UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00132
U.S. Patent No. RE 45,760E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 45,760

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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")
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1026	U.S. Patent No. 5,489,278 (“Abrahamson”)
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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”)
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1036	Williams et al., *Percutaneous Coronary Intervention in the Current Era Compared with 1985-1986*, Circulation (2000) 102:2945-2951.
1037	Dorros, G., et al., *Coronary Angioplasty in Patients with Prior Coronary Artery Bypass Surgery*, Cardiology Clinics 7(4): 791-803 (1989)
1038	Ozaki et al, *New Stent Technologies*, Progress in Cardiovascular Disease 2:129-140 (1996)
1039	Urban et al., *Coronary stenting through 6 French Guiding Catheters, Catheterization and Cardiovascular Diagnosis* (1993) 28:263-266
1040	Excerpt of McGraw-Hill Dictionary of Scientific and Technical Terms (5th edition) (1994) (defining “flexural modulus”)
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1053	U.S. Patent No. 5,720,300 (“Fagan”)
1054	U.S. Patent No. 5,120,323 (“Shockey”)
1055	Sakurada, *Improved Performance of a New Thrombus Aspiration Catheter*: Outcomes From In Vitro Experiments and a Case Presentation (“Sakurada”)
1056	Nordenstrom, *New Instruments for Catheterization and Angiocardiography* (“Nordenstrom”)
1057	U.S. Patent No. 5,445,625 (“Voda”)
1058	U.S. Patent No. 6,595,952 (“Forsberg”)
1059	U.S. Patent No. 6,860,876 (“Chen”)
1060	U.S. Patent No. 6,638,268 (“Niazi”)
1061	U.S. Patent No. 5,690,613 (“Verbeek”)
1062	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”)
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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)
1069	Excerpt of prosecution history for application 14/195,435 (Office Action, 10/06/15)
1070	Metz, *Comparison of 6f with 7f and 8f guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter,*

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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")
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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")
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I. PRELIMINARY STATEMENT

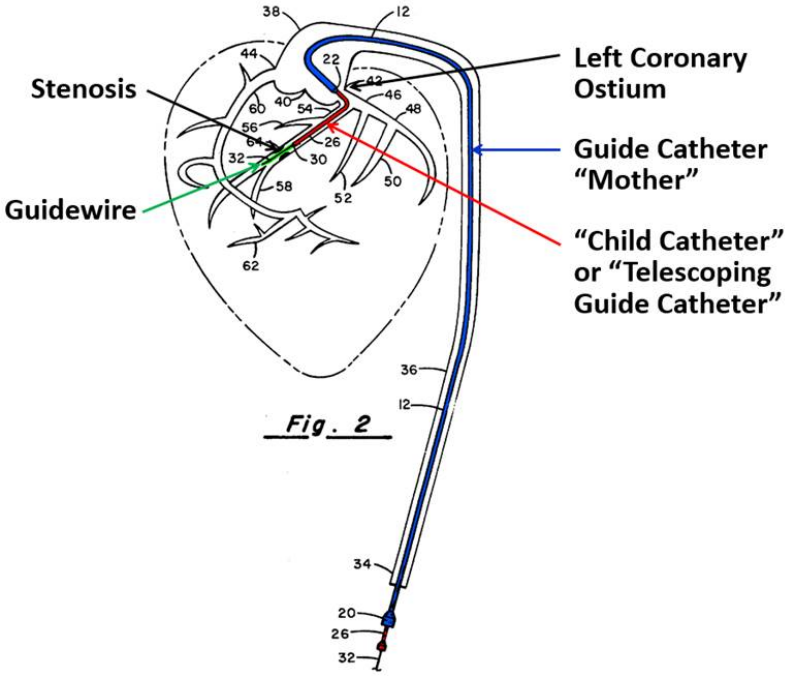
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 25-42, 44 and 47 ("Challenged Claims") of U.S. Pat. No. RE 45,760 ("the '760 patent," Ex-1001). The '760 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1001, [60])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id.*, [54], [72]. The Challenged Claims were issued on a first an Office Action, meaning there is no substantive file history for the '760 patent.

The '760 patent describes a catheter assembly system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a **g**uide **c**atheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery).

[1] The '760 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1005, ¶¶ 75 n.8, 129. A POSITA knew that the "coaxial guide catheter" of the '760 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1009, 5:49-52 (referring to body 12 "as a guide catheter extension").

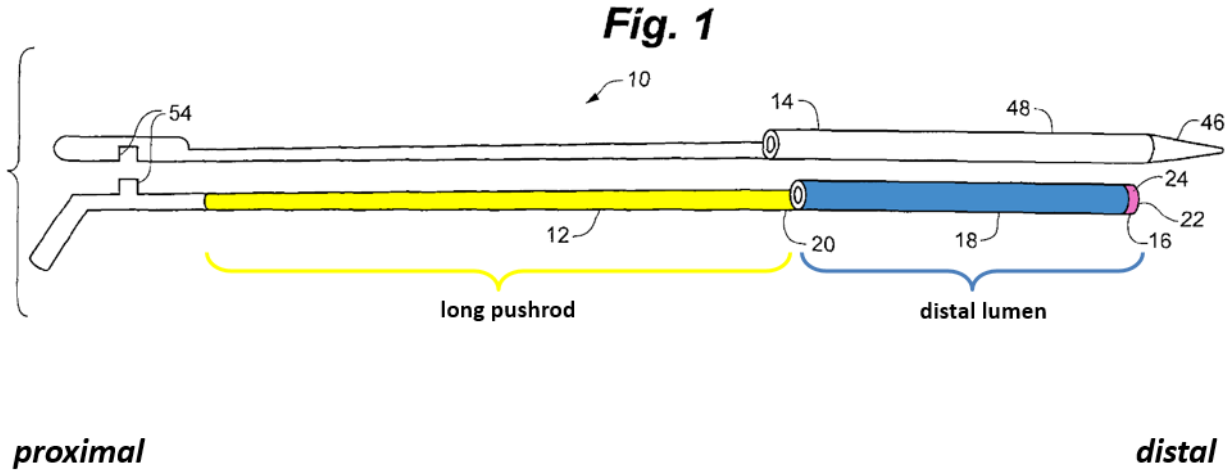
Id., Abstract, Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id*., 3:7-11; s*ee also id.*, 8:23-35.

The '760 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. Ex-1001, 2:46-61 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a "mother-and-child assembly." Ex-1005, ¶¶ 74-84. The child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. *Id*., ¶ 74.



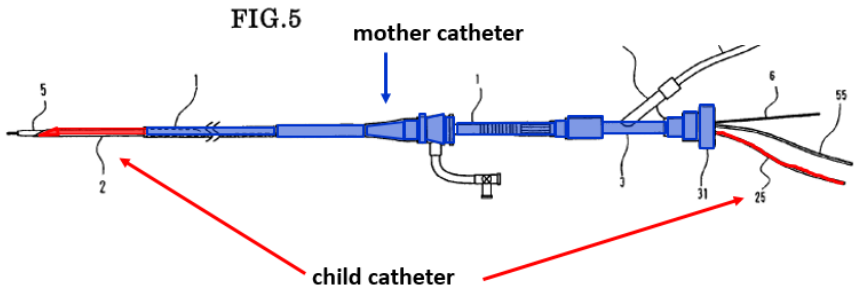
Ex-1054, Fig. 2 (annotations and color added).

The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id*. The '760 patent alleges that such a design had certain drawbacks (Ex-1001, 2:63-3:6) and modifies the child catheter of the mother-and-child assembly to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



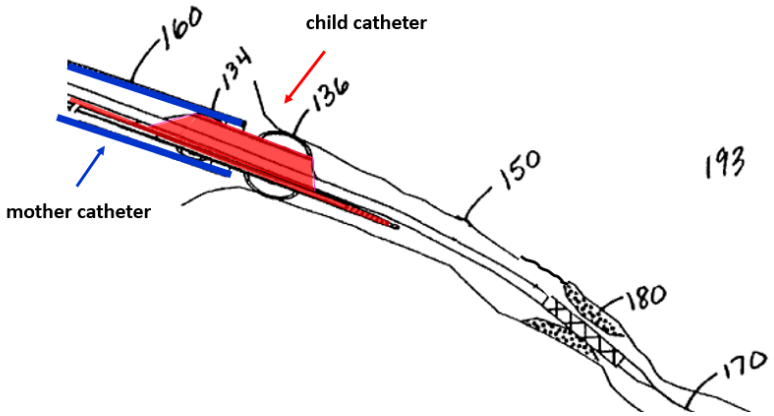
Ex-1001, Fig. 1 (annotations and color added).

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



Ex-1008, Fig, 6B (annotations and color added); *and see*, *infra*, §VII.A.

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



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

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the ’760 patent are unpatentable based on the Grounds discussed below. Accordingly, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the Challenged Claims.

II. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Party-in Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the ’760 patent is currently the subject of litigation in two separate actions in the U.S. District Court

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

Further, the '760 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent). The '850 patent was previously the subject of litigation (i) in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and (ii) at the PTAB in *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (P.T.A.B., terminated Aug. 11, 2014).

Petitioner is also concurrently filing other petitions for IPR challenging different claims of the '760 patent, or based on prior art references having different priority dates and different disclosures than the references discussed herein.

C. Lead and Backup Counsel

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

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

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

D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

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

Pursuant to 37 C.F.R. §42.104, Petitioner certifies that the ’760 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review of the ’760 patent on the identified grounds.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 25-42, 44 and 47 of the '760 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Itou anticipates claims 25-31, 33-38, 41, 42, 44 and 47.
2	Itou renders claims 25, 30, 32, 39 and 40 obvious in view of Ressemann and the knowledge of a POSITA
3	Itou renders claim 32 obvious in view of Kataishi and the knowledge of a POSITA
4	Itou renders claim 32 obvious in view of Enger and the common knowledge of a POSITA

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1005, ¶¶ 32, 34-36. This narrowing, sometimes called a stenosis,

[2] This petition is also 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 '760 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1078) to support the authenticity and public availability of the documents cited herein.

restricts blood flow and increases the risk of heart attack or stroke. *Id*. In response, physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery, and thus can treat CAD without the need for open-heart surgery. Ex-1005, ¶¶ 33, 38-44.

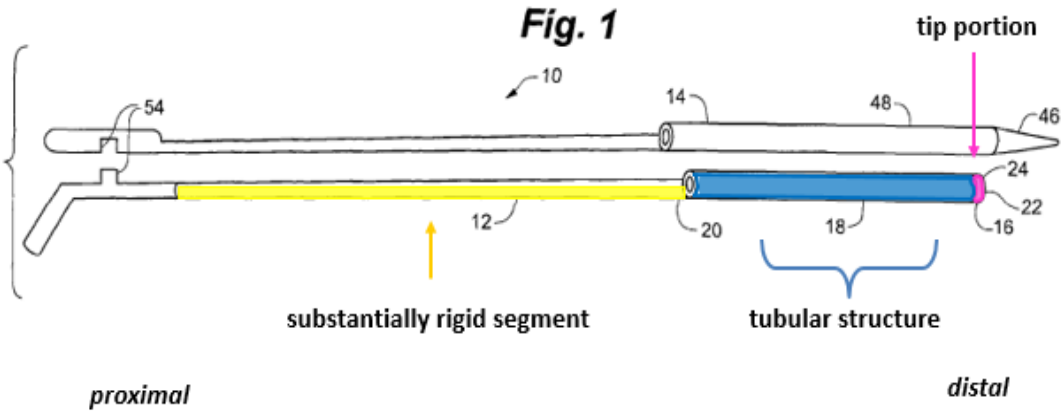
PCI was developed over forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1005, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. A guidewire is then introduced into the needle, the needle is removed, and an introducer sheath is inserted over the guidewire and into the artery. Next, a guide catheter can be introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id.*, ¶¶ 38, 46-59. At the proximal end, a hemostatic valve is coupled to 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*.

A smaller-diameter, more 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 guidewire and 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 guidewire and 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.

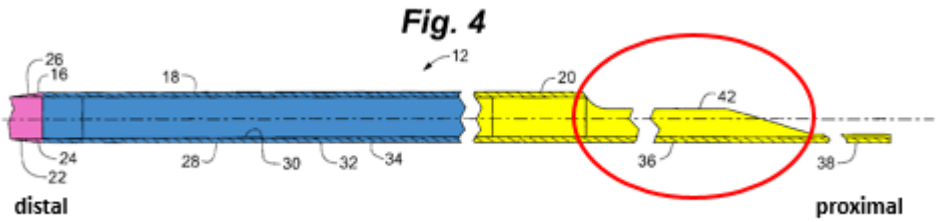
B. The ’760 Patent

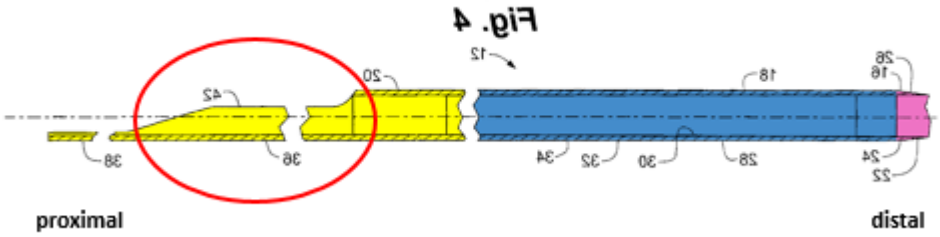
The ’760 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:37-38. In particular, the ’760 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends through the lumen of a GC, “beyond the distal end of the guide catheter, and insert[s] 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.*, 5:30-34; Ex-1005, ¶ 130. The ’760 patent claims a guide extension catheter 12 that includes a substantially rigid segment (yellow) and a tubular structure (blue) and a tip portion (pink). Color has been added to Figure 1, below, which has been annotated with the language of claims 25 and 35.



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

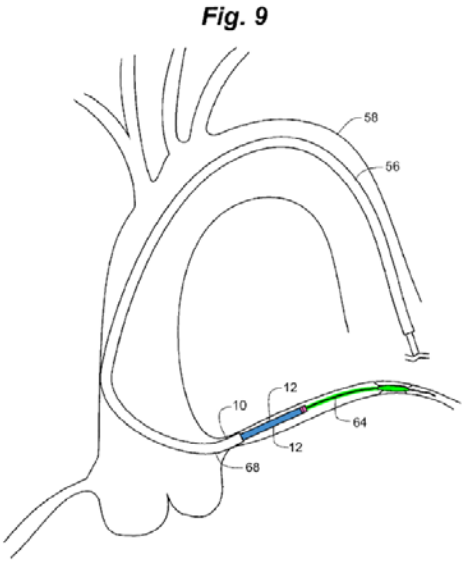
The ’760 patent also recites that the extension catheter include “in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure.” *Id.*, 13:36-14:7. The specification, however, provides no written description support for the placement of a “side opening” anywhere other than ***in*** the substantially rigid segment 20, circled in red below. Ex-1001, Figs. 4, 13-16; *see also id.*, 7:1-17, 8:63-9:5.





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

Regardless, the ’760 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56.



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

C. Prosecution History of the ’760 Patent

The predecessor, ’850 patent issued without an Office Action. *See generally* Ex-1002. According to the Examiner, the claims of the ’850 patent were allowable because “adding a guide catheter to the claimed rail structure[3] with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” Ex-1002 at 83 (Notice of Allowance at 3).

Patent Owner sought reissuance in 2014. The Examiner found the claims were patentable because he found no prior art disclosing “a guide extension catheter which is long enough to extend from both ends of the guide catheter and includes a rigid segment, a segment defining a side opening and a tubular structure, where the lumen of the tubular structure is shorter than the guide catheter.” Ex-1003 at 708 (Non-Final Rejection, December 10, 2014 at 10). In other words, in both the original prosecution of the ’850 patent, and the prosecution of the ’760 reissuance, the Examiner believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art, but he was not aware of Itou or Ressemann.

D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim that is not supported by a pre-March 16, 2013 application or claims priority to any

[3] *Infra*, § 6 (construing “rail structure”).

patent or application that is subject to the AIA first-to-file provisions. AIA § 3(n)(1)(A); MPEP § 2159.02. This would prevent, for instance, any attempt by Patent Owner to swear behind the Itou patent. The ’760 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority,[4] and (2) it claims priority to RE 45,380 (“the ’380 patent”), which is subject to the AIA first-to-file provisions. Thus, Patent Owner cannot swear behind Itou in this proceeding. First, no pre-AIA application to which the ’760 patent claims priority contains disclosure of “a side opening portion” that is not part of the substantially rigid segment, but the independent claims allow the side opening to, in the alternative, be in the reinforced segment. *Compare* Ex-1001, 13:36-14:7, *with id.*, 14:31-33. Second, claim 32 requires a side opening with two inclined slopes, while the only alleged support (*See* Ex-1003 at 163 (Preliminary Amendment, 03/03/14 at 21), Figure 4, discloses an arc and an inclined slope. Third, claim 32 requires a side opening that includes “at least two” inclined slopes but there is no support for more than two. Fourth, the ’380 patent, to which the ’760 patent claims priority, is an AIA patent because it includes at least one claim that lacks support in a pre-March 16, 2013

[4] The ’760 patent shares the same specification as all applications in its priority chain that were filed before March 16, 2013.

application. Similar to claim 32 of the ’760 patent, claim 27 of the ’380 patent requires “at least two different inclined slopes.” The ’760 and ’380 patents—at best—support ***only*** two inclined slopes. Ex-1001, Fig. 4; Ex-1081, Fig. 4.

