UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case IPR2020-01341
U.S. Patent No. 8,142,413

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,142,413

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1001	U.S. Patent No. 8,142,413 ("the '413 patent")
1002	[RESERVED]
1003	File history for U.S. Patent No. 8,142,413
1004	Assignment record of the '413 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	*New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, 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 *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (January 10, 2018), D.I. 36; D.I. 36-1.
1013	*Markman* Order in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (October 30, 2018), D.I. 102
1014	Meads, C., et al., *Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review*, Health Technology Assessment 2000 4(23) ("Meads")
1015	Excerpt from Grossman's Cardiac Catheterization, Angiography, and Intervention (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")
1018	U.S. Patent No. 5,891,056 ("Ramzipoor")
1019	U.S. Patent No. 6,398,773 ("Bagaoisan")

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1021	Excerpt of prosecution history for application 11/232,876 (Office Action, 6/20/09)
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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, *Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts*, Circulation 105:1285-1290 (2002) ("Baim")
1029	Limbruno, *Mechanical Prevention of Distal Embolization During Primary Angioplasty*, Circulation 108:171-176 (2003) ("Limbruno")
1030	U.S. Patent No. 5,413,560 ("Solar '560")
1031	Schöbel, *Percutaneous Coronary Interventions Using a New 5 French Guiding Catheter: Results of a Prospective Study*, Catheterization & Cardiovascular Interventions 53:308-312 (2001) ("Schöbel")
1032	*The sliding rail system (monorail): description of a new technique for intravascular instrumentation and its application to coronary angioplasty*, Z. Kardio. 76:Supp. 6, 119-122 (1987) ("Bonzel")
1033	U.S. Publication Application No. 2004/0236215 (Mihara)
1034	U.S. Patent No. 5,527,292 ("Adams '292")
1035	U.S. Publication Application No. 2004/0010280 ("Adams '280")
1036	Williams et al., *Percutaneous Coronary Intervention in the Current Era Compared with 1985-1986*, Circulation (2000) 102:2945-2951.

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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
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1050	U.S. Patent No. 5,980,486 ("Enger")
1051	U.S. Patent No. 5,911,715 ("Berg")
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1059	U.S. Patent No. 6,860,876 ("Chen")

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1061	U.S. Patent No. 5,690,613 ("Verbeek")
1062	lserson, *J.-F.-B. Charrière: The Man Behind the "French" Gauge*, 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 *QXMedical, LLC v. Vascular Solutions, Inc.*, 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, *QXMedical, LLC v. Vascular Solutions LLC et al.*, 17-cv-01969-PJS-TNL (D. Minn 2019)
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1071	Feldman, *Coronary Angioplasty Using New 6 French Guiding Catheters*, 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, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL
1074	Yokoyama, *Feasibility and safety of thrombectomy with TVAC aspiration catheter system for patients with acute myocardial infarction*, Heart Vessels (2006) 21:1–7 ("Yokoyama")
1075	[RESERVED]
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1079	Complaint in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
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1082	Declaration of Peter Keith in Support of Plaintiffs' Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL (July 12, 2019)
1083	Joint Fed. R. C. P. 26(f) Report [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL
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1116	IPR2020-00128 Institution Decision (Paper 22)
1117	Ex. 6 of Teleflex Infringement Disclosures and Claim Chart, *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL (March 1, 2020)
1118	[RESERVED]
1119	[RESERVED]
1120	[RESERVED]

I. PRELIMINARY STATEMENT

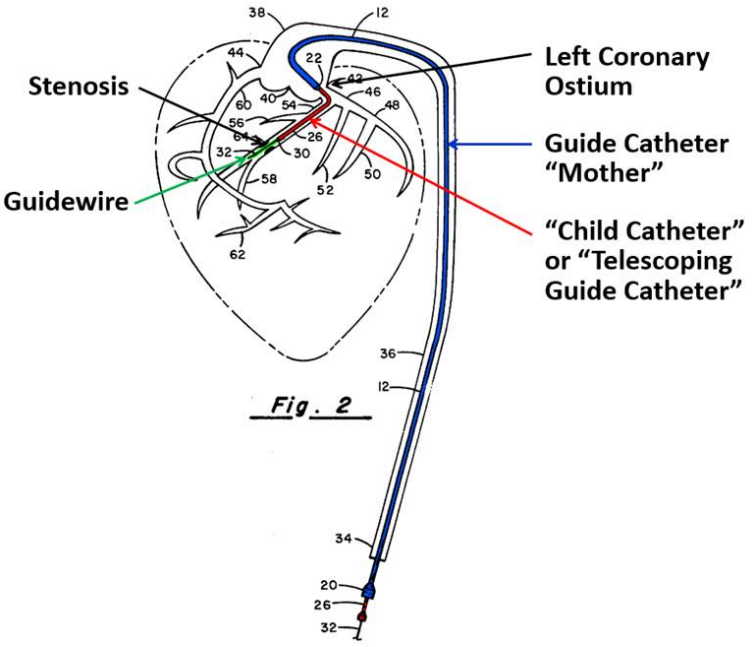
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 1-2, 4-5, and 7-14 ("Challenged Claims") of U.S. Pat. No. 8,142,413 ("the '413 patent," Ex-1001). The '413 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures*. Ex-1001, [54].

The '413 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 coaxial guide 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,

[1] Unlike the other patents in this family—that explicitly claim a "guide extension catheter" or, more vaguely, a device/system "for use" with a guide catheter—the '413 patent claims a "coaxial guide catheter." A POSITA knew, however, that the "coaxial guide catheter" of the '413 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. Ex-1005, ¶¶ 128-29; Ex-1009, 5:49-50 (referring to body 12 "as a guide catheter extension"). For ease of discussion, and to match the terminology of the '413 patent, Petitioner uses the phrase "coaxial guide catheter" when referring to the extension catheter of the '413 patent.

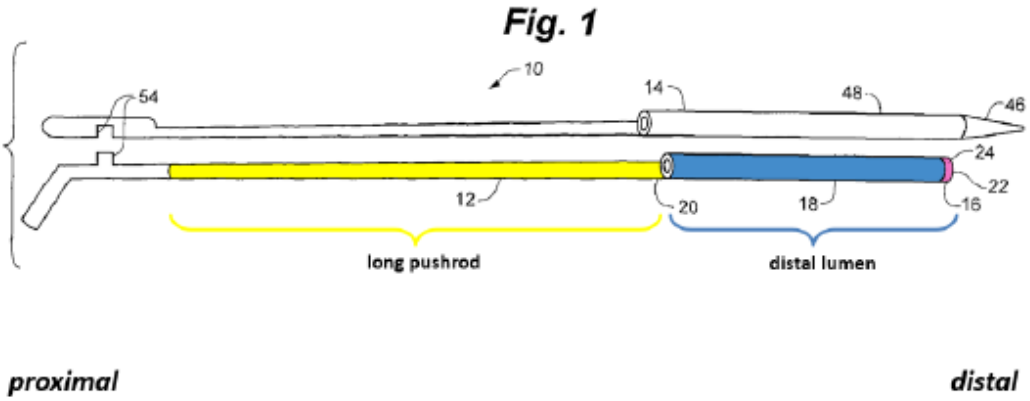
Figs. 8-9. In so doing, the coaxial guide catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id.*, 2:51-55, 7:66-8:12.

The '413 patent admits that use of a coaxial guide catheter inside an outer guide catheter was known. Ex-1001, 2:23-39 (describing use of a "smaller guide catheter within a larger guide catheter"). Such a catheter-in-a-catheter assembly was well-known in the art and described as a "mother-and-child assembly." Ex-1005, ¶¶ 74-84. The child catheter (red in below figure) (i.e., the coaxial guide 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.



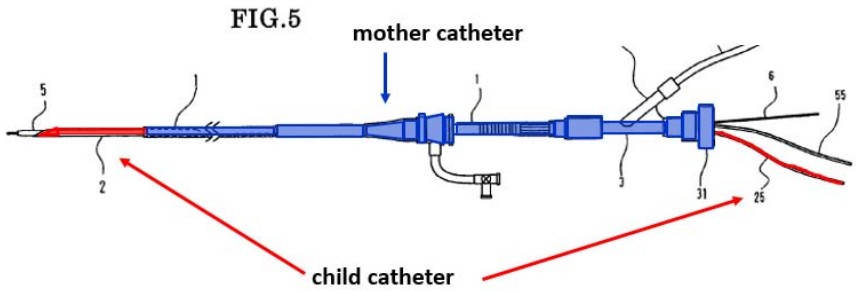
Ex-1054, Fig. 2 (color and labels added).

The child catheter in the mother-and-child assembly has a continuous lumen that is longer than the lumen of the guide ("mother") catheter. *Id.*; Ex-1005, ¶ 74. The '413 patent alleges that this design had certain drawbacks (Ex-1001, 2:40-50; Ex-1005, ¶¶ 85-93) and modifies the child catheter to have: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible.



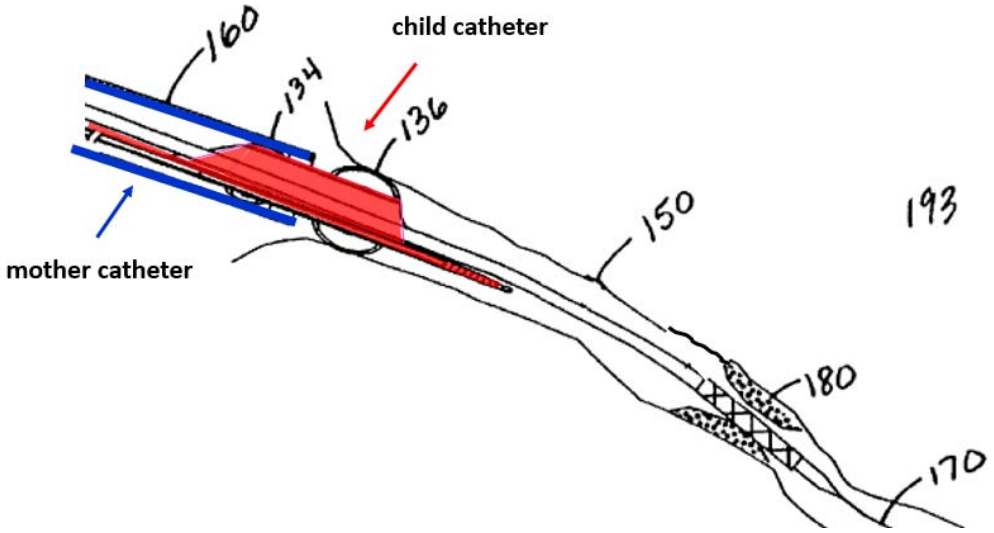
Id., Fig. 1 (annotations and color added).

But child catheters that served as guide extension catheters and had a short lumen connected to a long thin pushrod were already well-known in the art, as evidenced by U.S. Patent No. 7,736,355 ("Itou") (Ex-1007).



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

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



Ex-1008, Fig. 6E (annotations and color added).

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

A. Real Party-in-Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the '413 patent is currently the subject of litigation in two separate actions in the U.S. District Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic,*

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

The '413 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.*, IPR2014-00759 (P.T.A.B., terminated Aug. 11, 2014).

The '413 patent shares a common specification and is related to several patents that, as shown in the below table, Petitioner is currently challenging in IPR:

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

[2] The '413 patent was not originally asserted. The '413 patent was added by Amended Complaint on February 14, 2020. Ex-1114.

IPR2020-01342	8,142,413	Pending
IPR2020-01343	RE46,116	Pending
IPR2020-01344	RE46,116	Pending

C. Lead and Backup Counsel

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

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D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Petitioner certifies that the '413 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 1-2, 4-5, and 7-14 of the '413 patent and cancellation of these claims as unpatentable in view of the following grounds:[3]

No.	Grounds
1	Claims 1-2, 4, and 7-14 are anticipated by Itou
2	Claims 1-2, 4-5, and 7-14 are rendered obvious by Itou in view of the knowledge of a POSITA
3	Claims 1-2, 4-5, and 7-14 are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the

[3] This petition is supported by the Declarations of Stephen JD Brecker, MD (Ex-1005) and Richard A. Hillstead, PhD (Ex-1042), as experts in the field of the '413 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1078) to support authenticity and public availability of exhibits cited herein.

arterial lumen. Ex-1005, ¶¶ 32, 34-36. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id*. In response, physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery. *Id.*, ¶ 33. These procedures treat CAD without the need for open-heart surgery. *Id.*, ¶¶ 38-44.

PCI was developed more than forty years ago, and although catheter-based technology has advanced, the basic components of PCI remain largely unchanged. *Id.*, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. *Id.*, ¶ 38. A guidewire is then introduced through the needle and into the vasculature. *Id*. After removal of the needle, an introducer sheath is placed and then the guidewire and guide catheter are advanced along the vasculature until the guide catheter's distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id.*, ¶¶ 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*.

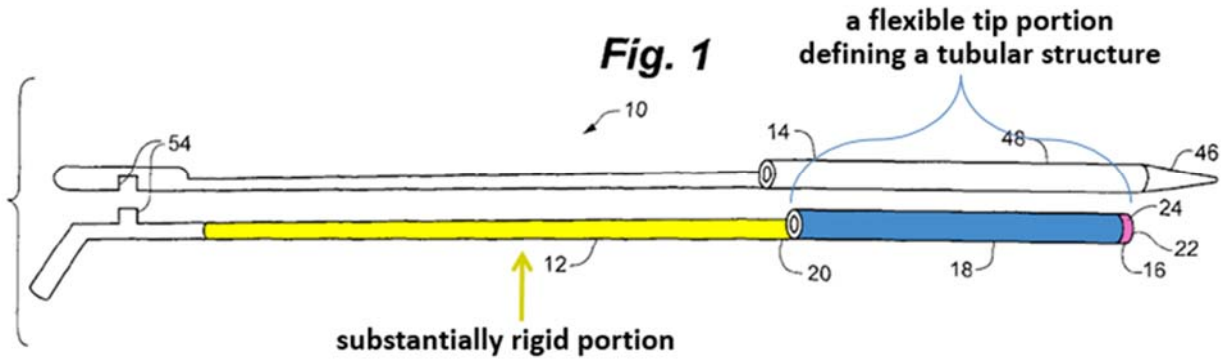
Another small diameter flexible guidewire can then be threaded through the lumen of the guide catheter to the target site. *Id.*, ¶¶ 60-62. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to

the occlusion. *Id*. The therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. *Id.*, ¶ 63-71. 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*., ¶¶ 72-84.

B. Overview of the ’413 Patent

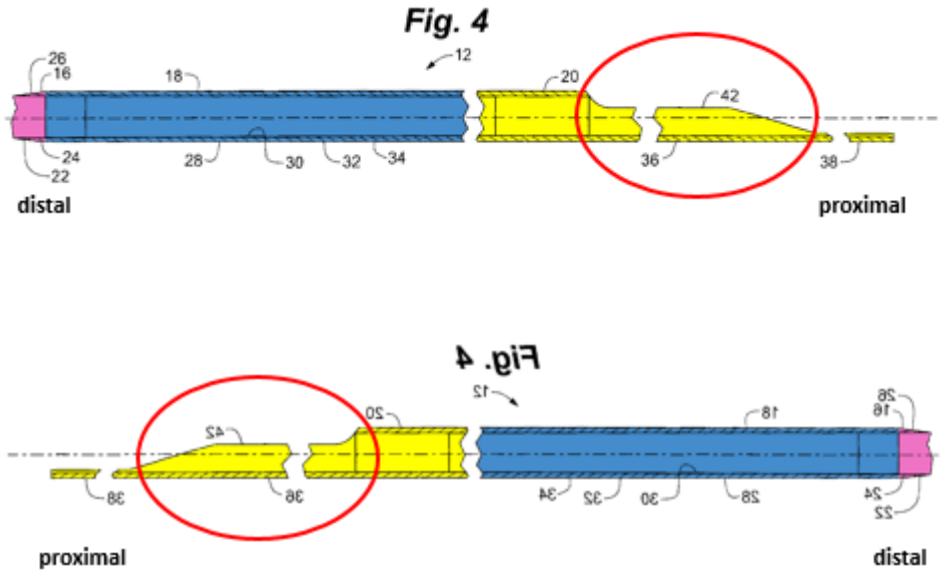
The ’413 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:13-17. In particular, the ’413 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends “beyond the distal end of the guide catheter, and … into [a] branch artery.” *Id*., Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:4-8.

The ’413 patent claims a coaxial guide catheter (12) that includes a substantially rigid segment (yellow) and a tubular structure (blue). Ex-1005, ¶ 130.



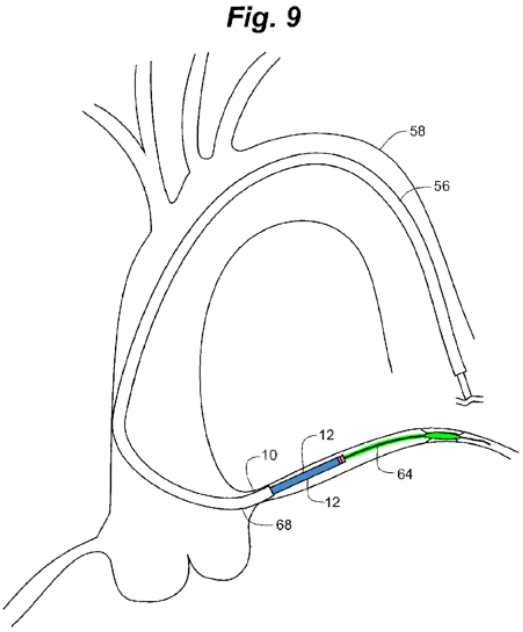
Ex-1001, Fig. 1 (annotations and color added).

The ’413 patent also addresses structural characteristics of the transition at or near the extension catheter’s reinforced and rigid portions, sometimes referred to as a “partially cylindrical portion” or a “side opening,” (red circle). *Id*., Figs. 4, 13-16, 6:44-60, 8:40-46, claim 9; Ex-1005, ¶¶ 103-120, 131.



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

As shown below, the ’413 patent describes that coaxial guide catheter (12) is deployed through guide catheter (56) (no color). A guidewire (64) and balloon (green) extend from the distal tip (pink) of the coaxial guide catheter. Moving distally to proximally, the coaxial guide catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter (56). Ex-1005, ¶ 132.



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

V. PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art (“POSITA”) was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical

engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a POSITA with an engineering degree may have access to one with a medical degree. Ex-1005, ¶ 31; Ex-1042, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

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

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (Ex-1012, 6; Ex-1013, 15).
- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1013, at 20)

Additionally, the district court provided the following constructions:

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

Further, Patent Owner stipulated that the claim term "reinforced portion" means "portion made stronger by additional material or support." Ex-1012, 2. Petitioner agrees with the above constructions for purposes of this IPR[4] (Ex-1005, ¶¶ 133-38) and proposes the following additional constructions:

A. "interventional cardiology device(s)" (all challenged claims)

In the QXMedical litigation, Patent Owner stipulated that "interventional cardiology device(s)" means "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters." *Compare* Ex-1012, 21 (Dkt. 36-1), *with* Ex-1064, at 1 n.1. Then in co-pending IPRs involving patents sharing a common specification with the '413 patent, Patent Owner argued that this stipulated construction requires the guide catheter to be sized such "that at least **all four enumerated devices** (guidewires, balloon catheters, stents, and stent catheters) be insertable into the lumen." Ex-1113, 11 (emphasis in original). The Board disagreed, explaining that "the term 'interventional cardiology device**s**' refers to at least two types of devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters." *Id.* at 20

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

(citing Ex-1001, 7:36-40, 7:42-8:7, Figs. 7-8).[5] Petitioner applies this construction for purposes of this IPR. Ex-1005, ¶¶ 139-40.

B. "standard guide catheter" (all challenged claims)

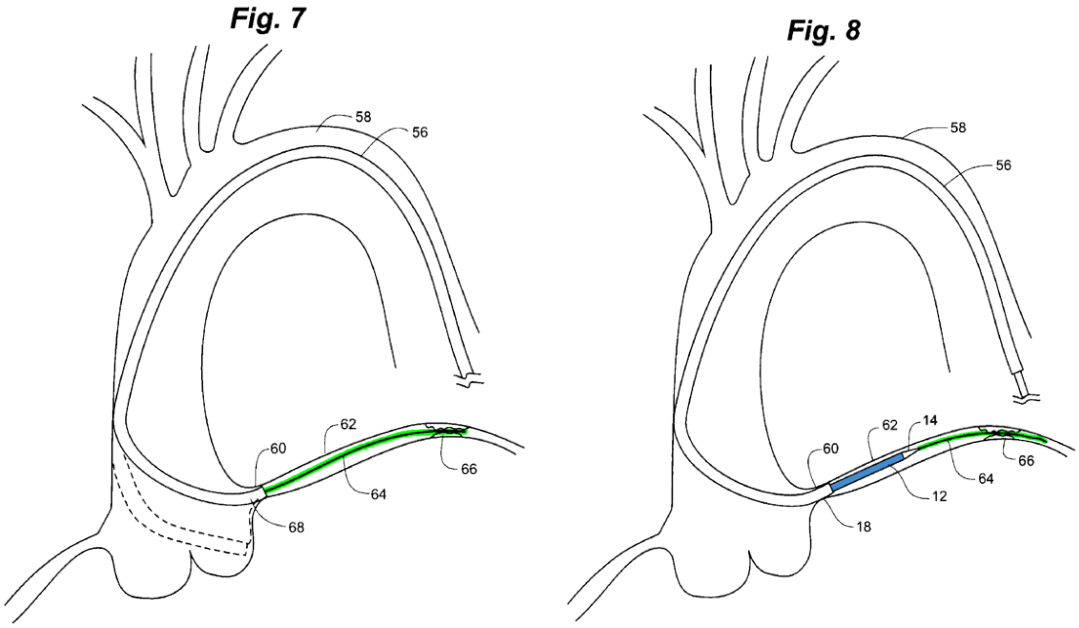
All challenged claims recite the use of a "standard guide catheter." As of the purported priority date of the '413 patent, "standard guide catheter" did not refer to a guide catheter of a specified length (although 100 cm was common (Ex-1001, 2:40-43; Ex-1015a, 549)), inner or outer diameter, or rigidity. Ex-1005, ¶ 141; Ex-1010, 454 (showing various "guiding catheter systems"). Further, the '413 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, 2:40-41. In other parts of the patent, the specification refers to "typical guide catheter" or references, more simply, "guide catheters." *Id*., 7:32-35. 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

[5] The Board's prior Institution Decisions addressed only the plural version of this claim term. Ex-1113, 20 (construing "interventional cardiology devices"). Accordingly, "interventional cardiology device," which is singular, will require only one of the enumerated devices. Ex-1005, ¶ 140.

vasculature." Ex-1005, ¶ 141.

C. "placed in a branch artery" (all challenged claims)

Claim 1 recites, *inter alia*, "positioning the distal end of the standard guide catheter in a branch artery." In the context of the '413 patent, "positioning in a branch artery" includes "placement in the ostium of a coronary artery." Ex-1005, ¶¶ 142-47. For instance, the '413 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 '413 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.*, 4:38-44, Figs. 7, 8.



Id., Figs. 7, 8 (color added).

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, ¶ 145. However, the '413 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, 9:51-55 (emphasis added). Thus, to the extent Petitioner's construction deviates from the plain meaning, the inventors acted as their own lexicographers. *Laryngeal Mask v. Ambu, A/S*, 618 F.3d 1367, 1371-72 (Fed. Cir. 2010).

