

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX LIFE SCIENCES LIMITED,
Patent Owner.

IPR2020-01344
Patent RE46,116 E

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

SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Medtronic, Inc., and Medtronic Vascular, Inc. (“Petitioner”) and Teleflex Life Sciences Limited (“Patent Owner”).¹ Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 25–55 (“the Challenged Claims”) of U.S. Patent No. RE46,116 E (Ex. 1401, “the ’116 patent”) are unpatentable.

A. Background

Petitioner filed a Petition requesting an *inter partes* review of claims 25–55 of the ’116 patent. Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 7. We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims was unpatentable over the cited art. Pursuant to 35 U.S.C. § 314, the Board instituted trial on February 24, 2021. Paper 9.

¹ Teleflex Life Sciences Limited (“Teleflex”) filed a notice identifying itself as the owner of U.S. Patent No. 8,142,413 B2. Paper 5, 2. Teleflex further explained, “Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L., and Teleflex Medical Devices S.A.R.L. transferred ownership of U.S. Patent No. 8,142,413 to Teleflex Life Sciences Limited.” *See id.* at 2 n.1 (furthering stating that “[t]he assignment documents were recorded with the United States Patent & Trademark Office on January 27, 2020”).

Following institution, Patent Owner filed a Response to the Petition (Paper 21, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 37, “Reply”), and Patent Owner filed a Sur-reply (Paper 47).²

On November 18, 2021, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 68.

II. BACKGROUND

A. The ’116 patent

The ’116 patent, titled “Coaxial Guide Catheter for Interventional Cardiology Procedures,” issued August 23, 2016, from Application No. 14/195,435, filed March 3, 2014. Ex. 1401, codes (21), (22), (45), (54). The ’116 patent is a reissue of U.S. Patent No. 8,292,850 (“the ’850 patent”) from Application No. 13/359,059 (“the ’059 application”) filed on January 26, 2012, which the ’116 patent states is a continuation of an application filed on November 1, 2013 (issued as U.S. Patent No. RE45,380), which is an application for the reissue of U.S. Patent No. 8,292,850, which is a division of an application filed on June 28, 2010 (issued as U.S. Patent No. 8,142,413), which is a division of an application filed on May 3, 2006 (issued as U.S. Patent No. 8,048,032). *Id.* codes (60), (64). The ’116 patent is directed to “methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.” *Id.* at 1:38–40.

The ’116 patent explains, as background, that in “[i]nterventional cardiology procedures,” guidewires or other instruments, such as balloon

² Redacted versions of the PO Response and Reply are entered as Papers 22 and 38, respectively.

catheters and stents, are often inserted through guide catheters into coronary arteries that branch off from the aorta. *Id.* at 1:44–50. 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 1:50–54. 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, “[c]rossing 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 1:66–2:3.

The ’116 patent discusses four categories of previous “attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as ‘backup support’).” *Id.* at 2:4–7. One category of guiding catheters “are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed.” *Id.* at 2:8–11. A second category are “guiding catheters that include a retractable appendage. *Id.* at 2:25–26. A third category are “guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium.” *Id.* at 2:36–41. A fourth category, or “technique,” of the prior attempts “includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents.” *Id.* at 2:50–53. The ’116 patent states this fourth technique was

described in Takahashi,³ which uses a guide catheter inserted “more deeply into the ostium of the coronary artery than typically has been done before.” *Id.* at 2:53–62. The ’116 patent states that such “deep seating” by this technique “creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery.” *Id.* at 2:63–65.

The ’116 patent purports to resolve issues identified with the prior procedures by using “a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter.” Ex. 1401, 3:20–23. According to the ’116 patent, 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 3:23–28.

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the ’116 patent:

³ Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, 63 CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS 452–456 (2004) (Ex. 1410, “Takahashi”).

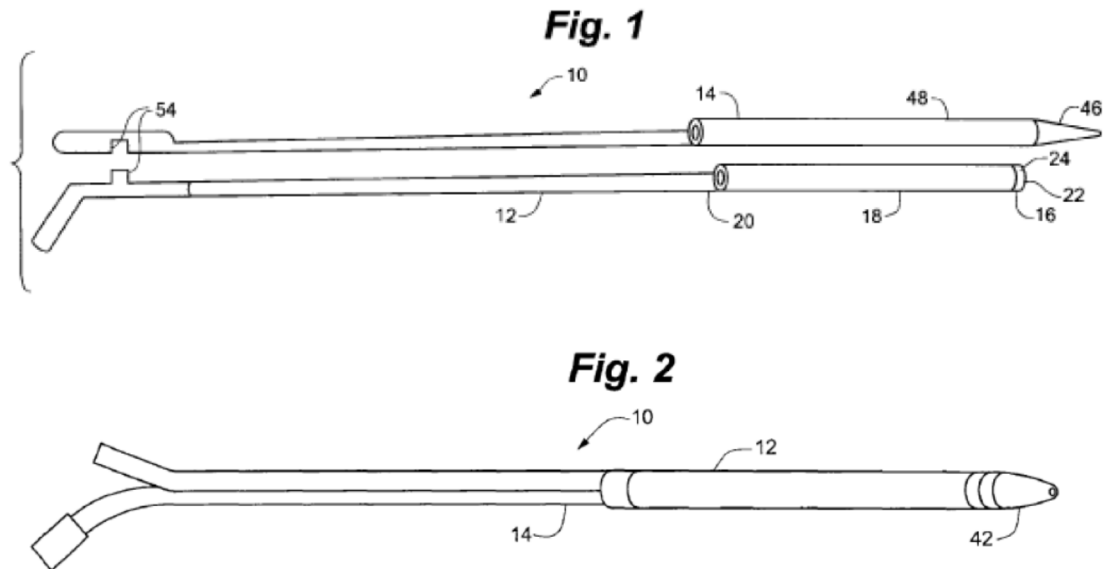


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:51–56; Figs. 1 and 2. As shown above, “coaxial guide catheter assembly 10” includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:42–44. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:45–46. Tapered inner catheter 14 “includes tapered inner catheter tip 42.” *Id.* at 7:26–27. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:30–31. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 7:31–32. “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 7:35–37. “The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.” *Id.* at 3:28–31. The coaxial guide catheter is made in

at least three sizes corresponding to sizes commonly used in interventional cardiology procedures. *Id.* at 3:39–42.

Figure 4, reproduced below, shows a coaxial guide catheter in accordance with the invention described in the '116 patent:

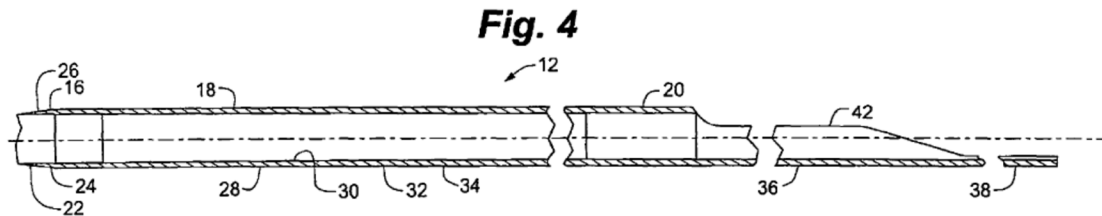


Figure 4 is a sectional view of the coaxial guide catheter with tip portion 16 depicted on the left side of the figure (rather than on the right side as shown in Figures 1 and 2). Ex. 1401, 5:60; Fig. 4. As shown above, coaxial guide catheter 12 has a rigid portion 20, which “includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full circumference portion 40” (second full circumference portion 40 is shown in Figure 3). *Id.* at 7:7–10.

In operation, a guide catheter and a guidewire are used along with the coaxial guide catheter and the tapered inner catheter. Ex. 1401, 8:20–22. Figure 8, reproduced below, shows the operation of the coaxial guide

catheter assembly in accordance with the invention described in the '116 patent:

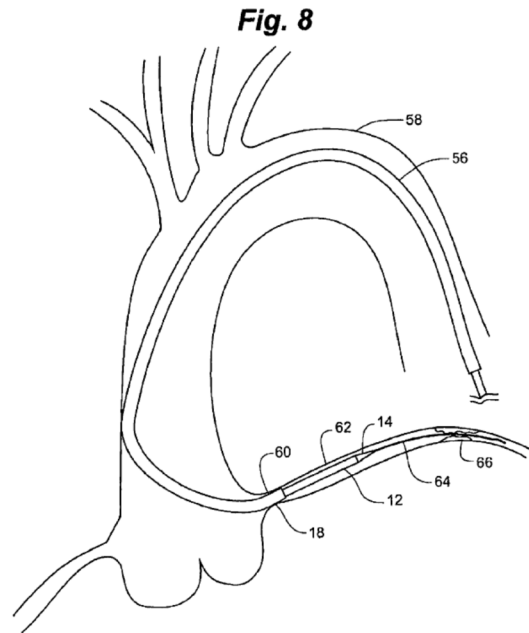


Figure 8 is a schematic view of a guide catheter and a guide wire in use with the coaxial guide catheter assembly within the aortic arch and coronary artery. *Id.* at 6:5–8; Fig. 8. First, guidewire 64 is inserted and passed through aortic arch 58 into ostium 60 of coronary artery 62. *Id.* at 7:65–66. Guide catheter 56 is then passed over guidewire 64 until the distal end of guide catheter 56 is seated in ostium 60. *Id.* at 8:4–6. Next, coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62. *Id.* at 8:22–24. The presence of coaxial guide catheter 12 within guide catheter 56 “provides stiffer back up support than guide catheter 56 alone.” *Id.* at 8:38–40. “Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed.” *Id.* at 4:58–62; *see also id.* at 8:30–32. Thereafter, coaxial guide catheter 12 can “accept a treatment

catheter such as a stent or [a] balloon catheter.” *Id.* at 8:33–34. “[T]he presence of 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 5:2–6. “[T]he invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters.” *Id.* at 5:42–44.

B. Illustrative Claim

Petitioner challenges claims 25–55 of the ’116 patent. Pet. 1. Claims 25, 51, and 52 are independent. Ex. 1401, 13:62–14:25, 15:51–16:15, 16:53–18:10. Claims 26–42 and 44–50 depend from claim 25 and claims 53–55 depend from claim 52. *Id.* at 14:62–18:26. Claim 25 is illustrative of the claimed subject matter and is reproduced below.

25. A method, comprising:

[25a] advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

[25b] advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter,

[25c] including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter,

[25d] the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis,

[25e] the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;

[25f] maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

[25g] while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

Id. at 13:62–14:25.

C. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	References/Basis
1	52, 53	103	Kontos, ⁴ Ressemann ⁵
2	25–40, 42, 44– 48	103	Kontos, Ressemann, Takahashi ⁶

⁴ U.S. Patent No. 5,439,445, issued August 8, 1995 (Ex. 1409, “Kontos”).

⁵ U.S. Patent No. 7,604,612 B2, issued October 20, 2009 (Ex. 1408, “Ressemann”).

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”).

Ground	Claim(s) Challenged	35 U.S.C. §	References/Basis
3	45	103	Kontos, Ressemann, Takahashi, Kataishi ⁷
4	25–55	103	Root ⁸
5	45, 46	103	Kontos, Ressemann, Takahashi, Root

Pet. 8.

