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Paper No. 9
Date: February 9, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

IPR2020-01342
Patent 8,142,413 B2

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1, 2, 4, 5, and 7–14 of U.S. Patent No. 8,142,413 B2 ("the '413 patent," Ex. 1401). Paper 1 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

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

A. Real Parties in Interest

Petitioner identifies its real parties-in-interest as Medtronic, Inc. and Medtronic Vascular, Inc., and notes 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 5, 2. Patent Owner also notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." *Id.*

B. Related Matters

Petitioner filed a separate Petition for *inter partes* review of claims 1, 2, 4, 5, and 7–14 of the '413 patent as IPR2020-01341.

The parties indicate that the '413 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 (D. Minn. filed July 2, 2019) ("*Medtronic*") and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("*QXM*"). Pet. 4–5; Paper 5, 2. Patent Owner indicates that both of these district court proceedings are currently stayed. Paper 5, 2.

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

The '413 patent was the subject of a previous *inter partes* review in IPR2014-00759 involving a distinct set of grounds, filed May 15, 2014, and terminated August 11, 2014, by way of joint motion to terminate. Paper 5, 2–3.

C. The '413 Patent

1. Specification

The '413 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on March 27, 2012, from a non-provisional application filed June 28, 2010. Ex. 1401, codes (45), (54), (22).

The ’413 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1001, Abstract. According to the ’413 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:21–23. In coronary artery disease, the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions in a phenomenon known as stenosis. *Id.* at 1:27–28. In treating the stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery, sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:35–37. However, crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated, which can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease. *Id.* at 1:41–45.

To solve this problem, the ’413 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 2:59–62. The ’413 patent teaches that the coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 2:63–67. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the ’413 patent:

Fig. 1

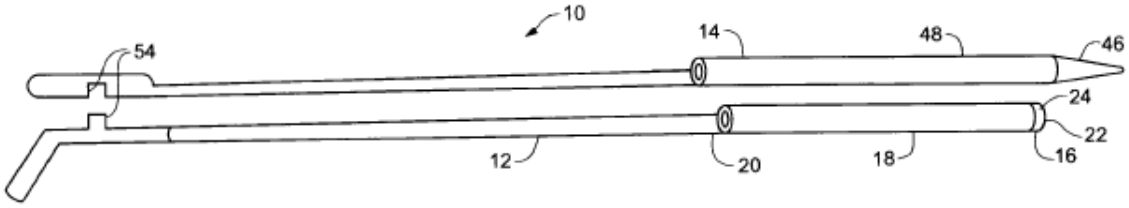


Fig. 2

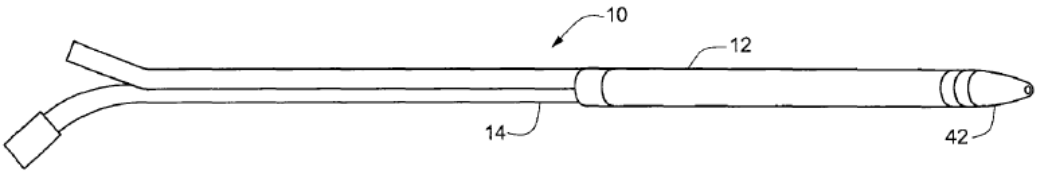


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:22–27; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:12–14. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:15–16. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:20–21. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:21–22. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:25–26. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:65–66. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:66–67. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:3–5.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:17–17. The coaxial guide catheter/

tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta, and advanced until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. *Id.* at 4:21–28. The tapered inner catheter may be removed once the coaxial guide catheter tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating. *Id.* at 4:28–31. Once the tapered inner catheter is removed, a cardiac treatment device, such as a guidewire, balloon, or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. *Id.* at 4:35–38. The presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter/guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion. *Id.* at 4:39–44.

2. Illustrative Claims

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

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

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

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

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

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

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

Ex. 1401, 10:3011:6.

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").