V. THE PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art (“POSITA”) was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer, s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and one with an engineering degree might have access to one with a medical degree. Ex-1005, ¶ 31; Ex-1042, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

For IPR proceedings, the Board applies the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). *See* 83 Fed. Reg. 51,340-51,359 (Oct. 11, 2018). Claim terms are typically given their

ordinary and customary meanings, as would have been understood by a POSITA at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. *Phillips*, 415 F.3d at 1312-16.

When, as here, claim terms have been construed by a district court, those constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation,[5] Patent Owner stipulated to the following constructions:

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1012 at 2)

Further, 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" (*Id.* at 2; Ex-1013 at 15)
- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1013 at 20)

Additionally, the district court provided the following construction:

[5] The full list of constructions advanced by Patent Owner in the QXMedical Litigation is found at Ex-1012.

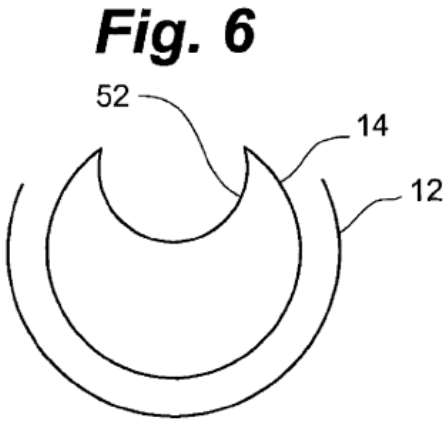
- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (*Id.* at 26)
- "lumen": "the cavity of a tube" (*Id.* at 25)
- "wherein a material forming the segment defining the side opening is more rigid than the tubular structure": "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure" (*Id*. at 31).

Petitioner agrees with the above constructions for purposes of this IPR[6] (Ex-1005, ¶¶ 134-140) and proposes the following additional construction:

A. "concave track" (cl. 30)

The '760 patent does not define the claim term "concave track." It mentions that a cutout portion, which supports a track, "may" have certain amounts removed and "may" extend for certain lengths, and later refers to cutout portion 44, which is not labeled in a Figure. Ex-1001, 4:11-23, 4:37-39, 7:25-26; Ex-1005, ¶¶ 141-143. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex-1001, 7:25-26; Fig. 6.

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



As a result, in the context of the ’760 patent, the claim term “concave track” means a “portion that is not fully circumferential.” *Id.*, ¶ 143.

B. “flexural modulus” (cl. 36, 44)

The claim term “flexural modulus” had a known and established meaning by 2006 (Ex-1042, ¶ 31), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means “[a] measure of resistance . . . to bending.” Ex-1040, 772. In other words, the “flexural modulus” is a measure of a device’s rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. Such an understanding is consistent with the ’760 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1001, 7:25-30; Ex-1005, ¶¶ 144-45. Stated differently, the extension catheter’s resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the

distal end (flexible tip) is the most flexible (least rigid).[7]

VII. GROUND 1: ITOU ANTICIPATES CLAIMS 25-31, 33-38, 41, 42, 44 AND 47.

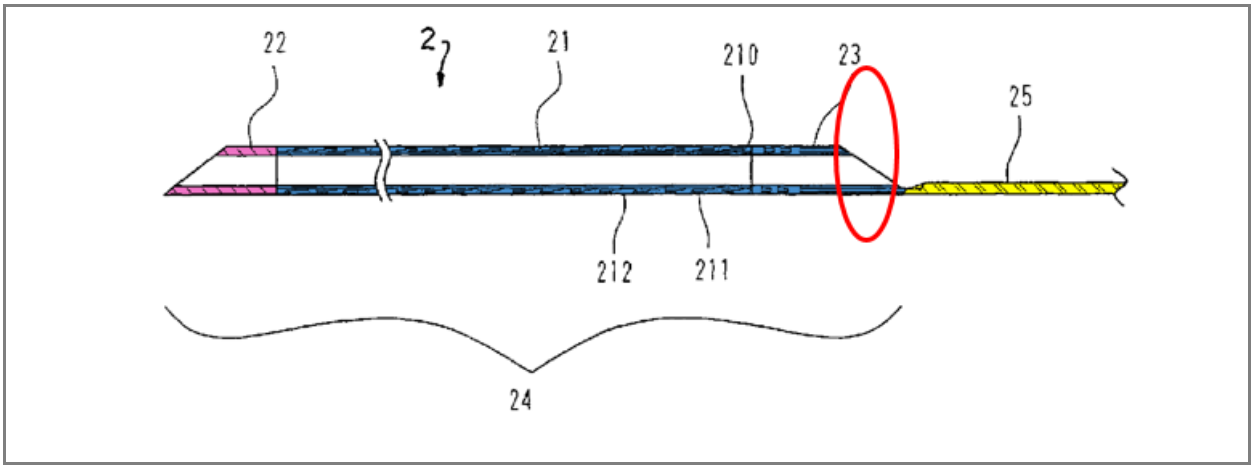
A. Itou

Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. It is prior art under both pre-AIA §102(e) and post-AIA §102(a)(1), (2), and was not cited or considered during prosecutions of either the original ’850 patent, or of the ’760 reissue patent. Exs-1001-1003.

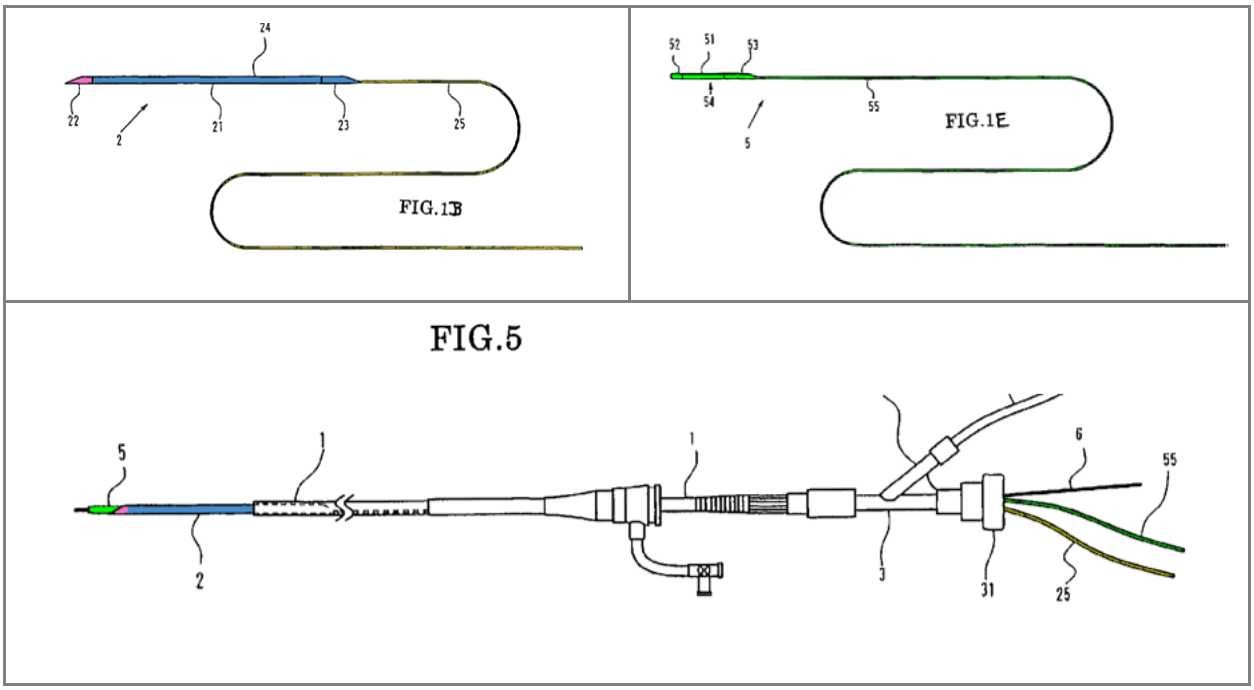
Itou discloses a catheter assembly for alleviating the obstruction of blood flow. Ex-1007 at 1:13-16. The assembly includes a GC that is inserted into a coronary artery ostium, *id*., 2:2-5, Abstract, 5:32-34, 7:7-11, and a suction catheter that is insertable through the GC. *Id.*, Abstract, 3:59-61,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

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

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).



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

Itou also describes a "distal end protective catheter" (5), shown above in green, which is insertable through the suction catheter (2). *Id*. Suction catheter (2) may be extended beyond the distal end of the GC (1) into a coronary artery. *Id*., Abstract, 2:29-38; Figs 5, 6; Ex-1005, ¶¶ 95-98, 146-149.; Ex-1042, ¶¶ 20-27.