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

When granting institution of patents related to the '413 patent, the Board declined to exercise its discretion under § 314(a). Ex-1113, 9-16. As set forth below, the relevant *Fintiv* factors dictate a similar result for this Petition.

Factors 1 & 2: On July 7, 2020, the district court stayed the litigation pending final resolution of the already-filed IPRs. Ex-1115 (Dkt 276). Given Judge Schiltz's past practice (Ex-1093), it is unlikely he will lift the stay prior to resolution of this IPR. Ex-1113, 12-14. Therefore, these factors support Petitioner.

Factor 3: When Petitioner filed IPR Petitions against related patents in Fall 2019, Patent Owner had not yet asserted the '413 patent. As a result, Petitioner did not file an IPR against the '413 patent at that time. Then, on February 14, 2020,

Patent Owner filed an Amended Complaint that asserted the '413 patent. Ex-1114. Thereafter, Petitioner diligently prepared its IPRs and filed this Petition roughly five months later and more than seven months before the statutory deadline. For the same reasons provided in its prior Institution Decision, the Board should find that this factor favors Petitioner. Ex-1113, 14-15.

Factor 4: In the District Court, Patent Owner asserts only 3 of the 12 claims challenged in this IPR. Ex-1095, 3. This factor favors Petitioner.

Factor 5 & 6: For the same reasons set forth in the prior Institution Decisions, the Board should find that factors 5 & 6 do not warrant discretionary denial. Ex-1113, 15-16.

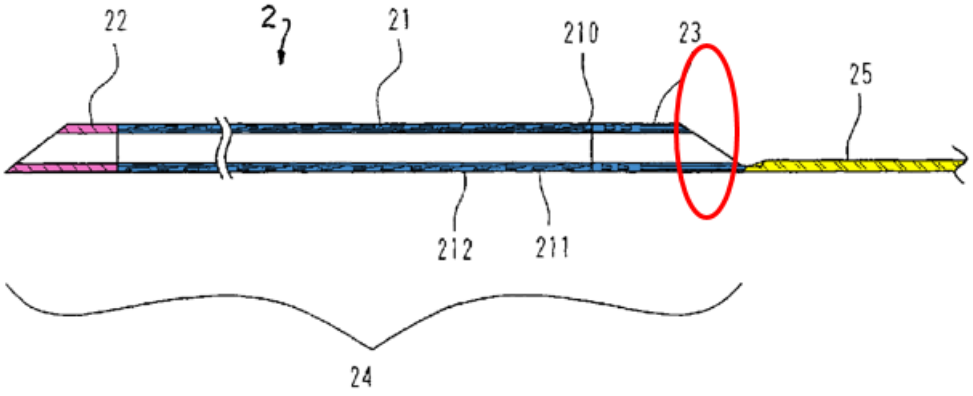
VIII. PRIOR ART

A. Itou

Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. Itou is prior art under pre-AIA §102(e), and was not cited or considered during prosecution of the '413 patent. *See generally* Exs-1001-03.

Itou discloses a catheter assembly for alleviating the obstruction of blood flow. Ex-1007 at 1:13-16. The assembly includes a GC and a suction catheter that is insertable through the GC. *Id*., Abstract, 2:2-5, 3:59-61 5:32-34, 7:7-11, 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 (color added) (tubular structure 21). Tubular portion 24's proximal opening is angled (red circle).



Id., Fig. 3 (color and annotations added).

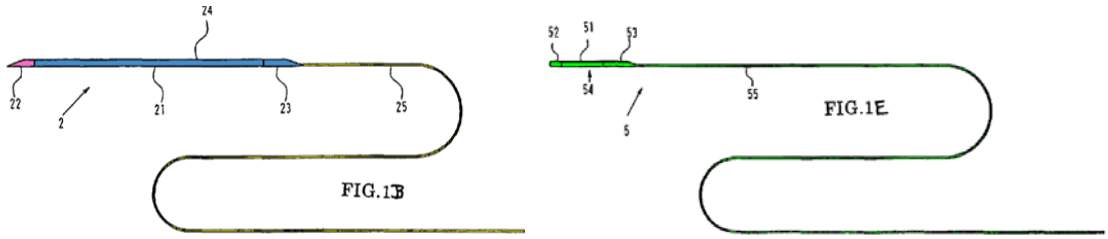
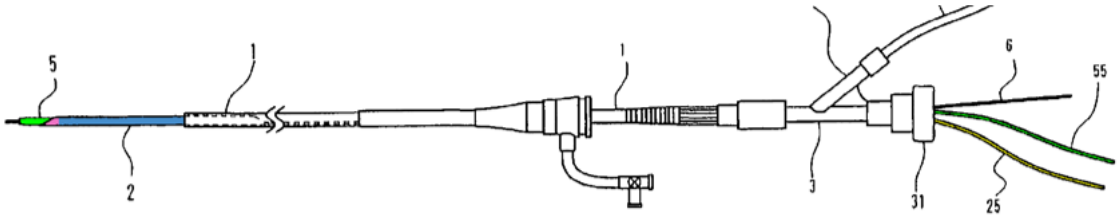


FIG.5



Id., Figs. 1B, 1E, 5 (color added). 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, ¶¶ 148-51; Ex-1042, ¶¶ 61-65. Itou also describes a "distal end protective catheter" (5), shown above in green, which is insertable through the suction catheter (2). *Id*.

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). By the time of the alleged invention of the '413 patent, a POSITA knew that suction (aspiration) catheters with a structure similar to Itou's may serve a dual purpose. Ex-1005, ¶¶ 152-53. 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, ¶¶ 94-102, 148-53.

B. Ressemann

Ressemann was filed on August 9, 2002, and issued as U.S. Pat. No. 7,604,612 on October 20, 2009. Ex-1008. It is prior art under at least pre-AIA §102(e). During prosecution of the '413 patent, Ressemann was neither disclosed by Patent Owner nor cited by the Examiner. *See generally* Ex-1001-03.

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 extends beyond the GC to treat a stenosis. *Id*., Abstract, 6:18-24, 12:9-12, 12:19-30, 29:56-58, Figs. 6A-F; Ex-1005 ¶¶ 154-57.

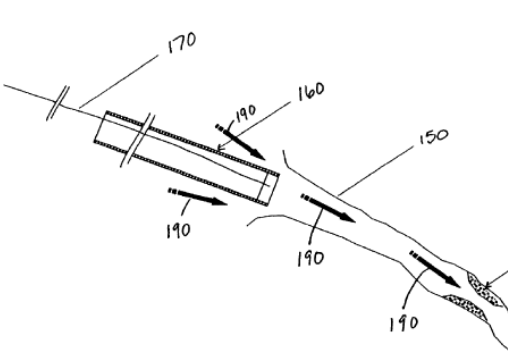


FIG. 6A

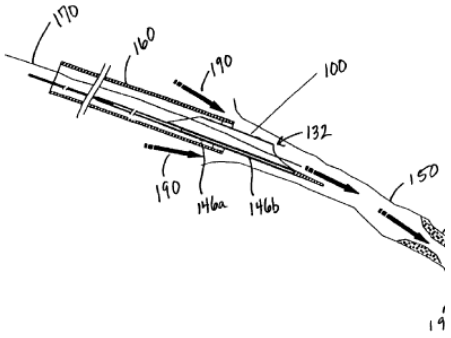
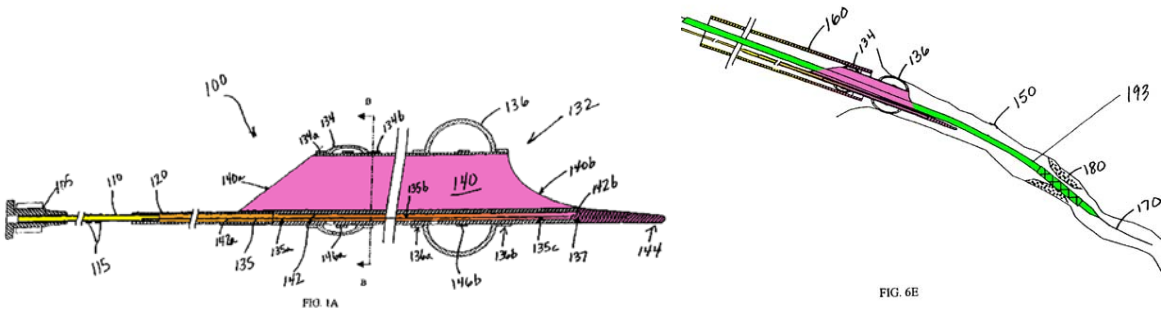


FIG. 6B

The evacuation sheath includes a distal evacuation head. *Id*., 6:19-20, Figs. 1A, 1C, 11A. The 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, ¶ 158.



Id., Figs. 1A, 6B (color added).

IX. GROUND 1: ITOU ANTICIPATES CLAIMS 1-2, 4, AND 7-14.

A. Claim 1

1. [1.pre.i] "A method of providing backup support for an interventional cardiology device for use in the coronary vasculature,"[6]

Long before the '413 patent, a POSITA knew that in order to advance an

[6] The preamble is not limiting when, as here, the claim "defines a structurally complete invention … and uses the preamble only to state a purpose or intended use for the invention." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Regardless, even if limiting, as set forth herein, Itou (and the Itou-Ressemann combination) teaches the preamble. Importantly, neither the claims nor the specification quantify the amount of "backup support" necessary to satisfy this claim limitation, and a POSITA would appreciate that Itou's suction catheter (2) necessarily teaches a method of providing backup support. Ex-1005, ¶¶ 160, 164.

interventional cardiology device through a GC and into the coronary vasculature, the GC had to have "sufficient stiffness to offer 'backup' support." Ex-1015a, 548; Ex-1005 ¶¶ 160, 164-65. As Dr. Brecker explains, and as taught in Grossman's Cardiac Catheterization, Angiography, and Intervention, the "backup 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 ¶¶ 166-71; Ex-1015, 549-50; Ex-1041, 20.

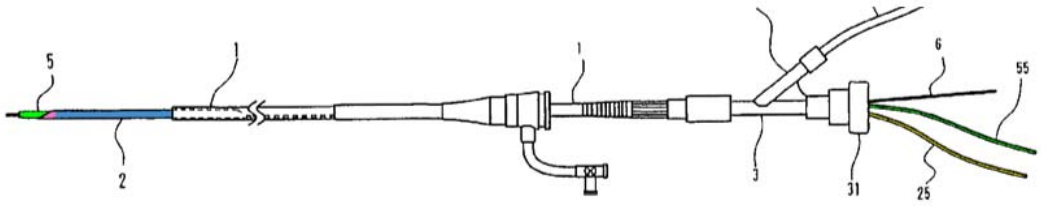
The '413 patent similarly teaches that because the disclosed, coaxial guide catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery," it "assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion." Ex-1001, Abstract, 4:64-5:9. The '413 patent explains that, essentially, it is the combination of a GC and an extension catheter inserted into a coronary ostium that improves distal anchoring of the system, and provides "stiffer back up support." *Id*., 8:4-6. This combination is what allows the claimed method to resist dislodgment, but this is no different than what was already known in the art and disclosed in Itou.

Here, claim [1.pre.i] is non-limiting, reciting only the purpose of providing backup support.

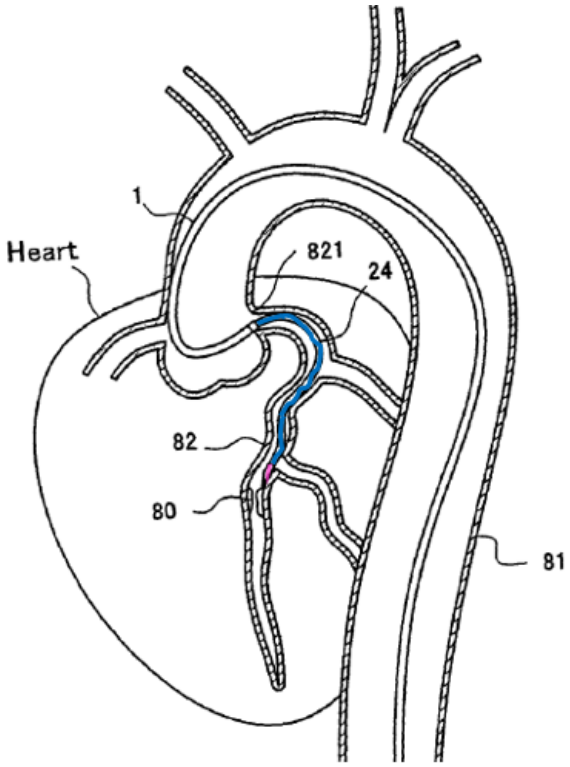
Ex-1005 ¶¶ 161-63.

Itou discloses a catheter assembly that includes a GC (1) that is inserted into a coronary artery ostium, Ex-1007, Abstract, 2:2-5, 5:32-34, 7:7-11, and a suction catheter (2) (blue) that is insertable through and beyond the GC. *Id*., Abstract, 3:59-61, Figs. 1A-B, 5, 6. Itou also discloses that a distal end protective catheter (5) (green)—an interventional cardiology device—that is advanced distal of suction catheter (2). *Id*., Abstract, 2:29-38, Figs. 5-6; *see* § **VI.A**, *supra*.

FIG.5



Ex-1007, Fig. 5 (color added). The distal portion of suction catheter (2) has a tubular portion that extends through and beyond the distal tip of GC (1), while the proximal portion of the tubular structure remains within the lumen of GC (1). *Id.*, Figs. 5, 6, 5:26-46.



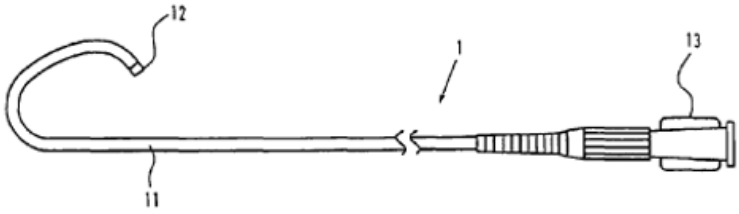
Id., Fig. 6 (color added). Itou discloses that the inner diameter of GC (1) and suction catheter (2) is precisely within the range—i.e., less than 1 French or 0.3 mm—disclosed in the '413 patent. Ex-1007, Table 1; Ex-1005, ¶ 172. Thus, Itou's use of suction catheter (2) in combination with a GC (1) discloses the claimed "method of providing backup support." Ex-1005, ¶ 173; Ex-1042, ¶¶ 61-65; *see also* §§ **IX.A.1-11**, *infra* (analysis and citations for remaining elements of claim 1).

2. [1.pre.ii] "the interventional cardiology device being adapted to be passed through a standard guide catheter,"

Itou discloses an "interventional cardiology device being adapted to be passed through a standard guide catheter." Ex-1005, ¶ 174. Itou discloses a GC (1) that is 1,000mm in length, consistent with guiding catheters "used in ordinary

catheter operation." Ex-1007, 5:65-6:3; Ex-1005, ¶ 175. Itou's GC (1) is a "standard guide catheter," as the term is properly construed. § **VI.B**, *supra*; Ex-1005, ¶ 141, 179.

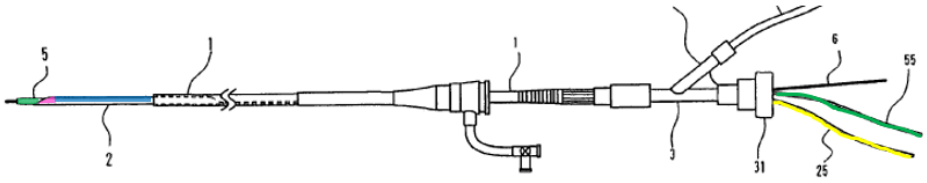
FIG.1A



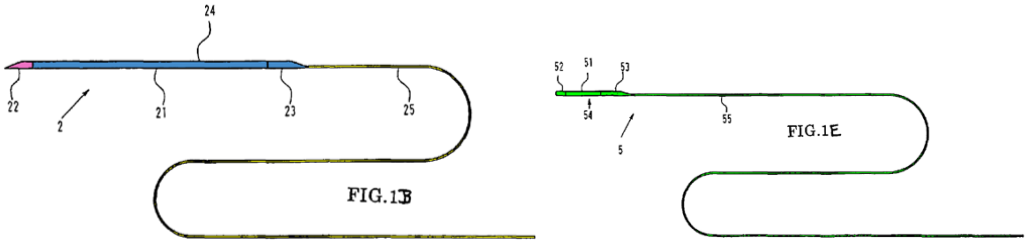
Ex-1007, Fig. 1A.

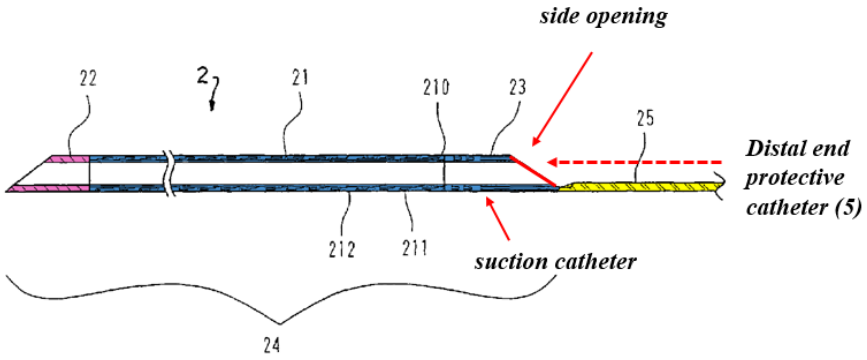
Itou teaches that a protective catheter (5) may be inserted into the lumen of suction catheter (2) and projected from its distal end through the GC (1), as shown below. *Id*., 4:48-51; Ex-1005, ¶ 176.

FIG.5



Ex-1007, Fig. 5 (color added). The suction catheter (2) has a tubular portion (24) with an inner diameter 1.5 mm, sized to be insertable through the continuous lumen of the GC. *Id*., Table 1, 1:59-65. The protective catheter (5) necessarily passes through the GC as seen in Figure 5. *Id*., Figs. 1B, 1E, 3, 5; Ex-1005, ¶ 177-80.



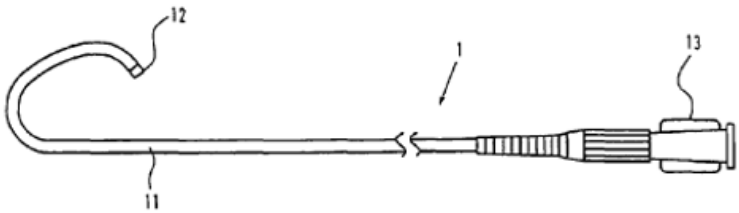


Ex-1007, Figs. 1B, 1E, 3 (color and annotations added).

3. [1.pre.iii] "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,"

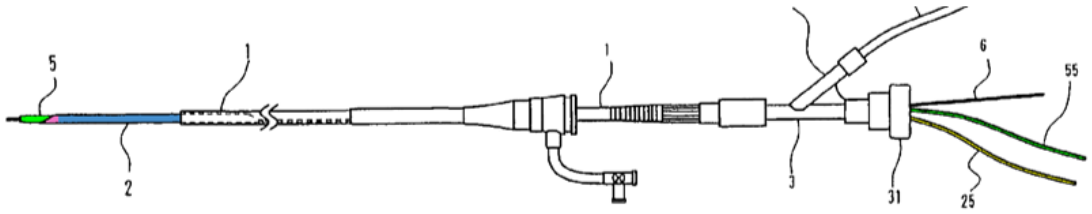
Itou's GC has a continuous lumen that extends the "predefined length" required of claim element [1.pre.iii]. Itou's GC (1) has distal end (12) and body portion (11), which terminates at connector (13). Ex-1007, Fig. 1A, 3:29-37.

FIG.1A



The proximal end of Itou's GC (1) is located at a hemostatic valve. Ex-1005, ¶ 181. As shown below, Itou's GC originates at connector (31)—"a valve (packing)[,] which that can close a bore" 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. Ex-1005, ¶ 181.

FIG.5

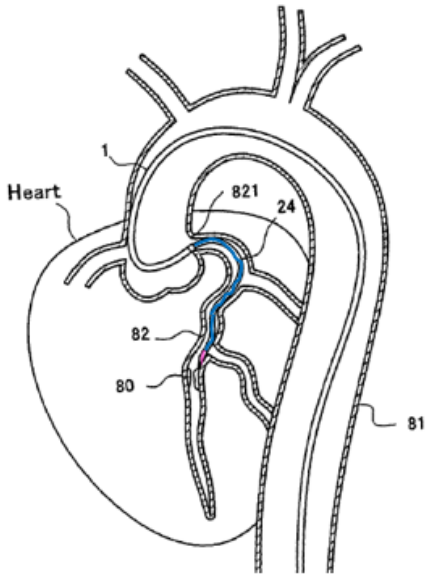


Itou's GC (1) necessarily has a "continuous lumen" because otherwise suction catheter (2), distal end protective catheter (5), and guidewire (6) could not be advanced through the GC. Ex-1007, Fig. 5; Ex-1005, ¶ 181. Additionally, the capability of a valve—connected to the proximal end of Itou's GC (1)—to prevent a leak indicates that GC (1) has a continuous lumen (meaning the walls of the GC (1) are continuous along its length). Ex-1005, ¶ 181. A POSITA understands Itou's teachings to disclose that the proximal end of GC (1) extends from a hemostatic

valve.[7] *Id.*

Itou's GC (1) necessarily has a "continuous lumen" that extends "to a distal end adapted to be placed in a branch artery." Itou teaches that GC (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 GC (1) is "to be inserted to a location on a proximal side of a target location," which may be deep in a coronary artery. *Id.*, 1:66-2:5, 5:32-34, 7:7-10; Ex-1005, ¶ 181.

[7] Itou's disclosure reflects what the '413 patent admits: the "guide catheter … can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter." Ex-1001, 3:3-10. As Patent Owner's expert in the co-pending litigation explained, a hemostatic valve is sometimes called a Y-connector, which is also known as a Y-adapter. Ex-1082, ¶ 18; Ex-1005, ¶ 181.



Id., Fig. 6 (color added). Itou explicitly discloses that the GC may be placed in "an ostium portion of a coronary artery"—"a branch artery" as the term is properly construed. § **VI.C**, *supra*; Ex-1005, ¶ 181.

4. [1.pre.iv] "the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:"

Itou's GC has a continuous lumen with a "circular cross-sectional inner diameter" sized such that "interventional cardiology devices" are "insertable into and through the lumen." Itou's GC (1) "preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation." Ex-1007, 5:65-67. Because GC (1) has an "inner ***diameter*** of 1.8 mm," it necessarily has a "circular cross section." Ex-1005, ¶ 182.

Distal end of protective catheter (5)—an "interventional cardiology

device"—has a maximal outer diameter of 1.35 mm. Ex-1007, Table 1, 4:61-63. Protective catheter (5) has a lumen of "a size sufficient to receive" guidewire (6), which is also an "interventional cardiology device." *Id*. Both protective catheter (5) and guidewire (6) are sized to be insertable into and through the lumen of the GC (1). *Id.*, 3:59-63, 4:43-52, Fig. 5; Ex-1005, ¶¶ 182-83.

