UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00131
U.S. Patent No. RE 45,380E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 45,380E

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1812	Joint Claim Construction Statement in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (January 10, 2018), D.I. 36; D.I. 36-1.
1813	*Markman* Order in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (October 30, 2018), D.I. 102
1814	Meads, C., et al., *Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review*, Health Technology Assessment 2000 4(23) ("Meads")
1815	Excerpt from Grossman's Cardiac Catheterization, Angiography, and Intervention (6th edition) (2000) (chapters 1, 4, 11, 23-25).
1816	US Patent Publication 2003/0233117 ("Adams '117")
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1819	U.S. Patent No. 6,398,773 ("Bagaoisan")
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1821	Excerpt of prosecution history for application 11/232,876 (Office Action, 6/20/09)
1822	Cordis, Instructions for Use, CYPHER™ (April 2003)
1823	Medtronic, Summary of Safety and Effectiveness Data, Driver™ Coronary Stent System (October 1, 2003)
1824	Boston Scientific, Summary of Safety and Effectiveness Data, TAXUS™ Express^{2}™ Drug-Eluting Coronary Stent System (March 4, 2004)
1825	U.S. Publication Application No. 2005/0015073 ("Kataishi")
1826	U.S. Patent No. 5,489,278 ("Abrahamson")
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1828	Baim, *Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts*, Circulation 105:1485-1490 (2002) ("Baim")
1829	Limbruno, *Mechanical Prevention of Distal Embolization During Primary Angioplasty*, Circulation 108:171-176 (2003) ("Limbruno")
1830	U.S. Patent No. 5,413,560 ("Solar '560")
1831	Schöbel, *Percutaneous Coronary Interventions Using a New 5 French Guiding Catheter: Results of a Prospective Study*, Catheterization & Cardiovascular Interventions 53:308-314 (2001) ("Schöbel")
1832	*The sliding rail system (monorail): description of a new technique for intravascular instrumentation and its application to coronary angioplasty*, Z. Kardio. 76:Supp. 6, 119-142 (1987) ("Bonzel")

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1833	U.S. Publication Application No. 2004/0236215 (Mihara)
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1837	Dorros, G., et al., *Coronary Angioplasty in Patients with Prior Coronary Artery Bypass Surgery*, Cardiology Clinics 7(4): 791-803 (1989)
1838	Ozaki et al, *New Stent Technologies*, Progress in Cardiovascular Disease 2:149-140 (1996)
1839	Urban et al., *Coronary stenting through 6 French Guiding Catheters, Catheterization and Cardiovascular Diagnosis* (1993) 28:263-266
1840	Excerpt of McGraw-Hill Dictionary of Scientific and Technical Terms (5th edition) (1994) (defining “flexural modulus”)
1841	Excerpt from Kern’s The Interventional Cardiac Catheterization Handbook (2nd edition) (2004) (chapter 1)).
1842	Declaration of Dr. Richard A. Hillstead, Ph.D.
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1853	U.S. Patent No. 5,720,300 (“Fagan”)
1854	U.S. Patent No. 5,140,323 (“Shockey”)
1855	Sakurada, *Improved Performance of a New Thrombus Aspiration Catheter*: Outcomes From In Vitro Experiments and a Case Presentation (“Sakurada”)
1856	Nordenstrom, *New Instruments for Catheterization and Angiocardiography* (“Nordenstrom”)
1857	U.S. Patent No. 5,445,625 (“Voda”)
1858	U.S. Patent No. 6,595,952 (“Forsberg”)
1859	U.S. Patent No. 6,860,876 (“Chen”)
1860	U.S. Patent No. 6,638,268 (“Niazi”)
1861	U.S. Patent No. 5,690,613 (“Verbeek”)
1862	lserson, *J.-F.-B. Charrière: The Man Behind the “French” Gauge,* The Journal of Emergency Medicine. Vol. 5 pp 545-548 (1987)
1863	U.S. Publication Application No. 2003/0195546 (“Solar ’546”)
1864	QXMédical, LLC’s Opening Claim Construction Memorandum *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (March 14, 2018), D.I. 56
1865	U.S. Patent No. 4,000,739 (“Stevens”)
1866	EP 0 881 921 B1 (“Lee”)
1867	U.S. Patent No. 5,451,209 (“Ainsworth”)
1868	Defendants’ Memorandum in Opposition to Plaintiff’s Summary Judgment Motion and in Support of Defendants’ Summary Judgment Motion, *QXMedical, LLC v. Vascular Solutions LLC et al*., 17-cv-01969-PJS-TNL (D. Minn 2019)
1869	Excerpt of prosecution history for application 14/195,435 (Office Action, 10/06/15)
1870	Metz, *Comparison of 6f with 7f and 8f guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter,*

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1873	Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL
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1883	Joint Fed. R. C. P. 26(f) Report [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL

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I. PRELIMINARY STATEMENT

Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 25-39 ("Challenged Claims") of U.S. Patent No. RE 45,380 ("the '380 patent," Ex-1801). The '380 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id*., [54], [72]. The Challenged Claims were never subject to an Office Action, meaning there is no substantive file history for the '380 patent.

The '380 patent describes a catheter system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a guide catheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*., Abstract, Figs. 8-9. In so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery,"

[1] The '380 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1805, ¶¶ 71 n.7, 118. A POSITA knew that the "coaxial guide catheter" of the '380 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1809, 5:49-52 (referring to body 12 "as a guide catheter extension").

thereby preventing the GC from dislodging from the ostium. *Id*., 3:1-5.

The ’380 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. *Id*., 2:40-56 (describing the use of a “smaller guide catheter within a larger guide catheter”). Indeed, such a catheter-in-a-catheter assembly was well-known in the art and described as a “mother-and-child assembly.” Ex-1805, ¶¶ 70-80. The child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. *Id*., ¶ 70.

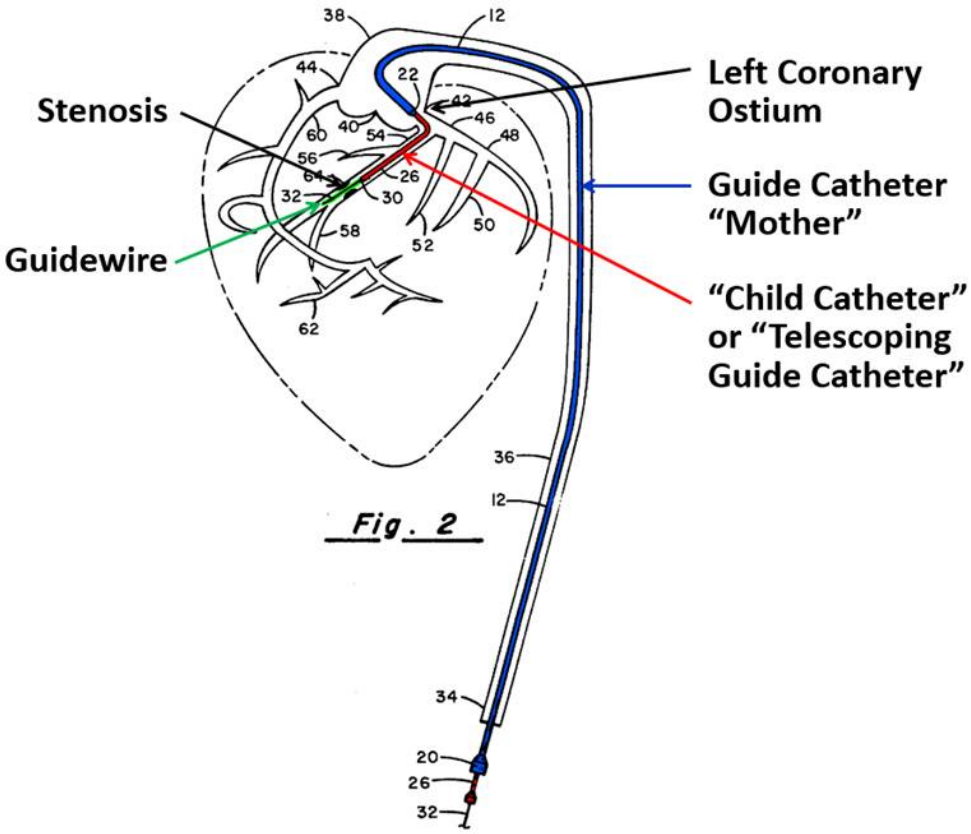
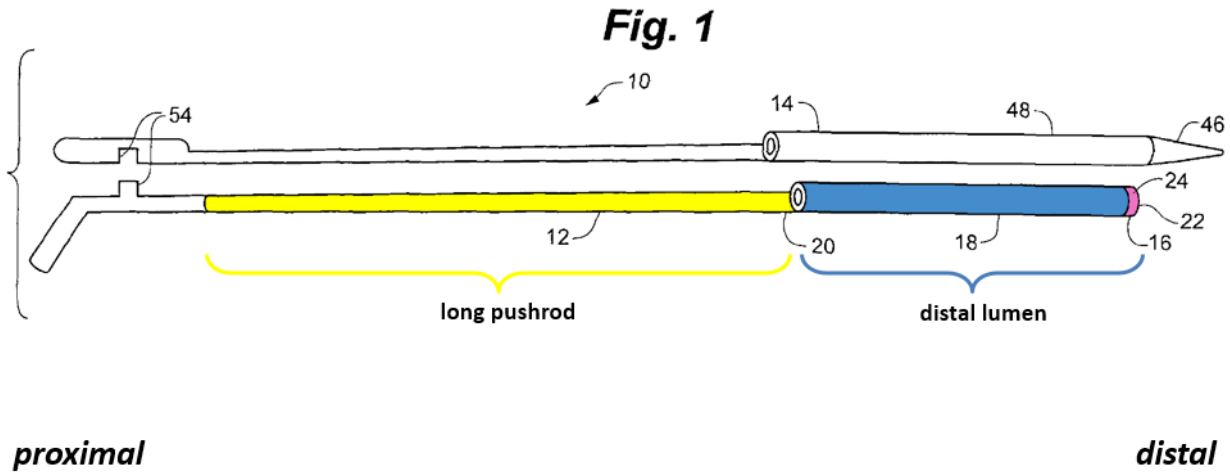


Fig. 2

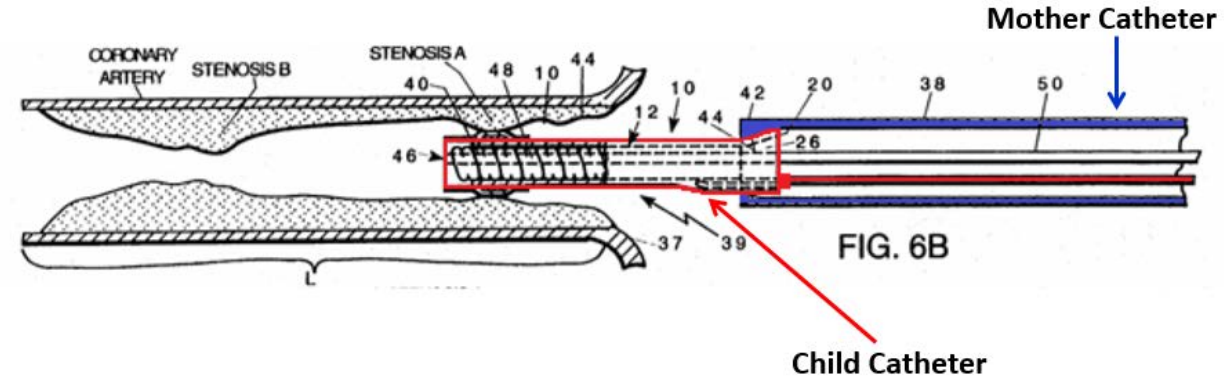
Ex-1854, Fig. 2 (color and labels added).

The child catheter in the mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id*. The '380 patent alleges that such a design had certain drawbacks (Ex-1801, 2:57-67; Ex-1805, ¶¶ 81-89) and modifies the child catheter (of the mother-and-child assembly) to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., tube) that is highly flexible so it can extend deep into the coronary artery.



Ex-1801, Fig. 1 (annotations and color added).

But such child catheters that served as guide extension catheters and had a short lumen connected to a long thin pushrod were already well-known in the art, as evidenced by U.S. Patent No. 5,439,445 ("Kontos"), which issued more than ten years before the earliest purported priority date of the '380 patent.



Ex-1808, Fig. 6B (annotations and color added).

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the ’380 patent are unpatentable. Accordingly, Petitioner respectfully requests institution of a trial and cancellation/invalidation of the Challenged Claims.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real Party-in Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc. as real parties-in-interest. Medtronic plc is the ultimate parent of both entities.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the ’380 patent is currently the subject of litigation in two separate actions in the U.S. District Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic,*

Inc., *et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019); and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("QXMedical Litigation").

Further, the '380 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent"). The '850 patent was previously the subject of litigation (i) in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and (ii) at the PTAB in *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (P.T.A.B., terminated, Aug. 11, 2014).

Petitioner is also concurrently filing another petition for IPR challenging the '380 patent based on prior art references having different priority dates and disclosures than the references discussed herein, or challenging different claims.

C. Lead and Backup Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following counsel of record:

Lead Counsel	**Back-Up Counsel**
Cyrus A. Morton (Reg. No. 44,954) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Cmorton@RobinsKaplan.com	Sharon Roberg-Perez (Reg. No. 69,600) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Sroberg-perez@robinskaplan.com

Additional Back-Up Counsel	
Christopher A. Pinahs (Reg. No. 76,375) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Cpinahs@RobinsKaplan.com	

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), please direct all correspondence to lead and back-up counsel at the above addresses. Petitioner consents to electronic service at the above-identified email addresses.

III. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to 37 C.F.R. §42.104, Petitioner certifies that the ’380 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 25-39 of the ’380 patent

and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Claims 25-26 and 28-31, 34-37, 39 are rendered obvious by Kontos in view of Adams and/or the knowledge of a POSITA.
2	Claim 27 is rendered obvious by Kontos in view of Adams, Kataishi, and/or the knowledge of a POSITA.
3	Claim 27 is rendered obvious by Kontos in view of Adams, Enger, and/or the knowledge of a POSITA.
4	Claims 32-33 are rendered obvious by Kontos in view of Adams, Takahashi, and/or the knowledge of a POSITA.
5	Claim 38 is rendered obvious by Kontos in view of Adams, Berg, and/or the knowledge of a POSITA.

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1805, ¶¶ 28, 30-32. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id.* In response,

[2] This petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1805), and Richard A. Hillstead, PhD (Ex-1842), as experts in the field of the '380 patent. Petitioner also submits the declaration of Sylvia S. Hall-Ellis, PhD (Ex-1878) to support the authenticity and public availability of the documents cited herein.

physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery, and thus can treat CAD without the need for open-heart surgery. *Id.*, ¶¶ 29, 34-40.

