

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00126
U.S. Patent No. 8,048,032

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,048,032**

TABLE OF CONTENTS

	Page
I. PRELIMINARY STATEMENT	1
II. MANDATORY NOTICES (37 C.F.R. § 42.8).....	5
A. Real Party-in-Interest	5
B. Related Matters	5
C. Lead and Backup Counsel	6
D. Service Information	6
III. REQUIREMENTS FOR INTER PARTES REVIEW.....	6
A. Grounds for Standing.....	6
B. Precise Relief Requested and Asserted Grounds.....	7
IV. BACKGROUND	7
A. Overview of the Technology	7
B. Overview of the '032 Patent	9
C. Prosecution History of the '032 Patent.....	12
D. Priority Date	14
V. THE PERSON OF ORDINARY SKILL IN THE ART	14
VI. CLAIM CONSTRUCTION	15
A. “standard guide catheter” (cl. 1, 11)	17
B. “placed in a branch artery” (cl. 1, 11).....	17
C. “flexural modulus” (cl. 19, 20)	18
VII. GROUND 1: ITOU ANTICIPATES CLAIMS 1-19 AND 22.	19
A. Overview of Itou	19
B. Claim 1	22
1. [1.pre.I].....	22
2. [1.pre.II]	22
3. [1.pre.III]	25
4. [1.a]	26
5. [1.b]	28
C. Claim 2	35

D. Claim 3.....	39
E. Claim 4.....	43
F. Claim 5.....	43
G. Claim 6.....	44
H. Claim 7.....	46
I. Claim 8.....	47
J. Claim 9.....	48
K. Claim 10.....	51
L. Claim 11	51
1. [11.pre.I].....	51
2. [11.pre.II]	52
3. [11.pre.III]	52
4. [11.a]	52
5. [11.b]	53
6. [11.c]	55
7. [11.d]	56
M. Claim 12.....	58
N. Claim 13.....	59
O. Claim 14.....	60
P. Claims 15-18	62
Q. Claim 19.....	63
R. Claim 22.....	65
VIII. GROUND II: CLAIMS 3, 13, AND 14 ARE RENDERED OBVIOUS BY ITOU IN VIEW OF RESSEMANN AND/OR THE COMMON KNOWLEDGE OF A POSITA.....	65
A. Overview of Ressemann	65
B. Claim 3.....	67
C. Claim 13	72
D. Claim 14.....	75
IX. GROUND III: ITOU RENDERS CLAIM 20 OBVIOUS IN VIEW OF BERG AND THE COMMON KNOWLEDGE OF A POSITA.....	76

A. Overview of Berg	76
B. Claim 20	77
X. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS	79
XI. CONCLUSION	80
XII. PAYMENT OF FEES (37 C.F.R. § 42.103).....	80

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Boston Scientific Corp. v. Vascular Solutions, Inc.</i> , IPR2014-00760, IPR2014-00761 (P.T.A.B., terminated Aug. 11, 2014)	5
<i>In re Harris</i> , 409 F.3d 1339 (Fed. Cir. 2005)	80
<i>In re Schreiber</i> , 128 F.3d 1473 (Fed. Cir. 1997)	37, 42, 62
<i>Laryngeal Mask Co. v. Ambu, A/S</i> , 618 F.3d 1367 (Fed. Cir. 2010)	18
<i>Legget & Platt, Inc. v. VUTEK, Inc.</i> , 537 F.3d 1349 (Fed. Cir. 2008)	22, 46
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (<i>en banc</i>)	15

LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 8,048,032 (“the ’032 patent”)
1002	File history for U.S. Patent No. 8,292,850
1003	File history for U.S. Patent No. 8,048,032
1004	Assignment record of the ’032 patent from the USPTO assignment database
1005	Declaration of Doctor Stephen JD Brecker, M.D.
1006	Curriculum Vitae of Doctor Stephen JD Brecker, M.D.
1007	U.S. Patent No. 7,736,355 (“Itou”)
1008	U.S. Patent No. 7,604,612 (“Ressemann”)
1009	U.S. Patent No. 5,439,445 (“Kontos”)
1010	<i>New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter</i> , Catheterization and Cardiovascular Interventions 63: 452-456 (2004) (“Takahashi”)
1011	Excerpt of prosecution history of U.S. Patent No. 8,048,032 (Application 11/416,629) (Amendment and Response, April 6, 2009)
1012	Joint Claim Construction Statement in <i>QXMedical, LLC v. Vascular Solutions, Inc.</i> , D. Minn., No. 17-cv-01969 (January 10, 2018), D.I. 36; D.I. 36-1.
1013	<i>Markman</i> Order in <i>QXMedical, LLC v. Vascular Solutions, Inc.</i> , D. Minn., No. 17-cv-01969 (October 30, 2018), D.I. 102
1014	Meads, C., et al., <i>Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review</i> , Health Technology Assessment 2000 4(23) (“Meads”)
1015	Excerpt from Grossman’s <i>Cardiac Catheterization, Angiography, and Intervention</i> (6th edition) (2000) (chapters 1, 4, 11, 23-25).
1016	US Patent Publication 2003/0233117 (“Adams ’117”)
1017	U.S. Patent No. 5,902,290 (“Peacock”)

Exhibit	Description
1018	U.S. Patent No. 5,891,056 (“Ramzipoor”)
1019	U.S. Patent No. 6,398,773 (“Bagaoisan”)
1020	Mehan, <i>Coronary Angioplasty through 4 French Diagnostic Catheters</i> , Catheterization and Cardiovascular Interventions 30:22-26 (1993) (“Mehan”)
1021	Excerpt of prosecution history for application 11/232,876 (Office Action, 6/20/09)
1022	Cordis, Instructions for Use, CYPHER™ (April 2003)
1023	Medtronic, Summary of Safety and Effectiveness Data, Driver™ Coronary Stent System (October 1, 2003)
1024	Boston Scientific, Summary of Safety and Effectiveness Data, TAXUS™ Express ² ™ Drug-Eluting Coronary Stent System (March 4, 2004)
1025	U.S. Publication Application No. 2005/0015073 (“Kataishi”)
1026	U.S. Patent No. 5,489,278 (“Abrahamson”)
1027	U.S. Patent No. RE45,776 (“Root”)
1028	Baim, <i>Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts</i> , Circulation 105:1285-1290 (2002) (“Baim”)
1029	Limbruno, <i>Mechanical Prevention of Distal Embolization During Primary Angioplasty</i> , Circulation 108:171-176 (2003) (“Limbruno”)
1030	U.S. Patent No. 5,413,560 (“Solar ’560”)
1031	Schöbel, <i>Percutaneous Coronary Interventions Using a New 5 French Guiding Catheter: Results of a Prospective Study</i> , Catheterization & Cardiovascular Interventions 53:308-312 (2001) (“Schöbel”)
1032	<i>The sliding rail system (monorail): description of a new technique for intravascular instrumentation and its application to coronary angioplasty</i> , Z. Kardio. 76:Supp. 6, 119-122 (1987) (“Bonzel”)
1033	U.S. Publication Application No. 2004/0236215 (Mihara)

Exhibit	Description
1034	U.S. Patent No. 5,527,292 (“Adams ’292”)
1035	U.S. Publication Application No. 2004/0010280 (“Adams ’280”)
1036	Williams et al., <i>Percutaneous Coronary Intervention in the Current Era Compared with 1985-1986</i> , Circulation (2000) 102:2945-2951.
1037	Dorros, G., et al., <i>Coronary Angioplasty in Patients with Prior Coronary Artery Bypass Surgery</i> , Cardiology Clinics 7(4): 791-803 (1989)
1038	Ozaki et al, <i>New Stent Technologies</i> , Progress in Cardiovascular Disease 2:129-140 (1996)
1039	Urban et al., <i>Coronary stenting through 6 French Guiding Catheters, Catheterization and Cardiovascular Diagnosis</i> (1993) 28:263-266
1040	Excerpt of McGraw-Hill Dictionary of Scientific and Technical Terms (5th edition) (1994) (defining “flexural modulus”)
1041	Excerpt from Kern’s The Interventional Cardiac Catheterization Handbook (2nd edition) (2004) (chapter 1)).
1042	Declaration of Dr. Richard A. Hillstead, Ph.D.
1043	Curriculum Vitae of Dr. Richard A. Hillstead, Ph.D.
1044	U.S. Patent No. 5,961,510 (“Fugoso”)
1045	U.S. Patent No. 6,199,262 (“Martin”)
1046	U.S. Patent No. 6,042,578 (“Dinh”)
1047	WO 97/37713 (“Truckai”)
1048	Terumo Heartrail II product literature
1049	Medtronic Launcher product literature
1050	U.S. Patent No. 5,980,486 (“Enger”)
1051	U.S. Patent No. 5,911,715 (“Berg”)
1052	U.S. Patent No. 5,545,149 (“Brin”)
1053	U.S. Patent No. 5,720,300 (“Fagan”)

Exhibit	Description
1054	U.S. Patent No. 5,120,323 (“Shockey”)
1055	Sakurada, <i>Improved Performance of a New Thrombus Aspiration Catheter: Outcomes From In Vitro Experiments and a Case Presentation</i> (“Sakurada”)
1056	Nordenstrom, <i>New Instruments for Catheterization and Angiocardiography</i> (“Nordenstrom”)
1057	U.S. Patent No. 5,445,625 (“Voda”)
1058	U.S. Patent No. 6,595,952 (“Forsberg”)
1059	U.S. Patent No. 6,860,876 (“Chen”)
1060	U.S. Patent No. 6,638,268 (“Niazi”)
1061	U.S. Patent No. 5,690,613 (“Verbeek”)
1062	Iserson, J.-F.-B. <i>Charrière: The Man Behind the “French” Gauge</i> , The Journal of Emergency Medicine. Vol. 5 pp 545-548 (1987)
1063	U.S. Publication Application No. 2003/0195546 (“Solar ’546”)
1064	QXMédical, LLC’s Opening Claim Construction Memorandum <i>QXMedical, LLC v. Vascular Solutions, Inc.</i> , D. Minn., No. 17-cv-01969 (March 14, 2018), D.I. 56
1065	U.S. Patent No. 4,000,739 (“Stevens”)
1066	EP 0 881 921 B1 (“Lee”)
1067	U.S. Patent No. 5,451,209 (“Ainsworth”)
1068	Defendants’ Memorandum in Opposition to Plaintiff’s Summary Judgment Motion and in Support of Defendants’ Summary Judgment Motion, <i>QXMedical, LLC v. Vascular Solutions LLC et al.</i> , 17-cv-01969-PJS-TNL (D. Minn 2019)
1069	Excerpt of prosecution history for application 14/195,435 (Office Action, 10/06/15)
1070	Metz, <i>Comparison of 6f with 7f and 8f guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter, randomized trial</i> , American Heart Journal. Vol. 134, Number 1, pp 132-137 (“Metz”)

Exhibit	Description
1071	Feldman, <i>Coronary Angioplasty Using New 6 French Guiding Catheters</i> , Catheterization and Cardiovascular Diagnosis 23:93-99 (1991) (“Feldman”)
1072	U.S. Patent No. 5,704,926 (“Sutton”)
1073	Plaintiffs’ Memorandum in Support of Motion for Preliminary Injunction, <i>Vascular Solutions LLC et al. v. Medtronic, Inc.</i> , 19:cv-01760-PJS-TNL
1074	Yokoyama, <i>Feasibility and safety of thrombectomy with TVAC aspiration catheter system for patients with acute myocardial infarction</i> , Heart Vessels (2006) 21:1–7 (“Yokoyama”)
1075	Excerpt from Plaintiff’s infringement allegations in <i>Vascular Solutions, LLC. v. Medtronic, Inc.</i> , D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1076	U.S. Patent No. 5,860,963 (“Azam”)
1077	10/16/2019 Deposition of Peter Keith in <i>Vascular Solutions, LLC. v. Medtronic, Inc.</i> , D. Minn., No. 19-cv-01760
1078	Sylvia Hall-Ellis’s Librarian Declaration
1079	Complaint in <i>Vascular Solutions, LLC. v. Medtronic, Inc.</i> , D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1080	U.S. Patent No. 5,061,273 (“Yock”)
1081	U.S. RE45,380 (“the ’380 patent”)
1082	Declaration of Peter Keith in Support of Plaintiffs’ Motion for Preliminary Injunction, <i>Vascular Solutions LLC et al. v. Medtronic, Inc.</i> , 19:cv-01760-PJS-TNL (July 12, 2019)
1083	Joint Fed. R. C. P. 26(f) Report [Excerpt], <i>Vascular Solutions LLC et al. v. Medtronic, Inc.</i> , 19:cv-01760-PJS-TNL
1084	Plaintiffs’ Objections and Responses to Interrogatories [Excerpt], <i>Vascular Solutions LLC et al. v. Medtronic, Inc.</i> , 19:cv-01760-PJS-TNL

I. PRELIMINARY STATEMENT

Medtronic, Inc. and Medtronic Vascular, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-20, and 22 (“Challenged Claims”) of U.S. Pat. No. 8,048,032 (“the ’032 patent,” Ex-1001). The ’032 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id.*, [54], [75]. The ’032 patent was filed on May 3, 2006. *Id.*, [22].

The ’032 patent describes a catheter assembly that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a guide catheter (“GC”) and a guide extension catheter.¹ The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id.*, Abstract, Figs. 8-9. In so doing, the guide extension catheter delivers “backup support by providing the ability to effectively create deep seating in the ostium of the coronary

¹ The ’032 patent refers to the guide extension catheter as a “coaxial guide catheter.” Ex-1005, ¶¶ 76 n.7, 131. A POSITA knew that the “coaxial guide catheter” of the ’032 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1009, 5:49-52 (referring to body 12 “as a guide catheter extension”).

artery,” thereby preventing the GC from dislodging from the ostium. *Id.*, 2:45-50;
see also id., 7:60-8:5.

The '032 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. *Id.*, 2:17-33 (describing the use of a “smaller guide catheter within a larger guide catheter”). Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a “mother-and-child assembly” (Ex-1005, ¶¶ 74-85, 104-09), where the child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. *Id.*, ¶ 74.

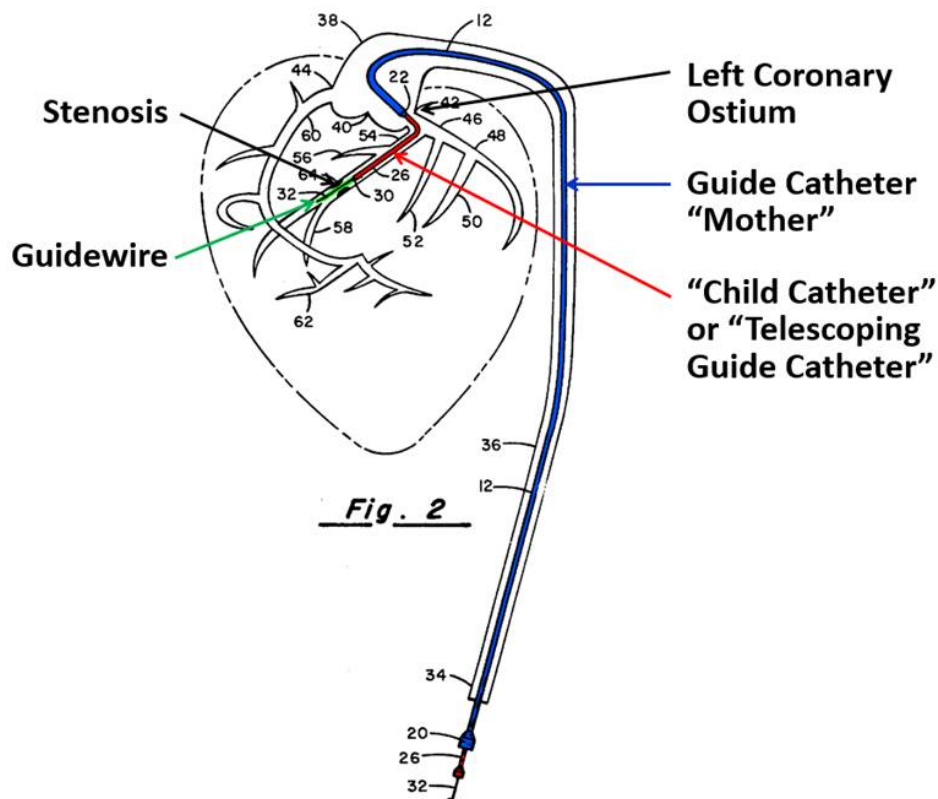


Fig. 1

10

54

14

48

46

12

20

18

24

22

16

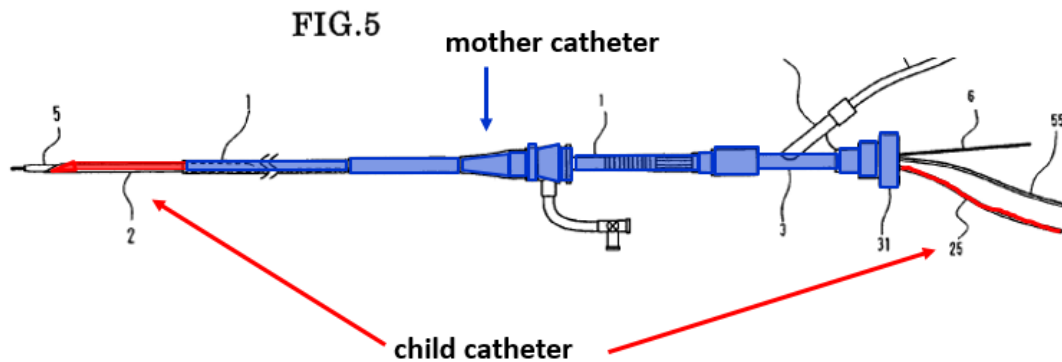
long pushrod

distal lumen

proximal

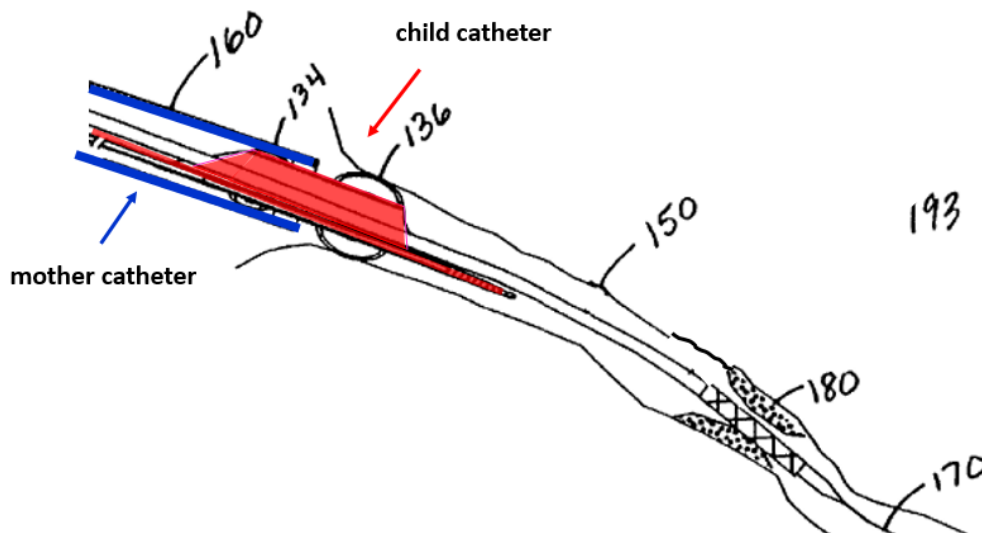
distal

But child catheters with a short lumen connected to a long thin pushrod were already well-known in the art, as evidenced by U.S. Patent No. 7,736,355 (“Itou”) (Ex-1007).



