

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.

---

IPR2020-01342  
Patent 8,142,413 B2

---

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”).<sup>1</sup> Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1, 2, 4, 5, and 7–14 of U.S. Patent No. 8,142,413 B2 (“the ’413 patent,” Ex. 1401) are unpatentable.

### A. Background

Petitioner filed a Petition for *inter partes* review of claims 1, 2, 4, 5, and 7–14 of the ’413 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 9, 2021. Paper 9.

Following institution, Patent Owner filed a Response to the Petition (Paper 24, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 40, “Reply”), and Patent Owner filed a Sur-reply (Paper 52).<sup>2</sup>

---

<sup>1</sup> 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”).

<sup>2</sup> Redacted versions of the PO Response and Reply are entered as Papers 25 and 41, respectively.

On November 18, 2021, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 73.

*B. Related Matters*

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

Petitioner also previously filed petitions challenging patents related to the '413 patent in the following proceedings: IPR2020-00126 and IPR2020-00127 (Patent 8,048,032 B2); IPR2020-00128, IPR2020-00129, IPR2020-00130, and IPR2020-00131 (Patent RE45,380 E); IPR2020-00132, IPR2020-00133, and IPR2020-00134 (Patent RE45,760 E); IPR2020-00135 and IPR2020-00136 (Patent RE45,776 E); IPR2020-00137 and IPR2020-00138 (Patent RE47,379 E); and IPR2021-01343 and IPR2021-01344 (Patent RE46,116 E). Institution of *inter partes* review was denied in IPR2020-00131 and IPR2020-00133. Final written decisions are pending in IPR2021-01343 and IPR2021-01344. We issued final written decisions determining that none of the challenged claims were unpatentable in the other proceedings.

The parties indicate that the '413 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn. filed July 2, 2019) and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn. filed June 8, 2017). Pet. 4–5; Paper 5, 2.

*C. The '413 Patent*

*1. Specification*

The '413 patent, titled “Coaxial Guide Catheter for Interventional Cardiology Procedures,” issued on March 27, 2012, from a non-provisional application filed June 28, 2010. Ex. 1001, codes (45), (54), (22). The '413 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1001, Abstract.

According to the '413 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:21–23.

In coronary artery disease, atherosclerotic plaques or other lesions may narrow or occlude the coronary arteries. *Id.* at 1:26–30. The '413 patent states that “[n]arrowing is referred to as stenosis.” *Id.* at 1:30–31.

“In treating a stenosis, a guide catheter is typically inserted through the aorta and into the ostium of the coronary artery,” sometimes with the aid of a guidewire. *Id.* at 1:35–37. The '413 patent further states as follows:

A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

*Id.* at 1:37–45. The '413 patent discusses “four categories” of “[p]rior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as ‘backup support’),” consisting of: (1) “guiding catheters that, through a combination of shape

and stiffness, are configured to draw backup support from engaging the wall of the aortic arch;” (2) “guiding catheters that include a retractable appendage;” (3) guide catheters that have apporation that seeks to expand laterally;” and, (4) “placement of a smaller guide catheter within a larger guide catheter in order to provide add support.” *Id.* at 1:46–2:39. The ’413 patent identifies various deficiencies with these prior attempts, including an increased risk of damage to the aortic wall and mechanical complexity. *See id.* Specifically, with regard to the fourth category of prior attempts, the ’413 patent states as follows:

This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

*Id.* at 2:30–50. The ’413 patent states “a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery” would be beneficial to “the interventional cardiology art.” *Id.* at 2:51–55.

The '413 patent describes “a coaxial guide catheter that is deliverable through standard catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter.” *Id.* at 2:59–62. “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,” allowing “removal of the tapered inner catheter after the coaxial guide catheter is in place.” *Id.* at 2:62–67. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter as described in the '413 patent:

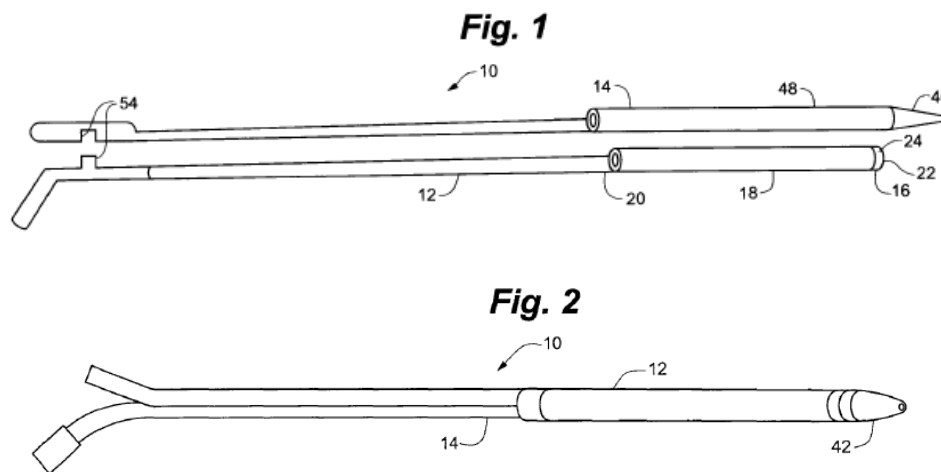
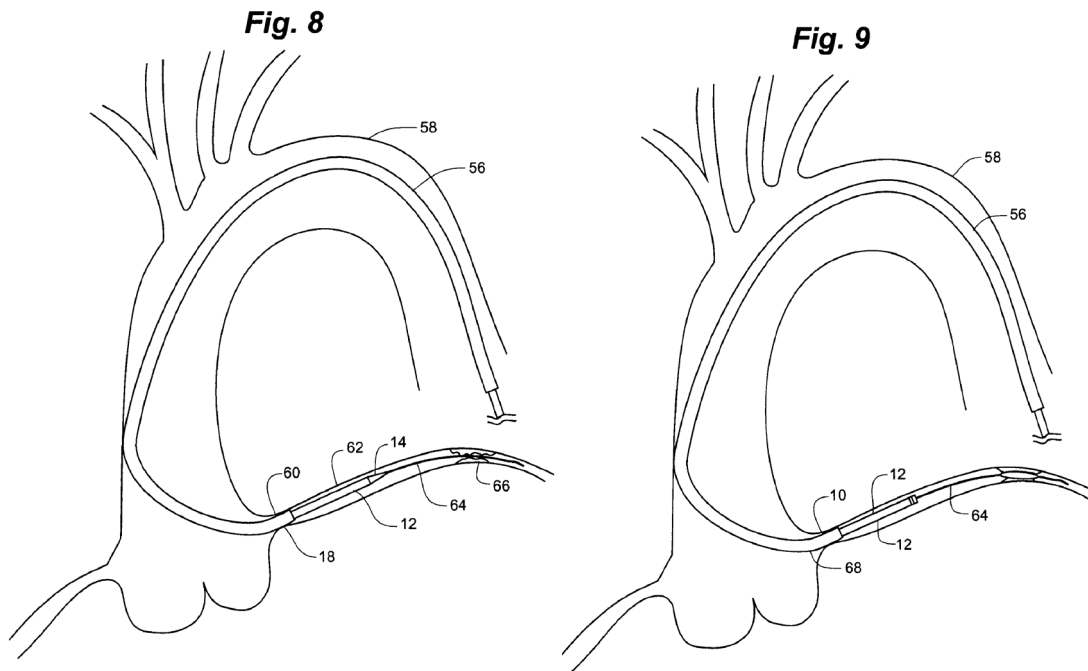