PCI was developed more than forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. *Id.*, ¶¶ 33, 41. During PCI, after a physician uses a hollow needle to gain access to the patient's vasculature, a guide catheter is introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id.*, ¶¶ 34, 42-55. A hemostatic valve is placed at the proximal end of the guide catheter and remains outside the patient's body. *Id.*, ¶¶ 35, 54. The hemostatic valve prevents blood from exiting the patient's artery and keeps air from entering the bloodstream. *Id.*

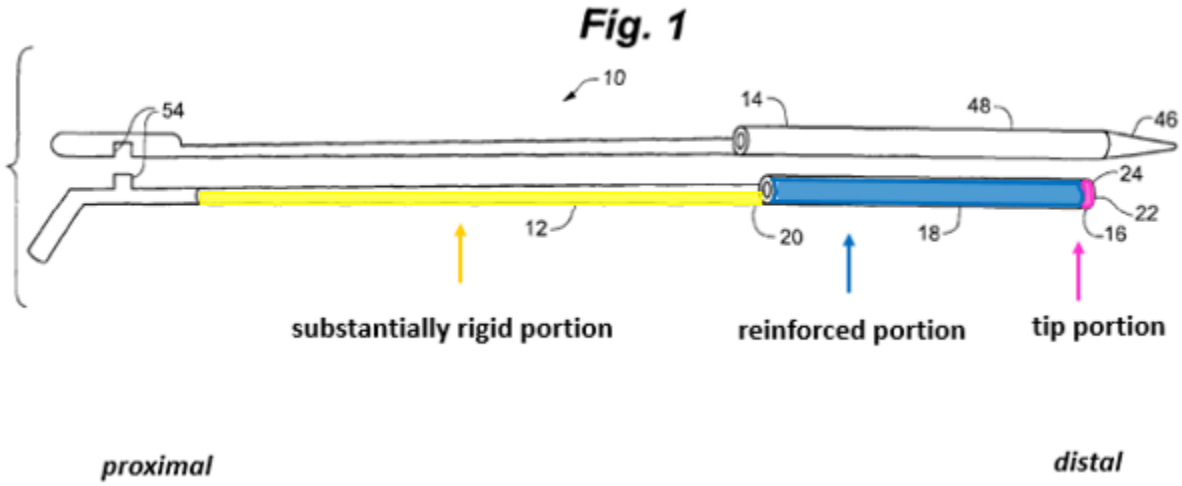
Another small diameter flexible guidewire can then be threaded through the lumen of the guide catheter to the target site. *Id.*, ¶¶ 56-58. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to the occlusion. *Id.* The therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. *Id.*, ¶¶ 59-67. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium. *Id.*, ¶¶ 66-67. As discussed above, one way to ameliorate this backward force is to use a mother-and-child

catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id.*, ¶¶ 68-80.

B. Overview of the ’380 Patent

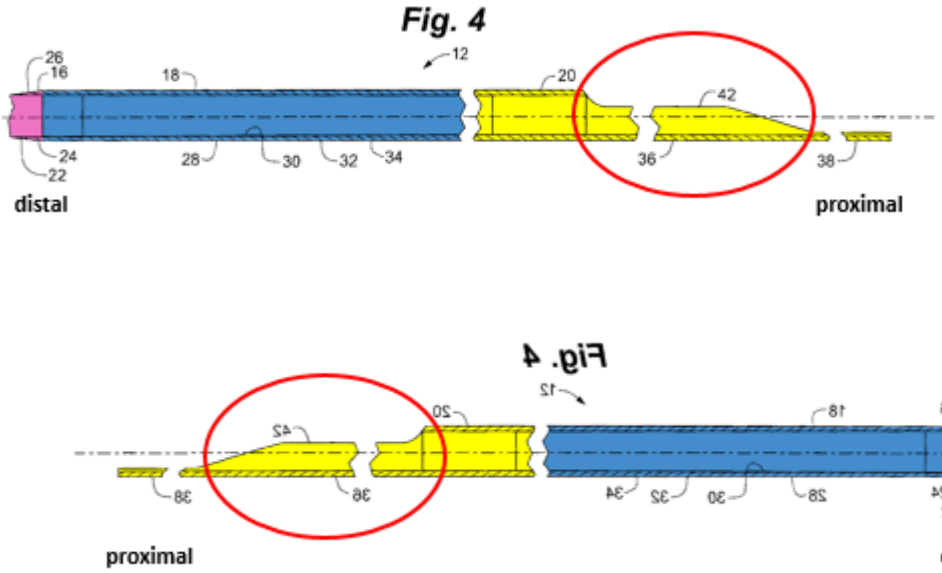
The ’380 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1801, 1:30-35. In particular, the ’380 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends “beyond the distal end of the guide catheter, and … into [a] branch artery.” *Id*., Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:23-27; Ex-1805, ¶¶ 118-19.

The ’380 patent explains that the guide extension catheter 12 has a tubular portion that includes a flexible distal tip 16 (pink) and a reinforced portion 18 (blue), as well as rigid portion 20 (yellow). *Id*., 3:51-53, 6:34-36, Fig. 1. Color has been added to Figure 1, below, which has been annotated with the language of claim 25. Ex-1805, ¶ 120.



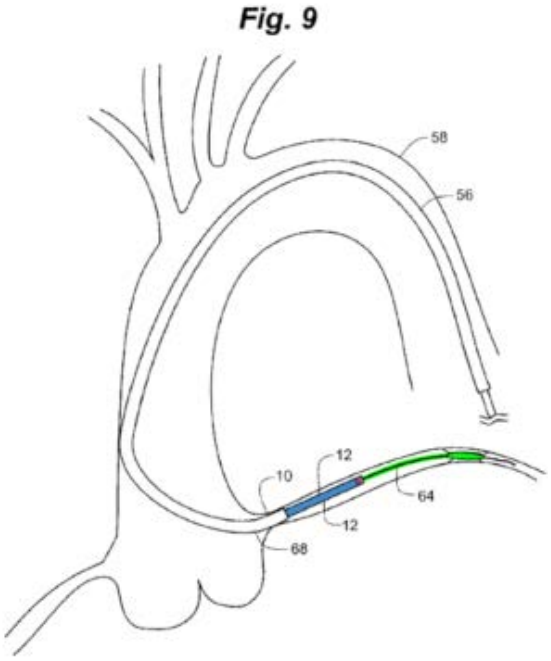
Ex-1801, Fig. 1 (annotations and color added).

The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "side opening," (red circle), which may have an "inclined slope." *Id*., 6:62-7:11, Figs. 4, 13-16; Ex-1805, ¶ 121.



Ex-1801, Fig 4 (annotations and color added).

As shown below, the ’380 patent describes that guide extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56. Ex-1805, ¶ 122.



Ex-1801, Fig. 9 (color added).

C. Prosecution History of the ’380 Patent

The parent ’850 patent issued without an Office Action. *See generally* Ex-1802. According to the Examiner, the claims of the ’850 patent were allowable because “adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested

by the prior art." Ex-1802 at 83 (Notice of Allowance at 3). In other words, he believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art. The Examiner, however, was not aware of Kontos. Patent Owner sought reissuance in 2013, and as with the original prosecution, the claims of the '380 patent issued without an Office Action. *See generally* Ex-1803.

V. PERSON OF ORDINARY SKILL IN THE ART

If 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. Alternatively, 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. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, 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. Ex-1805, ¶ 27; Ex-1842, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

Claim terms are typically given their ordinary and customary meanings, as would have been understood by a POSITA at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-16 (Fed. Cir. 2005) (*en banc*).

When, as here, claim terms have been construed by a district court, those constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation, Patent Owner stipulated to the following constructions:

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1812 at 2)
- "interventional cardiology device(s)": "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters" (*Compare* Ex-1812 at 21 (Dkt. 36-1) (Patent Owner construction), *with* Ex-1854 at 1 n.1 (agreeing to Patent Owner's construction))

Further, Patent Owner advanced,[3] and the district court adopted, the following construction:

[3] The full list of constructions advanced by Patent Owner in the QXMedical Litigation" are found at Ex-1812 (Dkt. 36-1).

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (Ex-1812 at 2 (Dkt. 36-1); Ex-1813, at 15)

Additionally, the district court provided the following constructions:

- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (*Id.*, 26)
- "lumen": "the cavity of a tube" (*Id.*, 25)

Petitioner agrees with the above constructions for purposes of this IPR[4] (Ex-1805, ¶¶ 123-28) and proposes the following additional constructions:

A. Means-Plus-Function Limitations (cl. 25)

Claim 25, and its dependents, recite various terms that use the phrase "means for," which presumptively invokes 35 U.S.C. § 112, ¶ 6. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). For "means" claims, a tribunal will first determine what the claimed function is and then determine the corresponding structures disclosed in the specification that perform that function. *In re Aoyama*, 656 F.3d 1293, 1296-1297 (Fed. Cir. 2011). But when a "claim recites sufficient structure for performing the described functions in their entirety, the presumption of § 112, ¶ 6 is overcome—the limitation is not a means-plus

[4] Petitioner proposes these constructions for purposes of this IPR only and reserves the right to raise different constructions in other forums.

function limitation." *TriMed*, 514 F.3d at 1259. "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an ***adequate understanding*** of the structure." *Id.* at 1259-60 (emphasis added).

Claim 25 recites the following "means" terms:

> (i) Means for **guiding an interventional cardiology device from a location outside a subject, through a main vessel, to a location near an ostium of a branch vessel**; and
>
> (ii) Means for **receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel**.

Ex-1801, 13:44-51 (claimed functions bolded).

For "means" term (i), the claim language does not recite sufficient structure to overcome the presumption of means-plus-function. Ex-1805, ¶¶ 131-32. The specification discloses that the structure is "a guide catheter." Ex-1801, Figs. 7-9 (depicting "typical guide catheter" at 56); Abstract; 7:50-64; Ex-1805, ¶¶ 131-32.

For "means" term (ii), the structure corresponding to that function is a "coaxial guide catheter." Ex-1801, Figs. 1-6, 8-9 (depicting a "coaxial guide catheter" at 12); Abstract; 5:40-56, 61-67; 6:31-37; 8:4-32; Ex-1805, ¶¶ 133-34. The rest of claim 25, however, recites far more detailed structure and overcomes

the presumption of means-plus-function. Ex-1805, ¶¶ 135-38. The claim provides that the very same "means for receiving" includes:

- "a tip portion, a reinforced portion, a side opening, and a substantially rigid portion" (which are all of the basic components of the coaxial guide catheter in the specification and other claims) (Ex-1801, 13:55-56);
- a "length" longer than the GC (*Id*., 13:56-64);
- a size "configured to be passed" through the lumen of the GC (*Id.*, 13:65-14:2); and,
- a "more rigid" side opening and substantially rigid portion than tip portion. *Id*. at 14:3-5.

Ex-1805, ¶¶ 135-38. This is more than "adequate understanding" of the structure. *Id.*

Here, because claim 25 recites the structural components that make up the disclosed coaxial guide catheter (Ex-1801, 6:34-35), including their length, size and relative rigidities, the means-plus-function-presumption is overcome. *TriMed*, 514 F.3d at 1260 (finding same when claim recited "size and shape of the claimed holes").

If, however, the Board finds that the presumption is not overcome, Petitioner is not aware of any additional structural component that would be appropriately

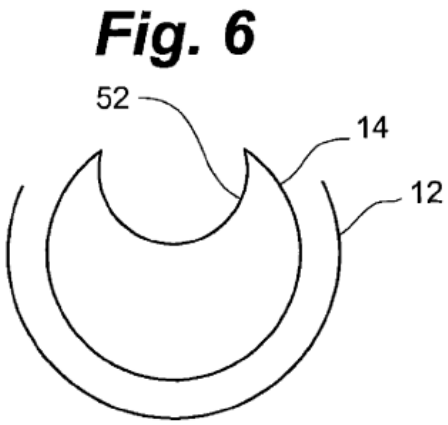
read into the claim. As stated above, the corresponding structure for the claimed function of receiving and guiding an interventional device deeper into a branch vessel is simply a coaxial guide catheter. The claimed side opening cannot be further limited by corresponding structure because the coaxial guide catheter of Figures 2-3 does not have a side opening. Similarly, no further limitations on the substantially rigid portion are appropriate because they are not required by the claimed function and are qualified by the word "may" in the specification. *See, e.g.*, Ex-1801 6:59-62 ("Rigid portion 20 may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well.") Thus, if the presumption is not rebutted, the only difference is that the prior art need only disclose a coaxial guide catheter *or equivalents* (i.e., extension catheter).[5]

B. "concave track" (cl. 34)

The '380 patent does not define the claim term "concave track." Ex-1805, ¶ 139. It mentions that a cutout portion, which supports a track, "may" have certain amounts removed and "may" extend for certain lengths, and later refers to cutout portion 44, which is not labeled in a Figure. Ex-1801, 4:7-15, 28-30; 7:19-20; Ex-

[5] For ease of discussion, hereinafter, Petitioner refers to the "coaxial guide catheter" as a "guide extension catheter." *See* footnote 1, *supra*.

1805, ¶ 139. Figure 6, though, discloses a cross-sectional view of a concave track 52. *Id.*, 7:19-20.



As a result, in the context of the ’380 patent, the claim term “concave track” means a “portion that is not fully circumferential.” Ex-1805, ¶ 140.

C. “flexural modulus” (cl. 38)

The claim term “flexural modulus” had a known and established meaning by 2006 (Ex-1842, ¶ 56), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means “[a] measure of resistance . . . to bending.” Ex-1840, 772. In other words, the “flexural modulus” is a measure of a device’s rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. This is admitted by the ’380 patent, which provides that the guide extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1801, 7:25-32; Ex-1805, ¶¶ 142-43. Stated

differently, the extension catheter's resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the distal end is the most flexible (least rigid).[6]

VII. GROUND 1: KONTOS RENDERS CLAIMS 25-26, 28-31, 34-37, and 39 OBVIOUS IN VIEW OF ADAMS AND/OR THE Knowledge of a POSITA.

A. Kontos

Kontos issued on August 8, 1995 and is prior art under pre-AIA §102(b). During prosecution of the '380 patent (and its previous iteration, the '850 patent), Kontos was neither disclosed by Patent Owner, nor cited by the Examiner. *See generally* Exs-1801-03.

Kontos is entitled "Support Catheter Assembly." Ex-1809, [54]. As the title suggests, Kontos discloses "[a] support catheter assembly for facilitating medical procedures, [and] includes a tubular body and a continuous lumen from its proximal end to its distal end." *Id.*, Abstract. In particular, Kontos describes "a

[6] In the QXMedical Litigation, Patent Owner stipulated to following construction of "flexural modulus": "a numeric, dimension-independent material property that captures the tendency of a material to bend." Ex-1812 at 2. From this construction, it is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

support catheter assembly with particular utility in facilitating insertion of a PTCA balloon into a lesion." *Id.*, 1:9-13. Just like the guide extension catheter 12 of the '380 patent, support catheter 10 of Kontos includes a short lumen (body 12) coupled to a pushrod (insertion/manipulation wire 14) for "inserting, advancing, withdrawing and maneuvering the body [12] during a medical procedure." *Id.*, 3:45-46, Abstract. As explained below, support catheter 10 performs the same functions as the guide extension catheter 12 of the '380 patent; namely, it serves as a guide extension catheter for providing backup support, such that dislodging of the guide catheter from the coronary ostium is prevented. Ex-1805, ¶¶ 146-47.