Ex-1007, Fig. 5 (annotations and color added); *see, infra*, § VII.A.

It was also evidenced by U.S. Patent No. 7,604,612 (“Ressemann”).



Ex-1008, Fig. 6E (annotations and color added), *see, infra*, § VIII.A.

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the '032 patent are unpatentable. Accordingly, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the Challenged Claims.

II. MANDATORY NOTICES (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 the real parties-in-interest. Medtronic plc is the ultimate parent of both entities.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the '032 patent is currently the subject of litigation in two separate actions in the U.S. District Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn., filed July 2, 2019); and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) (“QXMedical Litigation”).

The '032 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.*, IPR2014-00760, IPR2014-00761 (P.T.A.B., terminated Aug. 11, 2014).

Petitioner is also concurrently filing another petition for IPR challenging the '032 patent based on prior art references having different priority dates and disclosures than the references discussed herein.

C. Lead and Backup Counsel

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

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

D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the '032 patent is

available for IPR and that Petitioner is not barred or estopped from requesting such review on the identified grounds.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 1-20 and 22 of the '032 patent and cancellation of these claims as unpatentable in view of the following grounds²:

No.	Grounds
1	Claims 1-19 and 22 are anticipated by U.S. 7,736,355 ("Itou").
2	Claims 3, 13, and 14 are rendered obvious by Itou in view of U.S. 7,604,612 ("Ressemann") and the knowledge of a POSITA.
3	Claim 20 is rendered obvious by Itou in view of U.S. 5,911,715 ("Berg") 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-1005, ¶¶ 32-36. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id.* In response,

² This petition is also supported by the Declarations of Dr. Stephen JD Brecker, MD (Ex-1005), and Dr. Richard A. Hillstead (Ex-1042), as experts in the field of the '032 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1078) 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. Ex-1005, ¶¶ 33, 38-44.

PCI was developed more than forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1005, ¶¶ 37, 45. During PCI, after a physician uses a hollow needle to gain access to the patient’s vasculature, a guide catheter is introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of the coronary artery. *Id.*, ¶¶ 38, 46-59. A hemostatic valve is placed at the proximal end of the guide catheter and remains outside the patient’s body. *Id.*, ¶¶ 39, 58. 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.*, ¶¶ 60-62. 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.*, ¶¶ 63-69. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium. *Id.*, ¶¶ 70-71. As discussed

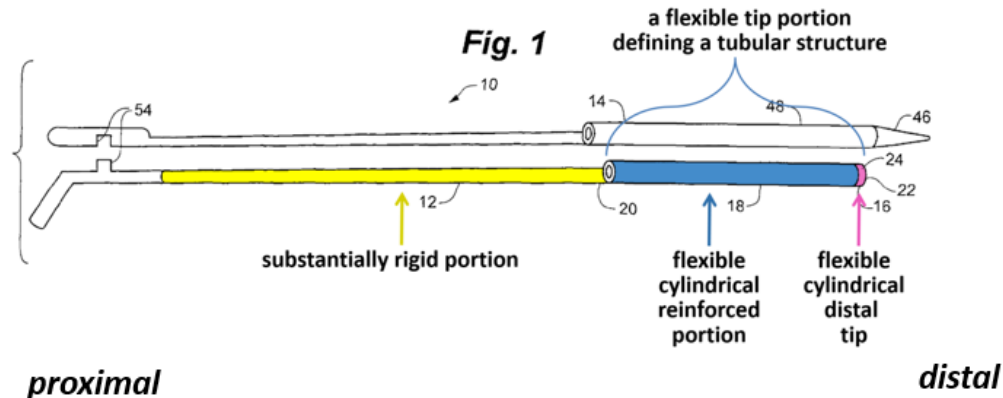
above, one way to ameliorate this backward force is to use a mother-and-child catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id.*, ¶¶ 72-85.

B. Overview of the '032 Patent

The '032 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:7-8. In particular, the '032 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends “beyond the distal end of the guide catheter and . . . into [a] branch artery.” *Id.*, Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id.*, 4:66-5:3; Ex-1005, ¶¶ 131-32.

The '032 patent explains that the guide extension catheter 12 has a tubular portion that includes a flexible distal tip 16 (pink) and a reinforced portion 18 (blue), as well as rigid portion 20 (yellow). *Id.*, 3:28-30, 6:9-12, Fig. 1. Color has been added to Figure 1, below, which has been annotated with the language of the claims.³ Ex-1005, ¶ 133.

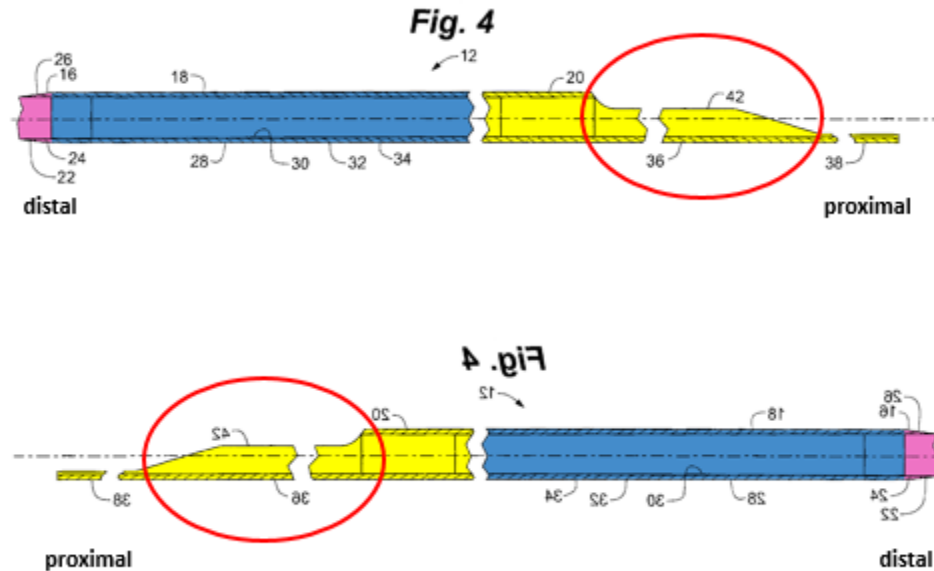
³ In claim 1, “a flexible tip portion” defines “a tubular structure.” Ex-1001, 10:29. The “tubular structure” in claim 1 further “includes a flexible cylindrical distal tip



Ex-1001, Fig. 1 (annotations and color added).

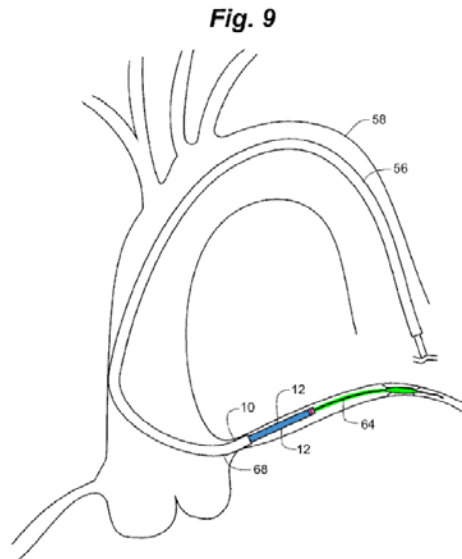
The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "side opening," (red circle), which may have an "inclined slope." *Id.*, Figs. 4, 13-16, 6:38-54, 8:34-40, 10:63-11:3; Ex-1005, ¶ 134.

portion (pink) and a flexible cylindrical reinforced portion (blue) (claim 6)." *Id.*, 11:10-13. Claim 11 describes the guide extension catheter using different language. Specifically, claim 11 recites "a flexible tip portion defining a tubular structure," and a "reinforced portion" that is proximal to the flexible tip portion. *Id.*, 11:39, 50 (corresponding, respectively, to the pink and blue portions of annotated Fig. 1).



Ex-1001, Fig. 4 (annotations and color added) (bottom figure inverted by Petitioner).

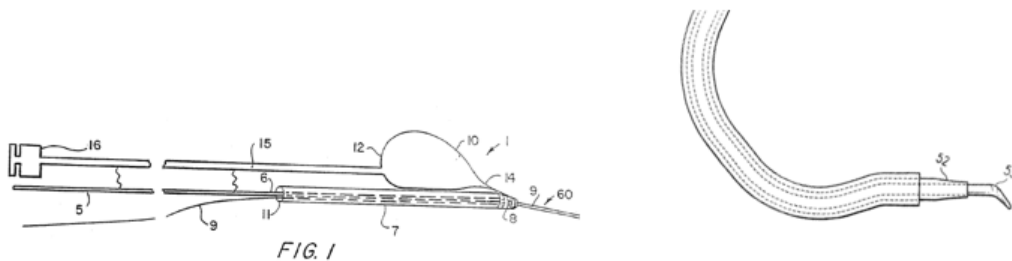
As shown below, the '032 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter's distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56. Ex-1005, ¶ 135.



Ex-1001, Fig. 9 (color added).

C. Prosecution History of the '032 Patent

During prosecution of the '032 patent, the Examiner rejected pending claims, finding (in part), that they were obvious over Niazi (6,638,268) (Ex-1060, below, right) in view of Solar (2003/0195546) (Ex-1063, below, left).



Ex-1063, Fig. 1; Ex-1060, Fig. 3 (respectively).

The Examiner explained that Niazi discloses “a coaxial guide catheter 52 comprising a tubular structure . . . sized to be insertable through the lumen of the guide catheter 51 and defines a coaxial lumen through which cardiology devices

are insertable.” Ex-1003. Moreover, the distal flexible tip of the guide catheter “is flexible and is suitable for extending beyond the distal end of the guide catheter,” where “a rigid portion is proximal of and connected to the flexible tip portion that when combined with the tip is longer than the lumen of the catheter.” *Id.* Niazi can be combined with Solar to disclose “an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally.” *Id.*, 5.

Patent Owner overcame the obviousness rejections by amending the independent claims to recite (among other limitations) a “standard guide catheter,” with a “continuous lumen extending for a predefined length,” and a “circular cross-sectional inner diameter.” The claims were also amended to clarify that the “substantially rigid portion” was “more rigid along a longitudinal axis” than the flexible tip portion, and that the length of the two portions together “defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter.” Ex-1001, 11:52-53, 10:45-47; Ex-1069.

According to the Examiner, the claims were allowable because “[w]hile many of the structures are known, the arrangement of a claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” Ex-1003 (8/3/11 Notice of Allowance at 2). In other words, she believed that a mother-and-child assembly—where the child catheter is

characterized by a short distal lumen coupled to a proximally-located pushrod—
was not described in the art. The Examiner, however, was not aware of Itou.

D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim that is not supported by a pre-March 16, 2013 application. AIA § 3(n)(1)(A); MPEP § 2159.02. The '032 patent is subject to the AIA's first-to-file provisions because it contains at least one claim that lacks a written description, and therefore, pre-AIA priority. Thus, Patent Owner cannot swear behind Itou in this proceeding. No pre-AIA application to which the '032 patent claims priority contains disclosure of “a proximal side opening” outside of the substantially rigid segment, but the independent claims permit the side opening to be in the “flexible tip portion” or “reinforced portion.” *Compare* Ex-1001, 10:21-53, 11:28-12:4 (independent claims not restricting location of side opening), *with id.*, 10:63-11:3 (dependent claim 3 requiring side opening to be in “tubular portion” of flexible tip portion).

V. THE 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-1005, ¶ 31; Ex-1042, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

Claim terms are typically given their ordinary and customary meanings as would have been understood by a POSITA at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-16 (Fed. Cir. 2005) (*en banc*). When, as here, claim terms have been construed by a district court, those constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation, Patent Owner stipulated to the following constructions:

- “reinforced portion”: “portion made stronger by additional material or support” (Ex-1012 at 2)
- “interventional cardiology device(s)”: “devices including, but not limited

to, guidewires, balloon catheters, stents, and stent catheters” (*Compare* Ex-1012 at 21 (Dkt. 36-1), *with* Ex-1064 at 1 n.1)

Further, Patent Owner advanced,⁴ and the district court adopted, the following constructions:

- “substantially rigid”: “rigid enough to allow the device to be advanced within the guide catheter” (Ex-1012 at 2 (Dkt. 36-1); Ex-1013 at 15)
- “rail structure”: “structure that facilitates monorail or sliding rail delivery” (Ex-1013 at 20)

Additionally, the district court provided the following construction:

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

Petitioner agrees with the above constructions for purposes of this IPR⁵ (Ex-1005, ¶¶ 136-42) and proposes the following additional constructions:

⁴ The full list of constructions advanced by Patent Owner in the QXMedical Litigation is found at Ex-1012 (Dkt. 36-1).

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

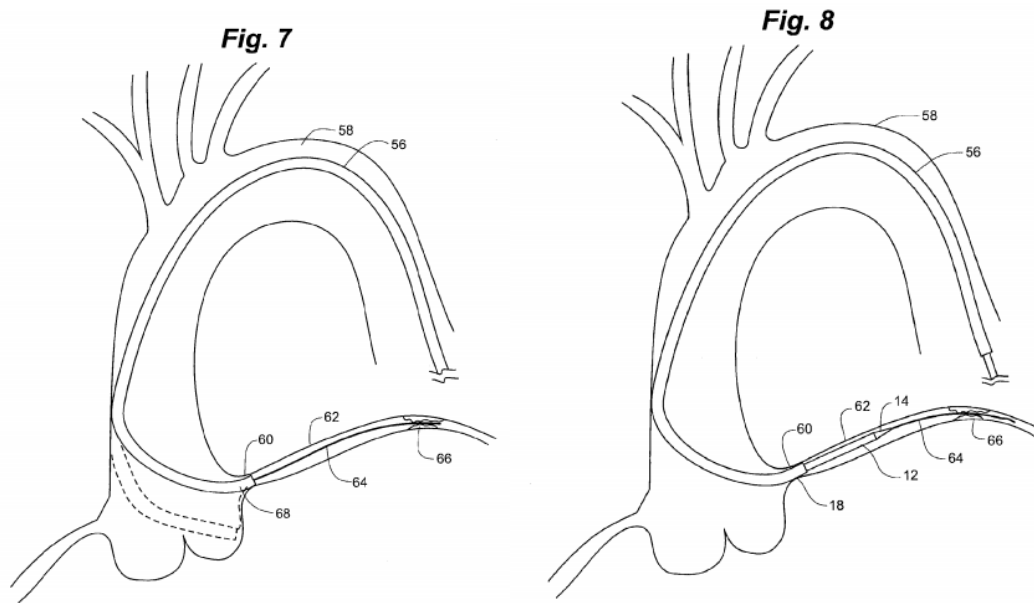
A. “standard guide catheter” (cl. 1, 11)

Claims 1 and 11 recite the use of a “standard guide catheter.” As of the purported priority date, “standard guide catheter” did not refer to a guide catheter of a specified length (although 100 cm was common (Ex-1001, 2:35-38; Ex-1015, 549)), inner or outer diameter, or rigidity. Ex-1005, ¶ 143; Ex-1010, 454 (showing various “guiding catheter systems”). Further, the patent does not define “standard guide catheter,” and, in fact, only uses this term (outside of the claims) once in the background when describing the drawbacks of previous catheter assemblies. Ex-1001, 2:34-35. Finally, in other parts of the patent, the specification instead refers to “typical guide catheter” or references, more simply, “guide catheters.” *Id.*, 7:26-29. Thus, “standard guide catheter” does not reference a specific guide catheter and means “one of a variety of catheters used to guide devices or smaller catheters from the site of insertion into the coronary vasculature.” Ex-1005, ¶ 143.

B. “placed in a branch artery” (cl. 1, 11)

Claims 1 and 11 recite, *inter alia*, “the standard guide catheter having . . . a distal end adapted to be placed in a branch artery.” In the context of the ’032 patent, “placed in a branch artery” includes “placement in the ostium of a coronary artery.” Ex-1005, ¶¶ 144-48. For instance, the ’032 patent notes, in its background, the well-understood fact that a “guide catheter is inserted . . . into the ostium of the coronary artery.” Ex-1001, 1:30-36. This is further shown in figures 7 and 8

(reproduced below), and confirmed by other description in the '032 patent. The patent describes that a GC is “inserted into the ostium of a branch artery where it branches off from a larger artery.” *Id.*, 4:40-46, Figs. 7, 8.



It is more common in the art to refer to arteries branching off *from* the coronary artery as branch arteries, rather than the coronary arteries themselves. Ex-1005 ¶¶ 144-46. However, the patent explicitly states that “guide catheter 56 is brought into proximity of ostium 60 of a smaller **branch** blood vessel, **such as coronary artery 62.**” Ex-1001, 9:44-48 (emphasis added). Thus, to the extent Petitioner’s construction deviates from the plain meaning, the inventors acted as their own lexicographers. *Laryngeal Mask Co. v. Ambu, A/S*, 618 F.3d 1367, 1371-72 (Fed. Cir. 2010).

C. “flexural modulus” (cl. 19, 20)

The claim term “flexural modulus” had a known and established meaning by

2006 (Ex-1042, ¶ 31), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means “[a] measure of resistance . . . to bending.” Ex-1040, 772.