Figure 1 depicts tapered inner catheter 14 separate and above coaxial guide catheter 12, and Figure 2 depicts coaxial guide catheter 12 and tapered inner catheter 14 assembled as coaxial guide catheter assembly 10. *Id.* at 5:22–27, 6:12–14; Figs. 1 and 2. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:15–16. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:20–21. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:21. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:25–26. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:65–66. Both tapered

portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:65–67. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:3–5.

Figures 8 and 9 of the '413 patent are reproduced below.



Figures 8 and 9 are schematic illustrations of guide catheter 56 with coaxial guide catheter 12 inserted into ostium 60 of coronary artery 62. *Id.* at 5:43–49, 7:53–55, 7:67–8:4. The catheter assembly of Figure 8 includes optional tapered inner catheter 14, whereas the apparatus of Figure 9 does not. *Id.*

The '413 patent states “the presence of coaxial guide catheter 12 within guide catheter 56” provides “improved distal anchoring of guide catheter 56 and coaxial guide catheter 56” and “stiffer back up support than guide catheter 56 alone.” *Id.* at 7:67–8:6. The '413 patent describes in detail a method of use, as follows:

In operation, a guide catheter 56 is inserted into a major blood vessel in the body such as aortic arch 58 over guidewire 64 and

the distal end 68 of guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62, that it is desired to enter. Coaxial guide catheter 12, with tapered inner catheter 14, is inserted through guide catheter 56 and over guidewire 64. Guide catheter 56, guidewire 64, coaxial guide catheter 12, and tapered inner catheter 14 are manipulated to insert tapered inner catheter tip 42 into the ostium 60 of the blood vessel that branches off from the major blood vessel. The bump tip 22 of coaxial guide catheter 12 is inserted with tapered inner catheter tip 42 well into ostium 60 of coronary artery 62 or other blood vessel until bump tip 22 of coaxial guide catheter 12 achieves a deep seated position. Tapered inner catheter 14 is then withdrawn from the lumen of coaxial guide catheter 12. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter 12 which remains inside guide catheter 56.

When the interventional cardiology device reaches a stenosis or blockage in coronary artery 62 or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion 18 and rigid portion 20 of coaxial guide catheter 12 provide back up support. The back force that would tend to dislodge bump tip 22 from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion 18 to rigid portion 20 of coaxial guide catheter 12. A physician may apply a force to the proximal end of the coaxial guide catheter 12 to resist dislodging of bump tip 22 from the ostium of the branch artery.

*Id.* at 9:51–10:15; *see also id.* at 1:23–26 (stating that “the term ‘interventional cardiology devices’ is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters”). Patent Owner summarizes the method described in the ’413 patent and notes the use of the tapered inner catheter is optional. *See* PO Resp. 3 (stating that “[o]ptionally, a tapered inner catheter may be inserted with the coaxial guide catheter and advanced to the second vessel, and removed before an

[interventional cardiology device] is inserted into the coaxial guide catheter”  
(citing Ex. 1001, 9:55–66).

## *2. Illustrative Claims*

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

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

[1a] inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

[1b] positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

[1c] inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,

[1d] further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the

device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;

[1e] advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

[1f] *inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion* and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.

Ex. 1401, 10:30–11:6 (emphasis and bracketing added).

#### *D. Evidence*

Petitioner relies upon the following prior art references.

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

Ex. 1410, S. 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) (“Takahashi”).

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

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

Patent Owner relies upon the Declarations of Peter T. Keith (Ex. 2138) and Dr. John J. Graham, MB, ChB, MRCP (UK) (Ex. 2145).