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). Regardless, by the time of the alleged invention of the '760 patent, and as Dr. Brecker explains, a POSITA knew that suction catheters with a structure similar to Itou's may serve a dual purpose. Ex-1005, ¶¶ 95-102, 149-156. An aspiration catheter could be "preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen." Ex-1019, 3:4-6. An aspiration lumen could be used both to remove thrombus from a coronary artery, as well as to deliver an angioplasty catheter or stent. *Id*., 3:34-36, 12:16-20; Ex-1008, 6:18-34, Figs. 6A-I; Ex-1005, ¶¶ 95-98, 99-102, 149-156, 232-240.

B. Claim 25

1. [25.pre] "A system, comprising:"

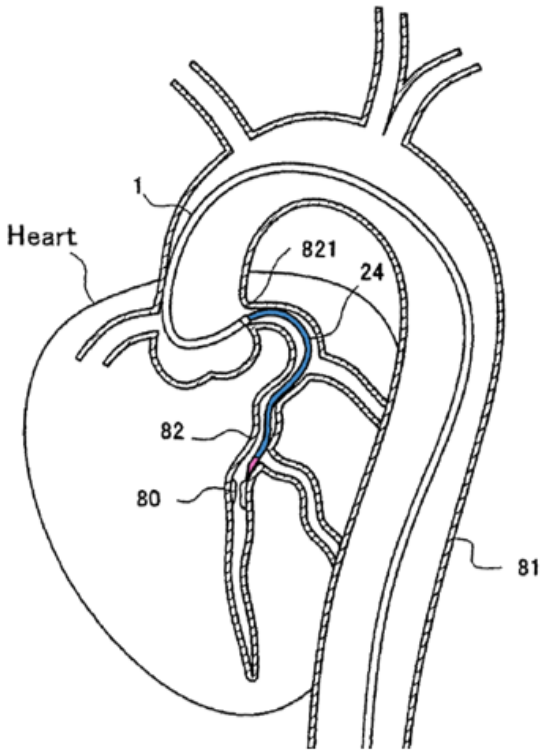
To the extent the preamble is limiting, Itou discloses it as set forth below. Ex-1005, ¶ 167.

2. [25.a] "a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and"

Itou discloses this limitation. *Id.* ¶ 168.

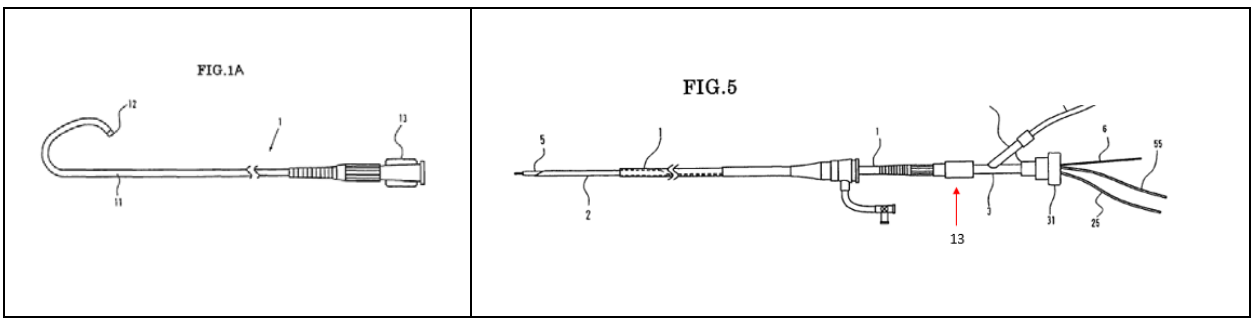
As Dr. Brecker explains, guiding catheter (1) is configured to be advanceable through a main blood vessel (an aorta) to a position adjacent an ostium of a coronary artery. Ex-1007, 5:29-32 (explaining that "guiding catheter 1 is disposed in the aorta," and its distal end is "hooked at an ostium . . . of a coronary artery"); 7:1-10. Ex-1005, ¶ 168.

FIG.6



Id., Fig. 6 (color added).

Itou teaches that guiding catheter (1) has a lumen that extends from a hemostatic valve at its proximal end, to its distal end. Guiding catheter (1) has distal end 12 and body portion (11), which terminates at connector (13). Ex-1007, Fig. 1A, 3:29-37. Connector (13) is coupled to Y-shaped connector (3), which includes main connector portion (31). *Id.*, 5:11-23.

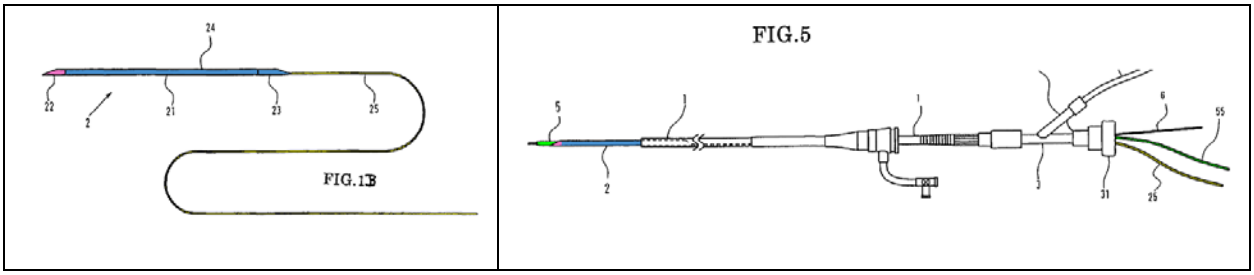


Id., Figs. 1A, 5 (annotation added)

Connector (31) includes a valve, which can close a bore in connector (31) and "selectively clamp and fix the guide wire 6, the wire-like portion 25 or 55 to prevent leakage of the blood." *Id.*, 5:20-23. Thus, guiding catheter (1) has a hemostatic valve (within connector 31 of connector 13 (arrow below)) at its proximal end. Ex-1005, ¶¶ 39, 168.[8]

Itou discloses that suction catheter (2) "is disposed in the lumen of guiding catheter 1," Ex-1007 5:11-17," and additionally teaches that suction catheter (2) may be inserted into guiding catheter (1) at its proximal end, to extend from its distal end.

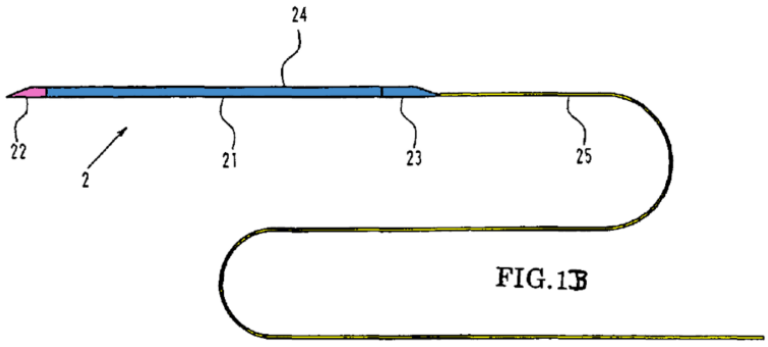
[8] The '760 patent admits that a "guide catheter . . . can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter." Ex-1001, 3:29-31. Similarly, Patent Owner's expert in the co-pending litigation explains that a hemostatic valve is sometimes called a Y-connector. Ex-1082, ¶18, also known as a Y-adapter. Ex-1005, ¶ 168.



Id., *compare* Fig. 1B *with* Fig. 5 (color added). Thus, Itou discloses 25.a. Ex-1005, ¶ 168.

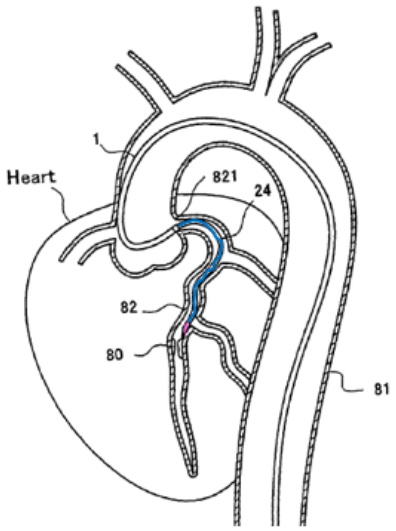
3. [25.b] "a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,"

Itou discloses a guide extension catheter (suction catheter 2), which is configured to be partially advanceable through the guide catheter and into the coronary artery. Ex-1005, ¶ 169.



