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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.

IPR2020-00136
Patent RE45,776 E

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

PAULRAJ, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

On November 12, 2019, Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 25–27, 29–33, 35–39, 41–49, and 52–56 of U.S. Patent No. RE45,776 ("the '776 patent," Ex. 1401). Paper 1 ("Pet."). Vascular Solutions, Inc. ("Patent Owner") filed a Preliminary Response. Papers 9 (confidential version), 10 (redacted version) ("Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply addressing Petitioner's burden on those issues. Paper 14; Paper 15. Also pursuant to our authorization, Petitioner filed another Reply and Patent Owner filed another Sur-Reply addressing the factors for discretionary denial under 35 U.S.C. § 314(a). Paper 17; Paper 18.

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. §42.4(a) (2019). We may not institute an *inter partes* review "unless . . . there is 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). Upon considering the arguments and evidence of record, we institute *inter partes* review of claims 25–27, 29–33, 35–37, 39, 41–49, and 52–56 of the '776 patent.

B. Real Parties-in-Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc. as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S.A.R.L., Vascular Solutions

LLC, Arrow International, Inc., and Teleflex LLC and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2.

C. Related Matters

Patent Owner is asserting the '776 patent against Petitioner in the United States District Court for the District of Minnesota in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 ("*Medtronic*"). Pet. 5–6; Paper 4, 2. The '776 patent is also the subject of a declaratory judgement action filed by another party, *QXMedical, LLC v. Vascular Solutions, LLC,* No. 17-cv-01969 ("*QXM*"), which has been currently stayed pending our institution decision. Paper 17; Paper 18. Petitioner further notes that the '776 patent is a reissue of U.S. Patent No. 8,292,850, which was the subject of a prior district court action and *inter partes* reviews in IPR2014-00762 and IPR2014-00763 filed by a different petitioner. Pet. 6.

Petitioner has also filed another petition challenging the '776 patent based on different prior art, and we instituted *inter partes* review based on that petition on June 8, 2020. IPR2020-00135, Paper 22.[1] In addition, Petitioner filed concurrent petitions challenging other related patents: U.S. Patent No. 8,048,032 (IPR2020-00126; IPR2020-00127), RE45,830 (IPR2020-00128; IPR2020-00129; IPR2020-00130; IPR2020-00131), RE 45,760 (IPR2020-00132; IPR2020-00133; IPR2020-00134), and RE47,379 (IPR2020-00137; IPR2020-00138).

[1] In accordance with our Trial Practice Guide, Petitioner provides an explanation of material differences and ranking for the multiple petitions directed to each challenged patent. Paper 3. Patent Owner responds that Petitioner has not justified institution on multiple petitions. Paper 8. We address Patent Owner's arguments for discretionary denial based on the multiple petitions below.

D. The '776 Patent

The '776 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on October 27, 2015, as a re-issue of U.S. Patent No. 8,292,850, which claims priority to a non-provisional application filed May 3, 2006. Ex. 1401, codes (45), (60), (64).[2]

The '776 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1401, Abstract. According to the '776 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:45–47. 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 1:50–55. 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 1:59–65. 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 1:65–67.

To solve this problem, the '776 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 3:15–18. The '776 patent teaches that the coaxial guide

[2] Petitioner does not contest the priority date for the '776 patent in this proceeding. We consider May 3, 2006 to be the effective filing date for purposes of our analysis.

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 3:24–27. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '776 patent:

Fig. 1

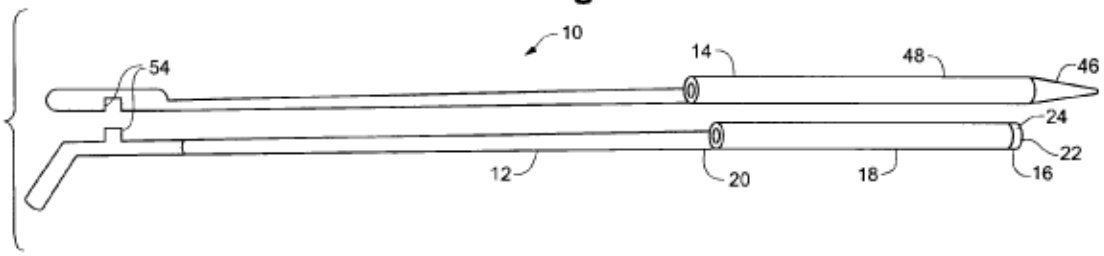


Fig. 2

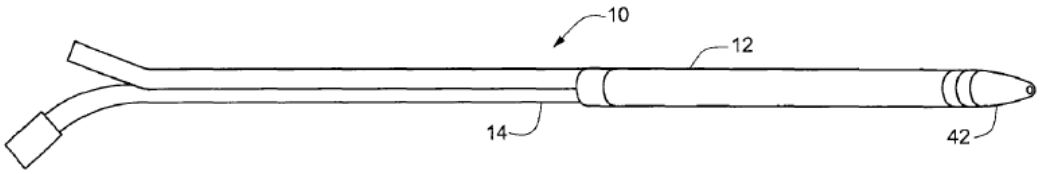


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:47–52; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:40–41. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:44–45. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:45–46. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:49–50. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:22–23. Both

tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 7:23–24. 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 7:27–29.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:43–44. 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 4:47–54. 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 4:54–57. 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 4:61–64. 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 4:64–5:3.

E. Illustrative Claims

Among the challenged claims, independent claim 25 is representative and reproduced below:

> 25. A guide extension catheter for use with a guide catheter, comprising:
>
> a substantially rigid segment;
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,
>
> wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

Ex. 1401, 13:35–52 (cl. 25).

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 25–27, 29–33, 35–37, 39, 41–49, and 52–56 would have been unpatentable based on the following grounds. Pet. 8.

Claim(s) Challenged	35 U.S.C. §[3]	Reference(s)/Basis
25–27, 29, 33, 35–37, 39, 41–49, 52	103(a)	Kontos,[4] Ressemann,[5] knowledge of POSITA

[3] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '776 patent issued was filed before this date, the pre-AIA version of § 103 applies.
[4] Kontos, US 5,439,445, issued August 8, 1995 (Ex. 1409) ("Kontos").
[5] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1408) ("Ressemann").