#### *E. Asserted Grounds of Unpatentability*

Petitioner asserts that claims 1, 2, 4, 5 and 7–14 would have been unpatentable on the following grounds.

| Ground | Claim(s)             | 35 U.S.C. § <sup>3</sup> | References/Basis         |
|--------|----------------------|--------------------------|--------------------------|
| 1      | 1, 2, 4, 5, 7–12, 14 | 103(a)                   | Kontos, Adams            |
| 2      | 13                   | 103(a)                   | Kontos, Adams, Takahashi |

## II. ANALYSIS

### *A. Level of Ordinary Skill in the Art*

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

Petitioner asserts “[i]f a person of ordinary skill in the art (‘POSITA’) was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist.” Pet. 11–12. Alternatively,

---

<sup>3</sup> The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 103. Because the challenged claims of the ’413 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103 throughout this Decision.

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

Patent Owner does not dispute Petitioner’s proposed definition of a person of ordinary skill in the art.

We apply both of Petitioner’s definitions for a POSITA, as they are undisputed and consistent with the level of skill reflected in the prior art and the specification of the ’413 patent. *See Okajima*, 261 F.3d at 1355 (the prior art itself can reflect the appropriate level of ordinary skill in the art).

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. 1042 ¶¶ 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*

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore, we need only construe the claims to the extent necessary resolve the dispute between the parties. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner proposes construction for several claim terms, including “interventional cardiology devices,” “standard guide catheter,” and “placed in a branch artery.” Pet. 13–16. We determine that it is unnecessary to expressly construe any claim term to resolve the dispute between the parties. However, we address the dispute between the parties as to whether claim 1 requires the recited steps to be performed sequentially.

Claim 1 of the ’413 patent recites a method comprised of six steps. Ex. 1401, 10:28–11:6; *see also, supra*, Section I.D. (reproducing claim 1 and labeling six steps [a] to [f]). Whether the steps recited in a method claim must be performed in a particular order is an issue of claim construction. *See, e.g., Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371–72 (Fed. Cir. 2003). Steps in a method claim need not necessarily be performed in the order they are written. The claims may be so limited, however, if grammar, logic, the specification, or the prosecution history

otherwise requires the steps to be performed sequentially. *Id.* at 1369; *see also Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999) (“Although not every process claim is limited to the performance of its steps in the order written, the language of the claim, the specification and the prosecution history support a limiting construction in this case.”).

“*Interactive Gift* recites a two-part test for determining if the steps of a method claim that do not otherwise recite an order, must nonetheless be performed in the order in which they are written.” *Altiris*, 318 F.3d 1369 (citing *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001)). “First, we look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written.” *Id.* “If not, we next look to the rest of the specification to determine whether *it* directly or implicitly requires such a narrow construction.” *Id.* at 1370 (citation omitted).

Petitioner argues that certain steps of claim 1 need not be performed in the order recited in the claim. Pet. 49 n.15. In abbreviated summary, claim 1 recites the following six steps:

- [1a] “inserting the standard guide catheter . . . into a first artery;”
- [1b] “positioning . . . the standard guide catheter in a branch artery;”
- [1c] “inserting a flexible tip portion of a coaxial guide catheter;”
- [1d] “further inserting a substantially rigid portion . . . connected to the flexible tip portion;”
- [1e] “advancing . . . the flexible tip portion” beyond the “end of the standard guide catheter and into the second artery;” and
- [1f] “inserting the [ICD] . . . alongside of the substantially rigid portion and advancing the [ICD] device through and beyond a lumen of the flexible tip portion.”

Ex. 1401, 10:28–11:6. Petitioner specifically contends that step 1f allows for either preassembly of a coaxial guide and ICD, or sequential insertion of the two. Pet. 2. According to Petitioner, “[t]here is nothing in the language” of step [f] “that requires the coaxial guide catheter to be inserted first, followed (separately) by the interventional cardiology device,” and that “[t]he devices are inserted ‘alongside’ one another” in either instance.

Pet. 49 n.15 (citing *Interactive Gift Express*, 256 F.3d at 1342). Petitioner further suggests that under its interpretation, step 1f

requires that two things be positioned “alongside” each other: (a) the [ICD]; and (b) the coaxial guide catheter’s substantially rigid portion. ‘Alongside’ is an adjective that accurately reflects the relative positions of (a) and (b), even where the two are preassembled.

Reply 3–4. Petitioner does not address in the Petition whether steps 1a to 1e must be performed sequentially, and, if so, how that comports with its argument that step 1f need not be in the sequence recited. Petitioner, in the Petition, also does not direct us to anything additional in the Specification of the ’413 patent to support its proposed construction. *See generally* Pet.

In determining whether steps of a method must be performed in order, we must first look to the claim language to determine whether, “as a matter of logic or grammar,” the method steps must be performed in the order written. *See Altiris*, 318 F.3d at 1369. Patent Owner argues, and we agree, that the method of claim 1 “only makes sense if the steps take place in order.” PO Resp. 13. As Patent Owner explains, step 1b (positioning the standard guide catheter) cannot logically occur until after step 1a (inserting the standard guide catheter), steps 1c–1e (inserting various parts of the coaxial guide catheter) must occur in sequence, and step 1e (advancing the coaxial guide catheter beyond the standard guide catheter) necessarily

requires performing steps 1a and 1b prior to steps 1c to 1e. *Id.* at 13–14 (citing Ex. 1401, 10:39–67; Ex. 2138 ¶ 102; Ex. 2145 ¶¶ 102–106; Ex. 2244, 61:24–62:3; Ex. 2245, 87:24–88:14, 89:21–90:3, 90:13–23).