Petitioner relies on the supporting Declarations of Dr. Stephen Jon David Brecker (Ex. 1405, 1806), Dr. Richard A. Hillstead (Ex. 1442), Mr. Michael Jones (Ex. 1807), Dr. Paul Zalesky (Ex. 1830).

Patent Owner relies on the supporting Declarations of Peter Keith (with attached Appendix B) (Exs. 2138), Dr. John Graham, MB ChB, MRCP (UK) (Ex. 2145); Dr. Lorenzo Azzalini, MD, PhD (Ex. 2151); Dr. Craig Thompson, MD, MMSc (Ex. 2215), Steve Jagodzinski, Sr. Manager Finance, Teleflex Inc. (Ex. 2153).

D. Related Proceedings

The parties identify the '116 patent as a subject of: (1) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.), and (2) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn.). Pet. 5; Paper 4, 2. Patent Owner states that both of these district court proceedings are currently stayed. Paper 4, 2. The parties further state that the '116 patent is a reissue of the '850 patent and that the

⁷ US 2005/0015073 A1, published January 20, 2005 (Ex. 1425, “Kataishi”).

⁸ US 2007/0260219 A1, published November 8, 2007 (Ex. 1512, “Root”) (publication of App. No. 11/416,629 (Ex. 1500), filed May 3, 2006, issued as U.S. Patent No. 8,048,032).

'850 patent was previously the subject of: (1) *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn.), and (2) *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (PTAB, terminated). Pet. 5–6.

Petitioner challenges claims 25–40, 42, 44–48, 52, and 53 of the '116 patent in IPR2020-01343 through another petition filed concurrently with the Petition in this case. Pet. 6 Additionally, Petitioner identifies the following patents related to the '116 patent that have been subject of *inter partes* review proceedings initiated by Petitioner: U.S. Patent Nos. 8,048,032 (IPR2020-00126; IPR2020-00127), RE45,830 (IPR2020-00128; IPR2020-00129; IPR2020-00130), RE45,760 (IPR2020-00132; IPR2020-00134), RE45,776 (IPR2020-00135; IPR2020-00136), RE47,379 (IPR2020-00137; IPR2020-00138), and 8,142,413 (IPR2020-01341; IPR2020-01342). *Id.*

E. Abbreviations

GC	Guide Catheter
IVCD	Intervascular Cardiac Device
PTCA	Percutaneous Transluminal Coronary Angioplasty
POSITA	Person of Ordinary Skill in the Art
RX	Rapid Exchange

III. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of

ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Id.* (citation omitted).

Petitioner contends that a person of ordinary skill in the art at the time of the invention would have been either: (1) a medical doctor who would have had “(a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist;” or (2) an engineer who “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.” Pet. 11–12. Additionally, Petitioner contends “[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience.” *Id.* at 12. Further, according to Petitioner, a person of ordinary skill in the art “with a medical degree” and a person of ordinary skill in the art “with an engineering degree” may have had access to each other. *Id.* (citing Ex. 1405 ¶ 27; Ex. 1442 ¶¶ 24-25).

Patent Owner does not dispute Petitioner’s proposed level of ordinary skill. PO Resp. 7. We adopt Petitioner’s proposed level of ordinary skill in the art as it is undisputed 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) (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)).

As their qualifications are undisputed, we also determine that the parties’ experts are qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 1442 ¶¶ 5, 10, 12 (Dr. Hillstead’s qualifications); Ex. 1807 ¶¶ 8–10 (Mr. Jones’s qualifications); Ex. 2138 ¶¶ 3–6 (Mr. Keith’s qualifications); Ex. 2145 ¶ 1 (Dr. Graham’s qualifications); *see Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369 (Fed. Cir. 2022) (“To offer expert testimony from the perspective of a skilled artisan in a patent case . . . a witness must at least have ordinary skill in the art.”).

B. Claim Construction

“In an inter partes review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). That standard “includ[es] construing 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.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Petitioner proposes the following constructions: (1) “side opening” needs no construction and should be given its plain and ordinary meaning, (2) “lumen” as “the cavity of a tube,” and (3) “flexural modulus”

as “[a] measure of resistance . . . to bending.” Pet. 12–13 (quoting Ex. 1440, 722).

Patent Owner does not dispute Petitioner’s proposed construction of these terms. *See generally* PO Resp.

In view of the issues we address below, we determine it is not necessary to address the express interpretation of any claim term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

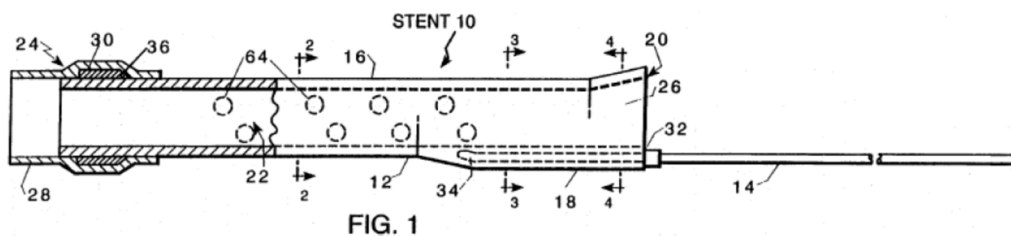
C. Scope and Content of the Prior Art

Petitioner relies on Kontos, Ressemann, Takahashi, Kataishi, and Root, each of which we briefly summarize in relevant part below.

1. Summary of Kontos (Ex. 1409)

Kontos, titled “Support Catheter Assembly,” 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 PTCA⁹ balloon into a lesion.” Ex. 1409, code (54), 1:9–13.

Figure 1 of Kontos is reproduced below:



⁹ 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.” 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 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 therethrough from proximal end 20 to distal end 24.” *Id.* at 3:49–50. Body 12 also includes 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. Ex. 1409, 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:

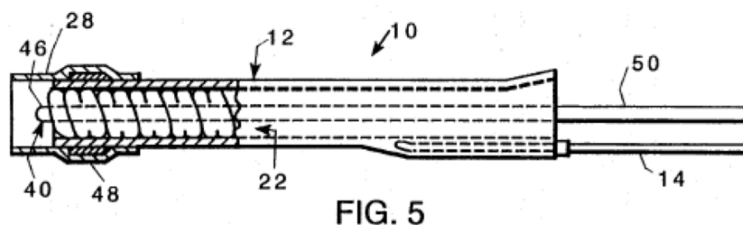
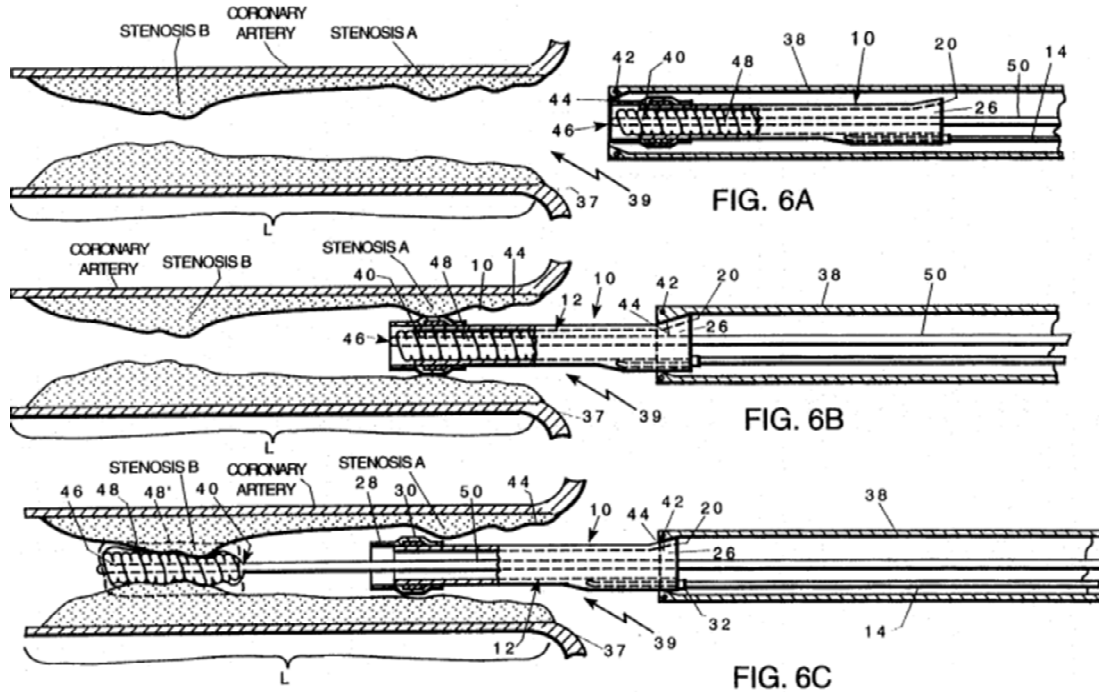


Figure 5 is a side schematic view of a support catheter having a PTCA catheter disposed therein. Ex. 1409, 2:64–66. In this figure, PTCA catheter

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. Ex. 1409, 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.

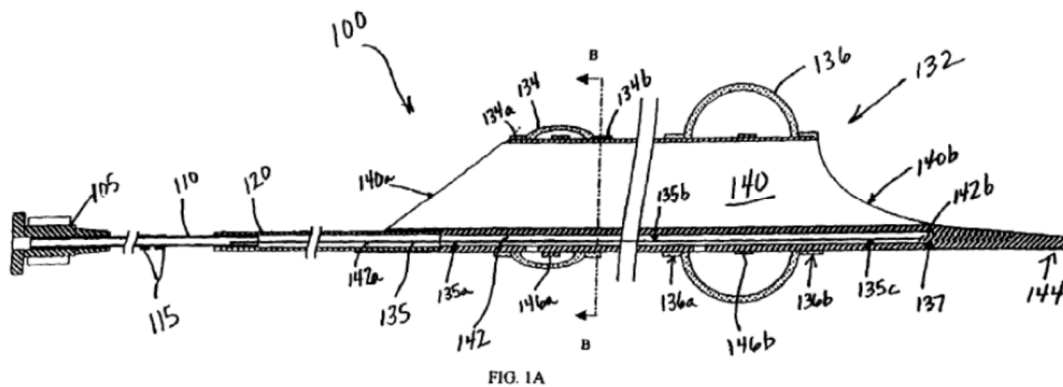
In Figure 6B, when the PTCA catheter/support catheter assembly reaches the distal end of guide catheter 38, “it may be advanced as a unit out of the distal end of guide catheter 38, into the coronary ostia 39.” Ex. 1409, 5:31–35. When extending beyond the distal end of guide catheter 38, body 12 functions 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. Ex. 1409, 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. Summary of Ressemann (Ex. 1408)

Ressemann, titled “Emboli Protection Devices and Related Methods of Use,” states that it is directed to an apparatus “used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels.” Ex. 1408, code (54), 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:



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. Ex. 1408, 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. Ex. 1408, 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:

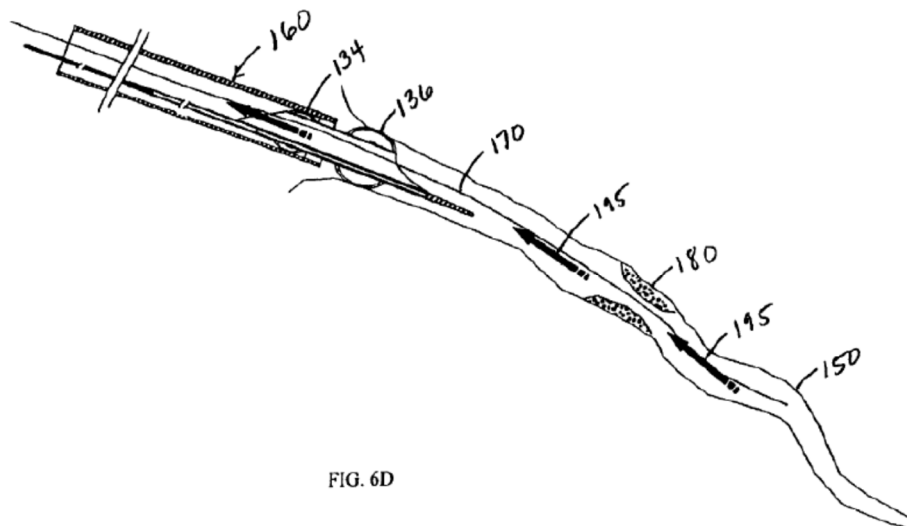


Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. Ex. 1408, 3:59–61. As shown in Figure 6D, guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may 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. The assembly, which includes a guide catheter, “may be positioned within the ostium of the target vessel.” *Id.* at 12:26–27.

