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.: IPR2020-00130
U.S. Patent No. RE 45,380E

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

LIST OF EXHIBITS

Exhibit	Description
1401	U.S. Patent No. RE45,380 ("the '380 patent")
1402	File history for U.S. Patent No. 8,292,850
1403	File history for U.S. Patent No. RE45,380
1404	Assignment record of the '380 patent from the USPTO assignment database
1405	Declaration of Doctor Stephen JD Brecker, M.D.
1406	Curriculum Vitae of Doctor Stephen JD Brecker, M.D.
1407	U.S. Patent No. 7,736,355 ("Itou")
1408	U.S. Patent No. 7,604,614 ("Ressemann")
1409	U.S. Patent No. 5,439,445 ("Kontos")
1410	*New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63: 452-456 (2004) ("Takahashi")
1411	Excerpt of prosecution history of U.S. Patent No. 8,048,032 (Application 11/416,629) (Amendment and Response, April 6, 2009)
1412	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.
1413	*Markman* Order in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (October 30, 2018), D.I. 102
1414	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")
1415	Excerpt from Grossman's Cardiac Catheterization, Angiography, and Intervention (6th edition) (2000) (chapters 1, 4, 11, 23-25).
1416	US Patent Publication 2003/0233117 ("Adams '117")
1417	U.S. Patent No. 5,902,290 ("Peacock")

Exhibit	Description
1418	U.S. Patent No. 5,891,056 (“Ramzipoor”)
1419	U.S. Patent No. 6,398,773 (“Bagaoisan”)
1420	Mehan, *Coronary Angioplasty through 4 French Diagnostic Catheters*, Catheterization and Cardiovascular Interventions 30:22-26 (1993) (“Mehan”)
1421	Excerpt of prosecution history for application 11/232,876 (Office Action, 6/20/09)
1422	Cordis, Instructions for Use, CYPHER™ (April 2003)
1423	Medtronic, Summary of Safety and Effectiveness Data, Driver™ Coronary Stent System (October 1, 2003)
1424	Boston Scientific, Summary of Safety and Effectiveness Data, TAXUS™ Express^{2}™ Drug-Eluting Coronary Stent System (March 4, 2004)
1425	U.S. Publication Application No. 2005/0015073 (“Kataishi”)
1426	U.S. Patent No. 5,489,278 (“Abrahamson”)
1427	U.S. Patent No. RE45,776 (“Root”)
1428	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”)
1429	Limbruno, *Mechanical Prevention of Distal Embolization During Primary Angioplasty*, Circulation 108:171-176 (2003) (“Limbruno”)
1430	U.S. Patent No. 5,413,560 (“Solar ’560”)
1431	Schöbel, *Percutaneous Coronary Interventions Using a New 5 French Guiding Catheter: Results of a Prospective Study*, Catheterization & Cardiovascular Interventions 53:308-314 (2001) (“Schöbel”)
1432	*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”)
1433	U.S. Publication Application No. 2004/0236215 (Mihara)

Exhibit	Description
1434	U.S. Patent No. 5,527,292 (“Adams ’292”)
1435	U.S. Publication Application No. 2004/0010280 (“Adams ’280”)
1436	Williams et al., *Percutaneous Coronary Intervention in the Current Era Compared with 1985-1986*, Circulation (2000) 102:2945-2951.
1437	Dorros, G., et al., *Coronary Angioplasty in Patients with Prior Coronary Artery Bypass Surgery*, Cardiology Clinics 7(4): 791-803 (1989)
1438	Ozaki et al, *New Stent Technologies*, Progress in Cardiovascular Disease 2:149-140 (1996)
1439	Urban et al., *Coronary stenting through 6 French Guiding Catheters, Catheterization and Cardiovascular Diagnosis* (1993) 28:263-266
1440	Excerpt of McGraw-Hill Dictionary of Scientific and Technical Terms (5th edition) (1994) (defining “flexural modulus”)
1441	Excerpt from Kern’s The Interventional Cardiac Catheterization Handbook (2nd edition) (2004) (chapter 1)).
1442	Declaration of Dr. Richard A. Hillstead, Ph.D.
1443	Curriculum Vitae of Dr. Richard A. Hillstead, Ph.D.
1444	U.S. Patent No. 5,961,510 (“Fugoso”)
1445	U.S. Patent No. 6,199,262 (“Martin”)
1446	U.S. Patent No. 6,042,578 (“Dinh”)
1447	WO 97/37713 (“Truckai”)
1448	Terumo Heartrail II product literature
1449	Medtronic Launcher product literature
1450	U.S. Patent No. 5,980,486 (“Enger”)
1451	U.S. Patent No. 5,911,715 (“Berg”)
1452	U.S. Patent No. 5,545,149 (“Brin”)
1453	U.S. Patent No. 5,720,300 (“Fagan”)

Exhibit	Description
1454	U.S. Patent No. 5,140,323 ("Shockey")
1455	Sakurada, *Improved Performance of a New Thrombus Aspiration Catheter*: Outcomes From In Vitro Experiments and a Case Presentation ("Sakurada")
1456	Nordenstrom, *New Instruments for Catheterization and Angiocardiography* ("Nordenstrom")
1457	U.S. Patent No. 5,445,625 ("Voda")
1458	U.S. Patent No. 6,595,952 ("Forsberg")
1459	U.S. Patent No. 6,860,876 ("Chen")
1460	U.S. Patent No. 6,638,268 ("Niazi")
1461	U.S. Patent No. 5,690,613 ("Verbeek")
1462	lserson, *J.-F.-B. Charrière: The Man Behind the "French" Gauge,* The Journal of Emergency Medicine. Vol. 5 pp 545-548 (1987)
1463	U.S. Publication Application No. 2003/0195546 ("Solar '546")
1464	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
1465	U.S. Patent No. 4,000,739 ("Stevens")
1466	EP 0 881 921 B1 ("Lee")
1467	U.S. Patent No. 5,451,209 ("Ainsworth")
1468	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)
1469	Excerpt of prosecution history for application 14/195,435 (Office Action, 10/06/15)
1470	Metz, *Comparison of 6f with 7f and 8f guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter, randomized trial*, American Heart Journal. Vol. 134, Number 1, pp 132-137 ("Metz")

Exhibit	Description
1471	Feldman, *Coronary Angioplasty Using New 6 French Guiding Catheters*, Catheterization and Cardiovascular Diagnosis 23:93-99 (1991) ("Feldman")
1472	U.S. Patent No. 5,704,926 ("Sutton")
1473	Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL
1474	Yokoyama, *Feasibility and safety of thrombectomy with TVAC aspiration catheter system for patients with acute myocardial infarction*, Heart Vessels (2006) 21:1–7 ("Yokoyama")
1475	Excerpt from Plaintiff's infringement allegations in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1476	U.S. Patent No. 5,860,963 ("Azam")
1477	10/16/2019 Deposition of Peter Keith in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760
1478	Sylvia Hall-Ellis's Librarian Declaration
1479	Complaint in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1480	U.S. Patent No. 5,061,273 ("Yock")
1481	Intentionally Left Blank
1482	Declaration of Peter Keith in Support of Plaintiffs' Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL (July 14, 2019)
1483	Joint Fed. R. C. P. 26(f) Report [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL
1484	Plaintiffs' Objections and Responses to Interrogatories [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL

I. PRELIMINARY STATEMENT

Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 1-4, 6-9, and 12-21 ("Challenged Claims") of U.S. Pat. No. RE 45,380 ("the '380 patent," Ex-1401). 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

[1] The '380 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1405, ¶¶ 71 n.6, 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-1409, 5:49-52 (referring to body 12 "as a guide catheter extension").

ability to effectively create deep seating in the ostium of the coronary artery," 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-1405, ¶¶ 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.

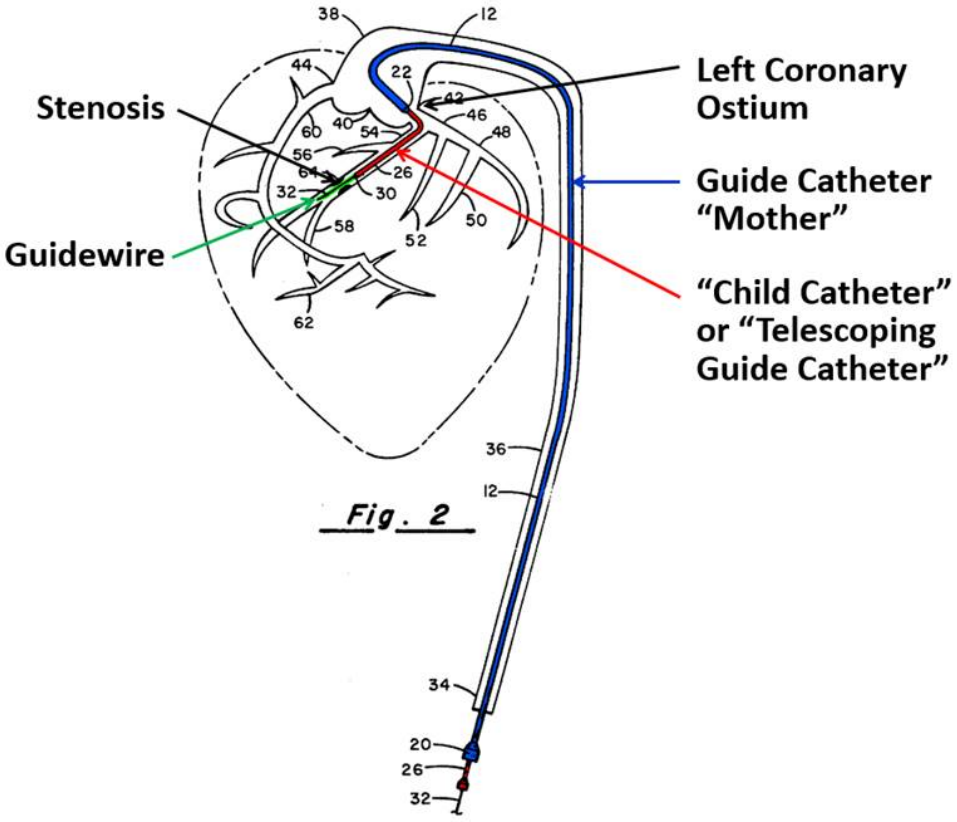
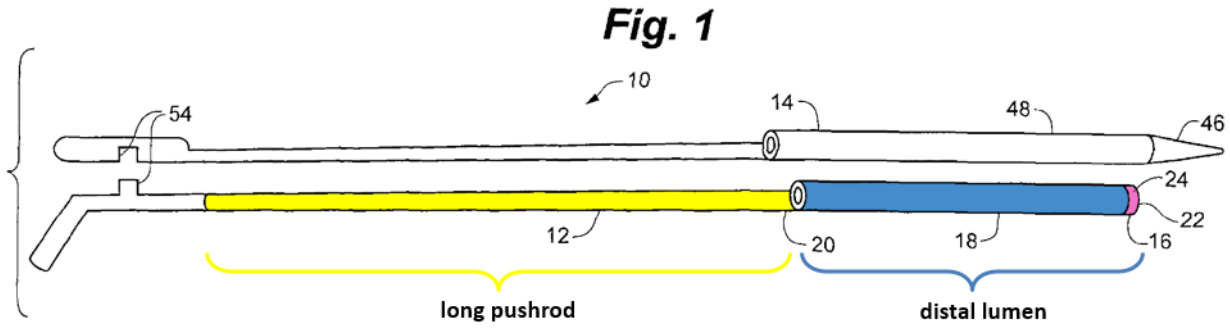


Fig. 2

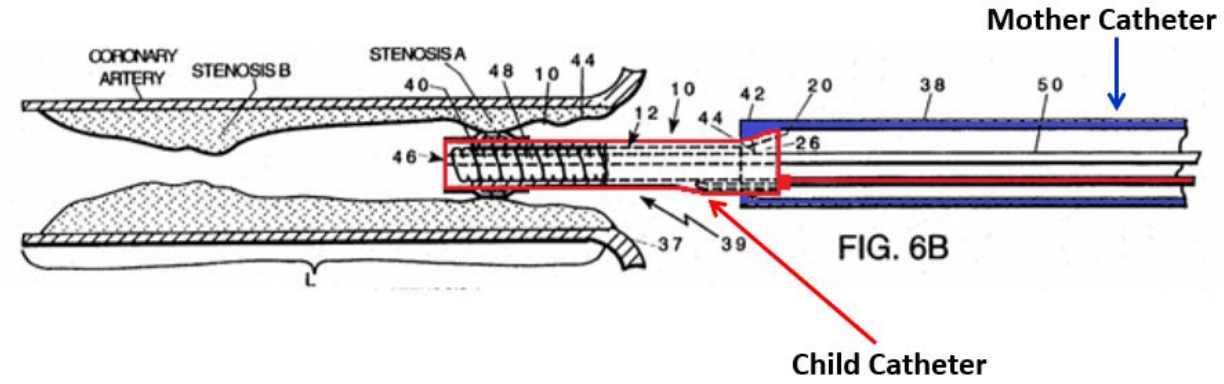
Ex-1454, Fig. 2 (color and labels added).

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-1401, 2:57-67; Ex-1405, ¶¶ 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-1401, 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-1409, 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.

C. Lead and Backup Counsel

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

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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 1-4, 6-9, and 12-21 of the ’380 patent and cancellation of these claims as unpatentable in view of the

following grounds:[2]

No.	Grounds
1	Claims 1-4, 6-7, 9, 12-17, and 19-20 are rendered obvious by Kontos in view of Adams and/or the knowledge of a POSITA.
2	Claim 8 & 18 are rendered obvious by Kontos in view of Adams, Takahashi, and/or the knowledge of a POSITA.
3	Claim 21 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-1405, ¶¶ 28, 30-32. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id.* In response, 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.

[2] This Petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1405) and Richard A Hillstead, PhD (Ex-1442), as experts in the field of the '380 patent. Petitioner also submits the declaration of Sylvia S. Hall-Ellis, PhD (Ex-1478) to support the authenticity and public availability of the documents cited herein.

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.