In other words, the “flexural modulus” is a measure of a device’s rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. This is admitted by the ’032 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1001, 7:1-8; Ex-1005 ¶¶ 149-150. Stated differently, the extension catheter’s resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the distal end is the most flexible (least rigid).⁶

VII. GROUND 1: ITOU ANTICIPATES CLAIMS 1-19 AND 22.

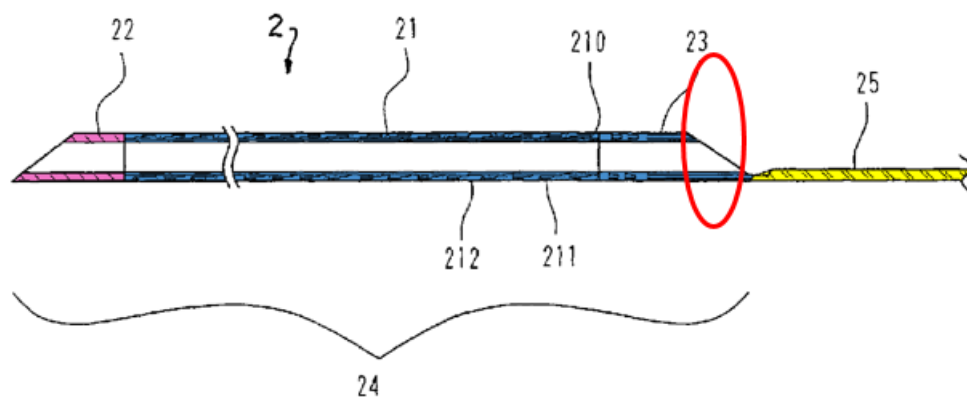
A. Overview of Itou

Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. It is prior art under both pre-AIA §102(e) and post-

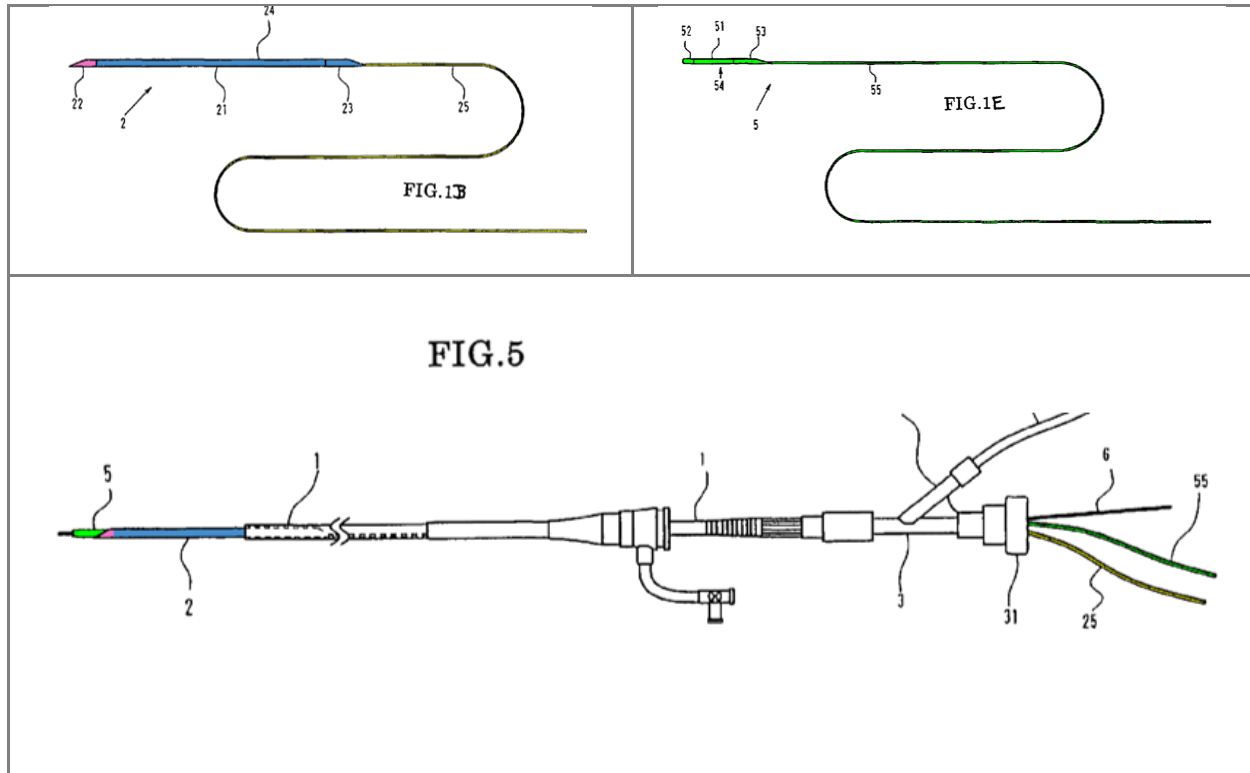
⁶ In the QXMedical Litigation, Patent Owner stipulated to following construction of “flexural modulus”: “a numeric, dimension-independent material property that captures the tendency of a material to bend.” Ex-1012 at 2. From this construction, it is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

AIA § 102(a)(1), (2), and was not cited or considered during prosecution of the '032 patent. *See generally* Exs-1001-03.

Itou discloses a catheter assembly for alleviating the obstruction of blood flow. Ex-1007, 1:13-16. The assembly includes a GC that is inserted into a coronary artery ostium, *id.*, Abstract, 2:2-5, 5:32-34, 7:7-11, and a suction catheter that is insertable through the GC. *Id.*, Abstract, 3:59-61, Figs. 1A-B, 5, 6. Suction catheter (2) has a proximal, “solid wire-like portion” (25), shown below in yellow, and a distal, tubular portion (24). *Id.*, Abstract, 1:53-60, 2:12-15; 3:46-50. Tubular portion (24) includes a “soft tip whose distal end is flexible in order to reduce the damage to the blood vessel,” (22) (pink), *id.*, 2:15-18, and a portion reinforced with a metal layer (211) (blue). *Id.*, 2:18; 3:50-56. The tubular structure’s proximal opening is angled (red circle).



Id., Fig. 3 (color and annotations added); Ex-1005, ¶¶ 95-99, 151-154.



Id. Figs. 1B, 1E, 5 (color added).

Itou also describes a “distal end protective catheter” (5), shown above in green, which is insertable through the suction catheter (2). *Id.* Suction catheter (2) may be extended beyond the distal end of the GC (1) into a coronary artery.

Id., Abstract, 2:29-38, Figs. 5-6; Ex-1005, ¶¶ 162-164.

Where a prior art reference contains the claim elements in the same order as the claims it is anticipatory, regardless of whether the prior art and the claimed invention are directed to achieving the same purpose. *Legget & Platt, Inc. v. VUTEK, Inc.*, 537 F.3d 1349, 1356 (Fed. Cir. 2008). Nevertheless, by the time of the alleged invention of the '032 patent, and as Dr. Brecker explains, a POSITA knew that suction catheters with a structure similar to Itou's may serve a dual

purpose. Ex-1005, ¶¶ 95-103, 151-61. An aspiration catheter could be “preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen.” Ex-1019, 3:4-6. An aspiration lumen could be used both to remove thrombus from a coronary artery, as well as to deliver an angioplasty catheter or stent. *Id.*, 3:34-36, 12:16-20; Ex-1008, 6:18-34, Figs. 6A-I; Ex-1005, ¶¶ 95-103, 151-61.

B. Claim 1

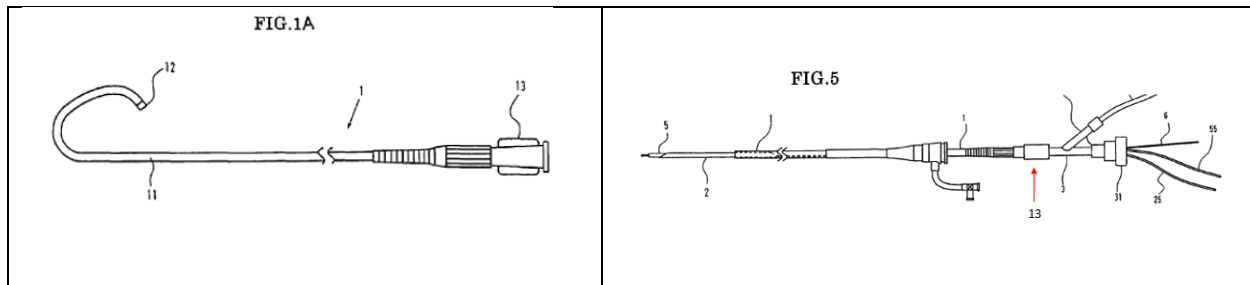
1. [1.pre.I] “A device for use with a standard guide catheter,”

To the extent the preamble is limiting, Itou discloses it. Ex-1007, 1:66-2:11; *and see id.*, Abstract, 5:32-34, 7:10, Fig. 6; Ex-1005, ¶¶ 162-66. As discussed herein, Itou discloses a combination of guiding catheter 1 and suction catheter 2 (i.e. “a device”) and further discloses the system’s use in delivering a protective catheter 5 and a guidewire 6 to the location of a coronary artery occlusion. Ex-1007, 5:35-38, 5:43-46, 7:1-23, 7:35-43, Figs. 5-6, 8.

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

Itou discloses [1.pre.II]. Ex-1005, ¶ 167. Guiding catheter (1) has distal end 12 and body portion (11), which terminates at connector (13). Ex-1007, Fig. 1A, 3:29-36. Connector (13) is coupled to Y-shaped connector (3), which includes main connector portion (31). *Id.*, 5:11-22. Connector (31) includes a valve, which

can close a bore in connector (31) and “selectively clamp and fix the guide wire 6, the wire-like portion (25) or (55) to prevent leakage of the blood.” *Id.*, 5:20-23.



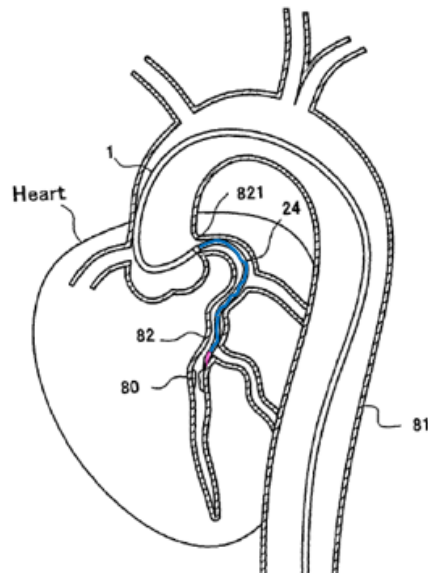
Id., Figs. 1A (left), 5 (right, annotation added).

Guiding catheter (1) necessarily has a “continuous lumen” (or “continuous cavity,” *supra* § VI.), because otherwise suction catheter (2), distal end protective catheter (5) and guidewire (6) could not be advanced through the guiding catheter. Ex-1007, Fig. 5; Ex-1005, ¶ 167.

Additionally, the capability of a valve, connected to the proximal end of guiding catheter (1), to prevent a leak indicates that guiding catheter (1) has a continuous lumen (meaning the walls of the guiding catheter (1) are continuous along its length). *Id.* Moreover, a POSITA understands Itou’s teachings to disclose that the proximal end of guiding catheter (1) extends from a hemostatic valve.⁷ *Id.*

⁷ Itou’s disclosure reflects what the ’032 patent admits, which is that the “guide catheter . . . can be delivered through *commonly existing hemostatic valves* used with guide catheters while still allowing injections *through the existing Y*

Itou teaches that guiding catheter (1) “preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation.” Ex-1007, 5:65-67. Distal end (12) of guiding catheter (1) is “to be inserted to a location on a proximal side of a target location,” which may be deep in a coronary artery. Ex-1007, 1:66-2:4, 5:32-34, 7:7-10.



Id., Fig. 6 (color added).

Itou explicitly discloses that the GC may be placed in “an ostium portion of a coronary artery.” *Id.*, 2:4-5. Thus, Itou teaches placement of guiding catheter (1) that meets the construction of “placed in a branch artery,” which includes

adapter.” Ex-1001, 2:65-3:1 (emphasis added). Similarly, Patent Owner’s expert in the co-pending litigation explains that a hemostatic valve is sometimes called a Y-connector, Ex-1082, ¶ 18; Ex-1005, ¶ 167, which is also known as a Y-adapter.

“placement in the ostium of a coronary artery.” *Supra*, § VI.B; Ex-1005,

¶¶ 144-46, 167.

3. [1.pre.III] “the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:”

Itou discloses [1.pre.III]. Ex-1005, ¶ 168.

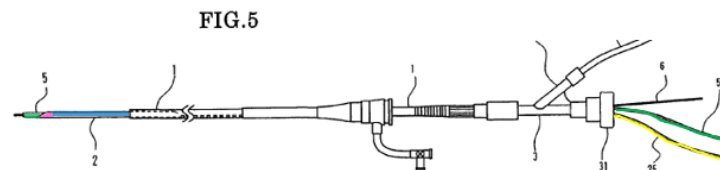
TABLE 1

Name of device	Overall length (mm)	Outer diameter (mm)	Inner diameter (mm)
Guiding catheter 1	1000	2.06	1.8
Suction catheter 2 (tubular portion)	150	1.72	1.5
Suction catheter 2 (wire-like portion)	1100	0.45	—
Distal end protective catheter 5 (tubular portion)	20	1.35	0.5
Distal end protective catheter 5 (wire-like portion)	1300	0.45	—

Ex-1007, Table 1.

Because guiding catheter (1) has an “inner *diameter* of 1.8 mm,” it necessarily has a “circular cross section.” Ex-1005, ¶ 168. Distal end protective catheter (5) has a maximal outer diameter of 1.35 mm, and has a lumen of “a size sufficient to receive . . . guidewire (6)” Ex-1007, Table 1, 4:61-63. Thus, both

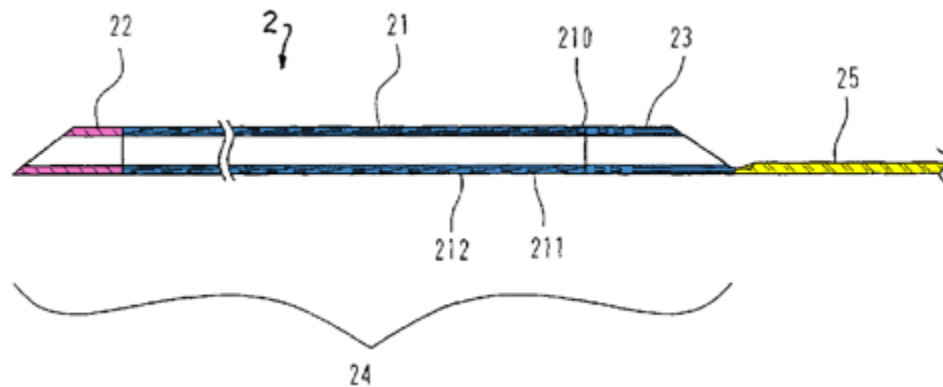
protective catheter (5) and guidewire (6), which are “interventional cardiology devices,” *supra*, § VI, are sized to be insertable into and through the lumen of the guiding catheter (1). Ex-1007, 3:59-63, 4:43-52, Fig. 5; Ex-1005, ¶¶ 46-59, 168.



Ex-1007, Fig. 5 (color added).

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

Itou discloses a flexible tip portion defining a tubular structure and having a circular cross-section. Ex-1005, ¶ 169. Tubular portion (21) and tip (22) of suction catheter (2) comprise the “flexible tip portion.” Ex-1007, 2:12-21, Fig. 3; *and see infra*, § VII.G.



Ex-1007, Fig. 3 (color added).

As shown above, “flexible tip portion” [21, 22] is part of tubular member 24. As a cross section through tubular member (24) is necessarily circular, *id.*, Table 1 (disclosing an inner *diameter* for catheter 2’s tubular portion of 1.5mm); *and see id.*, Fig. 7B, the same is true for a cross section through portion (21). Ex-1005, ¶ 169.

Because Itou explicitly teaches that tubular portion (24) “is shorter than the guiding catheter,” Ex-1007, 2:23-25, flexible tip portion [21, 22] necessarily has “a length that is shorter than the predefined length of the continuous lumen of the guide catheter.”

Itou also discloses that the tubular structure of catheter (2) has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter. Tubular portion 24 (and therefore flexible tip portion [21, 22]) have an outer diameter (1.72 mm) that is sized to be insertable through the cross-sectional inner diameter of the continuous

lumen of the guiding catheter (1.8 mm). *Id.*, Table 1, 1:59-65.

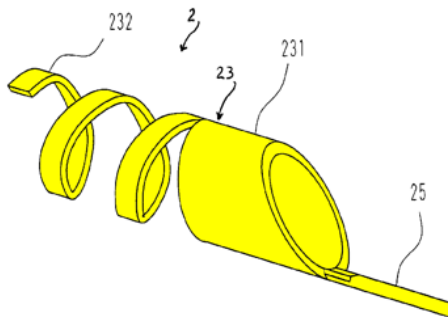
Flexible tip portion [21, 22] defines a lumen that is coaxial to the guiding catheter. *Id.*, Figs. 4-6; *and see id.*, Table 1 (providing both inner and outer diameters for suction catheter 2). Finally, protective catheter (5) is insertable through flexible tip portion [21, 22]. *Id.*, Table 1, 4:48-52, 7:1-23, Fig. 5. Thus, Itou discloses 1.a. Ex-1005, ¶ 169.

5. **[1.b] “a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion,⁸ defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.”**

Itou discloses [1.b]. Ex-1005, ¶ 170. Itou’s suction catheter (2) has a

⁸ The term “the flexible distal tip portion” lacks proper antecedents. The only logical interpretation—that Petitioner adopts for purposes of this proceeding only—is that this language refers to the previously recited “flexible tip portion.”

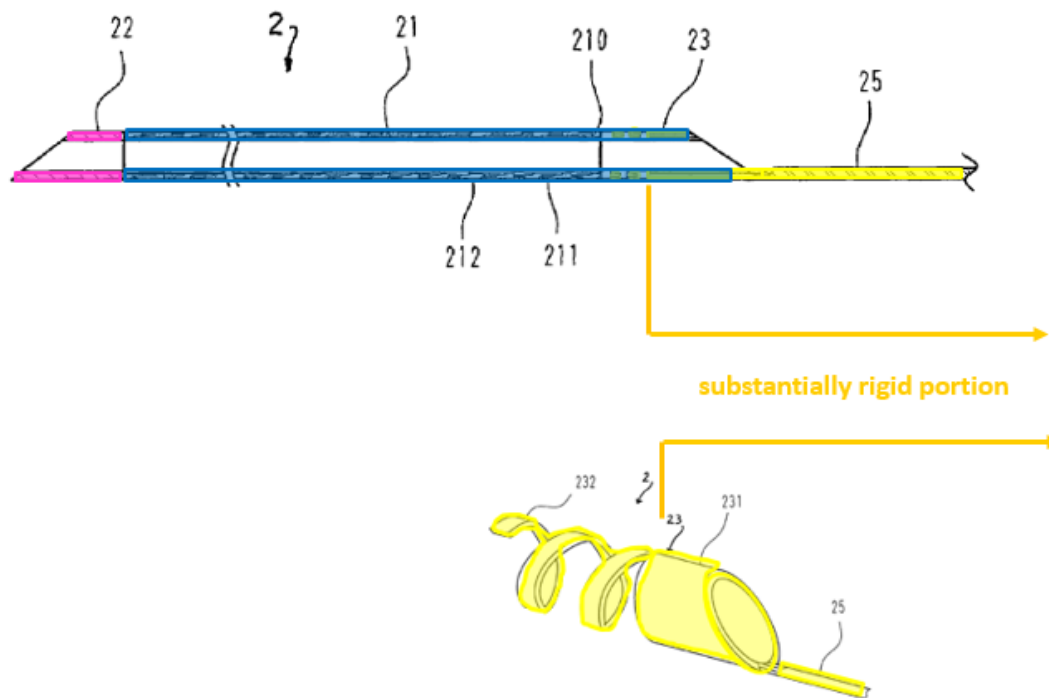
“substantially rigid portion,” which includes solid wire-like portion (25) on the catheter’s proximal end that is “formed from a solid metal wire and an outer layer such as a polymer coating.” Ex-1007, 3:48-50, Fig. 1B; Ex-1005, ¶ 170. Wire-like portion (25)’s distal end is fused to the proximal portion of an obliquely cut metal pipe (231), Ex-1007, 4:25-36, which is also part of the “substantially rigid” portion.⁹ (“Mapping-1”).