3. *Summary of Takahashi (Ex. 1410)*

Takahashi, titled “New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter,” 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.*

4. *Summary of Kataishi (Ex. 1425)*

Kataishi, titled “Thrombus Suction Catheter with Improved Suction and Crossing,” 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, code (54), ¶ 10. Figure 1 of Kataishi, reproduced below, is a front view of a thrombus suction catheter.

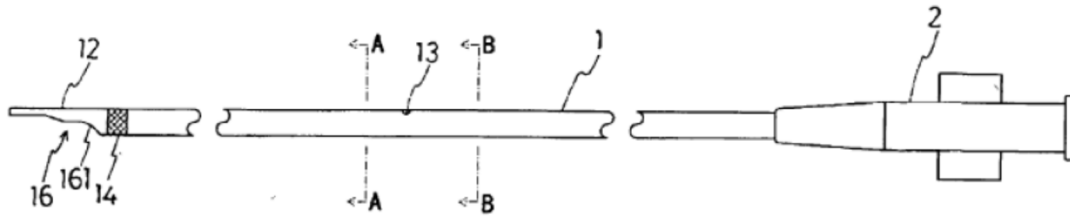


Fig. 1

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.* ¶¶ 27, 29.

5. Summary of Root (Ex. 1512)

The disclosure of Root, titled “Coaxial Guide Catheter for Interventional Cardiology Procedures,” is substantially similar and related to the ’116 patent. *Compare* Ex. 1512 to Ex. 1401. Root 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. 1512, code (54), Abstract.

Root discloses that interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* ¶ 2. 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.* 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.* ¶ 3. 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.*

To solve this problem, Root 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. Ex. 1512 ¶ 11. Root 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.*

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter:

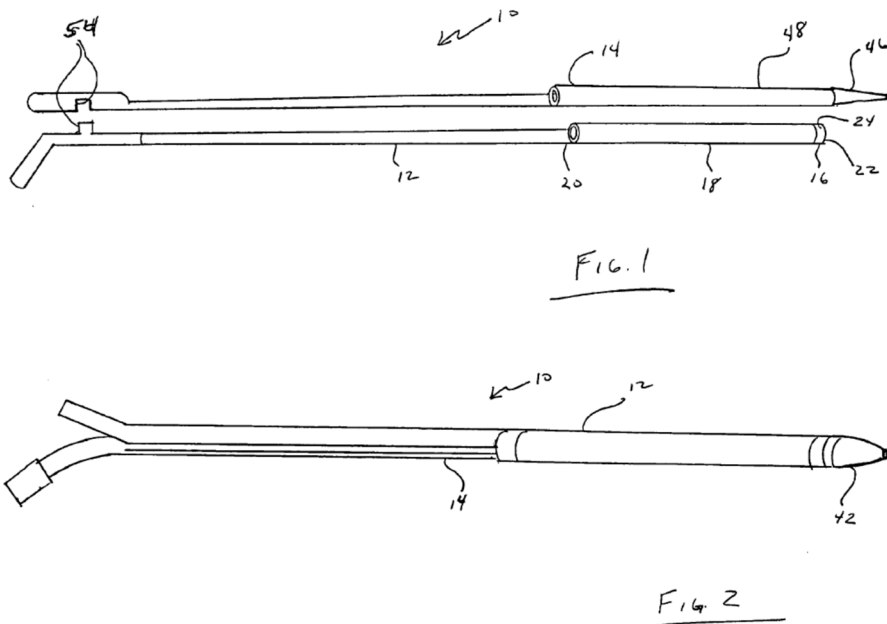


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. Ex. 1512, ¶¶ 28–29; Figs. 1 and 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* ¶ 50. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* ¶ 51. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* ¶ 52. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* ¶ 53. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* ¶ 62. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* 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.* ¶ 64.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. Ex. 1512, ¶ 22. 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.* 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.* 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.* ¶ 23. 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.*

D. Grounds 1 and 2: Alleged Obviousness over Kontos, Ressemann, and Takahashi

In Ground 1, Petitioner contends claims 52 and 53 would have been obvious over the combination of Kontos and Ressemann. Pet. 15–32. In Ground 2, Petitioner contends claims 25–40, 42, 44–48 would have been obvious over the combination of Kontos, Ressemann, and Takahashi. *Id.* at 32–48. For its analysis of claim 25 in Ground 2, Petitioner relies heavily on its analysis of claim 52 in Ground 1, and additionally relies on Takahashi in its analysis of element 25e of claim 25. *Id.* at 34–36.

Patent Owner first responds to Petitioner’s contentions with regard to independent claim 25. PO Resp. 7–30. As to claims 52 and 53, Patent Owner notes that claims 52 and 53 require the same “segment defining a side opening” recited in claim 25 and contends that “it would not have been obvious to modify the Kontos device to include such a side opening, for the reasons discussed” with regard to claim 25. PO Resp. 44. Accordingly, we first address the issues raised by the parties with regard to Grounds 1 and 2 together, with particular focus on independent claims 25 and 52.

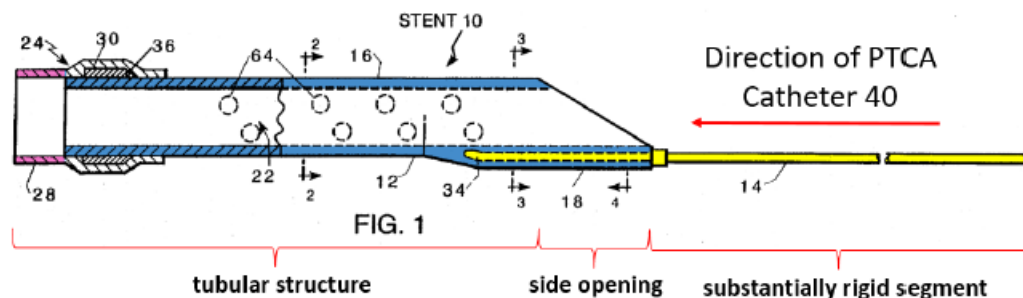
1. Independent Claims 25 and 52

a) Petitioner’s Contentions

Petitioner contends claims 25 and 52 would have been obvious over the combination of Kontos and Ressemann. Pet. 15–48. Petitioner provides a detailed explanation of how it contends each of the limitations of claims 25 and 52 are taught or suggested by the combination of Itou and Ressemann. *Id.* For example, as to claim 52, Petitioner relies on the teachings of Kontos

concerning the use of guide catheter 38 and catheter assembly 10 as a guide extension. Pet. 15–17. Petitioner states “Kontos does not teach . . . a side opening proximal to the tubular structure,” and relies on Ressemann as teaching “an evacuation assembly 100 (extension catheter) where the entry to the evacuation lumen 140a is ‘preferably angled.’” *Id.* at 18 (citing Ex. 1408, 6:52–60). 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 ¶¶ 155–156; Ex. 1408, 6:52–60 (100 embodiment), 24:33–38 (2100 embodiment)).

Petitioner contends that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to add Ressemann’s side opening to Kontos’s structure as shown in the annotated figure below:



Id. at 18–24, 28–29 (citing Ex. 1405 ¶¶ 160–173, 180–181; Ex. 1442 ¶¶ 120–139; 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 “side opening”) in between the wire 14 (labeled the “substantially rigid segment”) and tube 16 (labeled the “tubular structure”). *Id.* at 29. Petitioner further contends that

After adding Ressemann’s side opening to Kontos, the resulting combination would provide for a method of advancing a distal

portion of the tubular structure of the extension catheter beyond the distal end of the guide catheter while the side opening of the extension catheter remains within the guide catheter. Ex. 1405, ¶ 173.

Id. at 24.

Petitioner also provides “multiple reasons” for modifying Kontos to include a side opening as taught by Ressemann, including to “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 catheters.” *Id.* at 20–25 (citing Ex. 1405 ¶¶ 152–185; Ex. 1442 ¶¶ 120–143). First, Petitioner contends, “a POSITA would have known . . . that use of a side 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.” *Id.* at 20 (citing Ex. 1405 ¶ 162; Ex. 1442 ¶ 135). According to Petitioner, the reason for such a modification is because

In 1995, when Kontos issued, GCs were typically 7-8 French in diameter. Ex. 1405, ¶ 163. But by the purported priority date of the ’116 patent, use of a 6 French GC had become more common. *Id.* These smaller GCs had several advantages (*id.*), but as the diameter of a GC decreases, so too does the diameter of the extension catheter. This, in turn, means that the proximal opening 20 of Kontos’s tubular structure (body 12) must decrease. *Id.*; Ex. 1409, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex. 1405, ¶ 164. Therefore, as an alternative to the flared proximal opening 26 in Kontos, a POSITA would have been motivated to use a side opening, as then the diameter of the GC could be reduced without causing a commensurate reduction in the area of the proximal opening of the tubular structure of the extension catheter. *Id.*; Ex. 1442, ¶ 134. Alternatively, a POSITA would have been motivated to remove

Kontos's proximal funnel, as it would permit the inner diameter of the extension catheter to be increased without causing a commensurate increase in the outer diameter of the guide catheter.

Id. at 21 (citing Ex. 1405 ¶ 164; Ex. 1442, ¶ 135).

Second, Petitioner contends that a person of ordinary skill in the art would have been motivated to use a side opening because Ressemann suggests that “doing so facilitates ‘smoother’ reception of the interventional cardiology device as it enters the lumen of the child catheter.” Pet. 21–22 (citing Ex. 1408, 6:52–57; Ex. 1405 ¶¶ 165–167; Ex. 1442 ¶ 136–137; Ex. 1426, 3:10–14). In particular, a side opening reduces the likelihood that “the interventional cardiology device could snag or become ‘hung-up’ when entering the distal lumen of the child catheter.” *Id.*

In its Reply, Petitioner further explains its theory that a side opening reduces likelihood of problematic snags. Petitioner contends,

If Kontos was used with a 6 French GC, the gap between the support assembly's outer wall and the inner wall of the GC would be 0.005 inches. Given that a guidewire or the distal-most wire of a fixed-wire balloon typically have a 0.014 inch diameter, the PTCA catheter would not catch in the gap between tube 16 and the inner wall of the GC. Ex. 1806 ¶¶ 120-25. Ex. 1409, Fig. 1 (modified by Petitioner).