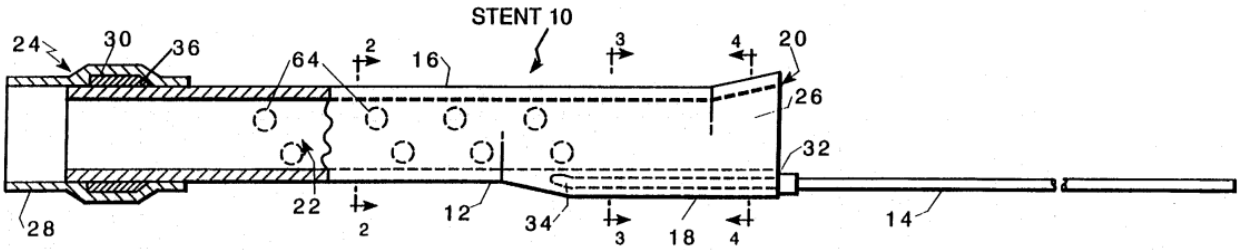


FIG. 1

Ex-1809, Fig. 1.

Kontos explains that when removing a stenosis, "[t]he guide catheter … can generally reach only to the coronary ostia, whereas the lesion to be opened is most commonly located in one of the coronary arteries leading from the ostia." *Id.*, 1:39-42. Because of this, "the balloon catheter must negotiate the ostia, enter the coronary artery and pass through the coronary artery to the lesion without the help of the guide catheter." *Id.*, 1:42-46. Kontos explains, however, that "those skilled

in the art know [that] the distal end of a PTCA catheter is made to be extremely soft and flexible," and thus is "readily susceptible to kinking and bending" during navigation to the location of the stenosis to be removed. *Id.*, 1:30-38. Kontos describes an apparatus that solves this problem and "facilitate[s] the passage of the balloon catheter from the end of the guide catheter to the lesion." *Id.*, 1:46-49.

Specifically, as shown in Figure 6B (below), support catheter 10 is "inserted into and passed through … and out the distal end of the guide catheter [38] so as to function as an extension of the guide catheter [38] to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." *Id.*, 2:16-23. This way, "the gap that PTCA catheter 40 must negotiate without assistance is made much shorter." *Id.*, 5:49-52, Fig. 6B.

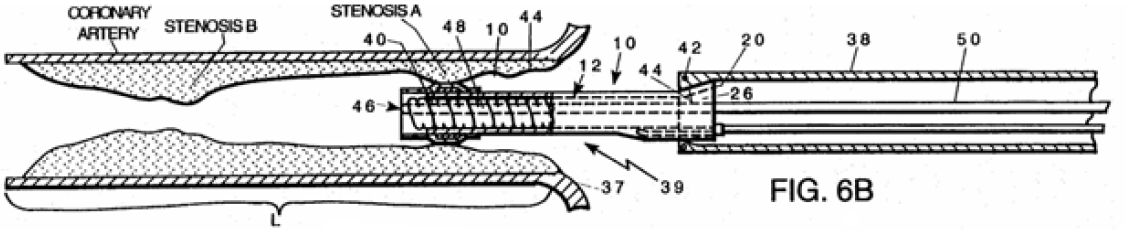


FIG. 6B

A POSITA would appreciate that Kontos's support catheter 10 operates no differently than guide extension catheter 12 of the '380 patent. Ex-1805, ¶¶ 144-49. The support catheter 10 extends further into the coronary artery than the guide catheter, while permitting a therapeutic device (e.g., PTCA catheter) to be passed

therethrough and provides backup support for the guide catheter, thereby preventing its dislodgment from the ostium. *Id.*, ¶¶ 146-47.

B. Adams

Adams published on January 15, 2004 and is prior art under pre-AIA § 102(b). Adams is not listed on the "References Cited" portion of the '380 patent. Ex-1801, [56]. Adams, though, eventually issued as U.S. Patent No. 7,232,452 ("the '452 patent") and that patent is listed on the face of the '380 patent. *Id.* Neither Adams nor the '452 patent were the basis of an Examiner rejection during prosecution of either the '380 patent or '850 patent (Exs-1801-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019) (explaining that a reference that "was neither applied against the claims nor discussed by the Examiner" does not weigh in favor of exercising discretion under § 325(d)); *Shenzhen Zhiyi Tech Co. v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (P.T.A.B. Apr. 2, 2018) (declining to apply § 325(d) when the reference was merely cited in a Notice of Reference Cited on face of patent-in-question).[7]

[7] During prosecution of a related child patent, U.S. Patent No. RE 46,116 ("the '116 patent"), Adams was applied against the then-pending claims and formed the basis of an Examiner rejection. Ex-1869 at 4. As a threshold matter, the

Adams discloses an apparatus for removing a coronary stenosis. Ex-1835, Abstract. More particularly, Adams describes a catheter assembly with (i) a guide catheter, (ii) a sealing device sized to fit within the lumen of, and advance distal to, the guide catheter, and (iii) a protection device that is advanced distal to both the guide catheter/sealing device assembly and the occlusion to be treated. *Id.*, [0045], [0064].

For example, the catheter assembly includes a guide catheter 10 that is advanced until its distal tip is in the ostium of the coronary vessel. *Id.*, [0012], [0059], [0061], [0064], Figs. 1B, 2A. A sealing device 20 is then advanced

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"presentation of [a reference] during prosecution of a child patent application, not the application that matured into the [patent-in-question,] has less relevance to the challenged claims." *Microsoft Corp. v. Parallel Networks Licensing LLC*, IPR2015-00483, Paper 10 at 15 (P.T.A.B. July 15, 2015). Regardless, "the present Petition relies primarily on [Kontos], not [Adams], and the combinations presented [here] were not before the Examiner or applied by the Examiner during prosecution." *Synaptic Medical Inc. v. Karl Storz-Endoscopy-America, Inc.*, IPR2018-00462, Paper 6 at 10 (P.T.A.B. July 16, 2018). "As such, the Examiner did not consider the combination and argument . . . presented" in this Petition, and the Board should not invoke §325(d). *Id.*

"through the lumen of the guide catheter until the distal sealing portion extends from the distal end of the guide catheter," whereupon it occludes the flow of blood though the vessel. *Id.*, [0012], [0059], [0061], [0064], Figs. 2A-C.

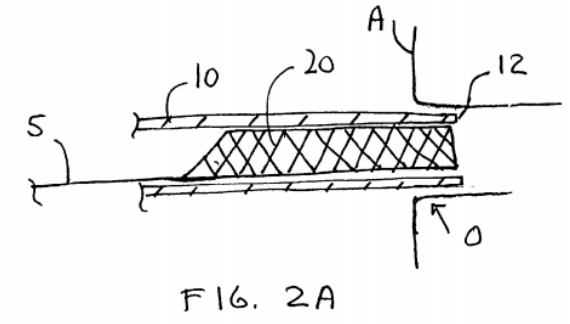


FIG. 2A

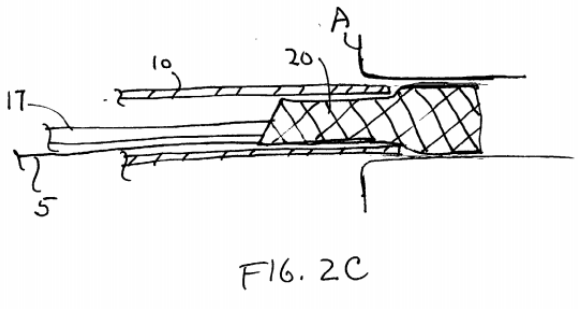


FIG. 2C

After blood flow has been occluded, a distal protection device 15 is advanced through the lumen of the sealing device 20 to a location distal to the treatment site. Ex-1835, [0012], [0061], [0064], Figs. 2D-2E. The distal protection device 15 is then deployed, the sealing device 20 is retracted, and a vascular treatment device is advanced to the site of occlusion for treatment. Ex-1835, [0012], Figs. 2E-F; *see also* Ex-1805, ¶¶ 150-54.

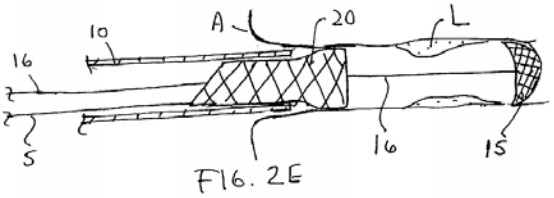


FIG. 2E

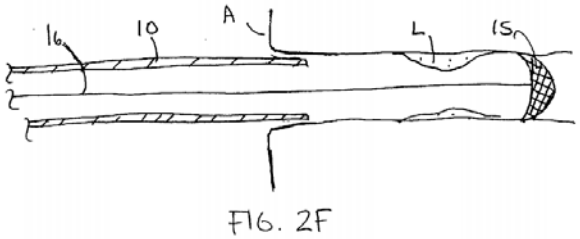


FIG. 2F

C. Claim 25

1. [25.p] "A system comprising:"

To the extent the preamble is limiting, Kontos describes a support catheter assembly 10 that is capable of being inserted into the coronary ostia while delivering a balloon catheter to treat a lesion in the same. Ex-1809, Abstract, 1:4648, 5:40-44, Fig. 6B; Ex-1805, ¶ 171. The support catheter assembly 10 is used in conjunction with a guide catheter 38 (Ex-1805, ¶ 171), and the combination of the two discloses the claimed "system." *See* Section VII.C.1-7, *infra* (analysis and citations for remaining elements of claim 25).

2. [25.a] "means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and"

Kontos discloses the function of guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel. Ex-1809, Fig. 14 (showing distal end of the guide catheter 38 (identified in green) placed in the coronary ostia 39); *see also id.*, 5:11-15, 9:61-10:21, 11:15-44, Fig. 14; Ex-1805, ¶ 172.

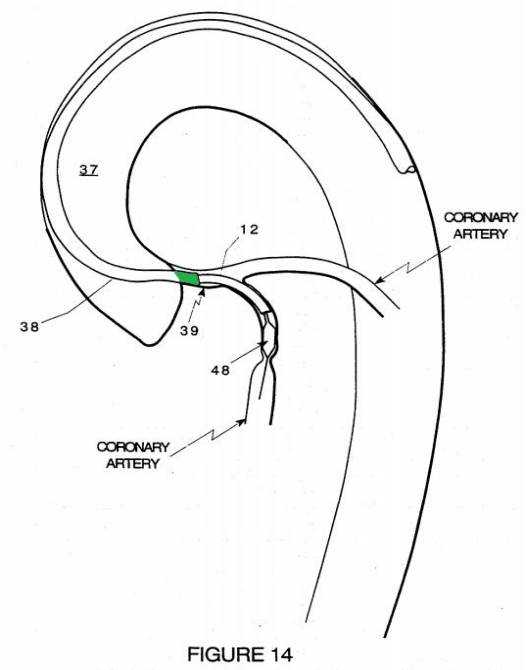


FIGURE 14

As discussed, the corresponding structure disclosed in the '380 specification is a guide catheter. *See* Section VI.A, *supra*.

Kontos discloses that (i) "a physician inserts a guide catheter 38 through the aorta 37 and into a patient's coronary ostia 39 using known medical procedures" (Ex-1809, 5:11-15), (ii) the guide catheter 38 is used in conjunction with support catheter 10, which is sized to be "inserted into and passed through . . . the guide catheter [38]," (*id.*, 2:16-22, Figs. 6A-6C), and (iii) the support catheter 10 is sized to allow an interventional cardiology device, such as a PTCA catheter 46 with balloon 48, to be inserted into and travel through the guide catheter 38. Ex-1809, 1:9-13, 1:46-49, 5:16-20, Figs. 6A-C. Thus, Kontos discloses limitation 25.a. Ex-1805, ¶ 172.

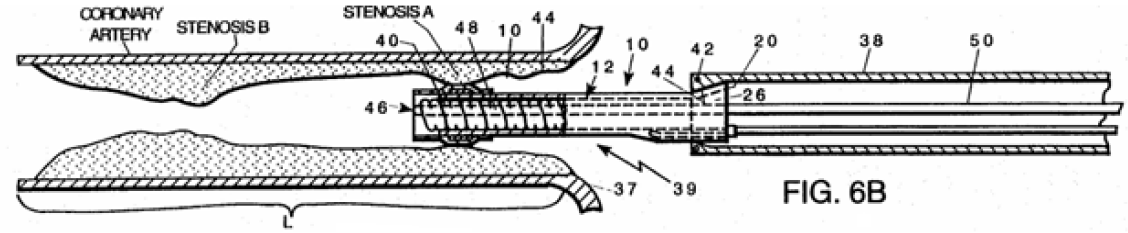


FIG. 6B

Ex-1809, Fig. 6B.

Kontos states that guide catheter 38 is placed "using known medical procedures." Ex-1809, 5:11-15. Kontos does not, however, specifically enumerate that guide catheter 38 originates from a location outside a patient's body, but the knowledge of a POSITA combined with Kontos must teach this limitation, as otherwise it would not be possible for the physician to use the "means for guiding" to deliver either the guide extension catheter or therapy catheter to the stenosis. Ex-1805, ¶ 173.

To the extent Patent Owner contends that the "means for guiding" (guide catheter 38) does not originate outside a patient's body, this limitation is obvious in view of Kontos, Adams, and/or the knowledge of a POSITA. Ex-1805, ¶¶ 174-77. 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 '380 patent. Ex-1805, ¶¶ 174-75.

For example, Adams discloses a device and method for using PTCA and stenting to treat vascular disease. Ex-1835, [0001]-[0002]. Adams discloses, just like Kontos, a guide catheter 10 that is located in the ostium of the coronary artery

and a sealing device 20 (i.e., an extension catheter) that is longer than and sized to fit into the guide catheter. Ex-1835, [0012], [0022], [0059]; Section VII.B, *supra*.

Adams further teaches that "[a] Y connector 7 is attached to the proximal end of the guide catheter [10]," and Figure 1A specifically shows guide catheter 10 attaching to the Y connector 7 outside of the vasculature. Ex-1835, [0059], Fig. 1 (double break line showing transition from inside to outside patient's body); Ex-1805, ¶ 175.