Ex-1007, Fig. 4 (color added).

⁹ Petitioner presents two different mappings for the claimed “substantially rigid” portion of claim 1. “Mapping-1,” presented for claim 1.b, applies unless otherwise indicated. In an alternative mapping for the “substantially rigid” portion of claim 1, only wire-like portion (25) comprises the “substantially rigid” portion of 1.b. (“Mapping-2”). Mapping-2 matches how Patent Owner believes the substantially rigid portion may (but is not required) to be mapped. Ex-1077, 123:14-17, 124:19-25, 127:24-128:14, 129:20-130:4.

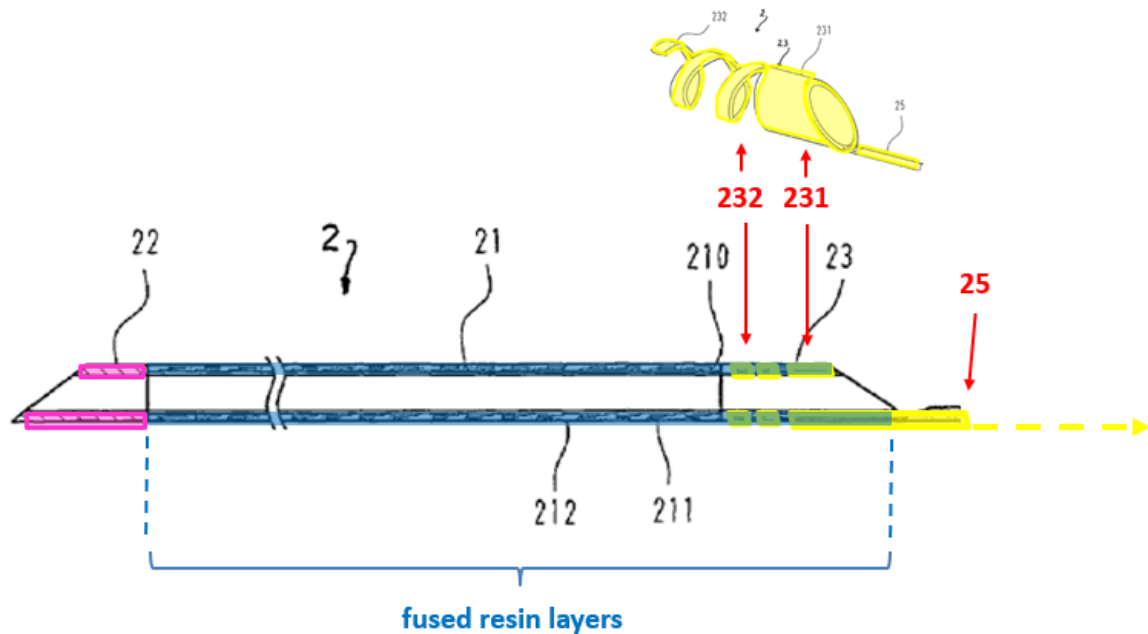
Wire-like portion (25) and end (231) are used to advance suction catheter (2) to a target location (80), which refers to a location deep in a coronary artery. *Id.*, 2:8-13, 5:35-38, 5:43-45. Thus, wire-like portion (25) and/or end (231) must be “rigid enough to allow the device to be advanced within the guide catheter.” *Supra* § VI (construction of “substantially rigid”). Ex-1005, ¶¶ 171-77.



Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).

Under both mappings, Itou’s substantially rigid portion [25 and 231, or 25 alone] is operably connected to its flexible tip portion [21, 22]. The distal end of wire-like portion (25) is welded to the proximal end of proximal tip (231). Ex-1007, 4:43-46. End (231) is formed by obliquely cutting the proximal end of a metal pipe, while the distal end of the metal pipe is formed into spiral shape (232).

Id., 4:27-32. Both the inner—and the outer—faces of end (231) and spiral (232) are encased in resin layers, which are fused to the resin layers of tubular portion (21), operably connecting it to portion 25 and 231. *Id.*, 3:50-55, 4:32-33, 4:36-38; Ex-1005, ¶ 170.



Ex-1007, Figs. 3, 4 (color and annotation added).

Each alternative substantially rigid portion is more rigid along a longitudinal axis than the flexible tip portion [21, 22]. First, both 25 and 231 are made of solid metal. *Id.*, 3:34, 4:28-30. By contrast, the “flexible tip portion” includes tip (22), which is described as soft and “flexible in order to reduce the damage to the blood vessel.” Ex-1007, 2:15-18. It also includes tubular body portion (21), which includes an inner layer made of resin (210), such as PTFE, a reinforcing layer made of metal (211), and outer layer (212). *Id.*, 3:50-55.

As Dr. Brecker and Dr. Hillstead explain, based on the known properties of the materials of portions 25 and 231 and flexible tip portion [22, 21], the former are more rigid along a longitudinal axis. Ex-1005, ¶¶ 169-70; Ex-1042, ¶¶ 64-71. This is further evidenced by the function Itou discloses for proximal, wire-like portion (25), which is to advance suction catheter (2) to a deep location in the coronary vasculature. Ex-1007, 5:43-46. It was well understood in the art that in order to advance through the coronary vasculature, the proximal portion of a catheter necessarily had to have sufficient rigidity or stiffness (in order to permit the catheter to be pushed through the vasculature), while its distal end was fairly flexible. Ex-1019, 9:30-50; Ex-1072, 2:29-43; Ex-1005, ¶¶ 171-76; Ex-1042, ¶¶ 21-22, 35-40, 63.

Each mapping includes a “rail structure without a lumen,” which is wire-like portion 25.¹⁰ Wire-like portion (25) does not have a “lumen” because it is “formed

¹⁰ Claim 1 (and claim 11) recite numerous limitations on the substantially rigid portion, including “defining a rail structure without a lumen.” Thus, while the substantially rigid portion includes a rail structure without a lumen, the claim does not say it is limited to only that structure, particularly where it is “operably connected to ... the flexible tip portion.” Dependent claims 9 and 13 confirm this

from a ***solid*** metal wire.” *Id.*, 3:48-50; *and see id.*, 2:12-14. Wire-like portion (25) is a “rail structure” because it facilitates the sliding rail delivery of suction catheter (2) through guiding catheter (1). *Id.*, Figs. 5, 6, 4:43-52, 5:26-46; Ex-1005, ¶ 177.

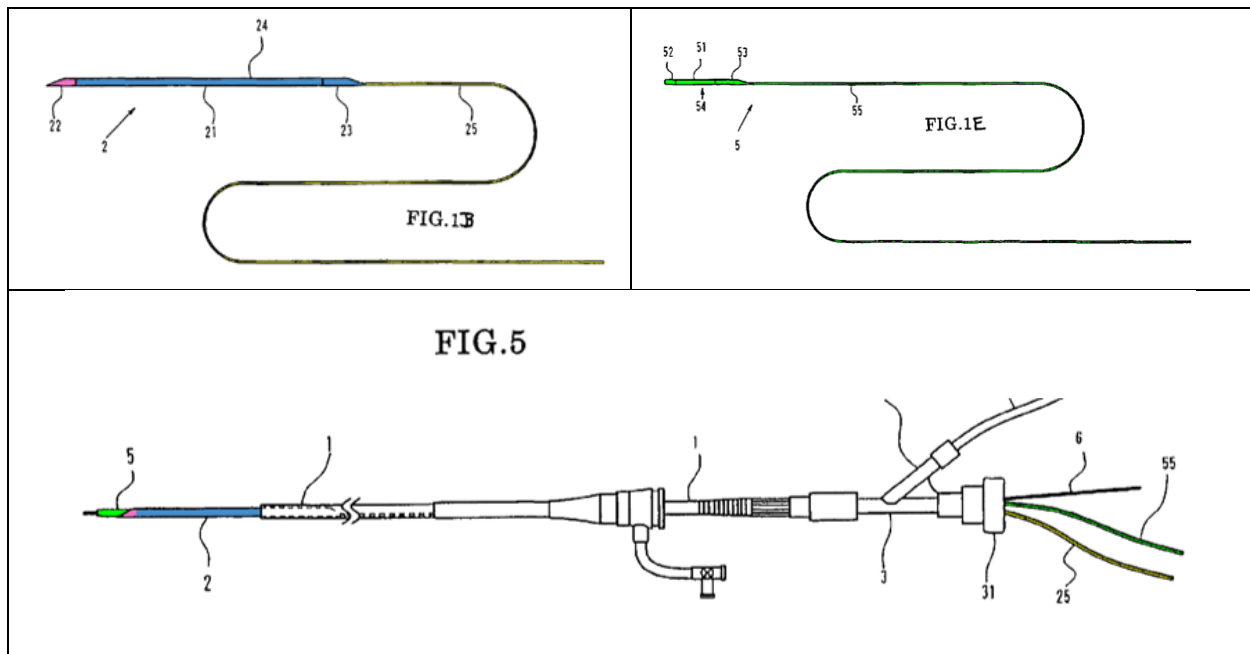
Wire-like portion 25 has a cross sectional outer diameter of 0.45 mm, which is smaller than the cross sectional outer diameter of the tubular portion of the suction catheter (including flexible tip portion [21, 22]), which is 1.72 mm. Ex-1007, 3:59-62; Table 1. Thus, the “rail structure without a lumen” in Itou has a “maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.”¹¹ Ex-1005, ¶ 178.

Wire-like portion (25) is 1100 mm long. Ex-1007, Table 1. This, alone, is longer than the 1000 mm length of the disclosed guiding catheter. *Id.*, Thus, the combined length of wire-like portion (25) and flexible distal tip portion [21, 22] is necessarily greater than that of the guiding catheter. *Id.*, 2:23-26; Ex-1005, ¶ 179.

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

¹¹ The claim language “maximal cross sectional dimension” permits, but does not require, the rail structure to vary in cross-sectional dimension. All the claims require is that the proximal rail structure cannot be bigger (in cross-sectional dimension) than the flexible tip portion (tubular structure).

When at least a distal portion of flexible tip [21, 22] is extended distally of the distal end of the guiding catheter, at least a portion of wire-like portion (25) extends proximally through the hemostatic valve in common with the hemostatic valve through which the distal end protective catheter 5 and guidewire 6 are insertable. *Id.*, 5:11-23; Ex-1005, ¶¶ 180-82.



Ex-1007, Figs. 1B, 1E, 5 (color added).

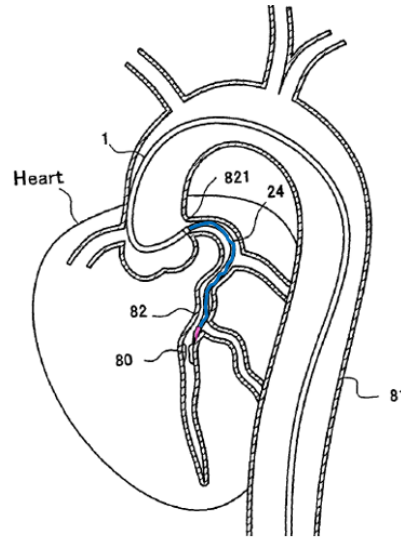
Connector (31) includes a valve, which can close a bore in connector (31) and “selectively clamp and fix the guide wire 6, the wire-like portion 25 or protective catheter 55 to prevent leakage of the blood.” *Id.*, 5:20-23. That the valve may clamp (6), (25), or (55) establishes that all three extend proximally through a

common hemostatic valve.¹² Ex-1005, ¶¶ 182. Thus, Itou discloses 1.b. Ex-1005, ¶¶ 170-83.

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

Itou discloses claim 2. Ex-1005, ¶ 184-94. Suction catheter (2) may be inserted into the lumen of guiding catheter (1). Ex-1007, Abstract; Fig. 5, 2:66-67, 5:11-25. As discussed above, flexible tip portion [21, 22] defines a tubular structure. *See supra* § VII.B.4. As illustrated below, the distal portion of the tubular structure is extended beyond the distal tip of guiding catheter (1). The proximal portion of the tubular structure remains within the lumen of guiding catheter (1). *Id.*, Figs. 5, 6, 5:26-46. Thus, Itou discloses the structural limitations of claim 2. Ex-1005, ¶ 184.

¹² *Supra*, n.7.



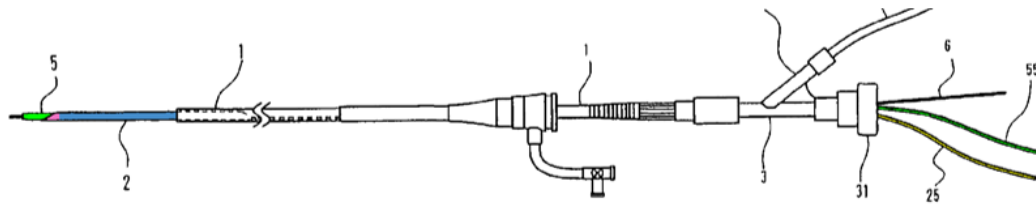
Id., Fig. 6 (color added).

To the extent that Patent Owner suggests that claim 2 requires anything more than the cited disclosure in *Itou*, it is mistaken. Claim 2 additionally recites an intended use (“such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (“It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.”).

Regardless, as Dr. Brecker explains, *Itou* discloses the remainder of claim 2 to a POSITA. Ex-1005, ¶¶ 185-94. First, *Itou* additionally teaches that distal end protective catheter (5) may be extended through suction catheter (2) and beyond its

distal tip. Ex-1007, 1:66-2:11; 4:43-52; *see id.*, Fig. 6.

FIG.5



Ex-1007, Fig. 5 (color added).

Second, long before the '032 patent, those working in the field knew that in order to advance an interventional cardiology device through a GC into the coronary vasculature, the GC had to have “sufficient stiffness to offer ‘backup’ support.” Ex-1015, 548; Ex-1005, ¶¶ 185-86. As Dr. Brecker explains, and as taught in Grossman’s Cardiac Catheterization, Angiography and Intervention, the support came from the GC’s shape, and the intrinsic stiffness of its material, as well as from its “deep engagement” with the coronary ostia. Ex-1005, ¶¶ 187-90; Ex-1015, 549-50; *and see* Ex-1041, 20.

The '032 patent also admits that because the disclosed, coaxial 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-1001, Abstract; *see id.*, 5:6-26. According to the '032 patent’s own disclosure, it is the

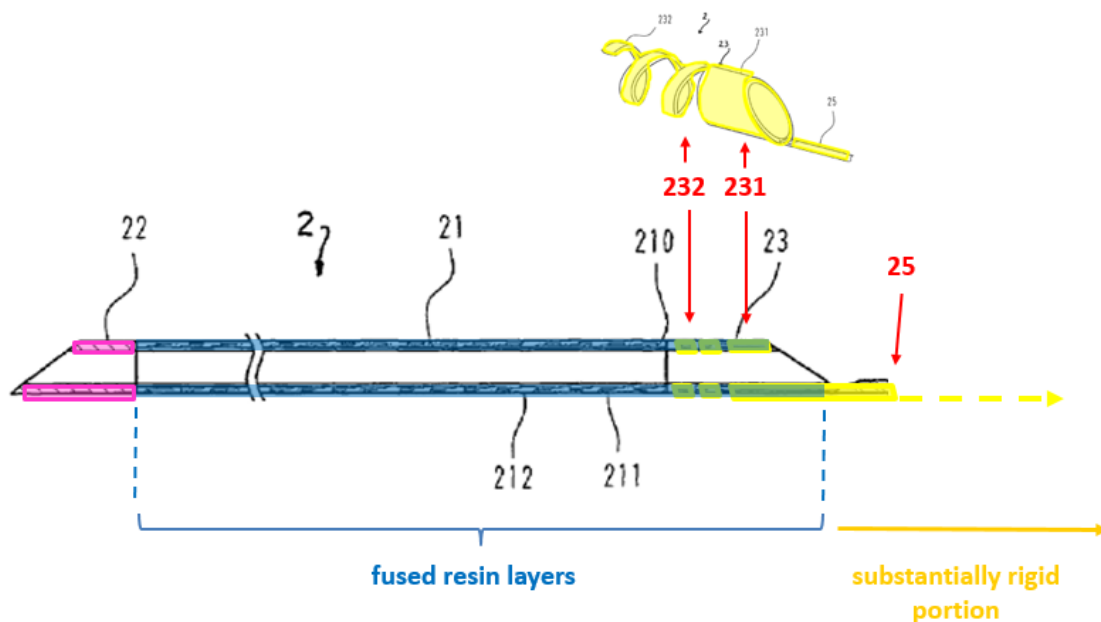
combination of a GC *and* an extension catheter inserted into a coronary ostium that improves distal anchoring of the system, and provides “stiffer back up support” than a GC alone. *Id.*, 7:65-67. But this is no different than what was already known in the prior art, and disclosed in Itou. Ex-1005, ¶¶ 184-94.

The '032 patent further admits that back-up support is achieved where the differential between the inner diameter of the guide catheter and the inner diameter of the coaxial catheter is between 0.20 and 0.35 mm (0.008 and 0.016 inches). Ex-1001, 3:5-20. Itou teaches a differential between the inner diameters of guiding catheter (1) and suction catheter (2) that is precisely within the range taught by the '032 patent: 0.3 mm. Ex-1007, Table 1; Ex-1005, ¶ 193. And Itou's disclosure of a suction catheter that is extended through a GC (and beyond its distal tip into a branch artery)—and used to deliver a distal end protective catheter—inherently discloses a “device [that] assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.” Ex-1005, ¶¶ 184-94.