Patent Owner may nevertheless argue that Petitioner must show that Itou's GC is sized sufficiently to receive all four devices exemplified in the specification of the '413 patent. *See* Ex-1001, 1:23-26. Patent Owner's argument is unfounded.

As an initial matter, as explained in the Institution Decisions in co-pending IPRs, the term "interventional cardiology device" should not be interpreted so broadly. Ex-1113, 19-20. Given the specification's use of the phrase "include but not be limited to," the prior art, including Itou, need only teach that one of the exemplified interventional cardiology devices can be passed through the GC. *Fed. Land Bank v. Bismarck Lumber*, 314 U.S. 95, 99–100 (1941) ("[T]he term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle.").

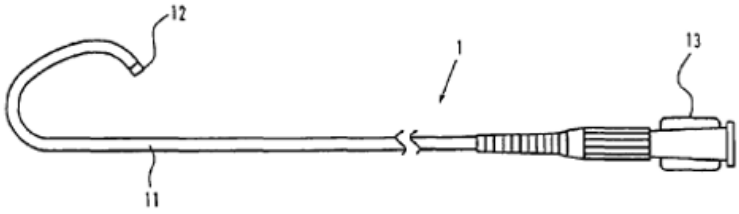
Regardless, Itou's assembly permits passage of all four devices exemplified in the specification of the '413 patent. Ex-1005, ¶¶ 184-85. Itou's GC "preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation;" Itou specifically discloses a GC with an "inner diameter of 1.8 mm."

Ex-1007, 5:65-67, 7:54-67. As Dr. Brecker explains, it was known that some guidewires, stents, and stent catheters had diameters *less than 1.8mm*. Ex-1005, ¶¶ 186-90; Ex-1097, 104 (Genic® stent with less than 0.9 mm (0.035 inch) profile), 143 (Lunar stent with 0.0382 inch profile), 269 (Spiral Force stent with 0.039 to 0.042 inch profile) 274 (Tsunami stent with 0.95 mm (0.038 inch) profile); Ex-1022, 3; Ex-1023, 9; Ex-1024, 10; Ex-1028, 641. Thus, regardless of the interpretation of "interventional cardiology device," Itou discloses this claim limitation. Ex-1005, ¶¶ 182-90.

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

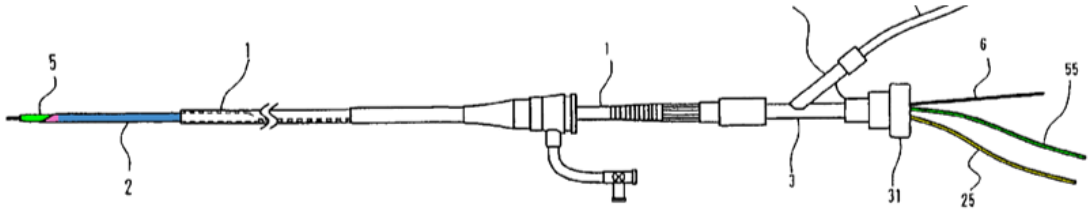
Itou discloses inserting the GC (1) into a first artery (aorta 81) over a guidewire (6), the standard guide catheter having a distal end (12). Ex-1005, ¶ 191.

FIG.1A



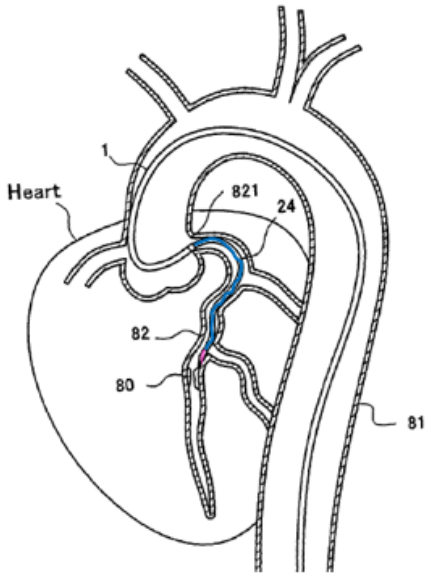
As shown in Figure 5, below, Itou's GC (1) is inserted over a guidewire (6) in addition to being over the suction catheter and distal end protective catheter.

FIG.5



Itou's GC may be placed in "an ostium portion of a coronary artery." Ex-1007, 1:66-2:5. Itou explains that GC (1) "has the guide wire 6 fitted therein," and is then "inserted into the introducer sheath 7 and secured to the ostium of a coronary artery." *Id.*, 7:7-10. Distal end (12) of guiding catheter (1) is "inserted to a location on a proximal side of a target location"—a location that may be deep in a coronary artery. *Id.*, 1:66-2:5, 5:32-34, 7:7-10.

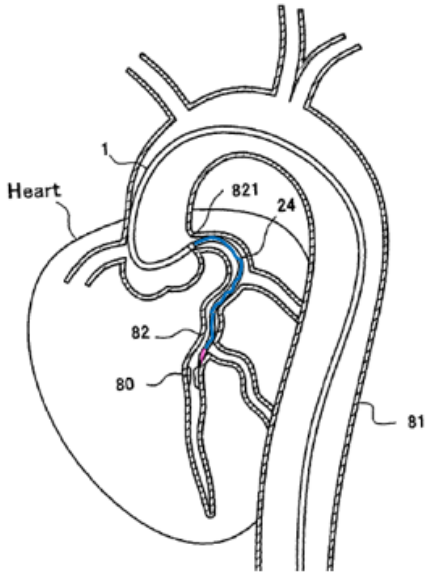
Figure 6, below, illustrates how Itou's GC assembly is located "at a target location 80 in a coronary artery of the heart." Ex-1007, 3:1-4.



Id., Fig. 6 (color added).

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

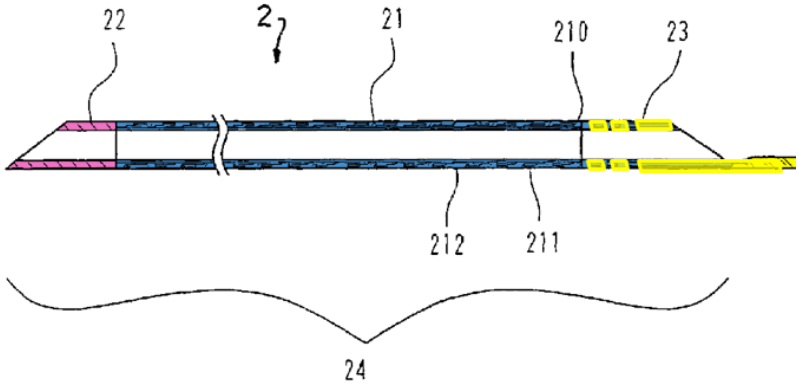
Itou discloses positioning the distal end of its GC (1) in a branch artery. As discussed above, § **XI.A.5**, *supra*, distal end (12) of Itou's GC (1) is "to be inserted to a location on a proximal side of a target location," which may be deep in a coronary artery. Ex-1007, 1:66-2:5, 5:32-34, 7:7-10. Itou explicitly discloses that the GC may be placed in "an ostium portion of a coronary artery"—a "branch artery" as the term is properly construed. § **VI.C**, *supra*; Ex-1005, ¶¶ 192-93. As seen in Figure 6 of Itou, the coronary artery (82) branches off from the aorta (81).



Ex-1007, Fig. 6 (color added).

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

Itou discloses a coaxial guide catheter—Itou's suction catheter (2, below). Ex-1005, ¶ 194.



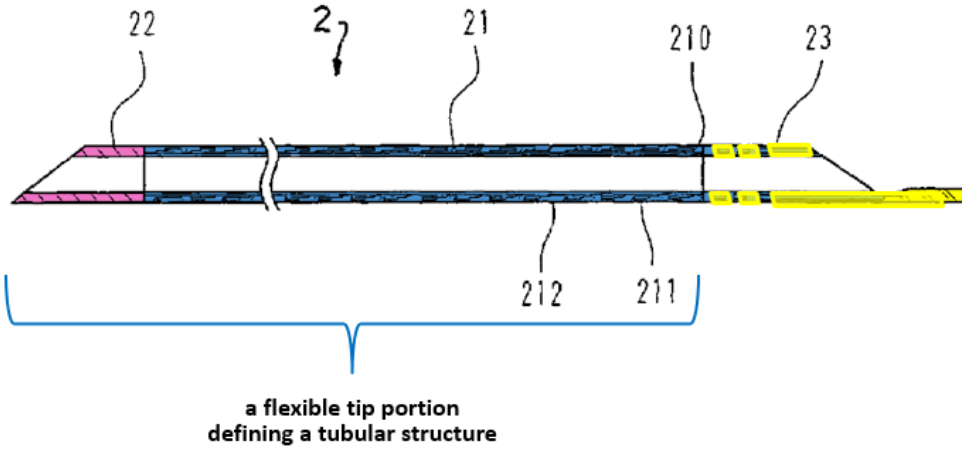
Itou's suction catheter (2) is coaxial.[8]

Itou's suction catheter (2) has a flexible tip portion defining a tubular structure and having a circular cross-section. Petitioner presents two mappings for

[8] The '413 patent recites a "coaxial guide catheter," but it does not explain what the extension catheter is supposed to be coaxial to. Ex-1005, ¶¶ 194-95. To the extent the "coaxial guide catheter" is somehow found to recite structure—despite not providing what the extension catheter is coaxial to—Itou's suction catheter (2) is "coaxial." Ex-1007, Figs. 5, 6; Ex-1005, ¶¶ 194-95.

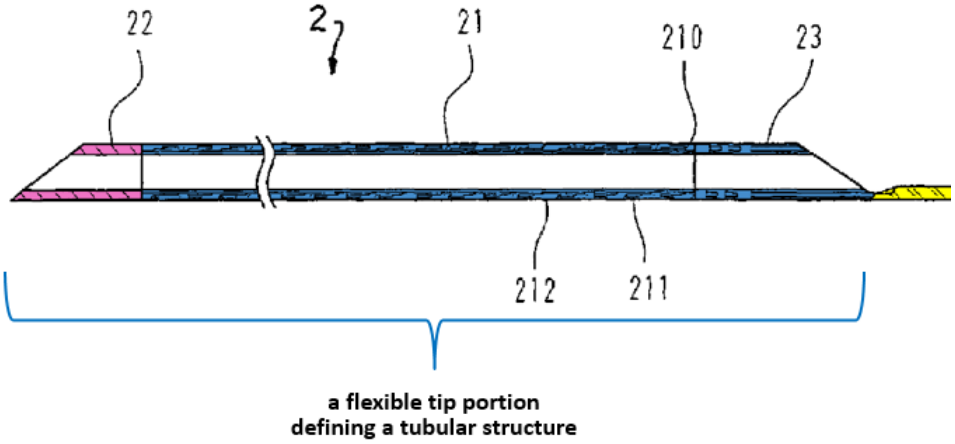
the claimed "flexible tip portion" of claim 1. "Mapping-1," applies unless otherwise indicated.

Mapping 1: Itou's suction catheter (2) has a "flexible tip portion" comprised of tubular body portion (21) and distal tip (22). Ex-1007, 2:12-21, Fig. 3.



Ex-1007, Fig. 3 (color added). Tubular body portion (21) and distal tip (22) are part of tubular portion (24). *Id.*, 3:47-58. Tubular member (24) has a circular cross-section. *Id.*, Table 1 (disclosing an inner diameter for catheter 2's tubular portion of 1.5mm), Fig. 7B. Accordingly, tubular portion (21) and tip (22) are also circular in cross-section. Ex-1005, ¶ 194.

Mapping-2: Mapping-2 matches how Patent Owner believes the "flexible tip portion" may (but is not required) to be mapped. *See* Ex-1077, 123:14-17, 124:19-25, 127:24-128:14, 129:20-130:4. Patent Owner views the "flexible tip portion" of Itou's suction catheter as comprising tubular body portion (21), tip (22), *and* proximal tip (23). Ex-1007, 2:12-21, Fig. 3.



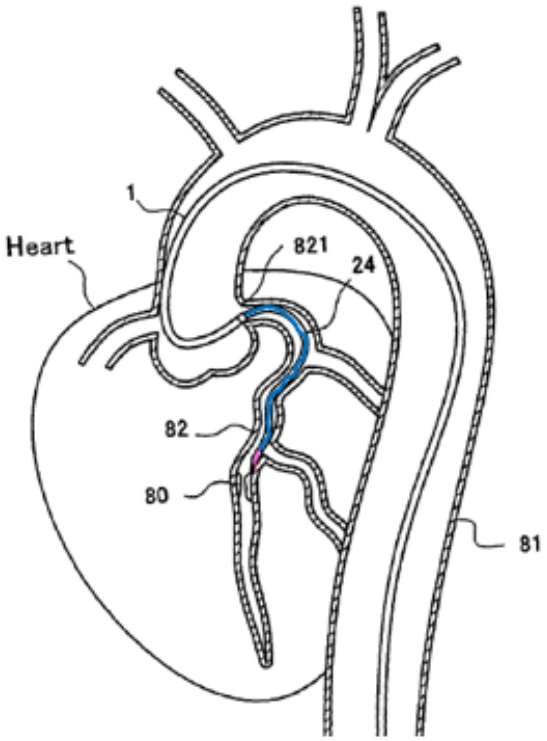
The "flexible tip portion" under this mapping also has a circular cross-section because tubular body portion (21), tip (22), *and* proximal tip (23) are part of tubular portion (24), which as discussed above has a circular cross-section. Ex-1005, ¶ 195.

Under either mapping, Itou's flexible tip portion [21 and 22, *or* 21, 22, and 23 *together*] defines a lumen with a length that is shorter than the predefined length of the continuous lumen of Itou's GC. Itou explicitly teaches that tubular portion (24)—which includes tubular body portion (21), tip (22), and proximal tip (23)—"is shorter than the guiding catheter." Ex-1007, 2:23-26.

Under either mapping, Itou's flexible tip portion [21 and 22, *or* 21, 22, and 23 *together*] is "flexible." Ex-1005, ¶ 194-95. As Dr. Brecker and Dr. Hillstead explain, portion 25 is more rigid along a longitudinal axis than flexible tip portion [21 and 22, *or* 21, 22, and 23 *together*]. Ex-1005, ¶ 195; Ex-1042, ¶¶ 48-59. This is evidenced by the function Itou discloses for proximal, wire-like portion (25),

which is to advance suction catheter (2) to a location deep in the coronary vasculature. Ex-1007, 5:43-46. A POSITA understood 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, 2:29-44; Ex-1005, ¶ 194-95; Ex-1042, ¶¶ 48-59.

Tubular portion 24 (and therefore flexible tip portion [21 and 22, *or* 21, 22, and 23 *together*]) of suction catheter (2) has an outer diameter (1.72 mm) that is sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the GC (1.8 mm). *Id.*, Table 1, 1:59-65. Further, Itou discloses inserting the suction catheter—and flexible tip portion [21 and 22, *or* 21, 22, and 23 *together*]—into the continuous lumen of the GC "along the guide wire 6." Ex-1007, 7:13-15. As shown below in Figure 6, the flexible tip portion of the suction catheter (2) (under either mapping) is inserted first. Ex-1005, ¶ 194-95.



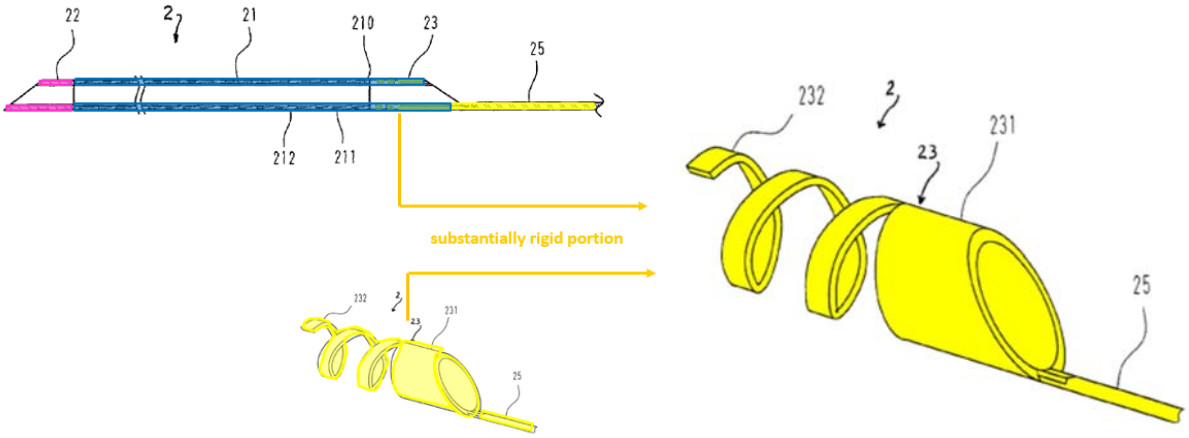
Ex-1007, Fig. 6 (color added).

8. [1.d.i] "further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter,"

Itou's suction catheter (2) has a "substantially rigid portion" that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. Petitioner presents two different mappings for the claimed "substantially rigid" portion. "Mapping-1," applies unless otherwise indicated.

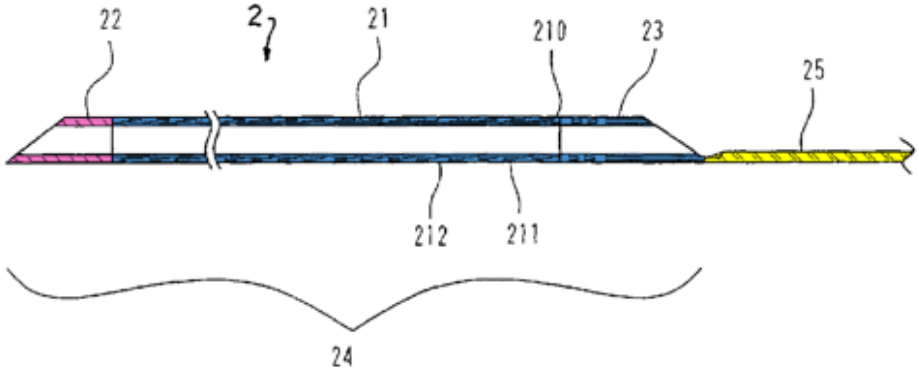
Mapping 1: Itou's suction catheter (2) has a "substantially rigid portion," which includes solid wire-like portion (25) on the catheter's proximal end "formed from a solid metal wire and an outer layer such as a polymer coating." Ex-1007,

3:46-50, Fig. 1B; Ex-1005, ¶¶ 196-97, 210-15. The distal end of wire-like portion (25) is fused to the proximal portion of an obliquely cut metal pipe (231), Ex-1007, 4:25-36, which *together* form the "substantially rigid" portion.

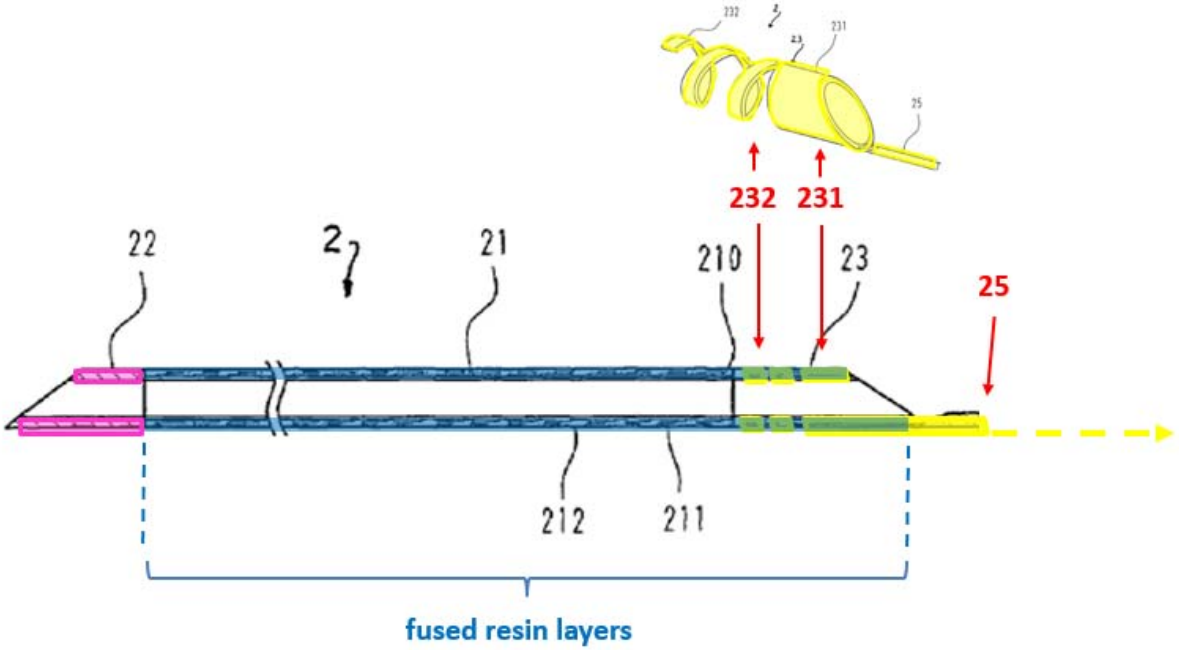


Id., Figs. 3, 4 (color added). Wire-like portion (25) and end (231) are used to advance suction catheter (2) to a target location (80). *Id.*, 2:5-11, 5:35-38, 5:43-46. Accordingly, wire-like portion (25) and/or end (231) must be "rigid enough to allow the device to be advanced within the guide catheter." **§ VI**, *supra* (construction of "substantially rigid"); Ex-1005, ¶ 196.

Mapping 2: Mapping-2 matches how Patent Owner believes the substantially rigid portion may (but is not required) to be mapped. *See* Ex-1077, 123:14-17, 124:19-25, 127:24-128:14, 129:20-130:4; Ex-1005, ¶¶ 196-97, 210-15. Patent Owner views the "substantially rigid portion" of Itou's coaxial guide catheter as being comprised only of wire-like portion (25).



Under either mapping, Itou's substantially rigid portion [25 and 231, *or* 25 *alone*] is operably connected to its flexible tip portion (21, 22, and 23, *or* 21, 22). The distal end of wire-like portion (25) is welded to the proximal end of proximal tip (231), as shown below. Ex-1007, 4:43-46, Fig. 3.



Id., Figs. 3, 4 (color and annotation added). 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, as shown above. *Id*., 3:50-55, 4:32-33, 4:36-38; Ex-1005, ¶ 196-97.

Under either mapping, Itou's "substantially rigid portion" [25 and 231, *or* 25 *alone*] is more rigid along a longitudinal axis than the flexible tip portion (21, 22). Ex-1005, ¶¶ 198-209.

First, both wire-like portion (25) and proximal tip (231) are made of solid metal. Ex-1007, 3:29-37, 4:27-32. The "flexible tip portion," by contrast, includes tip (22), which is described as soft and "flexible in order to reduce the damage to the blood vessel." Ex-1007, 2:15-21. "Flexible tip portion" 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*., 3:50-58. As Dr. Brecker and Dr. Hillstead explain, based on the known properties of the materials of portions 25 and 231 and flexible tip portions 21 and 22, the former are more rigid along a longitudinal axis than the latter. Ex-1005, ¶¶ 196-200; Ex-1042, ¶¶ 48-59.