30–32, 53–56	103(a)	Kontos, Ressemann, Takahashi,[6] knowledge of POSITA
52	103(a)	Kontos, Ressemann, Kataishi,[7] knowledge of POSITA
53–56	103(a)	Kontos, Ressemann, Takahashi, Kataishi, knowledge of POSITA

Petitioner relies upon the expert declarations of Dr. Stephen Brecker (Ex. 1405) and Dr. Richard Hillstead (Ex. 1442) in support of its Petition. Patent Owner relies upon the expert declaration of Peter Keith (Ex. 2042) in support of its Preliminary Response.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternatives for a person having ordinary skill in the art. First, Petitioner asserts that "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 13. Alternatively, Petitioner asserts that "if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical

[6] 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").
[7] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1425) ("Kataishi").

training might substitute for education, and advanced degrees might substitute for experience." *Id.*

Patent Owner indicates that "[f]or purposes of this Preliminary Response only, Teleflex does not currently dispute Medtronic's proposed definition of a POSITA." Prelim. Resp. 16.

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 '776 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).

B. 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). This standard requires that we construe claims "in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for the claim terms a "concave track" and "flexural modulus." Pet. 13–16. Patent Owner responds to Petitioner's proposed constructions by asserting that "no specific construction of claim terms [or any other terms] is necessary for the Board to deny the Petition." Prelim. Resp. 18.

At this stage of the proceeding, we do not perceive a need to construe any claim terms of the '776 patent for purposes of determining whether to institute trial. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed

that are in controversy, and only to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

C. Ground 1: Obviousness in View of Kontos, Ressemann, and the Knowledge of a POSITA

Petitioner asserts that claims 25–27, 29, 33, 35–37, 39, 41–49, and 52 are rendered obvious in view of Kontos, Ressemann, and the knowledge of a POSITA. Pet. 8. We focus our analysis on independent claim 25 for purposes of this decision.

1. Overview of Kontos (Ex. 1409)

Kontos is a U.S. patent that issued from an application filed on June 27, 1994. Ex. 1409. Thus, on its face, Kontos qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

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[8] balloon into a lesion." *Id.* at 1:9–13.

Figure 1 of Kontos is reproduced below:

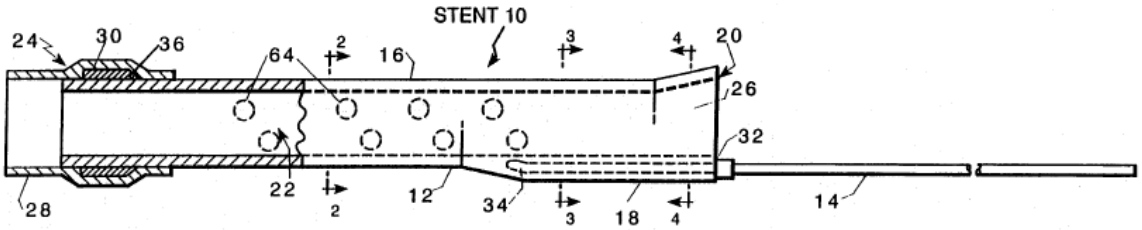


FIG. 1

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

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." *Id.* at 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 a tube 16 having a base portion 18 at its proximal end 20." *Id.* at 3:47–49. "Tube 16 has a continuous lumen 22 there through 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:

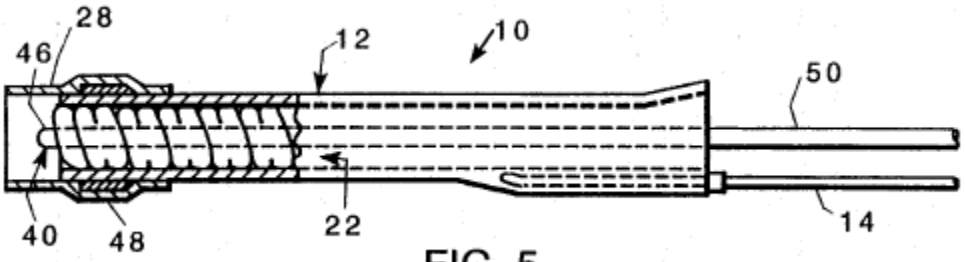
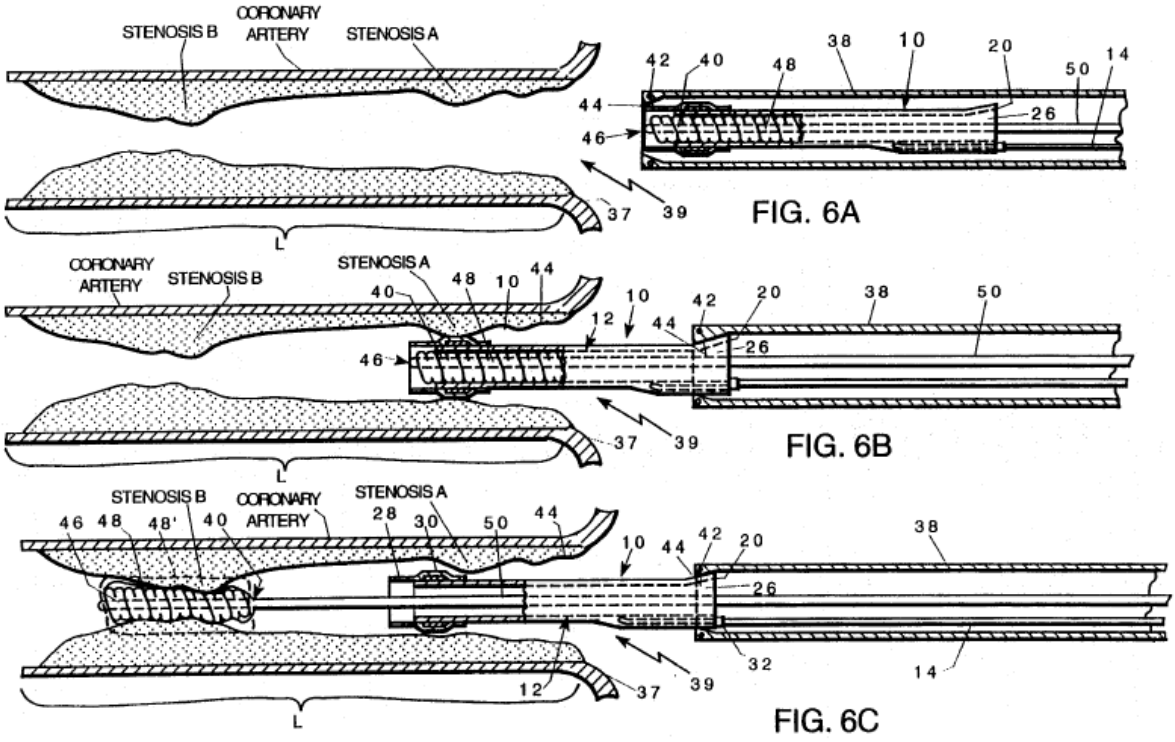


FIG. 5

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 exerting axial force on wire 14 and catheter tube 50 simultaneously. *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, into the 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 5:52–56.

