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.: IPR2020-01344
U.S. Patent No. RE46,116

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. RE46,116

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

LIST OF EXHIBITS

Exhibit	Description
1401	U.S. Patent No. RE 46,116 ("the '116 patent")
1402	File history for U.S. Patent No. 8,292,850
1403	File history for U.S. Patent No. RE 46,116
1404	Assignment record of the '116 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. 7,604,612 ("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 105:1285-1290 (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 53:308-312 (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, 119-122 (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 2:129-140 (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. 5,120,323 ("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)

Exhibit	Description
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")
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	[RESERVED]
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	U.S. RE45,380 ("the '380 patent")
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 12, 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, *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL

Exhibit	Description
1485	[RESERVED]
1486	[RESERVED]
1487	[RESERVED]
1488	Preliminary Injunction Order, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL (April 9, 2020)
1489	[RESERVED]
1490	[RESERVED]
1491	[RESERVED]
1492	[RESERVED]
1493	Screenshot from Docket Navigator regarding Judge Schiltz's Motions to Stay Pending Inter Partes Review
1494	[RESERVED]
1495	Plaintiffs' Infringement Disclosures in *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL (March 1, 2020)
1496	U.S. Patent No. 4,886,507 ("Patton")
1497	Excerpt of Patrick W. Serruys, *Handbook of Coronary Stents* (4th Edition) (2002)
1498	U.S. Patent No. 5,167,636 ("Clement")
1499	U.S. Patent No. 5,897,497 ("Fernandez")
1500	Originally filed Abstract, Specification, Drawings, and Claims from the '032 File History
1501	Originally filed Abstract, Specification, Drawings, and Claims from the '413 File History
1502	[RESERVED]
1503	Originally filed Abstract, Specification, Drawings, and Claims from the '380 File History
1504	[RESERVED]

Exhibit	Description
1505	Originally filed Abstract, Specification, Drawings, and Claims from the ’379 File History
1506	Non-Final Rejection from the ’379 File History filed on 2017-07-20
1507	Applicant Initiated Interview Summary from the ’379 File History filed on 2018-01-24
1508	Ex. 7 of Teleflex Infringement Disclosures and Claim Chart, *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL (March 1, 2020)
1509	Mamas A. Mamas, *Distal Stent Delivery with the Guideliner Catheter:* First in Man Experience (2010)
1510	Amendment to the claims from the ’379 File History filed on 2017-06-12
1511	Applicant Arguments and Remarks Made in an Amendment from the ’379 File History filed on 2018-01-19
1512	U.S. Patent Application Publication US2017/0260219 (“Root”)
1513	IPR2020-00127 Institution Decision (Paper 20)
1514	First Amended and Supplemental Complaint, *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL (February 14, 2020)
1515	Screenshot showing docket of Motion to Stay Order, Vascular Solutions LLC et al. v. Medtronic, Inc., 19:cv-01760-PJS-TNL (February 7, 2020)
1516	[RESERVED]
1517	[RESERVED]
1518	Amended Pretrial Scheduling Order, *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL (February 7, 2020)
1519	IPR2020-00136 Institution Decision (Paper 20)
1520	Plaintiffs’ Reply Brief in Support of Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL

I. PRELIMINARY STATEMENT

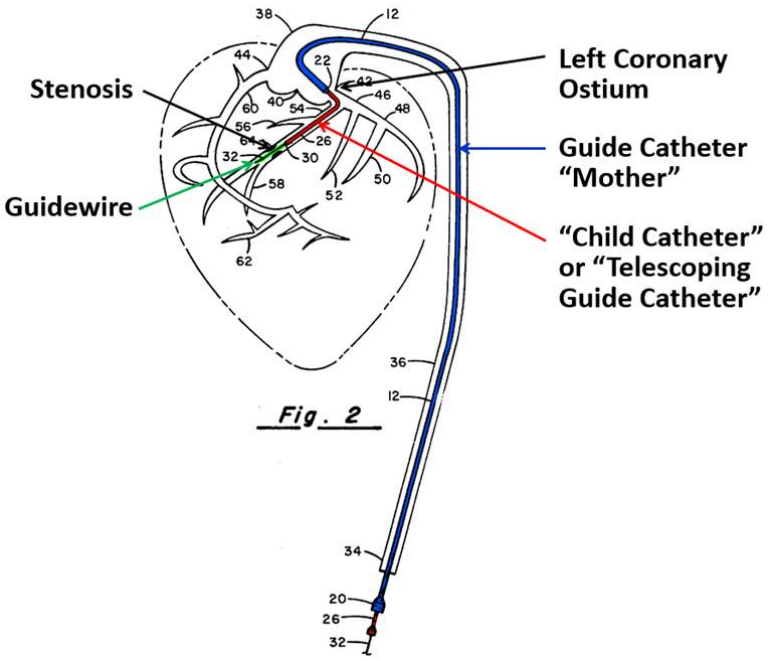
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 25-55 ("Challenged Claims") of U.S. Pat. No. RE46,116 ("the '116 patent," Ex-1401). The '116 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1401, [60])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures*. *Id*., [54].

The '116 patent describes a catheter system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during removal of a coronary stenosis. The purported invention requires a guide catheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*., Abstract, Figs. 8-9. In so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery,"

[1] Despite claiming a method of using a guide extension catheter, the specification of the '116 patent is silent regarding the use of a guide extension catheter and instead references a "coaxial guide catheter." Ex-1405, ¶¶ 120-22. A POSITA would have recognized that a "coaxial guide catheter" was commonly understood to be a guide extension catheter. *Id.*; Ex-1409, 5:49-50 (referring to body 12 "as a guide catheter extension").

thereby preventing the GC from dislodging from the ostium. *Id*., 3:12-16, 8:33-46.

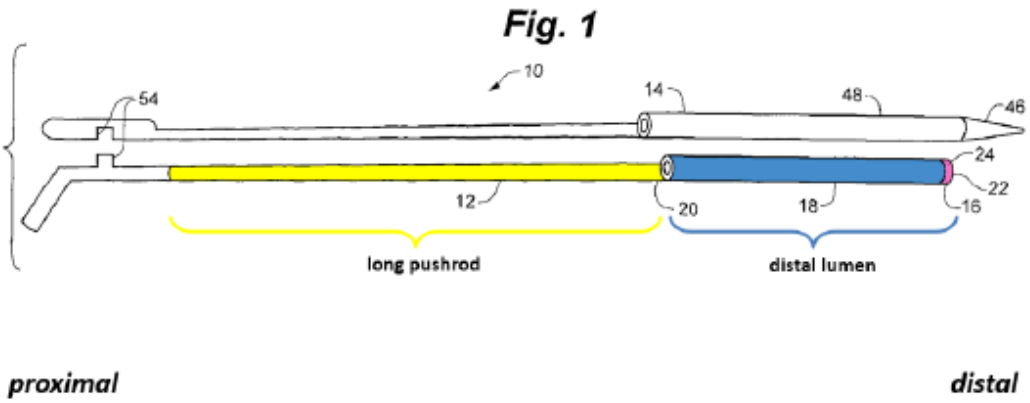
The ’116 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. *Id*., 2:50-67 (describing the use of a “smaller guide catheter within a larger guide catheter”); Ex-1405, ¶ 121. Indeed, such a catheter-in-catheter assembly was well-known in the art and described 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. Ex-1405, ¶ 70.



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

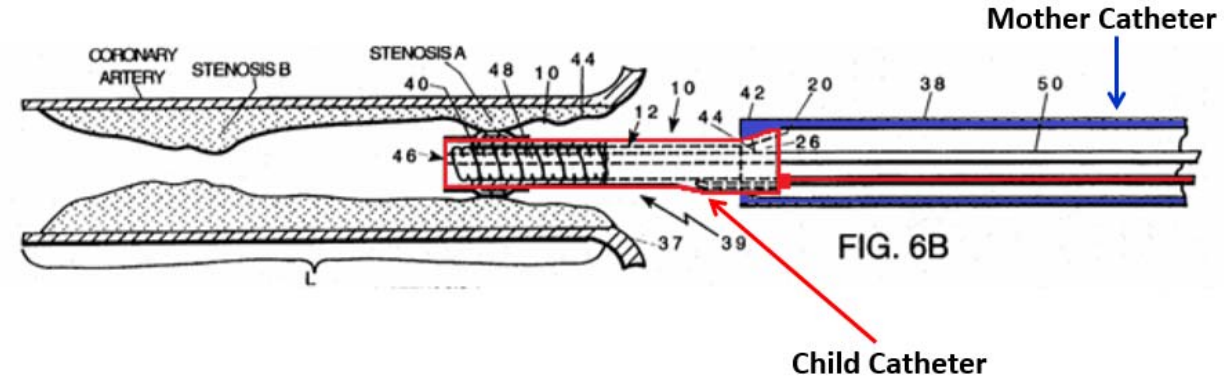
The child catheter in the original mother-and-child assembly had a

continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id.*; Ex-1405, ¶ 70. The '116 patent alleges that such a design had certain drawbacks (Ex-1401, 3:1-11; 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 can extend into the coronary artery.

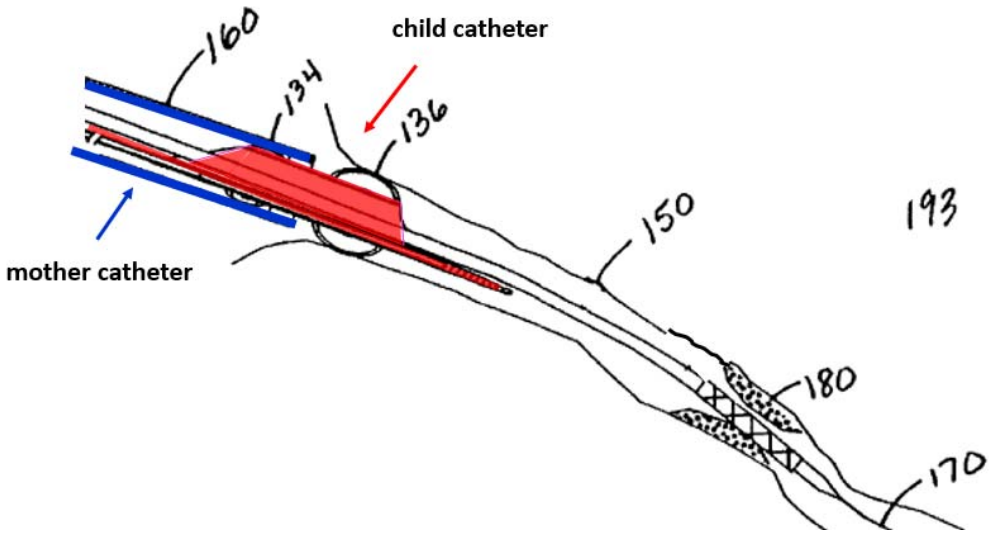


Ex-1401, Fig. 1 (annotations and color added).

But such child catheters that served as guide extension catheters and had a short lumen connected to a long thin push rod 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 '116 patent. Ex-1405, ¶¶ 131-36.



Ex-1409, Fig. 6B (annotations and color added). It was also evidenced by U.S. Patent No. 7,604,612 ("Ressemann"). Ex-1405, ¶¶ 137-41.



Ex-1408, Fig. 6B (annotations and color added).

There is more than a reasonable likelihood that the Challenged Claims are unpatentable. Petitioner respectfully requests institution of 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 Medtronic, Inc.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the '116 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)[2]; and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) ("QXMedical Litigation").

Further, the '116 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,

[2] The '116 patent was not originally asserted and was added by Amended Complaint on February 14, 2020. Ex-1514.

IPR2014-00763 (P.T.A.B., terminated Aug. 11, 2014).

The ’116 patent shares a common specification with and is related to several patents that, as shown in the below table, are currently subject to IPR:

IPR No.	U.S. Patent No.	Status
IPR2020-00126	8,048,032	Trial Instituted
IPR2020-00127	8,048,032	Trial Instituted
IPR2020-00128	RE45,380	Trial Instituted
IPR2020-00129	RE45,380	Trial Instituted
IPR2020-00130	RE45,380	Trial Instituted
IPR2020-00132	RE45,760	Trial Instituted
IPR2020-00134	RE45,760	Trial Instituted
IPR2020-00135	RE45,776	Trial Instituted
IPR2020-00136	RE45,776	Trial Instituted
IPR2020-00137	RE47,379	Trial Instituted
IPR2020-00138	RE47,379	Trial Instituted
IPR2020-01341	8,142,413	Pending
IPR2020-01342	8,142,413	Pending
IPR2020-01343	RE46,116	Pending[3]
IPR2020-01344	RE46,116	Pending (Present Petition)

C. Lead and Backup Counsel

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

[3] Petitioner concurrently filed a second IPR petition that applies Patent Owner’s interpretation of the claims and specification of the ’116 patent. Ex-1520, at 11-12 (arguing that written description permits “side opening” to be outside substantially rigid segment).

Lead Counsel	Back-Up Counsel
Cyrus A. Morton (Reg. No. 44,954) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Cmorton@RobinsKaplan.com	Sharon Roberg-Perez (Reg. No. 69,600) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Sroberg-perez@robinskaplan.com
Additional Back-Up Counsel	
Christopher A. Pinahs (Reg. No. 76,375) ROBINS KAPLAN LLP 800 LaSalle Avenue, Suite 2800 Minneapolis, MN 55401 Phone: 612.349.8500 Fax: 612.339.4181 Email: Cpinahs@RobinsKaplan.com	

D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the ’116 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review of the ’116 patent on the identified grounds.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully request review of claims 25-55 of the '116 patent and cancellation of these claims as unpatentable in view of the following grounds:[4]

No.	Grounds
I	Claims 52-53 are rendered obvious by Kontos in view of Ressemann, and the knowledge of a POSITA
II	Claims 25-40, 42, and 44-48 are rendered obvious by Kontos in view of Ressemann, Takahashi, and the knowledge of a POSITA
III	Claim 45 is rendered obvious by Kontos in view of Ressemann, Takahashi, Kataishi, and the knowledge of a POSITA
IV	Claims 25-55 are rendered obvious by Root and the knowledge of a POSITA
V	Claims 45-46 are rendered obvious by Kontos in view of Ressemann, Takahashi, Root, and 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,

[4] This Petition is also supported by the Declarations of Dr. Stephen JD Brecker, MD (Ex-1405) and Richard A. Hillstead, PhD (Ex-1442), as experts in the field of the '116 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1478) to support the authenticity and public availability of the documents cited herein.