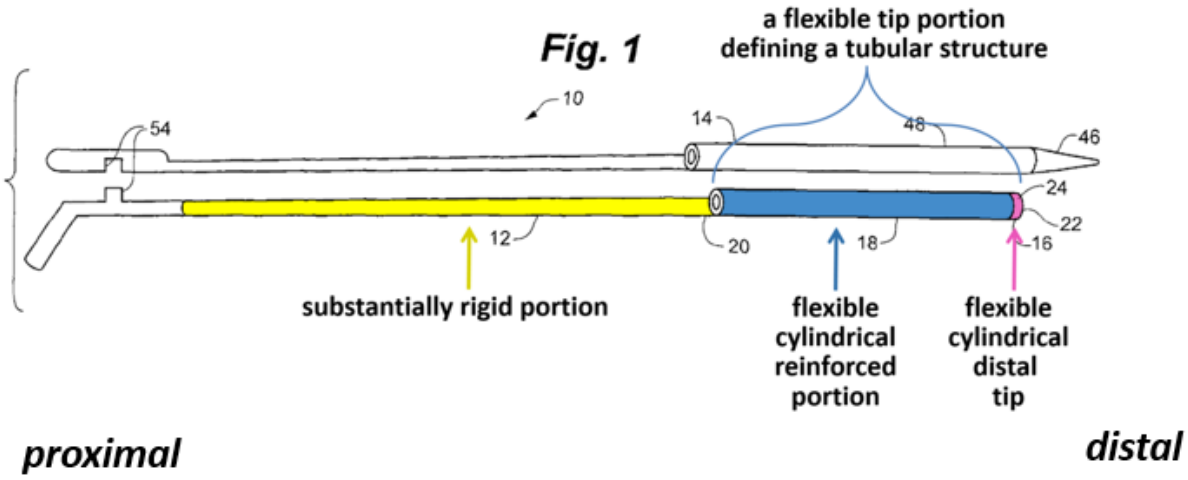
B. Overview of the ’380 Patent

The ’380 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1401, 1:32-35. 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-1405, ¶¶ 118-19.

The ’380 patent explains that the guide extension catheter 12 has a tubular portion that includes flexible distal tip 16 (pink) and 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 1.[3]

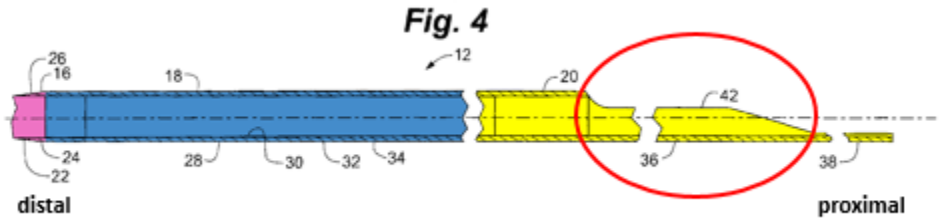
[3] In claim 1 “a flexible tip portion” defines “a tubular structure.” The “tubular structure” in claim 1 further “includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion.” Claim 12 describes the guide extension catheter using different language. Specifically, claim 12 recites “a flexible tip portion defining a tubular structure,” and a proximally-located “reinforced portion.”

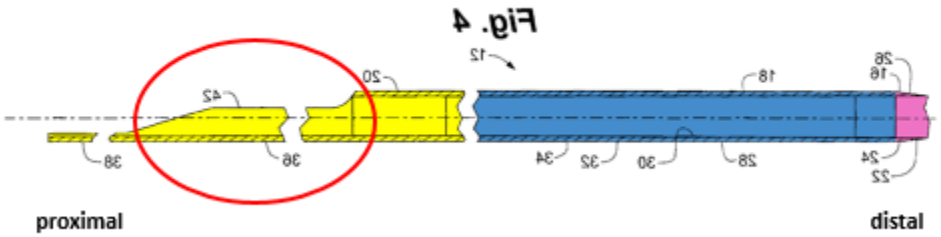
Ex-1405, ¶ 120.



Id., Fig. 1 (annotations and color added).

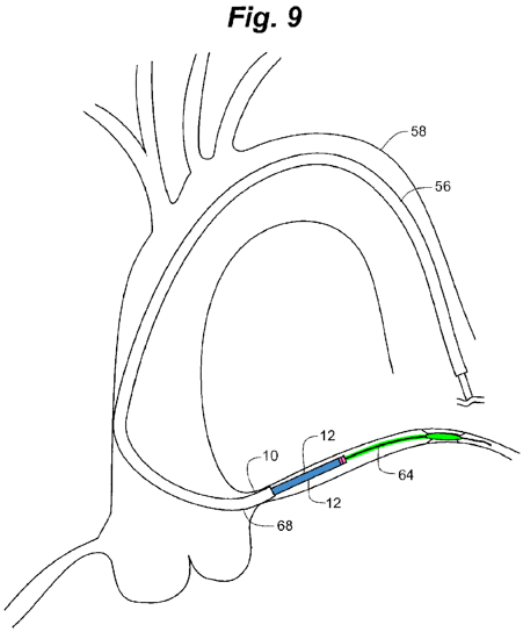
The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "side opening" (red circle), which may have an "inclined slope." *Id.*, 6:62-7:11, Figs. 4, 13-16; Ex-1405, ¶ 121.





Id., Fig 4 (annotations and color added).

As shown below, the ’380 patent describes that 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-1405, ¶ 122.



Ex-1401, Fig. 9 (color added).

C. Prosecution History of the ’380 Patent

The parent ’850 patent issued without an Office Action. *See generally* Ex-1402. 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-1402 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-1403.

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-1405, ¶ 27; Ex-1442, ¶¶ 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. *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-1412 at 2)
- "interventional cardiology device(s)": "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters" (*Compare* Ex-1412 at 21 (Dkt. 36-1), *with* Ex-1464 at 1 n.1)

Further, Patent Owner advanced,[4] and the district court adopted, the following

[4] The full list of constructions advanced by Patent Owner in the QXMedical Litigation is found at Ex-1412 (Dkt. 36-1).

constructions:

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (Ex-1412 at 2 (Dkt. 36-1); Ex-1413 at 15)
- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1413 at 20)

Additionally, the district court provided the following construction:

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

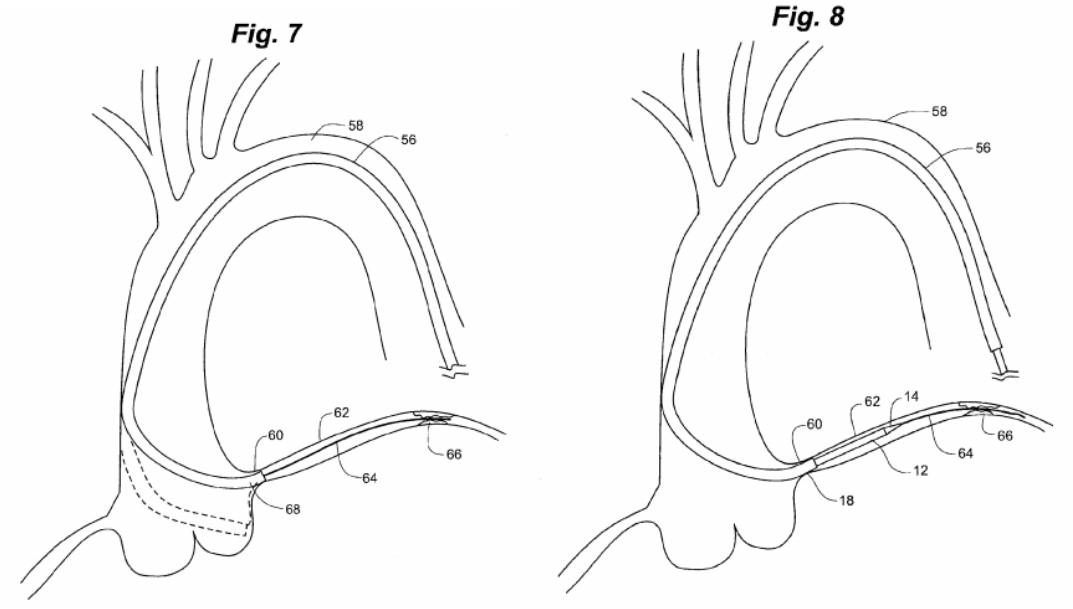
Petitioner agrees with the above constructions for purposes of this IPR[5] (Ex-1405, ¶¶ 123-29) and proposes the following additional constructions:

A. "placed in the branch artery" (cls. 1, 12)

Claims 1 and 12 recite, *inter alia*, "a guide catheter having … a distal end adapted to be placed in the branch artery." In the context of the '380 patent, "placed in the branch artery" includes "placement in the ostium of a coronary artery." Ex-1405, ¶¶ 133-34. For instance, the '380 patent notes, in its background, the well-understood fact that a "guide catheter is inserted … into the ostium of the

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

coronary artery." Ex-1401, 1:53-54. This is further shown in Figures 7 and 8 (reproduced below), and confirmed by other description in the '380 patent. The patent describes that an GC is "inserted into the ostium of a branch artery where it branches off from a larger artery." *Id*., 4:63-5:2, Figs. 7-8.



It is more common in the art to refer to arteries branching off *from* the coronary artery as branch arteries, rather than the coronary arteries themselves. Ex-1405, ¶¶ 132-33. The '380 patent, however, explicitly states that "guide catheter 56 is brought into proximity of ostium 60 of a smaller *branch* blood vessel, *such as coronary artery 62*." Ex-1401, 10:1-5 (emphasis added). Thus, to the extent Petitioner's construction deviates from the plain meaning, the inventors acted as their own lexicographers. *Laryngeal Mask Co. v. Ambu, A/S*, 618 F.3d 1367, 1371-72 (Fed. Cir. 2010).

B. "flexural modulus" (cl. 20)

The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1442, ¶ 45), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means "[a] measure of resistance … to bending." Ex-1440 at 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 coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1401, 7:25-32; Ex-1405, ¶¶ 136-37.[6]

[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-1412 at 2. It is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

VII. GROUND 1: KONTOS RENDERS CLAIMS 1-4, 6-7, 9, 12-17, and 19-20 OBVIOUS IN VIEW OF ADAMS AND/OR THE KNOWLEDGE OF A POSITA.

A. Prior Art

1. 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-1401-03.

Kontos is entitled “Support Catheter Assembly.” Ex-1409, [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 support catheter assembly with particular utility in facilitating insertion of a PTCA balloon into a lesion.” *Id.*, 1:9-13. Just like the coaxial guide 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 coaxial guide 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-1405, ¶¶ 140-41.

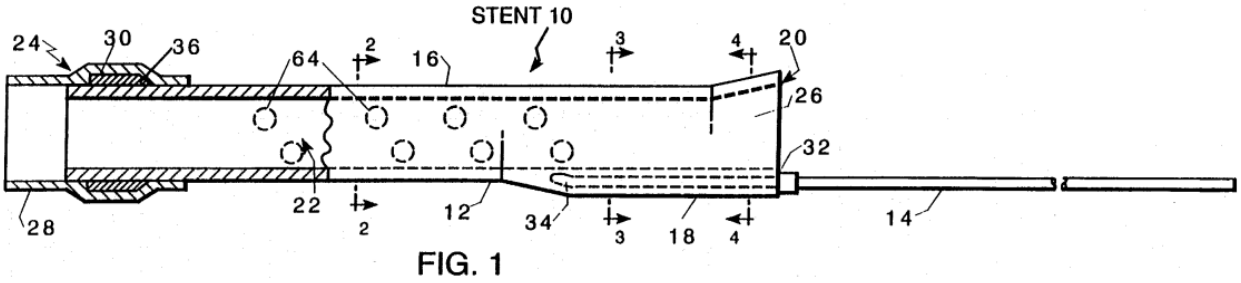


FIG. 1

Ex-1409, 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.

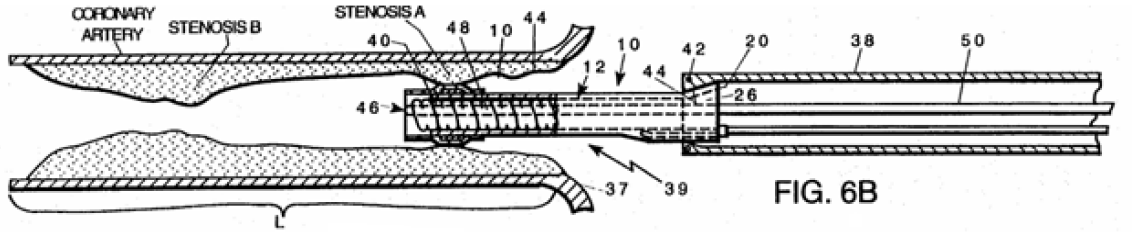


FIG. 6B

A POSITA would appreciate that Kontos's support catheter 10 operates no differently than coaxial guide catheter 12 of the '380 patent. Ex-1405, ¶¶ 138-43. 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.*, ¶ 140-41.

2. Adams

U.S. Patent Publication 2004/0010280 ("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-1401, [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-1401-03), 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-1469 at 4. As a threshold matter, the "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

Adams discloses an apparatus and method for removing a coronary stenosis. Ex-1435, 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], Figs. 1B, 2A. A sealing device 20 is then advanced "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-2C.

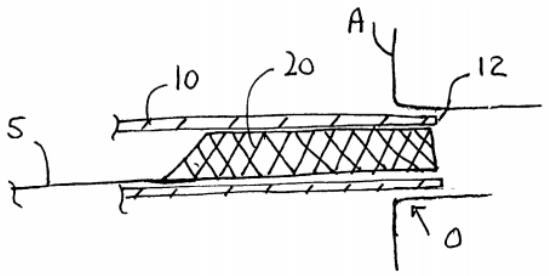


FIG. 2A

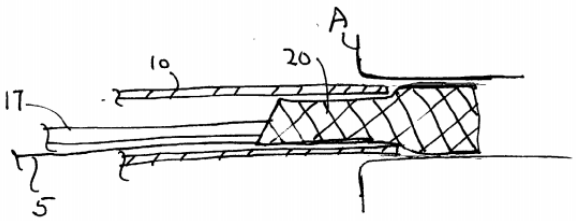


FIG. 2C

did not consider the combination and argument … presented" in this Petition, and the Board should not invoke § 325(d). *Id.*

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. *Id.*, [0012], Figs. 2D-E. 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. *Id.*, [0012], Figs. 2E-F; *see also* Ex-1405, ¶¶ 145-48.