Ressemann and Keith buttress this conclusion. Ex. 1806 ¶124. Both references teach side openings that are “preferably angled” to “facilitate smoother passage of other therapeutic devices,” and both teach a gap of at least 0.009 inches as shown below. *Id.*, ¶125. This is almost double Kontos's alleged “problematic” gap. *Id.*

Reply 10.

Third, Petitioner contends that a person of ordinary skill in the art would have been motivated to modify Kontos with a side opening because

“adding a side opening to the lumen of the extension catheter reduces the amount of force that a physician must exert to advance the catheter through winding vasculature.” *Id.* at 22–23 (citing Ex. 1405 ¶ 168; Ex. 1442 ¶ 138)

Fourth, Petitioner contends that a person of ordinary skill in the art would have been motivated to add a side opening to the extension catheter of Kontos because doing so permits smooth re-entry of the proximal end of the extension catheter after its extension beyond the distal end of the GC.

Pet. 23 (citing Ex. 1405 ¶¶ 169-71; Ex. 1442 ¶¶ 130-33). To support that contention, Petitioner directs our attention to Figure 7 of Kontos:

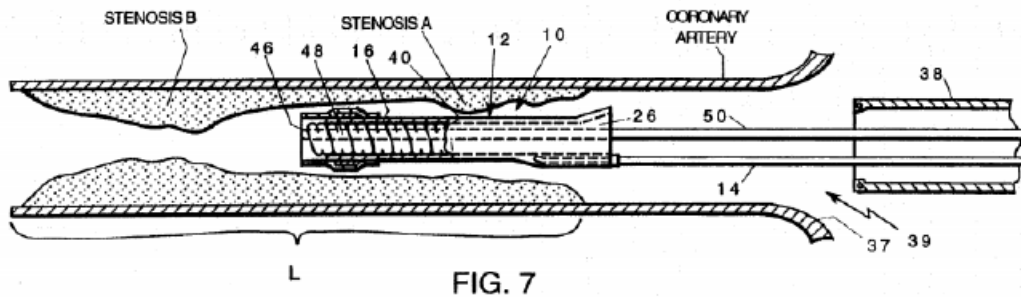


Figure 7 an embodiment depicts an embodiment where “the bridge body 12/PTCA catheter assembly may be passed completely out of guide catheter 38 and advanced as a unit to the site of restriction, restriction B.” Ex. 1409, 6:22–25. Petitioner contends that the support catheter 10 must return to the guide catheter 38 after angioplasty is performed and that

A POSITA would recognize, however, that a flared proximal opening of the tubular structure (tube 12) was a poor design choice, as this protrusion could damage the internal coronary wall and hinder re-entry into the GC. Ex. 1405, ¶ 170; Ex. 1442, ¶ 131. The smaller cross-sectional diameter of a side opening would reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the GC. Ex. 1405, ¶ 170; Ex. 1442, ¶ 131; Ex. 1435, [0066] (“Proximal end 31 is preferably cut or formed at an angle to the seal axis to facilitate unimpeded entry of the seal’s proximal end into the distal end of the guide catheter.”).

Pet. 23–24. Petitioner contends that using Ressemann’s side opening with the Kontos device “would have amounted to a simple substitution of a known element to obtain predictable results.” *Id.* at 24 (citing *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); Ex. 1405 ¶ 173; Ex. 1442 ¶ 139).

Specific to claim 25 and element 25e, Petitioner additionally relies on Takahashi for 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 catheter. Petitioner contends,

A POSITA would have been motivated to combine Takahashi with the Kontos-Ressemann combination, given the former teaches that the not-more-than-one French differential improved backup support of its catheter assembly. *Id.*; Ex. 1442, ¶¶ 194–201. Specifically, Takahashi describes a “five-in-six system [as] a method of inserting a 5 Fr guiding catheter . . . into a 6 Fr guiding catheter to increase backup support.” Ex. 1410, 452.

Pet. 35–36.

b) Patent Owner’s Contentions

Patent Owner contends that Petitioner’s proposed modifications would have required a person of ordinary skill in the art “to completely remove Kontos’ funnel and then replace it with Ressemann’s angled opening.” PO Resp. 14–15. Patent Owner contends that Petitioner’s proposed modifications to Kontos, such as removing Kontos’ funnel, would have been expected to create problems, not solve problems. *Id.* at 3–18.

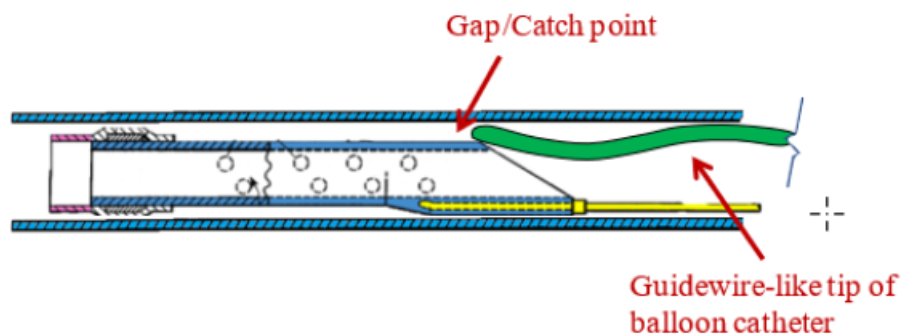
Patent Owner further contends that Petitioner’s four purported motivations for why a person of ordinary skill in the art would add Ressemann’s angled opening into Kontos’ support catheter are unsupported by the evidence and/or based on hindsight. PO Resp. 18–25. (citing Pet. 20–24. Regarding Petitioner’s first motivation—to “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. 20–21)—Patent Owner responds,

This argument is hindsight untethered from the actual teaching of the references. The Kontos device is not premised on employing the smallest guide catheter possible, but rather on creating a device that (1) can closely fit about existing balloon catheters, and (2) has outward protrusions at the proximal and distal ends of the device that create limited points of contact with the guide catheter. Ex 2138, ¶229; Ex. 2145, ¶¶204, 193.

PO Resp. 19. Patent Owner contends that it is the proximal protrusion of base portion 18, which provides the pushwire attachment point and is necessary to Kontos’ function, that primarily drives the outer diameter of Kontos’ device, not the funnel portion of Kontos. *Id.* at 19–20 (citing Ex. 2138 ¶ 230). Furthermore, Patent Owner contends that “the device described in Kontos is already sized consistent with usage of a 6 French guide catheter” and that Petitioner’s purported motivation is “based on the unsupported premise that a POSITA would want to reduce the outer diameter surrounding the guide catheter in the first place” and that “there was no desire or need to use guide catheters smaller than 6 French.” *Id.* at 21 (citing Ex. 2138 ¶¶ 232-33; Ex. 2145 ¶ 195; Ex. 2137, 319:3-6 (“Yeah, I think it would [fit inside a 6 French guiding catheter]”); Ex. 2167, 33 (“[M]ost procedures in current practice can be completed through 6F guiding catheters. Also available are 5F guiding catheters, but they offer no major advantage and are not routinely used.”); Ex. 2145 ¶ 194; Ex. 2137, 53:15–19 (“[I]n that [time]frame, I don’t think anybody had a five French”); Ex. 2116, 288:6–7 (“So early 2000s, I think would still have been 6, 7s, maybe some 8s”)).

Regarding Petitioner’s second purported motivation—to “facilitate[] ‘smoother’ reception of the interventional cardiology device as it enters the lumen of the child catheter” by reducing likelihood that the cardiology device will “snag or become ‘hung-up.’” (Pet. 21–22)—Patent Owner contends that this motivation fails because “removing Kontos’ funnel *increases* the likelihood that interventional cardiology devices will snag or become hung-up on the proximal opening of Kontos’ support catheter.” *Id.* at 22 (citing Pet. 21–22). Patent Owner illustrates that point by annotating Petitioner’s figure provided at page 20 of the Petition showing Kontos’s device modified to replace Kontos’s funnel portion of with Ressemann’s side opening, reproduced below.



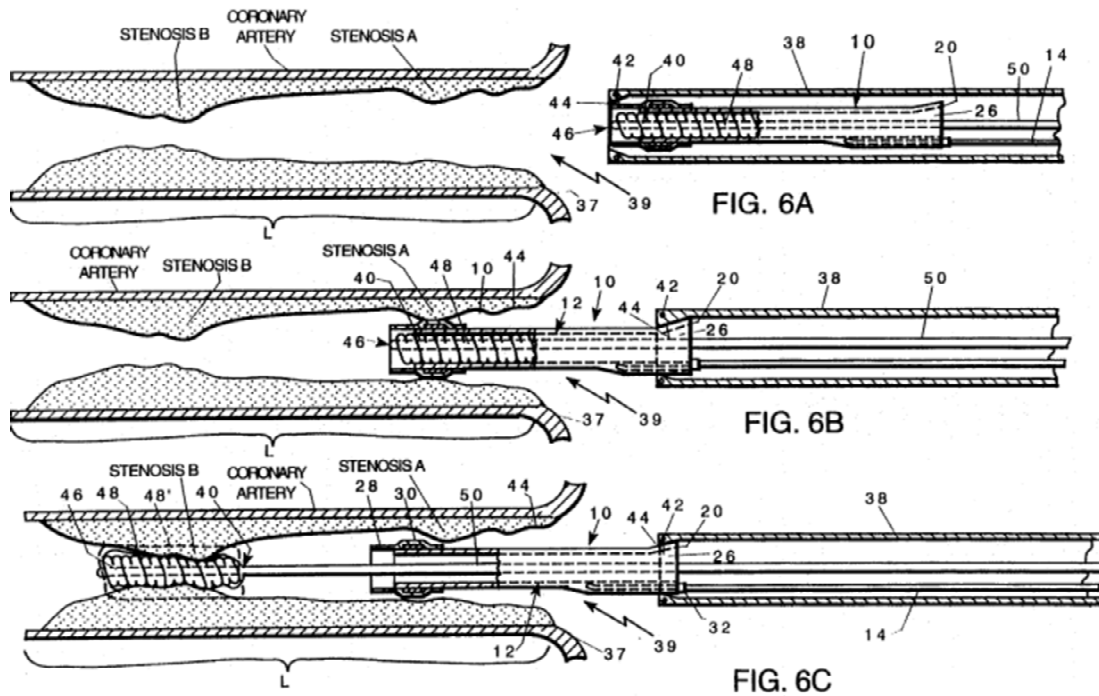
Id. at 15. According to Patent Owner, that modification creates the problem of “greatly increase[ing] the likelihood of an inserted device catching or hanging-up.” *Id.* at 14–15 (citing Ex. 2138 ¶ 211–15; Ex. 2145 ¶¶ 201–03; Ex. 2244, 105:1–5; Ex. 2137, 357:13–23, 452:7–17 (Dr. Hillstead agreeing that Ressemann discloses a potential “hang-up” problem with its angled proximal opening that is not present in the funnel embodiment)). In particular, Patent Owner contends that removing Kontos’ funnel portion would “expose the gap that the funnel was intended to bridge,” and thereby render Kontos’s device less effective for its intended purpose. *Id.*

Furthermore, Patent Owner contends that catching of interventional cardiology devices was a “known” problem at the time of the invention. *Id.* at 15 (citing Ex. 1442 ¶ 137). Here, Patent Owner directs our attention to the testimony of Dr. Hillstead that “it was known by May 3, 2006 that interventional cardiology devices could snag or get ‘hung-up’ when entering the distal lumen of either a guide catheter or a guide extension catheter, and that an angled side opening was helpful to reduce this.” Ex. 1442 ¶ 137 (citing Ex. 1408, 6:52–57). Patent Owner notes, however, that Ressemann teaches the opposite and cannot be relied upon as evidence that “an angled side opening was helpful to ‘reduce’ this likelihood of hang-up.” *Id.* at 23 (citing Ex. 2138 ¶¶ 214–215; Ex. 1408, 25:17-29 (“[s]tent delivery catheters, for example, are particularly subject to hanging-up” on the angled proximal opening of the evacuation head, and proposes using a different structure (“reverse bevel 2125”) to try to mitigate that problem).