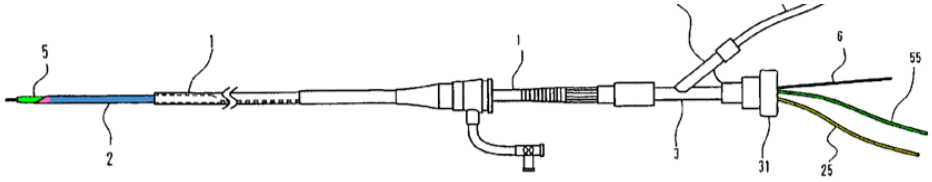
Ex-1007, Fig. 1B (color added); *supra* § VII.B.2.

Figure 6 illustrates suction catheter 2 partially extended through guiding catheter 1.



Ex-1007, Fig. 6 (color added, illustrating tip (22) (pink) and a portion of tubular structure (21) (blue) advanced through guiding catheter (1)'s distal end into the coronary artery); *and see id.*, Abstract, 1:47-65 (explaining that "tubular portion [24] is configured to project outwardly beyond the distal end" of guiding catheter (1); 5:38-42); Ex-1005, ¶ 169.

Itou also discloses that suction catheter (2) has a length such that when its distal end is extended through the lumen and beyond the distal end of guiding catheter (1) (below, left, colored blue and pink), its proximal end is extendtable through the hemostatic valve at the proximal end of the guide catheter (below, right, colored yellow). Ex-1005, ¶ 169.



Ex-1007, Fig. 5 (color added); *and see id.*, Table 1 (disclosing that suction catheter (2) is 1250 mm long, while guiding catheter (1) is 1000 mm long); *supra*, § VII.B.1 (discussing hemostatic valve located in connector 31 at the proximal end of the guide catheter 1). Thus, as Dr. Brecker explains, Itou discloses 25.b. Ex-1005, ¶ 169; *see also* ¶¶ 46-59, 63-84.

4. [25.c.i] "the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter,"

Itou discloses this limitation. Ex-1005, ¶ 170; *see also id.*, ¶¶ 46-59, 63-84, 85-93.

Guide extension catheter (suction catheter 2) includes, at its proximal end, wire-like portion 25 (below, yellow). Ex-1007, 2:12-15, 3:47-50.

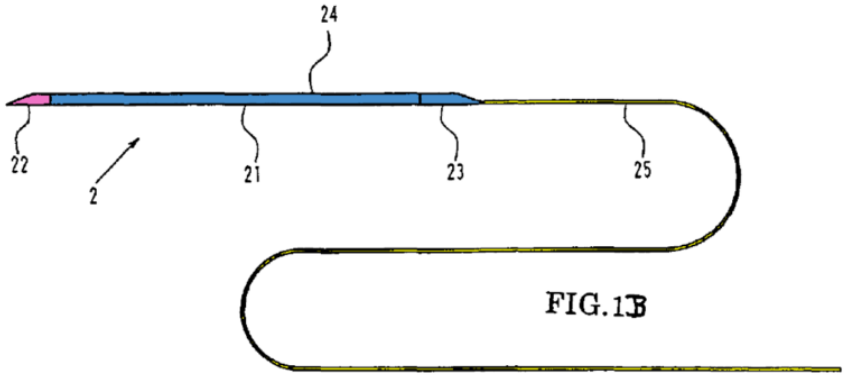
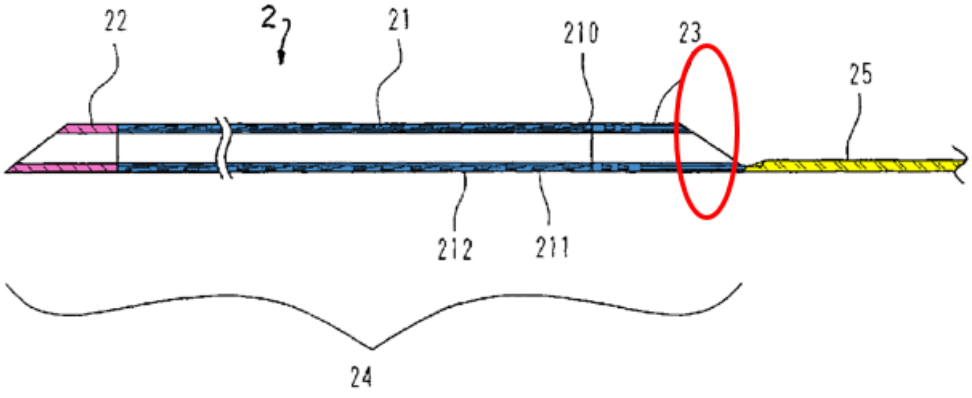


FIG. 1B

Id. (color added).

Wire-like portion 25 is a "substantially rigid" segment because it is used to advance suction catheter (2) through guiding catheter (1) until the distal portion of suction catheter (2) "projects forwardly beyond the distal side of the guiding catheter." *Id*., 2:32-38, 5:43-46; *and see* Abstract, Figs. 5, 6. Thus, "wire-like portion 25" meets the prior, district court claim construction of a segment that is "rigid enough to allow the device to be advanced within the guide catheter." *Supra*, § VI. ; Ex-1005, ¶ 170.

Moving distally, Itou discloses a segment defining a side opening (circled in red) in tubular portion 24. Ex-1007, Fig. 4, 3:47-50, 4:10-15, 4:27-32.



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

Distal to the side opening, Itou discloses tubular structure (21).[9] *Id*.; *and see id*., 3:47-58. Tubular structure (21) defines a lumen, into which distal end protective catheter (5) may be inserted. *Id*., 4:48-52; *and see id.*, Fig. 5.

[9] In general, use of the same words in different claims mean the same thing. Here, however, in claim 25 Patent Owner used "tubular structure" to refer to a structure that does not include the distal end of the extension catheter. *Compare* §VII.B.3, *with* § K (reciting that the extension catheter has a tip portion in addition to the tubular structure). But in claim 48 that is not the case, as Patent Owner does not recite, either in claim 48 or a dependent claim, a separate "tip portion" at the distal end of the extension catheter.

TABLE 1

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

Id., Table 1 (providing ***both*** inner and outer diameters for suction catheter, evidencing a "lumen"). [10] Ex-1005, ¶ 170.

The lumen of tubular structure (21) is coaxial to the lumen of guiding catheter (1). Ex-1007, Figs. 5, 6, 1:60-65, 2:32-38; Ex-1005, ¶ 170.

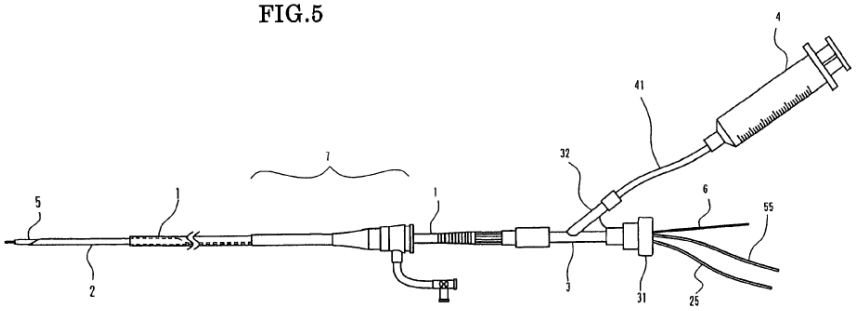
As Dr. Brecker explains, the lumen of tubular structure (21) is in fluid communication with the lumen of guiding catheter (1). First, the total length of suction catheter (2) is 1250 mm, while its distal, tubular portion is 150 mm in length. Guiding catheter (1) is 1000 mm. Ex-1007, Table 1. Necessarily, in use, the

[10] The tubular portion of suction catheter 2 is tubular portion 24, of which tubular structure (21) is a part. Ex-1007, Figs. 1B, 3.

proximal end of the tubular portion of the suction catheter opens into the lumen of guiding catheter (1), such that fluid may flow between the guiding catheter and the suction catheter. Ex-1005, ¶ 170.

Second, Itou explains that syringe (4) may be used to "recover foreign matter in the blood vessel," such as a thrombus, through the distal opening of suction catheter 2. Ex-1007, 7:13-26.

FIG.5



As syringe (4) is not connected to suction catheter (2)—but, instead, attached to guiding catheter (1) through Y-shaped connector (3), *id*., 5:11-25, Fig. 5—the recovery of foreign matter requires that the lumen of suction catheter (2), including tubular structure (21), be in fluid communication with the lumen of guiding catheter (1). Ex-1005, ¶ 170; *see also* Ex-1007, Figs. 9A, 10, 8:2-24 (describing suction of a glycerin solution through the distal tip of suction catheter (2), through guiding catheter (1) and into a tube connected to a Y-shaped connector).

5. [25.c.ii] "the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter,"

Itou discloses this limitation. Ex-1005, ¶ 171.

Itou teaches that tubular structure (21)'s lumen is shorter than the lumen of guiding catheter 1. This is necessarily the case because tubular structure (21) is part of longer, tubular portion (24), which, itself, is shorter than guiding catheter (1). Ex-1007, Table 1 (disclosing that the tubular portion (24) of suction catheter (2) is 150 mm in length, and guiding catheter (1) is 1000 mm in length); Ex-1005, ¶ 171.