Second, Itou's suction catheter (2), including wire-like portion (25), is meant to be advanced to a location deep in the coronary vasculature. Ex-1007, 5:43-46. It was well understood in the art that in order to advance through the coronary

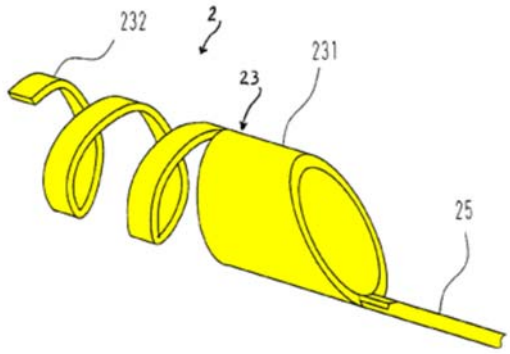
vasculature, the proximal portion of a catheter necessarily had to have sufficient rigidity or stiffness (in order to permit the catheter to be pushed through the vasculature), while its distal end was fairly flexible. Ex-1019, 9:30-50; Ex-1072, 2:29-43; Ex-1005, ¶¶ 201-09; Ex-1042, ¶¶ 48-59.

Itou discloses inserting the suction catheter—and at least a portion of substantially rigid portion [25 and 231, *or* 25 *alone*]—into the continuous lumen of the GC. Itou discloses that "a combination of the suction catheter 2 and the distal end protective catheter 5 is inserted into the guiding catheter 1 along the guide wire 6." Ex-1007, 7:13-15. "The introduction of the suction catheter 2 … is performed by pushing the wire-like portions 25 and 55 on the proximal end side." *Id.*, 5:42-46; Ex-1005, ¶¶ 201-03.

9. [1.d.ii] "the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;"

Under either mapping of the "substantially rigid portion," (§ **IX.A.9**, *supra*), Itou's coaxial guide catheter—suction catheter (2)—includes a "rail structure

without a lumen."[9] Ex-1005, ¶ 196. Wire-like portion (25) is a "rail structure" because it facilitates the sliding rail delivery of suction catheter (2) through GC (1). Ex-1007, Figs. 5, 6, 4:43-52, 5:26-46; Ex-1005, ¶ 196. Wire-like portion (25), shown below, does not have a "lumen" because it is "formed from a solid metal wire." Ex-1007, 2:12-14, 3:48-50; Ex-1009, ¶ 210.



The wire-like portion (25) of Itou's suction catheter (2) has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. Ex-1005, ¶ 211. Wire-like

[9] Claim 1 recites numerous limitations on the substantially rigid portion, including "defining a rail structure without a lumen." While the substantially rigid portion includes a rail structure without a lumen, the claim does not say it is limited to only that structure. Dependent claim 4 confirms this reading and requires an "opening along a side," which necessarily includes a lumen, to be part of the substantially rigid portion.

portion (25) has a cross sectional outer diameter of 0.45 mm. Ex-1007, 3:59-63; Table 1. This diameter is smaller than the cross-sectional outer diameter of the tubular portion of the suction catheter (including flexible tip portions [21, 22, and 23 or 21, 22]), which is 1.72 mm. *Id.*[10]

The wire-like portion (25) of Itou's suction catheter (2) has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of Itou's GC. Wire-like portion (25) is 1100 mm long. *Id.*, Table 1. By itself, wire-like portion (25) is longer than the 1000 mm length of Itou's GC. *Id*. The combined length of wire-like portion (25) and flexible distal tip portion [21, 22, and 23 or 21, 22] is thus necessarily greater than that of the GC. *Id*., 2:23-26; Ex-1005, ¶¶ 212-15.

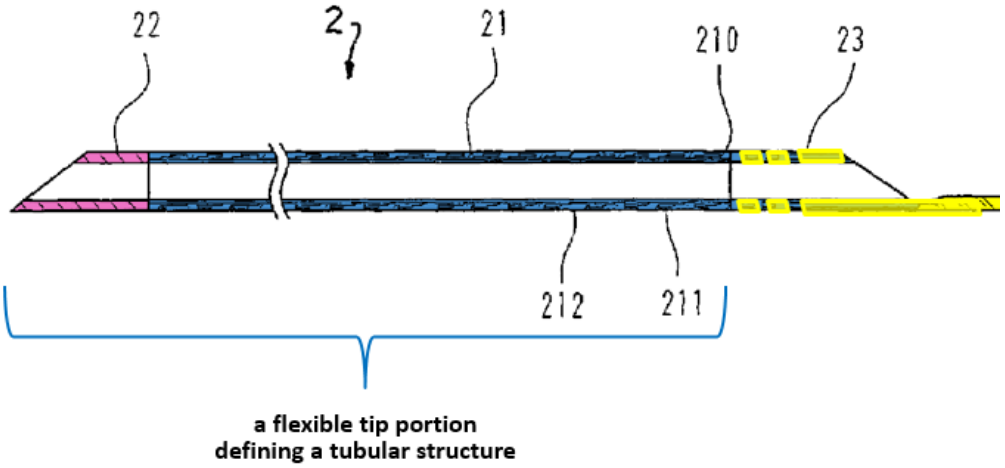
[10] The claim language "maximal cross sectional dimension" permits, but does not require, the rail structure to vary in cross-sectional dimension. All the claims require is that the proximal rail structure cannot be bigger (in cross-sectional dimension) than the flexible tip portion (tubular structure).

10. [1.e] "advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery[11] and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and"

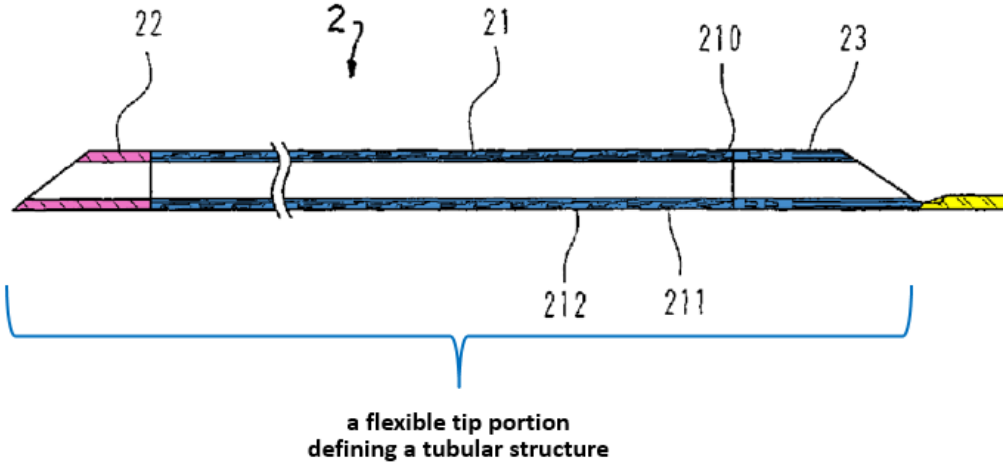
Itou discloses advancing a distal portion the "flexible tip portion" of its suction catheter (2) beyond the distal end of the GC and into a second, "branch

[11] Claim 1 refers to "first" and "second" arteries, but provides no antecedent basis for the latter. The specification also provides no direction as to these claim terms, as it never refers to a "first" or "second" artery. Because claim 1 also states that the distal end of the GC is "position[ed] … in a branch artery that branches off from the first artery," the "first artery" must be the aorta. Ex-1005, ¶ 217; Ex-1001, 1:35-39, Figs. 7-9 (showing that GC is placed in the ostium of the coronary artery); § **VI.C**, *supra* (construing "placed in a branch artery). As a result, the "second artery" must be an artery that is located downstream of the aorta. It is unclear, however, if it is the same as the claimed branch artery (coronary artery), or refers to a further branch (which is not described or shown in the specification). In other words, it is unclear whether the second artery is the initial portion of the coronary artery before any further branch, or if it must be a further branch. Regardless, this limitation is taught by Itou. Ex-1005, ¶ 217; Ex-1007, Fig. 6.

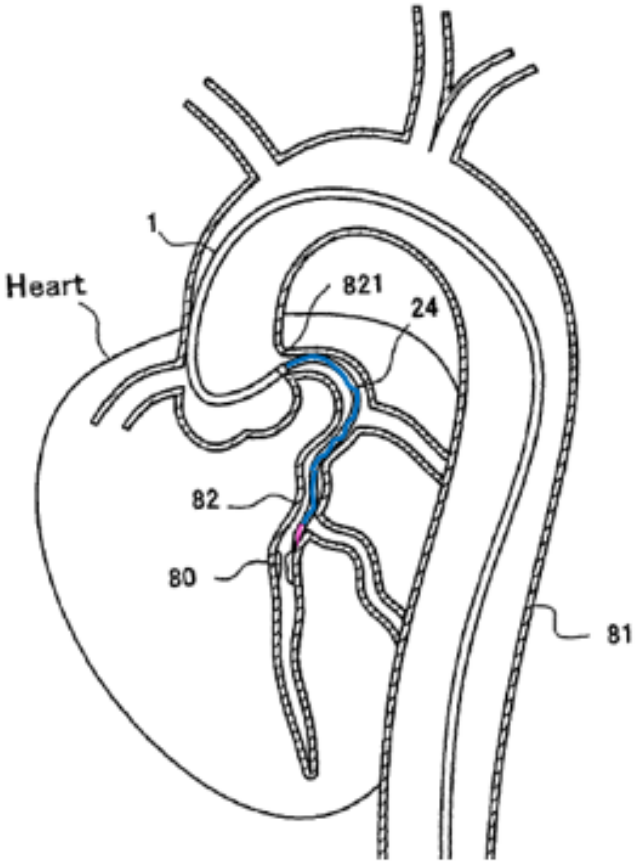
artery." Ex-1005, ¶ 216.



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



Id. (color added). Figure 6, below, illustrates how Itou's GC assembly is located "at a target location 80 in a coronary artery of the heart." *Id.*, 3:1-3.



Id., Fig. 6 (color added). Itou's suction catheter (2) with "flexible tip portion" (colored blue and pink above) extends "through the lumen of the [GC (1)] into the coronary artery further than the distal end" of the GC. *Id.*, 2:5-9; Ex-1005, ¶ 218.

Itou discloses "an example of a method of use," excerpted below, wherein at least a portion of the proximal portion of the substantially rigid portion of suction catheter (2) extends proximally through the hemostatic valve. As described in Itou, "the guide wire 6 is inserted to a target location while an X-ray image is observed." Ex-1007, 7:1-27. When at least a distal portion of flexible tip (21, 22) of the suction catheter (2) is extended distally of the distal end of the GC, 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.*, 5:11-24; Ex-1005, ¶ 219.

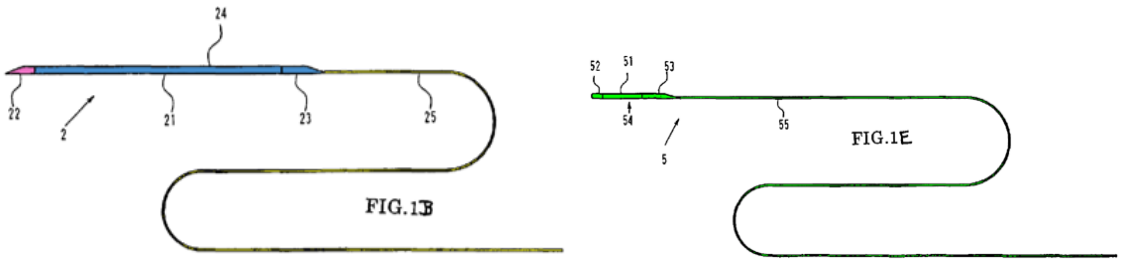
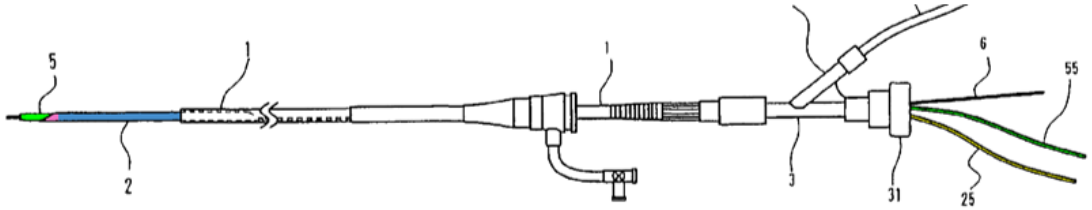


FIG.5



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.*, 5:20-24. That the valve may clamp guide wire (6), wire-like portion (25), or wire-like portion (55) and establishes that all three extend proximally through a common hemostatic valve. Ex-1005, ¶ 220.

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

Itou discloses "an example of a method of use," excerpted below, wherein at "the distal end protective catheter 5"—an interventional cardiology device—"is inserted into the guiding catheter 1 along the guide wire 6." Ex-1007, 7:1-27. The protective catheter (5) is inserted into catheter (2)—i.e. "preassembled"—before the combination of protective catheter (5) and catheter (2) (with its "substantially rigid portion") are inserted intothe GC (1) together. *Id.*, 7:13-15; Ex-1005, ¶ 221. Therefore, insertion of protective catheter (5) occurs "alongside" of the substantially rigid portion of Itou's suction catheter (2).[12] Ex-1005, ¶ 222. "The

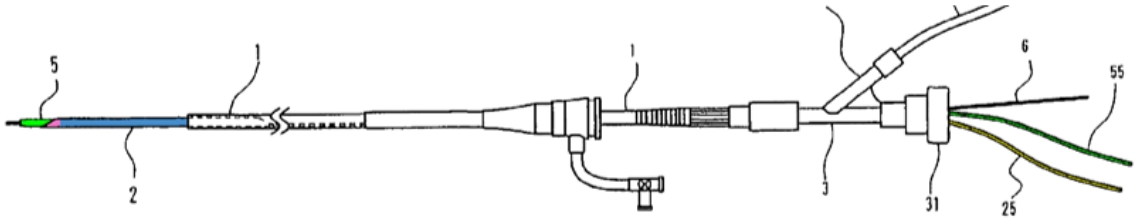
[12] Claim element 1.f does not recite two separate, sequential insertion steps with respect to the interventional cardiology device and coaxial guide catheter. There is nothing in the language of 1.f that requires the coaxial guide catheter to be inserted first, followed (separately) by the interventional cardiology device. The devices are inserted "alongside" one another. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one."); *Altiris Inc. v.*

introduction of the suction catheter 2 and the distal end of protective catheter 5 to the deep location is performed by pushing in wire-like portions 25 and 55 of the proximal end side." *Id.* 5:43-46; Ex-1005, ¶ 221.

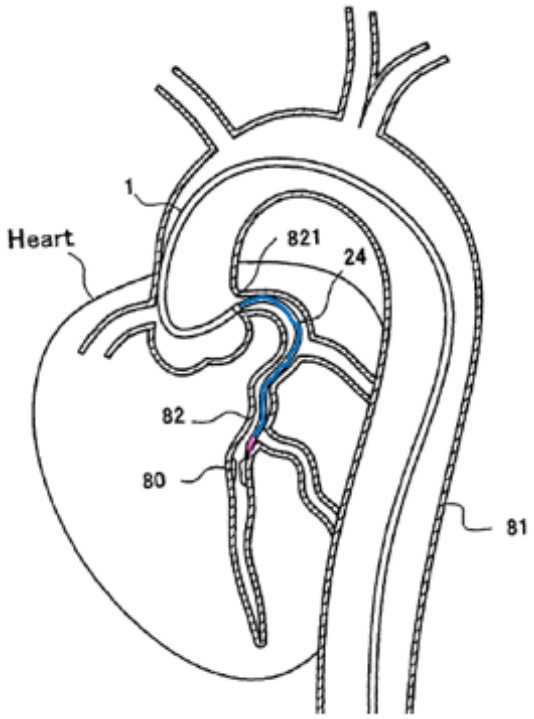
Itou discloses that "the distal end protective catheter 5" is advanced through and beyond a lumen of the flexible tip portion of Itou's suction catheter (2) into contact with a lesion in the second artery. "The distal end protective catheter 5 is inserted in the lumen of suction catheter 2 and projects from the distal end of suction catheter 2 such that it acts as a protective safety tip." Ex-1007, 4:48-52. Itou explains that "the distal end of the combination of the suction catheter 2 and the distal end protective catheter 5 is inserted *to the target location 80*." *Id.*, 7:1-27 (emphasis added); Ex-1005, ¶ 223, 225. As shown in Figure 5, below, the distal end protective catheter (5) extends beyond the lumen of the flexible tip portion of Itou's suction catheter (2).

Symantec Corp., 318 F.3d 1363, 1370-71 (Fed. Cir. 2003) (explaining that it is improper to read a specific order of steps into method claims unless logic or grammar requires such an interpretation).

FIG.5



Ex-1007, Fig. 5 (color added). Figure 6, below, shows Itou's assembly "disposed at a target location." *Id.*, 3:1-4; Ex-1005, ¶ 224.



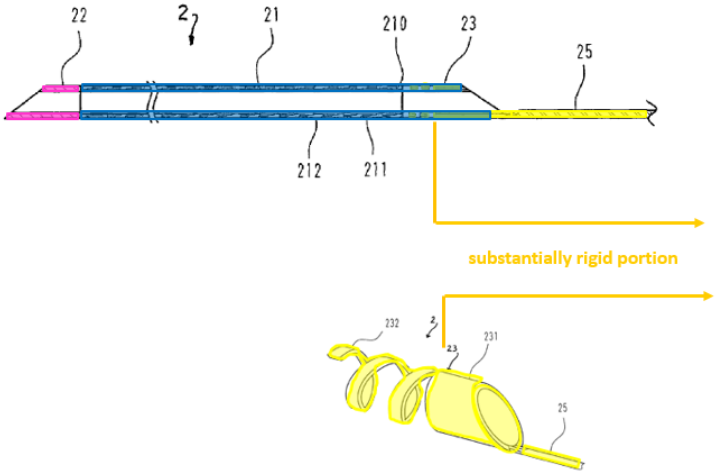
Ex-1007, Fig. 6 (color added).

B. Claim 2: The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal portion of the coaxial guide catheter remains seated in the second artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.

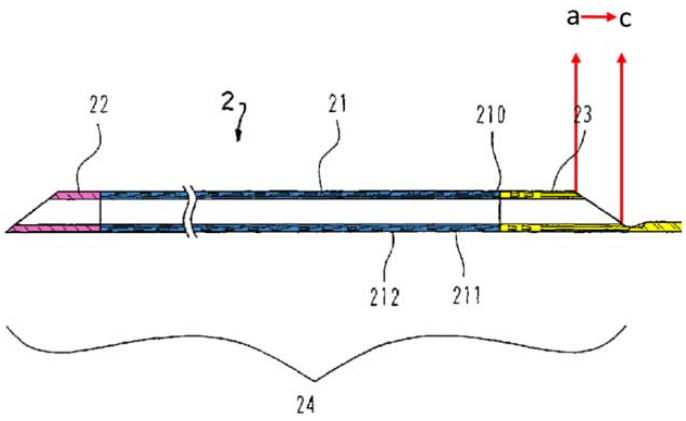
As discussed above, Itou discloses a method of providing backup support for an interventional cardiology device. § **IX.A.1**, *supra*. Backup support is achieved via application of force to a proximal portion of the coaxial guide catheter such that the distal portion of the coaxial guide catheter remains seated in the second artery in response to an opposing backward force exerted by the interventional cardiology device. Ex-1005, ¶¶ 160-73, 226; Ex-1042, ¶¶ 61-65.

C. Claim 4: The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.

The "substantially rigid portion" of Itou's suction catheter (2) comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof. As shown below, in *Mapping 1*, the "substantially rigid" portion includes both wire-like portion (25) and proximal tip (23).

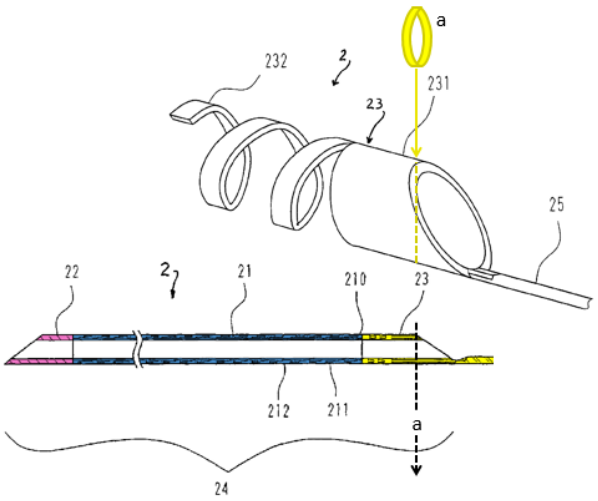


Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added). Proximal tip (23) includes end (231)—a proximal side opening that is "inclined obliquely" and formed by cutting one end of a metal pipe. *Id.*, 4:11, 4:27-32; Figs. 3-4. The proximal opening extends for a distance from (a) to (c) along the longitudinal axis of catheter (2), forming a "side opening."



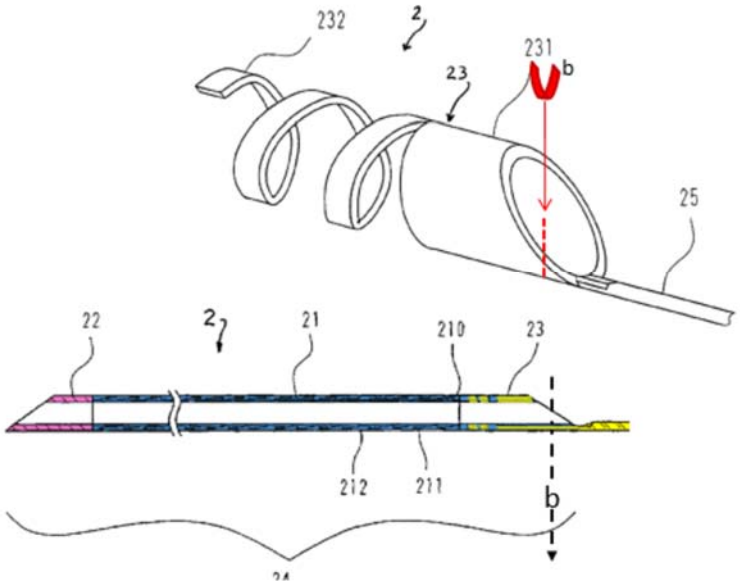
Id., Fig. 3 (annotation and color added).

The end (231) of the substantially rigid portion includes a cross-sectional shape having a full circumference portion (shown by line (a), below). Ex-1005, ¶ 227. This portion of the substantially rigid section comprises a "cylindrical portion."



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

Moving proximally, end (231) of the substantially rigid portion also has a partially cylindrical portion (cross section at "b") (Ex-1005, ¶ 227), which, according to the '413 patent is a portion that "desirably includes 40% to 70% of the circumference of a tube." Ex-1001, 6:44-46.



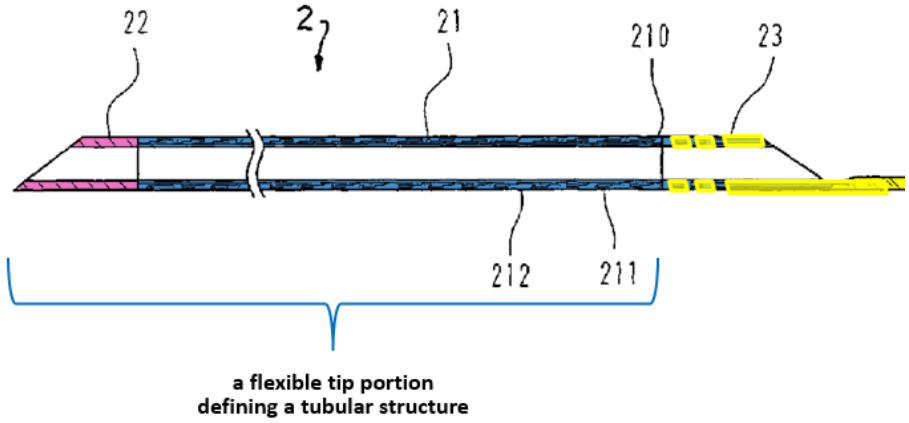
Ex-1007, Figs. 4 (top), 3 (bottom) (color and annotations added).