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

Although PCI was developed more than forty years ago, its basic components have remained largely unchanged. *Id*., ¶¶ 33, 41. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. *Id*., ¶ 34. A guidewire is then introduced into the needle, the needle is removed, and an introducer sheath is inserted over the guidewire and into the artery. Next, a guide catheter can be introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id*., ¶¶ 42-55. At the proximal end, a hemostatic valve is coupled to 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

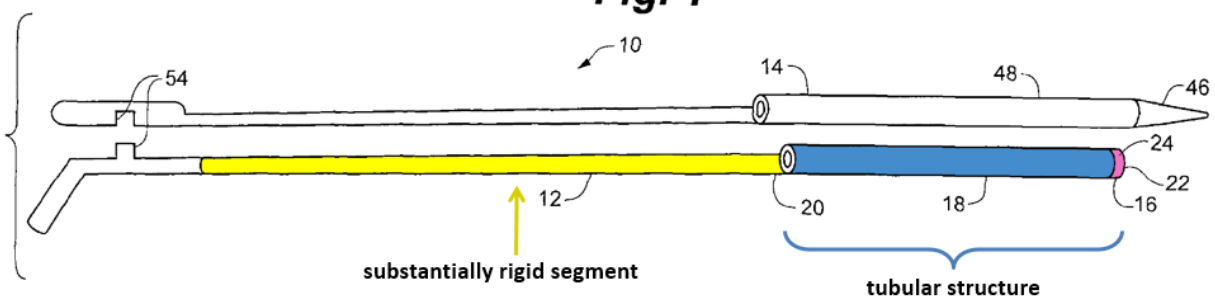
above, one way to ameliorate this backward force is to use a mother-and-child catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id.*, ¶¶ 68-80.

B. Overview of the '116 Patent

The '116 patent relates "generally to catheters used in interventional cardiology procedures." Ex-1401, 1:36-37. In particular, the '116 patent discloses 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.*, 5:35-38; Ex-1405, ¶¶ 115-21.

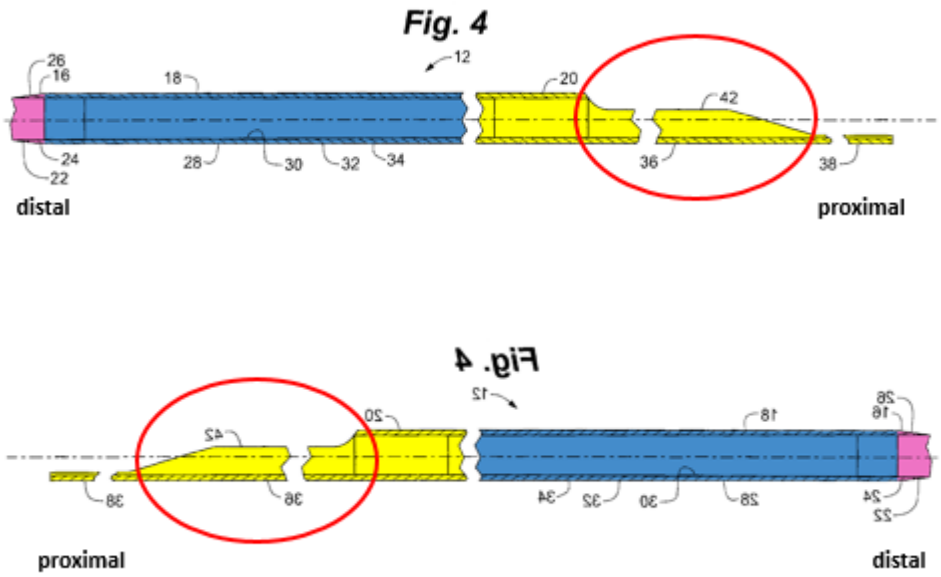
The '116 patent claims a guide extension catheter 12 that includes a substantially rigid segment (yellow) and a tubular structure (blue/pink). Ex-1405, ¶ 122.

Fig. 1



Ex-1401, Fig. 1 (annotations and color added).

The '116 patent also addresses structural characteristics of the transition at or near the extension catheter's tubular and rigid portions, which the patent refers to as "a segment defining a side opening," (red circle)." *Id*., Figs. 4, 13-16; Ex-1405, ¶¶ 123-24. As described below in Section X.A, the specification provides no written description support for the placement of a "side opening" anywhere other than ***in*** the substantially rigid segment 20, circled in red below.



Ex-1401, Fig. 4 (annotations and color added) (bottom figure inverted).

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, ¶¶ 24-25.

VI. CLAIM CONSTRUCTION

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 advanced, and the district court adopted, the following construction for "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). Additionally, the district court provided the following constructions:

- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (Ex-1413, 26)
- "lumen": "the cavity of a tube" (*Id.*, 25).

Petitioner agrees with the above constructions for purposes of this IPR[5] (Ex-1405, ¶¶ 125-28) and proposes the following additional constructions:

A. "flexural modulus"

The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1442, ¶ 96), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means "[a] measure of resistance … to bending." Ex-1440, 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. Such an understanding is consistent with the '116 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1401, 7:39-46; Ex-1405, ¶¶ 129-30.

VII. THE BOARD SHOULD NOT DECLINE TO INSTITUTE UNDER 35 U.S.C. § 314(a)

When granting institution of related patents, the Board declined to exercise its discretion under § 314(a). Ex-1513, at 9-16. As set forth below, the relevant *Fintiv* factors dictate a similar result for this Petition:

Fintiv Factors 1 & 2: On July 7, 2020, the district court stayed the litigation pending final resolution of the already-filed IPRs. Ex-1515 (Dkt 276). Given Judge

[5] Petitioner reserves the right to raise different constructions in other forums.

Schiltz's past practice (Ex-1493), it is unlikely he will lift the stay prior to resolution of this IPR. Ex-1513, at 12-14. Therefore, these factors support Petitioner.

Fintiv Factor 3: When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '116 patent. As a result, Petitioner did not file an IPR at that time. Then, on February 14, 2020, Patent Owner filed an Amended Complaint asserting the '116 patent. Ex-1514. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline. For the same reasons provided in its prior Institution Decision, the PTAB should find that this factor favors Petitioner. Ex-1513, at 14-15.

Fintiv Factor 4: In the District Court, Patent Owner asserts only 1 of the 30 claims challenged in this IPR. Ex-1495 at 3. This factor favors Petitioner.

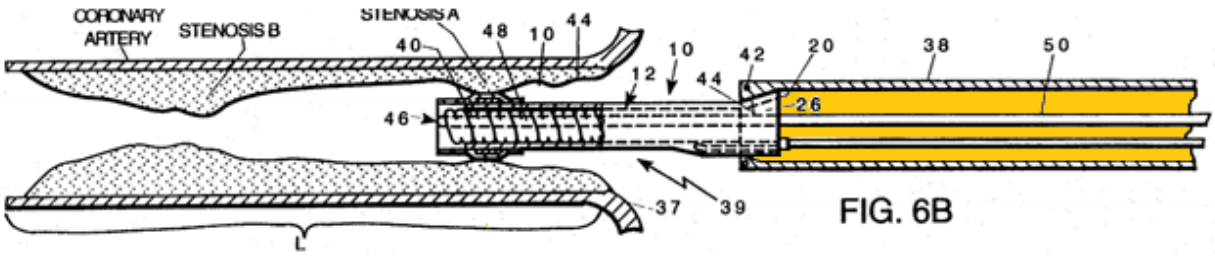
Fintiv Factors 5 & 6: For the same reasons set forth in the prior Institution Decisions, the PTAB should find that factors 5 & 6 do not warrant discretionary denial. Ex-1513, at 15-16.

VIII. GROUND I: KONTOS RENDERS CLAIMS 52-53 OBVIOUS IN VIEW OF RESSEMANN AND/OR THE KNOWLEDGE OF A POSITA

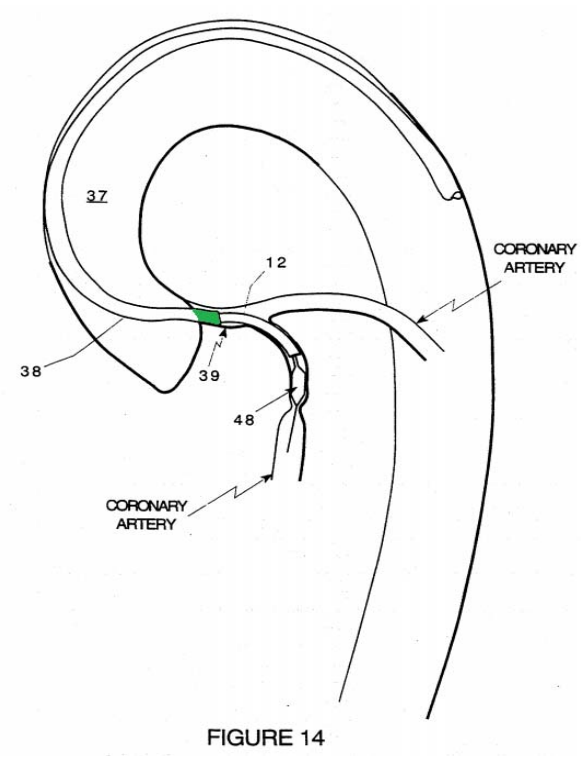
A. Claim 52

1. [52.a] "A method, comprising: advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;"

Kontos discloses this claim element. Ex-1405, ¶ 152. The guide catheter 38 has a lumen (yellow):



Ex-1409, Fig. 6B (color added). Further, 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 method of advancing "a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery."

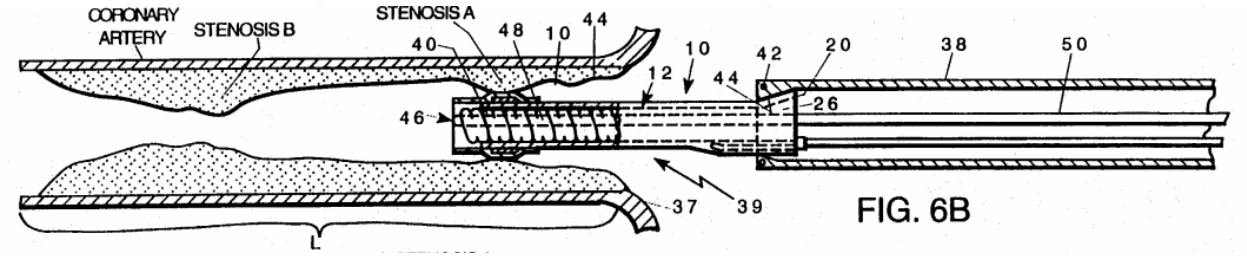


Ex-1409, Fig. 14 (color added).

2. [52.b] "advancing a distal end of a guide extension catheter through the guide catheter,"

Kontos teaches this claim element. Ex-1405, ¶ 153. Kontos's support catheter assembly 10 is a guide extension catheter. *Id*. 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. As shown in Figure 6B,

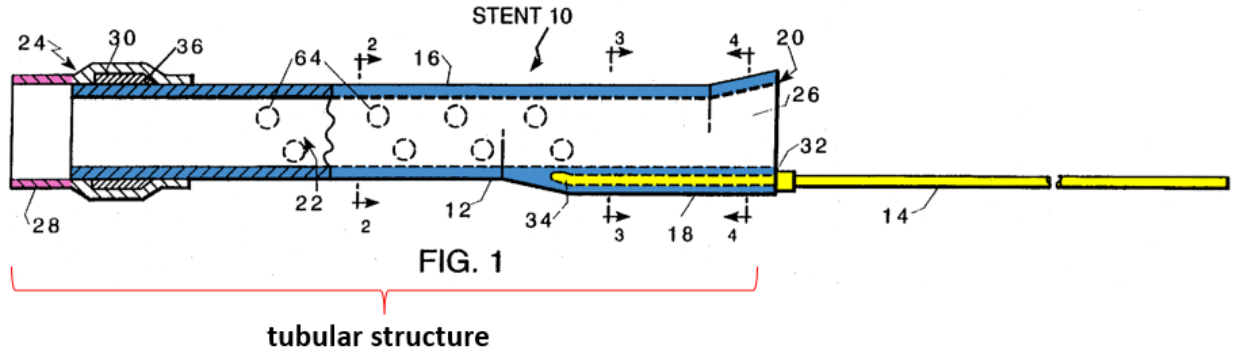
the distal end of support assembly 10 is advanced through the guide catheter.



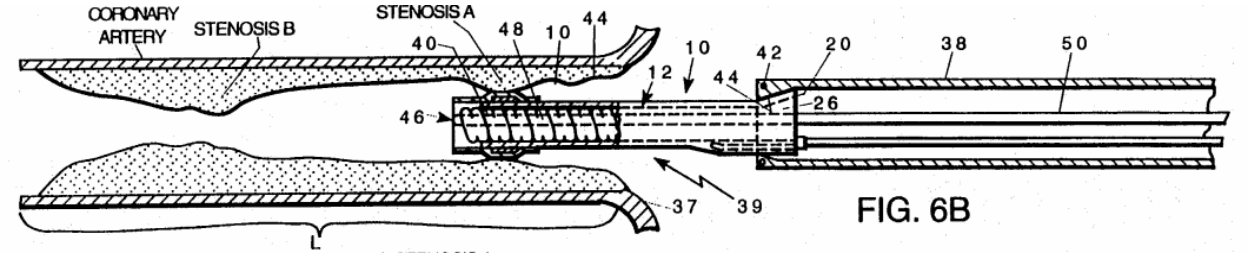
Ex-1409, Fig. 6B; Ex-1405, ¶ 153.

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

Kontos in combination with Ressemann discloses this claim limitation. Ex-1405, ¶ 154. In Kontos's support catheter 10, body 12 is the tubular structure. *Id.* Body 12 has a circular cross-section (i.e., tubular). Ex-1409, 2:51-54, 3:47-57, 4:5-7.



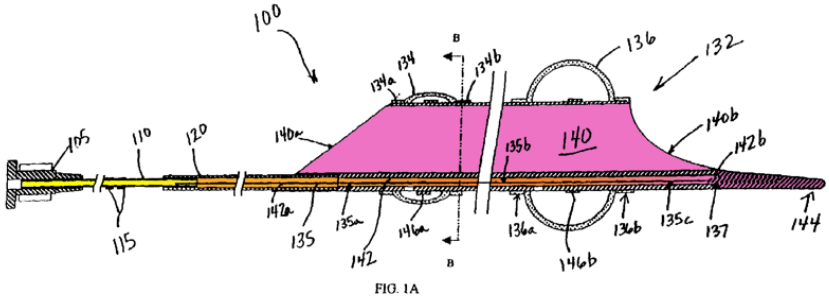
Id., Fig. 1 (color and annotations added). As shown in Figure 6B, when the distal end of body 12 extends beyond the distal end of guide catheter 38, the proximal end 20 remains within the guide catheter. Ex-1405, ¶ 154.



Ex-1409, Fig. 6B.

Kontos does not teach, however, a side opening proximal to the tubular structure. The use of side openings, however, were well-known. Ex-1405, ¶ 155; Ex-1407, 4:4-15; 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.

Ressemann is one such catheter assembly that has a side opening. Ex-1405, ¶¶ 155-56. In particular, Ressemann teaches an evacuation assembly 100 (extension catheter) where the entry to the evacuation lumen 140a is "preferably angled." Ex-1408, 6:52-60 (100 embodiment).

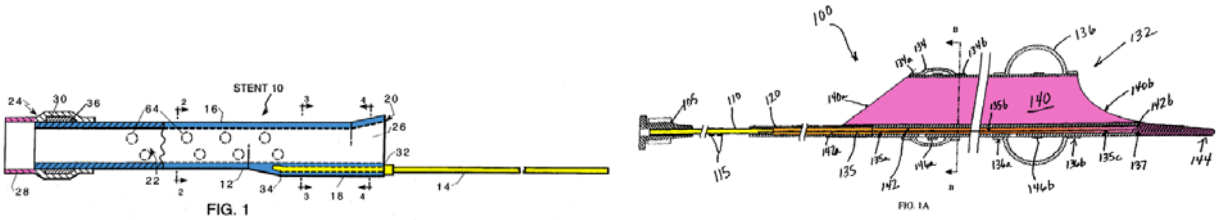


Ex-1408, Fig. 1A (color added).