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. Overview of Ressemann (Ex. 1408)

Ressemann is a U.S. patent that issued on October 20, 2009 from an application filed on August 9, 2002. Ex. 1408. Thus, on its face, Ressemann qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

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

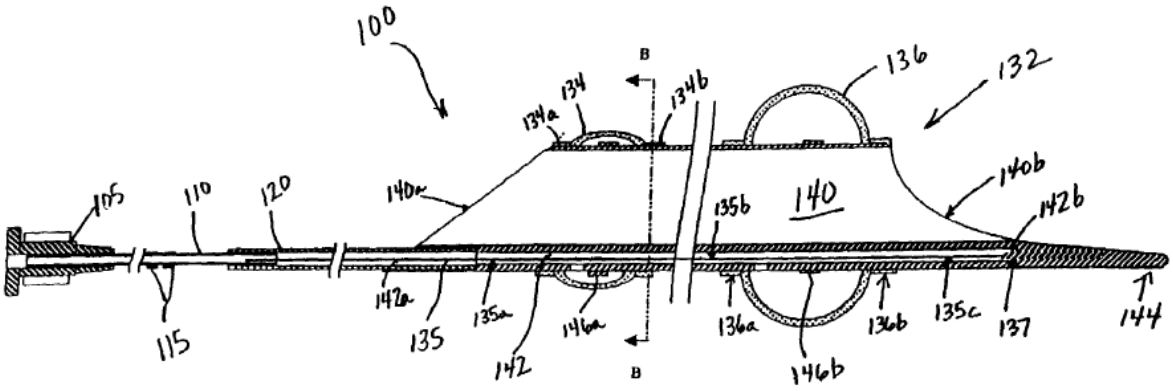


FIG. 1A

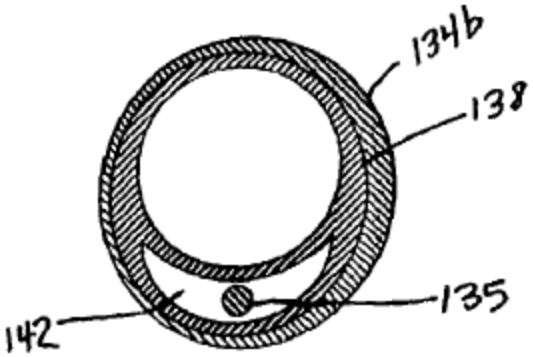


FIG. 1B

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

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

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

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

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

Figure 6D of Ressemann is reproduced below:

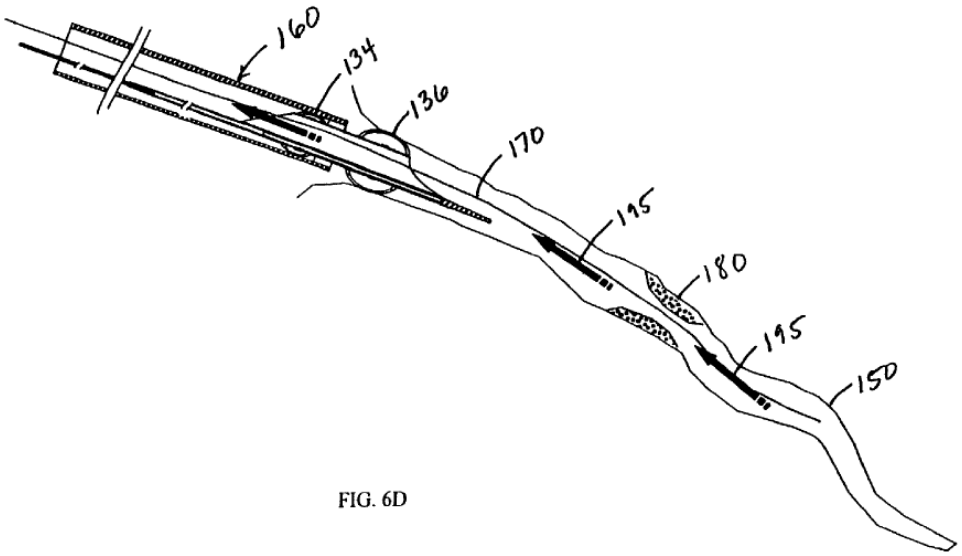


FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. As shown in Figure 6D, guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, "[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber." *Id.* at 13:43–44.

3. Independent Claim 25

Petitioner contends that the combination of Kontos and Ressemann teaches each of the limitations of independent claim 25 as follows:

With respect to the requirement for "[a] guide extension catheter for use with a guide catheter," Petitioner contends that, to the extent the preamble is limiting,[9] Kontos's support catheter assembly 10 meets this limitation. Pet. 21–22 (citing Ex. 1405 ¶ 154; Ex. 1409, 2:16–22, 3:45–46, 5:49–52, Fig. 1, Fig. 6B).

With respect to the requirement for "a substantially rigid segment." Petitioner contends that the insertion/manipulation wire 14 that is proximal of tube 16 in Kontos's support catheter 10 meets this limitation. *Id.* at 22–24 (citing Ex. 1405 ¶ 155; Ex. 1409, Abstract, 5:25–30, Fig. 1). Petitioner notes that the '776 patent precludes the substantially rigid segment from overlapping with the tubular structure, and has applied the claims as recited

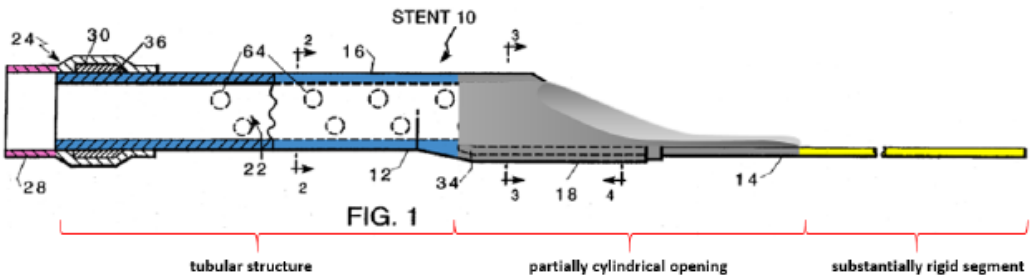
[9] We need not determine at this time whether the preamble of claim 25 is limiting because Petitioner shows sufficiently for purposes of institution that the recitation in the preamble is disclosed in Kontos.

in the '776 patent and as interpreted by Patent Owner in the district court. *Id.* at 23 n.6 (citing Ex. 1477, 127:24–128:14, 144:9–22, 145:9–17).