Similarly, Itou teaches that tubular structure (21)'s lumen has a "uniform cross-sectional inner diameter. Ex-1007, Fig. 3 (disclosing a longitudinal cross section through portion 21 with a constant diameter), Table 1 (disclosing that the tubular portion of suction catheter (2) has a (***singular***) inner diameter of 1.5 mm); Ex-1005, ¶ 171.

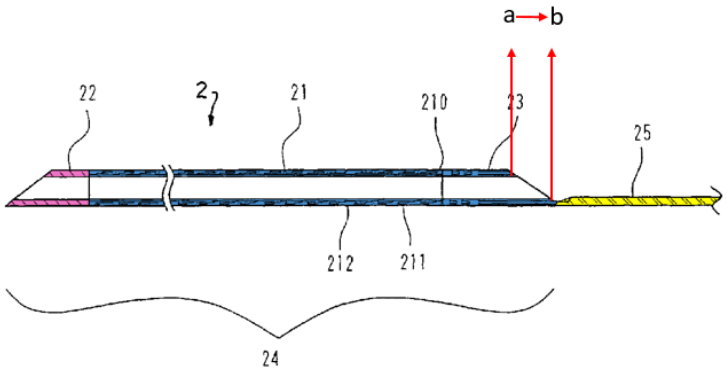
Itou teaches that there is not more than a one French size differential between the cross-sectional diameters of suction catheter (2) (including tubular structure (21)) and guiding catheter (1). Ex-1007, Table 1 (disclosing inner diameters, respectively, of 1.5 and 1.8 mm). As Dr. Brecker explains, a "one French" size differential is 0.33 mm, so the "0.3 mm" size differential between the inner

diameters of Itou's guiding and suction catheters is "not more than one French." Ex-1005, ¶ 171; Ex-1062 at 547.

6. [25.c.iii] "the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;"

Itou discloses this limitation, disclosing a side opening extending along a longitudinal axis that is accessible from a longitudinal side defined transverse to the longitudinal axis, and a tubular structure with a lumen. *Supra*, §§ VII.B.3-4; Ex-1005, ¶¶ 170-84.

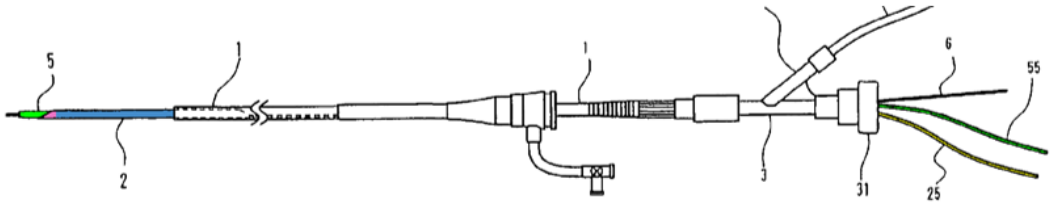
As shown below, the side opening in Itou's suction catheter 2 extends for a distance from (a) to (b) along the catheter's longitudinal axis.



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

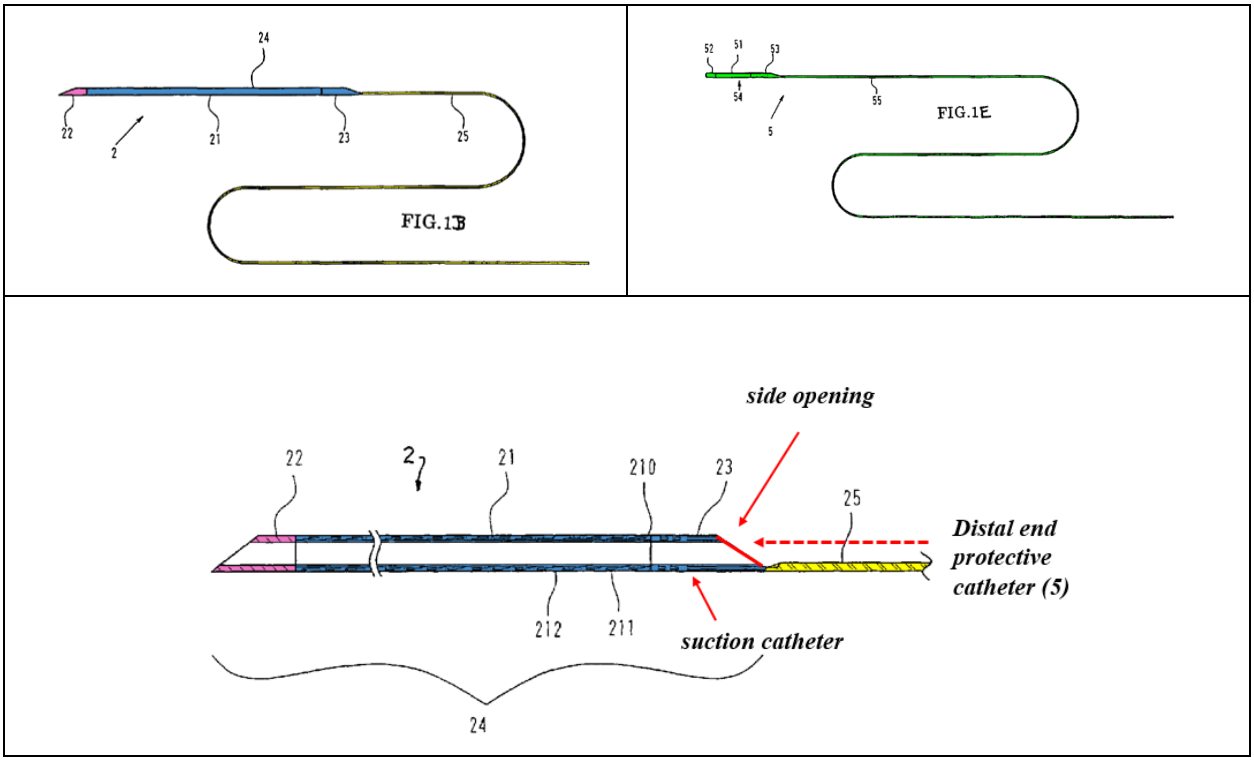
Moreover, Itou teaches that protective catheter (5) is inserted into the lumen of catheter (2), and projects from its distal end. Ex-1007, 4:48-52.

FIG.5



Id., Fig. 5 (color added).

This necessarily requires that protective catheter (5) pass through the proximal side opening in tubular portion (24), which is "accessible from a longitudinal side defined transverse to the longitudinal axis."



Id., Figs. 1B, 1E, 3 (color and annotation added); Ex-1005, ¶¶ 170-172.

Itou also explicitly teaches that tubular portion (24) is long enough so that while its distal end is advanced to a target location—distal to the distal end of the guiding catheter 1—its proximal end remains in guiding catheter 1. Ex-1007, 5:35-42; 6:30-35, Figs. 5, 6. This discloses that "when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter," that the "distal end of the guide extension catheter extends beyond the distal end of the guide catheter." Ex-1005, ¶¶ 172-173.

Thus, Itou discloses the structural limitations of 25.c.iii, and claim 25 is a system claim. To the extent that Patent Owner suggests that 25.c.iii requires anything more than the cited disclosure in Itou, it is mistaken. The additional language recites an intended use ("configured ***to receive one or more stents or balloon catheters when the segment defining the side opening*** . . . ***[is] positioned within the lumen of the guide catheter***") (emphasis added), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

Regardless, Itou explicitly teaches that the tubular portion (24) of suction catheter (2) (of which tubular structure 21 is a part) has an inner diameter of

1.5 mm, Ex-1007, Table 1, which Dr. Brecker explains is 0.059 inches.[11] This was large enough to accommodate the insertion of a balloon-expandable stent, several of which were available by the time of the purported invention of the '760 patent. Ex-1005, ¶¶ 174-184; Ex-1022, 3 (requiring a > 0.056 in. (1.4 mm) inner catheter diameter for CYPHER stents between 2.50-3.0 mm on an RX delivery system); Ex-1023, 9 (requiring a minimum, inner catheter diameter of 0.056 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1024, 10 (requiring an inner catheter diameter $\geq$ 0.058 in. (1.47 mm) for TAXUS Express^2 stents on a monorail delivery system).