Patent Owner also contends that Petitioner’s proposed modification to Kontos’ device “would also be counterproductive for the purpose of that device because it would reduce the target area for receiving fixed-wire balloons through the proximal opening in an axial direction.” *Id.* at 16 (citing Ex. 2138 ¶¶ 216–17 (“the reduced diameter angled opening reduces the target area of the proximal opening for devices entering the lumen of Kontos’ support catheter”).

Regarding Petitioner’s third purported motivation—“promot[ing] ‘smoother passage’ of the catheter assembly as it navigates the tortuous vasculature” (Pet. 22–23)—Patent Owner contends that a person of ordinary skill in the art “would expect the Kontos funnel to have minimal impact on its ability to negotiate tortuous vasculature.” PO Resp. 23 (citing Ex. 2138, ¶ 240; Ex. 2195 ¶ 197). Rather, the funnel portion of Kontos’ device is

important to its ability to perform its disclosed functions. *Id.* (citing Ex. 2138 ¶ 240). To that point, Figure 6A–6C of Kontos, reproduced below, illustrate the interplay between the outward flare of funnel 26 and inwardly extending ridge 44.



Figures 6A–6C are cross-sectional views showing three stages in a process for guiding a PTCA catheter to a coronary artery lesion. Ex. 1409, 2:67–3:2. Kontos discloses that “guide catheter 38 may be provided with a radially inwardly formed annular ridge 44 for impeding further axial movement of funnel 26 beyond the distal end of guide catheter 38.” *Id.* at 5:67–6:2. Patent Owner contends that proximal end 20 does not function to facilitate “smoother passage” of the catheter assembly, but rather that “[t]he distal end of Kontos’ device drives ease of advancement.” PO Resp. 23 (citing Ex. 2138 ¶ 240; Ex. 2195 ¶ 197).

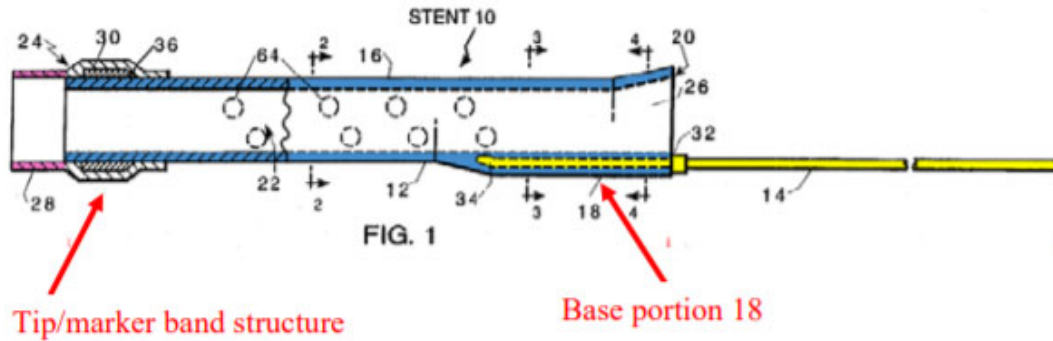
Regarding Petitioner’s fourth purported motivation of—permitting “smooth re-entry” if the support catheter is pushed entirely out of the end of

the guide catheter (Pet. 23)—Patent Owner contends that Kontos discloses that one of the functions of the funnel itself is to prevent this from accidentally happening. PO Resp. 24 (citing Ex. 1409, 5:49-62 (“it generally will be preferable that at least some portion of proximal end 20 of body 12 remains within guide catheter 38”), 6:6–9, Fig. 6B; Ex. 2138 ¶ 242; Ex. 2145 ¶198). Patent Owner further contends,

And while Kontos nonetheless indicates that this could be done (e.g., Ex. 1409, 6:23-28), Petitioner’s experts *agree* that a POSITA would never have actually wanted to do this. Ex. 2116, 365:18-22 (“[Y]ou wouldn’t do that with this design of device”); Ex. 2137, 329:4-9 (“It’s not a particularly recommended thing to do in any way”). Dr. Brecker testified that a POSITA would never want to extend Kontos’ support catheter completely out of the guide catheter even after removing the funnel. Ex. 2116, 366:22-367:5 (“I don’t think you would want to do that. I think you would want the body – some part of the body to remain within the guide catheter.”). The motivation to remove the funnel to facilitate something that all of the experts agree a POSITA would never have done is textbook hindsight.

PO Resp. 24.

Regarding Petitioner’s reliance on Takahashi for element 25e, Patent Owner contends that “Petitioner wrongly asserts that ‘removing Kontos’ funnel in favor of a proximal side opening . . . would permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi.’” PO Resp. 26 (quoting Pet. 35). Patent Owner directs us to an annotated Figure 1 of Kontos, reproduced below.



Patent Owner contends that “[e]ven if, contrary to the teaching of Kontos, the funnel was ‘removed’ and the support catheter was made tight-fitting within the guide catheter lumen, Kontos still has the outwardly protruding ‘base portion 18,’ needed to provide an attachment point for the wire 14, as well as the distal marker band/tip 28 structure.” *Id.* at 26–27 (citing Ex. 1405 ¶ 160). Patent Owner further contends, “neither Petitioner nor its experts provide any reason for why it would have been obvious to remove this raised-profile base portion 18 of Kontos’ support catheter, how such modification would be achieved, or whether it would have been successful.” *Id.* at 29.

c) Analysis of Prior Art Arguments

Claims 25–40, 42, 44–48, 52 and 53 require “advancing a balloon catheter or stent . . . through the side opening.” *E.g.*, Ex. 1401, 14:16–25. The parties do not dispute that Kontos does not teach the claimed “segment defining a side opening” as required by independent claims 25 and 52. Pet. 18; PO Resp. 12. As set forth above, the Petition provides multiple reasons why one of ordinary skill in the art would have wanted to remove the funnel of Kontos and provide a partially cylindrical opening proximal of the tubular structure, as taught by Ressemann. Patent Owner provides

several arguments in response as to why the modifications suggested by Petitioner are grounded in hindsight.

Upon review of the parties' arguments and supporting evidence, we agree with Patent Owner that Petitioner fails to establish why a person of ordinary skill in the art would have substantially redesigned Kontos (including removing the funnel portion) to provide the side opening configuration of independent claims 25 and 52 and the "one French size" differential of independent claim 25. We agree with Patent Owner, for the reasons Patent Owner provides as summarized above, that Petitioner's rationale is insufficient, and adopt Patent Owner analysis, as supported by the cited evidence, as our own.

Furthermore, while Petitioner may have established that side openings were known in the art, they appear in devices intended to receive an interventional cardiology device when positioned within a guide catheter. Switching to a side opening in Kontos to beneficially increase the available real estate within the catheter or to reduce the size of the guide catheter would require extensive modifications. Reply 5. To that point, we agree with Patent Owner that Petitioner fails to establish that a person of ordinary skill in the art would have been "motivated to completely redesign Kontos, with at least *six additional changes*," including (1) "recess[ing]" Kontos's marker bands; (2) attaching the distal soft tip in-line rather than with overlapping structure; (3) removing Kontos's base portion 18; (4) "taper[ing] the pushrod" down to less than 0.005 inches; (5) "attach[ing]" the thin-tapered pushrod to Kontos's tube wall without base portion 18, and (6) "increase[ing]" the diameter of "tube 16." Sur-reply 3–6.

We further note that the funnel portion of Kontos appears to be crucial to the device's ability to receive and facilitate exchange of balloon catheters:

“Because of flared funnel portion 26, the second catheter can negotiate the transition from guide catheter 38 into body 12.” Ex. 1409, 7:20-22; Ex. 2138 ¶ 209; Ex. 2145, ¶ 149. Ressemann, however, explains that the angled proximal opening on its 2100 embodiment creates potential issues with intravascular device catching or hang-up, and proposes a different structure (“reverse bevel 2125”) to try to mitigate this. Ex. 1408, 25:17–29; Ex. 2138 ¶ 214. In contrast, Ressemann’s Figure 11 embodiment has a “flare 131” similar to Kontos’s funnel, and Ressemann does not identify any catching or hang-up issues created by the flare. Ex. 1408, 7:40-47, Fig. 11A; Ex. 2138 ¶ 214. We credit the testimony of Patent Owner’s experts that a person of ordinary skill in the art would not have been motivated to slice off the funnel of Kontos as Petitioner advocates, in view of the significant catching/hang-up problems it would create. Ex. 2138 ¶¶ 214–215; Ex. 2145 ¶ 203.

d) Analysis of Objective Indicia Arguments

Patent Owner contends that objective evidence shows that the invention recited in claim 25 was not obvious. PO Resp. 61–82. In order to resolve this case of obviousness, we look, as we always must, to Patent Owner’s evidence of objective indicia of nonobviousness before reaching the ultimate conclusion of obviousness under 35 U.S.C. § 103. *Leo Pharmaceutical Products, Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013) (“[T]he Board should give the objective indicia its proper weight and place in the obviousness analysis, and not treat objective indicia of nonobviousness as an afterthought.”); *see also Apple Inc. v. Int’l Trade Comm’n*, 725 F.3d 1356, 1365 (Fed. Cir. 2013) (“[O]bjective evidence of secondary considerations . . . must be considered before determining

whether the claimed invention would have been obvious to one of skill in the art at the time of invention.”); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) (Objective indicia of nonobviousness must be “considered as part of all the evidence, not just when the decision[]maker remains in doubt after reviewing the art.”).

Objective indicia of non-obviousness, or “secondary considerations,” guard against hindsight reasoning in an obviousness analysis, and are often “the most probative and cogent evidence in the record.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (citations omitted). Objective indicia of non-obviousness include: (1) commercial success; (2) long-felt but unsolved needs; (3) failure of others; (4) copying; (5) praise in the art; (6) unexpected results; and (7) industry acceptance. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966); *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1092 (Fed. Cir. 1987)).