It would have been obvious to modify Kontos to add Ressemann's side

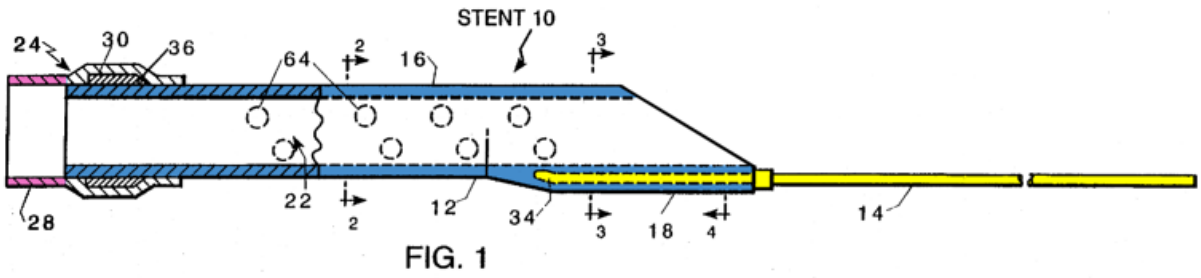
opening. Ex-1405, ¶ 157. Ressemann and Kontos are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the ’116 patent. *Id.*

Ressemann also discloses an assembly and method for using PTCA and stenting to treat vascular disease. *Id.*; Ex-1408, 6:25-34, 12:3-8, 23:8-11. The Ressemann assembly includes a GC, just like Kontos, that may be positioned within the ostium of a coronary artery. Ex-1405, ¶ 158; Ex-1408, 12:26-30. The evacuation assembly 100 is then insertable through and extends beyond the distal end of the GC. Ex-1405, ¶ 158; Ex-1408, Abstract, 6:18-24, 12:9-12, 12:19-30, Figs. 6A-B. As shown below, the Ressemann extension catheter, like the Kontos extension catheter, can be characterized by a short distal lumen (i.e., tube) that is coupled, at its proximal end, to a long thin pushrod. Ex-1405, ¶ 159.



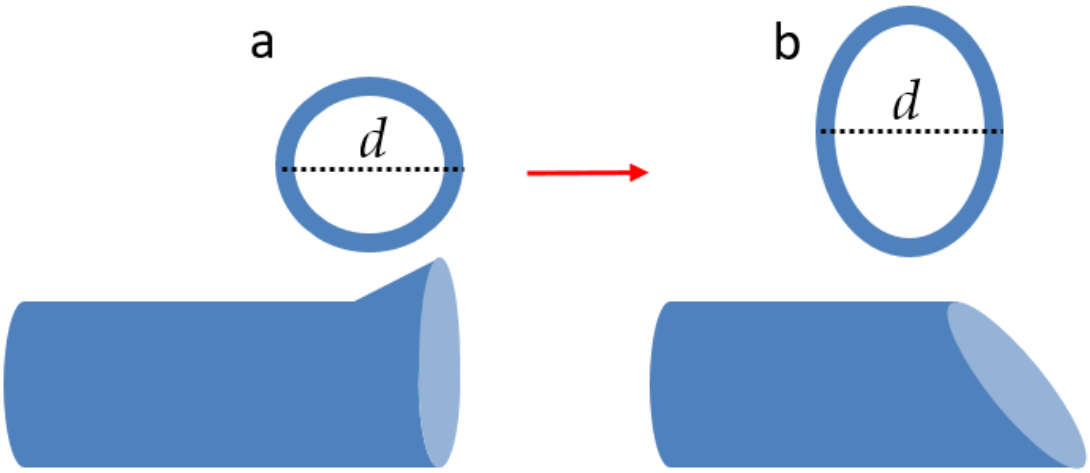
Ex-1409, Fig. 1A (color added); Ex-1408, Fig. 1A (color added). In Ressemann, as in Kontos, the proximal end of the tubular portion of the extension catheter remains within the guide catheter when the interventional device, such as a balloon catheter, is advanced through the lumen of the extension catheter and to the stenosis. Ex-1405, ¶ 159; Ex-1408, 6:25-34; 12:3-8, Fig. 6B; Ex-1409, Fig. 6B.

A POSITA would have been motivated, with a reasonable expectation of success, to add Ressemann's side opening to Kontos, as shown below. Ex-1405, ¶¶ 160-61; Ex-1442, ¶¶ 120-39.



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

A POSITA would have been motivated to modify Kontos to add a side opening, as taught by Ressemann, for multiple reasons. Ex-1405, ¶¶ 90-108, 161; Ex-1442, ¶¶ 131-38. 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, ¶ 162; Ex-1442, ¶ 135.

In 1995, when Kontos issued, GCs were typically 7-8 French in diameter. Ex-1405, ¶ 163. But by the purported priority date of the '116 patent, use of a 6 French GC had become more common. *Id.* These smaller GCs had several advantages (*id.*), but as the diameter of a GC decreases, so too does the diameter of the extension catheter. This, in turn, means that the proximal opening 20 of Kontos's tubular structure (body 12) must decrease. *Id.*; Ex-1409, Fig. 6B. And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex-1405, ¶ 164. Therefore, as an alternative to the flared proximal opening 26 in Kontos, a POSITA would have been motivated to use a side opening, as then the diameter of the GC could be reduced without causing a commensurate reduction in the area of the proximal opening of the tubular structure of the extension catheter. *Id.*; Ex-1442, ¶ 134. Alternatively, a POSITA would have been motivated to remove Kontos's proximal funnel, as it would permit the inner diameter of the extension catheter to be increased without causing a commensurate increase in the outer diameter of the guide catheter. Ex-1405, ¶ 164; Ex-1442, ¶ 135.

Second, a POSITA would have been motivated to use a side opening because, as taught by Ressemann, 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, ¶¶ 165-66; Ex-1442, ¶ 136; Ex-1426, 3:10-14. 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, ¶ 167; Ex-1442, ¶ 137. A 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.[6] Ex-1405, ¶¶ 165-67; Ex-1442, ¶ 137.

Third, a POSITA additionally would have been motivated to use a side opening, as taught by Ressemann, because such a design promotes "smoother passage" of the catheter assembly as it navigates the tortuous vasculature. Ex-1408, 6:52-57; *see also* Ex-1405, ¶ 168; Ex-1442, ¶ 138; Ex-1425, Abstract, [0034]. In

[6] 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. Also, 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.

other words, adding a side opening to the lumen of the extension catheter reduces the amount of force that a physician must exert to advance the catheter through winding vasculature. Ex-1405, ¶ 168; Ex-1442, ¶ 138.

Fourth, a POSITA was motivated to add a 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, ¶¶ 169-71; Ex-1442, ¶¶ 130-33. For example, Kontos teaches an embodiment where "the bridge body 12/PTCA catheter assembly may be passed completely out of guide catheter 38 and advanced as a unit to the site of restriction, restriction B." Ex-1409, 6:22-25.

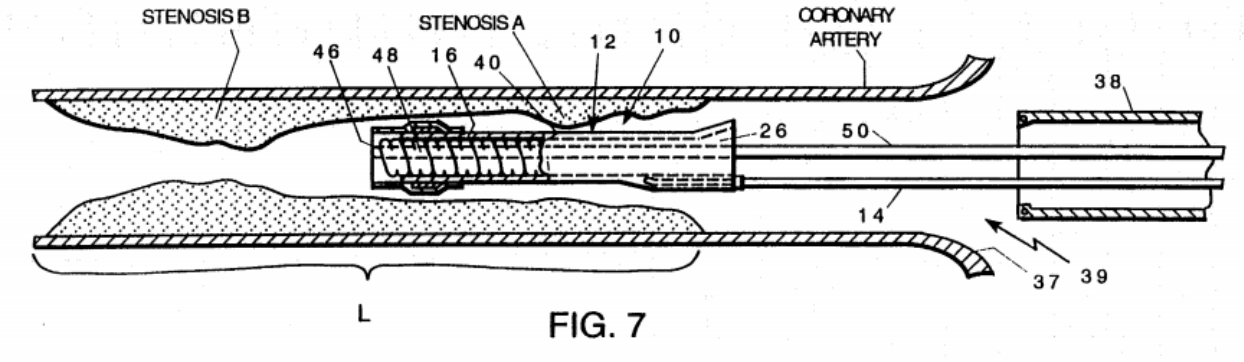


FIG. 7

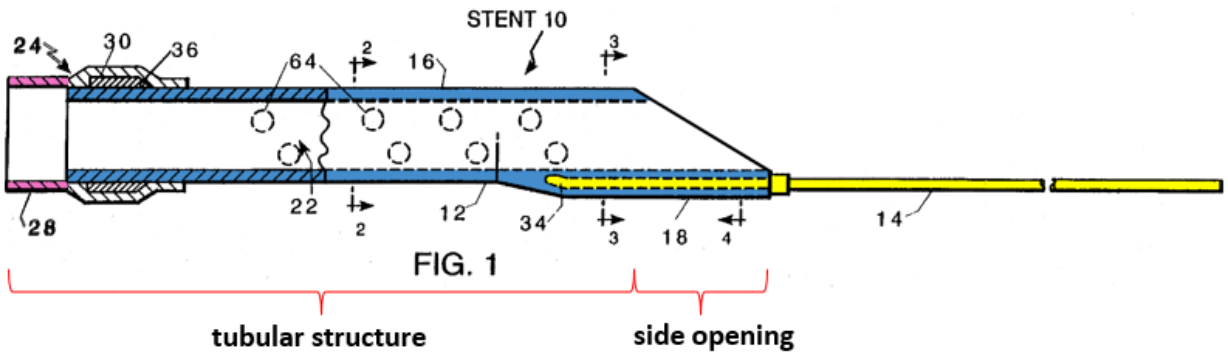
Ex-1409, Fig. 7.

In such an embodiment, after the angioplasty is performed, the support catheter 10 must return to the guide catheter 38. Ex-1405, ¶ 170; Ex-1442, ¶ 131. A POSITA would recognize, however, that a flared proximal opening of the tubular structure (tube 12) was a poor design choice, as this protrusion could damage the

internal coronary wall and hinder re-entry into the GC. Ex-1405, ¶ 170; Ex-1442, ¶ 131. The smaller cross-sectional diameter of a side opening would reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the GC. Ex-1405, ¶ 170; Ex-1442, ¶ 131; Ex-1435, [0066] ("Proximal end 31 is preferably cut or formed at an angle to the seal axis to facilitate unimpeded entry of the seal's proximal end into the distal end of the guide catheter.").

The prior art, including Ressemann, shows that the use of a side opening was well known. Ex-1405, ¶¶ 171-72. Employing Ressemann's side opening (as opposed to an opening perpendicular to the longitudinal axis) with the Kontos device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. Ex-1405, ¶ 173; Ex-1442, ¶ 139; *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

After adding Ressemann's side opening to Kontos, the resulting combination would provide for a method of advancing a distal portion of the tubular structure of the extension catheter beyond the distal end of the guide catheter while the side opening of the extension catheter remains within the guide catheter. Ex-1405, ¶ 173.



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

4. [52.d] "wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;"

As discussed for claim [52.c], a POSITA would have been motivated, with a reasonable expectation of success, to add a side opening. Section VIII.A.3, *supra*. In so doing, the material comprising the side opening would be the same as the material comprising tube 16, which is a "molded plastic material, such as polyethylene." Ex-1409, 4:1-4. The distal-most portion of the tubular structure (soft tip 28) "is composed of a soft plastic such as a copolymer of polyethylene and ethylvinylalcohol (EVA)." *Id.*, 4:5-15. Based on the known properties of these materials, Kontos expressly discloses to a POSITA that the material forming the side opening is "more rigid than the distal end portion of the tubular structure." Ex-1405, ¶ 174; Ex-1442, ¶¶ 140-43.

5. [52.e] "maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and"

Kontos teaches "maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter." Ex-1405, ¶ 175.

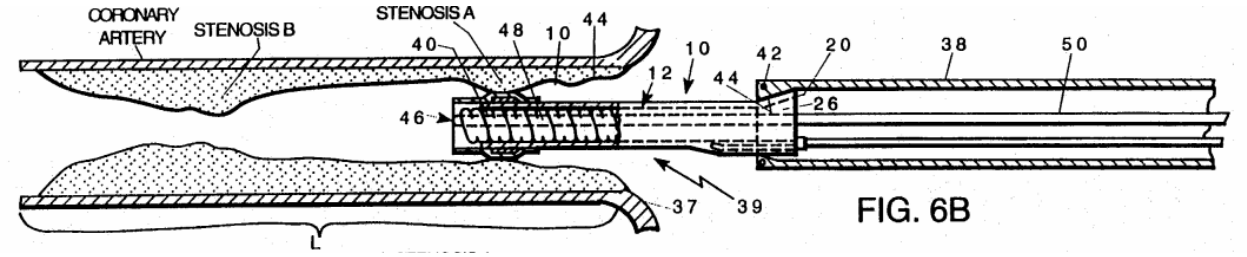


FIG. 6B

Ex-1409, Fig. 6B; *see also* Ex-1408, Figs. 6C-E.

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

Kontos in combination with Ressemann teaches this claim limitation. Ex-1405, ¶ 176. Although Kontos Figure 6 shows an embodiment where PTCA catheter 40 and support catheter 10 are fed together into the guide catheter, it also explains that, support assembly 10 can be advanced first, followed by PTCA catheter 40. Ex-1409, 7:45-52. In other words, Kontos teaches that body 12 is

advanced distal to guide catheter 38, and then PTCA catheter 40 with balloon 48 is advanced into the guide catheter/extension catheter assembly. Ex-1405, ¶ 176 (explaining that when separately inserting extension catheter and therapy catheter, a POSITA extends the extension catheter distal to the guide catheter prior to insertion of the therapy catheter).