D. Claim 7: The method as claimed in claim 1, further comprising extending a distal portion of the tubular structure beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter, such that the coaxial guide catheter 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 standard catheter from the branch artery.

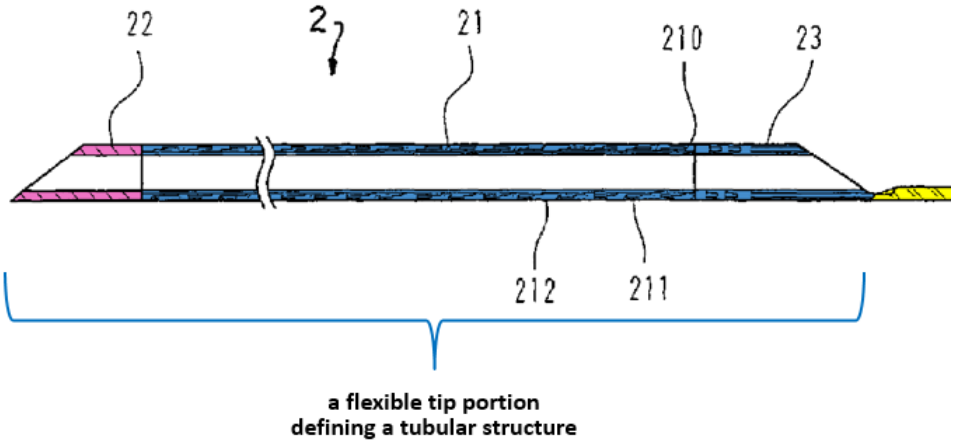
In either *Mapping-1* or *Mapping-2,* Itou's suction catheter (2) has a flexible tip portion defining a tubular structure (21) and having a circular cross-section.

Ex-1007, 2:12-21, Fig. 3.

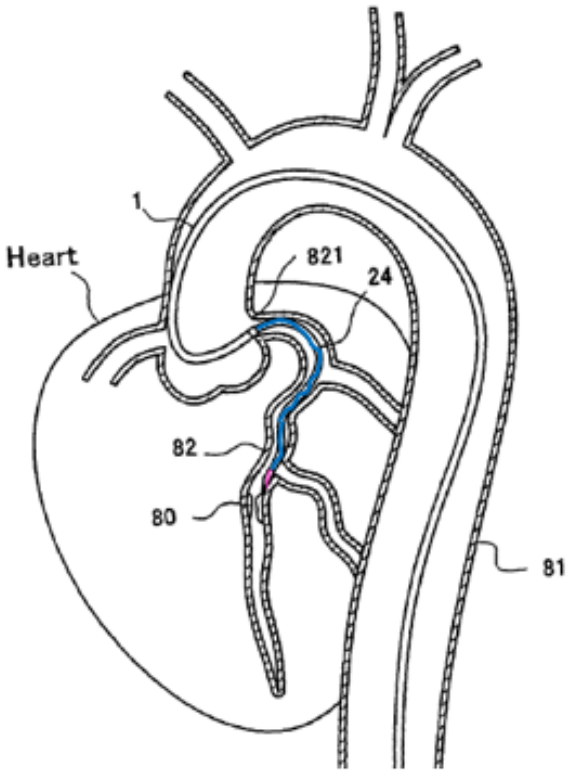
Mapping-1



Mapping-2



Id., Fig. 3 (color added). Figure 6, below, illustrates how Itou's GC assembly is located "at a target location 80 in a coronary artery." *Id.*, 3:1-3.



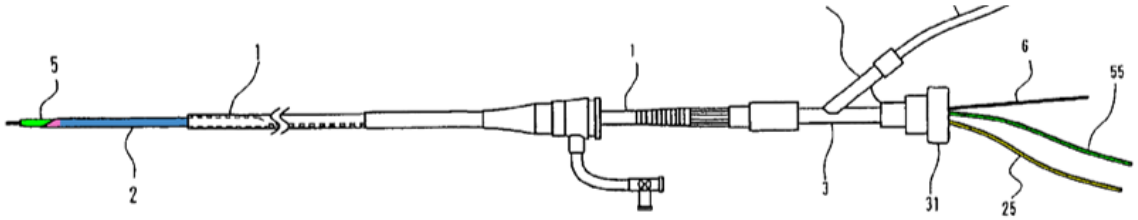
As illustrated above, the distal portion of the tubular structure is extended beyond the distal tip of GC (1). The proximal portion of the tubular structure remains within the lumen of GC (1). *Id*., Figs. 5, 6; 3:1-3; 5:26-46, 7:1-27; Ex-1005, ¶ 228.

As discussed above, Itou discloses a method of providing backup support for an interventional cardiology device. § **IX.A.1**, *supra*. The positioning of Itou's GC assembly discussed above 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 standard catheter from the branch artery. Ex-1005, ¶¶ 160-73, 228; Ex-1042, ¶¶ 61-65.

E. Claim 8: The method of claim 7, further comprising extending the interventional cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.

Itou includes a radiopaque marker proximate to the distal tip of suction catheter (2). Itou teaches that tip (22) of suction catheter (2) "is formed such that a filler such 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)." Ex-1007, 4:15-20; Ex-1005, ¶ 229. "Consequently, the operator can confirm the positions of the distal end portion of the suction catheter 2 and the proximal end portion of the tubular portion 24." Ex-1007, 4:20-24. As set forth in relation to Claim 1[f], Itou discloses extending a protective catheter (5)—an interventional cardiology device—past the distal tip (22) of Itou's suction catheter (2). § **IX.A.11**, *supra*; Ex-1005, ¶ 230.

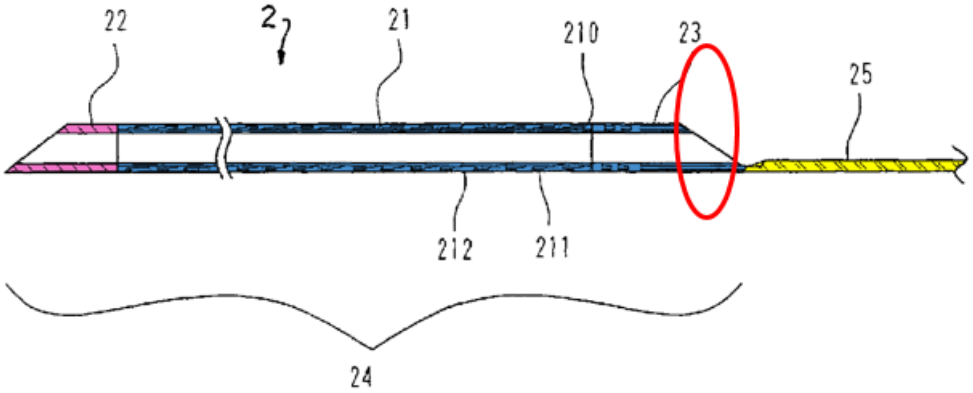
FIG.5



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

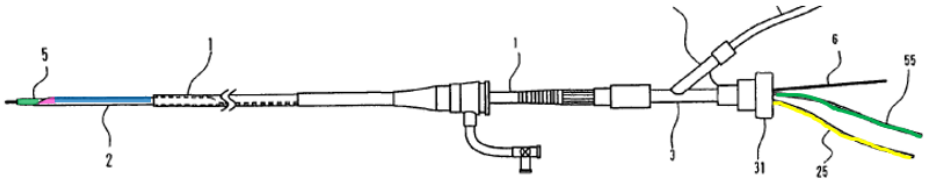
F. Claim 9: The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.

In *Mapping-2*, Itou discloses a side opening (circled in red) in tubular portion (24) of suction catheter (2). Ex-1007, Fig. 4, 3:47-50, 4:10-15, 4:27-32.



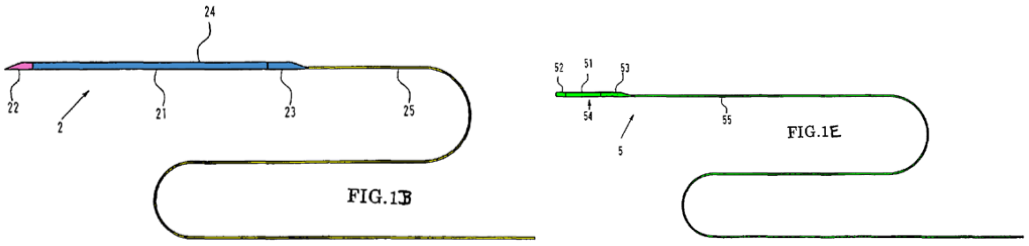
Itou teaches that a protective catheter (5)—an interventional cardiology device—may be inserted into the lumen of catheter (2) and projected from its distal end, as shown below. *Id.*, 4:48-52, 7:1-27.

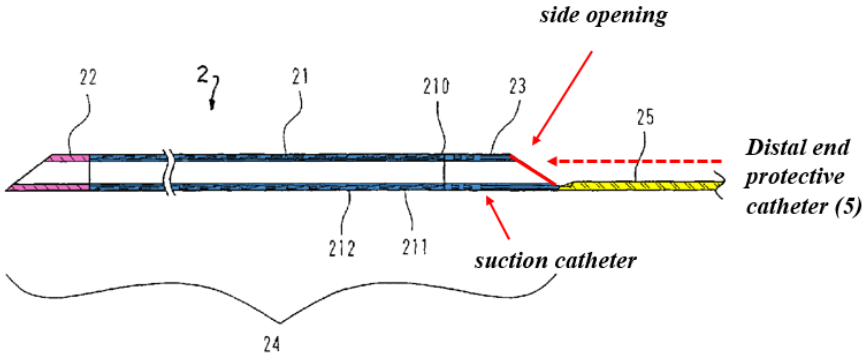
FIG.5



The protective catheter (5) necessarily extends through—and partially remains in the lumen of the GC. *Id.*, Figs. 1B, 1E, 3; Ex-1005, ¶¶ 195, 231. The proximal portion of the tubular portion (24) remains within the lumen of GC (1). *Id.*, Figs. 5,

6, 3:1-3, 5:26-46; Ex-1005, ¶¶ 232-35.





Id., Figs. 1B, 1E, 3 (color and annotations added). When protective catheter (5) is inserted to a target location, the proximal portion of protective catheter (5) remains within the lumen of Itou's GC. *Id.* ¶¶ 231-32.

G. Claim 10:

[10.pre] "The method of claim 9, further comprising

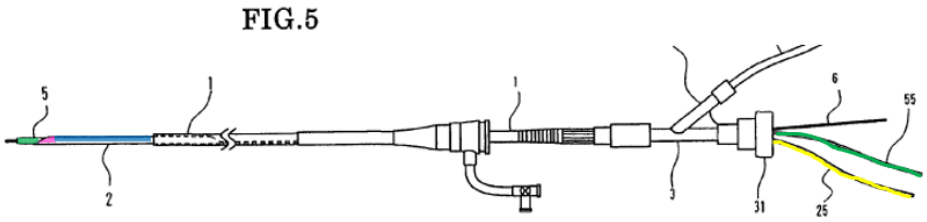
[10.a] "extending the interventional cardiology device through the proximal side opening;"

[10.b] "advancing the interventional cardiology device through structure defining a full circumference portion; and"

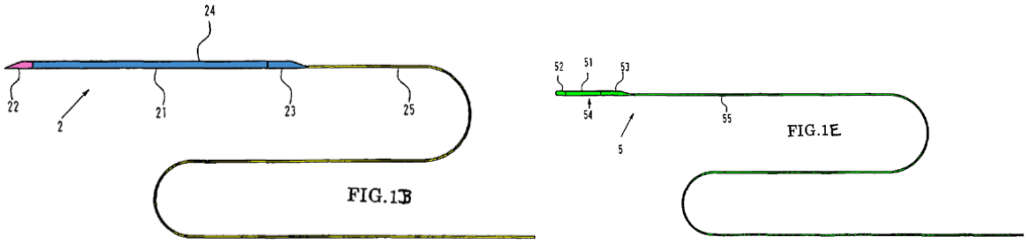
[10.c] "advancing the interventional cardiology device through structure defining a partially cylindrical portion."

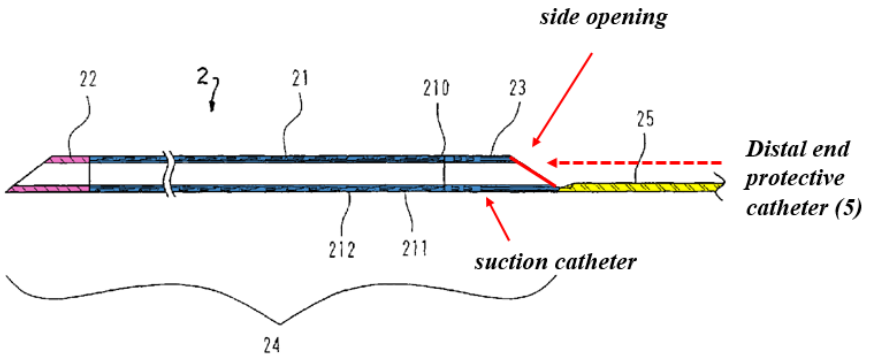
Itou teaches that protective catheter (5) may be inserted into the lumen of

catheter (2) and projected from its distal end, as shown below. Ex-1007, 4:48-52.

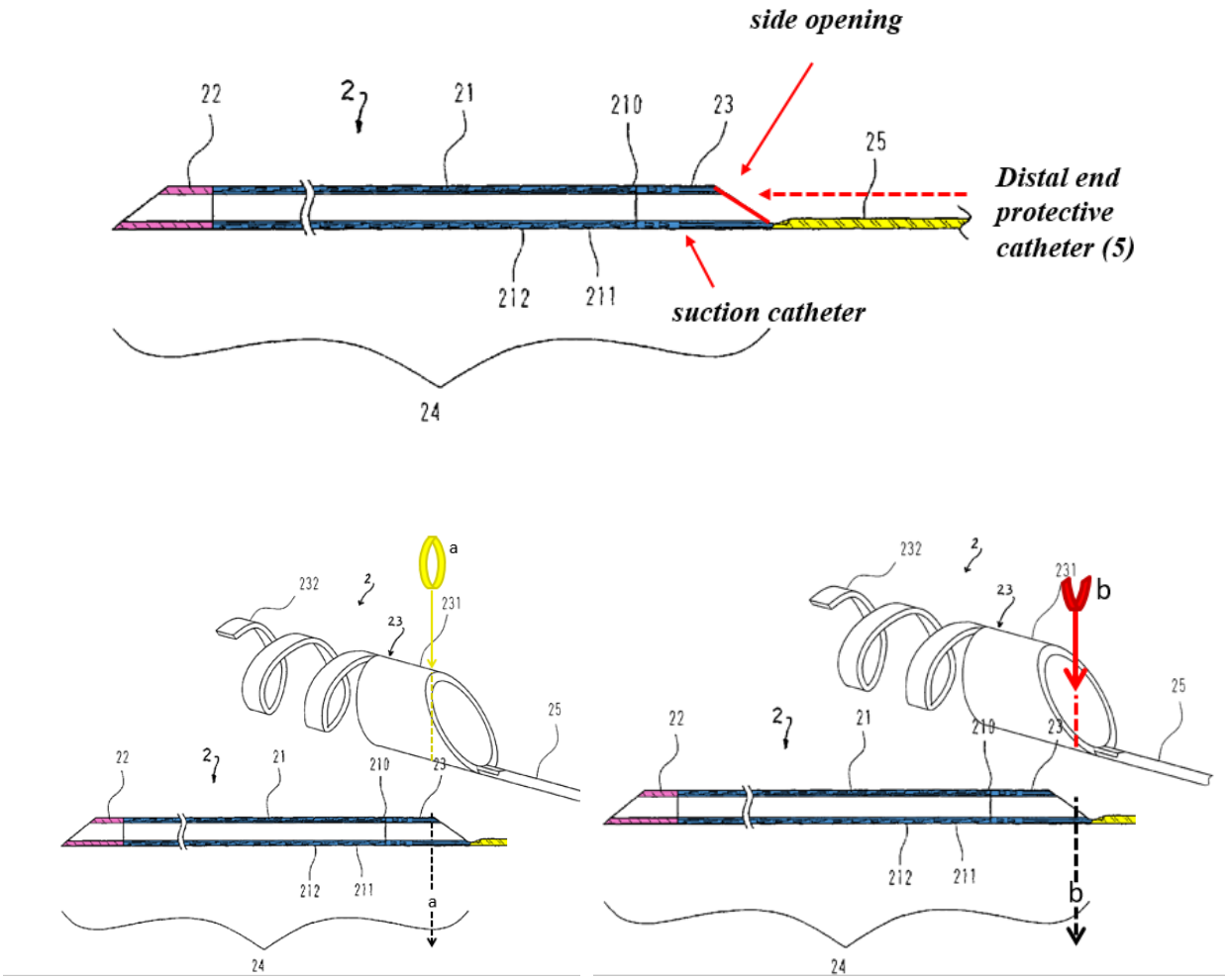


In this use, the protective catheter (5) necessarily extends (and advances) through the GC and the proximal side opening of the suction catheter (2) shown in *Mapping-2*. *Id*., 7:1-27, Figs. 1B, 1E, 3; Ex-1005, ¶¶ 236-39.



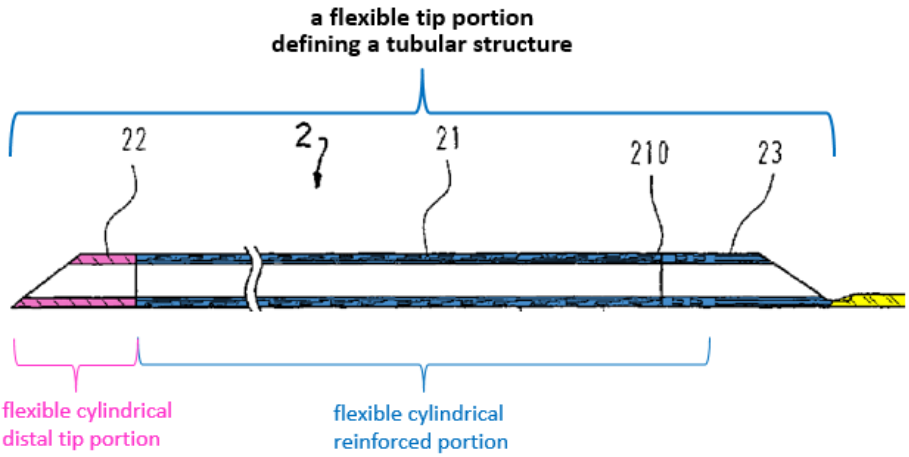


Id., Figs. 1B, 1E, 3 (color and annotations added); Ex-1005, ¶¶ 236-39. As the protective catheter (5) is advanced with suction catheter (2), it advances through the full circumference and partially cylindrical portions of the suction catheter (2), as shown below.



H. Claim 11: The method of claim 9, further comprising extending the interventional cardiology device through a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion of the tubular structure proximal to the flexible distal tip portion.

In *Mapping-2*, the flexible tip portion of Itou's suction catheter (2) has a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion, as shown below.



Tip (22) is soft and flexible to reduce the risk of potential blood vessel damage. Ex-1007, 2:12-21, 3:46-50; Ex-1005, ¶ 240; Ex-1042, ¶ 60.

The "flexible tip portion" also includes a portion reinforced with a metal layer (211) (blue)—a "reinforced portion." Ex-1007, 2:18, 3:50-56 (color added) (tubular structure 21). As discussed above, a "reinforced portion" is a "portion made stronger by additional material or support." *See* § **VI**, *supra*. 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, ¶ 240; Ex-1042, ¶ 60.

Itou's "flexible tip portion" is necessarily circular. *Supra* Cl. [1.c]. The same is true for a cross section through tip (22) and proximal tip (23). Ex-1005, ¶ 240.

Itou teaches that a protective catheter (5) may be inserted into the lumen of catheter (2) and projected from its distal end. *Id*., 4:48-52, 7:1-27. In this use, the

protective catheter (5) necessarily extends through flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion. Ex-1005, ¶ 240.

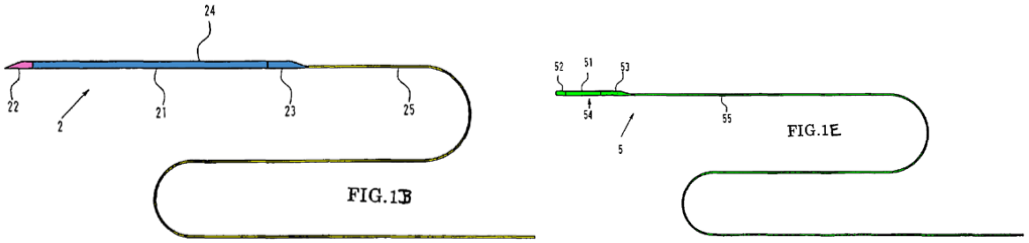
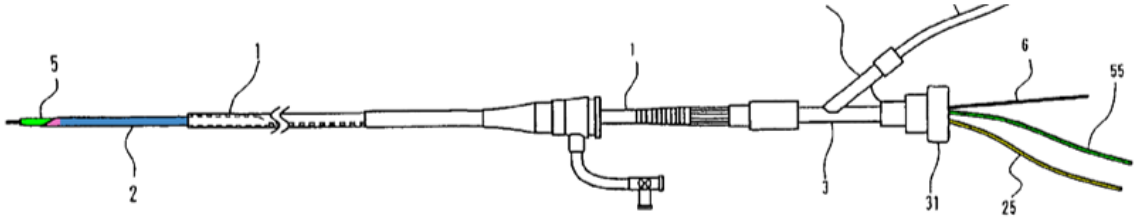
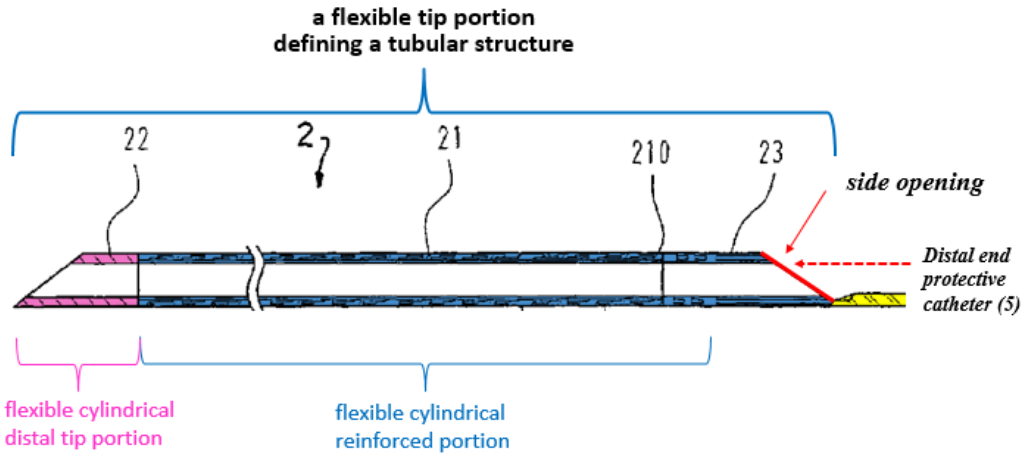


FIG.5



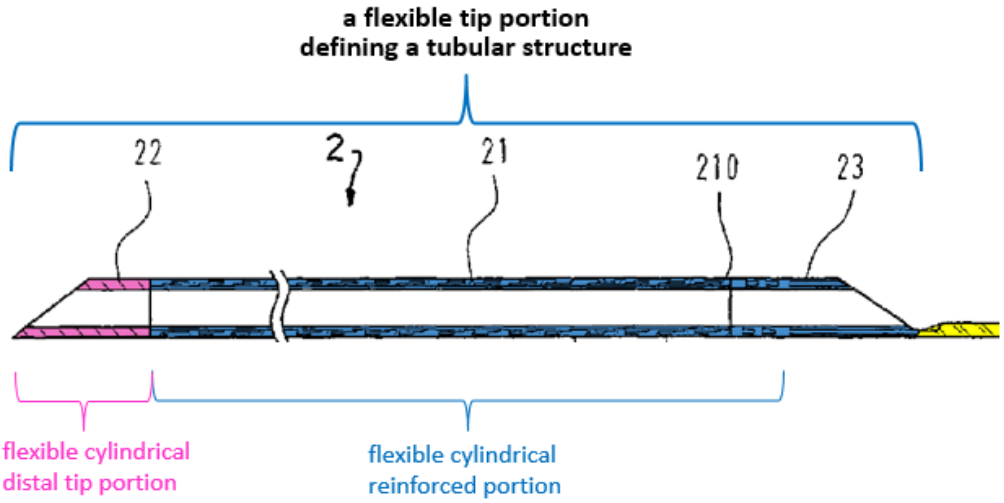
Ex-1007, Fig. 5 (color added).