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

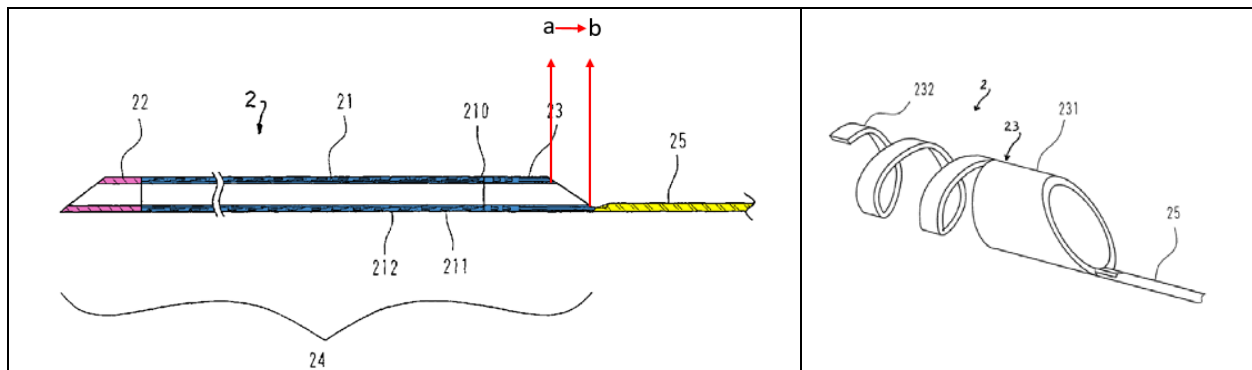
Itou discloses claim 3. Ex-1005, ¶ 195-99.

The claimed tubular structure is defined by Itou's flexible tip portion [21, 22]. *Supra*, § VII.B.4. Itou discloses that the tubular structure “further comprises structure defining a proximal side opening” because the resin layers of flexible tip portion [21, 22] are fused to the resin layers of tip (23). *Supra*, § VII.B.5.



Ex-1007, Figs. 3, 4 (color and annotation added).¹³

Tip (23) includes a proximal side opening (231) that is “inclined obliquely,” and formed by cutting one end of a metal pipe. Ex-1007, 4:11, 4:27-32, Figs. 3, 4. The proximal opening extends for a distance from (a) to (b) along the longitudinal axis of catheter (2), which forms a “side opening.”

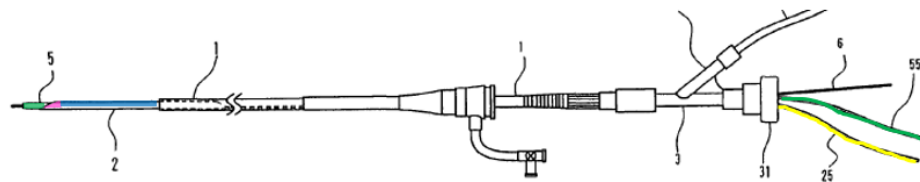


Id., Fig. 3 (annotation and color added), Fig. 4.

Itou additionally teaches that protective catheter (5) is inserted into the lumen of catheter (2), and projects from its distal end. *Id.*, 4:48-51.

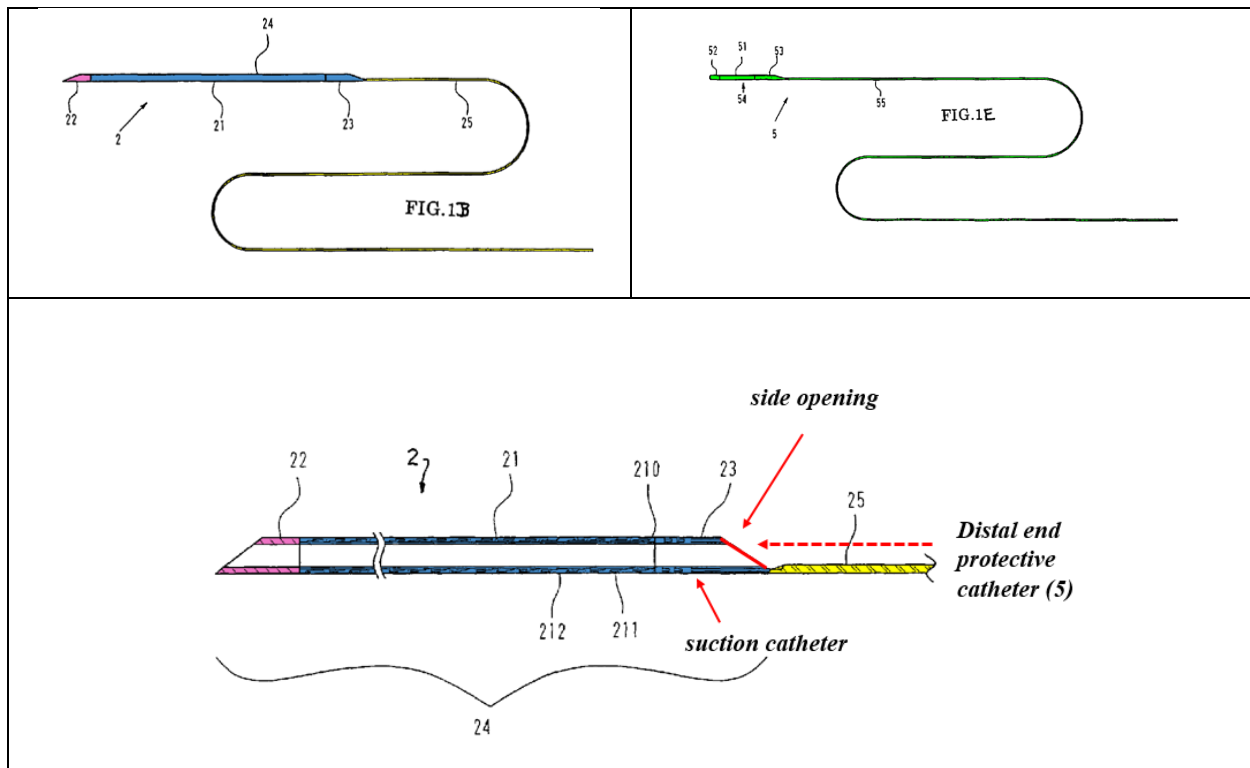
¹³ *Supra*, n.9. As discussed for claim 1, there are two possible mappings for the “substantially rigid” portion claimed in 1.b. Mapping-2, in which the “substantially rigid portion” consists solely of Itou’s wire-like portion (25), applies to claims 3 and 4. Ex-1005, ¶ 170.

FIG.5



Id., Fig. 5 (color added).

This necessarily requires that protective catheter (5) pass through the proximal side opening (231), which “is accessible from a longitudinal side defined transverse to the longitudinal axis.” *Id.*, Figs. 1B, 1E, 3; Ex-1005, ¶ 195.



Id., Figs. 1B, 1E, 3 (color and annotation added).

Thus, Itou discloses the limitations of claim 3. Ex-1005, ¶ 195.

To the extent that Patent Owner suggests that claim 3 requires anything

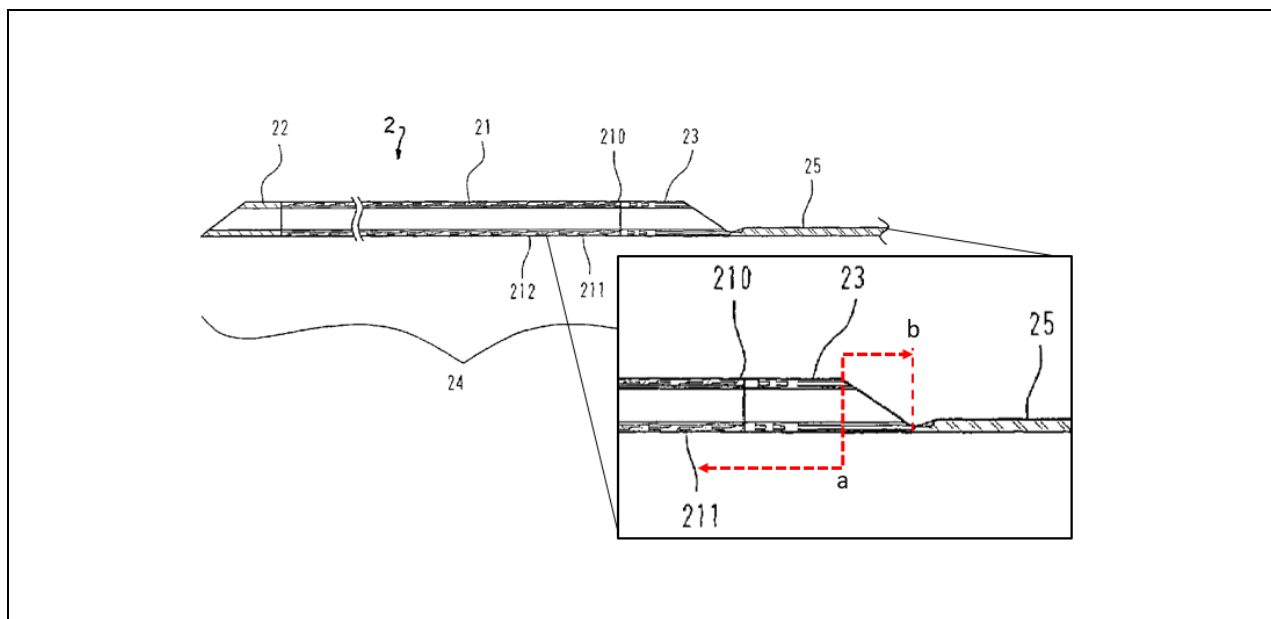
more than the cited disclosure in Itou, it is mistaken. Claim 3 additionally recites an intended use (“to receive the interventional cardiology devices into the coaxial lumen *while* the proximal portion remains within the lumen of the guide catheter”) (emphasis added), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

Regardless, Itou explicitly teaches that suction catheter (2) is long enough so that while its distal end is advanced to a target location—distal to the distal end of the GC—its proximal end (and side opening (231)) remains in the GC. Ex-1007, 5:35-42, 6:30-35. And, the tubular portion of suction catheter (2) has an inner diameter of 1.5 mm,¹⁴ as well as a side opening through which a distal end protective catheter with an outer diameter of 1.35 mm can be received. Ex-1007, 4:48-52, Fig. 5, Table 1. Thus, catheter (2) necessarily has an inner diameter that is large enough to “receive . . . interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.” And Itou, either explicitly or inherently, discloses claim 3. Ex-1005, ¶¶ 196-99.

¹⁴ This corresponds to the inner diameter of the extension catheter taught in the '032 patent. Ex-1001, 3:18-20 (“greater than or equal to 0.056 inches . . .”).

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

Itou discloses claim 4. Ex-1005, ¶ 200. As illustrated below, a cross section through line (a) of proximal tip 23 (and to the left) defines a full circumference portion, and a cross section taken through a portion to the right of line (a), and the left of line (b), defines a partially cylindrical portion.



Ex-1007, Fig. 3 (color and annotations added).

F. Claim 5: The device of claim 2 wherein the flexible cylindrical distal tip portion¹⁵ further comprises a radiopaque marker proximate a distal tip.

Itou discloses claim 5, teaching that tip 22 “is formed such that a filler such

¹⁵ The term “the flexible cylindrical distal tip portion” lacks proper antecedents.

The only logical interpretation—that Petitioner adopts for purposes of this

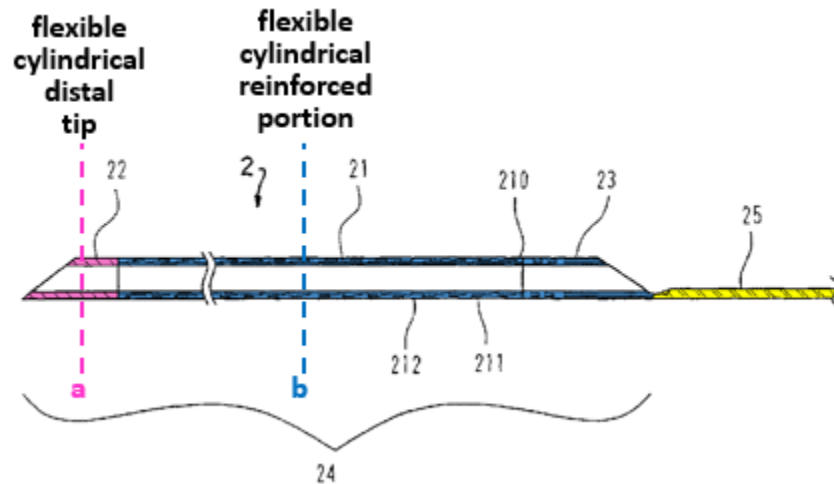
as tungsten, bismuth oxide or barium sulfate, which are X-ray contrast agents, is mixed by 50 to 70 wt % in a matrix made of a resin . . . [and] functions as an X-ray contrast marker (radiopaque marker).” Thus, Itou discloses a “radiopaque marker” that is part of (and therefore “proximate to”) the distal tip of the device. Ex-1007, 4:15-20; Ex-1005, ¶ 201.

G. Claim 6: The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

Flexible tip portion [21, 22] defines a tubular structure that includes both a (i) flexible cylindrical distal tip (22); and (ii) flexible cylindrical reinforced portion, tubular portion (21), which is proximal to tip (22).

Tip 22 is soft and flexible to reduce the risk of potential blood vessel damage. Ex-1007, 2:12-18; 3:47-55 (referring to distal tip 22). Ex-1005 ¶ 202; Ex-1042, ¶ 55.

proceeding only—is that this language refers to the previously recited “flexible tip portion” of claim 1.



Ex-1007, Fig. 3 (color and annotations added).

Tip 22 (pink) is cylindrical as a cross section taken through line (a) is circular, reflected by tubular portion (24) having an inner *diameter*. Ex-1007, Table 1, Fig. 7B; Ex-1005, ¶ 202. Thus, tip 22 is a “flexible cylindrical distal tip portion.” Ex-1005, ¶ 202.

Tubular portion (21) (blue) is proximal to tip (22). It is also cylindrical, as a cross section taken through line (b) is circular, reflected by tube portion (24) having an inner *diameter*. Ex-1007, Table 1, Fig. 7B; Ex-1005, ¶ 202. Tubular portion (21) is reinforced. As discussed above, a “reinforced portion” is a “portion made stronger by additional material or support.” *Supra*, § VI. Itou teaches that tubular portion (21) includes a reinforcing metal wire layer (211) to prevent kinking, an outer layer 212, and an inner layer 210 made of resin. Ex-1007, 2:15-21, 3:50-58; Ex-1005, ¶ 202; Ex-1042, ¶¶ 56-62.

Itou discloses that reinforced tubular portion (21) is also flexible. First, Itou

explicitly teaches that the “*tubular portion* of said suction catheter *is more flexible* than the distal end of said guiding catheter.” Ex-1007, 10:4-7 (emphasis added).

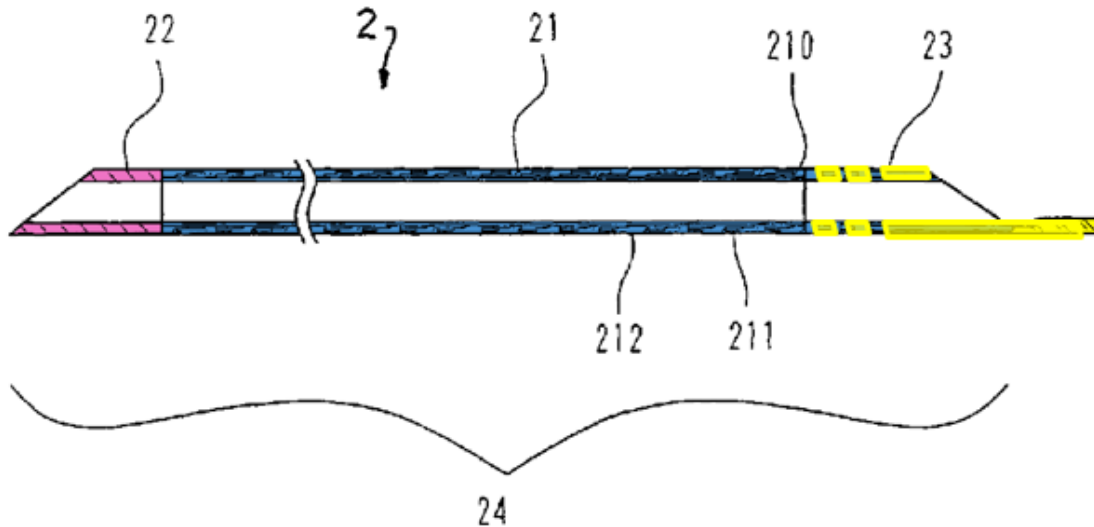
All the claim element requires is flexibility, so this element is met.

Alternatively, Itou inherently discloses that reinforced tubular portion (21) is flexible. A claim element is inherent when the prior art must “necessarily function[] in accordance with, or include[], the claimed limitations.” *Leggett & Platt*, 537 F.3d at 1354. As Dr. Brecker explains, the distal portion of a suction catheter must be “fairly flexible,” so that the catheter can be “navigated through tortuous blood vessel networks.” Ex-1019, 9:35-37; Ex-1005, ¶ 202. Itou is no different. Suction catheter (2) is specifically configured to extend beyond the distal tip of the guide catheter to remove foreign matter “*positioned at a deep location* in a coronary artery.” Ex-1007, 1:66-2:11. If reinforced tubular portion (21) lacked flexibility, suction catheter (2) would not be able to reach foreign matter at a “deep location” in a coronary artery. Tubular portion (21)’s location at the distal end of suction catheter (2) means that portion (21) is necessarily flexible. Ex-1005 ¶ 202; Ex-1042, ¶¶ 50-54.

H. Claim 7: The device of claim 6 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

Itou discloses claim 7. Ex-1005, ¶ 203. Tubular portion (21) has “an inner layer 210 made of a resin material . . . *a reinforcing layer (211)* made of a metal

wire made of stainless steel or the like, and an outer layer (212) for covering the reinforcing layer (211)” Ex-1007, 3:50-58 (emphasis added).



Id., Fig. 3 (color added).

From the disclosure of Itou, it is evident that reinforcing metal wire (211) is braided or coiled around inner layer 210. Ex-1005, ¶ 203; Ex-1042, ¶¶ 41-46, 60, 62.