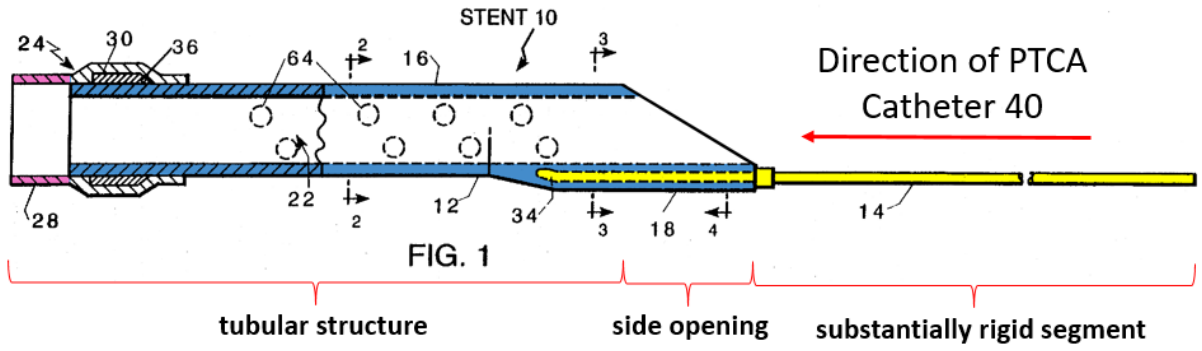
Regardless, Ressemann teaches placing the extension catheter distal to the guide catheter and then advancing a balloon catheter or stent through the guide catheter/extension catheter assembly. Ex-1405, ¶ 177. In particular, Ressemann teaches first "position[ing the GC] within the ostium of a target vessel." Ex-1408, 12:26-30, Fig. 6A. The evacuation assembly 100 (extension catheter) is then inserted into and advanced beyond the distal-most portion of the GC. *Id*., 12:19-40, Figs. 6B-C. That is, the distal end portion of the tubular structure of the extension catheter is positioned beyond the distal end of the guide catheter. Ex-1405, ¶ 177. Next, the "therapeutic device such as a stent delivery system 193" is inserted into the hemostatic valve and advanced in a distal direction until it is "positioned adjacent the stenosis 180" in the coronary artery. Ex-1408, 13:55-14:13, Figs. 6E-F; *see also id.*, 6:25-34, 12:3-8.

To the extent not taught by Kontos, a POSITA would have been motivated to, as provided by Ressemann, maintain the distal end of the guide extension catheter beyond the distal end of the guide catheter, and then advance the

interventional device into the coronary artery. Ex-1405, ¶ 178. Ressemann 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 '116 patent. *Id*. And as explained by Dr. Brecker, a physician will wait to advance the interventional device until after positioning the extension catheter for multiple reasons. For example, the extension catheter is easier to manipulate in the vasculature if the interventional device is not pre-loaded in its lumen. Ex-1405, ¶ 179. In other words, an extension catheter will have greater trackability (i.e., greater flexibility) while traversing a patient's vasculature if its lumen does not contain the therapy catheter. *Id*. Additionally, there is greater risk that an air embolism will form if the extension catheter is advanced at the same time as the therapy catheter. *Id*. Physicians routinely perform PCI in the claimed step-wise process and combining Kontos with Ressemann to perform the steps of maintaining the distal end of the guide extension catheter beyond the distal end of the guide catheter, and then advancing the interventional device into the coronary artery would have required no creativity, experimentation, or invention. *Id*.; *KSR*, 550 U.S. at 417.

Kontos or Kontos in combination with Ressemann teach maintaining the tubular portion of the extension catheter distal of the guide catheter and then advancing the therapeutic device through that combination to reach the coronary

artery. Ex-1405, ¶ 180. In so doing, to reach the coronary artery, the therapy catheter, as shown below, would necessarily travel along wire 14 ("a substantially rigid segment")[7], through the side opening, and then through the tubular structure. *Id*.



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

Although not specifically enumerated, when combined with the knowledge of a POSITA, Kontos teaches that the therapy catheter is first advanced through a hemostatic valve associated with the proximal end of guide catheter 38.[8] Ex-1405, ¶ 181. Indeed, without the proximal end being connected to a hemostatic valve, the

[7] Wire 14 is a "substantially rigid segment" because the support catheter 10 is "advanced through guide catheter 38 to the distal end thereof" by "exerting axial force" on wire 14. Ex-1409, 5:25-30, Abstract. Section VI, *supra*; Ex-1405, ¶ 180.

[8] The '116 patent admits as much. Ex-1401, 3:32-35 (describing "commonly existing hemostatic valves used with guide catheters").

catheter assembly would be exposed to the ambient environment, meaning the patient would risk excessive blood loss and/or develop an air embolism. *Id.*, ¶ 35 (testifying no responsible physician would perform a PCI procedure without hemostatic valve); Ex-1412, ¶ 14 (Dkt. 36-2) (inventor, Mr. Root, admitting same); Ex-1401, 2:62-67; Ex-1477, 43:2-15.

To the extent Patent Owner contends that Kontos does not teach advancing the therapeutic device through a hemostatic valve at the proximal end of the guide catheter, it would have been obvious to modify Kontos to add a hemostatic valve in view of Ressemann. Ex-1405, ¶ 181. Ressemann 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 '116 patent. *Id.*, ¶ 182. Further, Ressemann teaches that "[t]he touhy borst valve 184 [is] attached to the guide catheter 160" and that this same valve "seals against the proximal end of the therapeutic device."[9] Ex-1408, 13:55-64.

It would have been obvious to modify Kontos (to the extent not already obvious based on a POSITA's knowledge) in view of Ressemann to add a hemostatic valve at the proximal end of guide catheter 38. Ex-1405, ¶¶ 181-83. As

[9] A touhy borst valve is another name for a hemostatic valve. Ex-1405, ¶ 181.

Ressemann teaches, a POSITA would have been motivated to add a hemostatic valve to prevent back bleeding. Ex-1408, 13:64-14:6; Ex-1435, [0060].

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. Ex-1405, ¶ 183. Indeed, combining the teachings of Ressemann with Kontos to use a hemostatic valve at the proximal end of the guide catheter lumen would have required no creativity, experimentation, or invention. *Id.*; *KSR*, 550 U.S. at 417.

With a hemostatic valve at the proximal end of Kontos's guide catheter 36, to perform a PTCA procedure, a POSITA necessarily would "advance[e] the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure." Ex-1405, ¶ 184.

B. Claim 53: The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.

Kontos in combination with Ressemann teaches claim 53. Ex-1405, ¶ 185. As discussed for claim [52.c], the Kontos-Ressemann combination teaches advancing the extension catheter through and beyond distal end of the guide catheter, while also maintaining the side opening within the guide catheter. Section

VIII.A.3, *supra*. In so doing, the segment defining the side opening is necessarily positioned within the guide catheter to receive the balloon catheter or stent. *Id*.; Ex-1408, 12:9-14:35; Ex-1409, 5:16-18, 7:45-52. Indeed, as shown below, the side opening 141a remains within guide catheter 160 when receiving the stent delivery catheter 193.

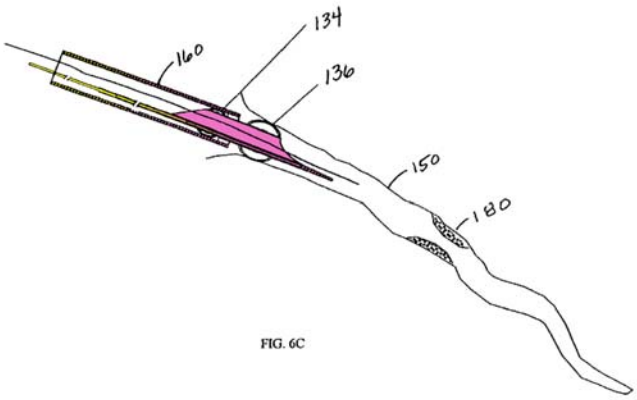


FIG. 6C

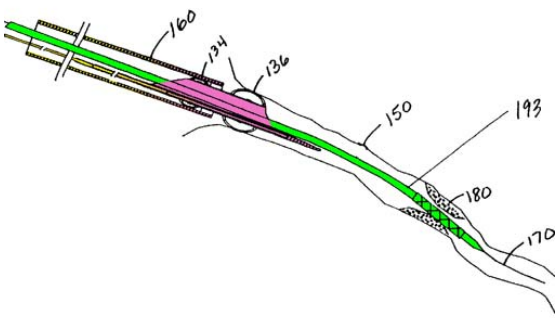


FIG. 6E

Ex-1408, Figs. 6C, 6E.

IX. GROUND II: KONTOS RENDERS CLAIMS 25-40, 42, AND 44-48 OBVIOUS IN VIEW OF RESSEMANN, TAKAHASHI AND/OR THE KNOWLEDGE OF A POSITA

A. Claim 25

1. [25.a] "A method comprising: advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;"

As discussed for claim [52.a], Kontos discloses this claim limitation. Section VIII.A.1, *supra*; Ex-1405, ¶ 186.

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

The language of this claim limitation differs from claim [52.b] only insofar as it [25.b] recites that the extension catheter is inserted through and beyond the guide catheter, whereas claim [52.b] requires only that the extension catheter is inserted through the guide catheter. Ex-1405, ¶ 187. As shown in Kontos Figure 6B, support assembly 10 discloses a method of "advancing a distal end of a[n] … extension catheter through, and beyond the distal end of, the guide catheter." Ex-1409, Fig. 6B. Kontos teaches this claim limitation. Section VIII.A.2, *supra*; Ex-1405, ¶ 187.

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

As discussed for claim [52.c], Kontos in combination with Ressemann discloses this claim limitation. Section VIII.A.3, *supra*; Ex-1405, ¶ 188.

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

Kontos in combination with Ressemann teaches this claim limitation. Ex-1405, ¶ 189. As shown below, the side opening of the Kontos-Ressemann combination extends for a distance from (a) to (b) along the extension catheter's

longitudinal axis. *Id.*

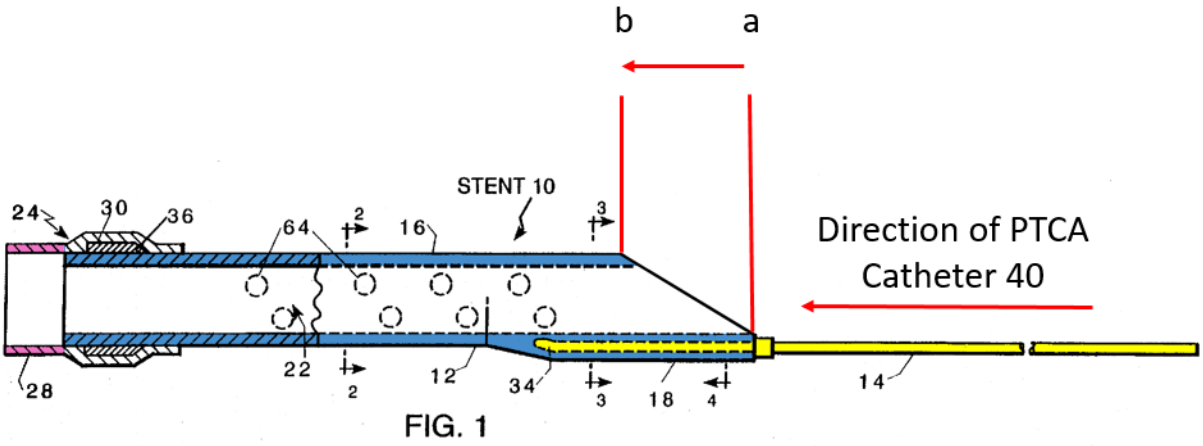


FIG. 1

Ex-1409, Fig. 1 (color and annotations added) (modified by Petitioner). When interventional devices, such as Kontos's PTCA catheter 40, pass through the side opening, they necessarily travel along "a longitudinal side defined transverse to the longitudinal axis." Ex-1405, ¶ 189.

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

This claim limitation is rendered obvious by Kontos in view of Ressemann and Takahashi. Ex-1405, ¶¶ 190-91. 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, ¶ 190. 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. *Id*., ¶ 192; Ex-1442, ¶ 199; Ex-1410, 452.

It would have been obvious to modify Kontos in light of Ressemann and Takahashi to achieve the not-more-than-one French differential. Kontos, Ressemann, 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 ’116 patent. Ex-1405, ¶ 192.

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

Further, a POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success. As discussed above for claim [25.c], a POSITA had a reasonable expectation of success when removing Kontos’s funnel in favor of a side opening. Section IX.A.3 *supra*. Doing so would permit a POSITA to achieve the not-more-than-one-French differential as taught by Takahashi. Ex-1442, ¶ 199 (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*., ¶ 200; Ex-1409, 4:21-24, 4:31-34, 4:61-5:2; Ex-1410, 452. Indeed, combining the teachings of Kontos with Ressemann 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, ¶ 193; Ex-1442, ¶¶ 191-93, 201; Ex-1519, 25-27 (preliminarily agreeing that Petitioner's combination teaches 1 French).

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

As discussed for claim [52.e], Kontos discloses this claim element. Section VIII.A.5, *supra*; Ex-1405, ¶ 194.

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

As discussed for claim [52.f], Kontos in combination with Ressemann discloses this claim element. Section VIII.A.6, *supra*; Ex-1405, ¶ 195.

B. Claim 26: The method of claim 25, further comprising injecting one or more fluids into the coronary artery via the proximal end of the guide catheter.

The Ground II combination teaches claim 26. Ex-1405, ¶ 196. As discussed for claim [25.g], Kontos in combination with Ressemann involves attaching a hemostatic valve to the proximal end of the guide catheter. Section IX.A.7, *supra*. While Kontos does not disclose the features of claim 26, Ressemann teaches that after advancing the evacuation assembly 100 (extension catheter) beyond the distal-most portion of the GC, "it may be desirable to inject a small amount of contrast into the blood vessel, via a dye injection apparatus 189 in fluid communication with the guide catheter 160 … and blood vessel 150, to aid in navigation of the guide wire 170 across the stenosis 180." Ex-1408, 13:3-10. As shown in Ressemann Figure 5A, the dye is injected through "[a] suitable valve 184, such as a touhy borst valve, attached to the guiding catheter 160." *Id.*, at 12:45-49.

A POSITA would have been motivated to inject one or more fluids into the coronary artery through the hemostatic valve as taught by Ressemann. Ex-1405, ¶ 197. Ressemann 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 '116 patent. *Id*. Further, the tubular portion of Kontos's support assembly 10 and Ressemann's evacuation assembly 100 both have radiopaque

markers. Ex-1408, 9:36-38, Ex-1409, 4:16-19. X-ray or fluoroscopy techniques permit the subcutaneous detection of these radiopaque markers in the vasculature after the addition of contrast dye. Ex-1405, ¶ 197. Because Kontos teaches the inclusion of marker band 30, a POSITA would have been motivated to inject one or more fluids (e.g., contrast dye) into the coronary artery via the guide catheter. *Id*., ¶ 198. Indeed, injection of such a fluid was standard operating procedure in this field and would have required no creativity, experimentation, or invention. *Id*., ¶ 199; *KSR*, 550 U.S. at 417.

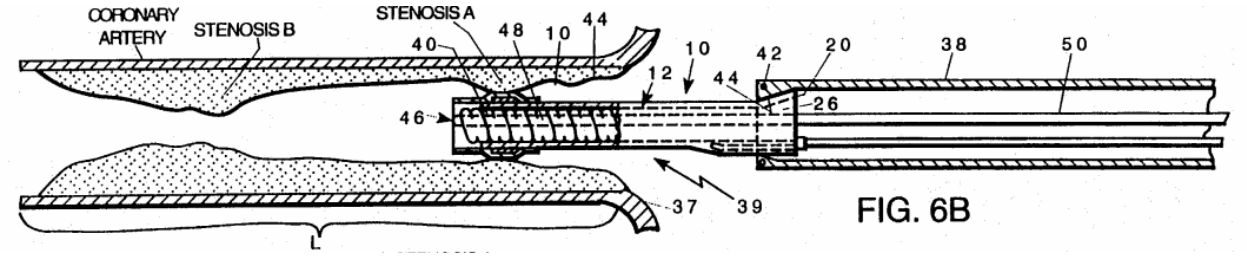
C. Claim 27: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes opening the hemostatic valve and advancing the distal end of the guide extension catheter through the hemostatic valve and into the guide catheter.