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, 2, 4, 5 and 7–14 would have been unpatentable on the following grounds.

Ground	Claim(s)	35 U.S.C. §[1]	References/Basis
1	1, 2, 4, 5, 7–12, 14	103(a)	Kontos, Adams
2	13	103(a)	Kontos, Adams, Takahashi

II. ANALYSIS

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

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

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '413 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

1356. ("[Section] 314(a) invests the Director with discretion on the question whether to institute review." (emphasis omitted)); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

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

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

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

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

1. Analysis

Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution due to the common issues being litigated in parallel district court cases. Prelim. Resp. 5–7. We have considered the circumstances and facts before us in view of the *Fintiv* factors and determine that the circumstances presented here weigh heavily against exercising discretion under § 314(a) to deny institution of *inter partes* review.

Relevant to *Fintiv* factors 1 and 2, the parties acknowledge that the parallel district court proceeding is stayed. Pet. 16; Prelim. Resp. 1; Paper 5, 2. The granting of a stay pending *inter partes* review has weighed strongly against exercising discretion to deny institution under *NHK* as it is a strong indication that the district court has a preference to wait for the Board's final resolution of the patentability issues raised in the petition before proceeding with the parallel litigation. *See Fintiv* at 6–7. Accordingly, consideration of the first and second *Fintiv* factors weighs strongly against exercising discretion to deny institution.

The third *Fintiv* factor also provides that a petitioner's diligence or delay in filing a petition may be relevant. *See Fintiv* at 11–12. If the evidence shows that a petitioner filed its petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against denying institution. *See id.* at 11 (citing *Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15 at 12–13 (PTAB Jan. 9, 2020); *Illumina Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19 at 8 (PTAB Dec. 18,

2019)). If, however, the evidence shows that the petitioner did not file its petition expeditiously, such as at or around the same time that the patent owner responded to the petitioner's invalidity contentions, or even if a petitioner cannot explain the delay in filing its petition, these facts have favored denial. *See Fintiv* at 11–12 (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019)).

Patent Owner contends that Petitioner's delay in filing the petition weighs in favor of denying institution under § 314(a). *See* Prelim. Resp. 46–47 (quoting *Next Caller*, Paper 10 at 15–16; *Fintiv* at 11–12). In particular, Patent Owner contends that Petitioner unjustifiably delayed filing this Petition (and the Petition in IPR2020-01342) as compared to challenges against related patents brought 9 months earlier, which rely on similar art and arguments. *Id.* at 5–6; *see* IPR2020-00126 (Itou and Ressemann), IPR2020-00128 (Itou and Ressemann), IPR2020-00129 (Itou and Ressemann), IPR2020-00132 (Itou and Ressemann), IPR2020-00133 (Ressemann), IPR2020-00134 (Itou and Ressemann), IPR2020-00135 (Itou and Ressemann), IPR2020-00137 (Itou and Ressemann), IPR2020-00138 (Ressemann). Patent Owner contends that Petitioner's "unjustified delay" in filing this petition prejudices Patent Owner. Prelim. Resp. 7. In particular, Patent Owner contends as follows:

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

Prelim. Resp. 7.

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

> When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '413 patent. As a result, Petitioner did not file an IPR against the '413 patent at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint that asserted the '413 patent. Ex-1514. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline.

Pet. 17.

We find that the current record does not support a finding that the Petition was filed with delay. Rather, the filing of the Petition was in response to Patent Owner's Amended Complaint adding the '413 patent to the related litigation. Ex. 1514. We do not consider, based on the current record, the filing of the Petition within 6 months of the filing of the Amended Complaint that asserted the '413 patent to be unjustified.

With respect to *Fintiv* Factor 4 (overlap of issues) and *Fintiv* Factor 5 (whether the same parties are involved), we find there is an overlap of issues and parties between the *Medtronic* case and this proceeding. In *Fintiv*, the Board noted "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Fintiv*, Paper 11 at 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 has stayed the parallel litigation and thus will not reach the merits of Petitioner's invalidity defenses before we issue our final written decision.