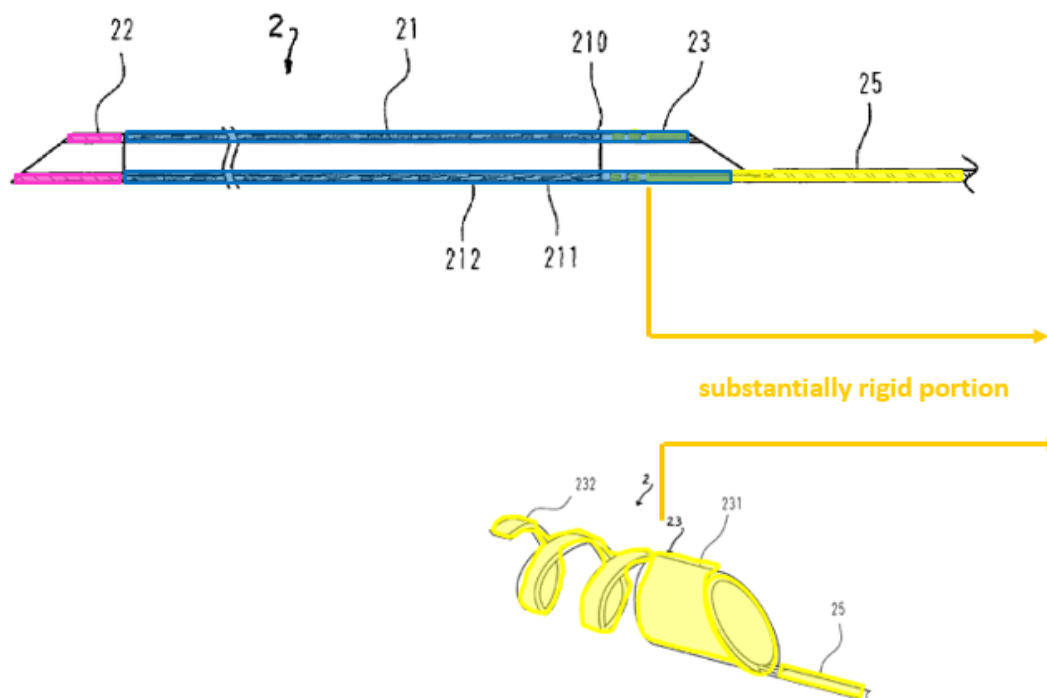
I. Claim 8: The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

Itou discloses claim 8. Ex-1005, ¶ 204. “[G]uiding catheter 1 is formed from a guiding catheter of 6 Fr (2.06 mm) which is used popularly and has an inner diameter of 1.8 mm.” Ex-1007, 6:46-55, Table 1. Catheter (2)’s tubular portion (24) (and therefore the “tubular structure” defined by flexible tip portion [21, 22]) has an inner diameter of 1.5 mm, *id.*, Table 1, which is 0.3 mm smaller than the

inner diameter of the GC. And 0.3 mm is “not more than one French smaller,” because one French is 0.33 mm. Ex-1062; Ex-1005, ¶ 50, n.6.

J. Claim 9: The device of claim 1 wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.¹⁶

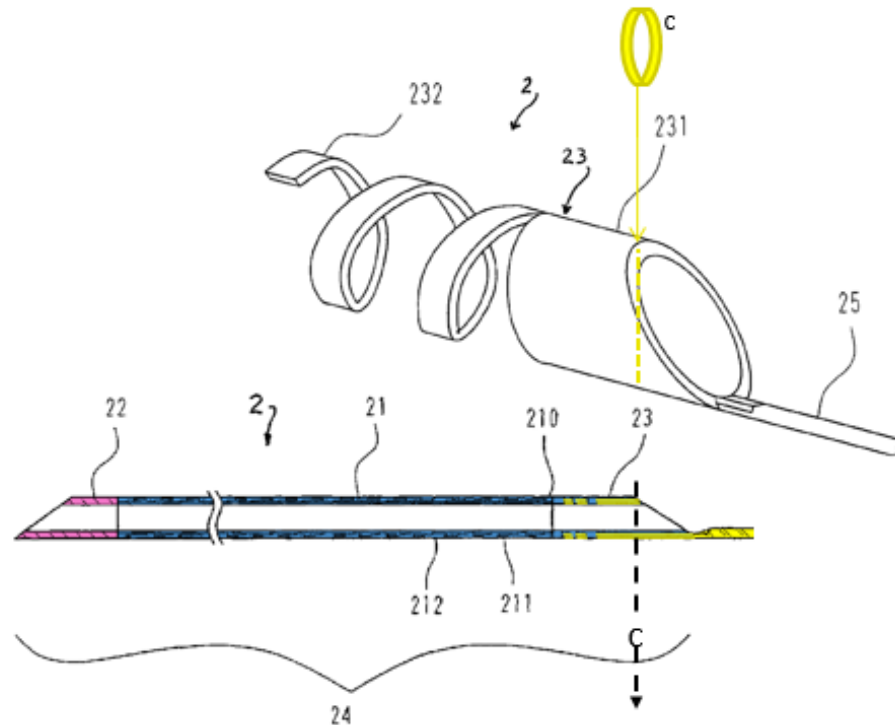
Itou discloses claim 9. Ex-1005, ¶ 205. The “substantially rigid portion” of Itou’s suction catheter (2) includes both wire-like portion (25) and end (231).



¹⁶ For purposes of consistency between claims 1 and 9, Petitioner assumes that the “substantially rigid portion” must include a “rail structure without a lumen,” but may also include structure in addition to the rail structure, such as the full circumference portion of claim 9.

Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).¹⁷

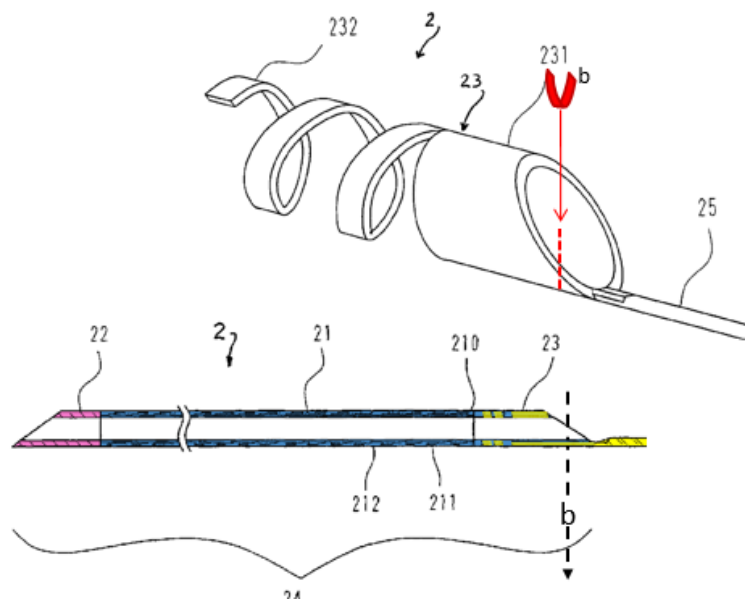
The substantially rigid portion necessarily includes a cross-sectional shape having a full circumference portion (shown by line (c)). Ex-1005, ¶ 205.



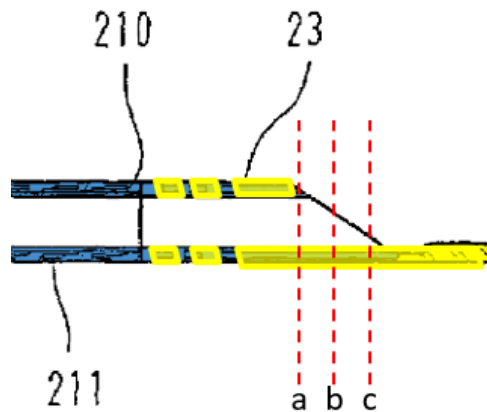
Ex-1007, Figs. 4 (top), 3 (bottom) (color and annotations added).

Moving distally, and as shown below, the substantially rigid portion has a hemicylindrical cross-sectional shape (cross section at “b”) (Ex-1005, ¶ 205), which, according to the ’032 patent is a portion that “desirably includes 40% to 70% of the circumference of a tube.” Ex-1001, 6:44-45.

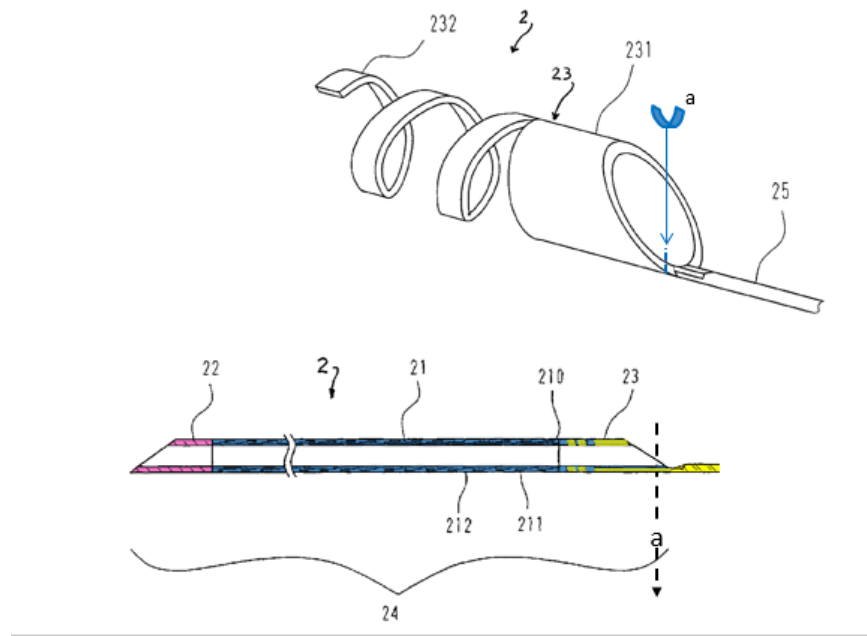
¹⁷ Mapping-1 for the “substantially rigid portion” applies to claim 9. *Supra*, n.9.



Id., Figs. 4 (top), 3 (bottom) (color and annotations added).



Finally, the side opening includes an arcuate cross sectional shape, which, according to the '032 patent is a portion that “extends from 25% to 40% of the circumference of the tube.” Ex-1001, 6:49-51.



Ex-1007, Figs. 4 (top), 3 (bottom) (color and annotations added).

K. Claim 10: The device of claim 1 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

Itou discloses claim 10. Ex-1005, ¶ 206. The guiding catheter 1 preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation. As a standard length of guiding catheter used normally, the total length is approximately 1,000 mm, or 100 cm. Ex-1007, 5:65-6:1. The total length of catheter 2 is the (tubular portion) plus (wire-like portion), which is 15 cm + 110 cm, respectively, equaling 125 cm. Ex-1007, Table 1.

L. Claim 11

1. [11.pre.I] “A device for use with a standard guide catheter,”

Itou discloses [11.pre.I]. *Supra*, § VII.B.1 ([1.pre.I]); Ex-1005, ¶ 207.

2. **[11.pre.II] “the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,”**

Itou discloses [11.pre.II]. *Supra*, § VII.B.2 ([1.pre.II]); Ex-1005, ¶ 208.

3. **[11.pre.III] “the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:”**

This language differs from claim 1 only insofar as claim 11 recites a “circular cross-section.” This additional language is taught by Itou for the same reason it teaches a circular cross-sectional inner diameter of the guide catheter.

Supra, § VII.B.3 ([1.pre.III]); Ex-1005, ¶ 209.

4. **[11.a] “an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:”**

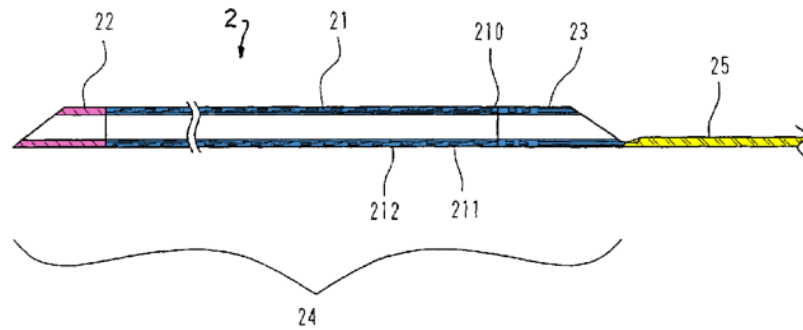
Itou discloses [11.a]. *Supra*, § VII.B.4-5 ([1a], [1b]); Ex-1005, ¶ 210. The “elongate structure” is the “device adapted for use with the guide catheter,” suction catheter (2). Ex-1007, Fig. 3. The combined length of its tubular portion (24) and wire-like portion (25) is greater than that of guiding catheter (1). *Id.*, 2:23-26; and *see id.* 5:67-6:18; *supra*, § VII.K.

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

Itou discloses [11.b]. Ex-1005, ¶ 211. Suction catheter (2) has a tubular portion (24), which includes distal tip (22), which is the “flexible tip portion.”¹⁸

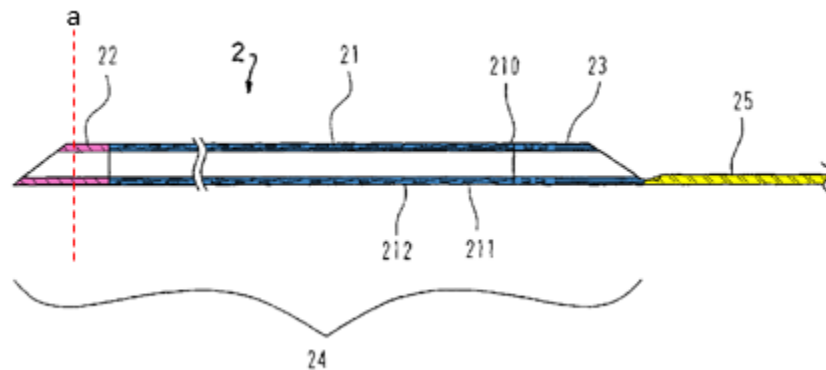
¹⁸ In general, use of the same words in different claims mean the same thing. In claim 1, however, Patent Owner used “flexible tip portion” to include both the “flexible cylindrical distal tip” and the “reinforced portion.” *See supra* § VII.G (claim 6). But, in claim 11 that is not the case, as Patent Owner separately recites a “reinforced portion proximal to the “flexible tip portion.” *Compare* Ex-1001, 11:39-49, *with id.* 11:50-51.

Patent Owner also drafted claim 11 such that the substantially rigid portion is “connected to” the flexible tip portion. The only disclosure in the specification, though, is an indirect connection, such that the flexible tip portion is connected to the reinforced portion, which is connected to the substantially rigid portion. For purposes of this IPR, and not for district court litigation, Petitioner assumes that



Ex-1007, Fig. 3 (color added).

Itou explains that the distal tip of catheter (2) is soft and flexible. Ex-1007, 2:12-21. A cross section through tip (22) at line (a) is necessarily circular. *Id.*, Table 1 (inner *diameter* of tubular portion (24) is 1.5mm). Ex-1005, ¶ 211.



Ex-1007, Fig. 3 (color and annotation added).

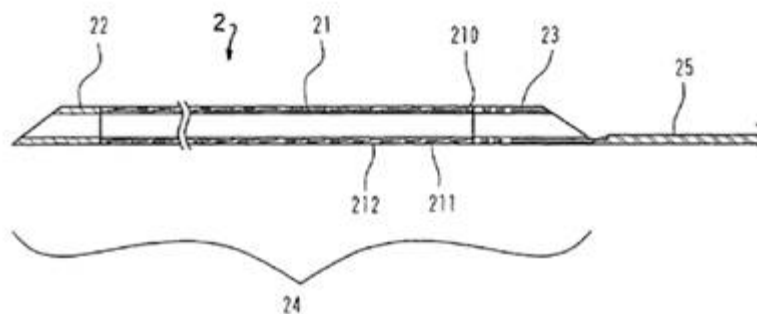
claim 11 allows for an indirect connection, because the claim would otherwise not make sense. Under any interpretation, this is simply an example of poor claim drafting and there is no inventive concept here worthy of patent protection in light of the prior art presented.

Tip (22) is shorter in length than tubular portion (24), which “is [itself] shorter than the guiding catheter.” Ex-1007, 2:23-26, Fig. 3. Tip (22) is therefore necessarily shorter than guiding catheter (1). Ex-1005, ¶ 211.

Tip (22) has an outer diameter of 1.72 mm, so it is sized to be insertable through the cross-sectional inner diameter (1.8 mm) of the continuous lumen of the guiding catheter. *Id.*, Table 1, 1:59-65. Tip (22) is also coaxial to the guiding catheter and defines a lumen. *Id.*, Figs. 5-6. Finally, both protective catheter (5) and guide wire (6) are insertable through tip (22), *id.*, Table 1, 4:48-52, 7:1-23, Fig. 5, and each meets the construction of “interventional cardiology device.” *Supra*, § VII.B.3 ([1.pre.iii]); Ex-1005, ¶ 211.

6. [11.c] “a reinforced portion proximal to the flexible tip portion; and”

Itou discloses [11.c]. Ex-1005, ¶ 211(i). Tubular portion (21) is proximal to tip (22).



Ex-1007, Fig. 3.

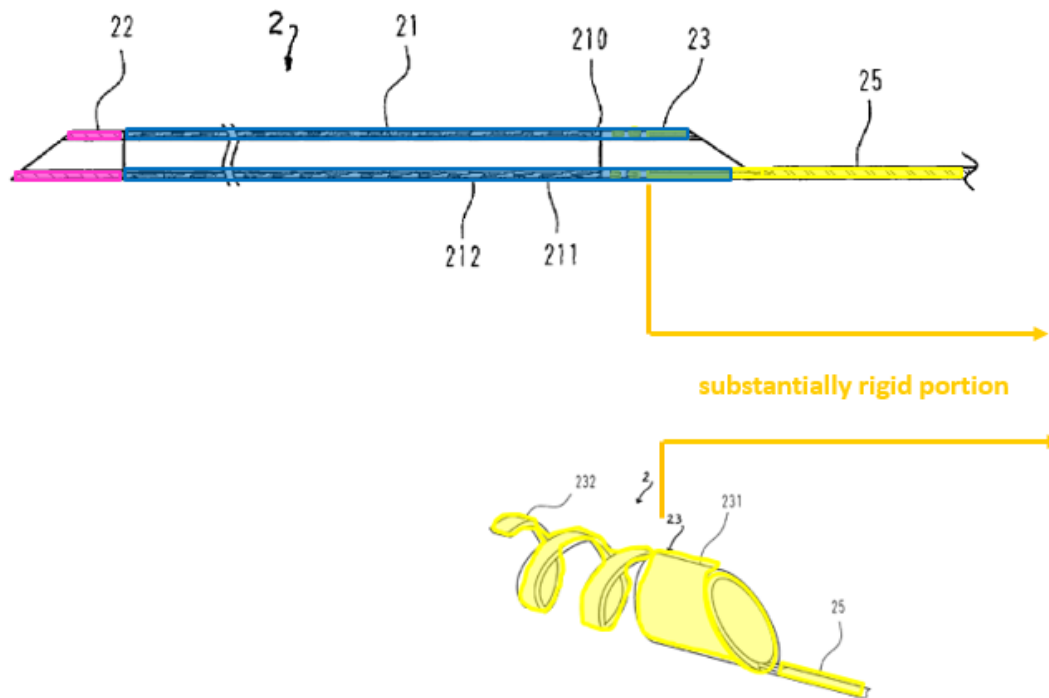
Tubular portion (21) is reinforced. As discussed above, a “reinforced

portion” is a “portion made stronger by additional material or support.” *Supra*, § VI. Itou teaches that tubular portion (21) includes a reinforcing metal wire layer (211) to prevent kinking, an outer layer 212, and an inner layer 210 made of resin. Ex-1007, 2:15-21, 3:50-58; Ex-1005, ¶ 211(i); Ex-1042, ¶¶ 50, 55-56, 59-60.