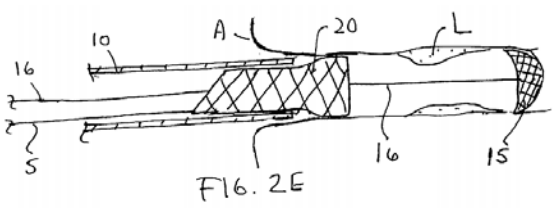


FIG. 2E

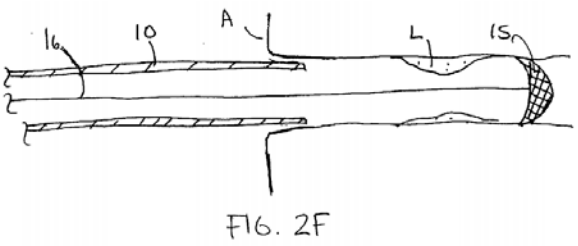


FIG. 2F

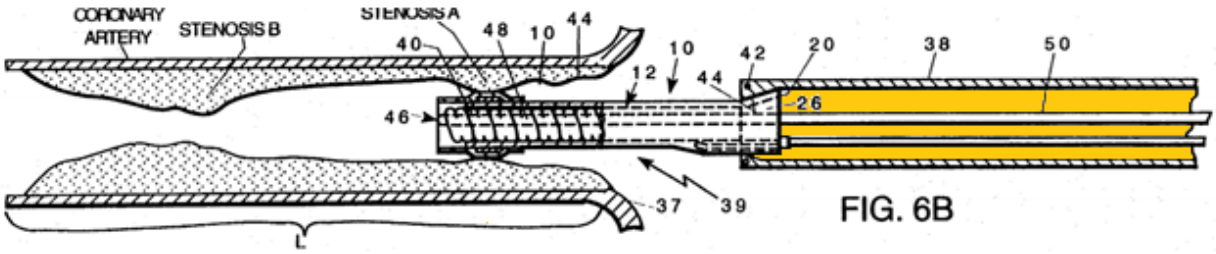
B. Claim 1

1. [1.pre] "A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the 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 artery while delivering a balloon catheter to treat a lesion in the same. Ex-1409, Abstract, 1:46-48, 5:40-44, Fig. 6B; Ex-1405, ¶ 157; *see also* Section VI, *supra* (claim construction for interventional cardiology device). The support catheter assembly 10 is used in conjunction with a guide catheter 38 (Ex-1405, ¶ 157), and the combination of the two discloses the claimed "system." *See* Section VII.B.2-7, *infra* (analysis and citations for remaining elements of claim 1).

2. [1.a.i] "a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery,"

Kontos discloses a guide catheter 38 having a continuous lumen that is identified in yellow below. Ex-1405, ¶ 158. The guide catheter 38, and thus the continuous lumen, necessarily has a predefined length.



Ex-1409, Fig. 6B (color added).

In characterizing Figure 6B, Kontos states that "a physician inserts a guide catheter 38 through the aorta 37 and into a patient's coronary ostia 39 using known medical procedures." *Id.*, 5:11-15. The distal end of the guide catheter 38 that is placed in the coronary ostia 39 is identified in green in Figure 14 below. Therefore, Kontos discloses "a guide catheter … having a distal end adapted to be placed in the branch artery." Section VI.A, *supra*.

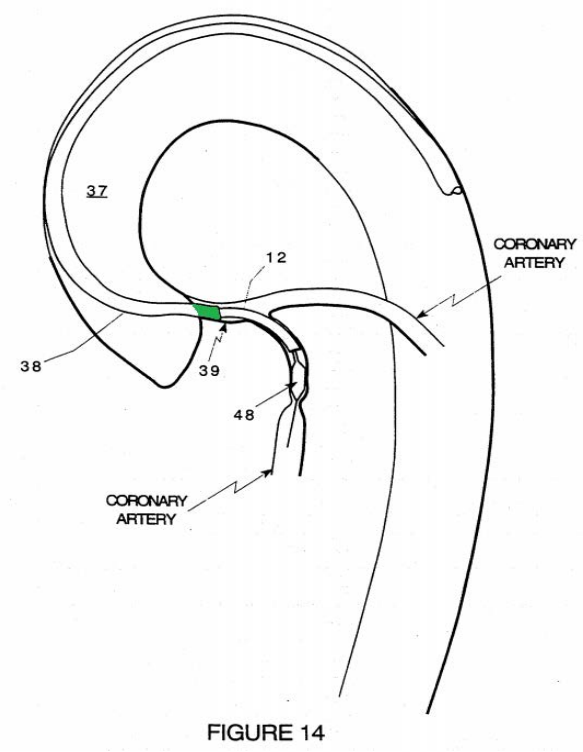


FIGURE 14

Ex-1409, Fig. 14 (color added).

Although not specifically enumerated in Kontos, the knowledge of a POSITA combined with Kontos would have taught that the proximal end of the continuous lumen of guide catheter 38 is connected to a hemostatic valve.[8] Ex-1405, ¶ 159. Indeed, without the proximal end being connected to a hemostatic valve, the catheter assembly would be exposed to the ambient environment, meaning the patient would risk excessive blood loss and/or develop an air embolism. *Id.* (testifying no responsible physician would perform a PCI procedure without

[8] The ’380 patent admits as much. Ex-1401, 3:21-24 (describing “commonly existing hemostatic valves used with guide catheters”).

hemostatic valve); Ex-1412, ¶ 13 (Dkt. 36-2) (inventor, Mr. Root, admitting same); Ex-1401, 2:63-67; Ex-1477, 43:2-15.

To the extent Patent Owner contends that the use of a hemostatic valve is not obvious in view of Kontos and the knowledge of a POSITA, it would have been obvious to modify Kontos to add a hemostatic valve in view of Adams. Ex-1405, ¶¶ 160-63. 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. *Id.*, ¶ 160.

For example, Adams discloses a device and method for using PTCA and stenting to treat vascular disease. Ex-1435, [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. *Id.*, [0012], [0022], [0059]; Section VII.A.2, *supra*.

Adams further teaches that "[a] Y connector with hemostasis valve typically is attached to the proximal end of the guide catheter for ease of device passage and reduced blood loss." *Id.*, [0060], Fig. 1A. Adams states that "[h]emostatsis valve 9 is at the proximal end of Y connector 7." *Id.*

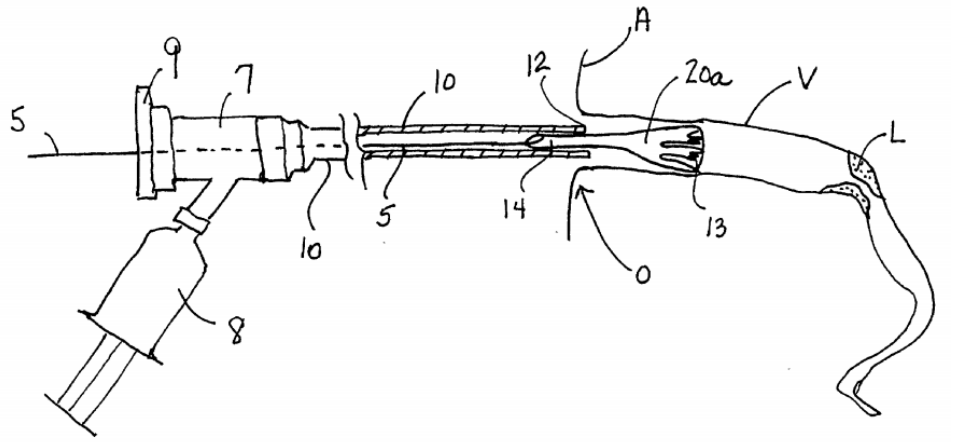


FIG. 1A

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 a hemostatic valve at the proximal end of the continuous lumen of Kontos's guide catheter 38 in view of Adams. Ex-1405, ¶¶ 160-63. As Adams teaches, a POSITA would have been motivated to add a hemostatic valve to a Y-fitting for the dual purpose of easing device passage and reducing blood loss. Ex-1435, [0060].

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-1405, ¶ 163. Indeed, combining the teachings of Adams with Kontos to provide a hemostatic valve at the proximal end of the guide catheter lumen would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*, ¶ 163; *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. [1.a.ii] "the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter;"

As shown in Kontos Figure 6A, the continuous lumen of the guide catheter 38 (yellow) has a cross section that is sized to allow an interventional cardiology device, such as a PTCA catheter 40 with balloon 48, to be inserted into and travel through the lumen of guide catheter 38. Ex-1409, 5:16-20, Figs. 6A-C; Ex-1405, ¶ 164.

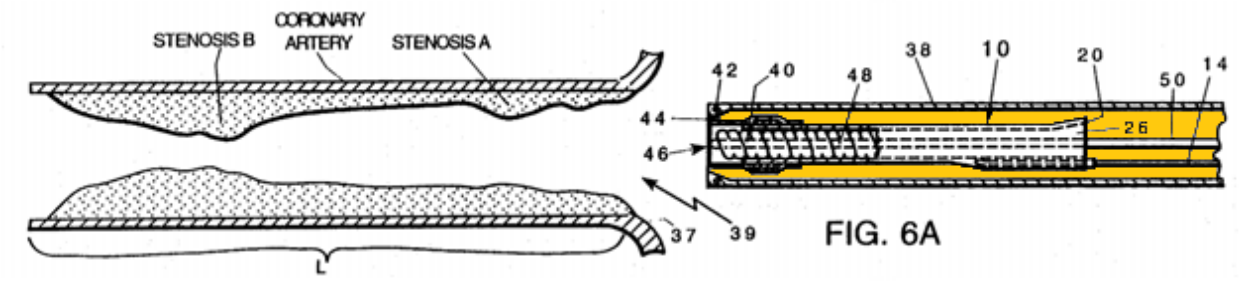


FIG. 6A

A POSITA would recognize that the guide catheter 38 has a circular cross-sectional inner diameter. Kontos describes both that the extension catheter has a "tubular body" and that a proximal portion may remain within the guide catheter 38. *Id.*, Abstract, 3:56-59, 5:57-62. As a result, because a tubular structure has a circular cross-section, a POSITA would expect that the continuous lumen of the guide catheter—which is coaxial to the extension catheter—also has a circular

cross-sectional diameter. Ex-1405, ¶¶ 4-8, 165 (explaining that he has performed thousands of PCI procedures and is unaware of guide catheters without a circular cross-sectional diameter).

To the extent Patent Owner argues that Kontos does not explicitly teach that guide catheter 38 has a circular cross-sectional diameter, it would have been obvious to modify Kontos to add this design feature in view of Adams. Ex-1405, ¶¶ 166-69. 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.B.2, *supra*. Further, Adams specifically teaches the use of a guide catheter with a circular cross-sectional inner diameter (Ex-1435, [0052], Fig. 1C,), and a POSITA would have been motivated to use a guide catheter with a circular inner diameter, as doing so would provide better seating between Kontos's guide catheter 38 and support catheter 10, thereby minimizing the outer diameter of the catheter assembly. Ex-1405, ¶¶ 167-68.

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-1405, ¶ 169. Indeed, combining the teachings of Adams with Kontos to provide a guide catheter with a circular cross-sectional diameter would have been nothing more than combining prior art

elements according to known methods to yield predictable results. *Id.*; *KSR*, 550 U.S. at 416-21.

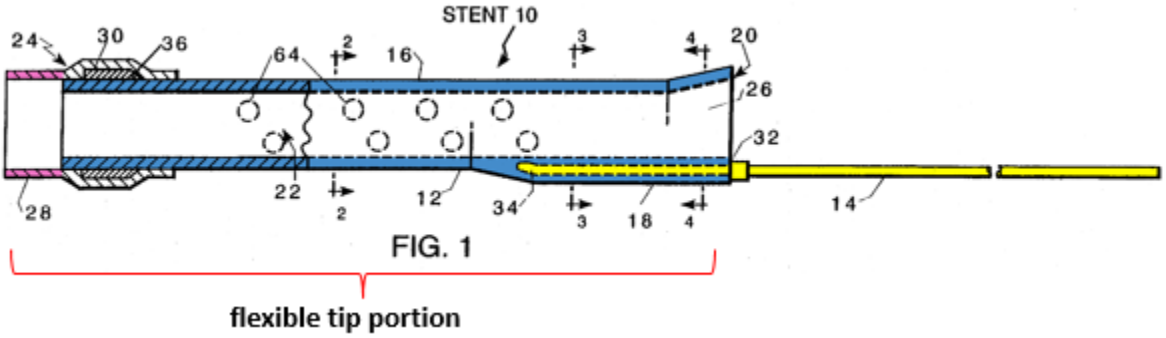
4. [1.b] "a device adapted for use with the guide catheter, including:"

Kontos's support catheter assembly 10 is a device adapted for use with the guide catheter. Ex-1405, ¶ 170. Kontos provides that "[s]upport assembly 10 is composed of two major elements, a body 12 and an insertion/manipulation wire 14." Ex-1409, 3:45-46, Fig. 1. Kontos further explains that "the support catheter can be inserted into and passed through a guide catheter … 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." *Id.*, 2:16-22 (emphasis added).

5. [1.b.i] "a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and"

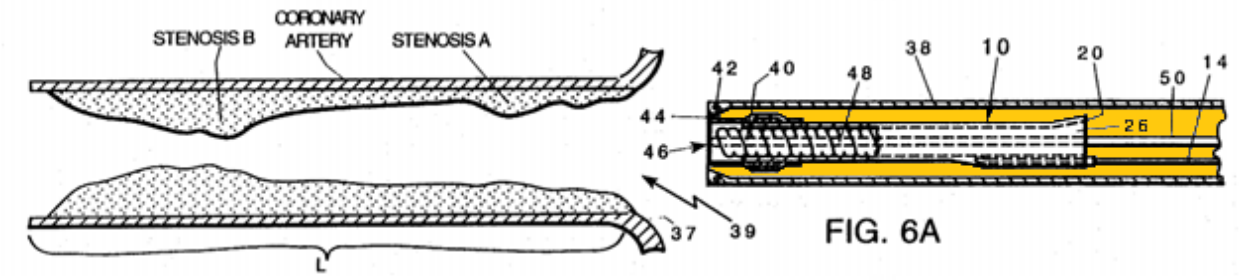
In Kontos's support catheter 10, the body 12 is the "flexible tip portion." Ex-1405, ¶ 171; Ex-1409, 4:1-15; Ex-1442, ¶¶ 60-61. Body 12 is a tubular structure

with a circular cross-section. Ex-1409, 2:51-54, 3:47-57, 4:5-7; Ex-1405, ¶ 171.