With respect to the requirement for "a tubular structure defining a lumen and positioned distal to the substantially rigid segment," Petitioner identifies the tube 16 in Kontos's support catheter as meeting this limitation. *Id.* at 24–25 (citing Ex. 1405 ¶ 156; Ex. 1409, 3:49–50, 3:56–57, Figs. 1, 6C).

With respect to the requirements for "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure" and the "segment defining the partially cylindrical opening having an angled proximal end," Petitioner relies upon the combination of Kontos with Ressemann and/or the knowledge of a POSITA as meeting these requirements. *Id.* at 25–34. Petitioner acknowledges that Kontos does not teach a partially cylindrical opening, but contends that such partially cylindrical openings were well-known in the art. *Id.* at 27 (citing Ex. 1405 ¶¶ 90–108, 158–59; Ex. 1442 ¶¶ 73-78; Ex. 1407, 4:11; Ex. 1408, 12:9–13:60, Figs. 6A–6E; Ex. 1418, Fig. 7; Ex. 1432, 119, Fig. 1; Ex. 1433 ¶¶ 035, 49, Fig. 2; Ex. 1435 ¶ 66; Ex. 1450, Fig. 7; Ex. 1461, 6:9–11, Fig. 1B). As one such example, Petitioner contends that Ressemann teaches an evacuation assembly 100/2100 ("extension catheter") where the entry to the evacuation lumen 140a/2140 is "preferably angled." *Id.* (citing Ex. 1405 ¶¶ 160–161; Ex. 1408, 6:52–60 (100 embodiment), 24:33–38 (2100 embodiment)).

Petitioner contends that a POSITA would have been motivated, with a reasonable expectation of success, to add Ressemann's partially cylindrical opening to Kontos's structure as shown in the annotated figure below:



Id. at 28–29 (citing Ex. 1405 ¶¶ 161–174; Ex. 1442 ¶¶ 91–100; Ex. 1409, Fig. 1). The annotated figure above shows a magnified version of Kontos's Figure 1 modified to include Ressemann's support collar (labeled the "partially cylindrical opening") in between the wire 14 (labeled the "substantially rigid segment") and tube 16 (labeled the "tubular structure"). Petitioner contends that the result of the combination would necessarily include a segment with an angled proximal end. *Id.* at 35 (citing Ex. 1405 ¶ 175).

Petitioner identifies multiple reasons as to why a POSITA would have been motivated to modify Kontos to add a partially cylindrical opening proximal of the tubular structure, as taught by Ressemann. *Id.* at 29 (citing Ex. 1405 ¶¶ 162–72; Ex. 1442 ¶¶ 91–99). Petitioner contends that the use of a partially cylindrical opening could permit a reduction of the outer diameter of the catheter assembly without resulting in a commensurate reduction in the area of the point of entry to the extension catheter, and this would have been beneficial for the small diameter (6 French) guiding catheters that were commonly used as of the priority date of the '776 patent. *Id.* at 29–31 (citing Ex. 1405 ¶¶ 163–165; Ex. 1406, Fig. 6B; Ex. 1442 ¶ 96). Petitioner further contends that a POSITA would have been motivated to use a partially cylindrical opening in order to facilitate "smoother" reception, passage, and reentry of the device as it enters the lumen of the child catheter

and navigates winding vasculature. *Id.* at 31–32 (citing Ex. 1405 ¶ 166–173; Ex. 1442 ¶¶ 80, 89–95, 98–100). Petitioner also contends that employing Ressemann's partially cylindrical opening (as opposed to an opening perpendicular to the longitudinal axis) with Kontos's device would have amounted to a simple substitution of a known element to obtain predictable results. *Id.* at 33–34 (citing *KSR Int'l co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)).

With respect to the requirement that the segment is "formed from a material more rigid than a material or material combination forming the tubular structure," Petitioner contends that the incorporation of Ressemann's support collar 2141 to Kontos's structure would meet this requirement. *Id.* at 35–36 (citing Ex. 1405 ¶¶ 176–177; 1442 ¶¶101–105). Petitioner points out that Ressemann's support collar is preferably "a metallic material" with "suitable rigidity to prevent kinking," while Kontos's tube 16 includes "any pliable material," but preferably is composed of a molded plastic material, such as polyethylene. *Id* at 36 (citing Ex. 1408, 24:47–55, 24:62–67, 25:13–16; Ex. 1409, 4:1–4).

With respect to the requirement that the segment is "configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter," Petitioner contends that Kontos teaches that the extension catheter (support catheter 10) is positioned within the guide catheter when it receives the interventional cardiology device. *Id.* at 37 (citing Ex. 1409, 4:66–5:2, 5:16–18, 7:45–52, Figs. 6A–C; Ex. 1405 ¶ 178). Petitioner also argues that the "configured to" language recites an intended use, to which no patentable weight should be given. *Id.* (citing *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

Finally, with respect to the requirement "wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen," Petitioner contends that Kontos discloses an extension catheter (support catheter 10) where a cross-section at the proximal end of the tubular structure defines a single lumen, and further contends that the addition of Ressemann's support collar 2141 would not result in more than one lumen. *Id.* at 37–38 (citing Ex. 1405 ¶ 179; Ex. 1442 ¶ 107).

Patent Owner argues that Petitioner has not shown, for several reasons, that the claimed guide extension catheter, including a "partially cylindrical opening," would have been obvious based on Kontos and Ressemann. Prelim. Resp. 31. First, Patent Owner asserts that the Petition does not adequately address why a POSITA would be motivated to focus on Ressemann's support collar, which Patent Owner contends does not form the proximal opening in Ressemann's device. *Id.* at 33–36 (citing Ex. 2042 ¶¶ 38–40, 52–56). Second, Patent Owner contends that the Petition does not address reasons why a POSITA would be motivated not to make the combination, such as that removing the proximal funnel from Kontos would be contrary to Kontos's intended purpose. *Id.* at 36–41 (citing Ex. 2042 ¶¶ 36, 57, 60). Third, Patent Owner contends that Petitioner's asserted motivations ignore key considerations, such as the fact that the preferred dimensions disclosed in Kontos already permit use within a 6 French guide catheter and that removing the funnel from Kontos's device would not facilitate use of a smaller diameter guide catheter. *Id.* at 42 (citing Ex. 2042 ¶¶ 35–36, 62). Patent Owner also contends that the opening of Ressemann's device actually increases the likelihood that an interventional cardiology device could "snag" or become "hung up," and Kontos already reduces

potential "hang-up" by providing a funnel. *Id.* at 42–43 (citing Ex. 2042 ¶¶ 58, 63). With respect to Petitioner's asserted motivation to reduce the amount of force that a physician must exert to advance the catheter through winding vasculature, Patent Owner contends that this is illogical on its face because what the prior art may have done on a distal or leading end opening of a catheter that interacts with the vasculature has nothing to do with an opening in a middle section of a device that does not interact with the vasculature, but rather is inside an enclosed guide catheter. *Id.* at 44 (citing Ex. 2042 ¶ 64).