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

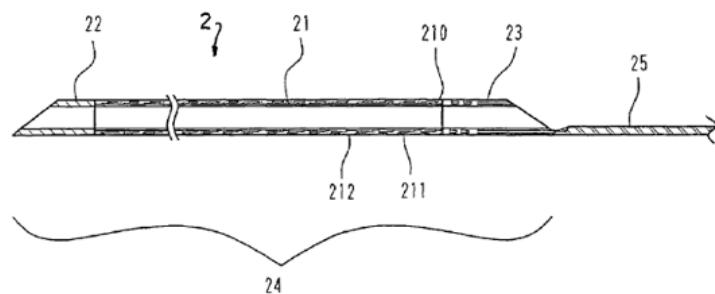
Itou discloses [11.d]. Ex-1005, ¶ 212. The “substantially rigid portion” of Itou’s suction catheter (2) is wire-like portion (25) and tip (231) (“Mapping-1”).¹⁹ *Supra*, § VII.B.5 (claim [1.b.]); Ex-1005, ¶ 212.

¹⁹ Because Mapping-1 (wire-like portion (25) and tip (231)) necessarily encompasses Mapping-2 (wire-like portion (25)), Petitioner analyzes Mapping-1 for claim 11, but the analysis is equally applicable should Mapping-2 apply. *See supra* n.9.



Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).

The “substantially rigid portion” is connected to and proximal of distal tip (22) (“flexible tip portion”).²⁰



Ex-1007, Fig. 3.

Wire-like portion (25) is more rigid along a longitudinal axis than tip (22).

²⁰ *Supra*, n.9.

As discussed in claim 1, tip (22) is soft and “flexible in order to reduce the damage to the blood vessel” (Ex-1007, 2:15-21) and is less rigid than the proximally-located wire-like portion (25). Ex-1042, ¶¶ 55, 64-71. Wire-like portion (25) is the “rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion [22], such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter” for the reasons set forth above. *Supra*, § VII.B.5 (claim [1.b]); Ex-1005, ¶ 212; *see also* Ex-1007, Figs 1B, 1E, 5, 5:11-23.

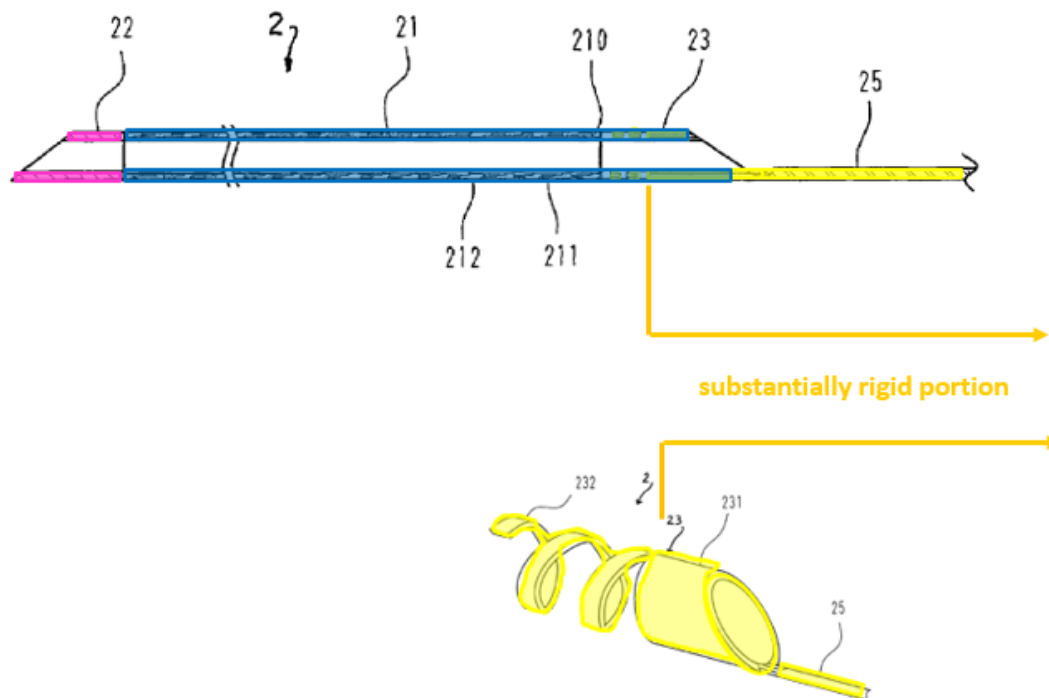
M. Claim 12: The device of claim 11 wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

Itou discloses claim 12. Ex-1005, ¶ 213. Itou discloses that a distal portion of tip 22 (“flexible tip portion”) is insertable through the continuous lumen of GC (1) and extends beyond the distal end of GC (1). Ex-1407, Abstract, 2:29-38, Figs.

5-6. When tip 22 extends beyond the distal end of GC (1) into the coronary artery, the device assists in resisting axial and shear forces as claimed. *Supra*, § 7.C (claim 2); Ex-1005, ¶ 213.

N. Claim 13: The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

Itou disclose claim 13. Ex-1005, ¶ 214. As discussed for claim [11.d], the “substantially rigid” portion includes both wire-like portion (25) and end (231).



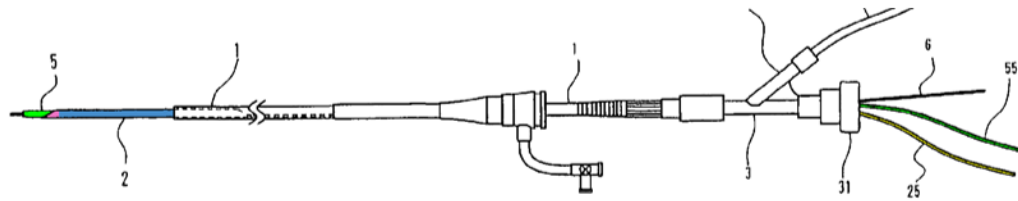
Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).

As discussed for claim 9, the substantially rigid portion includes a “partially cylindrical portion defining an opening.” The opening also extends for a distance along a side thereof defined transverse to a longitudinal axis, as explained for claim 3. Moreover, Itou teaches the remainder of claim 13, which is that the side opening “is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen” for the reasons discussed for claim 3. Ex-1005, ¶ 214.

- O. Claim 14: The device of claim 11 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.**

Itou discloses claim 14. Ex-1005, ¶ 215. Itou teaches a device (suction catheter 2), which may be inserted into a guide catheter (guiding catheter 1) to present an overall length of a coaxial lumen through which an interventional cardiology device may be inserted using only a single hemostatic valve. *Supra*, § VII.B.3, VII.C (claims [1.pre.iii], 2).

FIG. 5



As shown above in Fig. 5 (color added), distal end protective catheter (5) and guide wire (6) are inserted through the hemostatic valve found in connector (31).

To the extent that Patent Owner suggests that claim 14 requires anything more than the cited disclosure in Itou, it is mistaken. Claim 14 additionally recites an intended use, which is that there be an absence of “any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter,” to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

Regardless, and similar to claim 3, Itou explicitly teaches structure that allows for an interventional cardiology device to be inserted into suction catheter (2) while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter. Itou explains that a guide catheter may be inserted into the vasculature first, after which suction catheter 2 is inserted into the lumen of the guiding catheter. Ex-1007, 2:29-38. Itou also teaches that the tubular portion of

catheter 2 has an inner diameter (1.5 mm) large enough to receive distal end protective catheter (1.35 mm), *id.*, 4:48-52, Fig. 5, Table 1, as well as a proximal side opening into which the distal end protective catheter can be inserted. *Id.*, Fig. 5. Thus, Itou either explicitly or inherently discloses claim 14. Ex-1005, ¶ 215.

P. Claims 15-18

15. The device of claim 11, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion	Itou discloses claim 15. <i>Supra</i> , § VII.F (claim 5). Ex-1005, ¶ 216.
16. The device of claim 11, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	Itou discloses claim 16. <i>Supra</i> , § VII.H (claim 7). Ex-1005, ¶ 216.
17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion ²¹ is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	Itou discloses claim 17. <i>Supra</i> , § VII.I (claim 8). Ex-1005, ¶ 216.
18. The device of claim 11 wherein the substantially rigid portion includes, starting at a from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.	Itou discloses claim 18. <i>Supra</i> , § VII.J (claim 9). Ex-1005, ¶ 216.

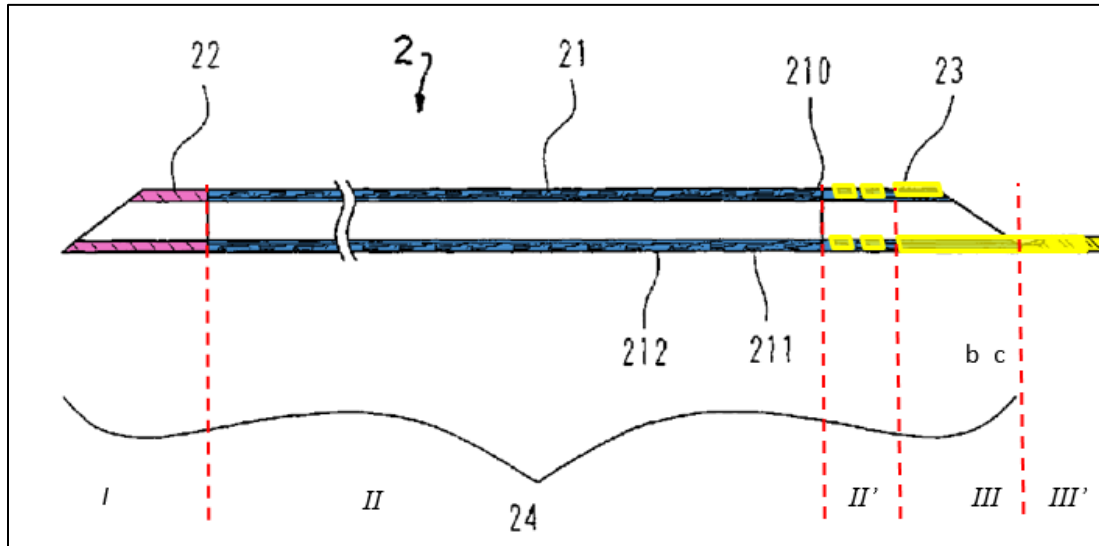
²¹ The term “the flexible distal portion” lacks proper antecedents. The only logical interpretation—that Petitioner adopts for purposes of this proceeding only—is that this language refers to the previously recited “flexible tip portion” of claim 11.

Q. Claim 19: The device of claim 11 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion,²² at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

Itou discloses claim 19, Ex-1005, ¶ 217-23, which requires at least three different portions in the elongate structure, each with a distinct flexural modulus. The claim also requires that the at least three flexural moduli increase in the distal to proximal direction. This is disclosed in Itou’s suction catheter (2), which is the “elongate structure.” *Supra*, § VII.L.4 ([11.a]).

Distal tip (22) is soft and flexible. *Supra*, § VII.B.4, VII.G (claims [1a] and 6). As explained by Dr. Brecker and Dr. Hillstead, tip (22)—shown below in pink—has a first flexural modulus. Ex-1005, ¶ 220; Ex-1042, ¶¶ 65-71. Thus, tip (22) is a “first portion having a first flexural modulus.” (Below, *I*).

²² The term “the flexible distal portion” lacks proper antecedents. The only logical interpretation—that Petitioner adopts for purposes of this proceeding only—is that this language refers to the previously recited “flexible tip portion” of claim 11.



Itou teaches that tubular portion (21) is proximal to tip (22). Tubular portion (21) has “an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211” Ex-1007, 3:50-58. Tubular portion (21) is flexible, but reinforced relative to flexible distal tip (22). *Supra*, VII.B.4, VII.G (claims [1a], 6). Tubular portion (21) has a second flexural modulus, greater than the first flexural modulus of tip (22). Ex-1005, ¶ 221; Ex-1042, ¶¶ 65-66, 73-75. Thus, tubular portion (21) is a “second portion having a second flexural modulus greater than the first flexural modulus.” (Above, *II*). Ex-1005, ¶ 221.

Itou also teaches that—proximal to tip (22) and tubular portion (21)—catheter (2) includes a metal pipe. At its proximal end, the metal pipe is cut obliquely into end (231). Ex-1007, Fig. 4. The portion of the elongate structure that includes (231) has a third flexural modulus that is greater than the second flexural

modulus of tubular portion (21). Ex-1005, ¶ 222; Ex-1042, ¶¶ 67-68. Thus, the portion of the elongate structure that includes metal pipe (231) is a “third portion having a third flexural modulus greater than the second flexural modulus” (Above, *III*). Ex-1005, ¶¶ 222-23. Itou discloses claim 19.

R. Claim 22: The device of claim 11 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

Itou discloses claim 22. *Supra*, § VII.K (claim 10). Ex-1005, ¶ 224.

VIII. GROUND II: CLAIMS 3, 13, AND 14 ARE RENDERED OBVIOUS BY ITOU IN VIEW OF RESSEMANN AND/OR THE COMMON KNOWLEDGE OF A POSITA.

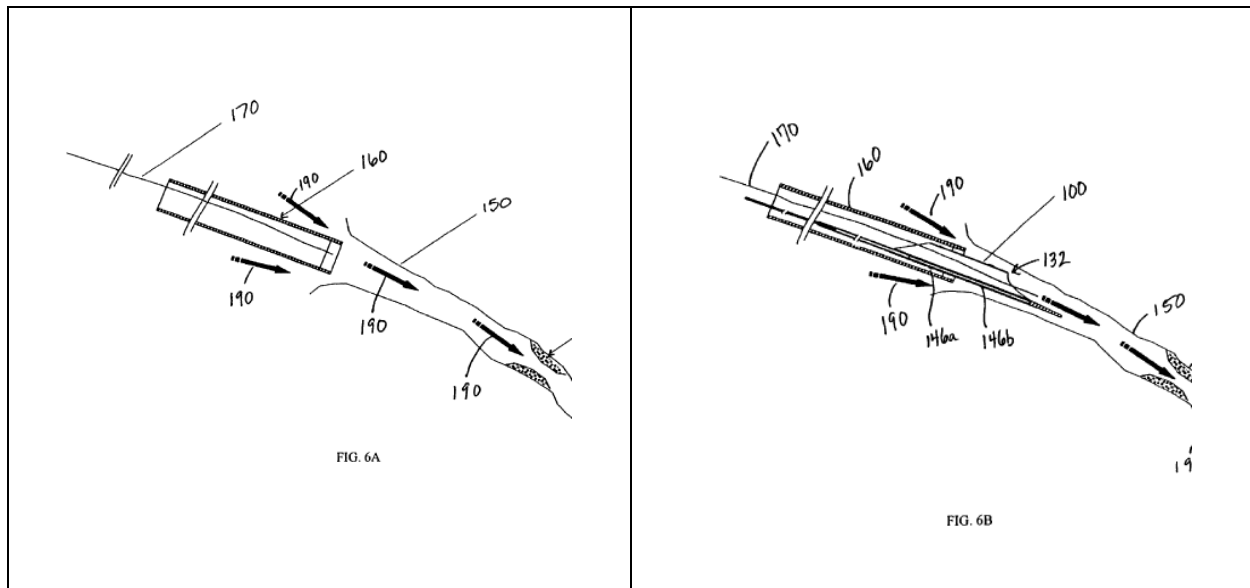
A. Overview of Ressemann

Ressemann was filed on August 9, 2002, issuing as U.S. Pat. No. 7,604,612 on October 20, 2009. It is prior art under both pre-AIA § 102(e) and post-AIA § 102(a)(1), 102(a)(2).²³ Ressemann was not cited or considered during prosecutions of the '032 patent. Ex-1001-1003.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1008, Abstract. The assembly includes a GC, which “may be positioned within the ostium of a target vessel,” *id.*, 12:26-30, and an evacuation sheath that is coaxially

²³ See *supra* § IV.D.

insertable through the GC, and advanceable beyond the GC's distal end to treat stenosis. *Id.*, Abstract, Figs. 6A-6F, 6:18-24, 12:9-14:39.



Sheath assembly is described for use in aspirating embolic material, *id.*, Abstract; 12:9-13:34, and for stent or balloon delivery. *Id.*, 6:25-34; 12:3-8; Ex-1005, ¶¶ 100-103, 110, 155-161.

As explained in § 7, Itou's suction catheter (2) has the structure that would allow it to receive an interventional cardiology device into its coaxial lumen while its proximal portion remains within the lumen of the guide catheter (claim 3), as well as to present an "overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter" (Claim 14). To the extent Patent Owner argues that Itou's teachings—alone—are insufficient

to anticipate claims 3, 13, or 14, then they are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA.²⁴

B. Claim 3

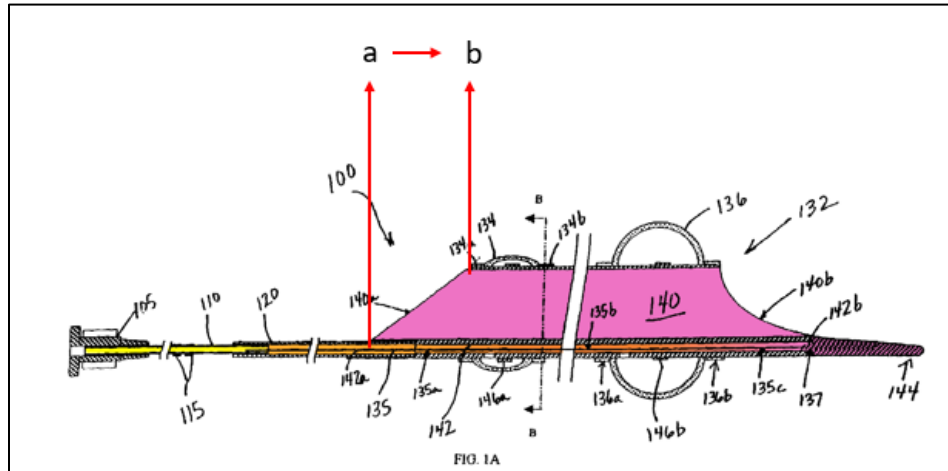
To the extent that Patent Owner argues that the intended use of the claimed structure—“to receive an interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter”—carries patentable weight and is a limitation, Itou discloses structure sufficient to meet this limitation. *Supra*, § VII.D. In the alternative, Itou and Ressemann render claim 3 obvious.²⁵ Ex-1005, ¶¶ 225-26.

The evacuation head of Ressemann has a proximal opening 140a that

²⁴ The cited disclosures, references and arguments set forth in § 7 are fully incorporated in § 8.