Ex-1409, Fig. 1 (color and annotation added).

The flexible tip portion is shorter in length than the predefined length of the continuous lumen of the guide catheter. Ex-1405, ¶ 171. As shown in Figure 6A (reproduced below), Kontos expressly discloses to a POSITA that the length of the body 12 is shorter than the length of the guide catheter 38. *Id.*; Ex-1409, 4:52-54, Figs. 6A-C.



The cross-sectional outer diameter of the tubular structure is sized to be insertable into and travel through the continuous lumen of the guide catheter. Ex-1405, ¶ 171. As shown in Figure 6A (reproduced above), the tubular, flexible tip

portion (body 12) is insertable through the continuous lumen in yellow of the guide catheter 38. *Id.*

Further, the tubular structure defines a coaxial lumen because, as shown in Figure 2 of Kontos, tube 16 of body 12 has a continuous lumen 22, which is coaxial with the outer surface of tube 16. Ex-1409, 3:56-59, 4:48-50, Fig. 2.[9]

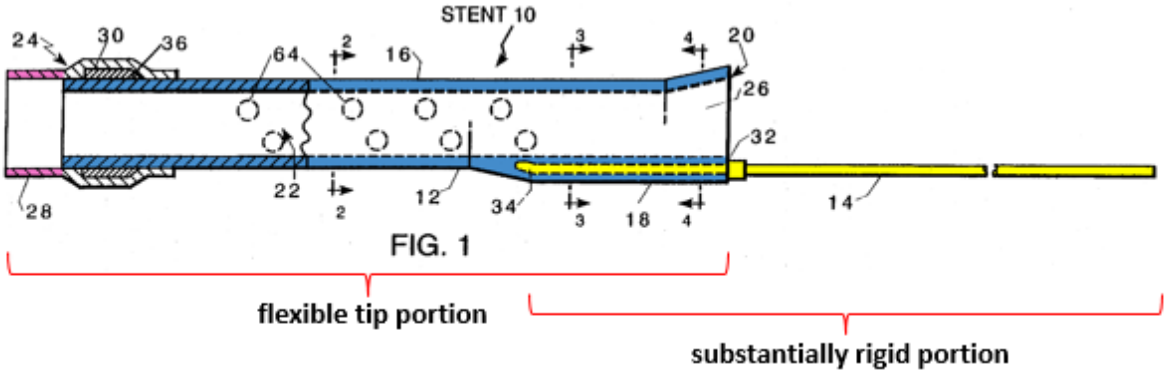
Moreover, an interventional cardiological device, such as a PTCA catheter 40 with balloon 48 is insertable through lumen 22 of tube 16, i.e., through the "cross-sectional inner diameter" of tube 16 and body 12. Ex-1405, ¶ 171; Ex-1409, 4:66-5:2, Figs. 6A-C.

[9] Patent Owner may argue that claim 1 requires the "tubular structure" to be coaxial to the guide catheter. If so, Kontos discloses such a feature. Ex-1405, ¶ 171 (explaining that a vertical cross section of Kontos's Figure 6A demonstrates that the body 12 and guide catheter 38 are coaxial); Ex-1409, Figs. 6A-6B.

6. [1.b.ii] "a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion,[10] defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;"

In Kontos's support catheter 10, the insertion/manipulation wire 14 is the "substantially rigid portion." Ex-1405, ¶ 172; *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-1409, 5:25-30, Figs. 6A-6C. As shown in Figure 1, the substantially rigid portion is located proximal of and "operably connected to" the flexible tip portion (body 12). *Id.*, 4:25-38.

[10] The '380 patent lacks antecedent basis for "the flexible distal tip portion." Petitioner assumes, for purposes of this proceeding, that this is a reference to the "flexible tip portion."



Id., Fig. 1 (color and annotations added).

Based on the known properties of the materials, Kontos expressly discloses to a POSITA that the substantially rigid portion is more rigid along the longitudinal axis than the flexible tip portion. Ex-1442, ¶¶ 59-62. Wire 14 ("substantially rigid portion") is stainless steel, whereas the tube 16 and soft tip 28 of body 12 ("flexible tip portion") are made of polyethylene and copolymer of polyethylene and ethylvinylalcohol ("PVA"), respectively. Ex-1409, 4:1-11, 4:58-61.

As demonstrated in Figure 1, the substantially rigid portion defines a "rail structure without a lumen."[11] Ex-1405, ¶ 172; Ex-1409, 3:45-46, Figs. 3-4

[11] Claim 1 (and claim 12) recite numerous limitations on the substantially rigid portion, including "defining a rail structure without a lumen." Thus, while the substantially rigid portion includes a rail structure without a lumen, the claim does not say it is limited to only that structure (Ex-1477, 138:24-139:10), particularly where it is "operably connected to … the flexible tip portion." Dependent claims 9

(showing wire 14 as a solid material (i.e., no lumen)). Further, wire 14 has a smaller cross-sectional diameter (0.020 inches) than the outer diameter of the tube 16 (0.055 inches) (and therefore, of body 12).[12] Ex-1409, 4:48-50, 4:58-61; Ex-1405, ¶ 172.

Kontos discloses a "combined length" of the flexible tip portion and the substantially rigid portion that is longer than the guide catheter. Ex-1405, ¶ 172. The flexible tip portion (body 12) is approximately twelve inches in length, and the substantially rigid portion (wire 14) "is generally at least about 50 inches long and preferably about 53 inches long." Ex-1409, 4:52-61. Kontos does not disclose the length of the guide catheter, but a POSITA would appreciate that the combined length of the flexible tip portion in combination with the substantially rigid portion is longer than the length of the guide catheter. Ex-1405, ¶ 172 (explaining that the

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and 14 confirm this reading and require the side opening, which necessarily includes a lumen, to be part of the substantially rigid portion.

[12] The claim language "maximal cross-sectional dimension" permits, but does not require, the rail structure to vary in cross-sectional dimension. All the claim requires is that the proximal rail structure cannot have a larger outer diameter than the flexible tip portion (body 12).

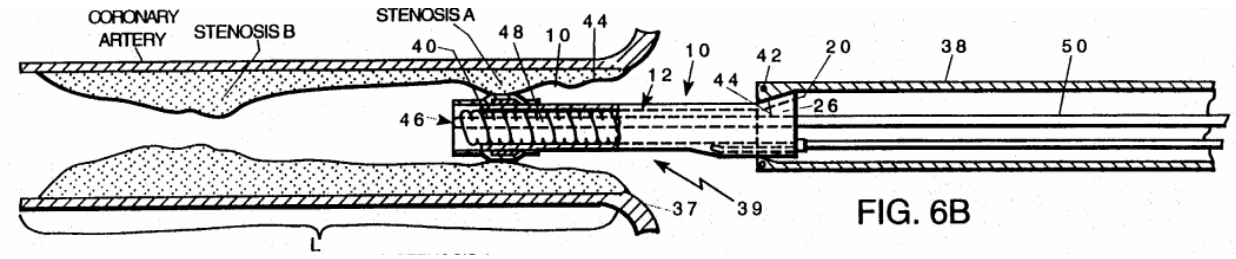
typical guide catheter is 100 cm[13] in length, which is shorter than the combined length of the flexible tip portion and substantially rigid portion—approximately 62 inches or 157 cm—as taught by Kontos).

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-1409, 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 distally to guide catheter 38 while advancing the PTCA catheter 40 with balloon 48. Ex-1405, ¶ 172. In other words, the combined length of the flexible tip portion and the substantially rigid portion must be longer than guide catheter 38. *Id.*, ¶¶ 172-73 (explaining that physician cannot treat a stenosis unless s/he can maintain physical contact with the extension catheter, meaning that it must be longer than GC).

Further, for the reasons discussed above, a POSITA would expect that the proximal end of the substantially rigid portion of Kontos extends proximally

[13] The background of the '380 patent admits that GCs are "one hundred centimeter[s]" in length. Ex-1401, 2:57:60.

through the hemostatic valve even when body 12 of the support catheter 10 extends distally to guide catheter 38, as shown in Figure 6B. *Id.* Specifically, a POSITA would have understood that wire 14 would need to extend proximally through the hemostatic valve regardless of the position of body 12 within the guide catheter 38 because the physician needs physical access to wire 14 to control the movement of body 12. *Id.*; Ex-1409, 9:62-10:15, 11:15-43. Further, a POSITA would expect the use of a single hemostatic valve (especially because the support catheter 10 has a short distal lumen), meaning the proximal portion of the substantially rigid portion extends through the same hemostatic valve as the PTCA catheter. Ex-1405, ¶¶ 172-73.



Ex-1409, Fig. 6B.

Even if it would not have been obvious for the flexible tip portion and substantially rigid portion to (i) have a combined length that is greater than the length of the guide catheter and (ii) extend proximally through the same hemostatic valve as the PTCA catheter in light of Kontos and the knowledge of a POSITA, it would have been obvious to modify Kontos to add these design features in view of

Adams. Ex-1405, ¶¶ 174-76. 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.B.2, *supra*. Further, as shown in Figure 1A, Adams specifically teaches that the combined length of the guide seal 20 (flexible tip portion) and control wire 5 (substantially rigid portion) (i) are greater than that of the guide catheter and (ii) extend proximal to the hemostatic valve 9 when the guide seal extends beyond the distal end of guide catheter 10. Ex-1435, ¶ [0060], Figs. 1A-B (showing only one hemostatic valve); Ex-1405, ¶ 175.

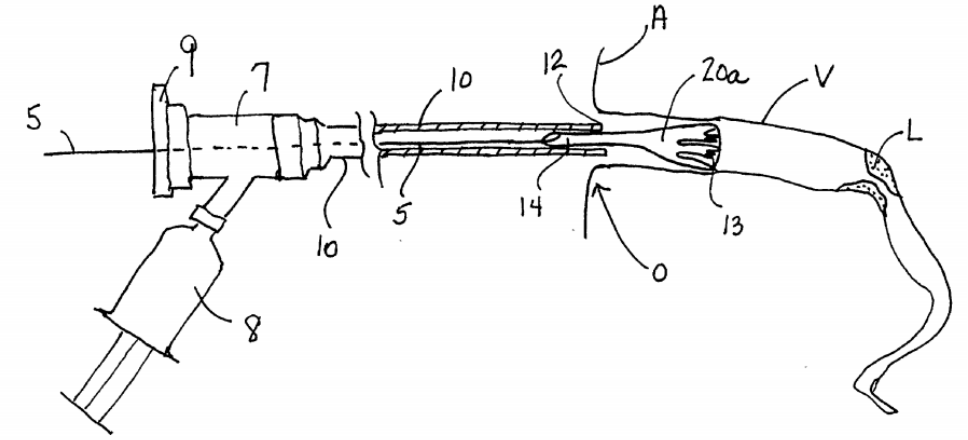


FIG. 1A

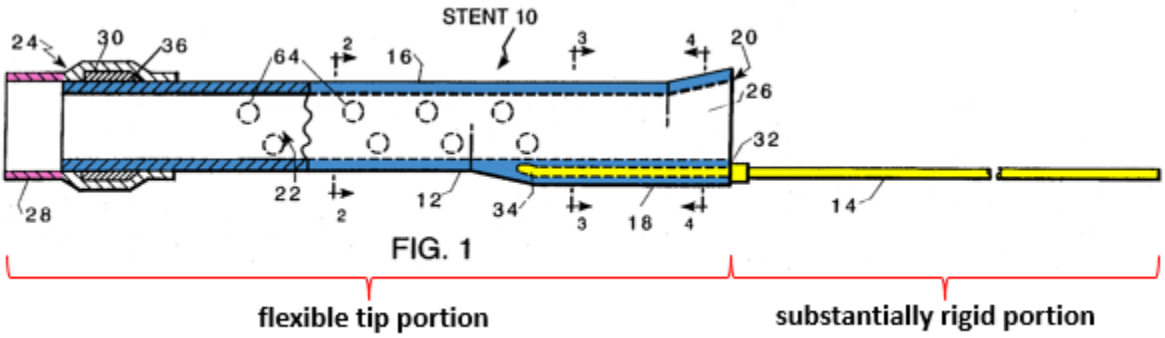
A POSITA would have been motivated to combine these well-known aspects from interventional cardiology, as disclosed by Adams, with Kontos’s disclosure given the latter’s teaching that the catheter assembly should “us[e] known medical procedures.” Ex-1409, 5:11-15; Ex-1405, ¶ 175. It would have been obvious to a

POSITA to modify Kontos (to the extent not already obvious based on a POSITA's knowledge) to add these claimed design features. Ex-1405, ¶¶ 174-76.

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-1405, ¶ 176. Indeed, combining the teachings of Adams with Kontos to provide a flexible tip portion and substantially rigid portion that is longer than the guide catheter and extends through a hemostatic valve that is commonly shared with an interventional cardiology device would have been nothing more than combining prior art elements according to known methods to yield predictable results. *Id.*

Finally, out of an abundance of caution, Petitioner notes that claim 1 requires the substantially rigid portion to be "proximal of" the flexible tip portion, and recites a combined "total length" of both portions. Should Patent Owner argue that these limitations require the entirety of the substantially rigid portion to be proximal of the entirety of flexible tip portion (Ex-1477, 123:14-17, 124:19-25, 127:24-128:14, 129:20-130:4), such that one structure does not overlap with the other, the results do not change. Ex-1405, ¶¶ 177-78. First, that interpretation is wrong. The two structures are "operably connected" as claimed and clearly two structures can overlap to connect. Ex-1401, 6:58-59, 9:43-45 (describing welding

bonding or adhesive). Second, even if they cannot overlap, Kontos can also be applied under that interpretation. Ex-1405, ¶¶ 177-78.



Ex-1409, Fig. 1 (color and annotations added).