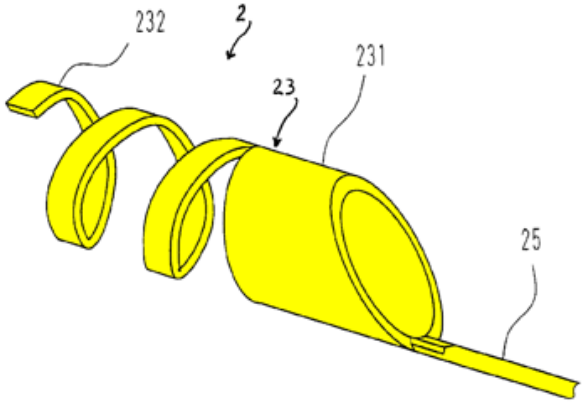
Thus, the proximal side opening of tubular portion (24) of suction catheter (2)—and tubular structure 21—are large enough (i.e. "configured to") "receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter." Ex-1005, ¶¶ 172-184.

7. [25.d] "wherein a material forming the segment defining the side opening is more rigid than the tubular structure."

[11] This corresponds to the inner diameter of the extension catheter taught in the '760. Ex-1001, 3:49-51 ("greater than or equal to 0.056 inches . . .").

Itou discloses this limitation. Ex-1005, ¶¶ 185-187.

Itou teaches that the side opening in tubular portion (24) is "formed by obliquely cutting one end of a metal pipe." Ex-1007, 4:27-32 (referring to end 231). The metal pipe is encased in resin layers. *Id*., 3:45-58, 4:36-38.



Id., Fig. 4 (color added).

By contrast, tubular structure (21) includes resign layers (210) and (212) and a "reinforcing layer 211 made of metal wire." Ex-1007, 3:50-57, Fig. 3; Ex-1005, ¶¶ 185-187; Ex-1042, ¶¶ 64-67; *see also* Ex-1042 ¶¶ 27-32.

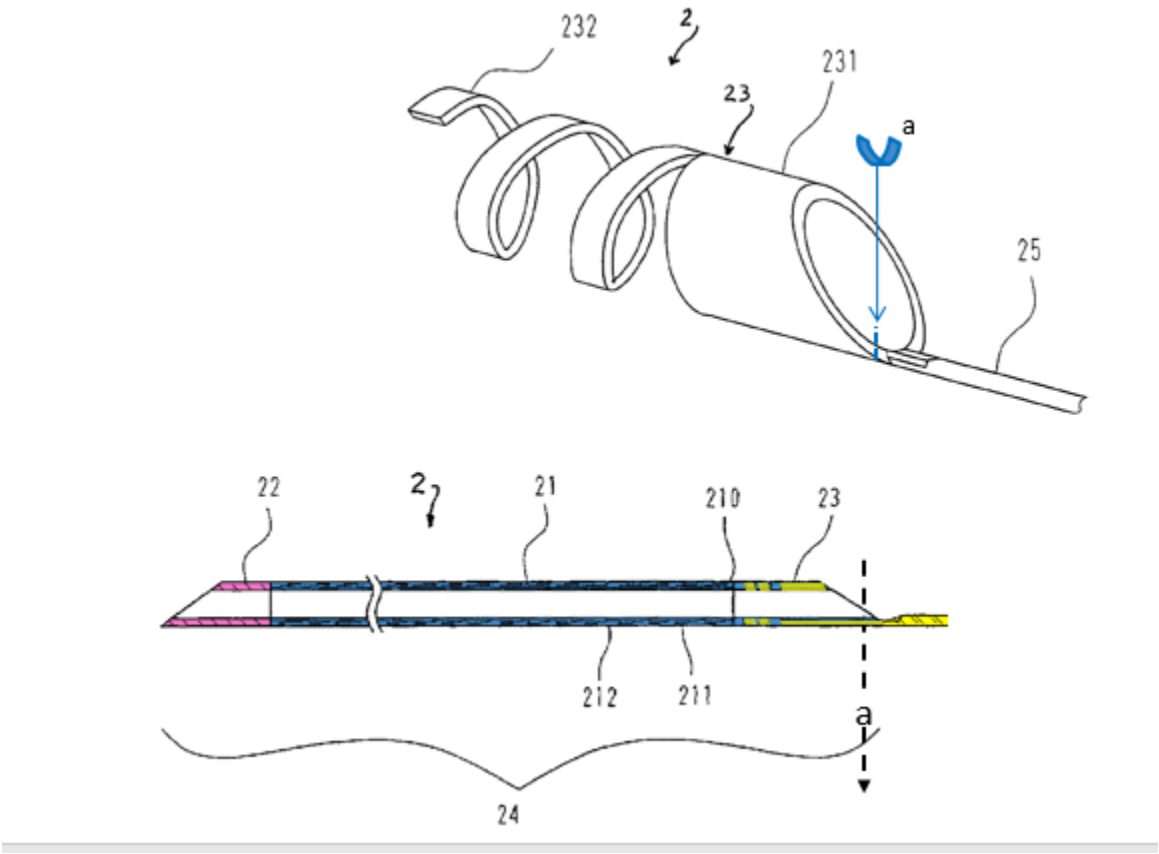
As Dr. Brecker and Dr. Hillstead explain, because side opening 231 is formed by cutting a metal pipe, it is necessarily more rigid than tubular structure 21, which includes resin layers and a wire reinforcing layer.

Given the differences in the materials that are used to form tubular structure (21) and the side opening of tubular portion 24, "a material forming the segment defining the side opening is more rigid than tubular structure." Ex-1005, ¶¶

185-187; Ex-1042, ¶¶ 68-69; *and see, supra* § VI (construing 25.d to mean "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure).

C. Claim 26: The system of claim 25, wherein the segment defining the side opening includes a portion having an arcuate cross-sectional shape.

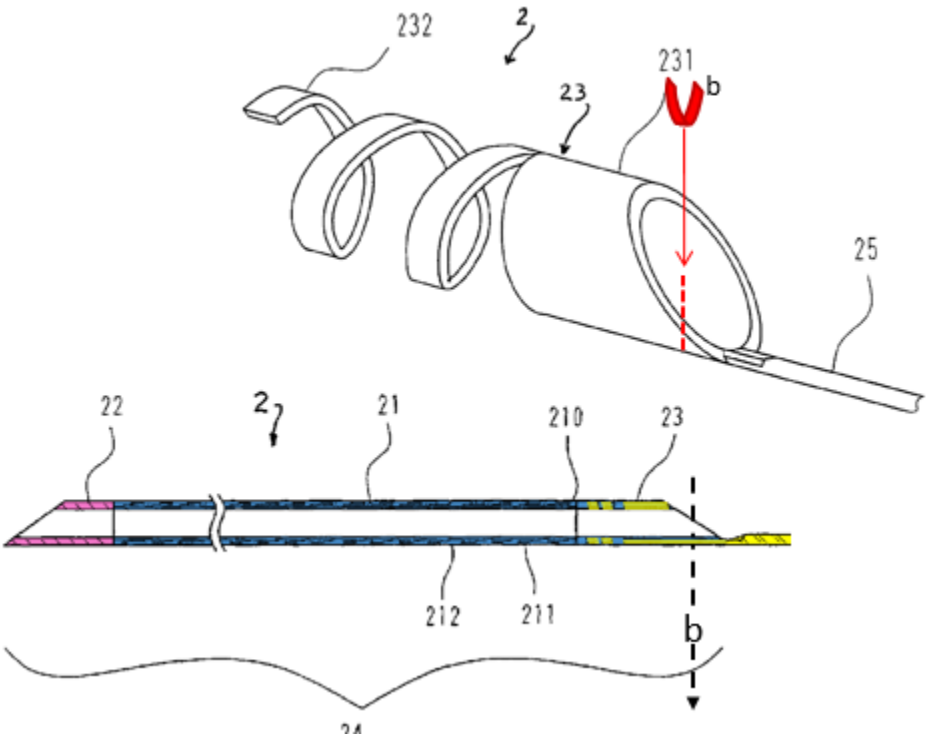
Itou discloses claim 26. Ex-1005, ¶ 188. As illustrated below, the segment defining the side opening of tubular portion 24 has a portion with an arcuate cross-sectional shape. As shown below, at a cross section of the proximal end 231 taken through line (a), the side opening includes an arcuate cross sectional shape, which, according to the '760 patent is a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1001, 7:12-13.



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

D. Claim 27. The system of claim 25, wherein the segment defining the side opening includes a portion having a hemicylindrical cross-sectional shape.