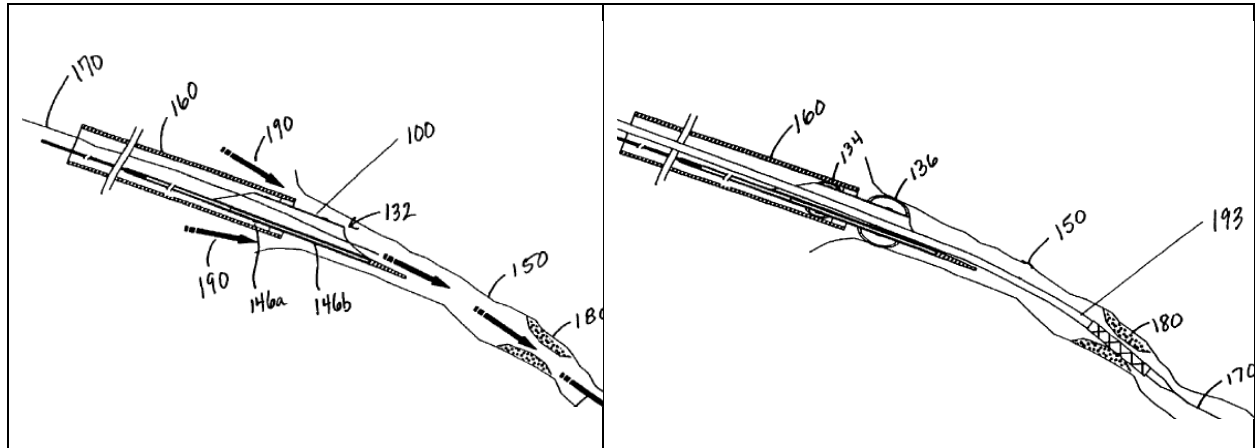
²⁵ A POSITA would look to Ressemann when modifying Itou because both references disclose devices that address the same problem in the same way—removing coronary vessel occlusions by using an aspiration catheter, the distal end of which is extended past a GC’s distal end, into a coronary artery. Ex-1005, ¶ 96-103, 151-161, 227; Ex-1007, Abstract, 1:13-16, 1:66-2:5, 2:29-38, 3:59-64, 5:32-34, 7:8-10, Figs. 1A, 1B, 5, 6; Ex-1008, Abstract, 6:18-24, 12:9-12, 19-30, Figs. 6A, 6B.

extends for a distance from (a) to (b) along the longitudinal axis of the evacuation sheath. Ex-1008, Figs. 1A, 11A. This is a side opening. Ex-1005, ¶ 228.



Ex-1008, Fig. 1A (color and annotation added).

The head's diameter is large enough to “allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, [and] atherectomy catheters” Ex-1008, 10:17-21; 12:3-4. Ressemann further teaches that the evacuation sheath should be advanced through a GC until the head's (a) distal end is distal to the distal end of the GC; and (b) proximal end remains in the GC. *Id.*, 12:19-26; Fig. 6B (below, left). Ex-1005, ¶¶ 229-30.



Ressemann also explains that a stent delivery system should be advanced through the evacuation sheath and then across a stenotic lesion. Ex-1008, 13:15-16, 57-60; Fig. 6E (above, right); Ex-1005, ¶¶ 229-30.

A POSITA would be motivated to combine the teachings of Itou and Ressemann because s/he knew that it was advantageous for an aspiration catheter to include a distal lumen of sufficient diameter for use in delivering an interventional cardiology device. Ex-1005, ¶¶ 231-39; Ex-1042, ¶¶ 87-92; Ex-1019, 3:4-6; 34-36 (explaining that an aspiration catheter is “preferably sized so as to allow the slidable insertion of a therapy catheter through the main” lumen of the aspiration catheter). And this is because angioplasty and coronary artery stenting come with a risk of embolization. Ex-1005, ¶¶ 236-244; Ex-1028, 1285; Ex-1029, 172, 176.

As Dr. Brecker explains, those working in the field knew that PCI such as angioplasty or stent delivery “may break free fragments of friable plaque.” Ex-

1005, ¶ 244; Ex-1015, 629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was a motivation to combine stent delivery with the use of an embolic protection device, Ex-1015, 629-630, and a reasonable expectation of success. Ex-1028, 1285 (“Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire.”); Ex-1029, 172, 176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of an embolic protection device in conjunction with stenting); Ex-1005, ¶ 244. Additionally, using a suction catheter large enough to deliver a therapy catheter ensures that a PCI procedure can be completed without having to switch catheters between suction and stenting. Ex-1005, ¶¶ 245-46; Ex-1008, 14:29-34 (“In some instances, once the particulate . . . has been removed, additional contrast delivery to the blood vessel may indicate a need for more therapeutic steps, e.g., further dilation of the stent with the balloon. In this case, it is more convenient to have the balloon catheter already in position for any subsequent use.”).

The inner lumen of Ressemann’s sheath is “approximately 0.061 inches,” allowing for the “passage of most therapeutic devices such as angioplasty catheters [and] stent delivery catheters” Ex-1008, 10:17-21. PTCA catheters were

insertable through support catheters with an 0.045 inch inner lumen. Ex-1009 (“Kontos”), 4:46-64. Angioplasty procedures had been performed through 4 French diagnostic catheters. Ex-1020 (“Mehan”), 22. Ressemann, Kontos and Mehan disclosed prior art catheters, which, respectively, had inner lumen diameters of approximately 1.54 mm, 1.14 mm and under 1.33 mm. Ex-1005, ¶¶ 247-50.

Similarly, Itou taught a suction catheter with an inner diameter of 1.5 mm, Ex-1007, Table 1. By reference to Ressemann, Kontos, and Mehan, a catheter with an inner diameter of 1.5 mm is large enough to accommodate the insertion of a therapy catheter.

Moreover, an inner diameter of 1.5 mm corresponds to an inner diameter of 0.059 inches. Ex-1042, ¶ 60. As Dr. Brecker explains, the suction catheter could be inserted into guiding catheter (1), and—as taught by Ressemann—used to receive a balloon-expandable stent. Several such stents, of the appropriate size, were available at the time of the purported invention of the ’032 patent. Ex-1005, ¶¶ 251-57; Ex-1022 at 3 (requiring a > 0.056 in. (1.4 mm) inner catheter diameter for CYPHER stents between 2.50-3.0 mm on an RX delivery system); Ex-1023 at 9 (requiring a minimum inner catheter diameter of 0.56 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1024 at 9 (requiring an inner catheter diameter ≥ 0.058 in. (1.47 mm) for TAXUS Express stents on a

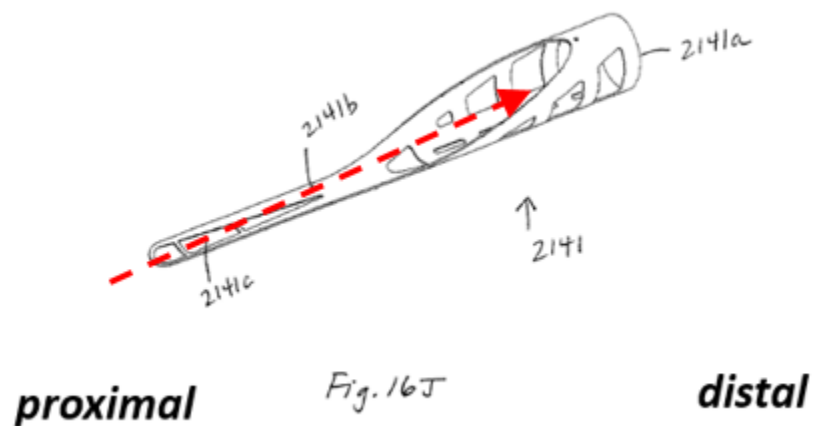
monorail delivery system).

Indeed, Itou's prosecution history demonstrates that it was appropriate to combine Itou and Ressemann. There, the Examiner rejected pending claims on a suction assembly based on a prior, angioplasty balloon catheter, because the latter was "capable of being an intravascular foreign matter suction assembly." Ex-1021 at 3. Claims were also rejected over the same art in combination with a prior aspiration catheter because—at the time of the invention—the references were analogous art, and it would have been obvious to combine angioplasty with removal of emboli. *Id.*, 4-5; Ex-1005, ¶¶ 257-61.

C. Claim 13

Itou discloses claim 13. *Supra*, § VII.N In the alternative, Itou in view of Ressemann also renders claim 13 obvious. Ex-1005, ¶ 262-72.

Ressemann discloses, as recited in claim 13, "wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis [dotted arrow below] . . . the opening extending substantially along at least a portion of a length of the substantially rigid portion." *Id.*, ¶ 264.



Ex-1008, Fig. 16J (annotation added).

Metal collar 2141 includes cylindrical portion 2141a that “fits into the proximal opening of the evacuation lumen,” providing hoop support. *Id.*, 24:55-58. “Distal tab 2141b” serves as a “flexibility transition” between the proximal end of the evacuation head and the evacuation sheath’s shaft. *Id.*, 24:62-67. As illustrated above, collar 2141 forms a concave track. *Id.*, Fig. 16J; Ex-1005, ¶ 265.

As Dr. Brecker and Dr. Hillstead explain, a POSITA would have been motivated to replace Itou’s proximal tip (23) with the support collar disclosed in Ressemann for the following reasons.

First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou’s suction catheter because s/he understood that it was large enough to be used to deliver a balloon and stent catheter, as explained above. By modifying the proximal opening of suction catheter (2) with Ressemann’s

collar 2141, a larger area for receiving a stent and/or balloon catheter would be achieved. Ex-1005, ¶¶ 266-68; Ex-1042, ¶¶ 23-25, 92-104.

Second, the concavity of tab 2141b ensures that adding the collar does not impede entry into the inflation lumen. Ex-1042, ¶¶ 100-01. Ressemann teaches the advantage to having an angled opening is that it “facilitate[s] smoother passage of other therapeutic devices” through the lumen. Ex-1008, 6:52-57, 23:17-20. The collar adds material to the opening of the lumen, as it is 0.002 inches thick. *Id.*, 25:8-10. And tab 2141b ranges from 0.020 to 0.050 inches in width. *Id.*, 25:11-12. Because tab 2141b is concave, it does not interfere with introducing a balloon or stent catheter into the angled opening of the inflation lumen. Ex-1005, ¶ 269; Ex-1042, ¶ 100. The same holds true for adding the collar to the proximal opening of the tubular portion of Itou’s suction catheter 2. Ex-1042, ¶¶ 100-05

A POSITA would have had a reasonable expectation of success because adding the support collar of Ressemann to the suction catheter of Itou is nothing more than combining prior art elements according to known methods to yield predictable results. Ex-1042, ¶¶ 106-07; *KSR Int’l Co.*, 550 U.S. at 417.

Moreover, for the reasons discussed above with respect to claim 3, Itou in view of Ressemann discloses “adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen.”

Thus, Itou in view of Ressemann renders claim 3 obvious. Ex-1005, ¶ 270.

D. Claim 14

To the extent it is determined that the language in claim 14 requiring an absence of “any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter” is entitled to patentable weight, Itou discloses structure sufficient to meet this limitation. *Supra*, § VII.O. In the alternative, Itou and Ressemann render claim 14 obvious. Ex-1005, ¶¶ 271-72; *and see supra*, § VII.O.

Itou teaches a device (suction catheter 2), which may be inserted into a guide catheter (guiding catheter 1) to present an overall length of a coaxial lumen through which an interventional cardiology device may be inserted using only a single hemostatic valve. *Supra*, § VII.B.3, VII.C (claims [1.pre.iii], 2). Itou does not, however, explicitly teach actually inserting an interventional cardiology device “without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.” It instead teaches that protective catheter (5) should be inserted into catheter (2)—i.e. “preassembled”—before the combination of catheter (2) and protective catheter (5) is inserted into guiding catheter (1). Ex-1007, 7:13-15.

By contrast, Ressemann teaches that evacuation sheath assembly (100) should be positioned in the guide catheter *before* an interventional cardiology

device (a stent delivery system) is advanced into guide catheter (160), and through the evacuation head. Ex-1008, 12:11-14:9; *and see, supra*, VII.D (claim 3). In other words, Ressemann explicitly discloses there ***not be*** “any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.” A POSITA would be motivated to use the device of Itou as taught by Ressemann for the reasons set forth for claim 3. Ex-1005, ¶ 272. Additionally, inserting the suction catheter into the guide catheter without a telescoping preassembly would allow the suction catheter to be used for extraction purposes prior to placement of a therapy device. *Id.*

IX. GROUND III: ITOU RENDERS CLAIM 20 OBVIOUS IN VIEW OF BERG AND THE COMMON KNOWLEDGE OF A POSITA.

A. Overview of Berg

Berg issued as U.S. Pat. No. 5,911,715 on June 15, 1999. It is prior art under pre-AIA §102(b). Berg was not cited during prosecution of the '032 patent. Exs-1001-1003.

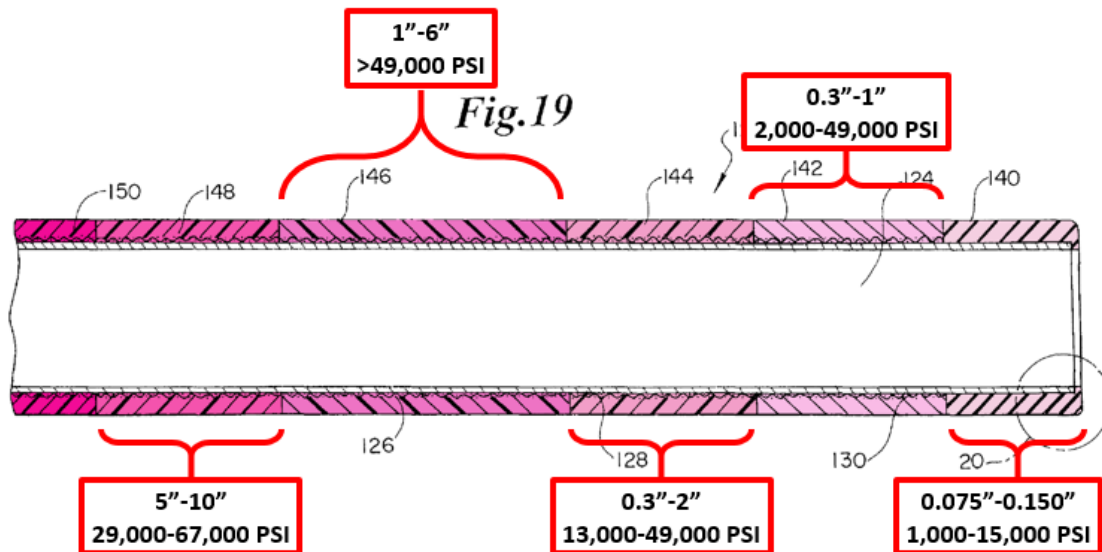
Berg discloses a “guiding catheter for use in coronary angioplasty and other cardiovascular interventions which incorporates a plurality of segment (sic) of selected flexural modulus in the shaft of the device.” Ex-1051, Abstract. Berg explains that in order to place a catheter at a correct location in a vessel, a physician “must apply longitudinal and rotational forces,” and that the catheter must be “rigid enough to push through the blood vessel, but yet flexible enough to

navigate the bends in the blood vessel.” *Id.*, 1:49-55. Moreover, “[i]t is preferable to have a soft tip or flexible section engage the ostium,” so “it is advantageous to have the proximal section be rigid to transmit the forces applied, but to have the distal end more flexible to allow for better placement of the guide catheter.” *Id.*, 1:65-2:2. Additionally, a more flexible, distal section causes less trauma to the blood vessel. *Id.*, 2:2-4.

B. Claim 20: The device of claim 19 in which the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

Itou in view of Berg renders claim 20 obvious in view of the common knowledge of a POSITA. Ex-1005, ¶¶ 46-59, 63-85, 122-126, 273-86.

By the time of the alleged invention of the '032 patent it was known that coronary catheters for PCI should have “a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions.” Ex-1044, 1:36-38; *see also* Ex-1019, Abstract (explaining that an aspiration catheter should have varying degrees of flexibility along its length); Ex-1005, ¶¶ 275-279; Ex-1042, ¶¶ 28-34.



Ex-1051, Fig. 19 (color and labels added).

Berg teaches a guide catheter with a soft tip with a flexural modulus of between 1,000 and 15,000 PSI. This was desirable because it “provide[d] an atraumatic end . . . for navigating vasculature . . .” Ex-1051 (“Berg”), 14:1-7. Berg also teaches that the catheter should be increasingly rigid in a distal to proximal direction, including a portion—just proximal to the soft tip—with a flexural modulus of between 2,000 and 49,000 PSI, which assists in positioning the catheter tip. *Id.*, 14:27-30. Berg additionally teaches that the next most proximal segments should be a portion with a flexural modulus of between 13,000 and 49,000 PSI, and then a portion with a flexural modulus of greater than 49,000 PSI. This configuration ensured both that the catheter had sufficient stiffness and backup support, as well as a smooth and flexible transition to the more flexible, distal portions. *Id.*, 14:35-51; Ex-1005, ¶¶ 280-82; Ex-1042, ¶¶ 33-36, 76-78.

	PSI known to a POSITA	PSI claimed in the '032
<i>first portion</i>	1,000-15,000	13,000 +/- 5,000
<i>second portion</i>	2,000-49,000	29,000 +/- 10,000
<i>third portion</i>	13,000-49,000 and >49,000	49,000 +/- 10,000

Thus, three regions of flexural moduli taught by Berg overlap with the claimed range. Ex-1005, ¶¶ 282-283; Ex-1042, ¶¶ 76-80. As a result, the claimed range would have been obvious. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005) (“[A] prima facie case of obviousness arises when the ranges of a claimed composition overlap the ranges disclosed in the prior art.”). A POSITA would have been motivated to modify Itou to include segments with flexural moduli in the above ranges (known to a POSITA, as evident in Berg’s teachings) because Itou explicitly teaches that suction catheter (2) was designed to reach “deep location[s] in a coronary artery.” Ex-1007, 2:1-2, 5:35-38. As Dr. Brecker and Dr. Hillstead explain, being able to advance a catheter to distal locations in the coronary vasculature often requires that the catheter be maneuvered through tortuous portions of the coronary vasculature. Ex-1042, ¶¶ 27, 78-79; Ex-1005, ¶¶ 283-85; *and see* Ex-1045, 1:39-44. This renders claim 20 obvious.

X. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1073. The “Facts”

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

XI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of claims 1-20, and 22 of the ’032 patent as unpatentable under 35 U.S.C. §§ 102 and/or 103.

XII. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 600615 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

IPR2020-00126
Patent 8,048,032

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 12, 2019
800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
612.349.8500

/Cyrus A. Morton /
Cyrus A. Morton

Attorney for Petitioner
Medtronic, Inc.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I hereby certify that the Petition for *inter partes* review consists of 13,690 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 November 12, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

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

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

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

/ Cyrus A. Morton /

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

Attorney for Petitioners