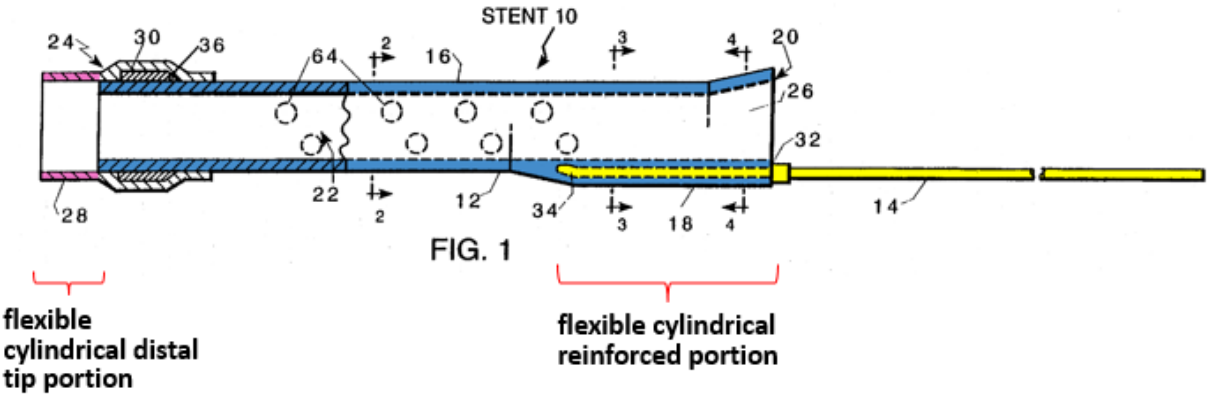
Mapping the portion of wire 14 that does not overlap with body 12 to the "substantially rigid portion" does not affect the analysis of the other claim limitations of claim 1. The substantially rigid portion, that is solely a rail structure without a lumen, would still be more rigid along the longitudinal axis and have a maximal cross-sectional dimension at a proximal portion that is less than the flexible tip portion. Ex-1405, ¶ 178; Ex-1442, ¶¶ 59-62. Moreover, the "combined length" of these portions (i.e., body 12 and portion of wire 14 outside of body 12) would be longer than that of the guide catheter. Ex-1405, ¶ 178; Ex-1409, 4:53-62. Finally, both Kontos alone and Kontos in combination with Adams disclose or suggest that the proximal end of the substantially rigid portion (wire 14) of Kontos extends proximally through the same hemostatic valve as the PTCA catheter even

when body 12 of the support catheter 10 extends distally to guide catheter 38, as shown in Figure 6B. Ex-1405, ¶ 178.

7. [1.b.iii] "wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion."

In Kontos's support catheter 10, the body 12 is the "flexible tip portion defining a tubular structure." Ex-1405, ¶ 179. The tubular structure (body 12) must also have a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion. As construed above, "reinforced portion" means a "portion made stronger by additional material or support." *See* Section VI, *supra*.

This limitation is satisfied by comparing the portion of body 12 that is coextensive with receiving hole 34 ("flexible cylindrical reinforced portion") to the portion of body 12, including soft tip 28, that is distal to the distal-most portion of tube 16 ("flexible cylindrical distal tip portion").



Ex-1409, Fig. 1 (color and annotations added). The proximal end of body 12 is the attachment location for the substantially rigid portion (wire 14).[14] *Id.*, 4:25-27, Fig. 1. One way to attach the substantially rigid portion, as shown in Figure 1, is to insert the substantially rigid portion into a receiving hole 34 that is located on the proximal end of body 12. *Id.*, 4:27-31. Thus, the proximal end of body 12—that is located proximal to soft tip 28—constitutes the "flexible cylindrical reinforced portion" because it provides more material and more support. Ex-1405, ¶ 179. A POSITA would have understood that the "flexible cylindrical reinforced portion" is less flexible than the portion of body 12 that is distal to the distal-most portion of tube 16. *Id.*; Ex-1442, ¶ 62.

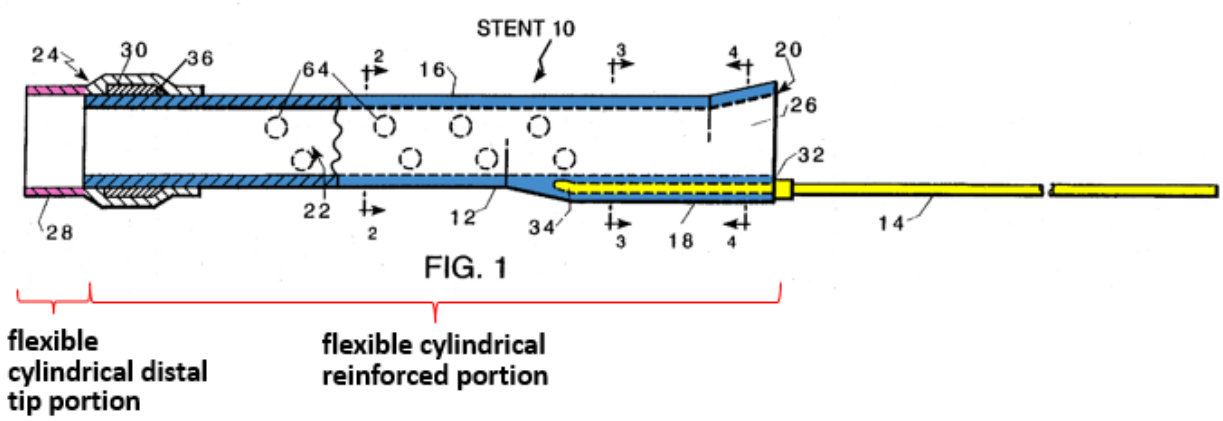
Even if Kontos does not disclose a "flexible cylindrical reinforced portion," it would have been obvious based on the knowledge of a POSITA to modify Kontos by adding metallic coiling or braiding (i.e., reinforcement) to tube 16. Ex-1405, ¶¶ 180-90; Ex-1442, ¶¶ 71-78. Metallic braiding or coiling was ubiquitous

[14] As discussed above, wire 14 is the substantially rigid portion. *See* Section VII.B.6, *supra*. This does not mean, however, that wire 14 cannot also satisfy the limitation reciting a "flexible cylindrical reinforced portion." Indeed, "a single element, feature, or mechanism can ordinarily satisfy multiple claim limitations." *Google LLC v. Pers. Audio, LLC*, 743 F. App'x 978, 985 (Fed. Cir. 2018).

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-1405, ¶ 180; Ex-1442, ¶¶ 74-78; Ex-1408, 6:66-7:7; Ex-1446, Abstract; Ex-1447, Abstract.

Should the Board require a reference to combine, Adams discloses braiding/coiling. Ex-1405, ¶ 188. 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. *Id.* In Adams, guide seal 30 is the the device adapted for use with the guide catheter as taught by the ’380 patent. *Id.*; Ex-1435, Fig. 3A. Adams discloses stainless steel or nitinol braiding in a polymer of the guide seal 30. Ex-1435, [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-1405, ¶¶ 180, 188; Ex-1442, ¶¶ 72-73, 75; Ex-1435, [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”); Ex-1446, Abstract; Ex-1447, 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-1405, ¶ 189; Ex-1442, ¶¶ 77-78.

If Kontos was reinforced with metallic braiding/coiling, then tube 16 would be the proximally-located, "flexible cylindrical reinforced portion." Ex-1405, ¶ 190. The portion of body 12 that is distal to tube 16, including soft tip 28, would remain the distally-located "flexible cylindrical distal tip portion." *Id.* A POSITA would have understood that if metallic braiding/coiling was added, tube 16 would be less flexible than the "flexible cylindrical distal tip portion." *Id.*; Ex-1442, ¶ 62.



Ex-1409, Fig. 1 (color and annotations added).

C. Claim 2: The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.[15]

The Kontos-Adams combination discloses claim 2. Ex-1405, ¶¶ 191-99; Ex-1442, ¶¶ 79-84. 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-1401, Abstract; 5:6-27. The ’380 patent explains that, essentially, it is the combination of a GC and an extension catheter inserted into a coronary ostium that improves distal anchoring of

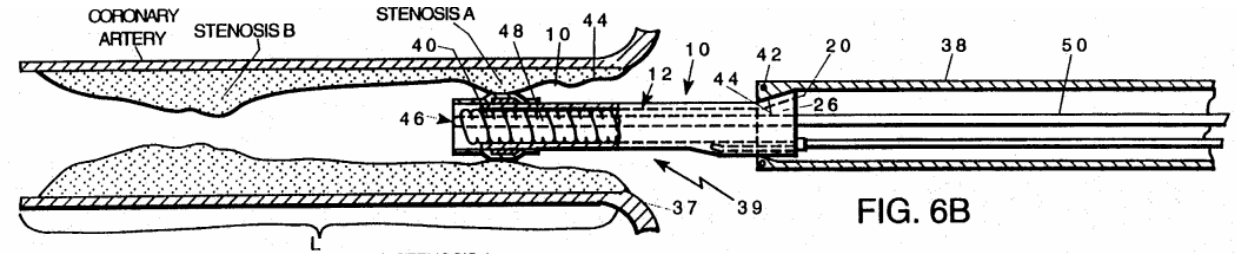
[15] Claim 2 recites an intended use—“the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”—that should be afforded no patentable weight. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Out of an abundance of caution, Petitioner addresses this claim limitation.

the system, and that the presence of the extension catheter in the GC provides "stiffer back up support" than a GC alone. *Id*., 8:18-32. This combination is what allows the claimed system to resist dislodgement. Ex-1405, ¶¶ 191, 198-99.

As discussed for claim 1, 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-1409, 5:11-15. Kontos further provides that "the support catheter can be 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." *Id.*, 2:16-22, Figs. 6A-C (showing proximal end of body 12 within guide catheter 38). 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 2. Ex-1405, ¶ 191.

D. Claim 3: The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

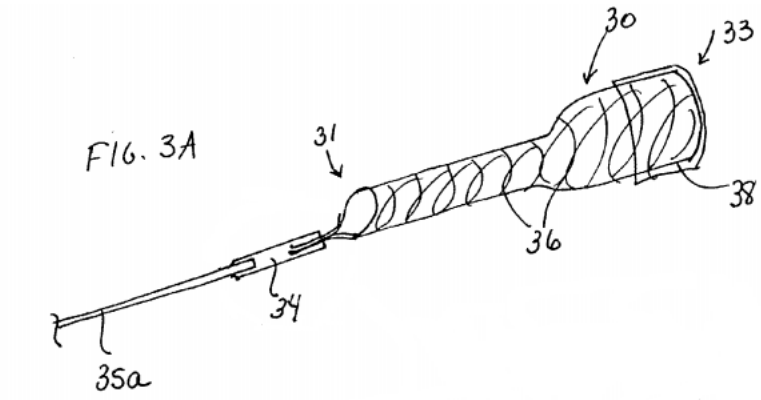
The combination of Kontos and Adams teach this limitation of the '380 patent. Ex-1405, ¶¶ 200-15. As discussed for claim 1, Kontos teaches that the interventional cardiology device is insertable into the coaxial lumen of the tubular structure (body 12). *See* Section VII.B.5, *supra*; Ex-1409, Fig. 6B; Ex-1405, ¶ 200. Kontos also shows in Figure 6B that the proximal portion of the tubular structure remains within the lumen of the guide catheter. Ex-1409, Fig. 6B. Thus, Kontos discloses "wherein the proximal portion of the tubular structure further comprises structure … accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." *Id.*



Ex-1409, Fig. 6B.

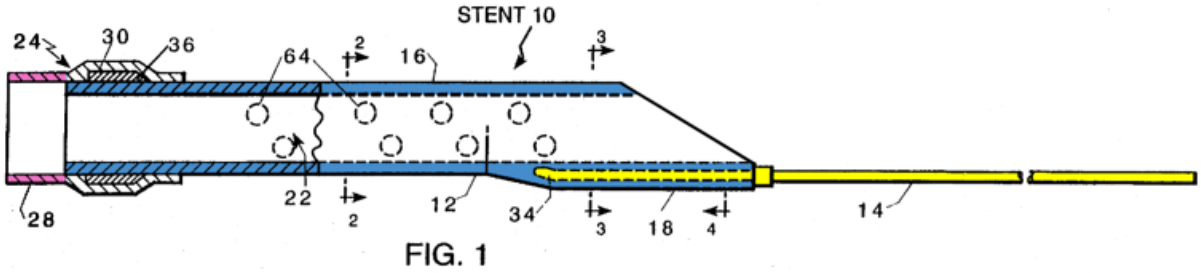
Kontos does not teach, however, that the proximal portion of the tubular structure has a side opening extending for a distance along the longitudinal axis. As seen in Kontos's Figure 1, the proximal opening of tube 16 does not extend along the longitudinal axis of the tubular structure, meaning it is not a side opening. Proximal side openings falling within the scope of claim 3 were, however, well-known in the art. Ex-1405, ¶¶ 95-108, 202; Ex-1407, 4:15; Ex-1408, 12:9-13:60, Fig. 6A-6E; Ex-1418, Fig. 7; Ex-1432, 119, Fig. 1; Ex-1433, [0035], [0049], Fig. 2; Ex-1435, [0066]; Ex-1450, Fig.7; Ex-1461, 6:9-11, Fig. 1B.

Adams is one such catheter assembly that uses a proximal side opening. Ex-1405, ¶¶ 201-03. In particular, Adams teaches a guide seal 30 (tubular portion) with proximal end 31 that "is preferably cut or formed at an angle." Ex-1435, [0066].



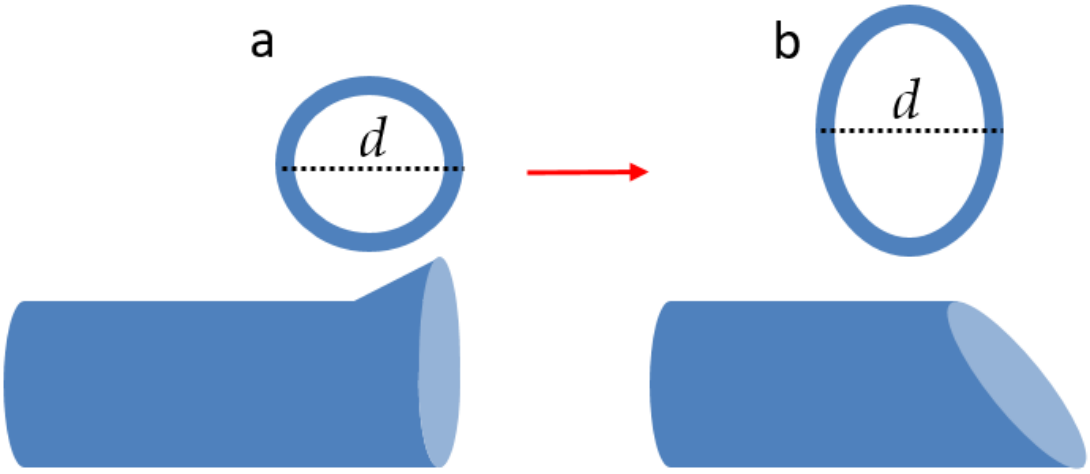
Id., Fig. 3A.