Based on the evidence and arguments of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing as to this ground with respect to at least claim 25 of the '776 patent. We are not persuaded by Patent Owner's arguments at this preliminary stage.

As to Patent Owner's argument that Ressemann's support collar is buried inside and underneath other components of Ressemann's suction catheter, and thus there is no reason a POSITA would be motivated to use it to define the opening into Kontos's catheter (Prelim. Resp. 33–36), we note that Ressemann teaches that "[t]he proximal end 2140*a* of the evacuation lumen 2140 is preferably angled to facilitate smooth passage of other therapeutic devices through the evacuation lumen 2140 of the evacuation head 2132." Ex. 1408, 23:17–20. Moreover, Ressemann teaches that the "support collar 2141 is positioned about the proximal end of the multi lumen tube 2138 and serves to reinforce the proximal opening of the evacuation lumen 2140 in the presence of deforming forces." *Id.* at 24:49–53. The tab portion 2141b of support collar 2141 "lies adjacent the exterior walls of the multi-lumen tube 2138." *Id.* at 24:62–63. Thus, contrary to Patent Owner's arguments, Ressemann's support collar does appear to help define the angled

shape of the proximal opening that facilitates smooth passage of other devices. The testimony of Petitioner's experts Dr. Brecker and Dr. Hillstead supports this interpretation of the prior art. Ex. 1405 ¶¶ 160–161, 174; Ex. 1442 ¶¶ 72, 79–80. Insofar as Patent Owner's expert Mr. Keith has a different understanding of the prior art (Ex. 2042 ¶¶ 38–40, 52–56), we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c). We further note that Patent Owner's incompatibility arguments are premised upon the bodily incorporation of Ressemann's support collar 2141 into Kontos's support catheter, but that is not required for obviousness. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, but rather whether a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention." *Allied Erecting & Dismantling Co. v. Genesis Attachments*, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (internal citations omitted).

We are also unpersuaded by Patent Owner's argument that removing the proximal funnel from Kontos would be contrary to Kontos's "intended purpose." Prelim. Resp. 36–41. The use of the funnel portion to facilitate insertion of a PTCA catheter appears to be one aspect of the invention described in Kontos. Ex. 1409, 3:60–68 (noting that the device "may be flared out at proximal end 20 to form funnel portion 26" and "[i]t will be appreciated that the conical opening of lumen 22 at funnel portion 26 facilitates insertion of a PTCA catheter or the like therethrough"). Petitioner's obviousness theory is premised upon replacing the funnel portion with a partially cylindrical opening that "could permit a reduction of the outer diameter of the catheter assembly without resulting in a

commensurate reduction in the area of the point of entry to the extension catheter." Pet. 29–30. Petitioner's experts Dr. Brecker and Dr. Hillstead contend that the proposed modification would *further* facilitate insertion of the catheter while maintaining the same area at the point of entry, which is consistent with the stated purpose of Kontos. Ex. 1405 ¶¶ 163–166; Ex. 1442 ¶¶ 96–100. To the extent that Patent Owner's expert Mr. Keith disagrees (Ex. 2042 ¶¶ 36, 57, 60), we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

We have also considered Patent Owner's other arguments as to why a POSITA would not have been motivated with a reasonable expectation of success to combine Kontos's device with Ressemann's support collar. Prelim. Resp. 42–45. Patent Owner's arguments in this regard are largely based upon the testimony of its expert Mr. Keith, who disagrees with the reasons set forth by Petitioner's experts Dr. Brecker and Dr. Hillstead. *Id.* (citing *generally* Ex. 2042). At this stage, we determine that Dr. Brecker and Dr. Hillstead have provided sufficient non-conclusory rationales and evidentiary support for their opinions. Ex. 1405 ¶¶ 161–174; Ex. 1442 ¶¶ 91–100. Insofar as Mr. Keith provides contrary opinions (Ex. 2042 ¶¶ 52–65), we determine that the testimony of the parties' experts raises genuine issues of material fact that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

Having determined that Petitioner meets the threshold for review of claim 25 based on obviousness in view of Kontos, Ressemann, and the knowledge of a POSITA, we institute a review as to all of challenged claims and grounds contained in the Petition. We address the remaining claims and grounds below to provide further guidance to the parties.

4. Claims 26, 27, 29, 33, 35–37, 39, 41–49, and 52

Petitioner also contends that the combination of Kontos, Ressemann, and the knowledge of a POSITA renders obvious claims 26, 27, 29, 33, 35–37, 39, 41–49, and 52 of the '776 patent. Pet. 38–56. In support of these arguments, Petitioner provides a detailed analysis of the teachings of Kontos and Ressemann, along with supporting testimony from Dr. Brecker and Dr. Hillstead explaining how each limitation is met. *Id.* (citing *generally* Ex. 1405; Ex. 1442). Patent Owner does not present additional arguments as to these claims that have not already been considered with respect to claim 25, as discussed above.

Upon review of Petitioner's arguments and the supporting evidence, we determine that Petitioner has demonstrated a reasonable likelihood that claims 26, 27, 29, 33, 35–37, 39, 41–49, and 52 are rendered obvious by Kontos, Ressemann, and the knowledge of a POSITA.

D. Ground 2: Obviousness in view of Kontos, Ressemann, Takahashi, and the Knowledge of a POSITA

For its Ground 2 challenge, Petitioner asserts that claims 30–32 and 53–56 would have been obvious in view of Kontos, Ressemann, Takahashi, and the knowledge of a POSITA. Pet. 56–66.