The Ground II combination teaches claim 27. Ex-1405, ¶ 200. As discussed for claim 25, Kontos in combination with Ressemann teaches both attaching a hemostatic valve to the proximal end of the guide catheter and advancing the extension catheter through and beyond the distal end of the guide catheter. Section IX.A.2-7, *supra*. Further, Kontos teaches that a physician first "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. Only then is support catheter 10 inserted into the system, advancing through and beyond the guide catheter. *Id.*, 5:16-18, Figs. 6A-C. Therefore, Kontos in combination with Ressemann necessarily teaches

the method of "opening the hemostatic valve and advancing the distal end of the guide extension catheter through the hemostatic valve and into the guide catheter." Ex-1405, ¶ 200; Ex-1408, 12:45-49, 13:60-64.

D. Claim 28: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes advancing the distal end of the guide extension catheter proximal to a location of a lesion to be treated in the coronary artery.

The Ground II combination teaches claim 28. Ex-1405, ¶ 201. As shown in Kontos Figure 6B, after "advancing the distal end of the … extension catheter through, and beyond the distal end of, the guide catheter," the distal end of the extension catheter (i.e., support assembly 10) is "proximal to a location of a lesion to be treated in the coronary artery."



Ex-1409, Fig. 6B.

E. Claim 29: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes manipulating the substantially rigid segment to advance the segment defining the side opening to a position within the lumen of the guide catheter.

The Ground II combination teaches claim 29. Ex-1405, ¶ 202. Kontos

teaches that advancement of support assembly 10 is "most efficiently … accomplished by exerting axial force on wire 14." Ex-1409, 5:28-30. In other words, "advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter," necessarily requires "manipulating the substantially rigid segment [of the Ground II combination] to advance the segment defining the side opening to a position within the lumen of the guide catheter." Ex-1405, ¶ 202; Section IX.A.2-3, *supra*.

F. Claim 30: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes sealing around the substantially rigid segment with the hemostatic valve associated with the proximal end of the guide catheter.

The Ground II combination teaches claim 30. Ex-1405, ¶ 203. As discussed for claim [25.g], a POSITA would have been motivated, with a reasonable expectation of success, to attach Ressemann's hemostatic valve to the proximal end of Kontos's guide catheter 38. Section IX.A.7, *supra*. In so doing, the hemostatic valve at the proximal end of the guide catheter, as taught by Ressemann, "provides a fluid tight seal against … the proximal shaft portion 110 [(i.e., substantially rigid portion)] of the evacuation sheath assembly 100." Ex-1408, 12:45-49, 13:60-64. Therefore, when "advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter," the Ground II combination necessarily teaches the method of "sealing around the

substantially rigid segment with the hemostatic valve associated with the proximal end of the guide catheter." Ex-1405, ¶ 203.

G. Claim 31: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes advancing the substantially rigid segment within the lumen of the guide catheter.

The Ground II combination teaches claim 31. *Id*., ¶ 204. As explained for claim 29, Kontos teaches advancing support assembly 10 by "exerting axial force on wire 14." Ex-1409, 5:28-30, Figs. 6A-B. By doing so, when "advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter" Kontos necessarily teaches the method of "advancing the substantially rigid segment within the lumen of the guide catheter." Ex-1405, ¶ 204.

H. Claim 32: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes coaxially aligning the tubular structure of the guide extension catheter with the lumen of the guide catheter.

The Ground II combination teaches claim 32. *Id*., ¶ 205. As shown in Figures 6A-6C, body 12 of support assembly 10 is coaxial to guide catheter 38. As a result, when "advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter," Kontos teaches a method of coaxially aligning the tubular structure 12 with the lumen of the guide catheter. *Id*.

I. Claim 33: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the balloon catheter or stent.

The Ground II combination teaches claim 33. *Id*., ¶ 206. As discussed for claim [25.b-c], Kontos in combination with Ressemann teaches advancing the extension catheter through and beyond distal end of the guide catheter, while also maintaining the proximal end of the extension catheter, including its side opening, within the guide catheter. Section IX.A.2-3, *supra*. In so doing, the segment defining the side opening is necessarily positioned within the guide catheter and does receive the balloon catheter or stent. Ex-1405, ¶ 206; Ex-1408, 12:9-14:35; Ex-1409, 5:16-18, 7:45-52. Indeed, as shown below, the proximal side opening remains within guide catheter 160 when receiving the stent delivery catheter 193.

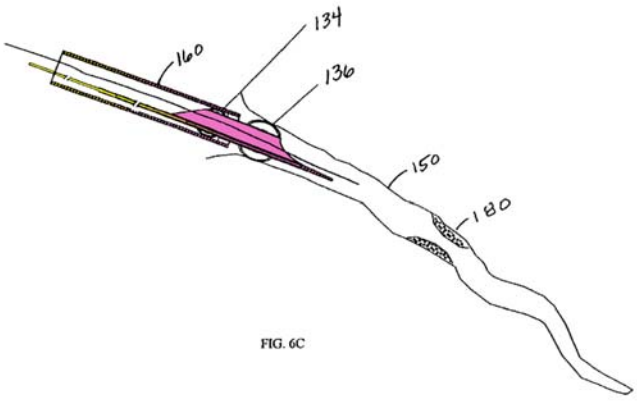


FIG. 6C

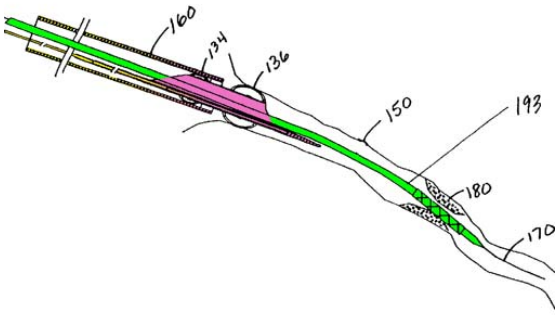


FIG. 6E

Ex-1408, Figs. 6C, 6E; Ex-1409, Figs. 6B-C.

J. Claim 34: The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.

The Ground II combination teaches claim 34. As discussed for claim 26, a POSITA would have been motivated, with a reasonable expectation of success, to inject one or more fluids—in particular, contrast dye—into the coronary artery via the hemostatic valve attached to the guide catheter. Section IX.B, *supra*. In so doing, and as explicitly taught by Ressemann, the "dye injection apparatus [is] in fluid communication with the guide catheter 160, evacuation head 132 [(tubular portion)], and blood vessel 150." Ex-1408, 13:3-7. Therefore, when "advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter," the Ground II combination teaches the method of "establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter." Ex-1405, ¶ 207.

K. Claim 35: The method of claim 25, wherein maintaining the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes resisting dislodging of the distal end of the guide catheter from the ostium of the coronary artery when the balloon catheter or stent is at least partially advanced through the guide catheter, through the guide extension catheter, and into the coronary artery.

The Ground II combination teaches claim 35. Ex-1405, ¶¶ 208-16; Ex-1442, ¶¶ 194-201. The '116 patent provides that because the 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, 5:18-38. The '116 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 the system, and that the presence of the extension catheter in the GC provides "stiffer back up support" than a GC alone. *Id*., 8:33-48. This combination is what allows the claimed method to resist dislodgement. Ex-1405, ¶¶ 208-16.

As discussed for claim 25, 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. For this reason, because the Ground II combination and the '116 patent contain the same teachings, to the extent the '116 patent has adequate written description support, a POSITA would understand that the Ground II combination must inherently disclose or, at a minimum, render obvious claim 35 when combined with the knowledge of a POSITA. Ex-1405, ¶ 208; Ex-1442,

¶¶ 180-85.

L. Claim 36: The method of claim 25, wherein maintaining the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes using the guide extension catheter to resist axial and shear forces exerted by the balloon catheter or stent when the balloon catheter or stent is advanced at least partially through the guide catheter, through the guide extension catheter, and into the coronary artery.

The Ground II combination renders claim 36 obvious for the same reason that claim 35 is obvious. Ex-1405, ¶ 217. Indeed, claim 36 differs from claim 35 insofar as the former adds that it is the extension catheter that resists axial and shear forces when the balloon catheter or stent is advanced at least partially through the guide catheter, through the guide extension catheter, and into the coronary artery. *Id.* As explained for claim 35, the extension catheter aids in resisting axial and shear forces. Section IX.K, *supra*.

M. Claim 37: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the guide catheter, through the guide extension catheter, and into the coronary artery includes advancing a delivery system including the stent into the coronary artery.

The Ground II combination teaches claim 37. Ex-1405, ¶ 218. Kontos discloses advancing a PTCA catheter 40 with balloon 48 to treat a stenosis (Ex-1409, Figs. 6A-C), but it does not explicitly disclose "advancing a delivery system including [a] stent into the coronary artery." Ressemann, however, teaches the method of "placing a stent within a vessel." Ex-1408, 6:25-47, 10:17-21.

It would have been obvious to combine Kontos with Ressemann to teach delivery of a stent to the coronary artery. Ex-1405, ¶ 219. Ressemann 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 '116 patent. *Id*.

A POSITA would have been motivated to deliver a stent, as taught by Ressemann, because doing so would offer a greater array of treatment options (as opposed to only delivering a balloon catheter). *Id*., ¶ 220; Ex-1442, ¶¶ 186-90. In particular, stent delivery has the added benefit of providing permanent structural support to help prevent the coronary artery from re-narrowing. Ex-1405, ¶ 220.

A POSITA would have accomplished the method of stent delivery with a reasonable expectation of success, as doing so was ubiquitous by 2006. *Id*., ¶ 221. Further, Kontos teaches that tube 16 has a 0.045 inch inner diameter (Ex-1409, 4:46-50), meaning stent and stent catheters could be advanced through Kontos's tube 16. Ex-1405, ¶ 221; Ex-1428, 641; Ex-1497, 104, 269, 274, 280; Ex-1409, 4:64-5:3. Regardless, the Ground II combination modifies Kontos's tube 16 (e.g., removal of funnel), such that it was possible to deliver larger sized stents. Ex-1405, ¶ 222; Ex-1442, ¶¶ 186-90. Stent delivery was common and combining Kontos with Ressemann would have required no creativity, experimentation, or invention. Ex-1405, ¶ 222; Ex-1442, ¶ 201.

N. Claim 38: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the guide catheter, through the guide extension catheter, and into the coronary artery includes advancing one or more interventional devices through a single seal, which is the hemostatic valve associated with the proximal end of the guide catheter.

The Ground II combination teaches claim 38. Ex-1405, ¶ 223. As discussed for claim [25.g], Kontos in combination with Ressemann involves attaching a hemostatic valve to the proximal end of the guide catheter. Section IX.A.7, *supra*. In so doing, as shown in Ressemann Fig. 5A, the device's only hemostatic valve, a touhy borst valve 184 attached to the guide catheter 160 … seals against the proximal end of the therapeutic device … and the proximal shaft portion 110 of the evacuation sheath assembly 100." Ex-1408, 13:60-64; Ex-1442, ¶¶ 117-18 (hemostatic valves typically have only one seal). Therefore, when "advancing the balloon catheter or stent," the Ground II combination necessarily teaches the method of "advancing one or more interventional devices through a single seal, which is the hemostatic valve associated with the proximal end of the guide catheter." Ex-1405, ¶ 223.

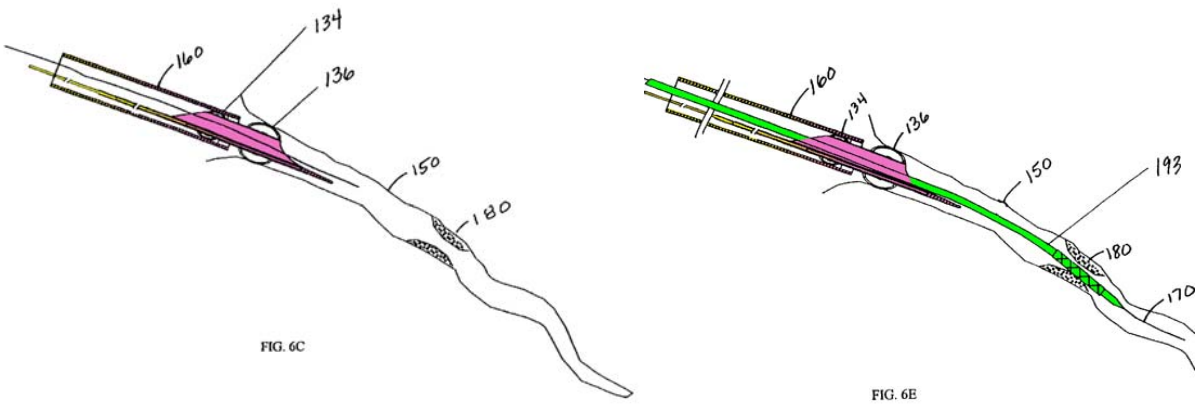
O. Claim 39: The method of claim 25, wherein, subsequent to advancing the balloon catheter or stent at least partially through the hemostatic valve, the method further comprises at least partially sealing around a proximal end portion of the balloon catheter or a delivery system including the stent with the hemostatic valve associated with the proximal end of the guide catheter.

The Ground II combination teaches claim 39. Ex-1405, ¶ 224. As discussed for claim [25.g], Kontos in combination with Ressemann involves attaching a hemostatic valve to the proximal end of the guide catheter. Section IX.A.7, *supra*. In particular, Ressemann teaches that, after a therapeutic device is inserted into guiding catheter 160, valve 184 "seals against the proximal end of the therapeutic device," which may be stent delivery system 193 that includes a delivery balloon. Ex-1408, 10:13-21, 13:60-64; Ex-1405, ¶ 224. Thus, "subsequent to advancing the balloon catheter or stent at least partially through the hemostatic valve" the Ground II combination necessarily teaches the method of "sealing around a proximal end portion of the balloon catheter or a delivery system including the stent with the hemostatic valve associated with the proximal end of the guide catheter." Ex-1405, ¶ 224.

P. Claim 40: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the side opening includes accessing the side opening of the guide extension catheter within the lumen of the guide catheter.

The Ground II combination teaches claim 40. Ex-1405, ¶ 225. As discussed

for claim [25.c], it would have been obvious to combine Ressemann's side opening with Kontos's support catheter 10, such that the side opening remains within the guide catheter when the distal end of the extension catheter is advanced into the coronary artery. Section IX.A.3, *supra.* With this combination, advancing the balloon catheter or stent at least partially through the side opening would, as shown below, necessarily include accessing the side opening of the guide extension catheter while it remains within the lumen of the guide catheter. Ex-1405, ¶ 225.



Ex-1408, Figs. 6C, 6E (color added); Ex-1409, Figs. 6A-C.