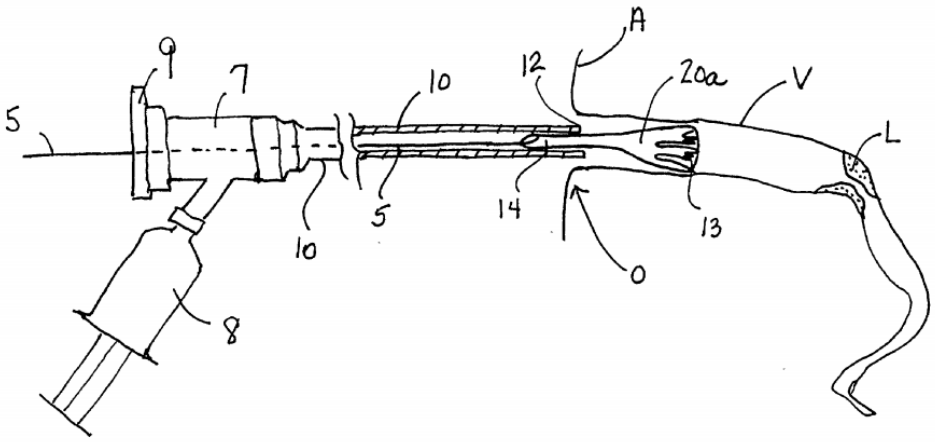


FIG. 1A

A POSITA would have been motivated (to the extent not taught by Kontos or a POSITA's knowledge) to have Kontos's guide catheter originate outside the body because otherwise (i) the physician could not perform the PTCA procedure, and (ii) the patient would risk excessive blood loss. Ex-1805, ¶ 176. Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the teachings of Kontos, Adams, and a

POSITA's knowledge. Ex-1805, ¶ 177. Indeed, combining the teachings of Adams with Kontos to have the "means for guiding" (guide catheter) originate outside of a patient's body would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*; *see also KSR Int'l co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a [POSITA] would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

3. [25.b] "means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,"

As discussed, this is not a means-plus-function limitation. *See* Section VI.A, *supra*. Kontos's support catheter 10 receives the interventional device from the distal end of the guide catheter near the ostium of the branch vessel and guides the interventional device deeper into the branch vessel. Ex-1805, ¶ 178. Indeed, Kontos describes that its support catheter 10 "facilitate[s] the passage of the balloon catheter from the end of the guide catheter to the lesion" located in the branch vessel. Ex-1809, 1:46-49; *see also id.*, 2:16-22, 5:31-39, 5:49-52, 7:45-49 (noting that "[b]ody 12 could be inserted first" into GC, and then "followed by the

PTCA catheter 40"), Figs. 6A-C; Ex-1805, ¶ 178.[8]

4. [25.c.i] "the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel [25.b] including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion,"

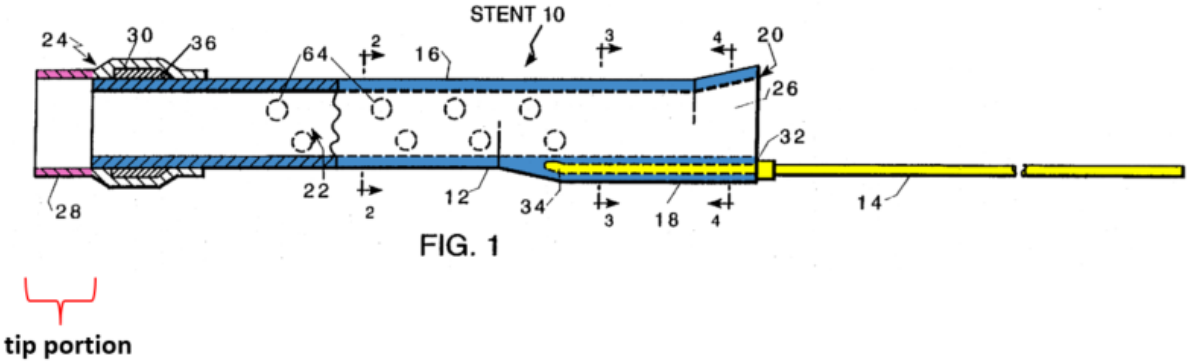
The remainder of claim 25 recites solely structure, meaning that regardless of whether the claim is construed as a means-plus-function limitation, the same disclosures from Kontos and Adams are applicable. Kontos in combination with Adams and/or the knowledge of a POSITA teaches, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion. Ex-1805, ¶¶ 179-208.

a. "a tip portion"

Kontos teaches that tip portion (soft tip 28) is made of "any highly flexible material," but preferably is composed of a soft plastic such as a copolymer of polyethylene and ethylvinylalcohol ("EVA") and "generally is cylindrical in shape and extends coaxially from distal end 34 of tube 16." Ex-1809, 4:5-15; Ex-1805,

[8] If this is a means-plus-function claim element, Kontos's support catheter 10 is the "coaxial guide catheter" that performs the claimed function for the same reasons provided herein. Ex-1805, ¶ 178; *see also* Ex-1809, 1:46-49, 2:16-22, 5:31-39, 5:49-52, 7:45-49, Figs. 6A-C.

¶ 179; Ex-1842, ¶¶ 74-76.



Ex-1809, Fig. 1 (color and annotations added).

b. "a reinforced portion"

Kontos or Kontos in combination with Adams teaches a reinforced potion proximal to the tip portion. Ex-1805, ¶¶ 178-91. As construed above, "reinforced portion" means a "portion made stronger by additional material or support." *See* Section VI, *supra*. The proximally-located, reinforced portion is the part of tube 16 that is co-extensive with receiving hole 34. Ex-1805, ¶ 179.

The proximal end of tube 16 is the attachment location for insertion/manipulation wire 14. Ex-1809, 4:25-27, Fig. 1. One way to attach wire 14, as shown in Figure 1 below, is to insert it into receiving hole 34 that is located on the proximal end of tube 16. Ex-1809, 4:27-31. Thus, the proximal end of tube 16—that is located proximal to the tip portion (soft tip 28)—has more material and support and constitutes the "reinforced portion." Ex-1805, ¶ 179.

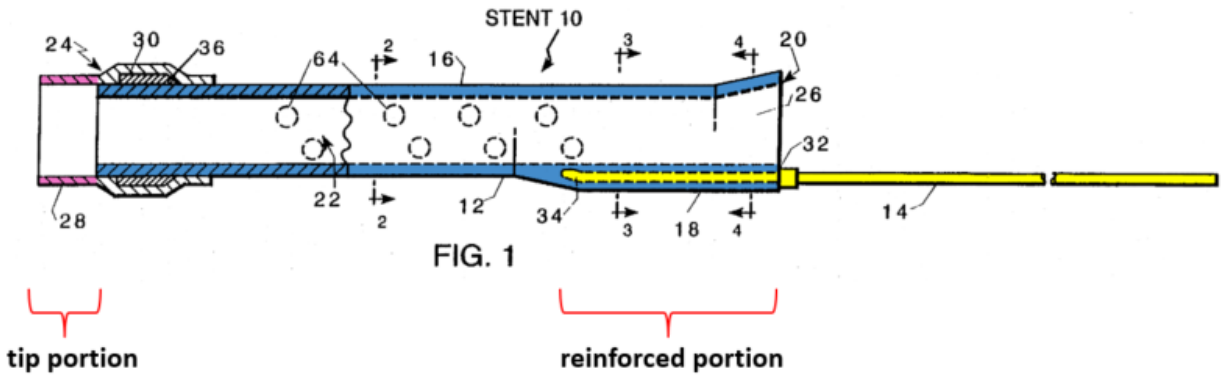


FIG. 1

Ex-1809, Fig. 1 (color and annotations added).[9]

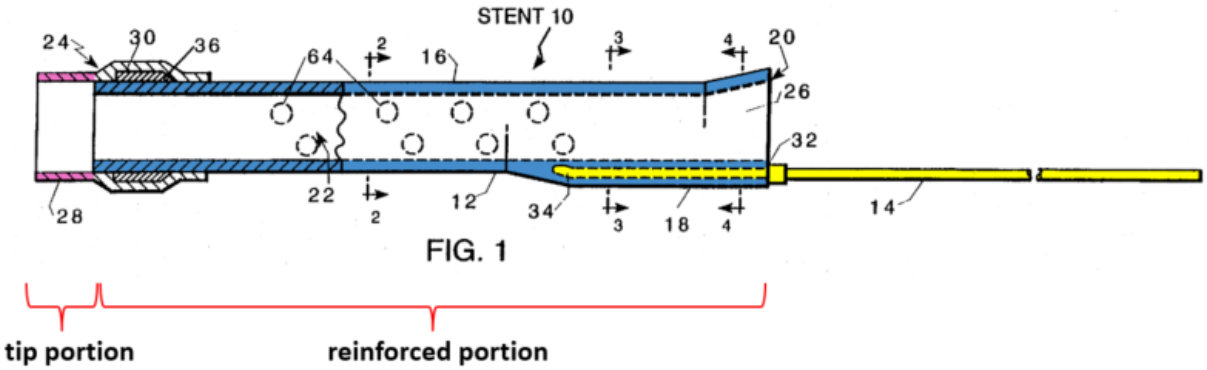
Even if the portion of tube 16 that is co-extensive with receiving hole 34 was not a "reinforced portion," it would have been obvious based on the knowledge of a POSITA to modify Kontos by adding metallic coiling or braiding (i.e., reinforcement) to tube 16. Ex-1805, ¶¶ 180-91; Ex-1842, ¶¶ 85-91. The addition of metallic braiding or coiling to a polymer tube was ubiquitous by the time of the claimed invention and was known to prevent or impart kink-resistance, thereby improving the pushability of the extension catheter. Ex-1805, ¶ 180; Ex-1842, ¶¶ 88-91; *see also* Ex-1808, 6:66-7:7; Ex-1846, Abstract; Ex-1847, Abstract.

Should the Board require a reference to combine, Adams discloses braiding/coiling in a polymer tube. Ex-1805, ¶ 188-89; Ex-1842, ¶¶ 87-90. Adams and Kontos are directed to the same type of device, are in the same field of

[9] According to Patent Owner, the tip portion and reinforced portion need not be physically connected. Ex-1877, 121:16-24.

endeavor, and are reasonably pertinent to the problem faced by the inventors of the '380 patent. Ex-1805, ¶ 189. In Adams, the guide seal 30 (extension catheter) is the device adapted for use with the guide catheter as taught by the '380 patent. *Id.*; *see also* Ex-1835, Fig. 3A. Adams discloses stainless steel or nitinol braiding in a polymer of the guide seal 30. Ex-1835, [0066]. A POSITA would have been motivated to add this design feature to tube 16 of Kontos because s/he knew that metallic braiding/coiling in a polymer promoted pushability and prevented kinking during advancement of the catheter. Ex-1805, ¶ 189; Ex-1842, ¶ 88; Ex-1835, [0075] (explaining that when coiling is used as an alternative to braiding, then "the guide seal may not be sufficiently rigid to be pushed through the lumen of the guide catheter"); *see also* Ex-1846, Abstract; Ex-1847, Abstract. Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the numerous teachings in the art. Ex-1805, ¶ 190; Ex-1842, ¶¶ 89-91.

If Kontos was reinforced with metallic braiding/coiling, then tube 16 would be the "reinforced portion" that is located proximal to the tip portion (soft tip 28). Ex-1805, ¶ 191.

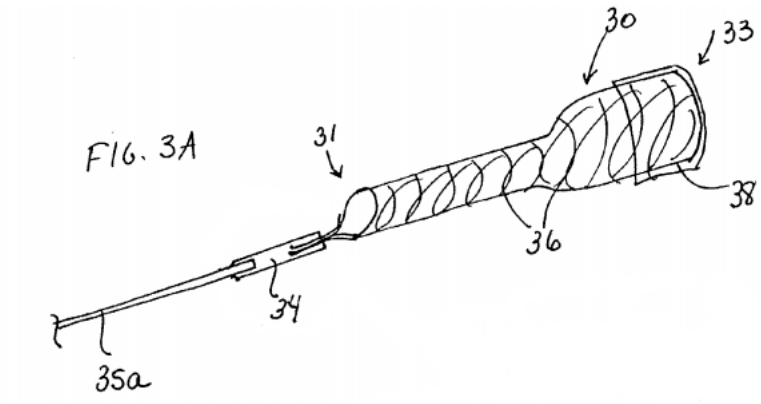


Ex-1809, Fig. 1 (color and annotation added).

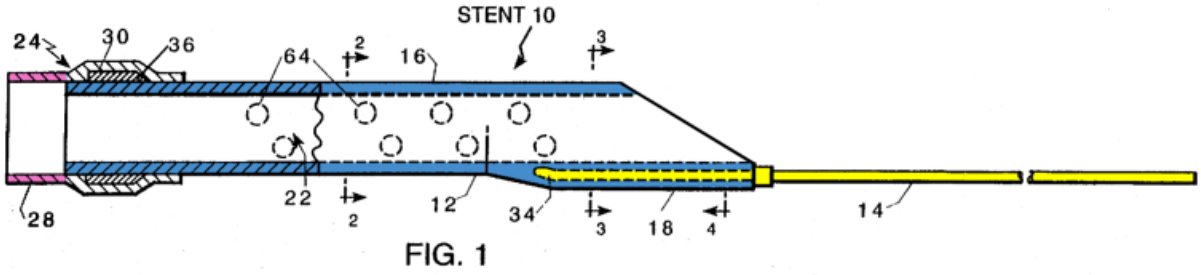
c. "a side opening"

The combination of Kontos and Adams teach this limitation of the '380 patent. Ex-1805, ¶¶ 192-207; Ex-1842, ¶¶ 97-116. As seen in Kontos Figure 1, the proximal opening of tube 16 does not extend along the longitudinal axis of the tubular structure, meaning it is not a side opening. Proximal side openings falling within the scope of claim 25 were, however, well-known in the art. Ex-1805, ¶ 193; *see also id.*, ¶¶ 90-108; Ex-1842, ¶¶ 103-08; Ex-1807, 4:11; Ex-1808, 12:9-13:60, Fig. 6A-6E; Ex-1818, Fig. 7; Ex-1832, 119, Fig. 1; Ex-1833, [0035], [0049], Fig. 2; Ex-1835, [0066]; Ex-1850, Fig.7; Ex-1861, 6:9-11, Fig. 1B.

Adams is one such catheter assembly that uses a proximal side opening. Ex-1805, ¶¶ 194, 206. In particular, Adams teaches a guide seal 30 with proximal end 31 that "is preferably cut or formed at an angle." Ex-1835, [0066].

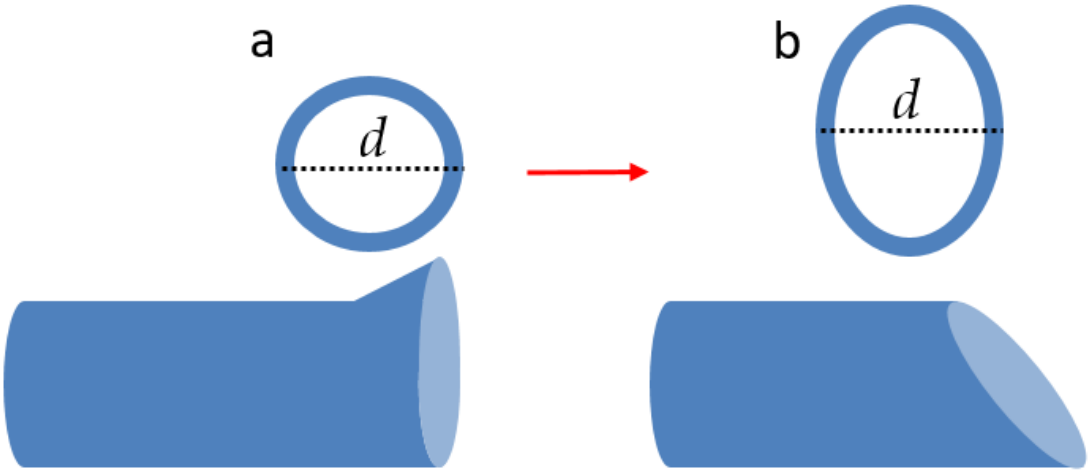


Ex-1835, Fig. 3A. A POSITA would have been motivated, with a reasonable expectation of success, to add Adams's proximal side opening to Kontos's tube 16, as shown below. Ex-1805, ¶ 207.



Ex-1809, Fig. 1 (color added and modified by Petitioner).

A POSITA would have been motivated to modify Kontos to add a side opening at the proximal end of tube 16, as taught by Adams, for multiple reasons. Ex-1805, ¶¶ 195-205; Ex-1842, ¶¶ 101-02, 109-15. First, a POSITA would have known, as shown in the below figure, 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.



Ex-1805, ¶ 196; Ex-1842, ¶ 112.

In 1995, when Kontos issued, GCs were typically 7-8 French in diameter. Ex-1805, ¶ 197. But by the purported priority date of the '380 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 tube 16 must decrease. *Id.*; Ex-1809, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tube 16 becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex-1805, ¶ 198. Therefore, as an alternative to the flared proximal opening 26 of tube 16 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-1842, ¶ 112.