1. Overview of Takahashi (Ex. 1410)

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 publication date of December 2004 and a copyright date of 2004. *Id.* To establish the public accessibility of Takahashi, Petitioner relies upon the declaration of Dr. Sylvia D. Hall-Ellis, who attests that "[i]n view of the MARC record for Exhibit 1410, the Takahashi article was publicly available no later than December 17, 2004, because the serial title had been cataloged

and indexed at the National Library of Medicine and made part of its online catalog database." Ex. 1478 ¶ 47. Based on this evidence, we are persuaded that Petitioner has established a reasonable likelihood that Takahashi qualifies as a prior art printed publication under 35 U.S.C. § 102(b). *See Hulu, LLC v. Sound View Innovations, LLC*, Case IPR2018-01039 (PTAB Dec. 20, 2019) (Paper 29) (precedential).

Takahashi discusses the use of a guiding catheter in percutaneous coronary intervention (PCI). *See generally* Ex. 1410. 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 the minimal damage and then it can be inserted more deeply into the artery." *Id.*

2. Claims 30–32 and 53–56

Claim 30 depends from claim 25, and recites:

> wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.

Ex. 1401, 13:66–14:5. Claim 53 is written in independent form, and recites "the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter." *Id.* at 16:2–5.

For these claims, and their respective dependent claims (claims 31, 32 and 54–56), Petitioner relies upon the teachings of Kontos and Ressemann, as discussed above, and further relies upon Takahashi's disclosure of a "five-in-six" system wherein the inner diameter of the 5 French catheter is not more than one French smaller than the cross–sectional inner diameter of the 6 French guide catheter. Pet. 59–60 (citing Ex. 1405 ¶¶ 233–235; Ex. 1442 ¶¶ 138–38, 142–145; Ex. 1410, 452). Petitioner contends it would have been obvious to modify Kontos in light of Ressemann and Takahashi to achieve the not-more-than-one French differential in order to improve backup support, and a POSITA would have had a reasonable expectation of success in removing Kontos's funnel in favor of a proximal side opening, which would result in a uniform diameter of the lumen and permit achievement of the not-more-than-one French differential. *Id.* at 60.

With respect to Ground 2 (and Ground 4 discussed below), Patent Owner further argues that the Petition does not acknowledge or discuss how to reconcile the inconsistency between its obviousness analysis premised on making Kontos's body 12 *larger* so it meets the five-in-six relationship described in Takahashi and Kontos's teaching of a "mini guide catheter" that is small enough to extend all the way into a stenosis so as to serve as a stent. Prelim. Resp. 46–47 (citing Ex. 1409, 2:16–32, 6:48–7:5, Figs. 8A–8C; Ex. 2042 ¶ 68). Patent Owner also argues that even after the allegedly obvious removal of Kontos's funnel, Kontos's body portion does not have a uniform outer diameter due to the marker band and soft tip that extend outwardly from the outer surface of the distal end of body 12. *Id.* at 47 (citing Ex. 2042 ¶ 67). Additionally, Patent Owner contends that Takahashi does not teach a "five-in-six" system being applied to a rapid exchange guide extension design. *Id.* at 48 (citing Ex. 2042 ¶¶ 46, 69).

Although we recognize that Patent Owner's expert has raised legitimate concerns about the combination of Kontos, Ressemann, and Takahashi in the manner asserted for Ground 2, we find there are genuine issues of material fact as to this dispute that are best resolved after a full trial record. *See* 37 C.F.R. § 42.108(c).

E. Ground 3: Obviousness in view of Kontos, Ressemann, Kataishi, and the Knowledge of a POSITA

For its Ground 3 challenge, Petitioner asserts that claim 52 would have been obvious in view of Kontos, Ressemann, Kataishi, and the knowledge of a POSITA. Pet. 66–72.

1. Overview of Kataishi (Ex. 1425)

Kataishi is a publication of a U.S. patent application that was filed on January 22, 2004, and published on January 20, 2005. Ex. 1425. Thus, on its face, Kataishi qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Kataishi teaches "a thrombus suction catheter with improved suction and crossing having a small pressure loss, which is a tube having a lumen passing through from a proximal end to a distal end, a distal end opening having an angled cut surface." Ex. 1425, ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

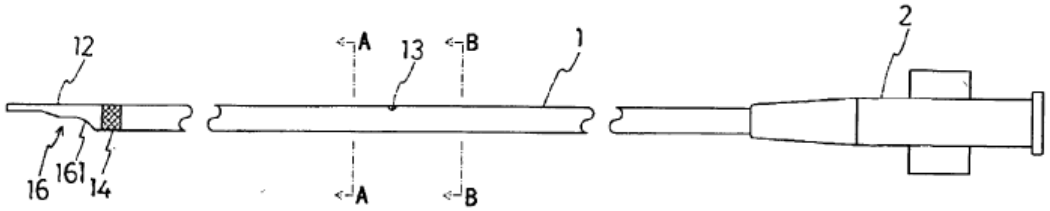


Fig. 1

As shown in Figure 1, a thrombus suction catheter includes a catheter body 1, a connector 2 provided at a proximal end of the catheter body 1, a distal

end opening 12 formed by an angled cut surface, and a guide wire insertion port 13. *Id.* at ¶¶ 27, 29.

2. Claim 52

Independent claim 52 recites a guide extension catheter similar to claim 25, except it requires that the segment is "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure," and further requires that "the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions." Ex. 1401, 15:15–34.

As noted above, we have determined that Petitioner has demonstrated a reasonable likelihood of establishing that claim 52 would have been obvious based on the combination of Kontos and Ressemann as set forth in Ground 1. In particular, Petitioner contends that Ressemann's support collar 2141 includes two inclined regions, and a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's support collar into Kontos's support catheter 10. Pet. 55–56 (citing Ex. 1405 ¶¶ 215–224; Ex. 1442 ¶¶ 134–137). We are unpersuaded by Patent Owner's arguments regarding the combination of Kontos and Ressemann.

However, to the extent that the Kontos-Ressemann combination fails to teach the requirement of "at least two inclined regions," Petitioner relies upon Kataishi as teaching this limitation. *Id.* at 68–72. Petitioner contends that a POSITA had motivation to modify the partially cylindrical opening of Itou's suction catheter 2 to include an inclined region because "Kataishi teaches a suction catheter with a distal end designed to do two things: (i) improve crossability of the catheter; and (ii) provide superior loading of matter (thrombus) into the distal end of the suction catheter," and "[t]hese

advantages are accomplished by the shape of Kataishi's distal end." *Id.* at 70 (citing Ex. 1405 ¶¶ 247–249; Ex. 1442 ¶¶ 152–158). Petitioner contends that adding a second, inclined slope to support collar 2141 would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. *Id.* at 70–71. Additionally, Petitioner contends that locating the two-incline opening on the proximal side would minimize kinking, thereby improving the crossability of the device by avoiding drag on the inside of the guide catheter. *Id.* at 71.