As to the disputed step 1f, Patent Owner further explains, and we agree, “as a matter of logic and grammar, . . . claim 1 requires that step 1.f (insertion and advancement of the ICD) occur after steps 1.c-1.e. (insertion of the coaxial guide catheter in the guide catheter).” *Id.* at 16. Specifically, Patent Owner shows “the ICD would not be inserted ‘into and through’ the lumen of the guide catheter ‘alongside of’ the substantially rigid portion of the coaxial guide catheter unless the coaxial guide catheter is already in the guide catheter.” *Id.* at 14 (citing Ex. 2138 ¶ 103; Ex. 2145 ¶ 103). That is, in the context of the claim, “inserting an ICD ‘alongside of the substantially rigid portion’ means that the substantially rigid portion is already in place inside the guide catheter, and when the ICD is inserted into the guide catheter it moves ‘alongside’ the already positioned substantially rigid portion.” *Id.* at 14–15 (citing Ex. 2138 ¶ 103; Ex. 2145 ¶ 103).

Furthermore, as Patent Owner notes, “Petitioner’s own expert, Dr. Hillstead, agrees that ‘alongside’ in this context means that the substantially rigid portion is already in place in the guide catheter when the ICD is inserted ‘alongside’ of it.” *Id.* at 15 (citing Ex. 2244, 63:6–64:1).

We further find that Patent Owner persuasively shows that the claim language of step 1f requires “advancing” the ICD “through and beyond a lumen of the flexible tip portion” of the coaxial guide catheter, which “strongly suggests that the flexible tip of the coaxial guide catheter is already in the anatomy.” *Id.* (citing Ex. 1401, 10:39–11:6; Ex. 2138 ¶ 103; Ex. 2145 ¶ 103). Patent Owner also shows that “Petitioner’s expert Dr. Hillstead agreed that step 1.f requires that insertion of the ICD in claim 1

of the '413 patent 'take place after the prior steps that are recited in the claim.'" *Id.* (citing Ex. 2244, 62:18–24; 63:13–64:1).

Having determined that, as a matter of logic or grammar, the steps of claim 1 must be performed in the order written, we need not look to the Specification "to determine whether *it* directly or implicitly requires" the same. *See Altiris*, 318 F.3d at 1370. Nevertheless, we note that our determination that claim 1 requires the steps to be performed in the order written is consistent with the Specification. Patent Owner explains, and we agree, that the Specification describes sequential operation as follows:

"a guide catheter 56 is inserted into a major blood vessel . . . [c]oaxial guide catheter 12 . . . is inserted through guide catheter 56 . . . coaxial guide catheter 12 achieves a deep seated position . . . [a]n interventional cardiology treatment device such as a catheter bearing a stent or balloon (not shown) *is then inserted* through the lumen of coaxial guide catheter 12, which remains inside guide catheter 56."

PO Resp. 17 (quoting Ex. 1401, 9:49–10:3 (emphasis added)).

Petitioner's arguments in reply in support of its proposed construction are not persuasive. Reply 2–4. Petitioner concedes that claim 1 requires some steps to be performed in the order written, including steps 1a to 1e, but maintains that "the plain language of the claims permits an [ICD] to be advanced *either* simultaneously with the guide extension catheter *or* sequentially." Pet. Reply 2 (citing Ex. 1405 ¶¶ 200–205; Ex. 1806 ¶¶ 17–23; Pet. 49–52). Petitioner's conclusory assertion fails to show any rationale based on logic or grammar in support of its assertion. Petitioner further argues that "[t]he [S]pecification's disclosure of an embodiment in which insertion is sequential does not limit the claims." *Id.* at 2–3 (citing *Altiris*, 318 F.3d at 1369–1371). We agree the single embodiment disclosed does not limit the claims, and do not rely on the disclosed embodiment in such a

manner; however, the single disclosed embodiment and the Specification as a whole consistently require the steps recited in claim 1 to be performed in the order written, which is consistent with the construction we adopt. We have considered Petitioner's remaining arguments and find they have no merit. *See* Reply 3–4. In sum, Petitioner seeks to show that “[t]his is not a case in which sequential insertion is *required* to perform the claimed method.” *Id.* at 3. The issue of claim construction presented is not whether the steps of the claimed method *could*, in the abstract, be performed out of the order in which they were written, but whether “as a matter of logic or grammar,” the steps of claim 1 *must* be performed in the order written. For the reasons discussed above, Patent Owner has shown that logic and grammar require that the steps of claim 1 must be performed in the order written.

Lastly, Petitioner argues that the ’413 patent does not require every step to be performed in the order recited based on arguments Petitioner raises based on steps required by dependent claims 10 and 11. Reply 4 n.1. Claims 10 and 11 recite additional requirements relevant to the insertion of the ICD and further limit step 1f in independent claim 1. Ex. 1401, 12:14–25. Petitioner's argument that claims 10 and 11 include additional steps that need not be performed in a specific sequence has no relevance to whether the steps of the method of claim 1 must be performed in the order written. For all of the reasons discussed above, we determine that claim 1 recites a method comprised of a series of steps that must be performed in the order written in the claim.

*C. Petitioner's Patentability Challenges*

*1. Ground 1: Obviousness in view of Kontos and Adams*

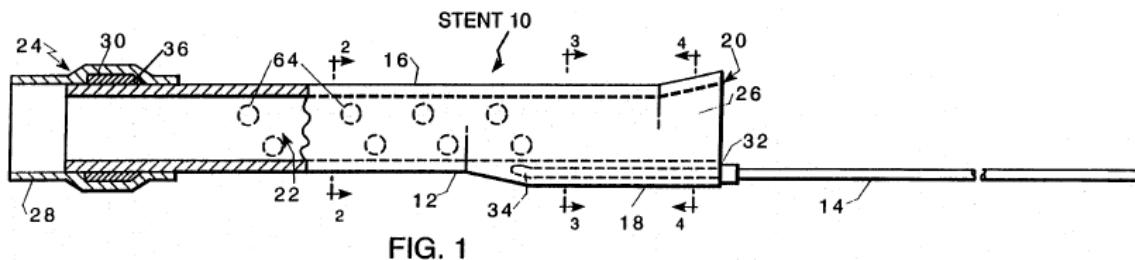
Petitioner asserts that claims 1, 2, 4, 5, 7–12, and 14 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos and Adams. Pet. 18–71. To support its position, Petitioner directs our attention to the following disclosures of Kontos and Adams and provides a detailed analysis addressing how each element of the challenged claims is disclosed by the combination of Kontos and Adams. *Id.* at 21–71 (citing *generally* Exs. 1405 and 1442). For the reasons set forth below, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1, 2, 4, 5, 7–12, and 14 would have been obvious over Kontos and Adams.