Q. Claim 42: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a structure having an arcuate cross-sectional shape.

As explained for claim [25.c], a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's side opening with Kontos's support catheter 10. Section IX.A.3, *supra*. In so doing, when "advancing the balloon catheter or stent," the Ground II combination necessarily teaches the

method of "advancing a balloon catheter or stent through a structure having an arcuate cross-sectional shape."[10] Ex-1405, ¶ 226.

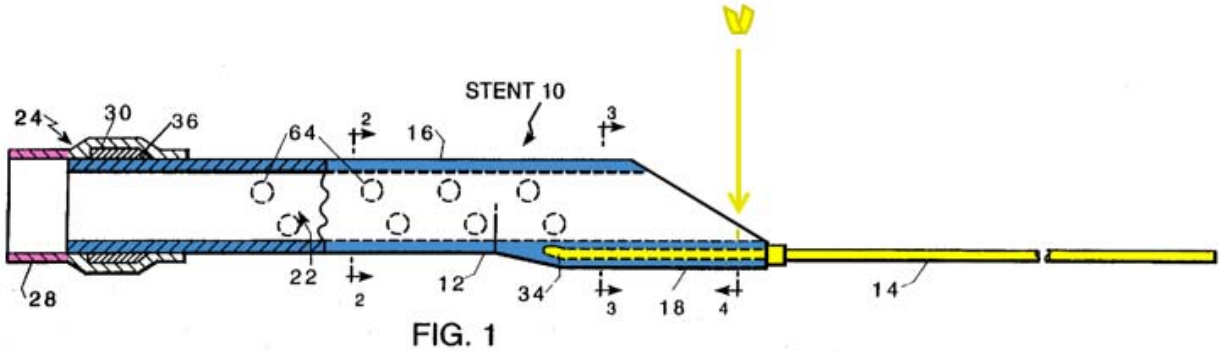


FIG. 1

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

R. Claim 44: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a structure having a hemicylindrical cross-sectional shape.

As explained for claim [25.c], a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's side opening with Kontos's support catheter 10. Section IX.A.3, *supra*. In so doing, when "advancing the balloon catheter or stent," the Ground II combination necessarily teaches the

[10] According to the '116 patent, arcuate means a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1401, 7:19-20.

method of "advancing a balloon catheter or stent through a structure having a hemicylindrical cross-sectional shape."[11] Ex-1405, ¶ 227.

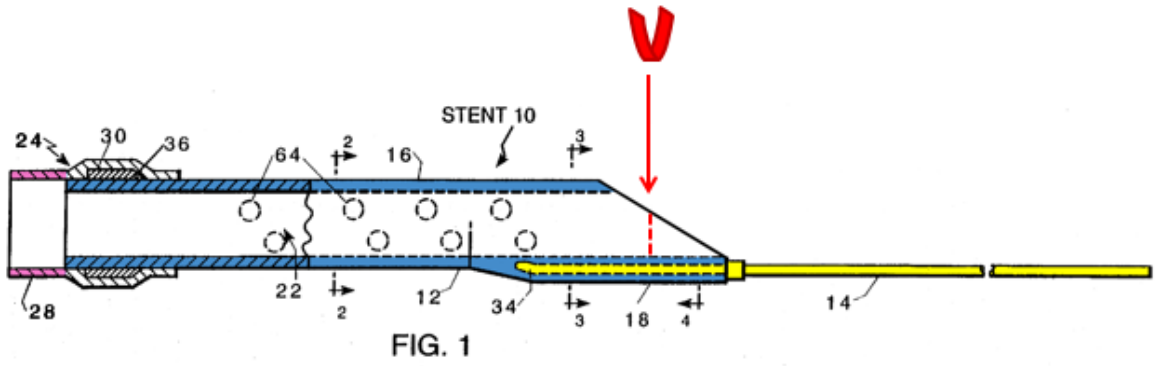


FIG. 1

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

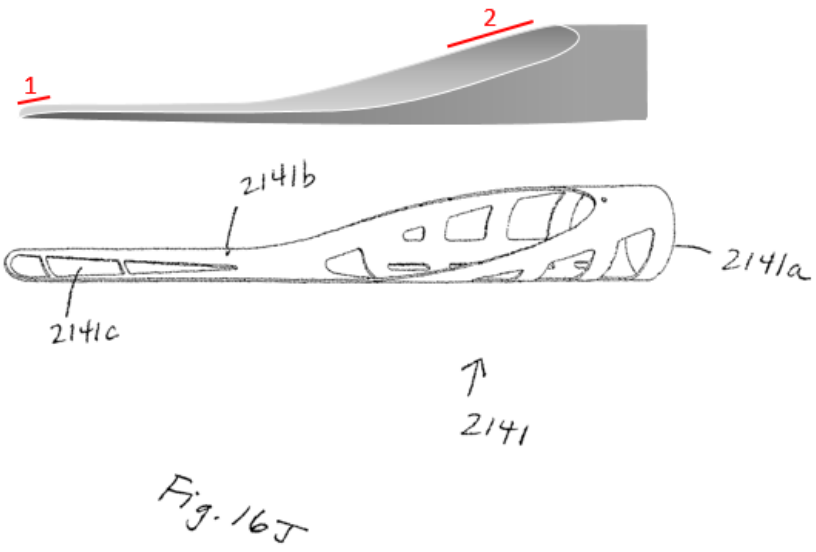
S. Claim 45: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through a side-opening structure having at least two inclined slopes.

The Ground II combination teaches claim 45.[12] Ex-1405, ¶ 228. As explained for claim [25.c], a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's side opening with

[11] According to the '116 patent, "[h]emicylindrical … desirably includes 40% to 70% of the circumference of the tube." Ex-1401, 7:14-15.

[12] The Ground II combination renders claim 45 obvious only if the Challenged Claims are interpreted to permit a rigid side opening. Section X.A, *infra* (explaining that Challenged Claims recite that the segment defining the side opening is outside of the substantially rigid segment).

Kontos's support catheter 10. Section IX.A.3, *supra*. The side opening discussed in claim [25.c]—Ressemann's side opening 140a—has one inclined slope. An alternative Ressemann embodiment, however, teaches a side opening with at least two inclined regions. In particular, Ressemann's support collar 2141 teaches, as shown below, a proximally-located, side opening with at least two included regions.



Ex-1408, Fig. 16J (annotations added) (top figure added). Ressemann's side opening 2141 is part of evacuation assembly 2100[13] (extension catheter), which

[13] Ressemann discloses different embodiments of its evacuation assembly. The first, discussed for claims 25 and 52, is the 100 series. The other is the 2100 series. Ressemann explains that "where these elements [for each embodiment] are

like Kontos's support assembly 10, is insertable through and extends beyond the distal end of the GC. Ex-1405; ¶ 229; Ex-1408, Abstract, 6:18-24, 12:9-12, , Figs. 6A-B. Further, Ressemann's evacuation assembly 2100, like Kontos, permits interventional cardiology devices, such as a balloon catheter, to be passed through the lumen of the extension catheter to treat the stenosis. Ex-1405, ¶ 229; Ex-1408, 6:25-34; 12:3-8.

For the reasons discussed for claim [25.c], a POSITA would have been motivated, with a reasonable expectation of success, to integrate Ressemann's side opening into Kontos's support catheter 10. Section IX.A.3, *supra.* These same reasons render claim 45 obvious. Ex-1405, ¶¶ 228-30; Ex-1442, ¶¶ 158-73.

T. Claim 46: The method of any one of claims 25 or 40-45, wherein advancing the balloon catheter or stent at least partially through the side opening includes advancing the balloon catheter or stent through an opening formed by a material or material combination more rigid than the distal end portion of the tubular structure.

As discussed for claim 52, Kontos in combination with Ressemann teaches

---

substantially the same, similar reference numerals [were] used." Ex-1408, 22:33-37. For example, in the evacuation assembly 100, the evacuation lumen in numbered 132, whereas for evacuation assembly 2100, the evacuation lumen is numbered 2132. *Compare id.*, 6:17-35, *with id.*, 22:31-33.

this claim. Section VIII.A.4-6, *supra*.[14]

U. Claim 47: The method of claim 25, wherein advancing the balloon catheter or stent at least partially through the tubular structure includes advancing the balloon catheter or stent through a reinforcing braid or coil having a length of 20 to 30 cm.

The Ground II combination teaches claim 47. Ex-1405, ¶ 232. The use of metallic braiding or coiling was ubiquitous by the time of the claimed invention and was known to prevent or impart kink-resistance, thereby improving the pushability of the extension catheter. Ex-1405, ¶ 232; Ex-1442, ¶¶ 144-54; Ex-1408, 6:66-7:12; Ex-1446, Abstract; Ex-1447, Abstract.

Ressemann teaches encassing a coil in the polymeric material of the evacualtion head 132 (tubular structure). Ex-1405, ¶ 232; Ex-1442, ¶¶ 145-46, 151. Ressemann 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 ’116 patent. Ex-1405, ¶ 232. In Ressemann, “tube 138 [of evacuation head 132] may be formed around a coil 139,” and “[a] covering of polyurethane can then be applied to contain the coil 139.” Ex-1408, 7:5-12; Fig.

[14] The Ground II combination adds Takahashi, but doing so would not change whether a POSITA was motivated, with a reasonable expectation of success, to practice the method of claim 46. Ex-1405, ¶ 231; Ex-1442, ¶ 201.

1C. A POSITA would have been motivated to add this design feature to tube 16 of Kontos because s/he knew that coiling, as taught by Ressemann, promoted pushability and prevented kinking during advancement of the catheter. Ex-1408, 6:66-7:4; Ex-1405 ¶ 232; Ex-1442 ¶ 152; 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, ¶ 232; Ex-1442, ¶ 154.

Kontos teaches that body 12 is approximately 1 foot (or 30.48 cm) in length. Ex-1409, 4:52-54. As explained by Dr. Hillstead, a POSITA would terminate the metallic braiding/coling of the tubular structure prior to reaching marker band 30 and soft tip 28. Ex-1442, ¶ 153. Marker band 30 and soft tip 28 are each 0.080 inches (0.20 cm) in length. Ex-1409, 4:46-58. Further, as descibed for claim [25.c], a POSITA would have replaced Kontos's funnel portion 26 with Ressemann's side opening. Section IX.A.3, *supra*. As shown below, Ressemann contemplates the metalic braiding/coiling terminitating at the distal-most portion of the side opening.

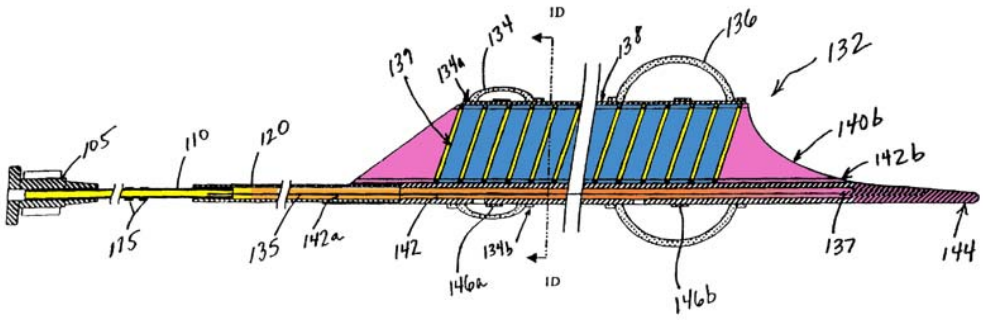
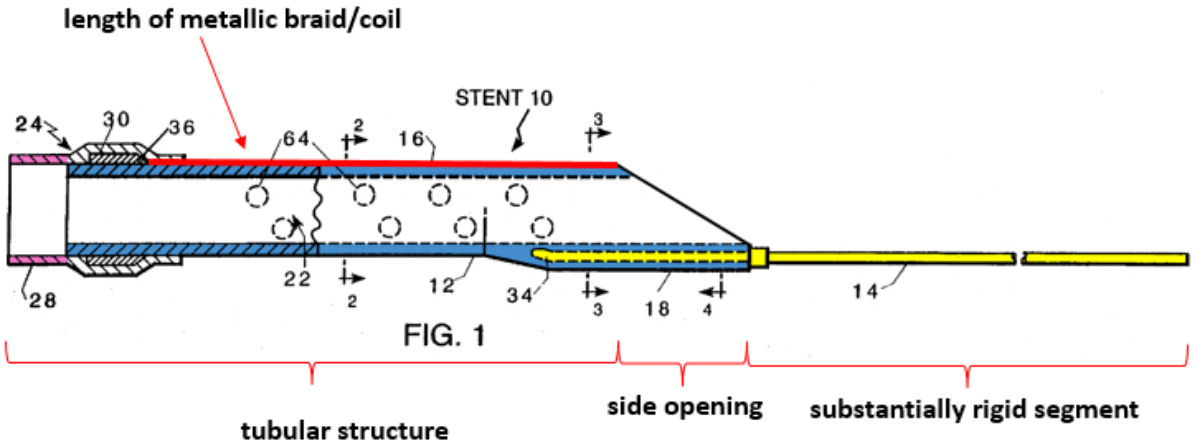


FIG. 1C

Ex-1408, Fig. 1C (color added). In so doing, as shown below (red line), the metallic braiding/coiling, as taught by Ressemann, would be between 20-30 cm in length. Ex-1405, ¶¶ 233-34; Ex-1442, ¶¶ 155-57.



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

V. Claim 48: The method of claim 25, wherein advancing the balloon catheter or stent though the side opening and through the tubular structure includes advancing the balloon catheter or stent respectively through a first portion of the guide extension catheter having a first flexural modulus and a second portion of the guide extension catheter having a second flexural modulus less than the first flexural modulus.

The Ground II combination discloses claim 48. Ex-1405, ¶ 235. In Kontos,

soft tip 28 (region III, below) is preferably a copolymer of polyethylene and EVA. Ex-1409, 4:5-11; Ex-1442, ¶¶ 174-77. Tube 16 (region II, below) preferably is composed of polyethylene. Ex-1409, 4:1-4.; Ex-1442, ¶ 177. Wire 14 (region I) is made of stainless steel. Ex-1409, 4:58-61; Ex-1442, ¶ 178.