With respect to Ground 3 (and Ground 4 discussed below), Patent Owner additionally argues that the Petition fails to explain why a POSITA would have been motivated to modify the proximal end of Kontos' guide catheter body based on the distal end of Kataishi's suction catheter. Prelim. Resp. 49–54. According to Patent Owner, the distal end of Kataishi's suction catheter is designed to suction a thrombus from the side of the distal end by being flexible and shaped to conform about the thrombus and against a vessel wall, and Petitioner has not shown how this relates to introducing interventional cardiology devices into the proximal end of a suction catheter. *Id.* at 52–53. On this record, we agree with Patent Owner that Petitioner does not explain sufficiently why the inclined shape of Kataishi's distal opening would have been applicable to the angled partially cylindrical opening at the proximal end of the catheter based on the Kontos-Ressemann combination. Nonetheless, because we are instituting trial in this proceeding, the parties may further develop the record with respect to this issue before we reach our final determination as to this ground.

F. Ground 4: Obviousness in view of Kontos, Ressemann, Takahashi, Kataishi, and the Knowledge of a POSITA

For its Ground 4 challenge, Petitioner asserts that claims 53–56 would have been obvious in view of Kontos, Ressemann, Takahashi, Kataishi, and the knowledge of a POSITA. Pet. 72–73. Petitioner relies upon each of the references the manner discussed above for similar claim limitations. Patent Owner also relies upon the same arguments presented with respect to the other grounds.

As discussed above, we find there are genuine issues of material fact as to whether the combination of Kontos, Ressemann, and Takahashi, satisfies the "not more than one French size smaller" requirement of claim 53. Additionally, with respect to the claim requirement of "at least two inclined regions," we determine that Petitioner does not sufficiently explain why explain sufficiently why the inclined shape of Kataishi's distal opening would have been applicable to the angled partially cylindrical opening at the proximal end of the catheter based on the Kontos-Ressemann combination. Nonetheless, because we are instituting trial in this proceeding, the parties may further develop the record with respect to these issues before we reach our final determination as to this ground.

G. Objective Indicia

Patent Owner contends Petitioner's obviousness grounds fail because Petitioner did not address known objective evidence of nonobviousness, including evidence of commercial success, industry praise, licensing by competitors, copying, and long-felt need. Prelim. Resp. 54–67. We are not persuaded by these arguments.

Objective evidence of nonobviousness is relevant only if there is a nexus between this evidence and the claimed invention. *Fox Factory, Inc. v.*

SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019). A presumption of nexus applies if the asserted objective evidence "is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (quoting *Polaris Indus., Inc. v. Artic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). To the extent that a presumption of nexus does not apply, Patent Owner may still prove nexus "by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

Patent Owner contends that a presumption of nexus applies in this case because its "GuideLiner" product "embodies challenged claims and is coextensive with them." Prelim. Resp. 59. 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 58 (citing Ex. 2056 ¶¶ 160–163, 168, App'x J (465–474), App'x K (515–518, App'x L (559–570)). Patent Owner provides no persuasive analysis, however, to explain why the claims of the '776 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. *Fox Factory*, 944 F.3d at 1378. Thus, on this record, a presumption of nexus does not apply.

Because Patent Owner asserts a nexus exists for multiple patents, it "retains the burden of proving the degree to which evidence of secondary considerations tied to a product is attributable to a particular claimed invention." *Fox Factory*, 944 F.3d at 1378. Patent Owner has not done so on the record before us at this time. Moreover, the question of nexus is highly fact specific and it is Patent Owner's burden to establish a sufficient nexus. *Id.* at 1373. Thus, here, as in most cases an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage.

H. Discretionary Denial § 314(a)

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. 24–28. Patent Owner also argues that we should exercise our discretion and deny institution because Petitioner has not justified multiple petitions challenging the '776 patent. *Id.* at 28–31.

1. Parallel Litigation

Patent Owner contends that the validity of at least some of the challenged claims of the '776 patent and other related patents is the subject of active litigation in two separate cases, the *QXM* case and the *Medtronic* case, which are both currently pending in the District of Minnesota. *Id.* at 12. As such, Patent Owner contends we should deny institution here since the same issues are already being litigated by the parties in the district court.

In *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential, designated May 7, 2019) ("*NHK*"), the

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

The parties address the *Fintiv* Factors in supplemental briefing that we authorized. Paper 17; Paper 18. We have considered each of these factors and conclude that, on balance, the circumstances here do not favor discretionary denial under § 314(a).

As to whether a stay of the parallel litigation exists or is likely to be granted (*Fintiv* Factor 1), Petitioner contends that the presiding district court judge in the *Medtronic* and *QXM* cases "has granted every post-institution request to stay litigation pending reexamination or IPR." Paper 17, 2 (citing Ex. 1493). Petitioner also points out that the *QXM* case, involving the '776 patent and other patents in the same family, has already been stayed pending our institution decisions, and the court indicated that if we institute trial "the Court will invite the parties to brief whether the stay should extend through

the conclusion of the review process." *Id.* (citing Ex. 1494). Thus, Petitioner contends that the same judge will also entertain Petitioner's motion to stay the *Medtronic* case in the event of institution. *Id.* With respect to *Fintiv* Factor 1, Patent Owner contends that Petitioner has not sought a stay of the *Medtronic* litigation, and the Board has previously declined to infer how the district court would rule when neither party has requested a stay. Paper 18, 1. Patent Owner contends that the *QXM* case was stayed only because QXMédical agreed to exit the market and waived its obviousness/anticipation defenses, and that the district court has not granted stays involving direct competitors or allegations of irreparable harm. *Id.* Having considered the parties position, we determine that *Fintiv* Factor 1 favors institution, especially in view of the fact that a stay has already been granted in the related *QXM* case and the district court's prior history of granting stays pending resolution of related IPRs.

As to the proximity of the court's trial dates to our statutory deadlines (*Fintiv* Factor 2), the parties agree that the district court has indicated that the *Medtronic* case must be "Ready for Trial" by August 1, 2021, which would be a few weeks *after* our statutory deadline for a final written decision in this proceeding and the related IPRs. PO Resp. 14; Paper 19, 1. Petitioner asserts the date for an actual trial will likely be extended even further, noting that district court's final "Ready for Trial" date in patent proceedings is, on average, over eight months after the originally scheduled date. Paper 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 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. 13. Although we agree that the parties have invested some time and effort in the related litigation, we are not persuaded that those cases are in such an advanced stage that would favor of denial of institution. The district court recently denied the preliminary injunction motion filed by Patent Owner, noting that there are substantial questions with respect to the validity of the asserted claims. Ex. 1488, 9–14. However, the district court has not issued a claim construction order or any other substantive order in the *Medtronic* case. *See*

Fintiv, Paper 11 at 10 (noting that if "the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*"). We, therefore, determine that resolution of those common issues by the Board may be beneficial to the resolution of the district court proceedings. Patent Owner also contends that Petitioner delayed bringing these challenges. Paper 20, 2. Petitioner, however, points out that it filed its IPR petitions roughly four months after the district court complaint in the *Medtronic* case, and before Patent Owner's infringement contentions were served in that case. Paper 17, 2; *see Fintiv*, Paper 11 at 11 (noting that "it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding"). We find that Petitioner did not unduly delay filing its IPR Petitions.

