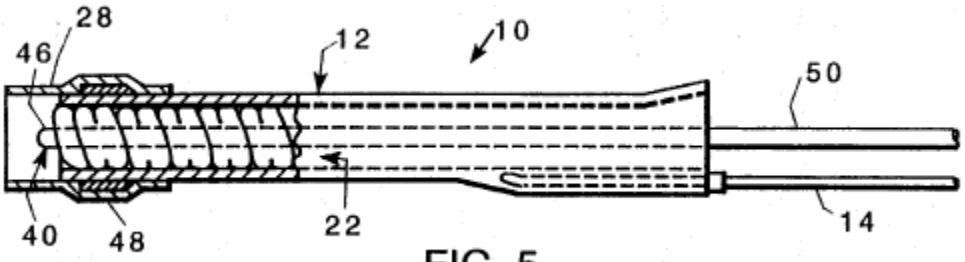
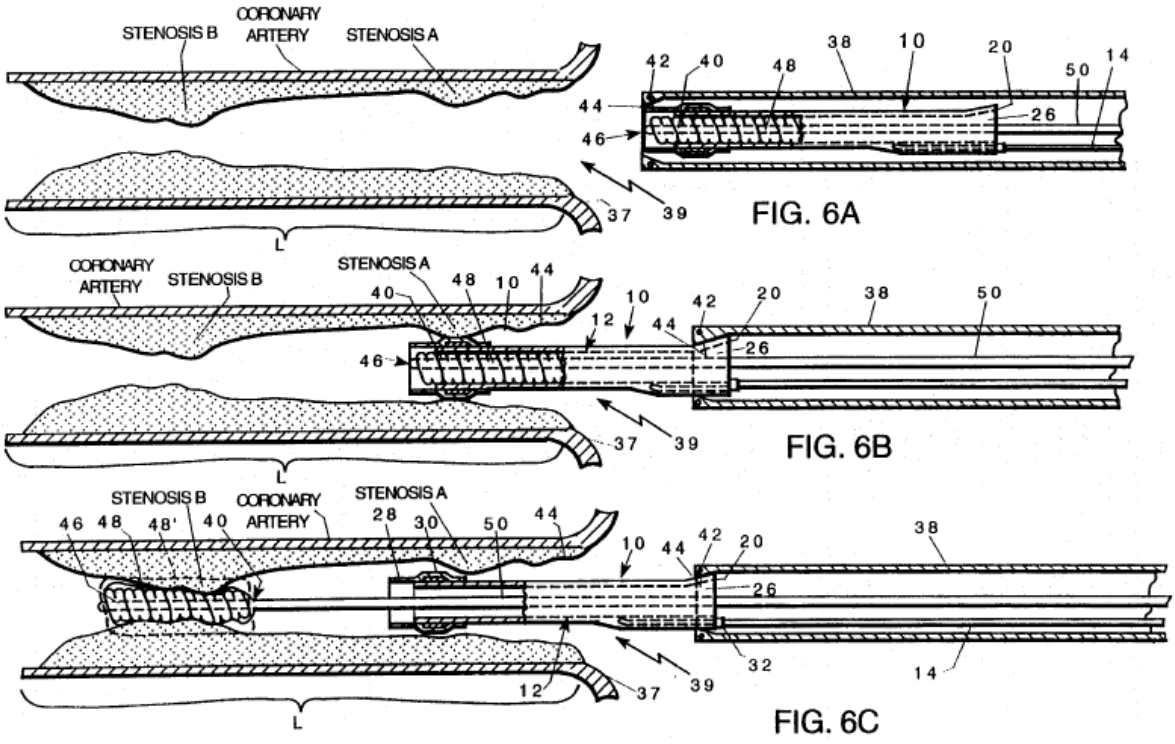


FIG. 5

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

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:

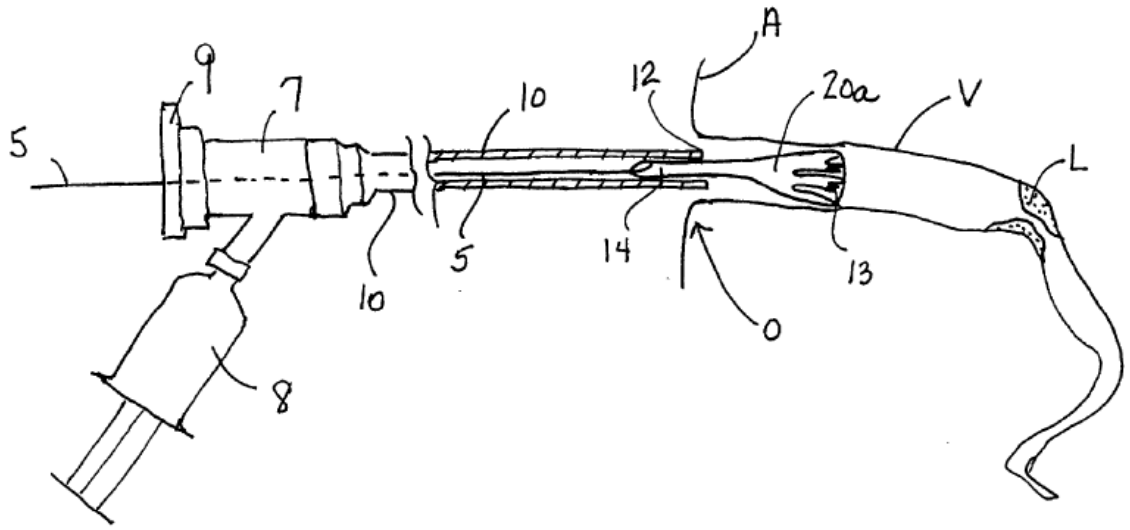


FIG. 1A

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.*

3. Independent Claims 1 and 12

Petitioner contends the combined disclosures of Kontos and Adams teach or suggest every limitation of independent claims 1 and 12. Pet. 22–43, 57–66. In particular, Petitioner contends Kontos teaches or suggests every limitation of claim 1, except for (1) a support catheter that has a total length (flexible tip and substantially rigid portion) that is longer than the length of the continuous lumen of the guide catheter and (2) at least a proximal 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. *Id.* at 32–36. Petitioner asserts, however, that one of ordinary skill in the art would have understood that in order for a physician to treat a stenosis the combined length of the support catheter must be longer than the length of the guide catheter and that the proximal end must extend through a hemostatic

valve. *Id.* at 34–36, 57 (relying on arguments made to support the challenged to claim 1).

Moreover, to the extent these structural limitations would not have been obvious over Kontos individually, Petitioner contends they would have been obvious in view of the additional disclosures of Adams. *Id.* at 36–37, 57–59. Petitioner identifies where Adams discloses a device having a combined length of its flexible tip portion and substantially rigid portion that "(i) are greater than that of the guide catheter and (ii) extend proximal to the hemostatic valve 9 when the guide seal extends beyond the distal end of guide catheter 10." *Id.* at 37. According to Petitioner, one of ordinary skill in the art would have sought to use the well-known aspects of interventional cardiology disclosed in Adams with the device of Kontos, because the relative sizes and designs of Adams were well known in the art and Kontos teaches that its catheter should "use known medical procedures." *Id.* at 37–38 (citing Ex. 1409, 5:11–15; Ex. 1405 ¶¶ 174–176).

Patent Owner contends Petitioner's arguments with respect to independent claims 1 and 12 fail because the Petition makes no attempt to show that Kontos and Adams disclose a flexible tip portion with a coaxial lumen having an inner diameter through which all four interventional devices identified in the '380 patent are insertable. Prelim. Resp. 30–31. According to Patent Owner, Petitioner only demonstrates that a balloon catheter and balloon are insertable into the lumen, but makes no effort to demonstrate that a stent or stent catheter are also insertable into this lumen. *Id.* at 31–32.