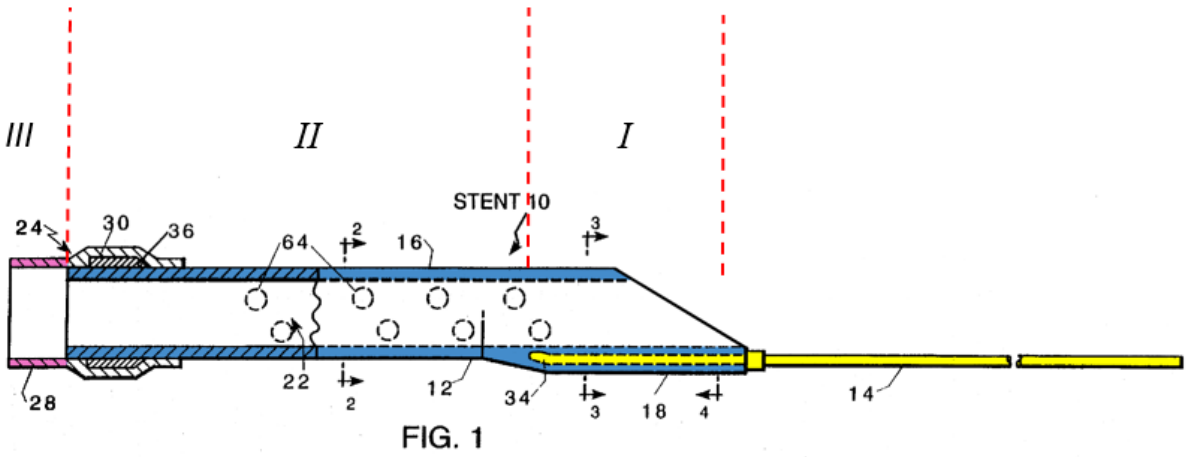


FIG. 1

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

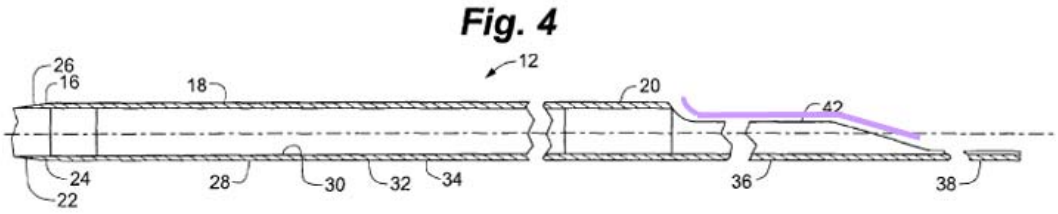
Based on the known material properties, region I has a greater flexural modulus than region II, which has a greater flexural modulus than region III. Ex-1405, ¶ 235; Ex-1442, ¶ 179. As a result, when "advancing the balloon catheter or stent though the side opening and through the tubular structure," the Ground II combination teaches a method of "advancing the balloon catheter or stent … through a first portion of the guide extension catheter having a first flexural modulus and a second portion of the guide extension catheter having a second

flexural modulus less than the first flexural modulus." Ex-1405, ¶ 235.[15]

II. GROUND III: KONTOS RENDERS CLAIM 45 OBVIOUS IN VIEW OF RESSEMANN, TAKAHASHI, KATAISHI, AND/OR THE COMMON KNOWLEDGE OF A POSITA

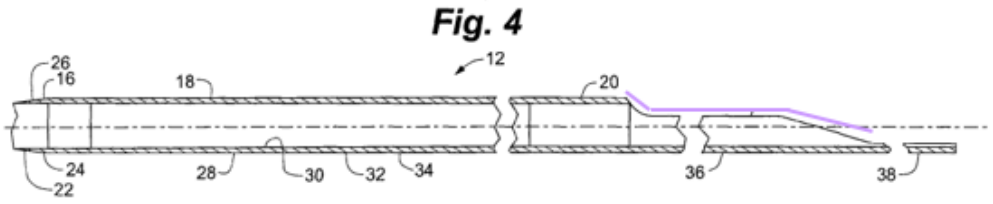
As discussed for claim 45, the Ground II combination teaches a side opening with at least two inclined regions. Section IX.S, *supra*. To the extent Patent Owner contends that combination does not teach two inclined regions, Kataishi also teaches this limitation. Ex-1405, ¶ 236; Ex-1442, ¶¶ 202-14.

In an attempt to support claim 45, Patent Owner represented that Figure 4 of the '116 patent demonstrates two different inclined slopes in the side opening. Ex-1403, 750 (claim 45).



[15] It is unclear what "portion" of the extension catheter Patent Owner will map. Out of an abundance of caution, Petitioner mapped multiple rigidity regions.

Ex-1401, Fig. 4 (color added). Of course, as shown below, the disclosure in the '116 patent is no different than what was disclosed in Kataishi. *Compare id.*, Fig. 4 (color added), *with* Ex-1425, Figs. 2, 10 (color added); Ex-1405, ¶¶ 237-38.



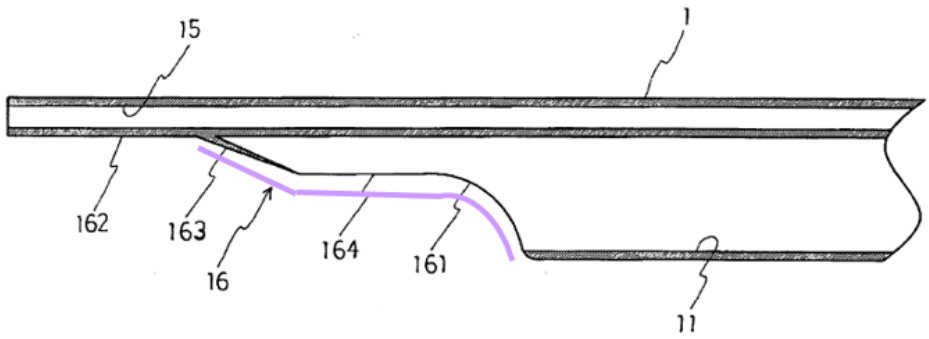


Fig. 2

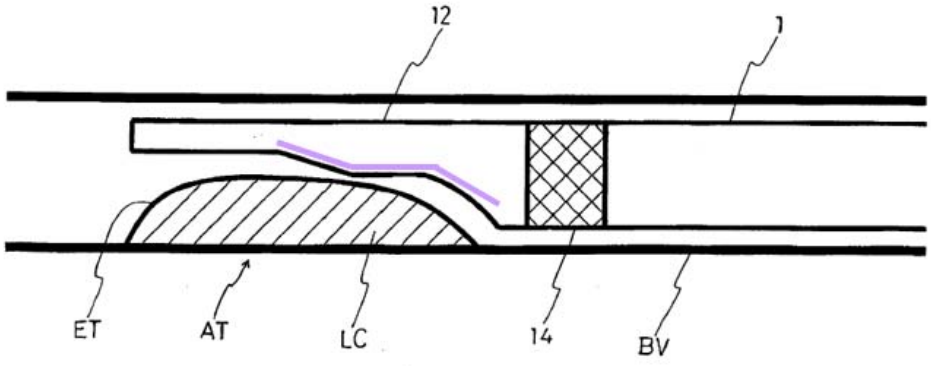


Fig. 10

It would have been obvious to modify the Ground II combination in light of

Kataishi to implement a two-inclined, side opening. Ex-1405, ¶ 239. Indeed, the Ground II references and Kataishi are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventors of the '116 patent. Ex-1405, ¶ 239; Ex-1442, ¶¶ 202-03.

A POSITA was motivated to modify Ressemann's side opening to include Kataishi's two-inclined, side opening. Ex-1405, ¶ 240; Ex-1442, ¶¶ 202-03. Kataishi teaches a suction catheter with a distal end designed to do two things: (i) improve crossability of the catheter; and (ii) provide superior loading of matter (thrombus) into the distal end of the suction catheter. Ex-1425, [0010]. These advantages are accomplished by the shape of Kataishi's distal end. Ex-1442, ¶¶ 204-08. These same considerations—crossability and the ability to load matter into a catheter opening—apply equally to the proximal end of a catheter, especially the catheters of Ground II, where loading is not just of thrombus, but of stents. Ex-1405, ¶ 240; Ex-1442, ¶ 209. As such, POSITA would be motivated to apply Kataishi's distal opening structure to the proximal opening of the Ground II combination.

First, adding a second, inclined slope to Ressemann's side opening would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex-1405, ¶ 241; Ex-1442, ¶ 210. A POSITA would be motivated to make this modification because it would allow the catheter to receive

a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1425, Abstract [0026]-[0027], Fig. 10; Ex-1455, 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end); Ex-1405, ¶ 241; Ex-1442, ¶ 210.

Second, a POSITA was aware that angled openings in the sidewall of a catheter—located proximal of the catheter's distal end—could "minimize … kinking … during insertion." Ex-1426, 3:6-14; 6:5-19, Fig. 2B; *see also* Ex-1405, ¶ 242; Ex-1442, ¶ 211; Ex-1808, 24:49-55. While Kataishi discloses two different inclined slopes on the distal end, a POSITA would be motivated to relocate to the proximal side opening in order to minimize kinking, thereby improving the crossability of the device by avoiding drag on the inside of the guide catheter. Ex-1405, ¶ 242; Ex-1442, ¶¶ 211-13.

A POSITA would have a reasonable expectation of success, as creating two inclined slopes in a side opening would have been a routine task when manufacturing an extension catheter. Ex-1442, ¶ 214; Ex-1450, Fig. 7 (disclosing double incline, proximal side opening). As such, a POSITA would have had a reasonable expectation of success in modifying the Ground II combination with the two-inclined, side opening disclosed in Kataishi. Ex-1405, ¶ 243; Ex-1442, ¶¶ 202-14.

X. THE CHALLENGED CLAIMS ARE NOT ENTITLED TO CLAIM PRIORITY TO MAY 6, 2006

For a patent to claim priority to an earlier-filed application, the claim must have written description support in that application. *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1047-48 (Fed. Cir. 2018). Here, the priority applications provide no written description support for (i) a side opening outside of the substantially rigid segment or (ii) a side opening with "*at least two* inclined slopes."

A. The Effective Filing Date of the Challenged Claims is no Earlier than January 28, 2012

The Challenged Claims recite an extension catheter having a "segment defining a side opening" that is in a separate and distinct region from the claimed "substantially rigid segment." Ex-1442, ¶¶ 35-40. There is no support in any specification in the priority chain or the original claims for a side opening that is outside the substantially rigid segment. *Id.*, ¶¶ 41-63. Therefore, the Challenged Claims are not entitled to their claim of priority.

1. The Challenged Claims Recite a Side Opening Outside of the Substantially Rigid Segment

The Challenged Claims require that the side opening is in a region separate and distinct from the substantially rigid segment. *Id.*, ¶¶ 35-40. In particular, when introducing the side opening in claim 25, Patentee chose not to describe the location as being in the substantially rigid segment or the tubular structure, but

instead recited a separate "segment defining the side opening." Ex-1401, 14:4. This interpretation is confirmed later in claim 25: the balloon catheter or stent is advanced "through a hemostatic valve … along a substantially rigid segment of the guide extension catheter, ***through the side opening***, and through the tubular structure." *Id.*, 14:21-25 (emphasis added). Importantly, if the side opening did not define its own region that is separate from, for example, the substantially rigid segment, there would be no reason to recite that the interventional cardiology device passes through the side opening after the substantially rigid segment and before the tubular structure. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). This means that the "side opening" is its own segment that cannot be found in the substantially rigid segment or the tubular portion. Ex-1442, ¶¶ 36-37.

Such an interpretation is confirmed by other patent claims in the Teleflex family. Indeed, when it wanted to, Patentee knew how to recite that the side opening was in the substantially rigid segment or the tubular portion. For example, claim 3 of the '380 patent recites that the "tubular structure further comprises structure defining a proximal side opening." Ex-1481, 11:33-35; Ex-1442, ¶ 38. Conversely, claim 9 of that same patent recites a side opening in the substantially rigid segment. Ex-1442, ¶ 38. This shows that Patent Owner knew how to recite a

side opening in the substantially rigid segment or the tubular portion, and because it chose not to do so here, the Board should find that the side opening is in its own region (i.e., outside the substantially rigid segment). *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("Our precedent instructs that different claim terms are presumed to have different meanings.").

This interpretation of the '116 patent is confirmed by the district court's interpretation of similar claims in the Teleflex family. The '116 patent was not subject to Patent Owner's preliminary injunction, but in denying that motion, the court found nearly identical claim language to recite the side opening outside of the substantially rigid segment. Specifically, the related '379 patent, which also claims a region "defining a side opening," was found to describe a side opening in a region outside of the substantially rigid segment. Ex-1488, at 5-9.[16] At bottom, the Challenged Claims require the side opening to be in a segment separate from the substantially rigid segment. Ex-1442, ¶¶ 35, 41.

[16] Patent Owner appears to interpret the '116 patent claims as reciting the side opening in a segment separate from the substantially rigid segment. Ex-1508, at 4, 12; Ex-1477, 181:9-16.

2. The Priority Applications Provide no Written Description Support for a Segment Defining a Side Opening Outside of the Substantially Rigid Segment

"When a patentee seeks reissuance of his patent, he cannot introduce any new matter into the reissue application." *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1366 (Fed. Cir. 2009). Because of this, in order to rely on the filing date of an earlier application, 35 U.S.C. § 120 requires that the earlier application include a disclosure that complies with the written description requirement of 35 U.S.C. § 112. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

As shown in the below table, the '116 patent is a reissue patent. The Challenged Claims cannot claim priority to the filing of the original May 3, 2006 application unless the entire priority chain provides written description support. *Id.*

U.S. Patent	U.S. Patent Application (Exhibit No.)	Filing Date
8,048,032	11/416,629 (Ex-1500)	May 3, 2006
8,142,413	12/824,734 (Ex-1501)	June 28, 2010
8,292,850	13/359,059 (Ex-1402)	Jan. 26, 2012
RE45,380	14/070,161 (Ex-1503)	Nov. 1, 2013
RE46,116	14/195,435 (Ex-1403)	March 3, 2014
RE47,379	14/984,273 (Ex-1505)	Dec. 30, 2015

Ex-1442, ¶¶ 31-32, 43.

In the original patent specification, which is substantively identical to the as-

issued '116 specification,[17] the side opening is only disclosed in the substantially rigid segment. *Id.*, ¶ 45. There, the disclosed extension catheter includes three parts: "a tip portion, a reinforced portion, and a substantially rigid portion." Ex-1500, 6:4-5. The substantially rigid portion includes a cutout (side opening) portion.

> The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed.

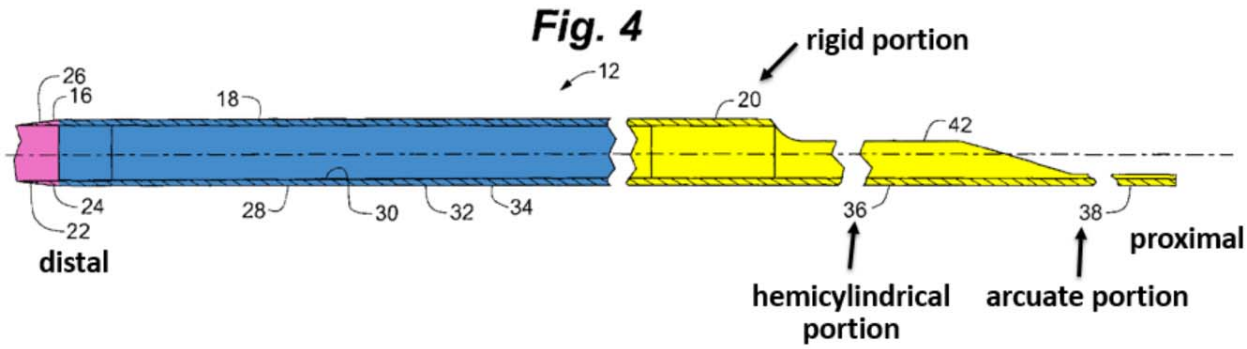
Id., 6:18-7:1.

The original specification also describes that "[r]igid portion 20 includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full circumference portion 40." *Id.*, 13:4-7. Patent Owner identified this teaching "as disclosing the structure of the side opening." Ex-1507, at 4. In other words, Patent Owner identified the side opening as being part of the substantially rigid segment. Ex-1442, ¶¶ 46-49.