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-1405, ¶ 201.



Ex-1409, 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 the tube 16 of body 12, as taught by Adams, for multiple reasons. Ex-1405, ¶ 204-14; Ex-1442, ¶¶ 87-90, 97-103. 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-1405, ¶ 205; Ex-1442, ¶ 100.

In 1995, when Kontos issued, the GCs were typically 7-8 French in diameter. Ex-1405, ¶ 206. But by the purported priority date, use of a 6 French GC had become more common. *Id*. These smaller GCs had several advantages (*id.*), but as the diameter of a GC decreases, so too does the diameter of the extension catheter. This, in turn, means that the proximal opening 20 of Kontos's tubular structure (tube 16) must decrease. *Id.*; Ex-1409, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex-1405, ¶ 207. Therefore, as an alternative to the flared proximal opening 26 of the tubular structure (tube 16) in Kontos, a POSITA would have been motivated to use a side opening, as then the diameter of the CG could be reduced without causing a commensurate reduction in the area of the proximal opening of the tubular structure of the extension catheter. Ex-1405, ¶¶ 205-07; Ex-1442, ¶ 100.

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-1408, 6:52-57; *see also* Ex-1405, ¶¶ 208-10; Ex-1442, ¶¶ 101-02; Ex-1426, 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-1405, ¶ 208-10; Ex-1442, ¶¶ 101-02. 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.[16] Ex-1405, ¶ 208-10; Ex-1442, ¶¶ 101-02.

Third, a POSITA additionally would have been motivated to use a proximal side opening because such a design promotes "smoother passage" of the catheter

[16] Kontos itself reflects the same concern, and provides funnel 26 to aid insertion of a therapy catheter. Ex-1409, 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.

assembly as it navigates the tortuous vasculature. Ex-1408, 6:52-57; *see also* Ex-1405, ¶ 211; Ex-1425, Abstract, [0034]. In other words, adding a side opening to the distal lumen of the extension catheter reduces the amount of force a physician must exert to advance the catheter through winding vasculature. Ex-1405, ¶ 211; Ex-1442, ¶ 103.

Fourth, a POSITA was motivated to add a proximal side opening to the extension catheter because doing so permitted smooth re-entry if the proximal end of the extension catheter was extended beyond the distal end of the GC. Ex-1405, ¶¶ 212-14; Ex-1442, ¶¶ 97-99. 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, stenosis B." Ex-1409, 6:22-25.

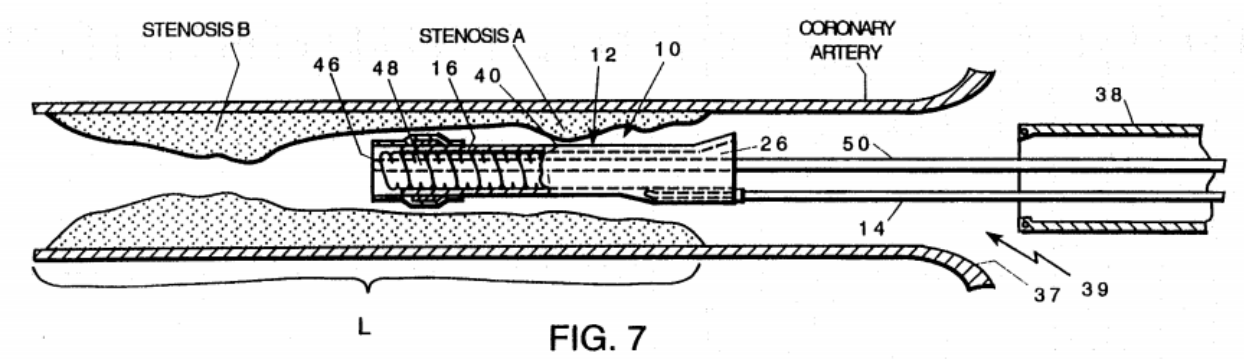


FIG. 7

Id., Fig. 7.

In such an embodiment, after the angioplasty is performed, the support catheter 10 must return to the guide catheter 38. Ex-1405, ¶ 213; Ex-1442, ¶ 97. A

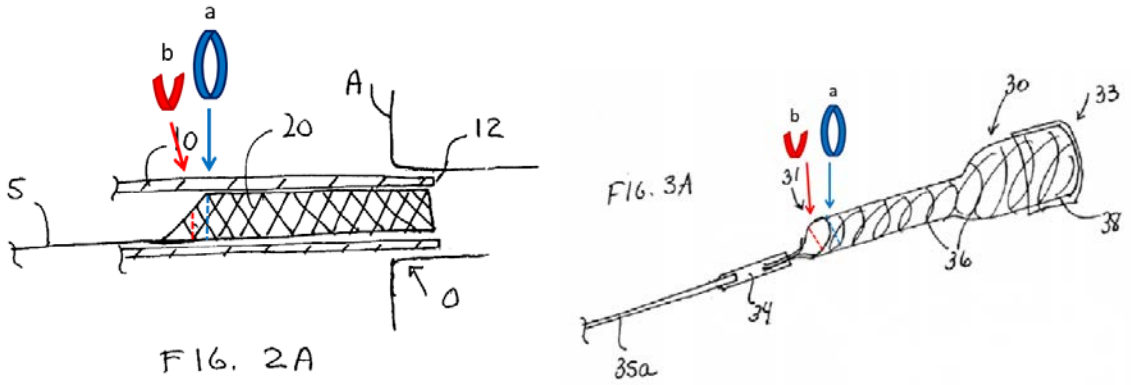
POSITA would recognize, however, that a flared proximal opening of the tubular structure (body 12) was a poor design choice, as this protrusion could damage the internal coronary wall and hinder re-entry of the tubular structure into the GC. Ex-1405, ¶ 213; Ex-1442, ¶ 98. The smaller cross-sectional 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-1405, ¶ 213; Ex-1442, ¶ 99.

In fact, Adams provided this exact rationale for using a proximal side opening on the guide seal. Ex-1435, [0066] ("Proximal end 31 is preferably cut or formed at an angle to the seal axis to facilitate unimpeded entry of the seal's proximal end into the distal end of the guide catheter."). 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 the tubular structure to aid in the retraction and re-insertion of the tubular structure into the GC, if it were necessary to do so. Ex-1405, ¶ 214.

The prior art, including Adams, shows that the use of a proximal side opening was well-known. Ex-1405, ¶ 215. 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. *Id.*; Ex-1442, ¶ 104.

E. Claim 4: The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

As discussed for claim 3, a POSITA would have been motivated, with a reasonable expectation of success, to design the tubular structure of Kontos with a proximal side opening. Ex-1405, ¶ 216. Thus, in the Kontos-Adams combination, the proximal side opening necessarily would encompass a partial circumference portion and a full circumference portion. Indeed, a cross-section of the circular guide catheter 10 and guide seal 20 (extension catheter) of Adams shows the partially cylindrical portion (red) and a full circumference portion (blue). *Id.*



Ex-1435, Figs. 2A, 3A (color and annotations added).

F. Claim 6: The system of claim 1, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

As discussed for claim 1, it would have been obvious to add metallic braiding/coiling to tube 16—thereby making it the "flexible cyclindrical reinforced portion"—of Kontos's body 12. Section VII.B.7, *supra*. Specifically, Adams

teaches using metallic elements in a braided or coiled pattern. Ex-1435, [0066] ("The guide seal is substantily tubular and comprises stainless steel or nitinol braid 36 …."); *id.* [0049], Fig. 3A. For the same reasons discussed for claim 1, it would be obvious to add metallic braiding or coiling to tube 16 of Kontos in view of Adams (Section VII.B.7, *supra*), meaning this claim element would be met. Ex-1405, ¶ 217.

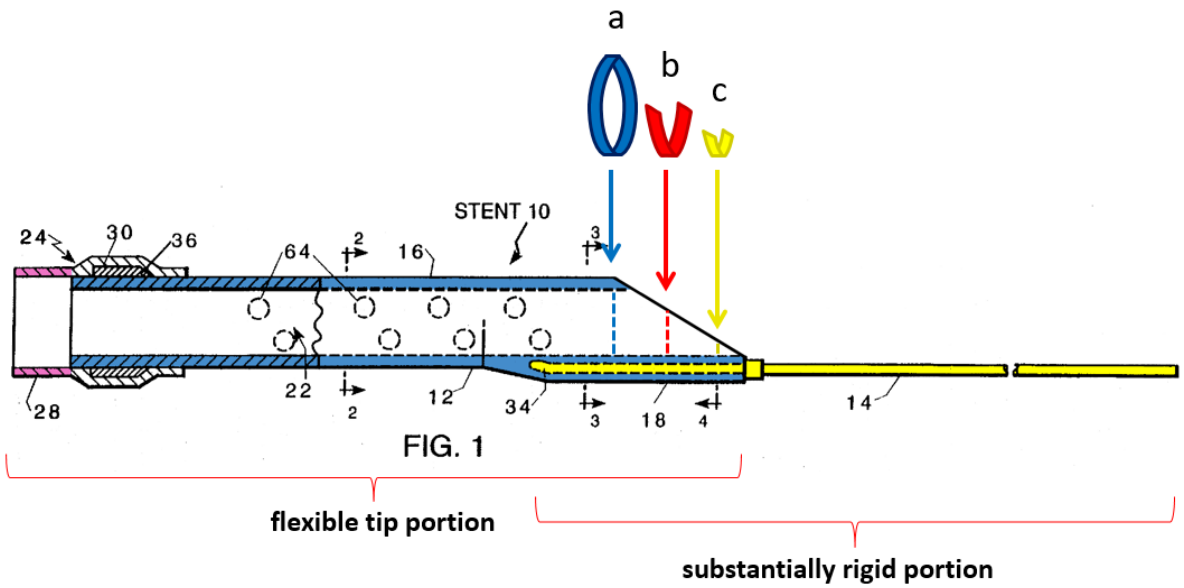
G. Claim 7: The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

Kontos or the Kontos-Adams combination teaches claim 7. Ex-1405, ¶ 218. Kontos explains that "marker band 30 [(radiopaque marker)] may be retained between soft tip 28 and tube 16." Ex-1409, 4:19-21. As a result, the flexible cylindrical distal tip portion, which is the portion of Kontos's body 12 that is distal to the distal-most portion of tube 16 (Section VII.B.7, *supra*), includes a radiopaque marker proximate a distal tip. Ex-1405, ¶ 218.

H. Claim 9: The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.[17]

The Kontos-Adams combination teaches claim 9. Ex-1405, ¶ 223. As discussed for claim 3, a POSITA would have been motivated, with a reasonable expectation of success, to design the tubular structure of Kontos with a proximal side opening. *See* Section VII.D, *supra*. Further, tube 16 is cylindrical with "a continuous lumen 22 therethrough." Ex-1409, 3:49-50; *see also id.*, 3:56-57, Fig. 6C.

[17] For purposes of consistency between claims 1 and 9, Petitioner notes that the "substantially rigid portion" must include "a rail structure without a lumen," but may include structure in addition to the rail structure, which is the full circumference portion of claim 9.



Ex-1409, Fig. 1 (annotations and color added).

As shown above in Figure 1, the extension of wire 14 into body 12 creates a substantially rigid portion with a side opening at the distal end of tube 16.[18] Ex-1405, ¶ 223. As a result, the substantially rigid portion necessarily includes, from distal to proximal direction, a cross-sectional shape having a full circumference

[18] As discussed above, the "substantially rigid portion" may include more than just the rail structure. In particular, the substantially rigid portion of the support catheter 10 may also encompass a tube 16, which is made rigid by insertion of wire 14 into receiving hole 34.

portion (blue), a hemicylindrical portion (red), and an arcuate portion (yellow).[19] Ex-1405, ¶ 223.

I. Claim 12

1. [12.pre] "A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:"

As discussed for claim 1, Kontos discloses this claim element. *See* Section VII.B.1, *supra*; Ex-1405, ¶ 224.

2. [12.a.i] "a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery,"

As discussed for claim 1, Kontos or Kontos in view of Adams and/or the knowledge of a POSITA discloses this claim element. *See* Section VII.B.2, *supra*; Ex-1405, ¶ 225.

3. [12.a.ii] "the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter;"

[19] The specification of the '380 patent states that a hemicylindrical portion "desirably includes 40% to 70% of the circumference of the tube" and that an arcuate portion "extends from 25% to 40% of the circumference of the tube." Ex-1401, 7:1-2, 7:6-7.

This language differs from claim 1 only insofar as claim 12 recites a "circular cross section." This additional language is taught by Kontos or Kontos in view of Adams and/or the knowledge of a POSITA for the same reason it teaches a circular cross-sectional inner diameter of the guide catheter. *See* Section VII.B.3, *supra*; Ex-1405, ¶ 226.

4. **[12.b] "a device adapted for use with the guide catheter, including:"**

Kontos's support catheter 10 is the device adapted for use with the guide catheter. Ex-1405, ¶ 227. As explained below, the device and elongate structure are the same structure in the "system" described in claim 12. *See* Section VII.I.5-9, *infra* (analysis and citations for remaining element of claim 12).