*a) Overview of the References Relied Upon*

*(1) Kontos (Ex. 1409)*

Kontos is directed to a support catheter assembly for facilitating medical procedures and, in particular, to a catheter assembly that has “particular utility in facilitating insertion of a PTCA<sup>4</sup> balloon into a lesion.” Ex. 1409, 1:9–13.

Figure 1 of Kontos is reproduced below:



<sup>4</sup> 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 tube 16 having a base portion 18 at its proximal end 20.” *Id.* at 3:47–49. “Tube 16 has a continuous lumen 22 therethrough from proximal end 20 to distal end 24.” *Id.* at 3:49–50. Body 12 also include a soft tip 28 disposed at distal end 24 and funnel portion 26 disposed at proximal end 20. *Id.* at 3:50–52. Wire 14 is attached to body 12 at base portion 18. *Id.* at 3:52–53. Support assembly 10 may also include distal marker band 30 and proximal marker band 32. *Id.* at 3:53–55.

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

Figure 5 of Kontos is reproduced below:

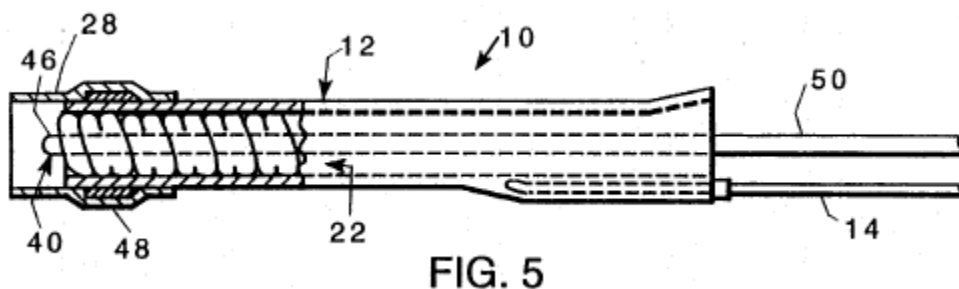


Figure 5 is a side schematic view of a support catheter having a PTCA catheter disposed therein. *Id.* at 2:64–66. In this figure, PTCA catheter 40

and its deflated balloon 48 reside in lumen 22 of support assembly 10. *Id.* at 5:2–5.

(2) *Adams (Ex. 1435)*

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

Figure 1A of Adams is reproduced below:

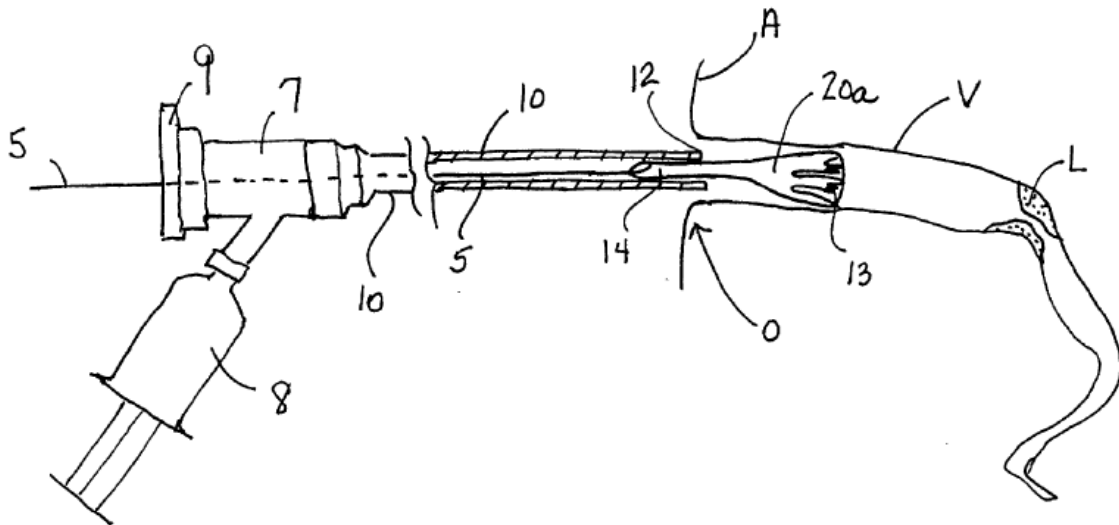


FIG. 1A

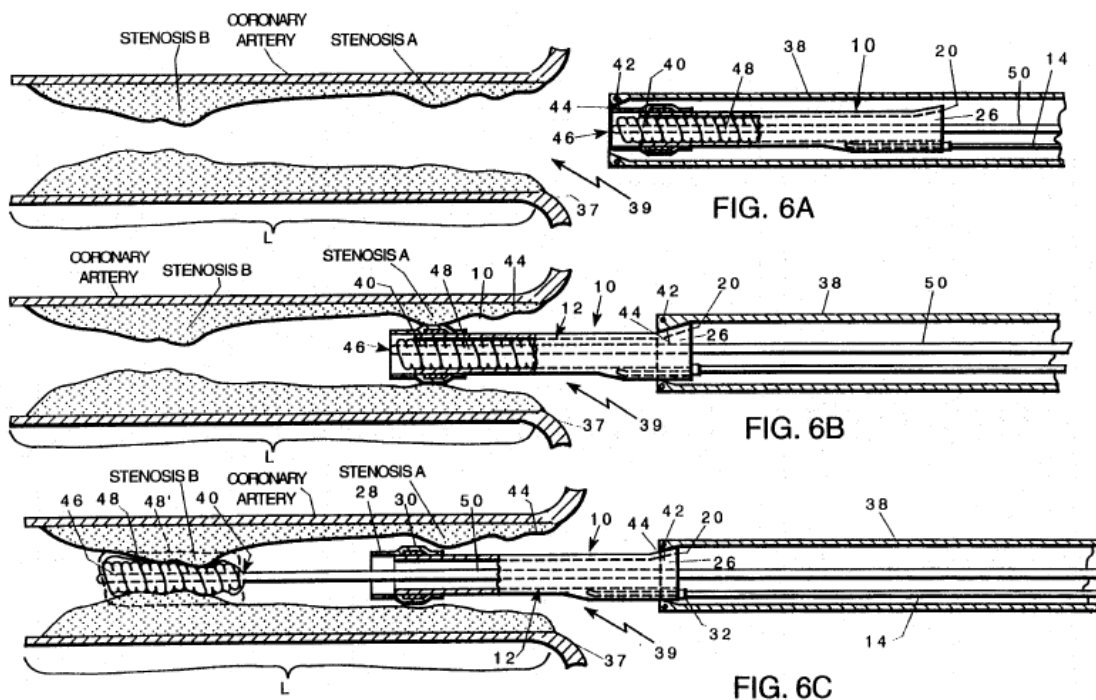
Figure 1A is a side view in partial cross-section of the device of Adams. *Id.* ¶ 28. In this figure, Y connector 7 is attached to the proximal end of guide catheter 10, and control wire 5 passes through Y connector 7. *Id.* ¶¶ 59–60. To reduce blood loss, Y connector 7 has hemostasis valve 9 at its proximal end. *Id.* ¶ 60. As shown in Figure 1A, distal end 12 of guide catheter 10 may be inserted into the ostium “O” of coronary vessel “V,” which has a lesion “L.” *Id.* ¶ 59. Guide seal 20a is then deployed beyond the distal end of guide catheter 10. *Id.*

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

*b) Independent Claim 1*

*(1) Whether Kontos discloses the claimed sequence of steps*

Petitioner contends that Kontos discloses the claimed sequence of steps even if element 1f “is interpreted to require insertion of the ‘interventional cardiology device’ after insertion of a ‘coaxial guide catheter.’” Pet. 49 (citing Ex. 1405 ¶ 201). To support its position, Petitioner directs our attention to Figure 6 of Kontos. *Id.* at 48–49. Figures 6A–6C of Kontos are reproduced below:



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

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

In “Figure 6C, after body 12 has been positioned adjacent the restricted area, PTCA catheter 40 is advanced so that balloon 48 exits body 12 and is advanced into the restricted area, e.g., stenosis B.” *Id.* at 6:9–13. Balloon 48 is then inflated, as represented by dotted lines 48, “to effect a well-known angioplasty procedure.” *Id.* at 6:13–15. Balloon 48 is then deflated, and PTCA catheter 40, support catheter assembly 10, and guiding catheter 38 may be withdrawn. *Id.* at 6:15–18.

The parties do not dispute that the embodiment of Kontos described above does not show the ICD being inserted after insertion of support catheter assembly 10. Pet. 49. Rather, Petitioner and Dr. Becker direct us to an alternative of the embodiment shown in Figures 6A–6C disclosed by Kontos which, according to Petitioner, suggests that support assembly 10 can be advanced first, followed by PTCA catheter 40. *Id.* (citing Ex. 1409, 7:45–52); Ex. 1405 ¶ 200. The disclosure of Kontos relied on by Petitioner provides as follows:

Although the procedure described above contemplates assembling body 12 and PTCA catheter 40 as a unit before passing them together into guide catheter 38, such preassembly is not necessary. *Body 12 could be inserted first, followed by the PTCA catheter 40.* As discussed above, funnel portion 26 facilitates passage of the PTCA catheter 40 from the guide catheter 38 into lumen 22 of body 12.

Ex. 1409, 7:45–52 (emphasis added). Petitioner contends,

Kontos explains that support assembly 10 can be advanced first, followed by PTCA catheter 40. Ex1409, 7:45-52. In other words, Kontos teaches that body 12 is advanced distal to guide catheter 38, and then the PTCA catheter 40 with balloon 48 is advanced into the guide catheter/extension catheter assembly. Ex-1405, ¶ 203 (explaining that when separately inserting extension catheter and therapy catheter, a [person of ordinary skill in the art] extends the extension catheter distal to the guide catheter prior to insertion of the therapy catheter).

Pet. 49.

“[T]he test for obviousness is what the combined teachings of the references would have suggested to those having ordinary skill in the art.” *See, e.g., In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012). We have considered that disclosure of Kontos and Petitioner’s arguments and supporting evidence, but conclude that Kontos does not disclose or suggest the claimed sequence of steps. In particular, Kontos does not disclose the sequence of inserting an ICD after advancing the substantially rigid portion of the coaxial guide catheter beyond the distal end of the standard guide catheter as required by step 1f of claim 1. To that point, we note that step 1f recites that the ICD is inserted “into and through” the lumen of the guide catheter “alongside of” the substantially rigid portion of the coaxial guide catheter after the coaxial guide catheter is already positioned distal to the guide catheter. Ex. 2138 ¶ 103; Ex. 2145 ¶ 103; Sur-reply 9–11. In either of

the alternative embodiments identified by Petitioner, PTCA catheter balloon 48 is in position prior to advancing the body 12 beyond the distal portion of guide catheter 38. In that regard, we credit the testimony of Patent Owner's expert, Mr. Peter Keith, that "[t]he cited portion of Kontos . . . does not disclose advancing a distal portion of body 12 beyond the distal end of the standard guide catheter before inserting the PTCA catheter." Ex. 2138 ¶ 210.