Furthermore, we note that the district court's stay of the litigation pending denial of institution or a final written decision allays concerns about inefficiency and duplication of efforts. *Id.* To the contrary, exercising our discretion to deny the Petition would force inefficiency and the possibility of conflicting decisions because the district court would then have to resolve similar and overlapping issues presented in the context of only the '413 patent, one of several related patents being asserted by Patent Owner in the related litigation.

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

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

B. Level of Ordinary Skill in the Art

The person having ordinary skill in the art is a hypothetical person who is presumed to be aware of all the relevant prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Kimberly-Clarke Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984). Moreover, the prior art itself is generally sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

Petitioner asserts "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 11–12. Alternatively, Petitioner asserts "if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* at 12. Additionally, Petitioner contends "[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.* (citing Ex. 1405 ¶ 27; Ex. 1442 ¶¶ 18–19).

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

On this record, in determining whether the evidence of record supports institution, we apply both of Petitioner's definitions for a POSITA, as they are undisputed at this time and consistent with the level of skill reflected in the prior art and the specification of the '413 patent. *See Okajima 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 "interventional cardiology devices," "standard guide catheter," and "placed in a branch artery" Pet. 13–16. Patent Owner does not address claim construction in its Preliminary Response, although Patent Owner previously addressed the term "interventional cardiology devices" in the related IPRs.

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

1. "interventional cardiology device(s)"

Independent claim 1 of the '413 patent recites a standard guide catheter having a continuous lumen sized "such that interventional cardiology devices are insertable into and through the lumen." Ex. 1401, 10:36–37. To that point, the Specification in regard to the claim term "interventional cardiology devices" as follows:

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

Id. at 1:23–26.

Petitioner contends that, in the *QXM* litigation, Patent Owner stipulated that the term "interventional cardiology device(s)" means "devices

including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." Pet. 13 (citing Ex. 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).

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

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

Finally, we recognize that the Specification discloses that "the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel" (*id.* at 5:15–18) and that the term "interventional cardiology devices" is not limited to guidewires, balloon catheters, stents and stent catheters (*id.* at 1:24–26). To the extent

further discussion of what additional devices may be encompassed by this term is required for the purposes of this Decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

1. 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 and Adams

Petitioner asserts that claims 1, 2, 4, 5, 7–12, and 14 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos and Adams. Pet. 18–71. For the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1, 2, 4, 5, 7–12, and 14 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[2] balloon into a lesion." Ex. 1409, 1:9–13.

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

Figure 1 of Kontos is reproduced below:

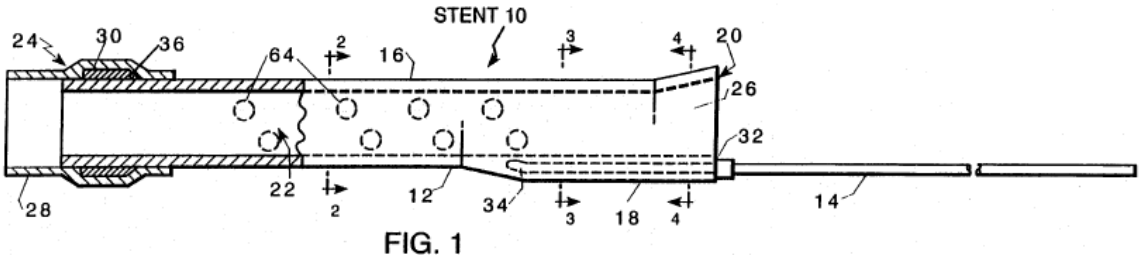


FIG. 1

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 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:

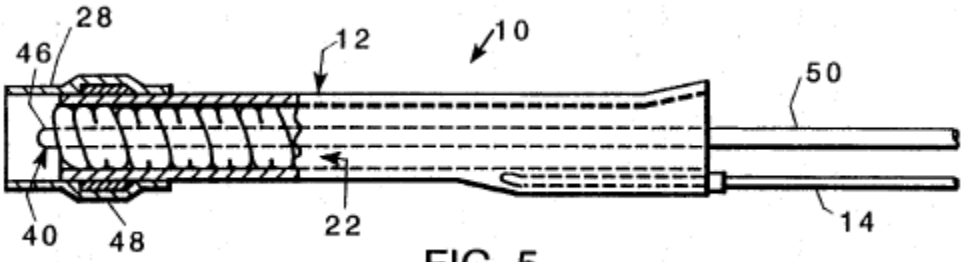
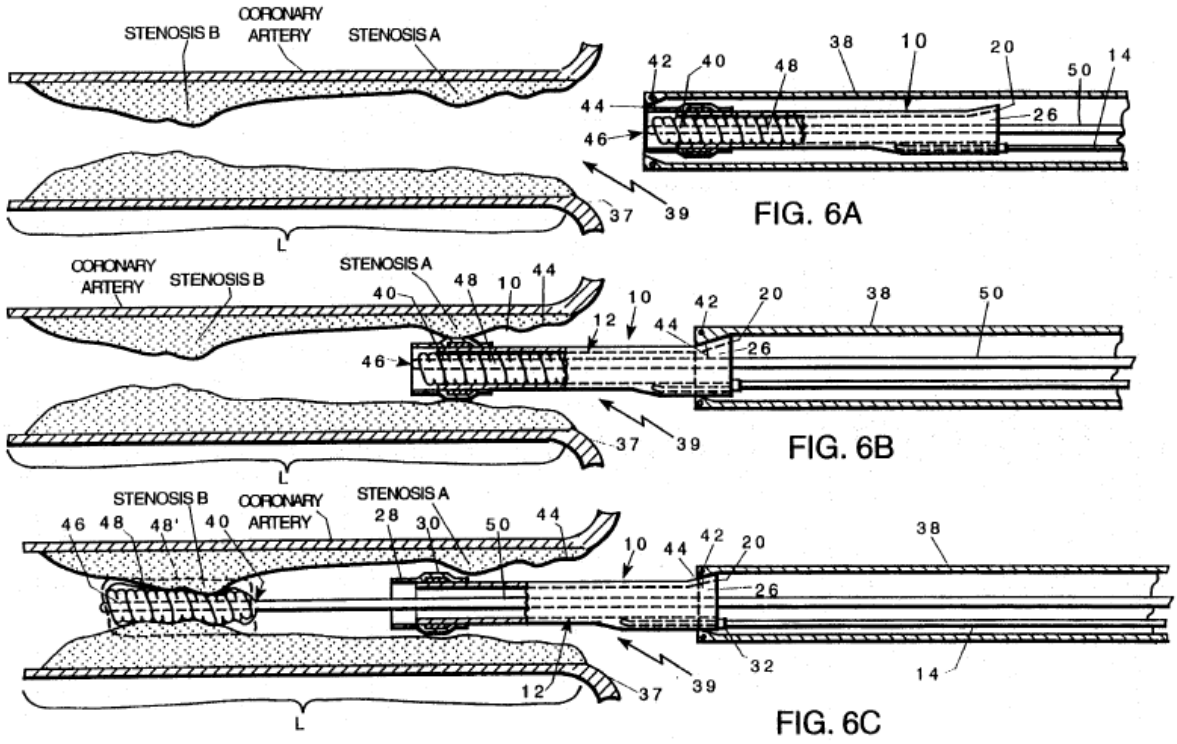


FIG. 5

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:

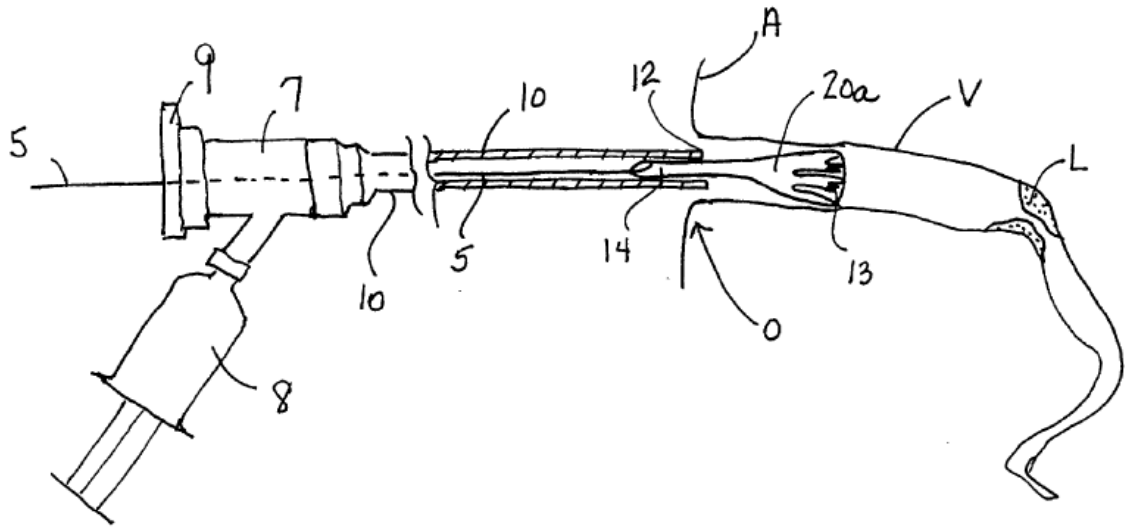


FIG. 1A

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, 2, 4, 5, 7–12, and 14 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos and Adams. Pet. 18–71. To support its position, Petitioner directs our attention to the foregoing discourses of Kontos and Adams, provides a detailed claim analysis addressing how each element of the challenges claims are disclosed by the combination of Kontos and Adams. *Id.* at 21–71 (citing *generally* Exs. 1405 and 1442).

Patent Owner does not address Petitioner's specific arguments with respect to claims 1, 2, 4, 5, 7–12, and 14. *See generally* Prelim. Resp.

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. Petitioner also provides sufficient explanation as to why one of ordinary skill in the art would have combined the references to arrive at the claimed invention. Accordingly, Petitioner has demonstrated a reasonable likelihood that claims 1, 2, 4, 5, 7–12, and 14 would have been obvious over Kontos and Adams.

2. Ground 2: Obviousness of Claim 13 in view of Kontos, Adams, and Takahashi

Claim 13 depends from claim 1. Ex. 1401, 12:30. Claim 13 further requires "selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter." *Id.* at 12:30–33.

Petitioner asserts that claim 13 is unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos, Adams, and Takahashi. Pet. 72–75. For the reasons set forth below, we determine that Petitioner has demonstrated a

reasonable likelihood that claim 13 would have been obvious over the combination of Kontos, Adams, and Takahashi.

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. 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 ¶¶ 101–102; Ex. 1409, 4:21–24, 4:31–34, 4:61–5:2 (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 claim 13. *See generally* Prelim. Resp.

On this record, Petitioner has demonstrated sufficiently that Kontos, Adams, and Takahashi teach or suggest every limitation of claim 13. 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, we determine that Petitioner has demonstrated a reasonable likelihood that claim 13 would have been obvious over Kontos, Adams, and Takahashi.

III. APPOINTMENTS CLAUSE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." Prelim. Resp. 8 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019)[3]). Patent Owner further argues that the "purported remedy imposed by the *Arthrex* decision . . . is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338–39).

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

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

IV. CONCLUSION

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

In this Decision, we address all issues raised by the parties in the pre-trial briefing. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing id. § 316(e)). Our final decision will be based on the record as fully developed during trial. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), that an *inter partes* review of claims 1, 2, 4, 5, and 7–14 of the '413 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '413 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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