Second, a POSITA would have been motivated to use a proximal side opening because doing so facilitates "smoother" reception of the interventional cardiology device as it enters the lumen of the child catheter. Ex-1808, 6:55-57; *see also* Ex-1805, ¶¶ 199-200; Ex-1842, ¶ 113; Ex-1826, 3:6-9. In particular, it was known that the interventional cardiology device could snag or become "hung-up" when entering the distal lumen of the child catheter. Ex-1805, ¶ 201; Ex-1842, ¶ 114. A proximal side opening reduces this likelihood—by comparison to a vertical opening—meaning it promotes better advancement of the therapy catheter as it travels to the occlusion.[10] Ex-1805, ¶¶ 199-200; Ex-1842, ¶ 114.

[10] Kontos itself reflects the same concern, and provides funnel 26 to aid insertion of a therapy catheter. Ex-1809, 3:66-68. A side opening is obvious because it provides the benefit Kontos seeks, as well as the additional benefits described herein. As an aside, it is irrelevant that Kontos's funnel can also be used in combination with annular ridge 44 to prevent unwanted advancement beyond the guide catheter 38. Marker ring 42 provides that function, and the interaction between funnel 26 and ridge 44 is an alternative, and therefore unnecessary, embodiment. *Id.*, 5:57-6:8.

Third, a POSITA additionally would have been motivated to use a proximal side opening because such a design promotes "smoother passage" of the catheter assembly as it navigates the tortuous vasculature. Ex-1808, 6:52-55; *see also* Ex-1805, ¶ 202; Ex-1842, ¶ 115; Ex-1825, Abstract, [0034]. In other words, adding a side opening to the distal lumen of the child catheter reduces the amount of force that a physician must exert to advance the catheter through winding vasculature. Ex-1805, ¶ 202; Ex-1842, ¶ 115.

Fourth, a POSITA was motivated to add a proximal side opening because doing so permitted smooth re-entry if the proximal end of the guide extension catheter was extended beyond the distal end of the GC. Ex-1805, ¶¶ 203-05; Ex-1842, ¶¶ 109-11. For example, Kontos teaches an embodiment where "the bridge body 12/PTCA catheter assembly must be passed completely out of guide catheter 38 and advanced as a unit to the site of restriction B." Ex-1809, 6:22-25.

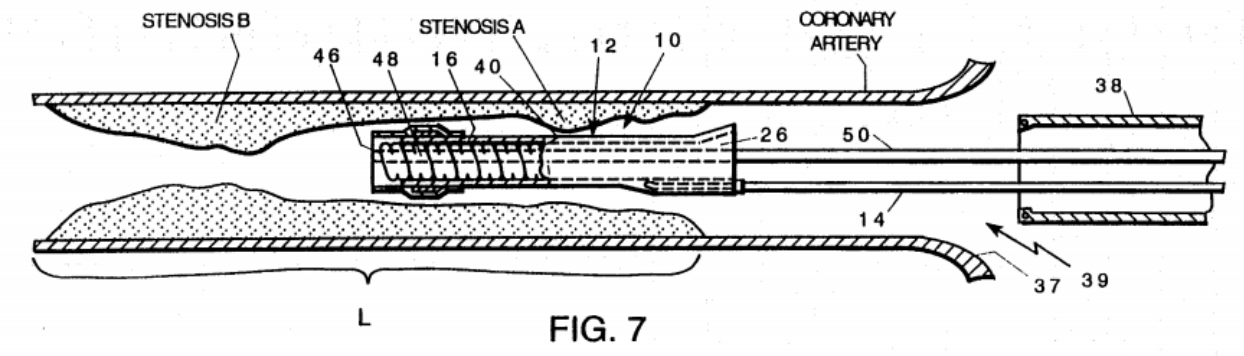


FIG. 7

Ex-1809, Fig. 7. In such an embodiment, after the angioplasty is performed, the support assembly 10, must return to the guide catheter 38. Ex-1805, ¶ 204; Ex-

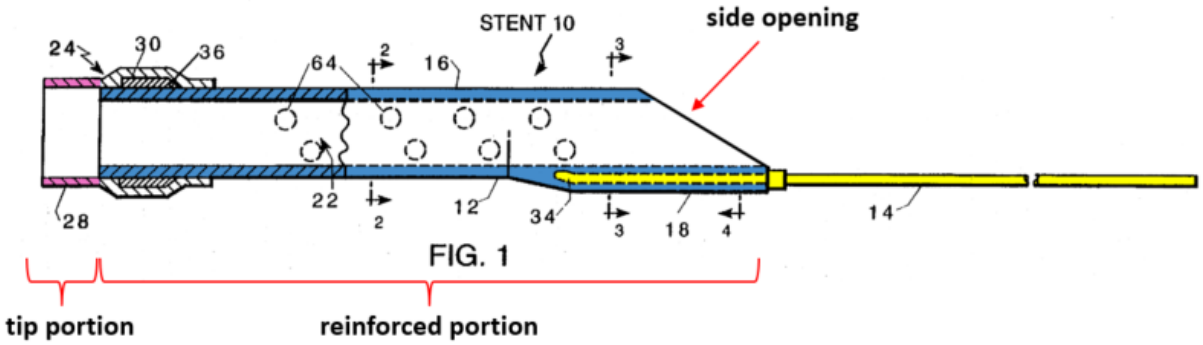
1842, ¶ 109. A POSITA would recognize, however, that a flared proximal opening of the tubular structure (tube 16) was a poor design choice, as this protrusion could damage the internal coronary wall and hinder re-entry of the tubular structure into the GC as the tubular structure travels proximally toward the GC. Ex-1805, ¶ 204; Ex-1842, ¶ 110. The smaller cross-sectional diameter of a proximal side opening would reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the GC. Ex-1805, ¶ 204; Ex-1842, ¶ 111.

In fact, Adams provided this exact rationale for using a proximal side opening of the guide seal. Ex-1835, [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."). Given this explicit motivation in the reference Petitioner seeks to combine, a POSITA would have been motivated to use a proximal side opening at the proximal end of tube 16 to aid in the retraction and re-insertion of the tubular structure into the guide catheter, if it were necessary to do so. Ex-1805, ¶ 205.

The prior art, including Adams, shows that the use of a proximal side opening was well-known. Ex-1805, ¶¶ 95, 193, 206. Employing a proximal side opening (as opposed to an opening perpendicular to the longitudinal axis) to the Kontos device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to

obtain predictable results. Ex-1805, ¶ 206; Ex-1842, ¶ 116; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 417.

After adding Adams's proximal side opening to Kontos's tube 16, the side opening would be located proximal to the reinforced portion. Ex-1805, ¶ 207; *see also* Ex-1877, 293:18-294:22 (patent owner expert testifying that portions need not be "wholly proximal" to one another).

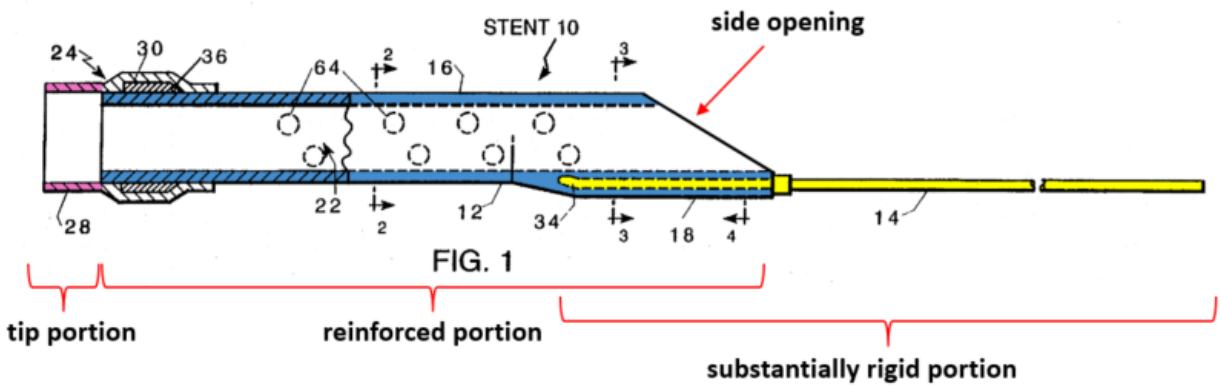


Ex-1809, Fig. 1 (color and annotations added) (modified by Petitioner).[11]

d. "substantially rigid portion"

[11] As set forth above, Kontos or the Kontos-Adams combination disclose two different reinforced portions: (i) portion of tube 16 coextensive with receiving hole 34, and (ii) tube 16 after the addition of braiding/coiling. *See* Section VII.C.4.b, *supra*. While both options are always applicable, for sake of simplicity, Petitioner hereinafter shows the outer bounds of the reinforced portion.

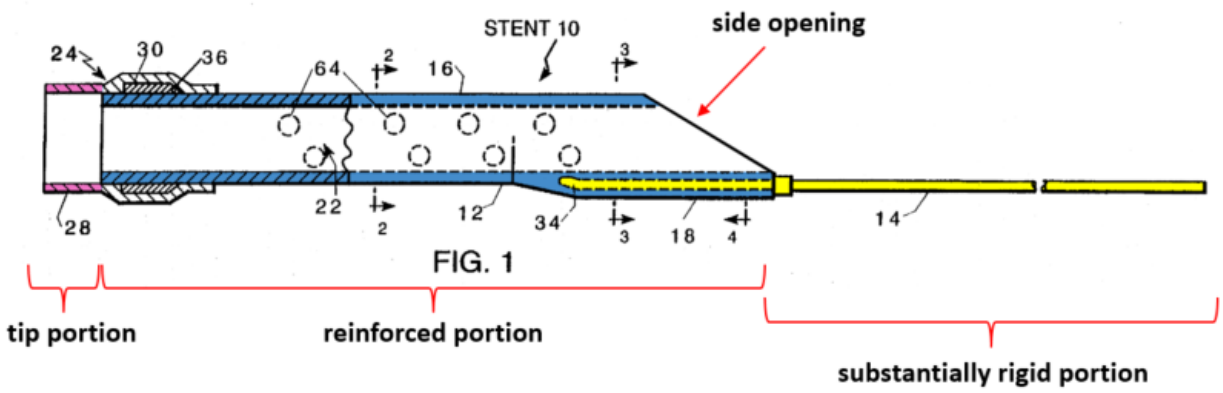
In Kontos's support catheter 10, the insertion/manipulation wire 14 is the "substantially rigid portion." Ex-1805, ¶ 179; *see also* Section VI, *supra* (construing "substantially rigid"). Wire 14 is used to advance support catheter 10 within the guide catheter, thus providing a structure that facilitates monorail or sliding rail delivery. Ex-1809, Figs. 6A-6C, 5:25-30. As shown in Figure 1, the substantially rigid portion is located proximal of the side opening. Ex-1805, ¶ 179, 207; *see also* Ex-1877, 293:18-294:22.



Ex-1809, Fig. 1 (color and annotations added) (modified by Petitioner).

Finally, Petitioner notes that in district court litigation, Patent Owner maps the distal end of the substantially rigid portion as the location where the pushrod enters the tubular structure. Ex-1877, 123:14-17, 124:19-25, 127:24-128:14. *But see id.*, 129:20-130:4 (admitting that another interpretation of '380 patent could allow overlap of the substantially rigid portion and reinforced portion). Thus, out of an abundance of caution, Petitioner notes that if claim 25 requires the entirety of the substantially rigid portion to be proximal of the entirety of the side opening and

reinforced portion, such that they do not overlap, the results do not change. Ex-1805, ¶¶ 179, 208.



Ex-1809, Fig. 1 (color and annotations added) (modified by Petitioner).

5. [25.c.ii] "and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,"

Kontos or Kontos in view of Adams and/or the knowledge of a POSITA teaches that support catheter 10 is longer than the guide catheter, such that when the distal end of the tip portion is extended distal to the guide catheter, a proximal portion of the support catheter 10 extends beyond the proximal end of the guide catheter. Ex-1805, ¶¶ 209-13. Support catheter 10 is composed of body 12 and wire 14. Ex-1809, 3:45-46, Fig. 1. Body 12, which is a combination of soft tip 28 and tube 16, is approximately twelve inches in length. *Id.*, 4:52-58. Wire 14 "is

generally at least about 50 inches long and preferably about 53 inches long." *Id.*, 4:58-61. Kontos does not disclose the length of the guide catheter (i.e., "means for guiding"), but a POSITA would appreciate that the length of support catheter 10 is longer than the guide catheter. Ex-1805, ¶¶ 209-10 (explaining that the typical guide catheter is 100 cm[12] in length, which is shorter than the combined length of the support assembly—approximately 62 inches or 157 cm—as taught by Kontos).

Moreover, Kontos teaches that the "proximal member [(substantially rigid portion)] is connected to said tubular body [(flexible tip portion)] and extend[s] proximally therefrom for providing communication between said tubular body and a region outside of the body of the patient." Ex-1809, 10:12-15, 11:35-39 (same). And not only does Kontos specifically teach that the substantially rigid portion extends outside of the body, but it also teaches in Figure 6B that body 12 of the support catheter 10 extends distal to guide catheter 38 while advancing the PTCA catheter 40 with balloon 48. Ex-1805, ¶ 209. In other words, the combined length of the support assembly 10 must be longer than the guide catheter 38. Ex-1805, ¶ 210 (explaining that physician cannot treat a stenosis unless s/he can maintain

[12] The background of the '380 patent admits that GCs are often "one hundred centimeter[s]" in length. Ex-1801, 2:57:60.

physical contact with the extension catheter, meaning that it must be longer than GC).

Even if Kontos and the knowledge of a POSITA do not teach that the support catheter 10 was longer than the guide catheter ("means for guiding"), it would have been obvious to modify Kontos to add this design feature in view of Adams. Ex-1805, ¶¶ 211-13. As discussed above, 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 '380 patent. *See* Section VII.C.4.b, *supra*. Further, Adams specifically teaches that the combined length of the guide seal 20 and control wire 5 are greater than that of the guide catheter 10, such that when the guide seal 20 extends beyond the distal end of guide catheter 10 a portion of the control wire 5 extends proximal to the guide catheter. Ex-1835, ¶ [0060], Figs. 1A, 1B; Ex-1805, ¶ 211.