Patent Owner contends that “[t]he substantial and compelling objective evidence of non-obviousness, including long-felt need, the GuideLiner’s category-creating commercial success, industry praise, licensing and copying, more than outweighs any prima facie evidence of obviousness.” PO Resp. 62. As objective indicia relevant to the challenged claims, Patent Owner presents evidence that its GuideLiner products, i.e., GuideLiner V1, GuideLiner V2, and GuideLiner V3, as a whole, solved a long-felt but unresolved need in the art, are commercially successful, were repeatedly copied by competitors, and received industry praise. PO Resp. 61–70. Patent Owner also presents evidence that the ’116 patent was

licensed by a competitor. *Id.* at 69–70. Patent Owner contends that the combination of rapid exchange (“RX”), guide extension, improved backup support, and a side opening drives GuideLiner’s success and that its objective evidence of non-obviousness precludes a determination of obviousness with respect to independent claim 25. *Id.* at 62, 78–79.¹⁰

(1) Long-Felt Need

“Evidence of long felt but unresolved need tends to show nonobviousness because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332. Patent Owner contends that in the late 1980s and early 1990s it was recognized in the interventional cardiology field that there was a tendency for a guide catheter to back out of the ostium if a stent or balloon encountered significant resistance within the coronary vasculature. PO Resp. 63 (citing Ex. Ex. 2145 ¶ 50; Ex. 2138 ¶¶ 51–53, 311). This problem often prevented successful procedures due to the inability to advance the stent or balloon into the lesion needing treatment. Ex. 2145 ¶¶ 49–50; Ex. 2215 ¶¶ 10–19; Ex. 2138 ¶¶ 58–67.

The long-felt need for a product that would not back out of the ostium when a stent or balloon encountered significant resistance is supported by

¹⁰ The same objective indicia evidence was considered and found persuasive in IPR2020-00127, -00129, -00130, -00136, and -00138. We consider that evidence as presented in the record of this proceeding in evaluating the obviousness of the challenged claim 25 as that is the focus of Patent Owner’s arguments. Nonetheless, our ultimate conclusion of obviousness for *all* the challenged claims 25–40, 42, 44–48, 52 and 53 is based on our evaluation of the *Graham* factors and our consideration of the totality of the evidence of record, including Petitioner’s *prima facie* showing discussed above.

the testimony of Dr. John Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), and Dr. Craig Thompson (Ex. 2215). Each of these doctors has performed thousands of percutaneous coronary interventions, including complex percutaneous coronary interventions, and they unanimously agree that since at least the early 1990s the field struggled with the problem of insufficient guide catheter backup support when seeking to navigate difficult anatomy or crossing difficult lesions. Ex. 2145 ¶¶ 10, 42; Ex. 2215 ¶¶ 2–6; Ex. 2151 ¶¶ 2, 4.

Dr. Graham explains that in this time period there were at least four approaches a physician could use in an attempt to overcome the lack of backup support: a physician could attempt to “deep seat” the guide catheter in the ostium; “upsized” the catheter or change to a stiffer catheter; thread a second guidewire, or “buddy” wire; or use a mother-and-child approach, inserting a smaller, full-length guide catheter into the already-in-place guide catheter. Ex. 2145 ¶ 58. Drs. Graham, Azzalini, and Thompson testify that each of these approaches presented significant difficulties related to time, expense, and potential injury to the patient. *Id.* ¶¶ 51–75; Ex. 2215 ¶¶ 9–19; Ex. 2151 ¶¶ 9–14. For example, Dr. Graham testifies that switching to a mother-and-child approach required a longer 300 cm “exchange length” guidewire that is more difficult to manage than the typical 180-200 cm guidewire and requires the assistance of a second operator. Ex. 2145 ¶¶ 71–72. The mother-and-child approach also required “re-crossing a lesion a second time,” which Dr. Graham explains is “highly undesirable and potentially dangerous.” *Id.* ¶ 72.

Dr. Graham, Dr. Thompson, and Dr. Azzalini agree that the GuideLiner products, with their pushrod structure, distal tubular structure, and side opening located at the junction of the pushrod and tubular structure,

overcame the backout problem, allowing for stents and balloons to be delivered deep into the coronary vasculature and allowing physicians to treat patients “who otherwise would have been untreatable with a catheter procedure.” Ex. 2215 ¶¶ 22–23; Ex. 2145 ¶ 76 (Dr. Graham testifying that the GuideLiner product “provided a highly effective, reliable solution to the longstanding problem of lack of backup support.”); Ex. 2151 ¶ 9 (Dr. Azzalini testifying that the GuideLiner product “changed the field of interventional cardiology” and gave cardiologists a device “that finally solved the long-existing guide catheter backout problem.”).

Petitioner does not generally dispute the impact the GuideLiner products had on the field of interventional cardiology, but contends that prior art devices, including those taught by Itou, Kontos, and Ressemann, “are RX, configured to deliver a wide variety of IVCDs, and provide increased backup support when extended partially past the end of a [guide extension catheter].” Reply 25. The evidence of record persuasively demonstrates, however, that the long-felt need for improved backup support was unresolved in the art prior to introduction of the GuideLiner devices. As noted by Petitioner, Kontos and Ressemann both provide some level of backup support, but there is no persuasive evidence that either of these products resolved the long-felt need in the art for a device that would avoid backout problems when difficult lesions are encountered during a procedure. *See* Ex. 2151 ¶¶ 8–9. And although mother-and-child devices were known to provide additional backup support, Patent Owner’s declarants persuasively demonstrate that a mother-and-child approach was not a safe or time- and cost-effective solution to the backout problem addressed by the GuideLiner products. PO Resp. 63–64; Ex. 2151 ¶¶ 6–8; Ex. 2145 ¶¶ 69–75; Ex. 2215 ¶¶ 16–19 (Dr. Thompson testifying that the problems related to

the mother-and-child approach led to very limited use of this technique). Indeed, in view of its inherent limitations, the mother-and-child approach was rarely, if ever, used by interventional cardiologists. Ex. 2145 ¶ 75 (Dr. Graham testifying that the mother-and-child approach “had many significant drawbacks” and he was “not aware of any instances in which a mother-and-child system was successfully marketed.”); Ex. 2215 ¶ 16 (“The mother-and-child approach was rarely, if at all, used by interventional cardiologist for a number of reasons.”).

In view of the foregoing, we credit the testimony of Drs. Graham, Thompson, and Azzalini and find that the GuideLiner products solved a long-felt but unmet need in the art, allowing physicians to perform previously impossible coronary procedures.

(2) Commercial Success

“Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Petitioner’s own internal documents concede that the GuideLiner products “created the market,” and Patent Owner’s uncontroverted evidence show that, through 2019, Patent Owner and its licensee (Boston Scientific) “had essentially 100% of the U.S. guide extension catheter market,” achieving a significant amount of annual revenue. PO Resp. 67–68 (citing Ex. 2198, 3; Ex. 2153 ¶¶ 7–8).

Petitioner does not dispute that Patent Owner’s GuideLiner products are commercially successful. *See generally* Reply 25–30.

Upon review of the arguments and the evidence of record, we find that the GuideLiner products achieved a high level of commercial success.

(3) Industry Praise

Evidence that the industry praised a claimed invention weighs against an assertion that the same claim would have been obvious because industry participants, especially competitors, are not likely to praise an obvious advance over the known art. *WBIP*, 829 F.3d at 1334.

Published scientific journals and text books praise the properties of the GuideLiner products. For example, a review article in the International Journal of Cardiology states that the GuideLiner product “provides an elegant method to overcome” the problem of “severe vessel angulation and tortuosity” and has “significantly improved procedural outcomes in complex lesion anatomy and broadened the subset of lesions where PCI can be successfully performed.” Ex. 2194, 142, 147; PO Resp. 68–69. A technical report in EuroIntervention reports that GuideLiner allowed a stent to be “easily and successfully” deployed in a case where stent delivery was otherwise “impossible despite the use of a highly supporting guiding catheter.” Ex. 2180, 279; PO Resp. 68–69. In addition, a text book on catheterization procedures notes that “[l]ack of backup support can be easily overcome by using a guide catheter extension such as a Guideliner,” which “does not add complexity to the intervention and provides extraordinary backup support for complex interventions.” Ex. 2167, 182; PO Resp. 69.

Petitioner does not generally dispute that Patent Owner’s GuideLiner product was praised in the industry. *See generally* Reply 25–32.

Upon review of the parties’ arguments and the evidence of record, we find that the GuideLiner product received significant praise in the industry.

(4) *Licensing*

Evidence that competitors or customers have licensed a patent may provide probative and cogent evidence of non-obviousness of the claims at issue. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). Patent Owner presents evidence that its competitor, Boston Scientific, licensed the GuideLiner patents and continues to pay royalties under this license. PO Resp. 69–70 (citing Ex. 2044 ¶ 34; Ex. 2153 ¶ 8). Patent Owner also asserts that Petitioner sought a license to the GuideLiner patent portfolio. *Id.* (citing Ex. 2068 ¶ 26).

Petitioner asserts that Patent Owner’s licensing evidence is not persuasive because it has not submitted the Boston Scientific license in this case or provided any context surrounding the license, which was entered into as part of a settlement agreement. Reply 29 n.4.

The mere existence of a license, without evidence that the license was entered into because of the merits of the claimed invention, is of limited probative value because it is often “cheaper to take a license than to defend infringement suits.” *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (Fed. Cir. 2004); *In re Antor Media Corp.*, 689 F.3d 1282, 1293–94 (Fed. Cir. 2012) (determining that the existence of licenses was insufficient because the licenses may have been entered into “as [a] business decision to avoid litigation, because of prior business relationships, or for other economic reasons”). Here, Patent Owner does not explain in any detail the terms of the Boston Scientific license or the circumstances under which the license was granted, except to concede that the license was taken in settlement of litigation. *See* PO Resp. 69–70. Thus, Patent Owner’s licensing efforts are of limited probative value in this case. *See Iron Grip*, 392 F.3d at 1324.