Ex-1007, Figs. 1B, 1E, 3 (color and annotation added); Ex-1005, ¶ 240.

I. Claim 12: The method of claim 11 further comprising extending the interventional cardiology device through the flexible cylindrical reinforced portion that is reinforced with metallic elements in a braided or coiled pattern.

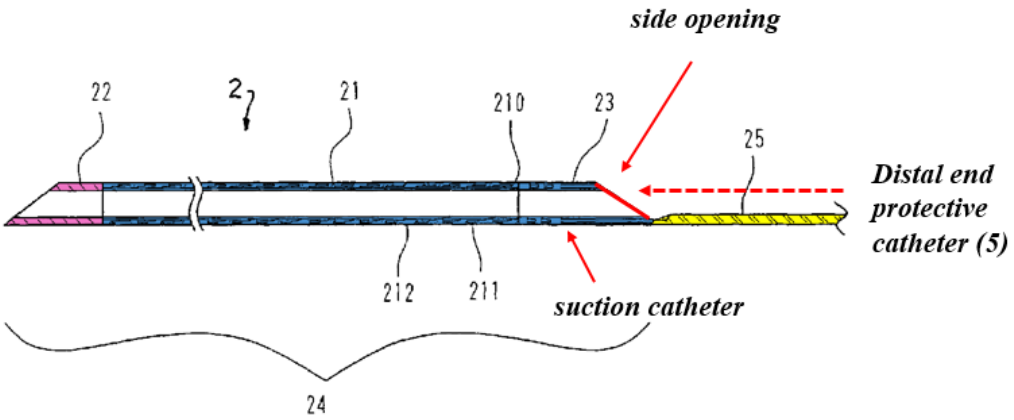
As discussed above with respect to Claim 11, in *Mapping-2*, the flexible tip portion of Itou's suction catheter (2) has a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion, as shown below.



Ex-1007, Fig. 3 (color and annotation added); Ex-1005, ¶ 241. 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, 2:18-20, 3:50-58 (emphasis added). From the disclosure of Itou, it is evident that reinforcing metal wire (211) is braided or coiled around inner layer 210. Ex-1005, ¶ 241; Ex-1042, ¶¶ 68-73.

As discussed above, Itou teaches that a protective catheter (5) may be

inserted into the lumen of catheter (2) and projected from its distal end. Ex-1007, 4:48-52, 7:1-27. In this use, the protective catheter (5) necessarily extends through the flexible cylindrical reinforced portion. *Id.*, Figs. 1B, 1E, 3; Ex-1005, ¶ 241.



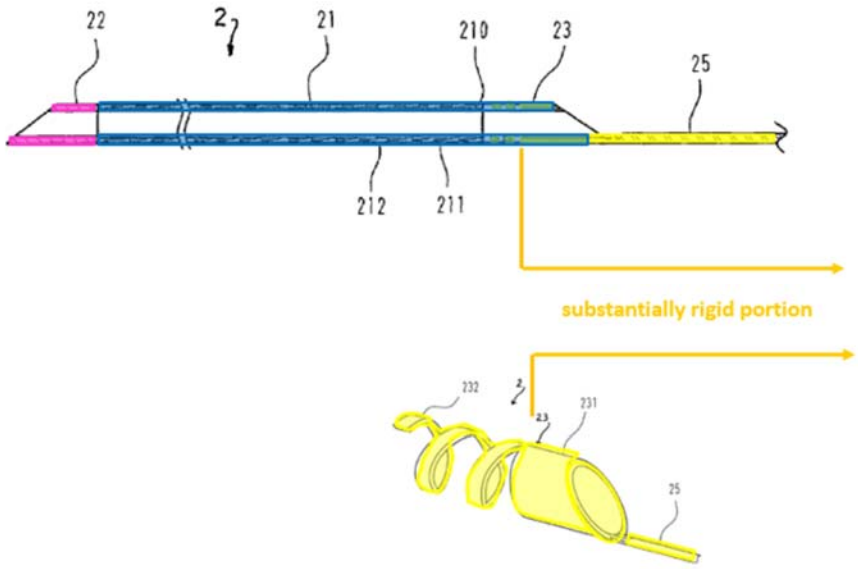
Ex-1007, Figs. 1B, 1E, 3 (color and annotation added); Ex-1005, ¶ 241.

J. Claim 13: The method of claim 1, further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

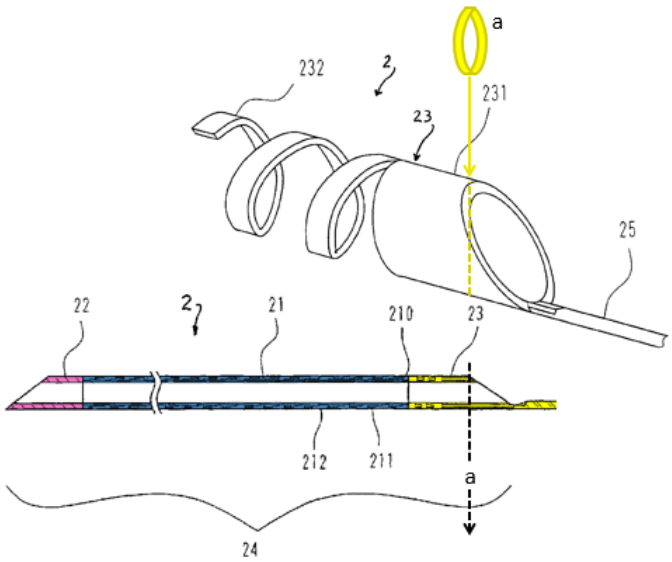
Itou explains that GC (1) "is formed from a guiding catheter of 6 Fr (2.06 mm) which is used popularly and has an inner diameter of 1.8 mm." Ex-1007, 6:46-55, Table 1. Itou's suction catheter (2) includes a tubular portion (24) with an inner diameter of 1.5 mm. *Id.*, Table 1. At 1.5 mm, the tubular portion (24) is 0.3 mm smaller than the inner diameter of the GC. And 0.3 mm is "not more than one French smaller," as one French equals 0.33 mm. Ex-1062; Ex-1005, ¶ 242.

K. Claim 14: The method of claim 1, further comprising extending the interventional cardiology device through the substantially rigid portion from proximal to distal through a cross-sectional shape having an arcuate portion, a hemicylindrical portion and a full circumference portion.

Itou's suction catheter (2) includes a substantially rigid portion with an arcuate portion, a hemicylindrical portion, and a full circumference portion. Under *Mapping-1*, the "substantially rigid portion" of Itou's suction catheter (2) includes both wire-like portion (25) and end (231), as shown below.

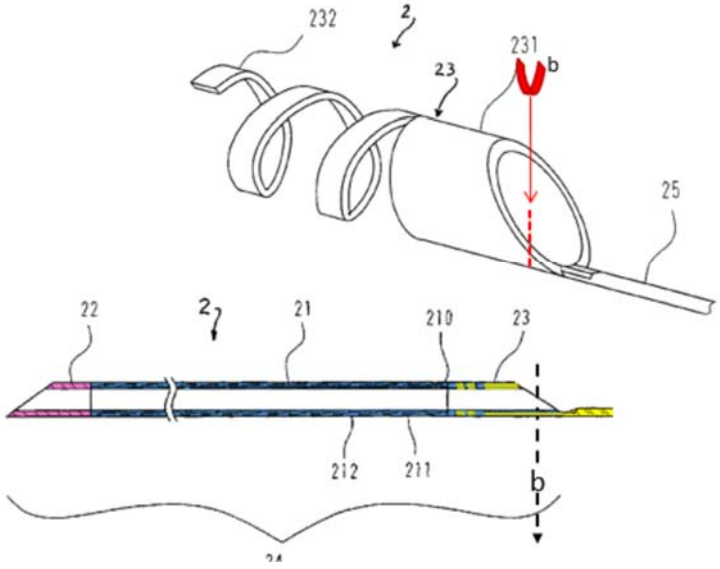


Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added). The substantially rigid portion includes a cross-sectional shape having a full circumference portion (shown by line (c)). Ex-1005, ¶ 243.



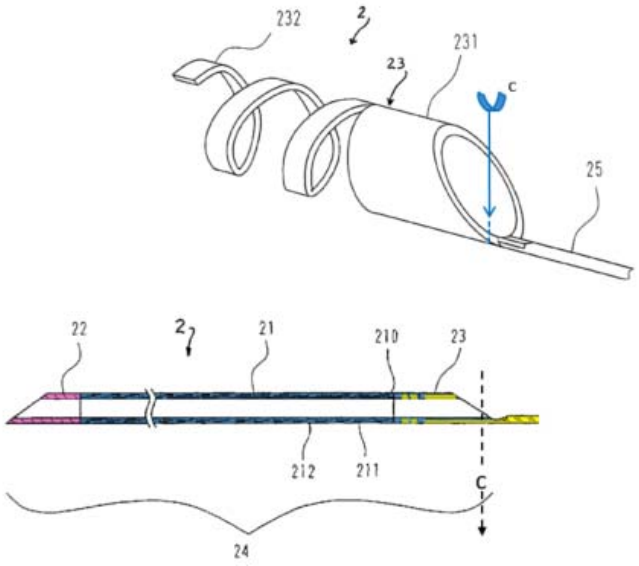
Ex-1007, Figs. 4 (top), 3 (bottom) (color and annotations added).

Moving distally, and as shown below, the substantially rigid portion also has a hemicylindrical cross-sectional shape (cross section at "b") (Ex-1005, ¶ 243), which, according to the '413 patent is a portion that "desirably includes 40% to 70% of the circumference of a tube." Ex-1001, 6:50-53.



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

Finally, the side opening includes an arcuate cross sectional shape, which, according to the ’413 patent is a portion that “extends from 25% to 40% of the circumference of the tube.” Ex-1001, 6:55-57.



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

As discussed above, Itou teaches that a protective catheter (5) may be inserted into the lumen of catheter (2) and projected from its distal end. *Id*., 4:48-52, 7:1-27. In this use, the protective catheter (5) necessarily extends through the “substantially rigid portion” having the above-described cross-sectional shapes. *Id*., Figs. 1B, 1E, 3; Ex-1005, ¶ 243.

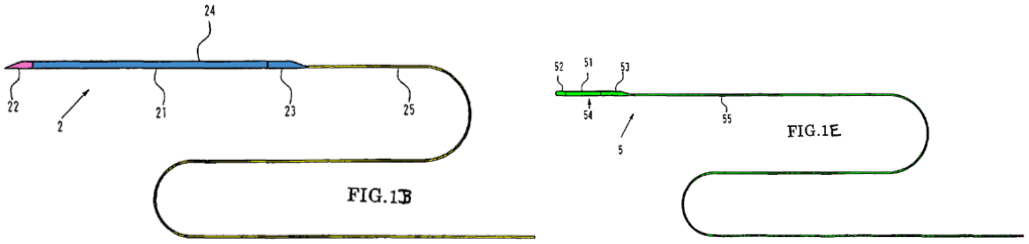
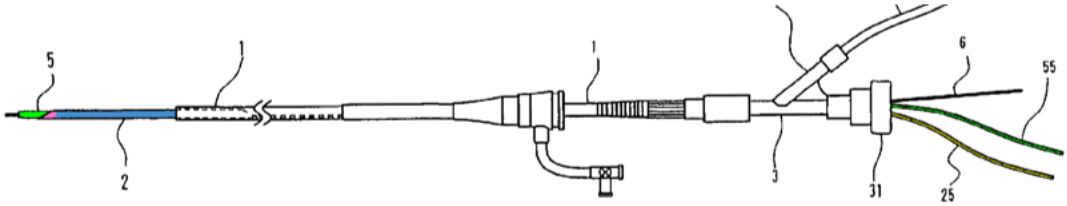
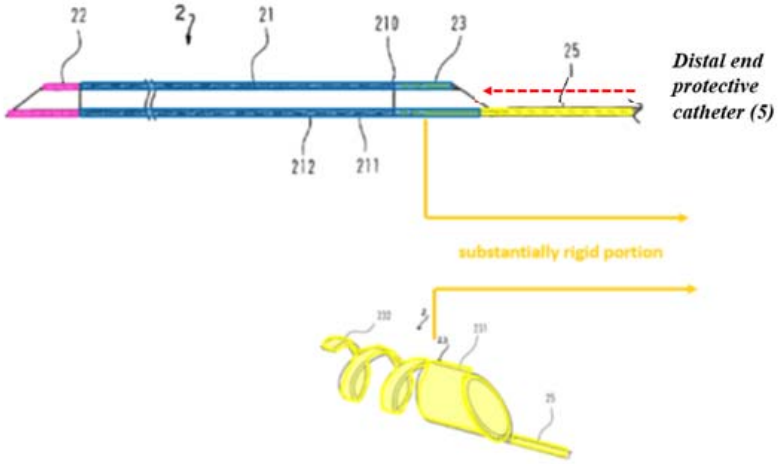


FIG.5



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



Ex-1007, Figs. 1B, 1E, 3 (color and annotation added); Ex-1005, ¶ 243.

X. GROUND 2: ITOU RENDERS CLAIMS 1-2, 4-5, AND 7-14 OBVIOUS IN VIEW OF THE COMMON KNOWLEDGE OF A POSITA.

A. Claim 1

As shown in §§ **IX.A.1-11**, *supra*, Itou expressly discloses all elements of

Claim 1 under an interpretation whereby (1) insertion of the GC occurs, as claimed, "over" (at a higher level or layer than) a guidewire [1.a]; and (2) insertion of the "the interventional cardiology device" occurs "alongside" of (at the same time as) the "substantially rigid portion" of the "coaxial guide catheter" [1.f]. To the extent Patent Owner argues that either of these "insertion" steps must occur in some specific sequence—e.g., for [1.a] the guide wire must be inserted first, or for [1.f] the "coaxial guide catheter" must be inserted first—a POSITA would understand this sequencing to be obvious. Ex-1005, ¶¶ 244-45.

[1.a] – Itou explains that GC (1) "has the guide wire 6 fitted therein," and is then "inserted into the introducer sheath 7 and secured to the ostium of a coronary artery." *Id.*, 7:7-10. In other words, in Itou, the GC (1) and guide wire (6) are advanced together. A POSITA would understand that the GC is not inserted (and advanced) into the vasculature *before* the guidewire. Ex-1005, ¶¶ 246-47; § **IV.A**, *supra*. Stated another way, a guide wire is already present when the GC is inserted—and the GC is advanced "over" the guidewire. *Id.* As explained by *Grossman*'s:

> Once the needle has been positioned within the vessel lumen, a flexible guidewire is advanced through the needle and well into the vessel being accessed. This guidewire remains in an intravascular position as the needle is withdrawn and provides the means for introducing the desired catheter. . . . [C]urrent practice is to first place an introducing sheath

over the guidewire, and then to advance the catheter through this sheath. Ex-1015a, 69; Ex-1005, ¶¶ 248-49. In prior proceedings, Patent Owner (through the '413 patent inventor and its experts) acknowledged as much. Ex-1012, 36-38 (¶¶ 10-11); Ex-1082, ¶¶ 15-16.

[1.f] – Itou discloses "an example of a method of use," wherein at "the distal end protective catheter 5"—an interventional cardiology device—"is inserted into the guiding catheter 1 along the guide wire 6." Ex-1007, 7:1-27. The protective catheter (5) is inserted into suction catheter (2) preassembled. *Id.*, 7:13-15; Ex-1005, ¶ 250-55. A POSITA would understand that suction catheter (2) could, however, be inserted first (separately) followed by a different interventional cardiology device. Ex-1005, ¶ 256.

First, a POSITA would understand that Itou's assembly could be used such that an "interventional cardiology device" is inserted into and through the continuous lumen of Itou's suction catheter (2). Itou's assembly permits passage of all four exemplar "interventional cardiology devices" identified in the '413 patent. Ex-1005, ¶ 257; §§ **VI.A**, **IX.A.4**, *supra*. The tubular portion of Itou's suction catheter (2) has an inner diameter of 1.5 mm and is configured to receive distal end protective catheter (5)—an interventional cardiology device. Ex-1007, Table 1,

Fig. 5, 4:48-50, 5:15. As Dr. Brecker explains 1.5mm converts to 0.059 inches.[13] Ex-1005, ¶ 257. This was large enough to accommodate the insertion of several interventional cardiology devices available at the time. *Id*. For example, PTCA catheters were insertable through support catheters with a 0.045 inch (1.14mm) inner lumen. Ex-1009, 4:46-64. And Angioplasty procedures had been performed through 4 French (1.33mm) diagnostic catheters. Ex-1020 ("Mehan"), 2 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, ¶ 257.

Second, the inner surface of the tubular portion of suction catheter (2) is suitable for receiving interventional cardiology devices. Itou teaches that section (21) of catheter (2) has an inner resin layer of a material "having a sliding property such as a fluorocarbon resin represented by PTFE." Ex-1007, 3:52-54. A POSITA appreciated that a catheter lined with PTFE was suitable for delivering a balloon or stent across a lesion. Ex-1017, 5:19-21, 8:1-2; Ex-1046, 2:32-39; Ex-1034, 8:29-32. Ex-1005, ¶ 258; Ex-1042, ¶¶ 66-67. After disclosing that section 21 is lined with resin, Itou additionally teaches that the proximal-most section of the tubular

[13] This corresponds to the inner diameter of the extension catheter taught in the '413 patent. Ex-1001, 3:26 ("greater than or equal to 0.056 inches ...").

structure, section (23), is also lined with resin. Ex-1007, 4:36-38. While Itou is silent as to the type of resin that is used, a POSITA would understand that the inner lining of section (23) would also be made of PTFE, or should at least have the same "sliding property" as the PTFE lining within section 21 of catheter (2). Ex-1042, ¶ 66-67. And this is because Itou explains that protective catheter (5) should be pulled out of suction catheter (2) before its distal end is positioned near a thrombus. Ex-1007, 7:19-22; Fig. 6. This necessarily requires that the ***entirety*** of the inner surface of the tubular portion of suction catheter (2) have a lubricity that allows for protective catheter (5) to be easily (inserted) and removed. Thus, the inner surface of the tubular portion of suction catheter (2) is also suitable to advance interventional cardiology devices such as a balloon catheter or stent. Ex-1042, ¶ 66-67; Ex-1005, ¶ 258.

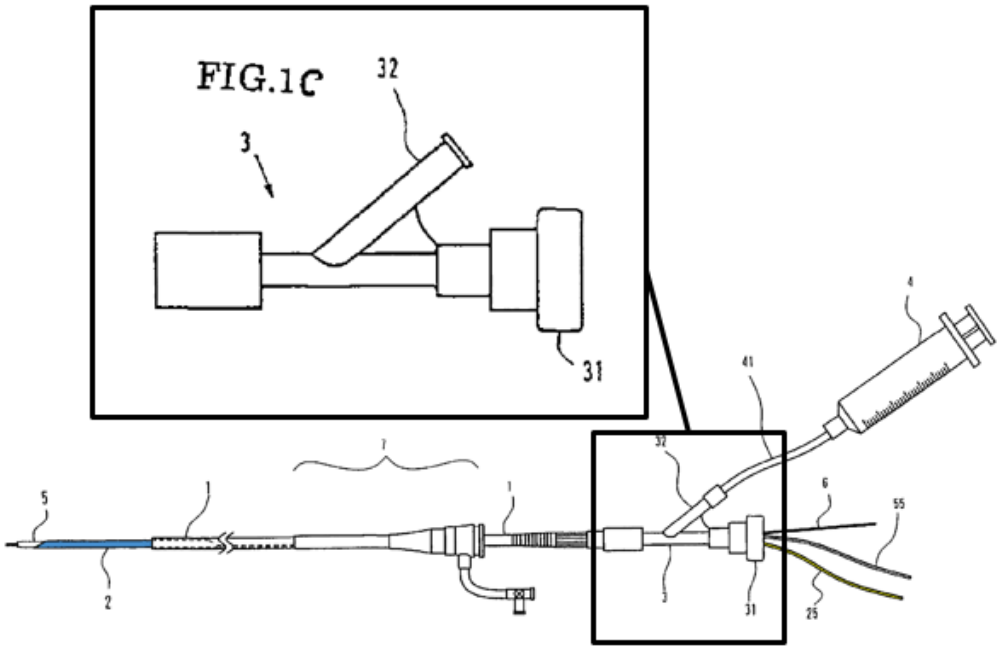
Third, PCI is routinely performed in a step-wise fashion, where a catheter is inserted first followed by a different interventional cardiology device. Ex-1005, ¶ 259; Ex-1008, Figs. 6B, 6E; 12:19-30; 13:60-14:10; Ex-1009, 7:45-52; 5:16-18. It is easier to manipulate the extension catheter in and through the vasculature if the interventional cardiology device is not pre-loaded in the lumen of the extension catheter. Ex-1005, ¶ 259. Further, the extension catheter will have greater trackability (i.e., flexibility) while traversing a patient's vasculature than it would if the extension catheter were advanced with a loaded interventional device. *Id.*

And there is less risk of an air embolism forming if the extension catheter is advanced first, followed by the interventional cardiology device. *Id.* Inserting Itou's suction catheter (2) first (separately) followed by a different interventional cardiology device would have been nothing more than combining prior art elements according to known methods to yield predictable results. Ex-1005, ¶ 259; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

B. Claims 2, 4-5, 7-14

Claims 2 and 4 – Itou discloses Claims 2 and 4. §§ **IX.B-C**, *supra*. Inserting Itou's guidewire, GC, and an "interventional cardiology device" in the sequence discussed above does not alter this disclosure. Ex-1005, ¶¶ 260-61.