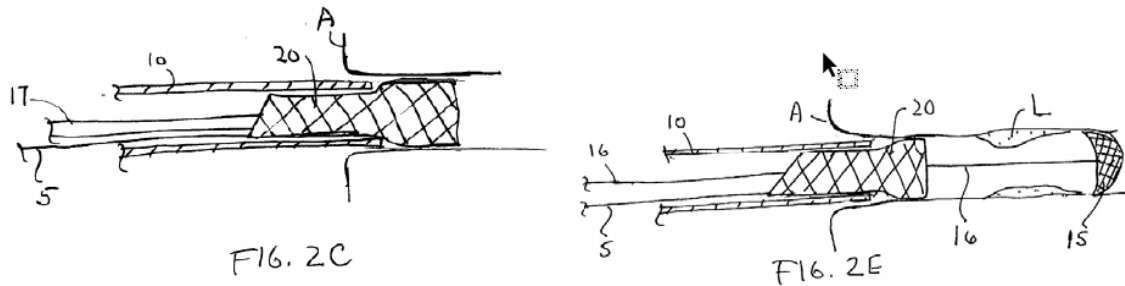
Furthermore, as noted by Patent Owner, Petitioner's argument with respect to claim 1 appears to rest entirely on claim construction, Petitioner does not direct us to any expert testimony supporting its argument that a person of ordinary skill in the art would have modified the teachings of Kontos alone to arrive at the claimed method. PO Resp. 18–19 (citing Pet. 49; Ex. 1405 ¶¶ 201, 203); Sur-reply 9–11.

In view of the above, we determine that Petitioner has failed to establish that Kontos discloses or suggests inserting an ICD into the already-positioned extended coaxial guide catheter assembly. Ex. 1401, 10:62–11:6. In the context of its disclosed method, Kontos does not disclose advancing a distal portion of body 12 beyond the distal end of the standard guide catheter before inserting PTCA catheter balloon 48 into and through the continuous lumen of guide catheter 38. *Id.*; Ex. 2138 ¶ 210. Petitioner fails to adequately account for this difference. Accordingly, Petitioner has failed to establish that Kontos discloses each element of claim 1.

*(2) Whether the combination of Kontos and Adams discloses the claimed sequence of steps*

Petitioner contends that the claimed sequence of steps would have been obvious over the combination of Kontos and Adams. Pet. 50–52. To

support its contention, Petitioner directs our attention to Figures 2C and 2E of Adams, reproduced below.



Figures 2C and 2E of Adams are part of a series of illustrations showing the stepwise deployment of guide seal 20 in a coronary artery. Ex. 1435 ¶¶ 29, 64. Guide seal 20 is attached to proximal control wire 5 inside guide catheter 10. *Id.* Adams discloses,

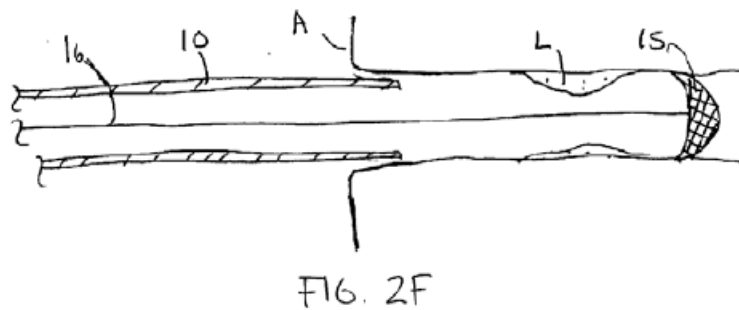
FIG. 2C shows the guide seal having been advanced distally so that its distal sealing portion seals against the walls of the vessel. At this point flow through the vessel has been stopped. After flow has stopped, a distal protection device is advanced through guide Seal 20 into the lumen of the vessel and across lesion L as shown in FIG. 2D. FIG. 2E shows delivery catheter 17 having been withdrawn proximally resulting in the deployment of a distal protection device 15 distal to the region of the lesion.

*Id.* at ¶ 64.

With reference to the above disclosure in Adams, Petitioner contends, a POSITA would have been motivated to, as provided by Adams, maintain the distal end of the extension catheter beyond the distal end of the guide catheter, and then advance the interventional device into the coronary artery alongside the substantially rigid portion. Ex. 1405, ¶ 203. Adams and Kontos are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '413 patent. *Id.* As explained by Dr. Brecker, a physician will wait to advance the interventional device until after positioning the extension catheter for multiple reasons. *Id.*, ¶ 204.

Pet. 51.

We have considered Petitioner's arguments and evidence, summarized above, and are not persuaded that Petitioner has established by a preponderance of evidence that a person of ordinary skill in the art would have combined the disclosures of Kontos and Adams to achieve the claimed method. We begin by noting that, while Adams discloses the use of guide seal 20 and delivery catheter 17, those devices are described as having limited functionality related to the specific deployment of distal protection device 15. As noted by Patent Owner, the next figure in the series of illustrations provided by Adams, is Figure 2F (reproduced below).