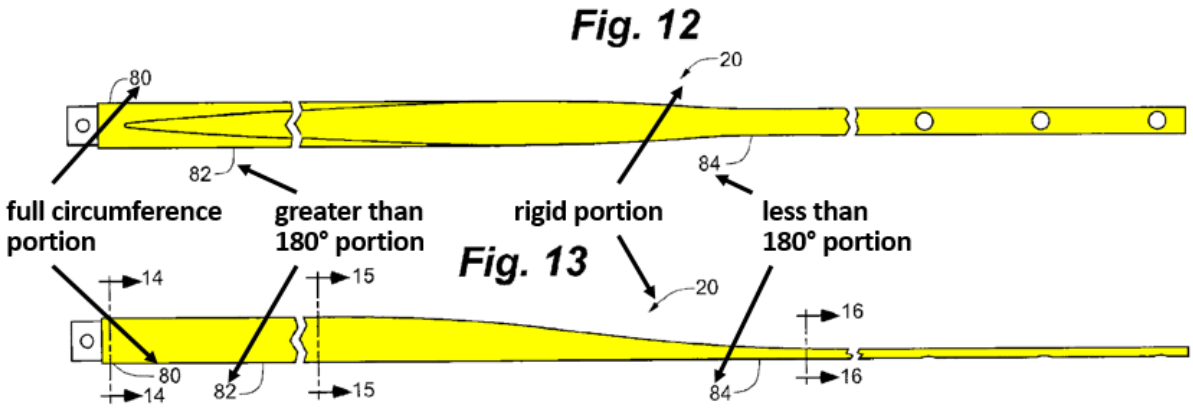
The Figures confirm this conclusion and show the side opening in the rigid

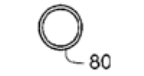
[17] Each specification in the priority chain is substantially identical. Ex-1442, ¶ 44. For this reason, unless otherwise noted, Petitioner cites the '629 Application.

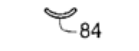
portion 20. For example, in Figure 4, the hemicylindrical portion 36 and arcuate portion 38, that necessarily comprise the side opening, are located in the substantially rigid segment. Ex-1442, ¶ 50.



Ex-1401, Fig. 4 (color and annotations added). Similarly, Figures 12-16—showing "view[s] of the rigid portion [20] in accordance with the present invention"—also contain the side opening. Ex-1500, 11:4-13.







Ex-1401, Figs. 12-16 (color and annotations added). Further, no original claims in the '629 Application recite the side opening in a region outside of the substantially rigid segment. Ex-1442, ¶¶ 53-57.

A POSITA would understand—having reviewed the original '629 Application and the other specifications in the priority chain—that the inventors were not in possession of an extension catheter having a side opening anywhere other than the substantially rigid segment. *Id.*, ¶ 62. The District Court confirmed as much, explaining—in its decision denying Patent Owner's preliminary injunction motion—that "[t]he fact remains …that the only disclosed location for the side opening is in the rigid portion." Ex-1488, at 7. Indeed, the specification is consistent with the first version of GuideLiner, which launched in 2009 and included a side opening in the substantially rigid segment. Ex-1509, at 9. It was not until after that product failed that Teleflex tried claiming the side opening in other regions of the extension catheter—several years after the relevant filing date.[18]

[18] It was not until the filing of the '059 Application (issued as '850 patent) on January 26, 2012 that originally-filed claims recited the side opening outside of the substantially rigid portion. Ex-1442, ¶ 63; Ex-1402, at 27 (cl. 3). Therefore, at best, the effective filing date of the Challenged Claims is January 26, 2012.

B. The Effective Filing Date of Claims 45-46 are no Earlier than November 1, 2013

Claim 45 requires "a side-opening structure having at least two inclined slopes." Ex-1401, 16:24-25. There is no support in any specification in the priority chain for the full scope of these claims and they are not entitled to their original claim of priority.

The original application makes no mention of the number of inclined slopes in the side opening. Ex-1442, ¶ 66. Indeed, when adding these claims during the reissue proceeding, patentee merely cited to Figure 4. Ex-1403a at 273. But Figure 4 shows, at best, only two inclined slopes. Ex-1442, ¶¶ 64-66. The disclosure of only two different inclined slopes is insufficient to support the open-ended range of "at least two different inclined slopes," which encompasses side openings with two *or more* different inclined slopes. *In re Barker*, 559 F.2d 588, 593-94 (C.C.P.A. 1977); *In re Wertheim*, 541 F.2d 257, 263-64 (C.C.P.A. 1976). Therefore, the effective filing date of claims 45-46 can be no earlier than November 1, 2013—the filing date of the application underling RE45,380 (Ex-1442, ¶ 67)—when the "at least two inclined slopes" was recited in original claims. Ex-1503, at 31 (cl. 27).

XI. GROUND IV: ROOT AND THE KNOWLEDGE OF A POSITA RENDERS CLAIMS 25-55 OBVIOUS

No Challenged Claim has an effective filing date before January 26, 2012. Section X, *infra*. Therefore, U.S. Patent Publication 2007/0260219 ("Root") and

the knowledge of a POSITA renders obvious the Challenged Claims. Ex-1405, ¶¶ 244-58.

A. Root (Ex-1512)

Root was filed on May 3, 2006 and published on November 8, 2007. Ex-1512, [22], [43]. Because the Challenged Claims are not entitled to an effective filing date of May 3, 2006, Root is prior art under at least pre-AIA § 102(b).

B. Root and the Knowledge of a POSITA Renders Claims 25-55 Obvious

While prosecuting the '435 Application (issued as '116 patent), Patentee represented that the claims found support in the '059 Application. Ex-1403, at 266-274, 745-755. As shown in the below chart, each disclosures in the '059 Application was also taught by Root. Ex-1405, ¶ 247.

Claim	'059 Application Citations Identified by Patentee to Support '116 Patent Issued Claims		Corresponding Disclosure in Root
	June 11, 2014 Applicant Arguments	Dec. 18, 2015 Applicant Arguments	
25	Abstract 5:3-18 6:1-4 7:14–8:9 9:11-14 15:1-18 19:2-14 FIGS. 2-4, 8-9, 14, 18	15:1-18 19:12-14	Abstract [0012]-[0013] [0015] [0022]-[0023] [0027] [0068]-[0069] [0087] FIGS. 2-4, 8-9, 14, 18

26	5:3-5 20:1-3		[0012] [0089]
27	5:3-5 9:11-12		[0012] [0027]
28	15:1-10 FIG. 8		[0068]-[0069] FIG. 8
29	6:2-3 19:2-14 FIG. 4	15:1-18 19:12-14	[0015] [0087] FIG. 4 [0068]-[0069] [0087]
30	5:3-5 6:2-3 9:11-12 17:4-6	5:3-5 9:11-12 17:4-6	[0012] [0015] [0027] [0074]
31	6:2-3 19:2-14 FIG. 4	19:2-14 FIG. 4	[0015] [0087] FIG. 4
32	4:16-18 5:3-7 15:1-5 FIG. 3		[0011] [0012] [0068] FIG. 3
33	5:5-7 8:3-5 19:12-14 FIG. 3	15:1-18 19:12-14	[0012] [0023] [0087] FIG. 3 [0068]-[0069]
34	5:3-7		[0012]

	FIG. 3		FIG. 3
35	15:10-18 FIG. 9	15:10-18 FIG. 9	[0069] FIG. 9
36	8:3–9:8 15:12-18 19:15-22 FIG. 8	15:9-18	[0023]-[0026] [0069] [0088] FIG. 8
37	5:5-7 8:3-9 15:9-10, 17-18 19:12-14 FIG. 9	15:9-18	[0012] [0023] [0069] [0087] FIG. 9
38	5:3-7 9:11-12 17:4-6 FIG. 3		[0012] [0027] [0074] FIG. 3
39	5:3-5 9:11-12 17:4-6 FIG. 3	15:9-18	[0012] [0027] [0074] FIG. 3 [0069]
40	7:14–8:2 19:12-14		[0022] [0087]
41	13:10-11 FIG. 6	12:19-20 13:10-11 FIG. 6	[0063] FIG. 6 [0057]
42	6:16-17 12:14-16	6:16-17 12:14-16	[0018] [0055]

	FIG. 16	FIG. 16	FIG. 16
43	6:17-22 13:1-2	5:3-18 6:1-4, 16-22 7:14–8:2 9:11-14 12:14-16 13:1-2 15:1-18 19:12-14 FIGS. 2, 4, 8-9, 14, 16, 18	[0018] [0059] [0012]-[0013] [0015] [0022] [0027] [0055] [0068]-[0069] [0087] FIGS. 2, 4, 8-9, 14, 16, 18
44	12:12-16, 19-20 FIG. 15	12:12-16, 19-20 FIG. 15	[0055], [0057] FIG. 15
45	FIG. 4	FIG. 4	FIG. 4
46	6:15, 17 14:3-8 13:15–14:8	6:15, 17 13:15–14:8	[0018] [0065]
47	6:10-14 12:9-11	6:10-14 12:9-11	[0017] [0054]
48	13:15-19	13:15–14:8	[0065]
49	7:3-4 10:15-17 15:19–16:14 FIGS. 10-11	7:3-4 10:15-17 15:19–16:14 FIGS. 10-11	[0019] [0037]-[0038] [0070]-[0072] FIGS. 10-11
50	7:3-4 10:15-17		[0019] [0037]-[0038]

	15:19–16:14 FIGS. 10-11		[0070]-[0072] FIGS. 10-11
51		5:3-18 6:1-4, 16-22 7:14–8:2 9:11-14 12:14-16 13:1-2 15:1-18 19:12-14 FIGS. 2, 4, 8-9, 14, 18	[0012]-[0013] [0015], [0018] [0022] [0027] [0055] [0059] [0068]-[0069] [0087] FIGS. 2, 4, 8-9, 14, 18
52		5:3-18 6:1-4, 15, 17 7:14–8:2 9:11-14 13:15–14:8 15:1-18 19:12-14 FIGS. 2, 4, 8-9, 14, 18	[0012]-[0013] [0015], [0018] [0022] [0027] [0065] [0068]-[0069] [0087] FIGS. 2, 4, 8-9, 14, 18
53			Support at [0022]-[0023], [0087], and FIGS. 8-9 of Root. Ex-1405, ¶ 247.
54		12:19-20 13:10-11 FIG. 6	[0057] [0063] FIG. 6
55		6:17-22	[0018]

		13:1-2	[0059]

As shown above, Root teaches nearly every limitation of the Challenged Claims. Ex-1405, ¶ 247. But as explained in Section X.A, no application in the priority chain, including Root, teaches placement of the side opening outside of the substantially rigid segment. Root in combination of with knowledge of a POSITA would have taught this limitation. Ex-1405, ¶ 248.

A POSITA would have been motivated to construct the side opening of a material that was not rigid, as it was known that "stents can get damaged entering [a] metal collar." Ex-1509, at 10; Ex-1442, ¶¶ 219-220. In particular, a "main limitation" of Teleflex's original GuideLiner product was that the metal collar (a side opening in the substantially rigid segment) could damage stents, which is why the art suggested "[f]uture catheter design modifications" to eliminate this risk. *Id*. A POSITA would have been able to accomplish the claimed combination with a reasonable expectation of success given that side openings outside of the substantially rigid segment were known in the art. Ex-1405, ¶¶ 249-50; Ex-1442, ¶ 221. Accordingly, Root in combination with the knowledge of a POSITA renders the Challanged claims obvious. Ex-1405, ¶ 251.

XII. GROUND V: CLAIMS 45-46 ARE RENDERED OBVIOUS BY KONTOS IN VIEW OF RESSEMANN, TAKAHASHI, ROOT, AND/OR THE KNOWLEDGE OF A POSITA

To the extent the Ground II combination does not teach claims 45-46, Kontos renders obvious in view of Ressemann, Takahashi, and Root. Ex-1405, ¶ 252; Ex-1442, ¶¶ 215-17. The Ground V combination would differ from the Ground II combination only insofar as a POSITA would replace Kontos's funnel 26 with the shape of the side opening in Root Figure 4.

For the reasons discussed for [claim 25.c], a POSITA would have been motivated, with a reasonable expectation of success, to replace Kontos's funnel with a side opening (e.g., the Root Figure 4 side opening). Section IX.A.3, *supra*; Ex-1405, ¶¶ 253-57; Ex-1442, ¶¶ 215-17. In so doing, the Ground V combination would necessarily teach a side opening with two inclines (claim 45) that was made from a material or material combination more rigid than the distal end portion (soft tip 28) of the tubular structure (claim 46). Ex-1405, ¶ 258.

XIII. SECONDARY CONSIDERATIONS

Any purported secondary indicia should not preclude institution. The PTAB already addressed this issue in its institution decision for related patents, explaining that, "as in most cases, an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage." Ex-1513, at 27. That rationale aligns with the PTAB's prior

practice of not—absent a previous finding at the Patent Office or by a Court that such evidence exists—addressing secondary indicia of non-obviousness until the trial phase. *Lowe's, Cos., Inc. v. Nichia Corp.*, IPR2017-02011, Paper 13 at 18 (P.T.A.B. Mar. 12, 2018); *Arctic Cat, Inc. v. Polaris Industries Inc.*, IPR2017-00433, Paper 17 at 9-10, 19 (P.T.A.B. July 5, 2017).

Even if a pre-institution obligation existed, the PTAB explained in its institution decisions for related patents that Patent Owner has identified no secondary indicia for Petitioner to prebut in this Petition. Indeed, Patent Owner attempted to identify secondary indicia of nonobviousness in prior IPRs, but the PTAB held that the purported evidence of non-obviousness lacked any nexus to the alleged invention. Ex-1513, at 27-29. In other words, because Patent Owner has not provided any "persuasive analysis" demonstrating a nexus between the alleged secondary indicia and the claims of this patent (or any related patents), there is nothing for Petitioner to respond to in this Petition. *Id.*

Regardless, even if secondary indicia existed, they could not overcome Petitioner's strong showing of obviousness. *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1374 (Fed. Cir. 2018). Therefore, even if Patent Owner advances secondary indicia in its preliminary response, this Board should grant institution.

XIV. CONCLUSION

Petitioner respectfully requests institution of a trial and invalidation of claims 25-55 of the '116 patent.

Date: July 31, 2020

Respectfully Submitted,

/Cyrus A. Morton/
Cyrus A. Morton

Reg. No. 44,954
Robins Kaplan LLP
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402
Attorney for Patent Owner

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I hereby certify that the Petition for *inter partes* review consists of 13,868 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.

/Cyrus A. Morton/

Cyrus A. Morton
Reg. No. 44,954
Robins Kaplan LLP
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence was served on July 31, 2020, by Federal Express mail to the USPTO correspondence address of record listed below:

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

Courtesy copies were also sent to IPR counsel in the related proceedings at the following email addresses:

J. Derek Vandenburgh, Reg. No. 32,179
dvandenburgh@carlsoncaspers.com

Dennis C. Bremer, Reg. No. 40,528
dbremer@carlsoncaspers.com

/ Cyrus A. Morton /

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

Attorney for Petitioners