Claim 5 – As shown below, Itou's connector (13) is coupled to Y-shaped connector (3) that includes main connector portion (31). Ex-1007, 5:11-22.



Id., Figs. 1C, 5. Itou further discloses that syringe (4) can be used to create negative pressure in order to produce suction. *Id.*, 3:24-26. "The syringe 4 is connected to a sub connector portion 32 of the Y-shaped connector 3 through a tube 41." *Id.*, 5:24-25. A POSITA understands that syringe 4 of Itou could be used to inject a fluid through sub connector 32 into Itou's GC. Ex-1005, ¶¶ 262-63. As Dr. Brecker explains, in practice, suction catheter (2) and guiding catheter (1) would be flushed with saline prior to their introduction into the body, and it was standard practice to flush the catheter with a saline solution once it had been placed in the body. Ex-1005, ¶ 263. The process of flushing a catheter requires that fluids be introduced via the proximal end of the guide catheter, which would occur through the Y-adapter. *Id.*, ¶ 264.

Claims 7-14 – Itou discloses Claims 7-14. §§ **IX.D-K**, *supra*. Inserting Itou's guidewire, GC, and an "interventional cardiology device" in the sequence discussed above does not alter this disclosure. Ex-1005, ¶¶ 265-68.

XI. GROUND 3: ITOU RENDERS CLAIMS 1-2, 4-5, AND 7-14 OBVIOUS IN VIEW OF RESSEMANN AND THE COMMON KNOWLEDGE OF A POSITA.

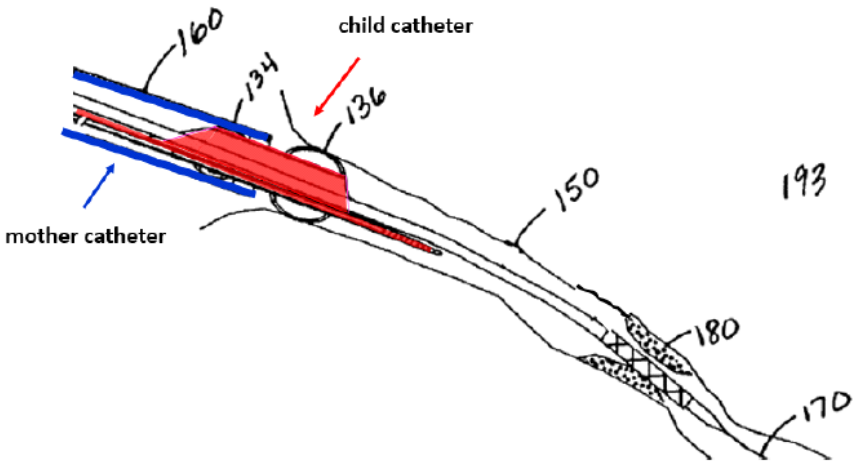
Patent Owner may argue—as it has in co-pending IPR proceedings—that while Itou's GC has a sufficient diameter to receive an "interventional cardiology device," the reference does not supply the teaching to actually pass such a device through Itou's GC or suction catheter, or do so in the order allegedly required by the '413 patent. Patent Owner is mistaken. Even if not expressly disclosed in Itou or otherwise within the common knowledge of a POSITA, all challenged claims are obvious over Itou in view of Ressemann and the knowledge of a POSITA.

A. Claim 1

As shown above, Itou expressly discloses all elements of Claim 1 under an interpretation where insertion of the "the interventional cardiology device" occurs "alongside" of (at the same time) as insertion of the "substantially rigid portion" of the "coaxial guide catheter." §§ **IX.A.1-11**, *supra.* To the extent that element 1[f] is interpreted to require insertion of the "interventional cardiology device" *after* insertion of a "coaxial guide catheter," a POSITA would also understand such sequencing to be obvious in view of Ressemann and the knowledge of one of skill

in the art. Ex-1005, ¶¶ 269-70, 315-24.

Ressemann, like Itou, discloses a mother-and-child assembly for use during PCI procedures.



In Ressemann, the GC (160) (below) is used in conjunction with an evacuation assembly (100). The GC (160) is inserted into the artery over a guide wire, as shown in Figure 6A below. Ex-1008, 12:9-14, Fig. 6A.

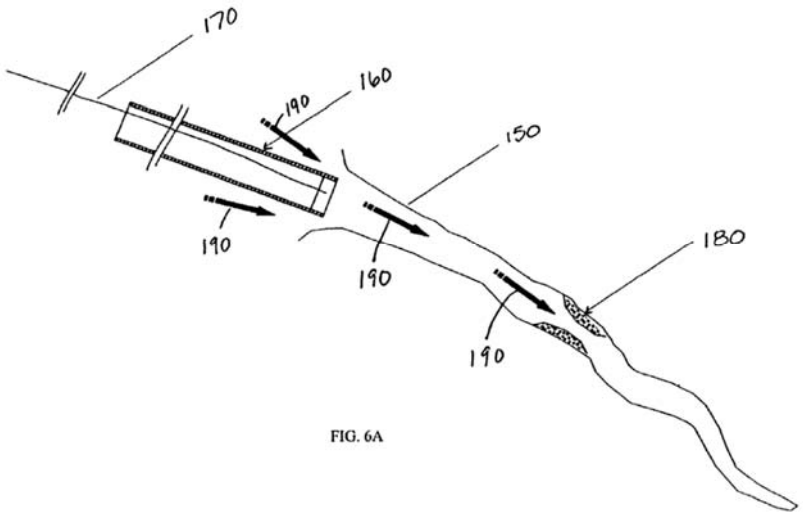


FIG. 6A

Next, evacuation sheath assembly (100) is advanced over a guidewire (170). *Id.*, 12:19-30, Fig. 6B.

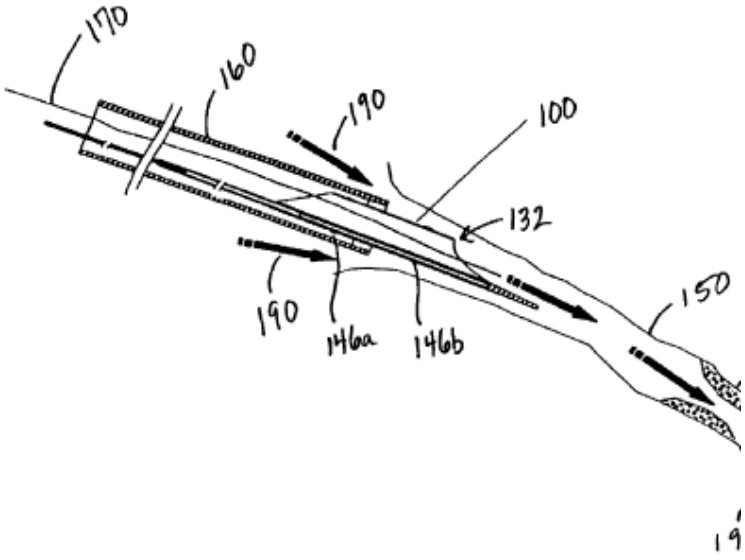


FIG. 6B

The evacuation assembly (100) of Ressemann includes a lumen (140) with a proximal end opening (140a) large enough to "allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, atherectomy catheters." *Id.*, 10:17-20, 12:3-4, 28:54-55.

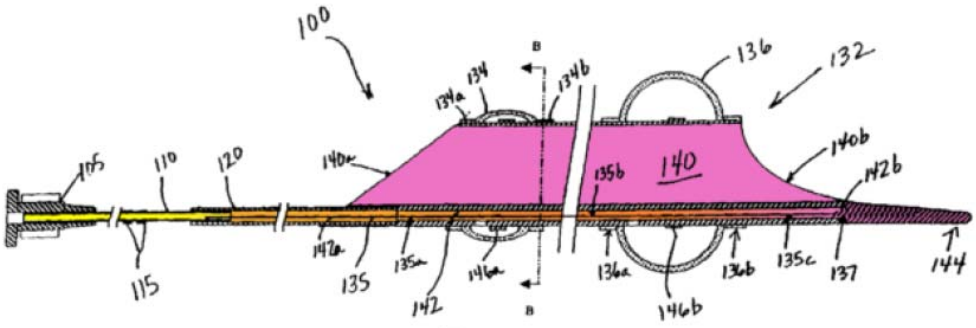


FIG. 1A

Ressemann explicitly discloses the insertion of a balloon catheter with a stent (193, below green) into the side opening of the evacuation assembly (100). *Id.*, Figs. 6A-F, 12:9-14, 29:56-59.

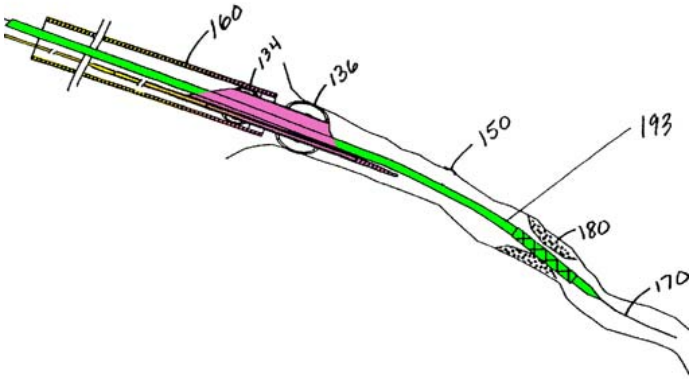


FIG. 6E

Ressemann teaches placing the extension catheter distal to the guide catheter *and then* advancing a balloon catheter or stent through the guide catheter/extension catheter assembly. Ex-1005, ¶¶ 271-73. Ressemann teaches first "position[ing the GC] within the ostium of a target vessel." Ex-1008, 12:26-30, Fig. 6A. The

evacuation assembly 100/2100 ("extension catheter") is then inserted into and advanced beyond the distal-most portion of the GC. *Id*., 12:19-40, Figs. 6B-C. That is, the distal end portion of the tubular structure of the guide extension catheter is positioned beyond the distal end of the guide catheter. Ex-1005, ¶ 273. Next, the "therapeutic device such as a stent delivery system 193" is inserted into the hemostatic valve and advanced until it is "positioned adjacent the stenosis 180" in the coronary artery. Ex-1008, 6:25-34, 12:3-8, 13:55-14:14, Figs. 6E-F; Ex-1005, ¶ 274.

A POSITA would understand that Itou's assembly could be used such that an "interventional cardiology device" is inserted into and through the continuous lumen of Itou's GC (1) and suction catheter (2). §§ **IX.A.2**, **X.A**., *supra*. As discussed above, the inner surface of the tubular portion of suction catheter (2) is suitable for receiving a stent or balloon catheter, such as that taught by Ressemann. § **X.A**., *supra*.

A POSITA would look to Ressemann when considering Itou because both references disclose devices that address the same problem in the same way—removing coronary vessel occlusions by using an aspiration catheter. Ex-1005, ¶¶ 271-87; Ex-1007, Abstract; 1:13-16; 2:2-5, 2:29-38, 3:59-61, 5:32-34, 7:10, Figs. 1A, 1B, 5, 6; Ex-1008, Abstract, 6:18-24, 12:9-12, 12:19-30; Figs. 6A-B. As Dr. Brecker explains, those working in the field knew that angioplasty or stent

delivery "may break free fragments of friable plaque." Ex-1005, ¶ 288; Ex-1015b, 629. Thus, it was beneficial to be able to remove emboli from a coronary artery when delivering a stent. Further, there was a motivation to combine stent delivery with the use of an embolic protection device, Ex-1015b, 629-30, and a reasonable expectation of success. *Id.*, 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, 174, 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, ¶¶ 277-87.

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, ¶ 289. Indeed, Ressemann identifies a potential "need for more therapeutic steps, e.g., further dilation of the stent with the balloon," where "it is more convenient to have the balloon catheter already in position for any subsequent use." Ex-1008, 14:29-34.

Itou's prosecution history also demonstrates that it was appropriate to combine Itou and Ressemann. During prosecution of Itou, 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, 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, ¶¶ 290-314.

B. Claim 2

As discussed above in Ground 1, Itou discloses a method of providing backup support for an interventional cardiology device. *Supra* **IX**.**A.1**. The "backup support" is a result of Itou's suction catheter (2) remaining seated in the second artery in response to an opposing backward force exerted by an interventional cardiology device. *Id.* Inserting an interventional cardiology device *after* placement of a GC and coaxial guide catheter does not alter this disclosure. Ex-1005, ¶¶ 160-73, 325; Ex-1042, ¶¶ 61-65.

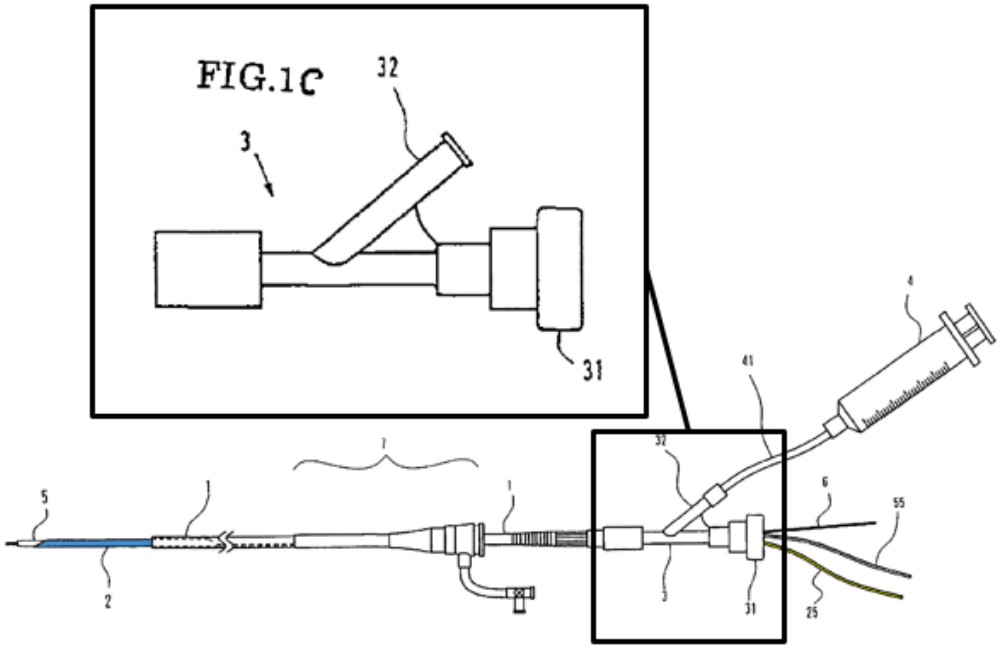
C. Claim 4

As discussed above in Ground 1, the "substantially rigid portion" of Itou's suction catheter (2) comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof. § **IX.C**, *supra*; Ex-1005, ¶ 326.

D. Claim 5

Itou in view of Ressemann renders claim 5 obvious. Ex-1005, ¶ 327. As discussed above in Ground 2, Itou discloses a connector (13) coupled to Y-shaped connector (3) that includes main connector portion (31). § **X.B**., *supra*; Ex-1007,

5:11-25.



Ex-1007, Figs. 1C, 5. Itou discloses a syringe (4) that can be used to create negative pressure in order to produce suction. *Id.*, 3:24-26; 5:24-25. A POSITA understands that syringe (4) could be used to inject a fluid through the Y-adapter into Itou's GC. Ex-1005, ¶ 328; § **X.B**, *supra*.

Ressemann explicitly teaches injecting a fluid through the Y-adapter into the standard guide catheter. Ex-1008, Fig. 5A. Figure 5A of Ressemann, below, shows the disclosed device "deployed within a vessel."

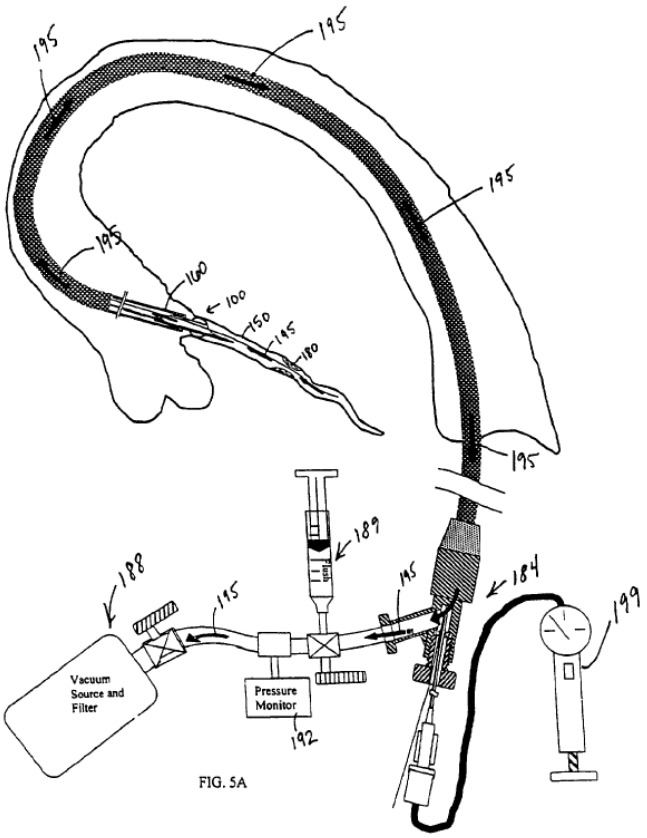


FIG. 5A

Id., Fig. 5A. As detailed in Ressemann, "it may be desirable to inject a small amount of contrast into the blood vessel, via a dye injection apparatus 189 … to aid in navigation of the guide wire 170 across the stenosis 180." *Id.*, 13:3-8. A POSITA would understand that injecting this "contrast" would allow the size and shape (and any lesions) of the artery to be observed under x-ray. Ex-1005, ¶¶ 329-30; Ex-1012, 36-38 (¶¶ 10-11).

E. Claim 7

As discussed in Ground 1, above, in both *Mapping-1* and *Mapping-2,* Itou's

suction catheter (2) has a flexible tip portion defining a tubular structure (21) and having a circular cross-section. § **IX.D**, *supra*; Ex-1007, 2:12-21, Fig. 3; Ex-1005, ¶¶ 331-34. The distal portion of the tubular structure is extended beyond the distal tip of GC (1). The proximal portion of the tubular structure remains within the lumen of GC (1). *Id*., Figs. 5, 6; 3:1-3, 5:26-46, Ex-1005, ¶ 334.

Inserting an "interventional cardiology device" *after* placement of a GC and coaxial guide catheter does not alter this disclosure. Ex-1005, ¶ 334. The "backup support" is a result of Itou's suction catheter (2) remaining seated in the second artery in response to an opposing backward force exerted by an interventional cardiology device. *Id.*; § **IX.A.2**, *supra*.

F. Claim 8

As discussed in Ground 1, above, Itou discloses a radiopaque marker at the distal tip of its coaxial guide catheter. § **IX.E**, *supra*; Ex-1007, 4:15-24; Ex-1005, ¶ 335. Ressemann demonstrates how a POSITA would understand an interventional cardiology device inserted *after* Itou's suction catheter (2) would be extended past "a radiopaque marker proximate a distal tip of the coaxial guide catheter."

As shown in Figure 6B, below, Ressemann's sheath assembly (100) may be "advanced over the guide wire 170 and positioned within the vessel 150 with the distal radiopaque marker 146b distal of the distal tip of the guiding catheter 160

(i.e., within the vessel 150) and the proximal marker 146a proximal of the distal tip of the guiding catheter 160 (i.e., within catheter 160)." Ex-1008, 12:19-30; Ex-1005, ¶¶ 336-37.

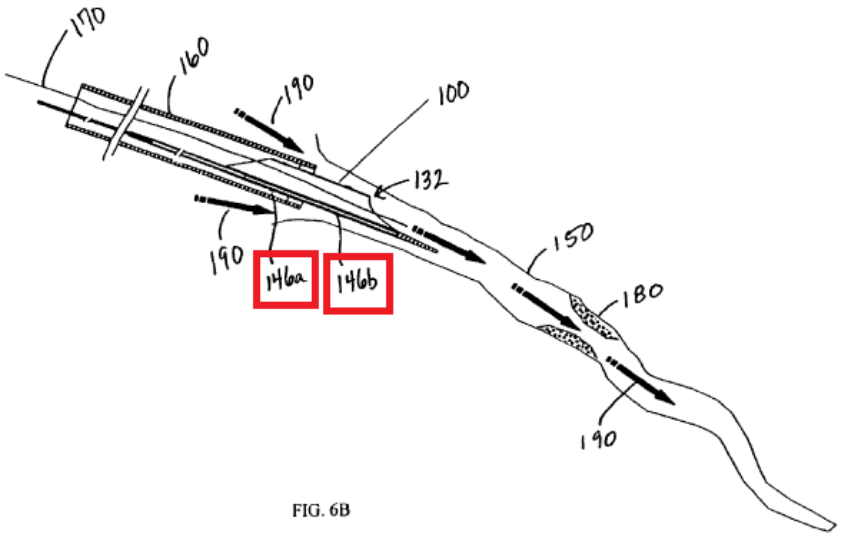


FIG. 6B

Proximal and distal radiopaque markers (146*a*, 146*b*) are placed at sites 134 and 136, as shown below in Figure 6E. Ex-1008, 9:35-43.

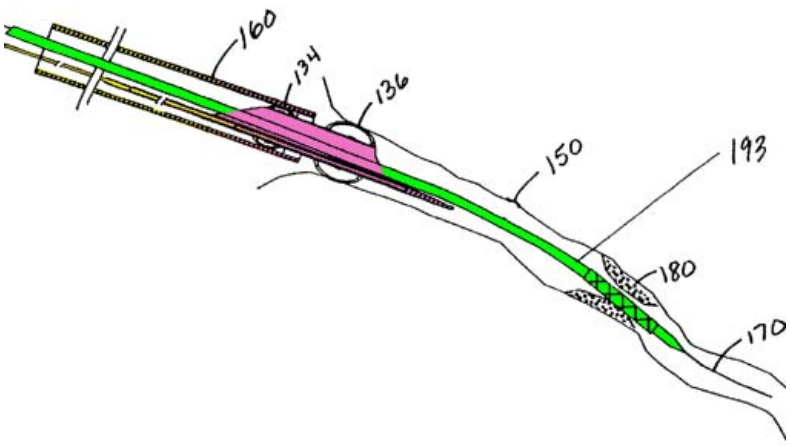
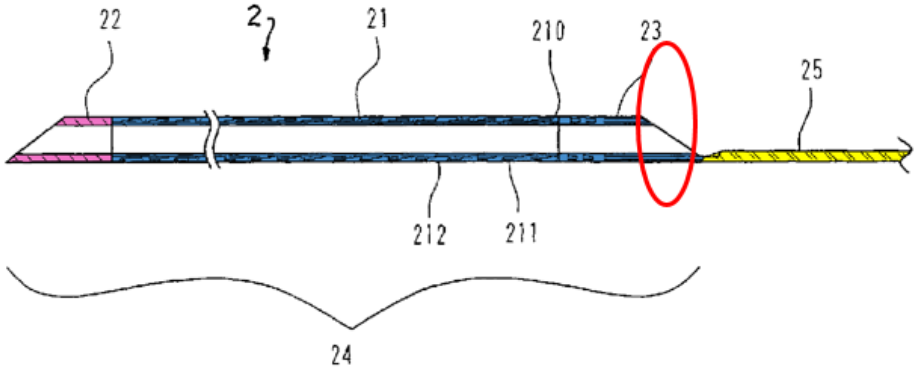


FIG. 6E

Next, "a therapeutic device such as a stent delivery system 193 is advanced across the stenosis 180 with antegrade flow stopped." *Id.*, 13:57-60. The stent delivery system—an interventional cardiology device—advances past radiopaque markers at sites 134 and 136. *Id.*, 9:35-43; Ex-1005, ¶¶ 338-39.