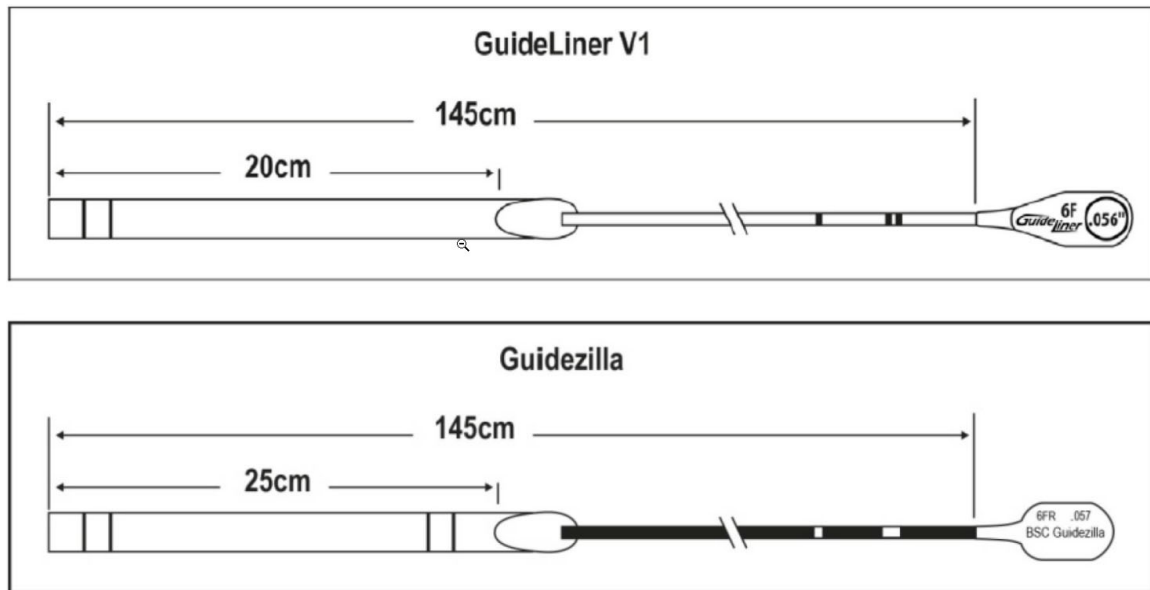
(5) Copying

Evidence of copying of the claimed invention by a competitor, rather than one within the public domain, tends to show nonobviousness. *WBIP*, 829 F.3d at 1336. As discussed below, Patent Owner contends its competitors copied the GuideLiner products, whereas Petitioner contends the competing products identified by Patent Owner merely copied what was known in the prior art.

(a) The Parties' Arguments for Copying

Patent Owner asserts that after the introduction of the GuideLiner product “three companies launched products that not only infringed the GuideLiner patents but were close copies of then-existing versions of the commercial GuideLiner products.” PO Resp. 70–71. These products are Boston Scientific’s “Guidezilla” product, QXMedical’s “Boosting Catheter,” and Petitioner’s “Telescope” product.

Patent Owner contends that Boston Scientific’s Guidezilla product is virtually identical to the GuideLiner V1 product. *Id.* In support of its arguments, Patent Owner provides the following annotated comparison of GuideLiner V1 and the Guidezilla product. *Id.*

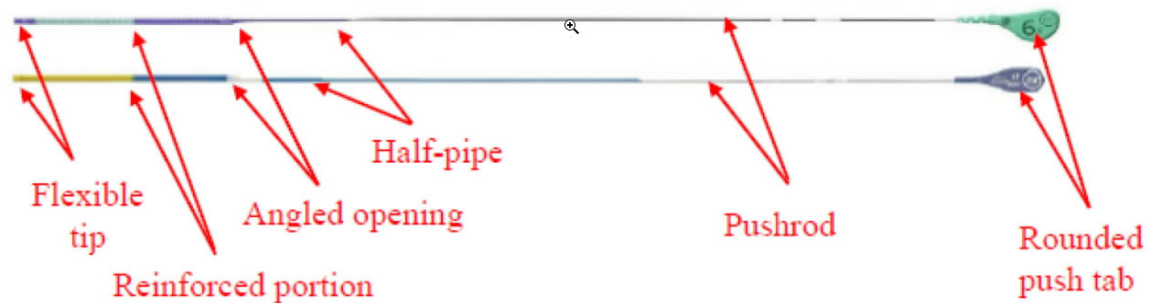


The figure above shows the general structure and length of the GuideLiner V1 and Guidezilla products. Referencing the above figures, Mr. Keith testifies that the two devices both have a flexible tube with a lumen, a rigid collar, a rigid metallic pushrod, and a handle that is marked with the device's size. Ex. 2138 ¶¶ 328–335. When all of the elements of the two devices are considered in combination, Mr. Keith testifies that the two devices are “virtually identical.” *Id.* at ¶ 335. Dr. Graham likewise testifies that both products are “substantially similar” and that in his clinical experience Guidezilla functions and performs similarly to GuideLiner. Ex. 2145 ¶¶ 244–248.

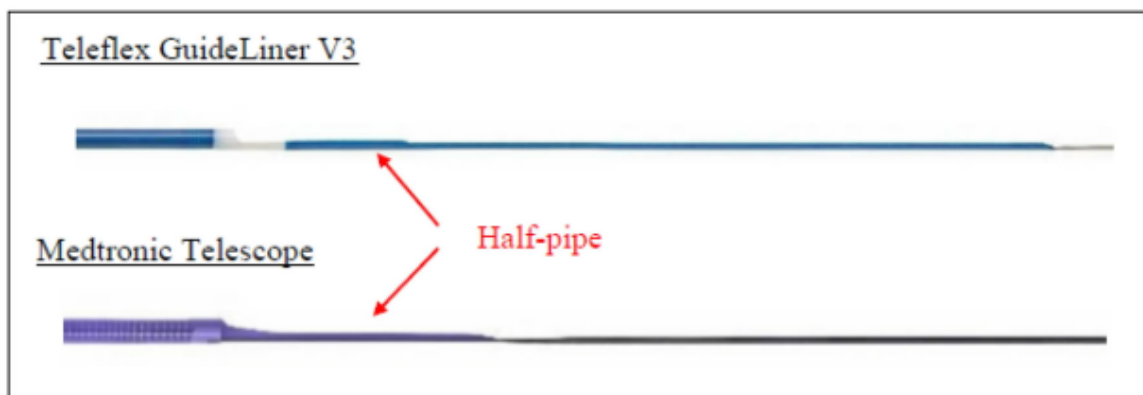
With respect to the “Boosting Catheter,” Patent Owner contends that QXMedical had access to the GuideLiner V1 and developed a “substantially similar” product. PO Resp. 72 (citing Ex. 2138 ¶¶ 337–347; Ex. 2196, 1).

With respect to Petitioner's Telescope product, Patent Owner contends that Petitioner obtained and tested dozens of GuideLiner devices in the course of developing its product and, as shown in the annotated figure

below, that Petitioner's Telescope product is a striking copy of Patent Owner's GuideLiner V3 product. PO Resp. 73.



The figure above is annotated by Patent Owner to identify the alleged similarities between GuideLiner V3 and Petitioner's Telescope product, including a flexible tip, reinforced portion, angled opening, Half-pipe, pushrod, and rounded push tab. *Id.* Patent Owner contends that Boston Scientific confirmed the substantially similar nature of the two devices in its regulatory filings, informing regulators that Telescope was “substantially equivalent” to GuideLiner. PO Resp. 76 (citing Ex. 1479 ¶ 18; Ex. 2069, 5). Addressing the product's “Half-pipe” feature, Patent Owner provides the following annotated figure showing the similarities between the half-pipe of GuideLiner V3 and the Telescope product (*id.* at 75).



The figure above is an annotated, side-by-side comparison of the “Half-pipe” of Patent Owner's GuideLiner V3 product and Petitioner's Telescope product. *Id.* Patent Owner contends Petitioner's internal

documents demonstrate that it sought to build its own “Half Pipe” design and comparison of the two devices demonstrates that “Petitioner succeeded in its efforts to copy” this feature into its Telescope product. *Id.* at 76 (Patent Owner asserting that, “[i]n addition to the side opening, the other features of Telescope, including its distal tip and pushrod, are substantially similar to the corresponding features of GuideLiner”); Ex. 2197, 1 (“Finalizing the material required to build our own ‘Half Pipe’ design”); Ex. 2138 ¶ 343.

Petitioner argues that the elements identified by Patent Owner to establish copying of Guidezilla and the Boosting Catheter are all found in the prior art. Reply 25–30. In particular, Petitioner asserts that Guidezilla and the Boosting Catheter are similar to Ressemann in that they are rapid exchange devices that are “configured to deliver a wide variety of IVCDs and provide increased backup support when extended partially past a [guide catheter].” *Id.* at 29. Petitioner further asserts that Guidezilla and Boosting Catheter, like the devices in Itou and Ressemann, have a side opening. *Id.*

With respect to its Telescope product, Petitioner contends this product simply “practices the prior art.” *Id.* at 29–30. In addition, Petitioner contends that Patent Owner “ignores other important differences between GuideLiner and Telescope . . . including Telescope’s hydrophilic coating and round pushwire,” which are differences Patent Owner “itself emphasizes . . . as core distinguishing features” between the two products. *Id.* at 30–31 (citing Ex. 1824, 4:22–5:10).

(b) Analysis for Copying

Evidence of copying may take the form of “internal documents, direct evidence such as photos or patented features[,], or disassembly of products,

or access and similarity to a patented product.” *Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019).

Patent Owner persuasively demonstrates that Guidezilla, the Boosting Catheter, and Petitioner’s Telescope product were launched into the market after the relevant GuideLiner products. Thus, each competitor had access to the GuideLiner products. *See* Ex. 2200, 1; Ex. 2138 ¶ 334; Ex. 2196, 1; Ex. 2202, 1–2. Patent Owner and Mr. Keith also persuasively demonstrate that the Guidezilla and Telescope products, when considered as a whole, are substantially similar in design to the then-existing GuideLiner products on the market, including the combined use of a flexible tip, reinforced portion, angled opening, pushrod, and rounded push tab. PO Resp. 70–77; Ex. 2138 ¶¶ 318–327.

Petitioner contends that Itou and Ressemann disclose rapid exchange devices and have a side opening. Reply 25–30. But Guidezilla did not merely apply the idea of rapid exchange or the use of a side opening, as the device reproduces the entire combination of features that were assembled for the first time by the GuideLiner products. As such, we do not find persuasive Petitioner’s argument that Guidezilla merely copied the prior art, as opposed to the relevant GuideLiner products.

Petitioner’s Telescope product differs from GuideLiner V3 in its use of a hydrophilic coating and a round pushwire, and the “half-pipe” design of the two products is not identical. Reply 30. We credit the testimony of Mr. Keith, however, that the overall designs of the two products are substantially similar (Ex. 2138 ¶¶ 337–350), and there is little doubt that Petitioner had access to GuideLiner products and intentionally sought to enter the market created by the GuideLiner products by producing a design that was “substantially equivalent” to that of GuideLiner V3, including its

use of a half-pipe design. Ex. 2235, 5 (noting that the Telescope product is “based on long existing technology (such as the equivalent device: GuideLiner® by Vascular Solutions”)), 15–17 (comparing Telescope to GuideLiner V3); Ex. 2198, 3 (“GuideLiner (created the market)”; Ex. 2197, 1 (noting that Patent Owner was seeking to build is “own” “Half Pipe” design); Ex. 2069, 5. As such, the evidence of copying by Petitioner is relevant in this case and favors, at least to some extent, a conclusion of nonobviousness of the claims at issue. *See Liqwd*, 941 F.3d at 1138–39.

(6) *Nexus*

To be relevant, a nexus must be established between the evidence of secondary considerations and the merits of the claimed invention. *Liqwd*, 941 F.3d at 1138. A presumption of nexus exists “when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’” *WBIP*, 829 F.3d at 1329 (quoting *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)).

Mr. Keith provides unrebutted claim charts demonstrating that the GuideLiner V1, V2, and V3 products read on every limitation of claim 25 of the ’116 patent. Ex. 2138, Appendix B at 1–12 (Declaration of Peter Keith). Patent Owner also persuasively ties its evidence of long-felt need, commercial success, industry praise, and copying to one or more of the GuideLiner V1, V2, and V3 products. PO Resp. 61–82. Accordingly, a presumption of nexus applies in this case. *Id.*; Ex. 2138, Appendix B; *WBIP*, 829 F.3d at 1329–30.