Ex. 1435, Fig. 2F; PO Resp. 11. Figure 2F shows that mesh guide seal 20 has been “withdrawn . . . out of the guide catheter,” thereby “resulting in the deployment of distal protection device 15.” Ex. 1435 ¶ 64. Then, after the guide seal has been removed from the guide catheter, a “treatment device” such as a “balloon” or “stent . . . may be advanced . . . to the treatment site.” *Id.*; see also Ex. 2138 ¶ 142 (same), ¶ 144 (“Adams emphasizes that occluding blood flow is undesirable, and therefore teaches that the guide seal is deployed only during deployment of the filter and not during the subsequent delivery of interventional cardiology devices such as balloons and stents.”). Thus, the positioning of guide seal 20 distal to guide catheter 10 for the subsequent delivery of an ICD, such as Kontos’s PTCA catheter, is not disclosed by Adams. In this regard, Petitioner’s discussion of Adams

fails to adequately explain how that use of mesh guide seal 20 would have motivated a person of ordinary skill in the art to advance an ICD into an already-positioned extended coaxial guide catheter as required by the claims.

We also note Petitioner's contention that, "[t]o the extent not taught by Kontos, a POSITA would have been motivated to, as provided by Adams, maintain the distal end of the extension catheter beyond the distal end of the guide catheter, and then advance the interventional device into the coronary artery alongside the substantially rigid portion." Pet. 51 (citing Ex. 1405 ¶ 203). To that point, however, we are persuaded by Patent Owner's contentions, in the specific context of the step recited in element 1f, that

[T]here are numerous fundamental differences between Kontos and Adams, which Petitioner's experts acknowledge. For example, Kontos discloses a support catheter assembly to protect a fragile balloon catheter. *E.g.*, Ex. 1409, 1:9-16, 1:30-37, 5:52-56; Ex-2244, 103:12-15; Ex-2245, 129:7-11; Ex-2138, ¶¶122, 212; Ex-2145, ¶¶146-47. Adams, on the other hand, is a device whose sole purpose is to temporarily create stasis (by occluding blood flow) during delivery of an embolic protection filter. *E.g.*, Ex-1435, Abstract; Ex-2145, ¶155; Ex-2244, 110:14-23; Ex-2245, 143:11-15, 144:4-7.

PO Resp. 20. The discussion set forth in the Petition fails to account for those differences. Pet. 50–52. That is, even assuming that the proposed combination is technically possible and a person of ordinary skill in the art could have combined the disclosures in the manner proposed by Petitioner, the record lacks sufficient guidance as to why a person of ordinary skill in the art would have been motivated to make the changes necessary to achieve the claimed sequence of steps required by claim 1.

*(3) Conclusion*

Petitioner fails to persuasively identify where every limitation of claim 1 is disclosed by Kontos. Petitioner also fails to persuasively explain why one of ordinary skill in the art would have combined Kontos and Adams to arrive at the subject matter of claim 1 with a reasonable expectation of success. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that independent claim 1 would have been obvious over Kontos and Adams.

*c) Dependent Claims 2, 4, 5, 7–12, and 14*

Claims 2, 4, 5, 7–12, and 14 depend from claim 1. Because Petitioner's arguments with respect to claims 2, 4, 5, 7–12, and 14 do not overcome the issues addressed above with respect to claim 1, we also determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 2, 4, 5, 7–12, and 14 would have been obvious over Kontos and Adams.

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

Petitioner asserts that claim 13 is unpatentable under 35 U.S.C. § 103(a) as obvious over Kontos, Adams, and Takahashi. Pet. 72–75. Claim 13 depends from independent claim 1. As such, Ground 2 fails for the same reasons discussed above with respect to claim 1.

III. CONCLUSION

Having considered all the evidence, Petitioner has not demonstrated by a preponderance of the evidence the unpatentability of claims 1, 2, 4, 5, and 7–14 of the '413 patent.

In summary:

| <b>Claims</b>              | <b>35<br/>U.S.C. §</b> | <b>Reference(s)/Basis</b>   | <b>Claims<br/>Shown<br/>Unpatentable</b> | <b>Claims<br/>Not Shown<br/>Unpatentable</b> |
|----------------------------|------------------------|-----------------------------|------------------------------------------|----------------------------------------------|
| 1, 2, 4, 5,<br>7–12, 14    | 103(a)                 | Kontos, Adams               |                                          | 1, 2, 4, 5, 7–<br>12, 14                     |
| 13                         | 103(a)                 | Kontos, Adams,<br>Takahashi |                                          | 13                                           |
| <b>Overall<br/>Outcome</b> |                        |                             |                                          | 1, 2, 4, 5, 7–<br>14                         |

#### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 2, 4, 5, and 7–14 of the '413 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.

IPR2020-01342  
Patent 8,142,413 B2

For PETITIONER:

Cyrus A. Morton  
Sharon Roberg-Perez  
Christopher A. Pinahs  
Ryan E. Dornberger  
ROBINS KAPLAN LLP  
Cmorton@RobinsKaplan.com  
Srobergperez@robinskaplan.com  
Cpinahs@RobinsKaplan.com  
EDornberger@RobinsKaplan.com

For PATENT OWNER:

J. Derek Vandenburg  
Dennis C. Bremer  
Joseph W. Winkels  
Peter Kohlhepp  
Alexander S. Rinn  
Meghan Christner  
Shelleaha Jonas  
Tara C. Norgard  
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.  
dvandenburg@carlsoncaspers.com  
dbremer@carlsoncaspers.com  
jwinkels@carlsoncaspers.com  
pkohlhepp@carlsoncaspers.com  
arinn@carlsoncasper.com  
mchristner@carlsoncaspers.com  
sjonas@carlsoncaspers.com  
tnorgard@carlsoncaspers.com