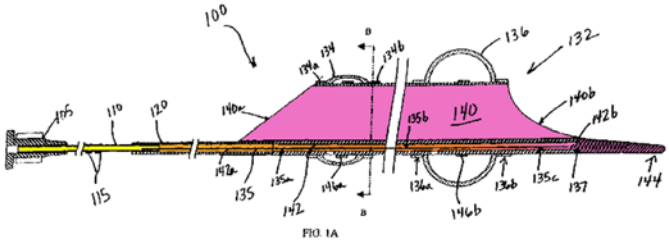
G. Claim 9

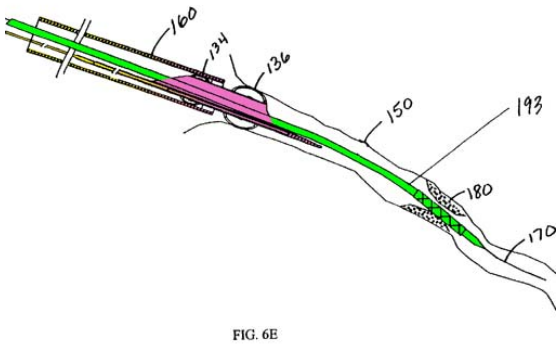
As discussed above in Ground 1, in *Mapping 2*, Itou discloses a side opening (circled in red) in tubular portion (24) of suction catheter (2). § **IX.F**, *supra*; Ex-1007, Fig. 4, 3:47-50, 4:10-15, 4:27-32; Ex-1005, ¶ 340.



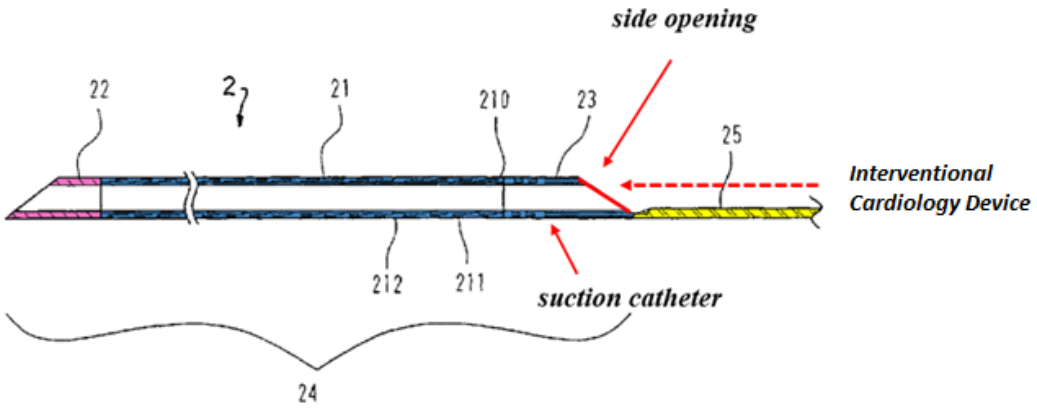
Ressemann provides an example of how a POSITA would understand an interventional cardiology device could inserted *after* Itou's suction catheter (2). Ex-1005, ¶ 340.

As shown in Figure 6B, below, Ressemann's sheath assembly (100) may be "advanced over the guide wire 170 and positioned within the vessel." Ex-1008, 12:19-30. Next, "a therapeutic device such as a stent delivery system 193," shown below, "is advanced across the stenosis 180 with antegrade flow stopped." *Id.*, 13:57-60.



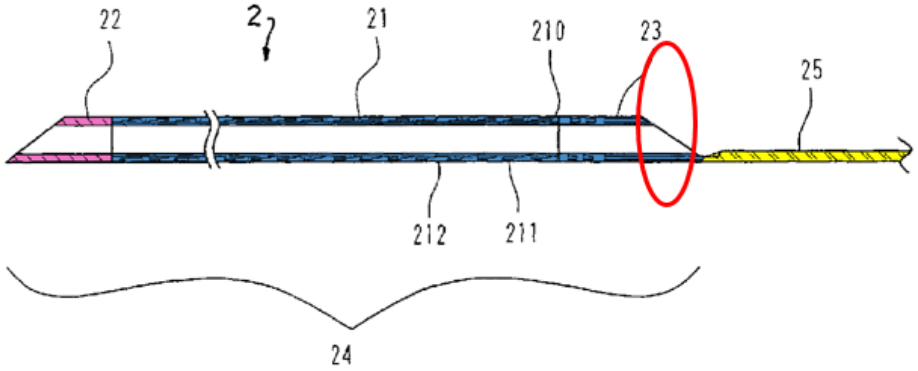


Id., Fig. 1A, Fig. 6B (color added). Applying Ressemann's teachings to Itou's structure, a POSITA would understand that *en route* to the target area, the interventional cardiology device is extended through the proximal side opening of Itou's suction catheter (2) while the proximal portion of the device remains within the lumen of the GC. Ex-1005, ¶¶ 341-45.

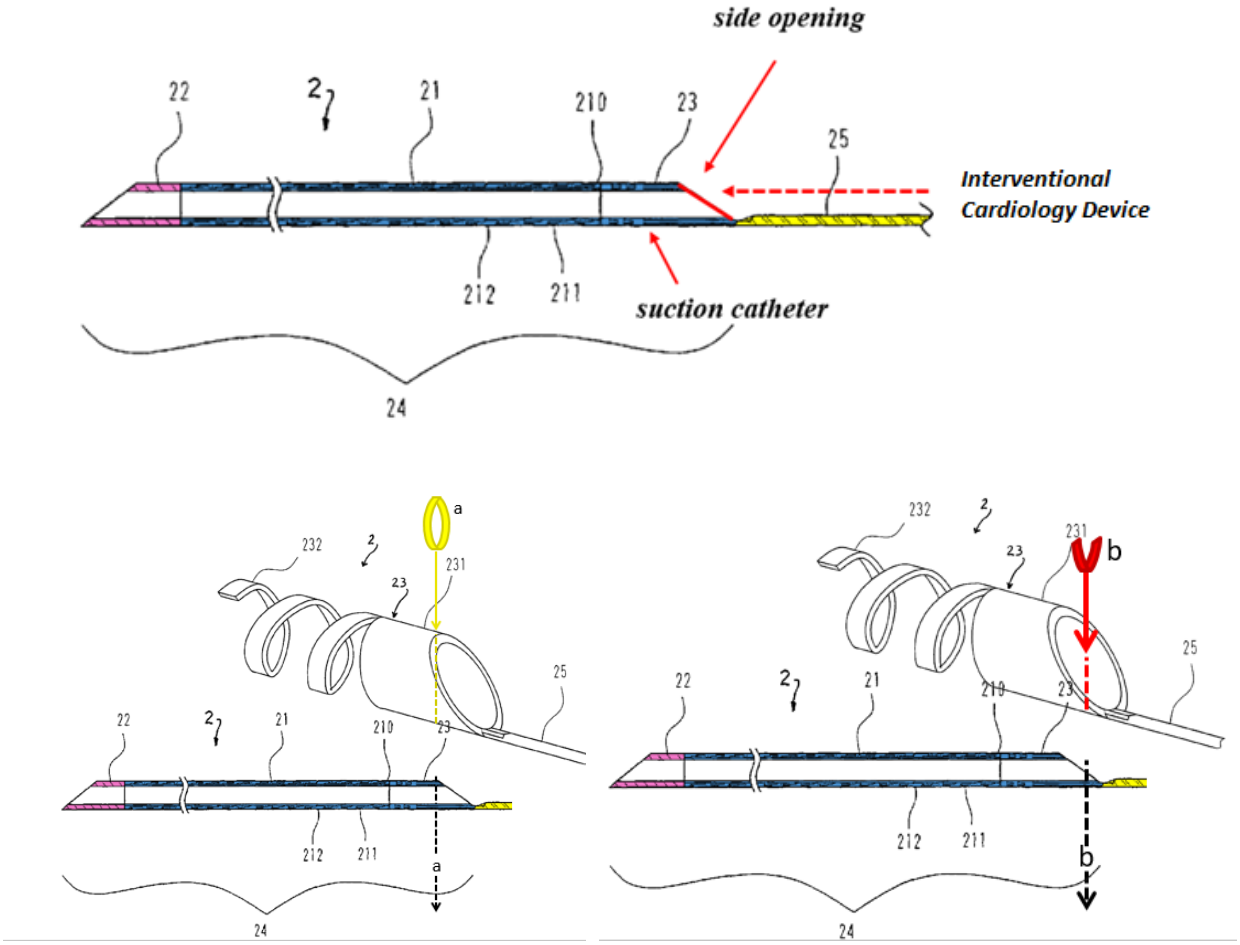


H. Claim 10

As discussed above in Ground 1, in *Mapping 2*, Itou discloses a side opening (circled in red) in tubular portion (24) of suction catheter (2). § **IX.G**, *supra*; Ex-1007, Fig. 4, 3:47-50, 4:10-15, 4:27-32; Ex-1005, ¶ 346-49.

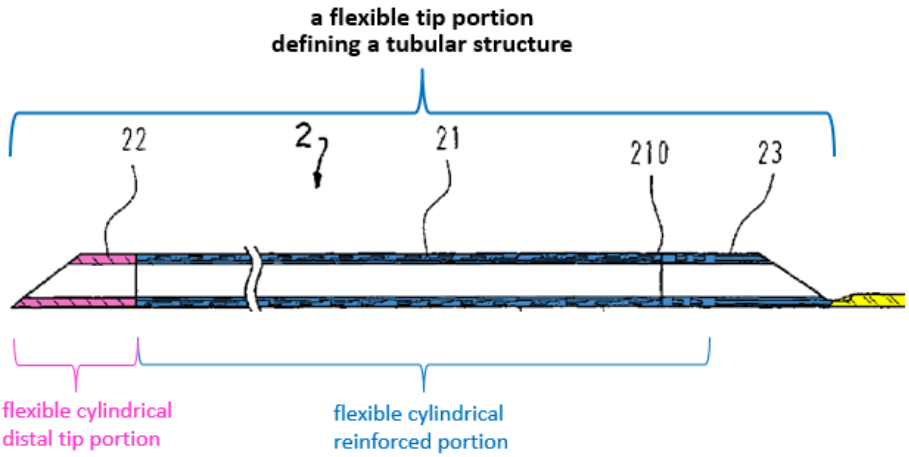


A POSITA would understand that as the claimed interventional cardiology device is advanced to a target area it extends and advances through the full circumference (a, yellow) and partially cylindrical (b, red) portions of Itou's suction catheter (2) shown below. Ex-1005, ¶¶ 348-50.



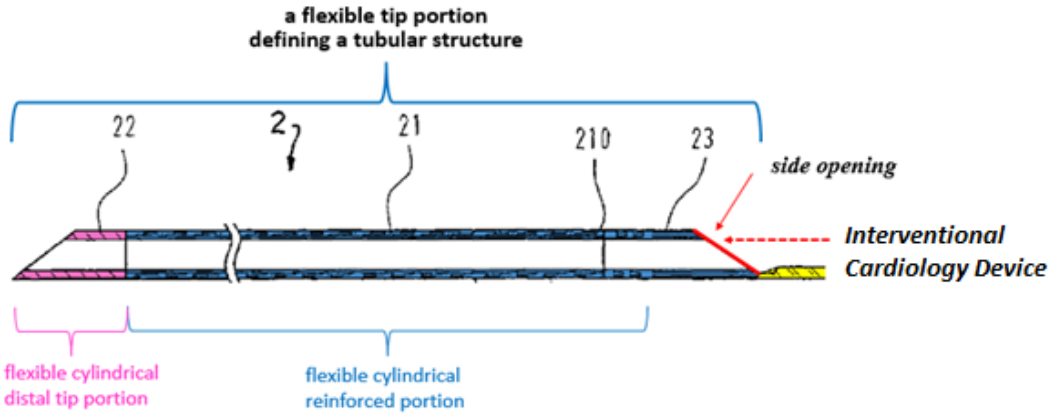
I. Claims 11-12

As discussed above in Ground 1, in *Mapping 2*, the flexible tip portion of Itou's suction catheter (2) has a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion, as shown below. §§ **IX.H-I**, *supra*; Ex-1005, ¶¶ 351-54.



Tip (22) is soft and flexible to reduce the risk of potential blood vessel damage. Ex-1007, 2:12-21, 3:47-50; Ex-1005, ¶¶ 351, 353; Ex-1042, ¶¶ 54-59. The "flexible tip portion" also includes a portion reinforced with a metal layer (211) (blue)—a "reinforced portion." Ex-1007, 2:12-21, 3:50-58 (color added) (tubular structure 21). From the disclosure of Itou, it is evident that reinforcing metal wire (211) is braided or coiled around inner layer 210. Ex-1005, ¶¶ 351, 353; Ex-1042, ¶¶ 71-73.

A POSITA would understand that as the claimed interventional cardiology device is advanced to a target area it extends and advances the through flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion. Ex-1005, ¶¶ 352, 354.



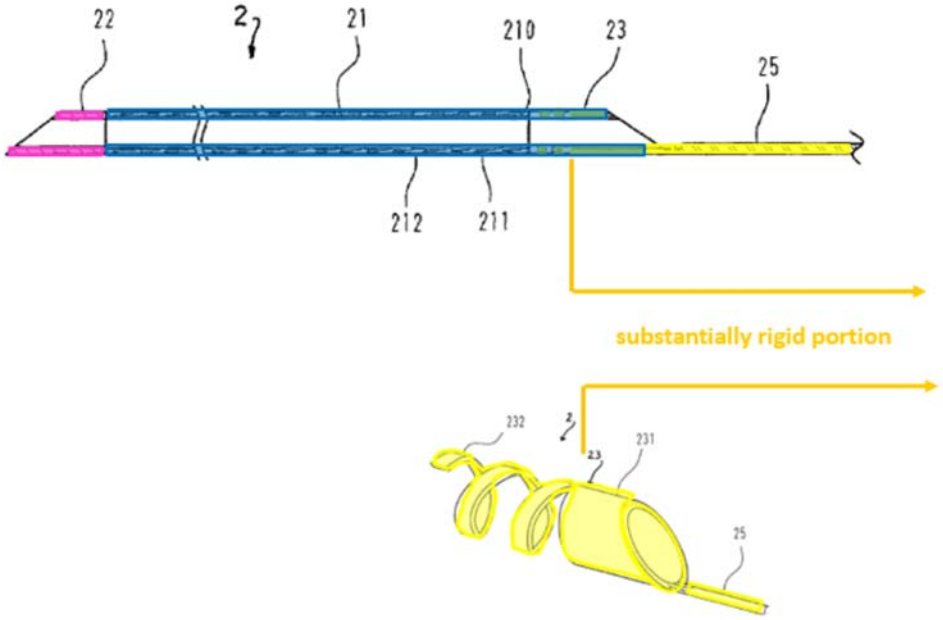
Ex-1007, Fig. 3 (color and annotation added); Ex-1005, ¶¶ 351, 353.

J. Claim 13

As discussed above in Ground 1, the cross-section inner diameter of Itou's suction catheter (2) is not more than one French smaller than the cross sectional inner diameter of Itou's GC. § **IX.J**, *supra*. Itou's suction catheter (2)—a coaxial guide catheter—includes a tubular portion (24) with an inner diameter of 1.5 mm. Ex-1007, 6:47-55, Table 1. At 1.5 mm, the tubular portion (24) is 0.3 mm smaller than the inner diameter of the GC. And 0.3 mm is "not more than one French smaller," as one French equals 0.33 mm. Ex-1062; Ex-1005, ¶ 355.

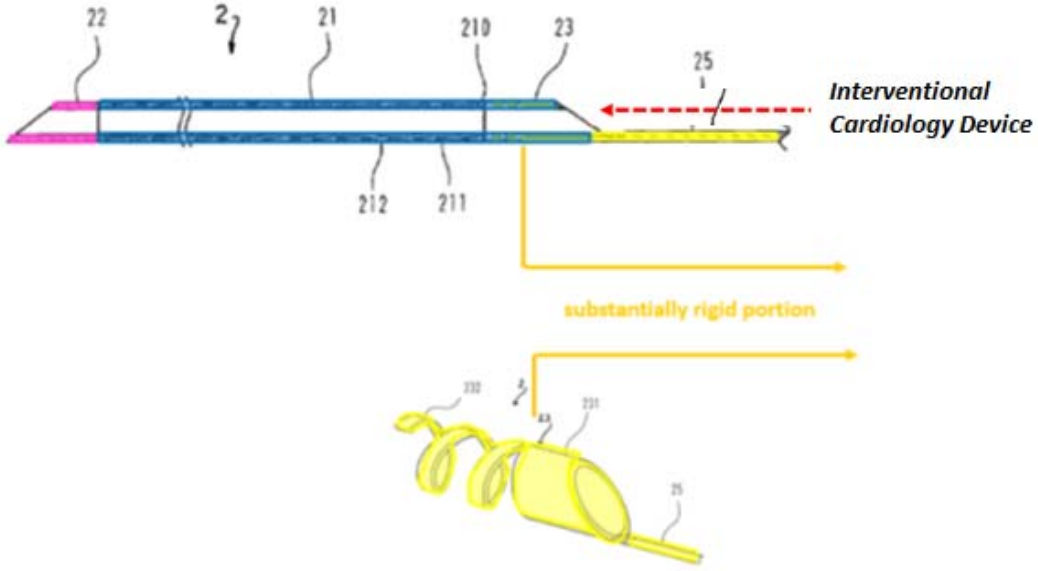
K. Claim 14

As discussed above in Ground 1, in *Mapping 1*, the "substantially rigid portion" of Itou's suction catheter (2) includes both wire-like portion (25) and end (231), as shown below.



The substantially rigid portion includes a cross-sectional shape having a full circumference portion, a hemicylindrical cross-sectional shape, and an arcuate cross sectional shape. § **IX.L**, *supra*; Ex-1005, ¶ 356.

A POSITA would understand that as the claimed interventional cardiology device is advanced to a target area it extends through the substantially rigid portion and its full circumference, hemicylindrical, and an arcuate cross sectional portions. Ex-1005, ¶ 357.



Ex-1007, Fig. 3 (color and annotation added); Ex-1005, ¶¶ 356-57.

XII. ANY ARGUMENT BY PATENT OWNER OF AN EARLY CONCEPTION AND REDUCTION TO PRACTICE DATE SHOULD NOT PRECLUDE INSTITUTION.

Petitioner has no obligation to preemptively address Patent Owner's alleged evidence of conception and reduction to practice in the Petition. The Board explained as much in its decision granting institution in the co-pending IPRs: "Given that Patent Owner bears the burden of producing evidence to support its antedating contention, *we determine Petitioner did not have an obligation to preemptively address Patent Owner's evidence in its Petition*." Ex-1116, 13 n.6 ('380 Institution Decision) (emphasis added); *Mylan Pharms. Inc. v. Boehringer Ingelheim*, IPR2016-01563, Paper 14 at 4 (PTAB Dec. 7, 2016) ("It is premature at

the institution stage to address the merits of Patent Owner's antedating contention."). The Board should reach a similar conclusion here.

Even if Petitioner has an obligation to address Patent Owner's alleged conception and reduction to practice, that evidence fails on the merits. Indeed, in denying Patent Owner's motion for preliminary injunction, the district court found that Itou was prior art. Ex-1088, 9-14. Based on "[t]he dearth of … documentation, coupled with the unimpressive nature of the corroborating documents," the district court found that Patent Owner failed to meet its burden to establish that Itou was not prior art. *Id.* In particular, the district court noted that "a report dated December 1, 2005—months *after* [Patent Owner's] claimed reduction to practice—states that '[t]he rapid exchange version [i.e., the claimed invention] requires additional engineering and is not included in our 2006 forecasts.'" *Id.,* 13 (emphasis in original). And in the co-pending IPRs and based on an even more robust record, this Board found that "genuine issues of material fact remain about the alleged invention date and that these questions are best resolved after trial and on a complete trial record." Ex-1116, 13. Petitioner has no obligation to address Patent Owner's alleged conception and reduction to practice in its Petition, but regardless, Patent Owner's alleged showing is insufficient to preclude institution.

XIII. SECONDARY CONSIDERATIONS

Any purported evidence of secondary indicia should not preclude institution.

As a threshold matter, the Board already addressed this issue in its institution decision for related patents, explaining that, "as in most cases, an analysis of objective evidence of nonobviousness is best made on a complete trial record, and not upon the incomplete record presented at the institution stage." Ex-1113, 27. That rationale aligns with the PTAB's prior practice of not—absent a previous finding at the Patent Office or by a Court that such evidence exists—addressing secondary indicia of non-obviousness until the trial phase. *Lowe's, Cos., Inc. v. Nichia Corp.*, IPR2017-02011, Paper 13 at 18 (P.T.A.B. Mar. 12, 2018) (granting institution and rejecting Patent Owner's argument that the Board should consider secondary indicia prior to the trial phase); *C&D Zodiac, Inc. v. b/e Aerospace*, IPR2017-01275, Paper 12 at 15 (P.T.A.B. Oct. 31, 2017) (same); *Arctic Cat v. Polaris Industries*, IPR2017-00433, Paper 17 at 9-10, 19 (P.T.A.B. July 5, 2017) (same); *Petroleum Geo-Services v. W. Geco LLC,* IPR2014-01477, Paper 18 at *32 (P.T.A.B. Mar. 17, 2015) (same).

Even if a pre-institution obligation existed, the Board explained in its institution decisions for related patents that Patent Owner has identified no secondary indicia for Petitioner to rebut in this Petition. Indeed, Patent Owner attempted to identify secondary indicia of nonobviousness in prior IPRs, but the Board held that the purported evidence of non-obviousness lacked any nexus to the alleged invention. Ex-1113, 27-29. In other words, because Patent Owner has not

provided any "persuasive analysis" demonstrating a nexus between the alleged secondary indicia and the claims of this patent (or any related patents), there is nothing for Petitioner to respond to in this Petition.

Regardless, even if secondary indicia of nonobviousness did exist, they could not overcome Petitioner's strong showing of obviousness. *ZUP, LLC v. Nash Mfg.*, 896 F.3d 1365, 1374 (Fed. Cir. 2018) ("a strong showing of obviousness may stand even in the face of considerable evidence of secondary considerations"). Thus, even if Patent Owner advances evidence of secondary indicia in its preliminary response, this Board should grant institution.

XIV. CONCLUSION

Petitioner respectfully requests institution of a trial and cancellation/invalidation of claims 1-2, 4-5, and 7-14 of the '413 patent.

Date: July 30, 2020

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I hereby certify that the Petition for *inter partes* review consists of 13,926 words in 14 point Times New Roman font as calculated by the word count feature Microsoft Office 2016, in compliance with 37 C.F.R. § 42.24(a)(i). This word count is inclusive of all text and footnotes but not including a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence was served on July 30, 2020, by Federal Express mail to the USPTO correspondence address of record listed below:

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