The presumption of nexus may be rebutted by showing that the proffered objective evidence was due to extraneous factors other than the

patented invention, such as additional unclaimed features or improvements in marketing, etc. *WBIP*, 829 F.3d at 1329. The presumption of nexus may also be rebutted by showing that the objective evidence results from a feature that was known in the prior art. *Id.*; *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (“where the offered secondary considerations actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.”).

Petitioner argues that the “side opening” was generally known in the art, and there is no evidence that the presence of such a side opening drove sales of the GuideLiner. Reply 26–27. Petitioner further argues that all that is necessary to apply the benefits of modern guide extension catheters is rapid exchange, a side opening, and a lumen relatively close to the size of the guide catheter, and the prior art including Kontos and Ressemann all disclose rapid exchange and a lumen close in size to the guide catheter (providing backup support), while Ressemann included side openings. *Id.* at 27.

As noted by Petitioner, every element of the disputed claims was individually known in the prior art. But evidence of secondary considerations may be tied to the combination of features as a whole, as opposed to one or more “novel” elements of a claimed invention. *See WBIP*, 829 F.3d at 1331–32. In line with this precedent, Drs. Graham, Thompson, and Azzalini persuasively testify that it was the GuideLiner devices as a whole that resulted in the evidence of secondary considerations, not any individual feature in isolation. Ex. 2138 ¶ 215; Ex. 2145 ¶¶ 71, 82, 238–241 (Dr. Graham); Ex. 2215 ¶ 22 (Dr. Thompson); *see generally* Ex. 2151 ¶¶ 5–15 (Dr. Azzalini). According to these declarants, despite the fact that the individual features of the GuideLiner device were known in the prior art,

including mother-and-child catheters and catheters with a side opening, devices prior to GuideLiner did not provide an effective, reliable solution to the long-standing problem of lack of backup support. Ex. 2145 ¶¶ 71–75, 91. When the various features of the prior art were combined to form the GuideLiner device, however, the result was a new, market-making, commercially successful product that provided significant benefits over prior art devices, received praise in the art, and was copied by competitors. *Id.* at ¶¶ 85, 91; Ex. 2198, 3; Ex. 2215 ¶¶ 21–23 (Dr. Thompson testifying that the GuideLiner products “fundamentally changed the way patients were treated” and allowed him “to treat patients who otherwise would have been untreatable with a catheter procedure”); Ex. 2151 ¶ 15 (Dr. Azzalini testifying that “GuideLiner made cases possible that were previously impossible, and made cases faster, safer, and more reliable”).

In view of the foregoing, we find that there is a nexus between the invention recited in claim 25 of the ’116 patent and Patent Owner’s evidence of long-felt but unmet need, industry praise, and commercial success. With respect to copying, we find a nexus exists for this evidence because (1) competitors had access to the GuideLiner products and produced substantially similar designs, and (2) there is direct evidence of copying of at least a portion of the GuideLiner device by Petitioner. *See Liqwd*, 941 F.3d at 1138 (“But where there is evidence of actual copying efforts, that evidence is always relevant.”).

*e) Conclusion with Respect to Claims 25–40, 42, 44–48, 52, and 53
(Grounds 1 and 2)*

Weighing all the evidence presented by the parties, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 25 and 52 would have been obvious over Kontos, Ressemann, and

Takahashi. *See Transocean*, 699 F.3d at 1354–55. Because claims 26–40, 42, 44–48, and 53 depend from claim 25 or 52, and because Petitioner’s arguments with respect to these dependent claims do not overcome the issues addressed above with respect to the independent claims or the objective indicia of unpatentability, we also determine that Petitioner has not demonstrated by a preponderance of the evidence that these dependent claims would have been obvious over Kontos, Ressemann, and Takahashi.

E. Ground 3: Alleged over Kontos, Ressemann, Takahashi, and Kataishi

Petitioner contends claim 45 would have been obvious over the combination of Kontos, Ressemann, Takahashi, and Kataishi. Pet. 58–61. Petitioner’s contentions are supported by Dr. Brecker and Dr. Hillstead. Ex. 1405 ¶¶ 236–243; Ex. 1442 ¶¶ 202–214.

Claim 45 depends from claim 25 and further recites “wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a side-opening structure having at least two inclined slopes.” Ex. 1401, 16:21–25.

As noted above, we have determined that Petitioner has not demonstrated by a preponderance of the evidence that claim 25 would have been obvious based on the combination of Kontos and Ressemann as set forth in Ground 1. 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. Pet. 58–61. Petitioner contends that a person of ordinary skill in the art had motivation to modify the Ressemann’s support collar 2141 to include Kataishi’s two inclined, partially cylindrical opening 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 60 (citing Ex. 1405 ¶¶ 240; Ex. 1442 ¶¶ 204–208). 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 60–61. 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 61.

With respect to Ground 3, Patent Owner additionally argues that the Petition fails to explain why a person of ordinary skill in the art would have been motivated to modify the proximal end of Kontos’ guide catheter body based on the distal end of Kataishi’s suction catheter. PO Resp. 46–50. 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.*

We agree with Patent Owner’s contentions regarding Kataishi. In particular, Kataishi’s complex side opening is located at its distal tip and is used to improve suction in Kataishi’s device. Ex. 1425 ¶ 1, Fig. 10. Petitioner provides no reasoned explanation as to why one of ordinary skill in the art would have sought to implement such a suction-improving distal tip at the proximal opening of Kontos. Petitioner’s arguments related to Kontos and Ressemann do not address this issue.

F. Ground 4: Alleged Obviousness over Root

Petitioner contends claims 25–55 would have been obvious over Root. Pet. 69–75. According to Petitioner, “Root is prior art under at least pre-AIA § 102(b).” Pet. 70. Specifically, Petitioner argues the effective filing date of the Challenged Claims is no earlier than January 28, 2012, because “the priority applications provide no written description support for (i) a side opening outside of the substantially rigid segment or (ii) a side opening with ‘at least two inclined slopes.’” *Id.* at 62.

Petitioner provides a table identifying in the first column each Challenged Claim; in the second and third columns, citations from arguments presented by the applicant during prosecution of the ’116 patent to show support from the ’059 application; and, in the third column, citations purportedly corresponding to the disclosure in Root. 116. Pet. 70–75 (citing Ex. 1402 266–274, 745–755). Petitioner argues that the table shows “Root teaches nearly every limitation of the Challenged Claims.” *Id.* (citing Ex. 1405 ¶ 247). Further, according to Petitioner, Root does not teach “placement of the side opening outside of the substantially rigid segment.” *Id.* at 75. Petitioner reasons that a person of ordinary skill in the art “would have been motivated to construct the side opening of a material that was not rigid, as it was known that ‘stents can get damaged entering [a] metal collar.’” *Id.* (quoting Ex. 1509, 10).

Patent Owner contends,

[t]he challenged claims recite a device having a “substantially rigid segment” and a “segment defining a side opening.” Ex. 1401, 14:3-5, 23-25, 15:58, 16:8-10, 16:61-64, 17:19, 18:7-9. Figures 4 and 12-16 of the ’629 application disclose such a device, with a substantially rigid segment and a segment defining a side opening, using the same figures and description as in the ’116 patent itself.

PO Resp. 52 (citing Ex. 1500, 28, 34; Ex. 2138 ¶ 298; Ex. 2244, 60:16–61:2). Patent Owner further contends,

While the '629 application discloses that the devices shown in Figures 4 and 13 “may” be formed by cutting down a tube (Ex. 1500, 9), there is nothing improper with claiming an integrally formed part of a device as including two “segments.” Ex. 2138, ¶299; Ex. 2245, 117:2-8 (“I don’t think the materials dictate where one defines a segment starting and ending.”). Indeed, Petitioner has not proposed construing “segment” in a way that would preclude reading the two claimed “segments” on an integrally formed structure like that shown in Figures 4 or 13 of the patent.

Id. at 53.

Having considered the parties positions and evidence of record, summarized above, we find Patent Owner to have the better position and adopt its analysis as our own. PO Resp. 51–60. Specifically, we determine that at least Figures 4 and 10–16 of the '629 application disclose a device having a “substantially rigid segment” and a segment defining “a side opening” or “an arcuate cross-sectional shape” as required by the Challenged Claims. PO Resp. 52–54 (citing Ex. 1500, 28, 34; Ex. 2138 ¶ 298; Ex. 2244, 60:16–61:2). Furthermore, Figures 10–11 expressly teach that the side opening segment can be made more flexible than the proximal portion with the addition of relief cuts. Ex. 2138 ¶ 301 (citing Ex. 1500, 10, 16, 19, 33).

The '629 application also expressly shows an embodiment with a side opening having two different inclined slopes. Ex. 1500, 28 (Fig. 4); Ex. 2138 ¶ 304. Accordingly, there is sufficient written description support for a claim directed to a side opening having “at least two” different inclined slopes.

Accordingly, we determine that Petitioner has failed to establish that the '629 application lacks written description support for “(i) a side opening outside of the substantially rigid segment or (ii) a side opening with ‘*at least two* inclined slopes.’” Accordingly, we determine that Petitioner has failed to establish that Root is prior art. Pet. 62.

G. Ground 5: Alleged Obviousness over Kontos, Ressemann, Takahashi, and Root

Petitioner argues that “[t]o the extent” the combination of Kontos, Ressemann, Takahashi does not teach claims 45 and 46, these claims would have been obvious over the combination of Kontos, Ressemann, Takahashi, and Root. Pet. 76. In particular, Petitioner argues a person of ordinary skill in the art “would replace Kontos’s funnel 26 with the shape of the side opening in Root Figure 4.” *Id.* Petitioner asserts a person of ordinary skill would have been motivated to replace Kontos’s funnel with a side opening, but does not explain why. Instead, Petitioner cites “Section IX.A.3” of the Petition, which provides no explanation for a motivation. Pet. 33.

As discussed above, we determine that Petitioner has fail to establish that Root is prior art. As such, Ground 5 fails for the same reasons discussed above in Ground 2.

IV. CONCLUSION

Having considered all the evidence, Petitioner has not demonstrated by a preponderance of the evidence the unpatentability of claims 25–55 of the '116 patent.

In summary:

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not Shown Unpatentable
52, 53	103	Kontos, Ressemann		52, 53
25–40, 42, 44– 48	103	Kontos, Ressemann, Takahashi		25–40, 42, 44–48
45	103	Kontos, Ressemann, Takahashi, Kataishi		45
25–55	103	Root		25–55
45, 46	103	Kontos, Ressemann, Takahashi, Root		45, 46
Overall Outcome				25–55

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 25–55 of the '116 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2020-01344
Patent RE46,116 E

For PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
ROBINS KAPLAN LLP
Cmorton@RobinsKaplan.com
Sroberg-perez@robinskaplan.com
Cpinahs@RobinsKaplan.com

For PATENT OWNER:

Derek Vandenburg
Dennis Bremer
Megan Christner
Shelleaha Jonas
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburg@carlsoncaspers.com
dbremer@carlsoncaspers.com
mchristner@carlsoncaspers.com
sjonas@carlsoncaspers.com