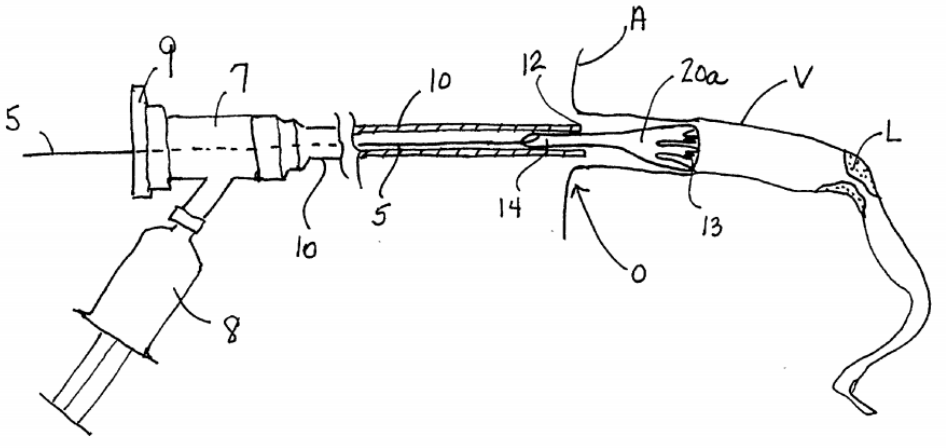


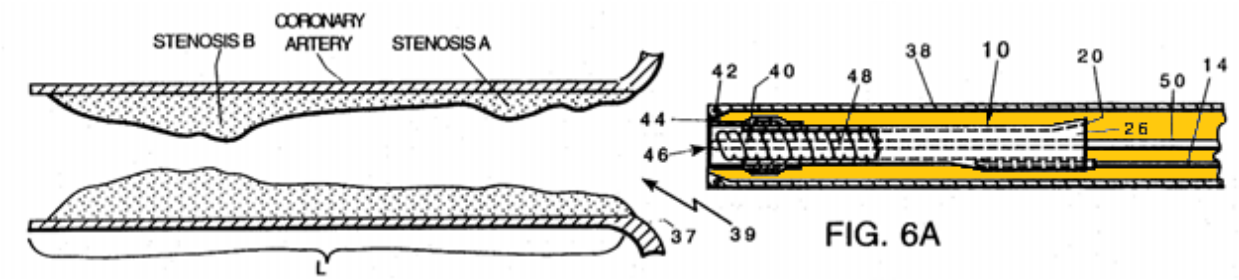
FIG. 1A

A POSITA would have been motivated to combine these well-known aspects from interventional cardiology, as disclosed by Adams, with Kontos's disclosure given the latter's teaching that the catheter assembly should "us[e] known medical procedures." Ex-1809, 5:11-15; Ex-1805, ¶ 212. It would have been obvious to a POSITA to modify Kontos (to the extent not already obvious based on a POSITA's knowledge) to add this claimed design features. Ex-1805, ¶¶ 211-13.

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the teachings of Kontos, Adams, and a POSITA's knowledge. Ex-1805, ¶ 213. Indeed, combining the teachings of Adams with Kontos to provide that Kontos's support catheter 10 (extension catheter) was longer than the guide catheter 38 ("means for guiding")—such that when the distal end of the tip portion was extended distal to the guide catheter, a proximal portion of the support catheter 10 extended beyond the proximal end of the guide catheter—would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*

6. [25.d] "wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel,"

Kontos teaches that support catheter 10 (extension catheter) is sized to travel through the GC ("means for guiding"). Ex-1805, ¶ 214. As shown in Figure 6A below, the support catheter 10, which includes the tip portion, the reinforced portion, the side opening,[13] and the substantially rigid portion, is insertable through the continuous lumen in yellow of the guide catheter 38.



Ex-1809, Fig. 6A (color added).

7. [25.e] "the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion."

The Kontos-Adams combination discloses this limitation. Ex-1805, ¶ 215. As discussed in Section VII.C.4.c, *supra*, Kontos in view of Adams discloses a

[13] As discussed in Section VII.C.4.c, *supra*, Kontos in view of Adams discloses a side opening.

side opening. Further, the side opening and reinforced portion would be more rigid than tip portion (soft tip 28). Ex-1805, ¶ 215.

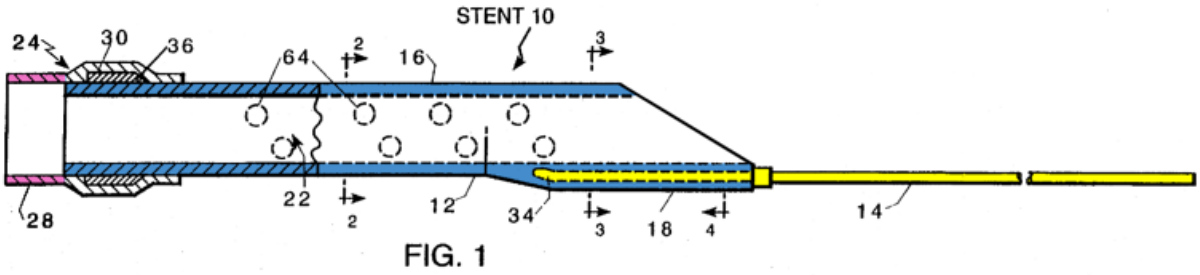


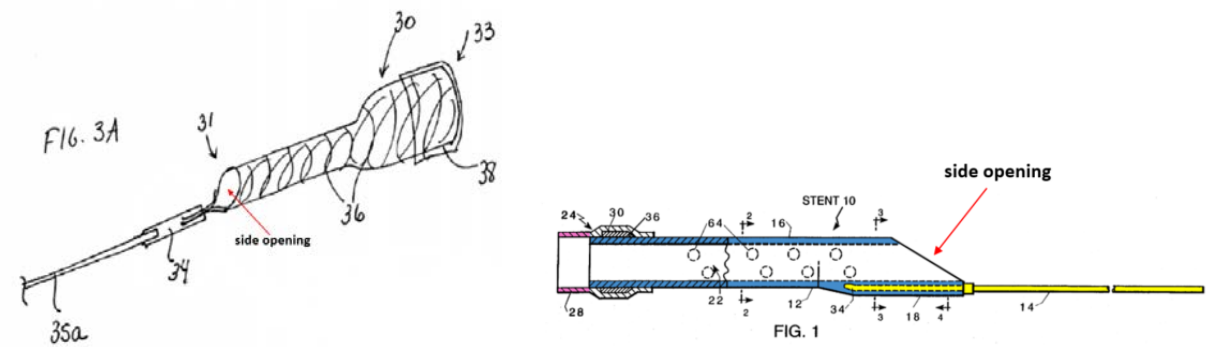
FIG. 1

Ex-1809, Fig. 1 (color added) (modified by Petitioner).

In Kontos, tube 16, which contains the side opening, preferably is made of a molded plastic material, such as polyethylene. Ex-1809, 4:1-4. Wire 14 is stainless steel. *Id.*, 4:58-61. Soft tip 28 preferably is composed of a soft plastic such as a copolymer of polyethylene and EVA. *Id.*, 4:5-15. Based on the known material properties, the Kontos-Adams combination discloses that the side opening and substantially rigid portion are configured to be more rigid along a length than the tip portion. Ex-1805, ¶ 215; Ex-1842, ¶¶ 73-76.

D. Claim 26: "The system of claim 25, wherein the side opening includes at least one inclined slope."

As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to add a proximal side opening to Kontos's tube 16. *See* Section VII.C.4.c, *supra*. As shown below, the side opening would include an inclined slope.



Ex-1835, Fig. 3A (annotation added); Ex-1809, Fig. 1 (color and annotations added) (modified by Petitioner). Thus, the Kontos-Adams combination renders claim 26 obvious. Ex-1805, ¶ 216.

E. Claims 28-30

The Kontos-Adams combination teaches claims 28-30 of the '380 patent. Ex-1805, ¶¶ 217-19. As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to add a proximal side opening to Kontos's tube 16. *See* Section VII.C.4.c, *supra*. Because tube 16 is cylindrical with "a continuous lumen 22 therethrough" (Ex-1809, 3:49-50; *see also id.*, 3:56-57, Fig. 6C), the side opening necessarily would include each of the cross-sectional shapes recited in claims 28-30, as shown below in Figure 1 (modified by Petitioner). Ex-1805, ¶¶ 217-19.

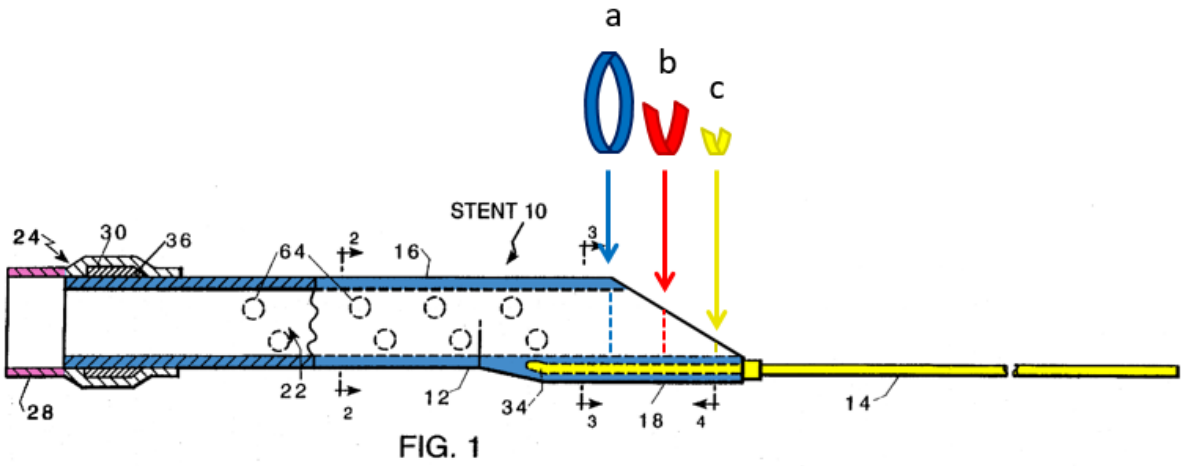


FIG. 1

Ex-1809, Fig. 1 (color and modifications added).

Claim	Claim Language	Location
28	"The system of claim 25, wherein a portion of the side opening includes an arcuate cross-sectional shape extending less than 180° of a full circumference."	Portion proximal of red line (b). Ex-1805, ¶ 217.
29	"The system of claim 28, wherein the portion of the side opening having the arcuate cross-sectional shape extends 25% to 40% of a full circumference."	Portion proximal of yellow line (c). Ex-1805, ¶ 218.
30	"The system of claim 28, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape."	Portion between blue line (a) and red line (b). Ex-1805, ¶ 219.

Thus, the Kontos-Adams combination renders claims 28-30 obvious. Ex-1805,

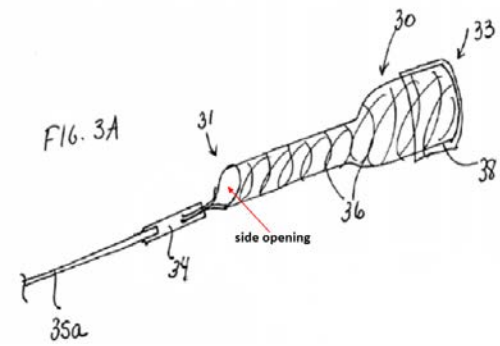
¶¶ 217-19.

F. Claim 31: "The system of claim 25, wherein the reinforced portion includes one or more braided elements embedded in a polymer."

As discussed for claim 25, a POSTIA would have been motivated, with a reasonable expectation of success, to embed metallic braiding in the polymer of tube 16, thereby making it a reinforced portion. *See* Section VII.C.4.b, *supra*; *see also* Ex-1835, [0066] (disclosing stainless steel braid). Thus, the Kontos-Adams combination renders claim 31 obvious. Ex-1805, ¶ 220.

G. Claim 34: "The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes a concave track along a portion of a length thereof."

As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to add a proximal side opening to Kontos's tube 16. *See* Section VII.C.4.c, *supra*. As shown below, the side opening necessarily includes a concave track (i.e., a "portion that is not fully circumferential").



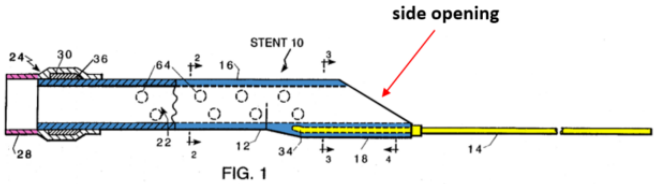


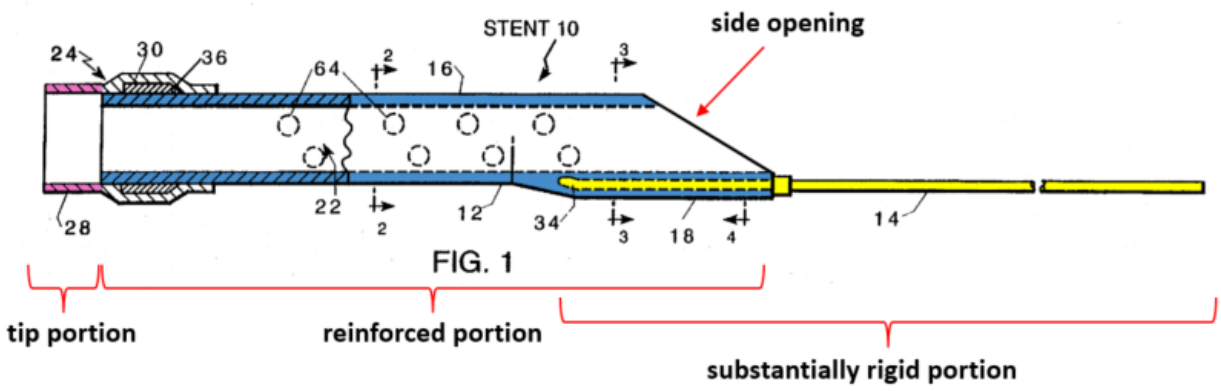
FIG. 1

Ex-1835, Fig. 3A (annotation added); Ex-1809, Fig. 1 (color and annotation added) (modified by Petitioner); *see also* Section VI.B (construing concave track). Thus, the Kontos-Adams combination renders claim 34 obvious. Ex-1805, ¶ 221.

H. Claim 35-36

Claim 35 recites that the side opening is incorporated with the distal end of the substantially rigid portion, whereas claim 36 provides that the side opening is incorporated with the proximal end of the reinforced portion. The Kontos-Adams combination discloses both limitations. Ex-1805, ¶¶ 222-23.

As discussed for claim 25, a POSITA would have been motivated, with a reasonable expectation of success, to add a proximal side opening to Kontos's tube 16. *See* Section VII.C.4.c, *supra*. As shown below in modified Figure 1, the side opening is incorporated both with the distal end of the substantially rigid portion (claim 35) and the proximal end of the reinforced portion (claim 36). Ex-1805, ¶ 222-23. Thus, Kontos in view of Adams renders claims 35-36 obvious. *Id.*



Ex-1809, Fig. 1 (color added).

I. Claim 37: The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes, starting at the distal end of the tip portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus."

The Kontos-Adams combination discloses claim 37. Ex-1805, ¶ 224. As set forth in Section VI.B, "flexural modulus" means a measure of resistance to bending. Ex-1842, ¶ 56. As such, higher flexural moduli correspond with less flexible materials. *Id.*

In Kontos, the tip portion (soft tip 28) is preferably a copolymer of polyethylene and EVA. Ex-1809, 4:5-11. This is the first flexural modulus (region I). Ex-1842, ¶¶ 77-80. The tube 16 preferably is composed of polyethylene. Ex-1809, 4:1-4. This is the second flexural modulus (region II). *Id.* Finally, the insertion/manipulation wire 14 is made of stainless steel. Ex-1809, 4:58-61. This is the third flexural modulus (region III). *Id.*, ¶¶ 77-81.