5. **[12.b.i] "an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:"**

Kontos's support catheter 10 is the "elongate structure." Ex-1405, ¶ 228. The "[s]upport assembly 10 is composed of two major elements, a body 12 and an insertion/manipulation wire 14." Ex-1409, 3:45-46, Fig. 1. As discussed above, a POSITA knew that the combined length of the body 12 and insertion/manipulation wire 14 was longer than the length of the guide catheter. Section VII.B.6, *supra*. Regardless, as discussed above, a POSITA would have found it obvious to

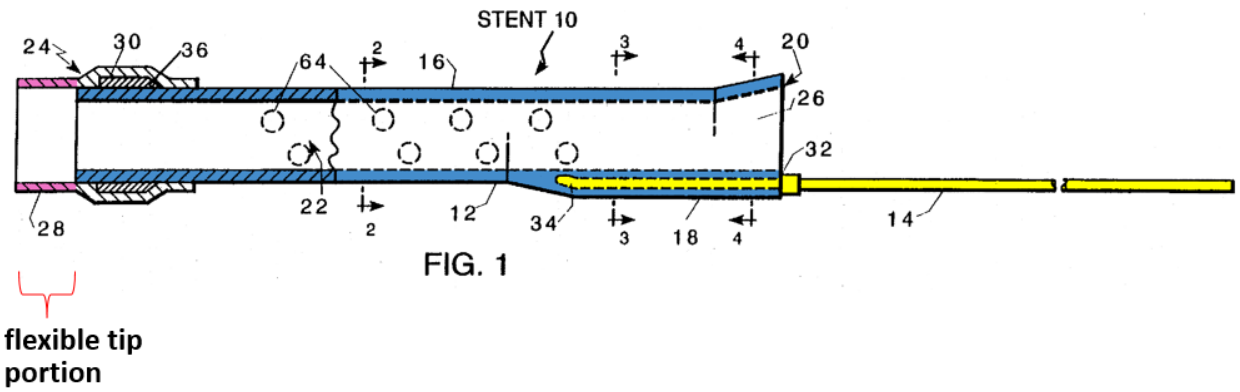
combine Adams's teachings with Kontos, thereby using an elongate structure that is longer than the guide catheter. *Id.*

6. **[12.b.ii] "a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;"**

For claim 12,[20] Kontos's soft tip 28 is the "flexible tip portion." Ex-1405, ¶ 229; Ex-1442, ¶ 60; Ex-1409, 4:5-15.

[20] In general, use of the same words in different claims have the same meaning. Here, however, in claim 1 "flexible tip portion" includes both the "flexible cylindrical distal tip" and the "flexible cylindrical reinforced portion." *See* Section VII.B.7. That is not the case for claim 12, where Patent Owner separately recites the "reinforced portion," which is different than and proximal to the "flexible tip portion."

Patent Owner also drafted claim 12 such that the substantially rigid portion is "connected to" the flexible tip portion in 12.b.iv. The only disclosure in the specification, though, is an indirect connection. For purposes of this IPR, and not



Ex-1409, Fig. 1 (color and annotation added).

The flexible tip portion "generally is cylindrical in shape and extends coaxially from distal end 34 of tube 16." Ex-1409, 4:5-7. As shown in Figures 6A-C, the circular cross-section of the flexible tip portion is smaller than, and insertable through, the continuous lumen of the guide catheter. Ex-1405, ¶ 229. Further, these same figures demonstrate that the length of the flexible tip portion is shorter than that of the guide catheter. *Id.*; *see also* Ex-1409, 4:54-58, Figs. 6A-C. The coaxial lumen of the guide catheter and flexible tip portion have a cross-

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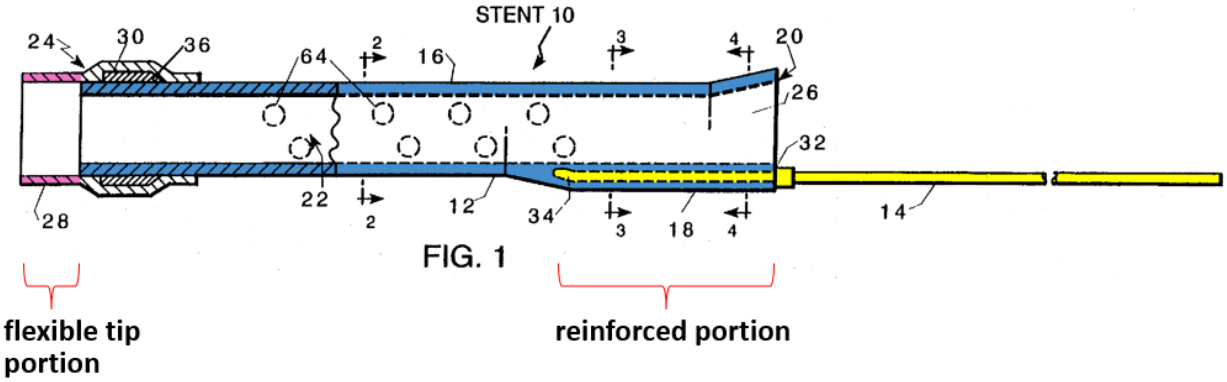
for district court litigation, Petitioner assumes that claim 12 allows for an indirect connection, because the claim would otherwise not make sense. Under any interpretation, this is simply an example of poor claim drafting and there is no inventive concept here worthy of patent protection in light of the prior art.

sectional diameter through which interventional cardiology devices (e.g., PTCA catheter 40) are insertable. Ex-1409, Figs. 6A-C; Ex-1405, ¶ 229.

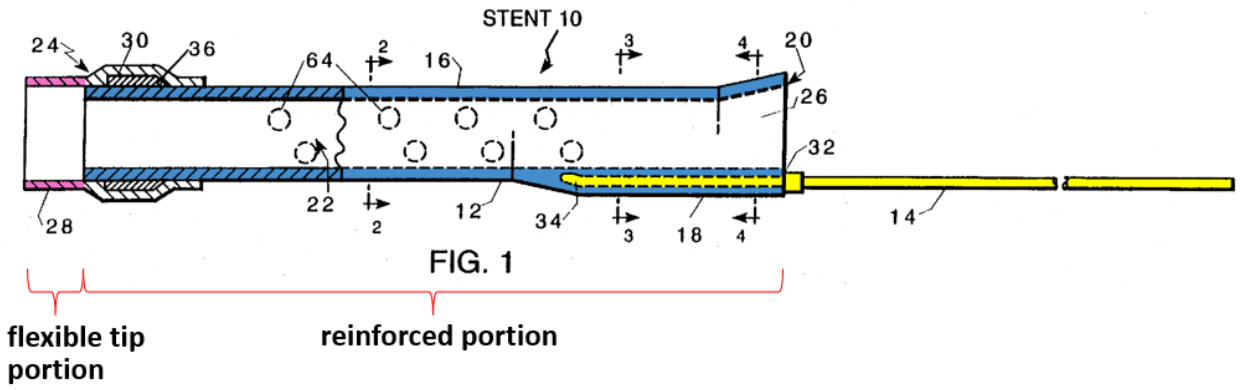
7. [12.b.iii] "a reinforced portion proximal to the flexible tip portion;"

For claim 12, Kontos or the Kontos-Adams combination teaches a reinforced portion proximal to the flexible tip portion. Ex-1405, ¶ 230. According to Patent Owner, the tip portion and reinforced portion need not be physically connected. Ex-1477, 121:16-24. Under such an interpretation of claim 12, as shown below, the reinforced portion is the part of tube 16 that is co-extensive with receiving hole 34. Ex-1405, ¶ 230.



Ex-1409, Fig. 1 (color and annotations added).

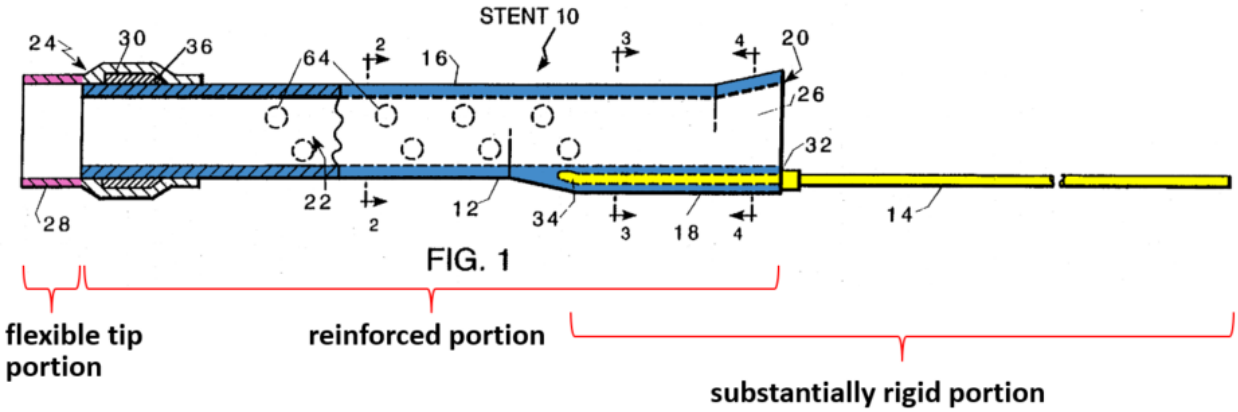
Further, as discussed for claim 1, it would have been obvious to add metallic braiding/coiling to the tube 16. *See* Section VII.B.7, *supra*. If braiding/coiling is added, then tube 16 becomes the reinforced portion, as shown below. Ex-1405, ¶ 230.



Ex-1409, Fig. 1 (color and annotation added).

8. **[12.b.iv] "a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;" and**

For claim 12, Kontos's insertion/manipulation wire 14 is the "substantially rigid portion." Ex-1405, ¶ 231; *see also* Section VI, *supra* (construing "substantially rigid"). Wire 14 is used to advance support catheter 10 within the guide catheter. Ex-1409, 9:25-34, Figs. 6A-6C. As shown in Figure 1, the substantially rigid portion is proximal of and connected to (through the reinforced portion) the flexible tip portion. Ex-1405, ¶ 231.



Ex-1409, Fig. 1 (color and annotation added).[21]

Wire 14 is stainless steel, whereas the soft tip 28 is "composed of any highly flexible material," but preferably a copolymer of polyethylene and EVA. Ex-1409, 4:5-11. Based on the known properties of these materials, Kontos expressly discloses to a POSITA that the substantially rigid portion was more rigid along the longitudinal axis than the flexible tip portion. Ex-1442, ¶¶ 59-62.

[21] 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.I.7, *supra*. While both options are always applicable, for sake of simplicity, Petitioner hereinafter shows the outer bounds of the reinforced portion.

The substantially rigid portion is a rail structure without a lumen and has a smaller cross-sectional diameter (0.020 inches) than the outer diameter of the soft tip (0.055 inches). Ex-1405, ¶ 231; Ex-1409, 4:48-61.

As shown in Figure 6B, when a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter 38, the proximal end of the reinforced portion remains within the continuous lumen (yellow) of the guide catheter. Ex-1405, ¶ 231.

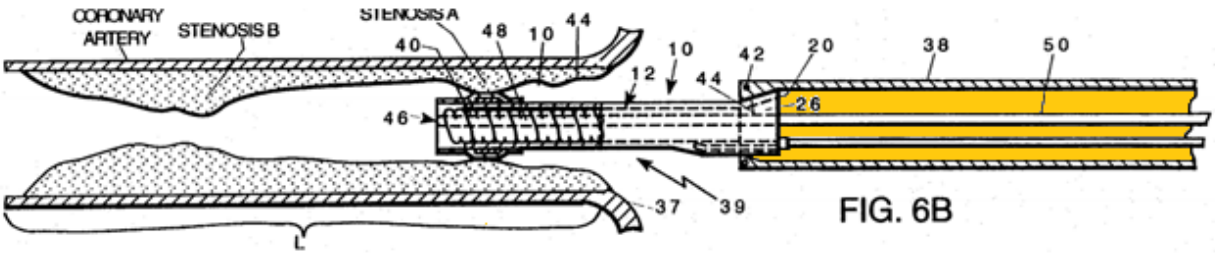


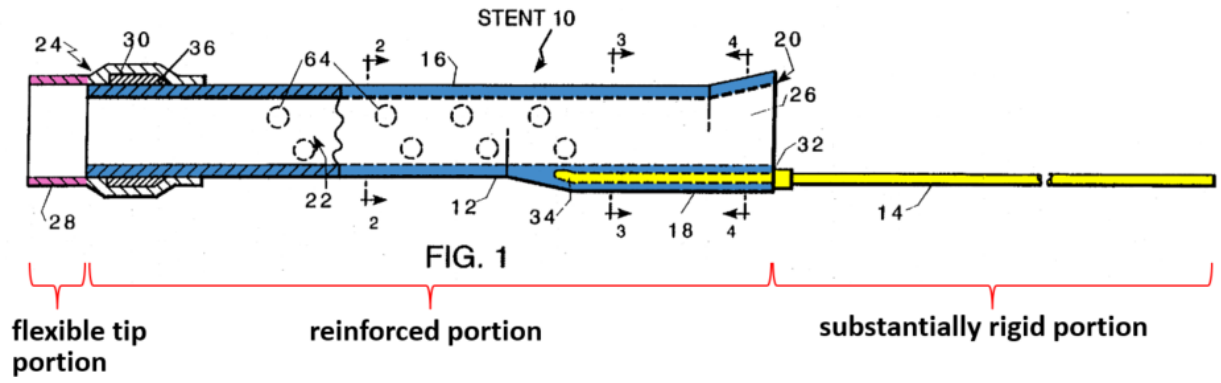
FIG. 6B

As discussed for claim 1, in such a scenario, a POSITA would expect that the proximal end of the substantially rigid portion (wire 14) extends proximally through the hemostatic valve. Section VII.B.2, *supra*.[22] Finally, in such a system (especially because the support catheter 10 has a short distal lumen), a POSITA would expect that only one hemostatic valve is implemented, such that the substantially rigid portion and interventional cardiology device pass through the

[22] Regardless, as also discussed claim 1, Kontos in combination with Adams renders this claim element obvious. Section VII.B.2, *supra*.

same hemostatic valve. Ex-1405, ¶ 231; *see also* Ex-1435, Fig. 1A (showing only one hemostatic valve).

As with claim 1, Patent Owner may argue that the entirety of the substantially rigid portion must be proximal of the reinforced portion. In such a scenario, as shown below, Kontos nevertheless teaches that the substantially rigid portion is located proximal of and connected to (through the reinforced portion) the flexible tip portion. Ex-1405, ¶¶ 232-33.



Ex-1409, Fig. 1 (color and annotation added).