We do not find this argument persuasive because we do not construe the relevant claim phrase to require evidence that all interventional

cardiology devices discussed in the ’380 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. 33–45. 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. 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. 37–38. 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 36–37 (citing Ex. 2056 ¶¶ 160–163, 166, 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. 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.[7] *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. 38–39. But, as noted above, Patent Owner asserts that a nexus exists for

[7] 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.

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.

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 12. 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 12 would have been obvious over the combined disclosures of Kontos and Adams.

4. Dependent Claims 2–4, 6, 7, 9, 13–17, 19, 20

Petitioner identifies where it contends Kontos and Adams disclose every limitation of dependent claims 2–4, 6, 7, 9, 13–17, 19, and 20. Pet. 44–57, 66–71. 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 2–4, 6, 7, 9, 13–17, 19, 20

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 2–4, 6, 7, 9, 13–17, 19, 20 would have been obvious over Kontos and Adams.

D. Claims 8 and 18 over Kontos, Adams, and Takahashi

Claim 8 depends from claim 1 and claim 18 depends from claim 12. Ex. 1401, 11:54, 13:13. 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 11:54–57, 13:14–17.

Petitioner contends the subject matter of claims 8 and 18 would have been obvious over the combined disclosures of Kontos, Adams, and Takahashi. Pet. 72–75.

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. 1410, 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.*

2. Analysis

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. 73–74. 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 74 (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 18.

On this record, Petitioner has demonstrated sufficiently that Kontos, Adams, and Takahashi teach of suggest every limitation of claims 8 and 18. 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 18 would have been obvious over Kontos, Adams, and Takahashi.

E. Claim 21 over Kontos, Adams, and Berg

Claim 21 depends from claim 20 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, 13:29–33. Petitioner contends the subject matter of claim 21 would have been obvious over the combined disclosures of Kontos, Adams, and Berg. Pet. 75–77.

1. 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 guide catheter back-out." *Id.* at 2:35–39. Figure 19 of Berg is reproduced below:

Fig.19

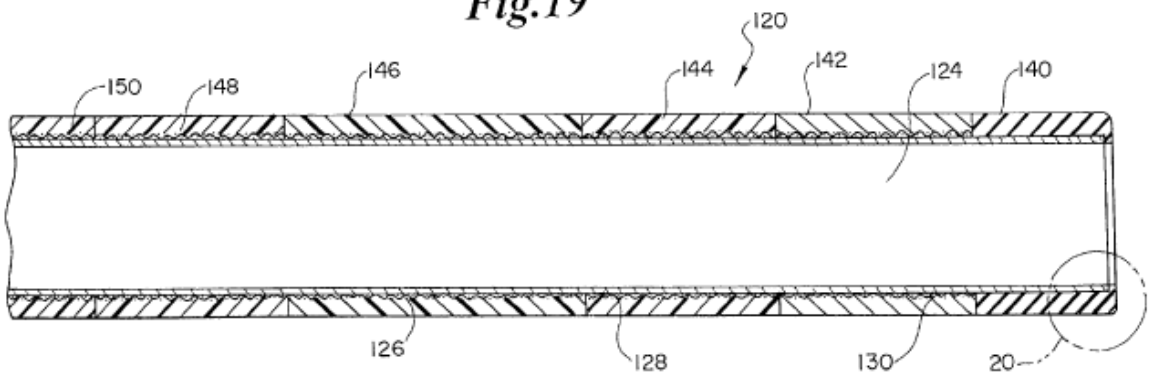


Figure 19 is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter. *Id.* at 5:49–51. The guide catheter of Figure 19 has a plurality of discrete outer tubular member segments 140, 142, 144, 146, 148, and 150. *Id.* at 13:53–55. Soft tip zone 140 has a flexural modulus 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 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 21. Pet. 75–77. 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 76 (quoting Ex. 1444, 1:36–38, 2:37–39; Ex. 1442 ¶ 117).

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 Kontos, Adams, and Berg teach or suggest every limitation of claim 21, 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 21 would have been obvious over the combined disclosures of Kontos, Adams, and Berg.

F. 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. 46 (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.* at 46-47 (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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