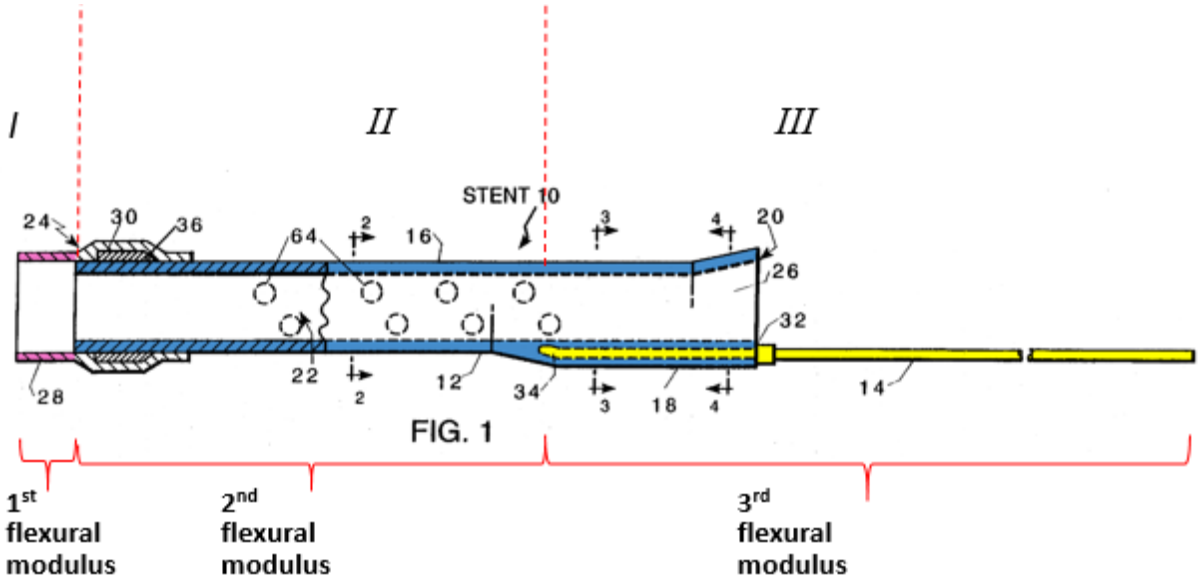


FIG. 1

Based on the known material properties, Kontos expressly discloses to a POSITA that the second flexural modulus is greater than the first flexural modulus and that the third flexural modulus is greater than the second flexural modulus. Ex-1805, ¶ 224; Ex-1842, ¶ 82.

J. Claim 39: "The system of claim 25, wherein a distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received interventional device that would otherwise tend to dislodge the distal portion."[14]

The Kontos-Adams combination teaches claim 39. Ex-1805, ¶¶ 225-33.

[14] Patent Owner drafted claim 39 such that the "distal portion" of the extension catheter "anchor[s] within the ostium of the branch vessel." That cannot be correct

The ’380 patent provides that because the guide extension catheter is “extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery,” it “assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion.” Ex-1801, Abstract; *see also id.* 5:6-27. The ’380 patent explains that, essentially, it is the combination of a guide catheter and a guide extension catheter inserted into a coronary ostium that improves distal anchoring of the system, and that the presence of the extension catheter in the GC provides “stiffer back up support” than a guide catheter alone. *Id*., 8:19-32. This combination is what allows the claimed system to resist dislodgement. Ex-1805, ¶¶ 225, 232-33.

Kontos discloses that “a physician inserts a guide catheter 38 through the aorta 37 and into a patient’s coronary ostia 39 using known medical procedures.” Ex-1809, 5:11-15. Kontos further provides that “the support catheter can be

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as the ’380 patent specification and claims teach that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter is advanced further into the coronary artery. Ex-1801, Fig. 8. For purposes of this IPR, Petitioner assumes this was a drafting error and that the extension catheter need not anchor in the ostium.

inserted into and … out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." Ex-1809, 2:16-22, Figs. 6A-C. In so doing, a distal portion of soft tip 28 is insertable through the continuous lumen of guide catheter 38 and extends beyond the distal end of guide catheter 38. Ex-1809, 3:50-52, 5:31-59, Figs. 6A-6C. When the soft tip 28 extends beyond the distal end of guide catheter 38 into the coronary artery, support catheter 10 assists in resisting axial and shear forces as claimed. For this reason, because Kontos and the '380 patent contain the same teachings, to the extent the '380 patent has adequate written description support, a POSITA would understand that Kontos must inherently disclose or, at a minimum, render obvious when combined with the knowledge of a POSITA, the limitation of claim 39. Ex-1805, ¶ 225; Ex-1842, ¶¶ 92-96.

VIII. GROUND 2: KONTOS RENDERS CLAIM 27 OBVIOUS IN VIEW OF ADAMS, KATAISHI, AND/OR THE KNOWLEDGE OF A POSITA.

A. Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under pre-AIA §102(b). Ex-1825, [43]. During prosecution of the '380 patent (and its previous iteration, the '850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. *See generally* Ex-1801-03.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1825, [0001]. It teaches a distal opening with two inclines designed, in part, to improve the catheter's "crossing ability," which is its ability to smoothly reach a desired target site. *Id*., Abstract, [0001]; s*ee also* Ex-1842, ¶¶ 136-37. In addition to providing flexibility, the two-incline shape of the catheter's distal opening improves its ability to suction thrombi, *id*., Abstract [0026]-[0027]; Fig. 10, which corresponds to loading a thrombus into the catheter's distal end. Ex-1805, ¶ 163.

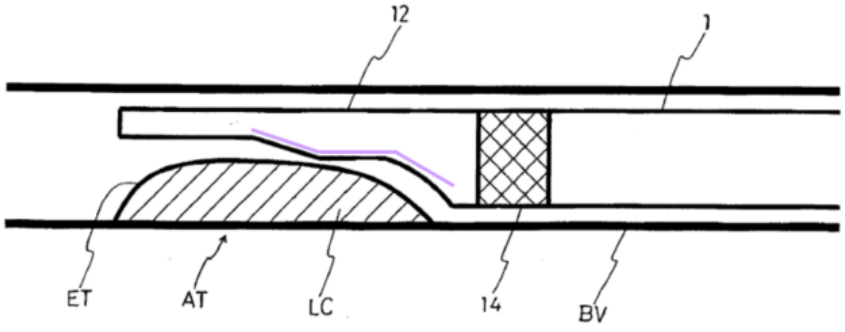
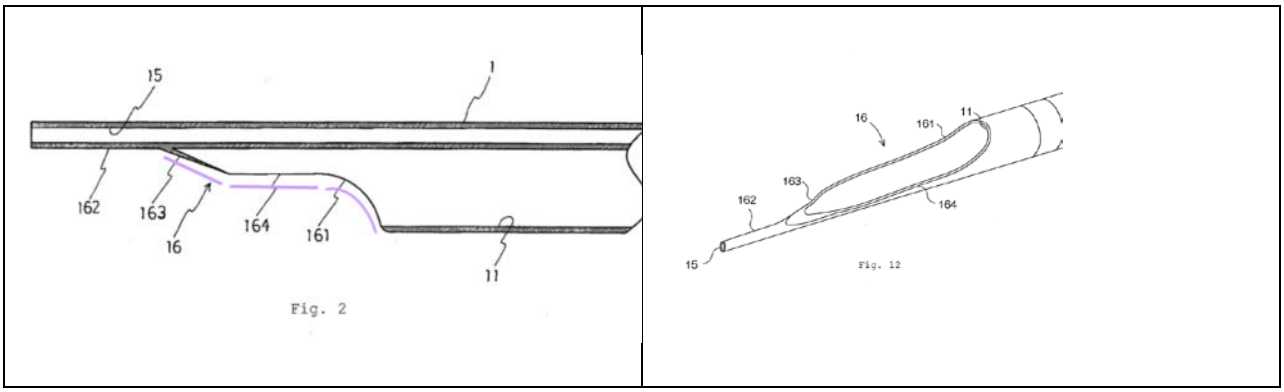


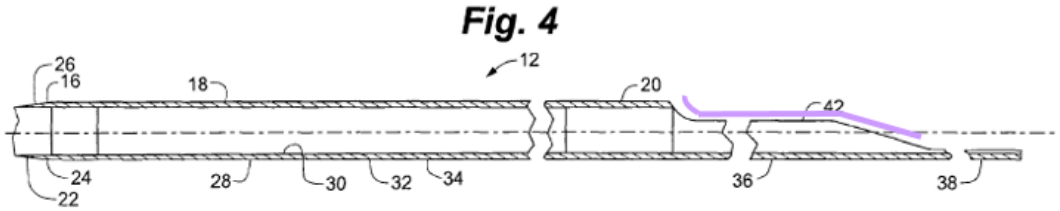
Fig. 10

The distal end has an "angled cut surface, in which at least a part of the proximal end side of the angled surface is formed in a concave shape in the angled direction and the distal end side of the cut surface is formed to be flat and flexible . . . ." *Id*., [0010]. The catheter tip is shown below. *Id*., Figs. 2, 12; *see also* Ex-1805, ¶¶ 164-65.

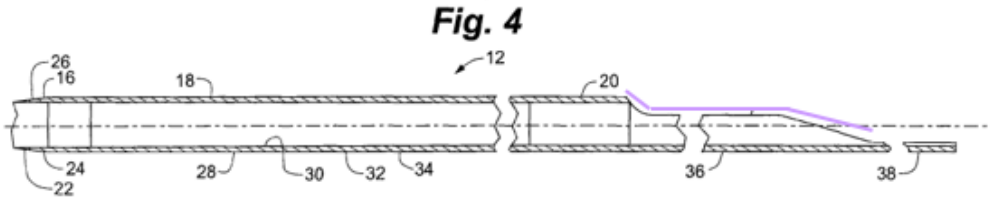


B. Claim 27: "The system of claim 26, wherein the side opening includes at least two different inclined slopes."

In an attempt to support claim 27, Patent Owner represented to the Examiner that Figure 4 of the '380 patent showed two different inclined slopes in the side opening. Ex-1803, Preliminary Amendment at 17 (11/1/13).



Ex-1801, Fig. 4 (color added). Of course, that disclosure in the '380 patent is no different than what was disclosed in Kataishi. *Compare id.*, Fig. 4 (color added), *with* Ex-1825, Figs. 2, 10 (color added); Ex-1805, ¶¶ 234-36.



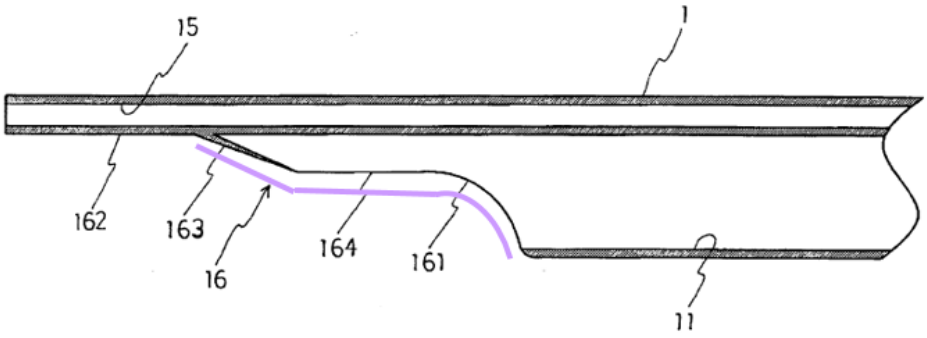


Fig. 2

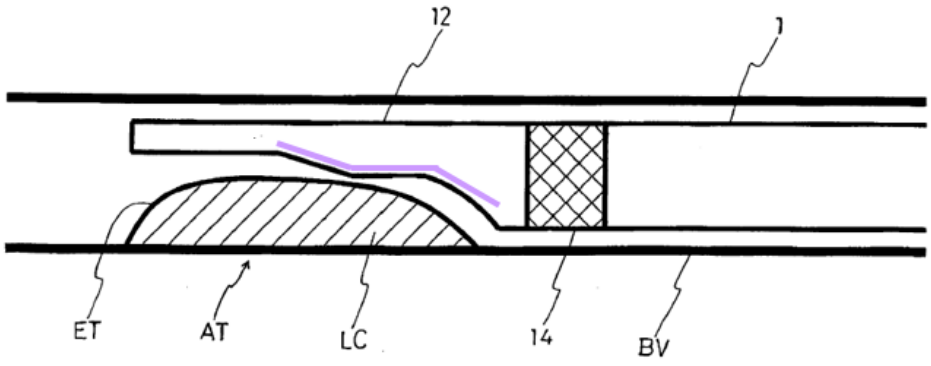


Fig. 10

It would have been obvious to modify the Kontos-Adams combination in light of Kataishi to implement a side opening with two different inclined slopes. Ex-1805, ¶¶ 237-41. Indeed, Kontos, Adams, and Kataishi 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 ’380 patent. *Id.*, ¶ 237; Ex-1842, ¶¶ 131-34.

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. Ex-1825, [0010]. These advantages are accomplished by the shape of Kataishi’s distal end. Ex-1842, ¶¶ 136-37. These same considerations—crossability and the ability to load something into a catheter opening—apply equally to the proximal end of a catheter, especially catheters such as the Kontos-Adams combination in which loading is not just of thrombus, but of balloon catheters. Ex-1805, ¶ 238; Ex-1842, ¶ 138. As such, POSITA would be motivated to apply Kataishi’s distal opening structure to the proximal opening of the Kontos-Adams combination.

First, adding a second, inclined slope to the proximal side opening would have increased the area of entry for the stent or balloon, without increasing the catheter’s outer diameter. Ex-1805, ¶ 239; Ex-1842, ¶ 139. A POSITA would be motivated to make this modification because it would allow the catheter to receive a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1825, Abstract [0026]-[0027], Fig. 10; Ex-1855 at 300, 304 (disclosing a better ability to load

because of two different inclined slopes on the end); Ex-1805, ¶ 239; Ex-1842, ¶ 139.

Second, a POSITA was aware that angled openings in the sidewall of a catheter—located proximal of the catheter's distal end—could "minimize … kinking … during insertion." Ex-1826, 3:6-14; 6:5-19, Fig. 2B; *see also* Ex-1805, ¶ 240; Ex-1842, ¶¶ 140-42; Ex-1808, 24:49-55. While Kataishi discloses two different inclined slopes on the distal end, a POSITA would be motivated to relocate to the proximal side opening in order to minimize kinking, thereby improving the crossability of the device by avoiding drag on the inside of the guide catheter. Ex-1805, ¶ 240; Ex-1842, ¶¶ 140-42.

A POSITA would have had a reasonable expectation of success, as creating two inclined slopes in a side opening would have been a routine task when manufacturing an extension catheter. Ex-1842, ¶ 143; Ex-1850, Fig. 7 (disclosing double incline, proximal side opening). As such, a POSITA would have had a reasonable expectation of success in adding a two-inclined, proximal side opening. Ex-1805, ¶ 241; Ex-1842, ¶ 143.

IX. GROUND 3: KONTOS RENDERS CLAIM 27 OBVIOUS IN VIEW OF ADAMS, ENGER, AND/OR THE KNOWLEDGE OF A POSITA.

A. Enger

U.S. Patent No. 5,980,486 ("Enger") issued on November 9, 1999 and is prior art under pre-AIA § 102(b). Ex-1850, [45]. Enger was not cited or considered during prosecution of the '850 patent. *See generally* Ex-1802. Enger is cited on the face of the '380 patent, but was not discussed during the prosecutions.[15] *See generally* Ex-1801, 1003.

Enger discloses a balloon catheter for use in a coronary artery. Ex-1850, Abstract. The proximal opening to the guidewire lumen of Enger has two inclined slopes.