Mapping the portion of wire 14 that does not overlap with body 12 to the "substantially rigid portion" does not affect the analysis of the other claim limitations of claim 12. The substantially rigid portion, that is solely a rail structure without a lumen, would still be more rigid along the longitudinal axis and have a maximal cross-sectional dimension at a proximal portion that is less than the flexible tip portion. Ex-1405, ¶ 232-33; Ex-1442, ¶¶ 59-62. Finally, both Kontos alone and Kontos in combination with Adams disclose or suggest that when a

distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter 38, the proximal end of the reinforced portion remains within the continuous lumen of the guide catheter, while the proximal end of wire 14 extends through a hemostatic valve in common with the interventional cardiology device. Ex-1405, ¶¶ 232-33; Ex-1409, Fig. 6B.

9. **[12.b.v] "wherein the flexible tip portion is more flexible than the reinforced portion"**

The flexible tip portion (soft tip 28) is more flexible—regardless of whether tube 16 of Kontos is reinforced with metallic braiding or coiling—than the reinforced portion. *See* Section VII.B.7, *supra*; Ex-1405, ¶ 234.

J. Claim 13: The system of claim 12, wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.[23]

Kontos discloses the limitation of claim 13. Ex-1405, ¶ 235. Kontos discloses that a distal portion of soft tip 28 ("flexible tip portion") is insertable through the

[23] Claim 13, like claim 2, appears to assert an intended use that should be afforded no patentable weight. *See* footnote 15, *supra*. Petitioner addresses this claim limitation out of an abundance of caution.

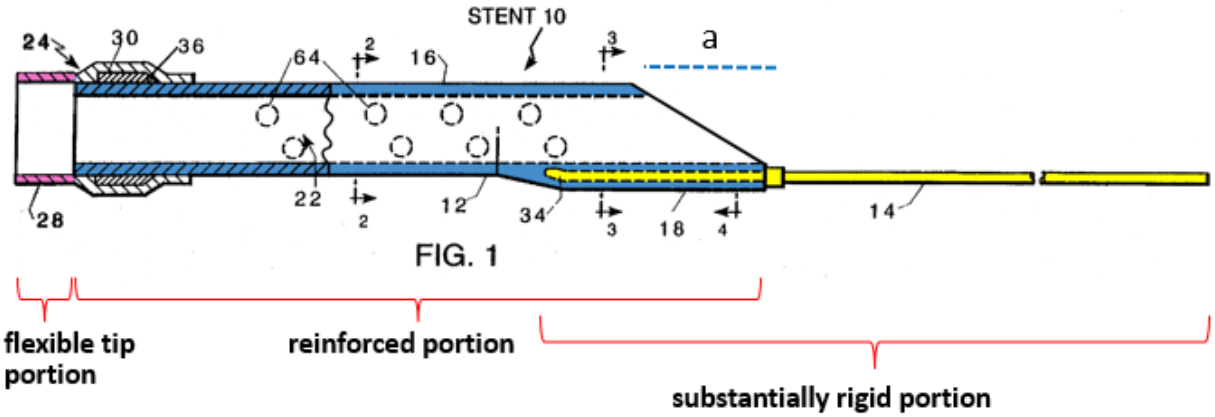
continuous lumen of guide catheter 38 and extends beyond the distal end of guide catheter 38. Ex-1409, 3:50-52, 5:31-59, Figs. 6A-C. When the soft tip 28 extends beyond the distal end of guide catheter 38 into the coronary artery, support catheter 10 ("the device") assists in resisting axial and shear forces as claimed. Section VII.C, *supra*; Ex-1405, ¶ 235.

K. Claim 14: The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

The Kontos-Adams combination teaches claim 14. Ex-1405, ¶ 236. As discussed for claim 3, a POSITA would have been motivated, with a reasonable expectation of success, to design the tubular structure of Kontos with a proximal side opening. *See* Section VII.D, *supra*. The proximal end of the tubular structure of claim 3 is also the reinforced portion of claim 12, meaning a POSITA would similarly have found it obvious to add a proximal side opening in the reinforced portion. Ex-1405, ¶ 236.

As shown below in Figure 1 (modified by Petitioner), if the reinforced portion and the substantially rigid portion overlap, then the proximal side opening extends substantially along at least a portion of a length of the substantially rigid portion

(shown by horizontal line marked "a"). Ex-1405, ¶ 236. Finally, as discussed for claim 12, the coaxial lumen receives the interventional cardiology device passed through continuous lumen of the guide catheter. *See* Section VII.I.3-6, *supra*.



Ex-1409, Fig. 1 (modified and color and annotations added).

L. Claim 15: The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

The Kontos-Adams combination teaches claim 15. Ex-1405, ¶ 237. As discussed for claim 12, the support catheter 10 (the "device") (i) is inserted into the continuous lumen of the guide catheter and (ii) extends an overall effective length of a coaxial lumen traversed by the interventional cardiology device (e.g., PTCA catheter 40). *See* Section VII.I.8, *supra*. Moreover, as discussed above, the interventional cardiology device may be inserted while using only one hemostatic valve. *Id.* Further, Kontos teaches that the support structure 10 can be inserted into

and placed within the guide catheter before insertion of the interventional cardiology device. Ex-1409, 7:45-52 (noting that "[b]ody 12 could be inserted first" into GC, and then "followed by the PTCA catheter 40"); *see also id.* 5:16-18. Thus, Kontos discloses that the interventional cardiology device is inserted into the extension catheter without preassembly of any telescoping structure.[24] Ex-1405, ¶ 237.

M. Claim 16: The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

Kontos teaches claim 16. The marker band 30 is proximate the distal end of soft tip 28 ("flexible tip portion"). Ex-1405, ¶ 238; Ex-1409, Fig. 1.

N. Claim 17: The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

The Kontos-Adams combination renders this claim obvious for the same reasons discussed for claim 6. Section VII.F, *supra*; Ex-1405, ¶ 239.

[24] Claim 15 recites an intended use ("any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter") that should be afforded no patentable weight. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Petitioner addresses out of an abundance of caution.

O. Claim 19: The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

As discussed for claim 9, if the reinforced portion and the substantially rigid portion overlap, then the Kontos-Adams combination renders this claim obvious. Section VII.H, *supra*; Ex-1405, ¶ 241.

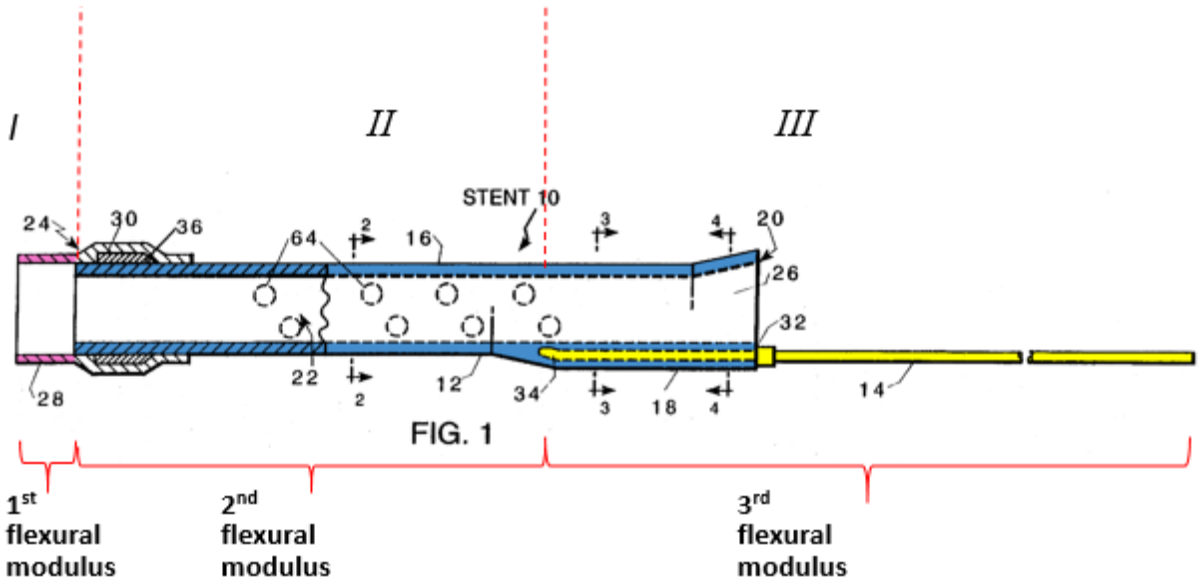
P. Claim 20: The system of claim 12, wherein the elongate structure includes, starting at the distal portion of the flexible distal portion[25], at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

Kontos discloses claim 20. Ex-1405, ¶ 242. As set forth in Section VI.B, "flexural modulus" means a measure of resistance to bending. Ex-1405, ¶¶ 136-37; Ex-1442, ¶ 45. As such, higher flexural moduli correspond with less flexible materials. Ex-1442, ¶ 45.

In Kontos, soft tip 28 of the flexible tip portion is preferably a copolymer of polyethylene and EVA. Ex-1409, 4:5-11. This is the first flexural modulus (region I). Ex-1442, ¶¶ 64-66. The tube 16 preferably is composed of polyethylene. Ex-

[25] There is no antecedent basis for "the flexible distal portion" in claim 20, or in claim 18, neither of which make sense unless it is the same as the "flexible tip portion" claimed in 12.b.ii.

1409, 4:1-4. This is the second flexural modulus (region II). Ex-1442, ¶¶ 65-66. Finally, the insertion/manipulation wire 14 is made of stainless steel. Ex-1409, 4:58-61. This is the third flexural modulus (region III). Ex-1442, ¶ 67.



Ex-1409, Fig. 1 (color and annotations added).

Based on the known material properties, Kontos expressly teaches 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-1405, ¶ 242; Ex-1442, ¶ 68.

VIII. GROUND II: CLAIM 8 & 18 ARE RENDERED OBVIOUS BY KONTOS 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-1478, ¶¶ 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 (Exs-1401-03), 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-1410 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-1405, ¶¶ 149-54; Ex-1442, ¶ 106.

B. Claim 8: "The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter."

This claim is rendered obvious by Kontos in view of Adams, Takahashi, and/or the knowledge of a POSITA. Ex-1405, ¶¶ 219-22. Kontos discloses a cross-sectional outer diameter and inner diameter of body 12 that is 0.055 inches and 0.045 inches, respectively. Ex-1409, 3:56-59, 4:48-50. Kontos does not disclose

the cross-sectional inner diameter of the guide catheter. Ex-1405, ¶ 219. 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-1405, ¶ 221; Ex-1442, ¶¶ 105-06; Ex-1410 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-1405, ¶ 221.

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-1442, ¶¶ 107-09. Specifically, Takahashi describes a "five-in-six system [as] a method of inserting a 5 Fr guiding catheter … into a 6 Fr guiding catheter to increase backup support." Ex-1410 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 3, 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.D, *supra*. Doing so would permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi. Ex-1442, ¶ 109 (describing that use of side opening permits close seating of child and mother catheters). 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. *Id.*, ¶¶ 109-10; Ex-1409, 4:64-65; Ex-1410 at 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-1405, ¶ 222; Ex-1442, ¶ 111.

C. Claim 18: "The system of claim 12, wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter."

Claim 18 differs from claim 8 only insofar as the former matches the inner diameter of the soft tip 28 ("flexible tip portion") of Kontos to the inner diameter of the GC, whereas the latter matches the inner diameter of the body 12 of Kontos to the inner diameter of the GC. Ex-1405, ¶ 240. "Soft tip 28 is arranged to extend coaxially from distal end 24" of tube 16, meaning the soft tip has the same inner

diameter as tube 16 of body 12. Ex-1409, 4:54-58; Ex-1405, ¶ 240. Thus, claim 18 is obvious for the same reasons that claim 8 is obvious. Ex-1405, ¶ 240.

IX. GROUND III: CLAIM 21 IS RENDERED OBVIOUS BY KONTOS 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, but was not the basis of an Examiner rejection during prosecution of either the '380 patent or predecessor '850 patent. *See generally* Exs-1401-03. 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-1451, 2:66-3:9; Ex-1405, ¶¶ 155-56.

B. Claim 21: The system of claim 20, in which the first flexural modulus is about 13,000 PSI plus or minus 5000 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 the knowledge of a POSITA discloses claim 21. Ex-1405, ¶¶ 243-54. As discussed for claim 20, Kontos has at least three regions of flexural moduli. Section VII.P, *supra.* Kontos does not, however, disclose the psi of those regions. Ex-1442, ¶¶ 112-14.

Berg, however, teaches a guide catheter with at least three different flexural moduli. Ex-1451, 2:66-3:3. Specifically, the distal soft tip has a flexural modulus between 1,000 to 15,000 psi, which "provide[s] an atraumatic end … for navigating vasculature." Ex-1451, 14:1-7, Fig. 19; Ex-1442, ¶ 114. 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 2,000 to 49,000 psi. Ex-1451, 14:27-30; Ex-1442, ¶ 115. This second flexural moduli assists in the positioning of the catheter tip. Ex-1451, 14:27-30; Ex-1442, ¶ 115. Finally, Berg additionally teaches that the next-most proximal segment should be a portion with a flexural modulus between about 13,000 to 49,000 psi, and then a portion with a flexural modulus of greater than 49,000 psi. Ex-1451, 14:35-51; Ex-1442, ¶ 116

A POSITA would have been motivated to modify Kontos to target the flexural moduli enumerated by Berg. Ex-1442, ¶ 117. 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-1444, 1:36-38; Ex-1442, ¶ 117. 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-1451, 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-1405, ¶ 254; Ex-1442, ¶ 118.

The three regions of flexural moduli taught by Berg overlap with the claimed range. Ex-1405, ¶¶ 253-54; Ex-1442, ¶ 119. 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.").

X. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1473. The "Facts" section 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.

XI. CONCLUSION

Petitioner respectfully requests institution of a trial and cancellation/invalidation of the claims 1-4, 6-9, and 12-21 of the '380 patent.

XII. PAYMENT OF FEES

The Office is authorized to charge Deposit Account No. 600615 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review.

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 12, 2019

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I hereby certify that the Petition for *inter partes* review consists of 13,975 words in 14 point Times New Roman font as calculated by the word count feature Microsoft Office 2016, in compliance with 37 C.F.R. § 42.24(a)(i). This word count is inclusive of all text and footnotes but not including a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence. was served on November 12, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

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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):

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