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

proceeding. In *Fintiv*, the Board noted that "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial." *Fintiv*, Paper 11 at 13. In this case, however, any concerns about inefficiency and the possibility of conflicting decisions may be mitigated by the fact that the district court may stay the parallel litigation and thus not reach the merits of Petitioner's invalidity defenses before we issue our Final Written Decision. Finally, under *Fintiv* Factor 6, we have taken into account the merits of Petitioner's challenges, as discussed above, and find that this favors institution.

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

2. Multiple Petitions

Petitioner concurrently filed two petitions for *inter partes* review of the '776 patent. In IPR2020-00135, Petitioner relies upon Itou (Ex. 1407) as the primary anticipating reference for most of the challenged claims. We recently instituted *inter partes* review based on that first petition. IPR2020-00135, Paper 22 (granting institution on June 8, 2020). In this proceeding, as discussed above, Petitioner relies upon the combination of Kontos and Ressemann as the primary basis for its obviousness challenges. Petitioner ranks its petition for IPR2020-00135 as "Petition 1" and this current Petition as "Petition 2," and also provides an explanation of material differences between the petitions. Paper 2. Patent Owner contends we should exercise our discretion to deny institution on this second Petition challenging the same claims of the '776 patent. Prelim. Resp. 28–31; Paper 8.

The Board's Trial Practice Guide addresses the situation where there are parallel petitions challenging the same patent, as here, noting that "[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns" and that "multiple petitions by a petitioner are not necessary in the vast majority of cases." *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide ("Consolidated Practice Guide") (Nov. 2019)[10] 59; *see also* 84 Fed. Reg. 64,280 (Nov. 21, 2019). "Nonetheless, the Board recognizes that there may be circumstances in which more than one petition may be necessary, including, for example, when the patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date requiring arguments under multiple prior art references." *Id.*

Petitioner contends that this second Petition challenging the '776 patent is necessary because of the priority date dispute concerning Patent Owner's attempts to swear behind the Itou reference in IPR2020-00135. Paper 2, 1–2. Petitioner argues "[i]t would be manifestly unfair and prejudicial to Petitioner if the Board exercises its discretion under § 314(a) to deny Petition 2 and post-institution Patent Owner successfully swears behind Itou." *Id.* at 3. Petitioner also contends that two petitions are necessary because of the length and number of claims asserted by Patent Owner in district court. *Id.* at 3–4.

Patent Owner responds that Petitioner's strategic choice to rely on a § 102(e) reference (Itou) does not justify multiple petitions. Paper 8, 1–2.

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

Patent Owner argues that Itou's prior art status was at issue in the district court litigation, and Petitioner did not even try to address the invention date in its petitions, and thus this is not one of the "rare" cases in which two petitions are needed. *Id*. at 1. Patent Owner contends that Petition's choice to include excessive, duplicative challenges to the same claims does not justify institution on multiple petitions. *Id.* at 3–4. Patent Owner also contends that, if we are inclined to institute trial on one of the petitions, institution on only the Kontos-based petition (IPR2020-0136) would avoid at least some of the inefficiencies resulting from having to address duplicative issues before both the district court and the Board. *Id*. at 4–5.

We have considered the parties' respective positions and determine that the circumstances here justify institution of this second Petition challenging the '776 patent. Contrary to Patent Owner's argument that it was a "strategic choice," Petitioner was entitled to rely upon Itou as § 102(e) prior art as a statutory basis for unpatentability. *See* 35 U.S.C. § 311(b) ("A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."). Given the possibility that we may determine that Itou does not qualify as prior art after fully considering Patent Owner's priority date arguments, we determine that Petitioner provides a sufficient explanation as to why it was necessary to rely upon the obviousness challenges presented here as an alternative basis for unpatentability. Indeed, this is precisely one of the circumstances recognized in our Trial Practice Guide "in which more than one petition may be necessary." Consolidated Practice Guide at 59.

Moreover, we find that the challenges presented in the two petitions are not excessive or duplicative. Although Petitioner challenges the same claims in each petition, the prior art and issues to be decided do not significantly overlap with each other. For instance, the obviousness challenges presented here require an assessment of the motivation to combine the teachings of Kontos and Ressemann, reasonable expectation of success, and secondary considerations that are not relevant to the anticipation challenge presented in IPR2020-00135. And although there were also obviousness challenges presented in the first petition that relied upon Ressemann or Kataishi for certain additional claims, the manner in which those references are relied upon in combination with Kontos in this second Petition is different. Finally, given the number and length of the 26 challenged claims (including 3 independent claims), which are all potentially the basis for Patent Owner's infringement allegations in the parallel litigation, and the complexity of the arguments that have been raised by both parties for each challenge, we determine that it was appropriate for Petitioner to rely upon multiple petitions for its alternative challenges in light of the word count limits for each petition.

In light of the circumstances presented here, we decline to exercise our discretion under § 314(a) to deny institution based on the multiple petitions challenging the '776 patent. To the extent that conducting separate proceedings is burdensome on the Board, the Board may separately exercise its authority under 37 C.F.R. §§ 42.1(b), 42.122(a) to consolidate the trials.

I. Appointments Clause

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." Prelim. Resp. 67–68 (citing *Arthrex, Inc. v. Smith &*

Nephew, Inc., 941 F.3d 1320, 1325 (Fed. Cir. 2019)). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

III. CONCLUSION

Considering the information presented in the Petition and the evidence of the record, we determine that Petitioner has shown a reasonable likelihood that it will prevail in showing that at least one of the challenged claims of the '776 patent is unpatentable. Thus, we institute *inter partes* review of all challenged claims based on all of the grounds set forth in the Petition. Our findings and conclusions are not final and may change after considering the full record developed during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 25–27, 29–33, 35–37, 39, 41–49, and 52–56 of the '776 patent based on the unpatentability challenges presented in the Petition.

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