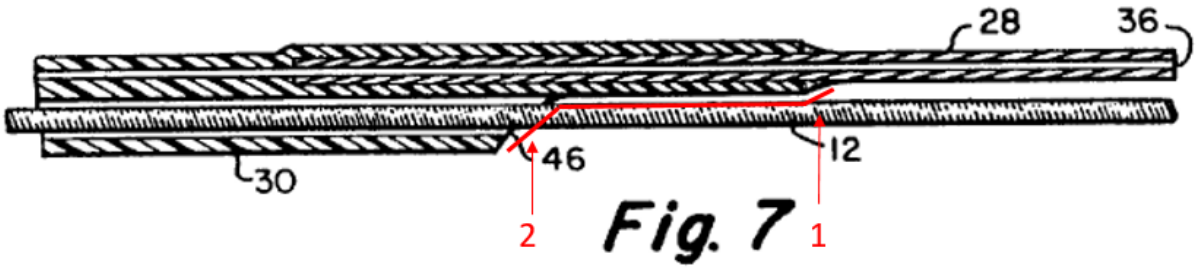


Fig. 7

Ex-1850, Fig. 7 (color and annotation added); Ex-1805, ¶¶ 166-71.

[15] Enger was not discussed in any Office Action and was not considered in combination with Kontos or Adams, and thus this Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See* Section VII.B, *supra* (citing cases declining to invoke § 325(d)).

B. Claim 27

Kontos in light of Adams, Enger, and/or the knowledge of a POSITA renders claim 27 obvious. Ex-1805, ¶¶ 242-46. Like Kontos and Adams, Enger is directed to a catheter system for treating occluded coronary arteries. Ex-1850, 1:13-15; *see also* Ex-1805, ¶ 244; Ex-1842, ¶¶ 144-45. Like Kontos's support catheter 10, Enger's angioplasty catheter is inserted through a guide catheter and into the coronary artery. Ex-1850, 3:25-27. And like Kontos's support assembly 10, Enger's angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*., 3:9-12.

Enger explains that prior art balloon angioplasty catheters lacking a guidewire lumen running along their entire length presented a risk because the portion of the catheter lacking guidewire support tended to "buckle" within the guide catheter. *Id*., 2:31-38. This would result in friction between the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy catheter. *Id*., 2:38-49. To address this problem, Enger's angioplasty catheter includes an "elongate proximal segment" 28, an intermediate segment 30, and a distal segment to which the dilation balloon 34 is mounted. *Id*., 4:66-5:11.

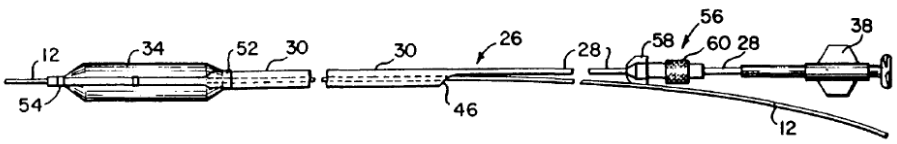


Fig. 1

The catheter is designed to have a short, distally-located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*. 3:9-10, 5:34-40.

The proximal opening to the guidewire lumen has at least two inclined slopes.[16]

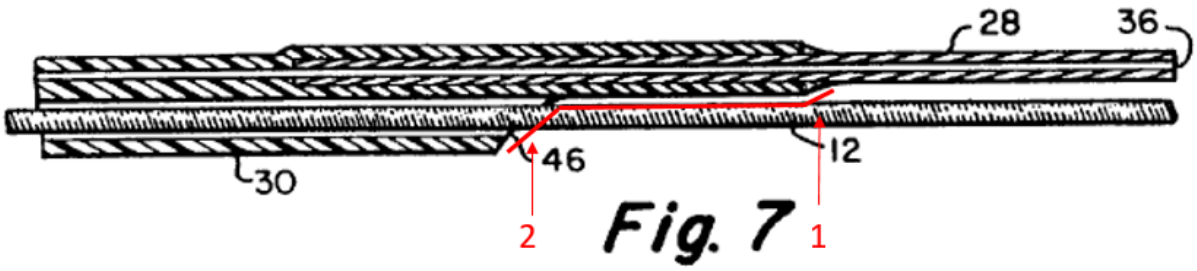


Fig. 7

Ex-1850, Fig. 7 (color and annotation added).

[16] Enger teaches that enclosing the guidewire in a lumen in the distal and intermediate segments of the catheter (over a 35-45 cm length) is advantageous because it allows those segments to be "supported by the guidewire" that extends through the lumen. Ex-1850, 3:9-10, 21-24. This ensures that the catheter "does not tend to bind up" in the guide catheter, thereby facilitating advancement of the distal end of the catheter "into more distal regions of a patient's coronary anatomy." *Id*., 3:25-29.

Enger's incline #1 functions as a start of an incline to the entry port located at incline #2. This incline functions to guide the interventional device (in this case a guidewire) into its designated lumen. Ex-1842, ¶ 147. A POSITA would be motivated to provide a first incline to function as an incline to guide interventional devices, such as Kontos's PTCA catheter 40, into the lumen of Kontos's tube 16. Ex-1805, ¶ 245; Ex-1842, ¶¶ 144-45, 149.

The first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1842, ¶¶ 146, 148. A POSITA would understand that the first incline of Enger could be incorporated into the Kontos-Adams combination by adding Enger's inclined polymer collar to wire 14. Ex-1805, ¶ 246; Ex-1842, ¶ 148. This would result in a two-incline opening as shown schematically below in Kontos's modified Figure 1.

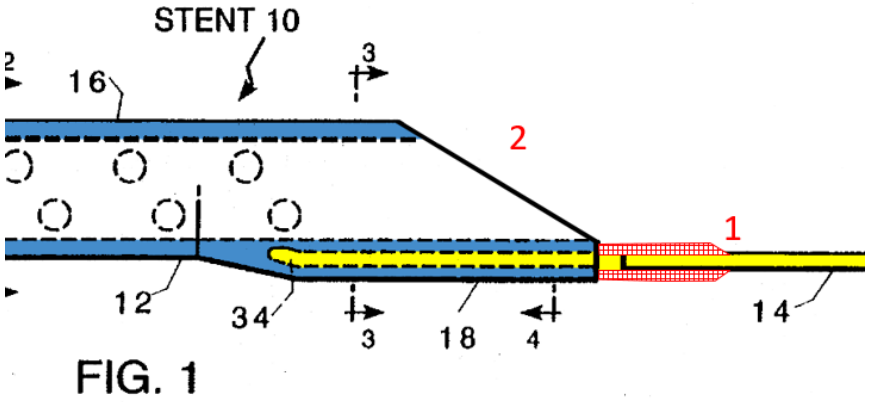


FIG. 1

Ex-1809, Fig. 1 (modified with Adams in further view of Enger).

X. GROUND 4: KONTOS RENDERS CLAIMS 32 AND 33 OBVIOUS IN VIEW OF ADAMS, TAKAHASHI, AND/OR THE KNOWLEDGE OF A POSITA.

A. Takahashi

Takahashi et al. ("Takahashi") is entitled *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*" and published in 2004, making it prior art under pre-AIA § 102(b). Ex-1878, ¶¶ 43-52. Takahashi is cited in the Background of the '380 patent, but was not the basis of an Examiner rejection during prosecution of either the '380 patent or the '850 patent (*see generally* Exs-1801-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d).

Takahashi explains that "[t]he five-in-six system is a method of inserting a 5 FR guiding catheter … into a 6 Fr guiding catheter to increase backup support." Ex-1810 at 452. Takahashi states that the inner lumen of the 5 French and 6 French catheters is 0.059 inches and 0.071 inches, respectively (*id.*), which is less than a 1 French difference in inner diameters. Ex-1805, ¶¶ 155-60; Ex-1842, ¶ 118.

B. Claim 32: "The system of claim 25, wherein a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is not more than one French smaller than a second inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel."

Claim 32 is rendered obvious by Kontos in view of Adams, Takahashi, and/or the knowledge of a POSITA. Ex-1805, ¶¶ 247-50. Kontos discloses a cross-sectional outer diameter and inner diameter of body 12 that is 0.055 inches and 0.045 inches, respectively. Ex-1809, 3:56-59, 4:48-50. Kontos does not disclose the cross-sectional inner diameter of the guide catheter. Ex-1805, ¶ 247. Takahashi, however, discloses 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. Ex-1805, ¶ 249; Ex-1842, ¶¶ 117-18; Ex-1810 at 452.

It would have been obvious to modify Kontos in light of Adams and Takahashi to achieve the not-more-than-one French differential. Indeed, Kontos, Adams, and Takahashi 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 '380 patent. Ex-1805, ¶ 249.

A POSITA would have been motivated to combine Takahashi with the Kontos-Adams combination, given that the former teaches that the not-more-than-

one French differential improved backup support of its catheter assembly. *Id.*; Ex-1842, ¶¶ 119-20. 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-1810, at 452.

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given the teachings of Kontos, Adams, Takahashi, and/or a POSITA's knowledge. In particular, as discussed for claim 25, a POSITA would have had a reasonable expectation of success when removing Kontos's funnel in favor of a proximal side opening. *See* Section VII.C.4.c, *supra*. Doing so would result in a uniform inner diameter of the lumen of the extension catheter (tube 16) and permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi. Ex-1842, ¶¶ 121, 121(i) (describing that use of side opening permits close seating of child and mother catheters and eliminates the need for a funnel at proximal end of the tubular structure, which results in a uniform inner-diameter of the tubular structure). Implementing the five-in-six system would increase the diameter of Kontos's body 12, but this modification was well within the skill of a POSITA, as appropriately sized catheters were ubiquitous in the art. Ex-1842, ¶¶ 121-121(i); Ex-1809, 5:64-65; Ex-1810, 452. Indeed, combining the teachings of Kontos with Adams and Takahashi to achieve the not-more-than-one French differential would have been

nothing more than combining prior art elements according to known methods to yield predictable results. Ex-1805, ¶ 250; Ex-1842, ¶¶ 121-22.

C. Claim 33: "The system of claim 32 where the lumen for the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to receive a stent and a balloon catheter."

As discussed for claim 32, a POSITA would have been motivated and have had a reasonable expectation of success in combining Kontos with Adams and Takahashi to implement the five-in-six system. *See* Section X.B, *supra*. In so doing, tube 16 of Kontos would be appropriately sized to receive both balloon catheters and stents. Ex-1805, ¶ 251; Ex-1842, ¶¶ 118, 121(i); *see also* Ex-1809, 4:66-5:2 (balloon catheter); Ex-1810, 456 (placing stent). As such, claim 33 is obvious. Ex-1805, ¶ 251.

XI. GROUND 5: KONTOS RENDERS CLAIM 38 OBVIOUS IN VIEW OF ADAMS, BERG, AND/OR THE KNOWLEDGE OF A POSITA.

A. Berg

U.S. Patent No. 5,911,715 ("Berg") issued on June 15, 1999 and is prior art under pre-AIA § 102(b). Berg is listed on the "References Cited" portion of the '380 patent. Ex-1801, [56]. Berg was not the basis of an Examiner rejection during prosecution of either the '380 patent or the '850 patent (*see generally* Exs-1801-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d).

Berg teaches a guide catheter that has a distal tip that is the most flexible portion and, moving distal to proximal, the catheter increases in rigidity. Ex-1850, 2:66-3:9. In particular, the "soft tip zone of flexural modulus [is] between 1 and 15 Kpsi." *Id.*, 3:3-9. The second and third flexural modulus is between 2 and 49 Kpsi and 13 and 49 Kpsi, respectively. *Id.*

B. Claim 38: "The system of claim 37, wherein the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI."

Kontos in combination with Adams, Berg and/or the knowledge of a POSITA renders claim 38 obvious. Ex-1805, ¶¶ 252-62. As discussed above for claim 37, Kontos has at least three regions of flexural moduli. Section VII.I, *supra.* Kontos does not, however, disclose the psi of those regions. Ex-1842, ¶¶ 123-25.

Berg, however, teaches a guide catheter with at least three different flexural moduli. Ex-1851, 2:66-3:3. Specifically, the distal soft tip has a flexural modulus between "1 to about 15 Kpsi," or 1,000 to 15,000 psi, which "provide[s] an atraumatic end . . . for navigating vasculature" Ex-1851, 14:2-7, Fig. 19; Ex-1842, ¶ 125. Berg also teaches that—just proximal to the soft tip—the catheter should be increasingly rigid in a distal to proximal direction, including a portion with a flexural modulus "between about 2 and about 49 Kpsi" or 2,000 to 49,000 psi. *Id.*, 14:27-30; Ex-1842, ¶ 126. This second flexural modulus assists in the positioning

of the catheter tip. *Id.*, 14:27-30; Ex-1842, ¶ 126. Finally, Berg additionally teaches that the next most proximal segment should be a portion with a flexural modulus "between about 13 and about 49 Kpsi" or 13,000 to 49,000 psi, and then a portion with a flexural modulus of greater than 49,000 psi. *Id.*, 14:35-51; Ex-1842, ¶ 127.

A POSITA would have been motivated to modify Kontos to target the flexural moduli enumerated by Berg. Ex-1805, ¶¶ 253-61; Ex-1842, ¶ 128. In particular, it was known that coronary catheters for PCI should have "a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions." Ex-1844, 1:37-38; *see also* Ex-1842, ¶ 128. The guide catheter of Berg parrots this teaching, explaining that "the present invention allows for flexibility of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out." Ex-1851-2:37-39. Further, although Berg's teachings are directed to a guide catheter, and not an extension catheter, a POSITA would have had a similar expectation of success, as both are part of the same catheter assembly and need to traverse the same vasculature. Ex-1805, ¶ 262; Ex-1842, ¶ 129.

The three regions of flexural moduli taught by Berg overlap with the claimed range. Ex-1805, ¶ 260; Ex-1842, ¶¶ 124, 130. As a result, the claimed range would have been obvious. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005) ("[A] prima

facie case of obviousness arises when the ranges of a claimed composition overlap the ranges disclosed in the prior art.").

XII. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1873. The "Facts" section of the memorandum in support states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioner launched a "copycat" product. *Id.*, 2, 5, 9. Patent Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

XIII. CONCLUSION

Petitioner respectfully requests institution of a trial and cancellation/invalidation of the claims 25-39 of the '380 patent.

XIII. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.15 and 42.103, the required fees are submitted herewith. If additional fees are due during this proceeding, the Office is authorized to charge Deposit Account No. 600615.

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 14, 2019
800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
612.349.8500

/ Cyrus A. Morton /
Cyrus A. Morton

Attorney for Petitioner
Medtronic, Inc.

WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 12,325 words, excluding any Mandatory Notices. I further certify that, in preparation of this Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 14, 2019

/ Cyrus A. Morton /

Cyrus A. Morton
Registration No. 44,954
Robins Kaplan LLP
cmorton@robinskaplan.com

Attorney for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence. was served on November 14, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

Paul Onderick
PATTERSON THUENTE PEDERSEN, P.A.
80 South 8th Street
4800 IDS Center
Minneapolis, MN 55402-2100

Courtesy copies were also sent to the following address of record for counsel in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019):

CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402

/ Cyrus A. Morton /

Cyrus A. Morton
Registration No. 44,954
Robins Kaplan LLP
cmorton@robinskaplan.com

Attorney for Petitioners