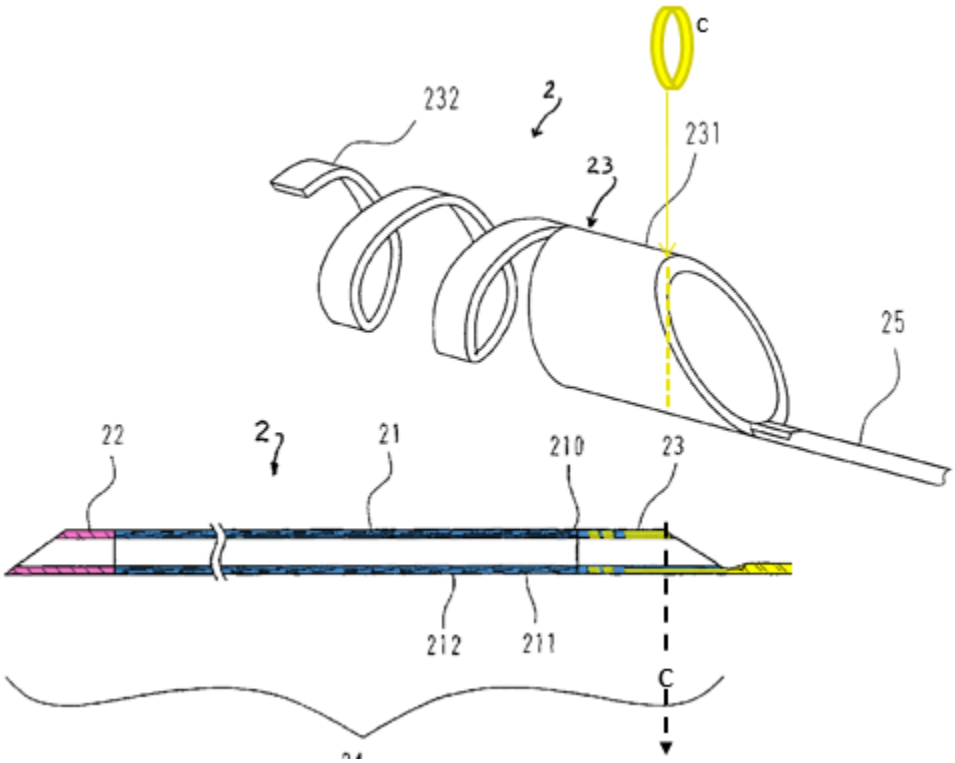
Itou discloses claim 27. Ex-1005, ¶ 189. As illustrated below, the segment defining the side opening of tubular portion 24 has a portion with a hemicylindrical cross-sectional shape. As shown below, at a cross section of the proximal end 231 taken through line (b), the side opening includes a hemicylindrical cross-sectional shape, which, according to the ’760 patent is a portion that “desirably includes 40% to 70% of the circumference of a tube.” *Id*., 7:7-8.



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

E. Claim 28: The system of claim 25, wherein the segment defining the side opening includes a portion having a full circumference cross-sectional shape.

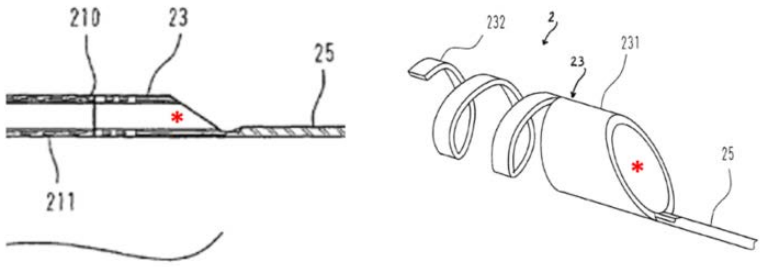
Itou discloses claim 28. Ex-1005, ¶ 190. As illustrated below, the segment defining the side opening of tubular portion 24 has a portion with a full circumference cross-sectional shape. This may be seen at a cross section of the proximal end 231 taken through line (c).



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

F. Claim 29: The system of claim 28, wherein the cross-section of the guide extension catheter at the portion of the segment defining the side opening having the full circumference cross-sectional shape includes a single lumen.

Itou discloses claim 29. Ex-1005, ¶ 191. Proximal end portion (231) is welded to the distal end of wire-like portion 25, Ex-1007, 4:33-36, which is "formed from a solid metal wire" that has an outer polymer coating. *Id*., 3:47-50. Thus, as illustrated below, a cross section through tubular portion 24 at the portion of the segment defining the side opening that has a full circumference has only one lumen.



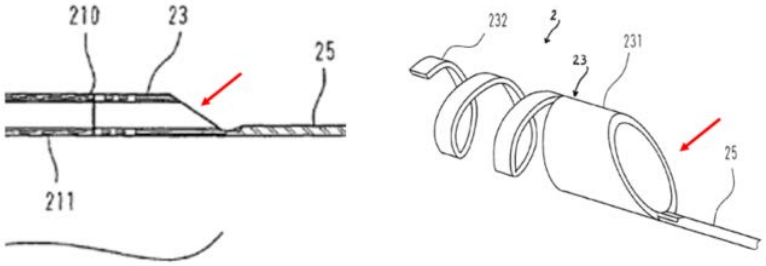
Id., Figs. 3, 4 (asterisk added).

G. Claim 30: The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

Itou discloses claim 30. Ex-1005, ¶ 192. In the context of the '760 patent, "concave track" refers to a portion that is not fully circumferential. *Supra*, § VI. Itou discloses that side opening of proximal end 231 includes a portion that is not fully circumferential. *Supra*, § VI.D-E. Itou additionally discloses that the concave track is "configured to guide the one or more stents or balloon catheters along a length of the concave track" for the reasons set forth for claim 25.c.iii.

H. Claim 31: The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.

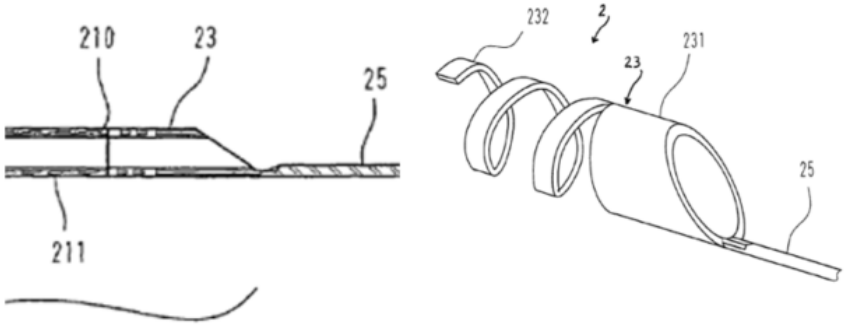
Itou discloses claim 31. Ex-1005, ¶ 193. The side opening of tubular portion 24 includes at least one inclined slope (arrow).



Id., Figs. 3, 4 (arrow added).

I. Claim 33: The system of claim 25, wherein the side opening is formed by a cutout portion of a cylindrical tubular structure.

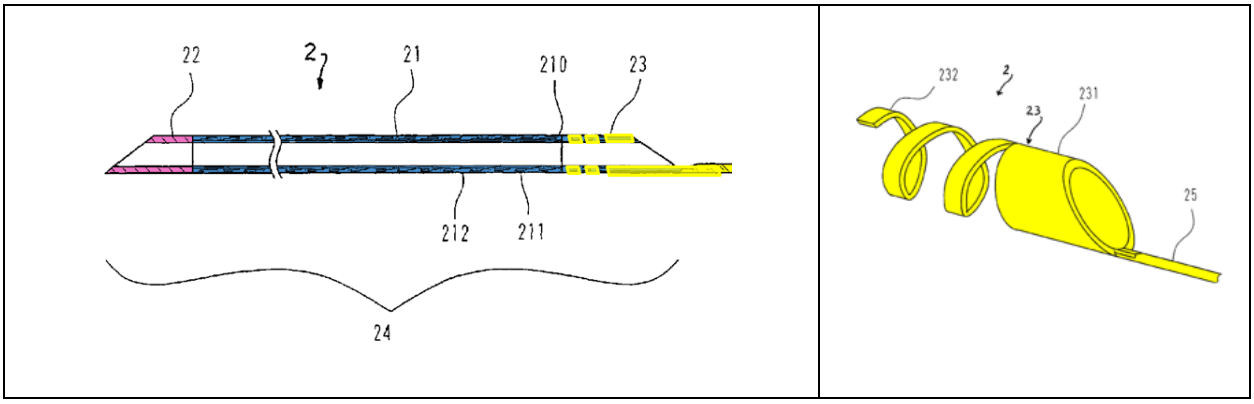
Itou discloses claim 33. Ex-1005, ¶ 194. The proximal tip of tubular portion (24), "proximal end portion 231" is "formed ***by obliquely cutting*** one end of a metal pipe." Ex-1007, 4:27-32.



Id., Figs. 3, 4. The metal pipe is a cylindrical tubular structure. *Id.*, Fig. 4; *and see id.*, Table 1 (providing inner and outer ***diameters*** for tubular portion (24)).

J. Claim 34: The system of claim 25, wherein the segment defining the side opening and the tubular structure comprise a reinforced portion of the guide extension catheter.

Itou discloses claim 34. Ex-1005, ¶ 195. The segment defining the side opening includes a metal pipe that, at its proximal end 231, is cut obliquely, and, at its distal end 232, is formed into a spiral shape. Ex-1007, 4:27-32, Fig. 4.

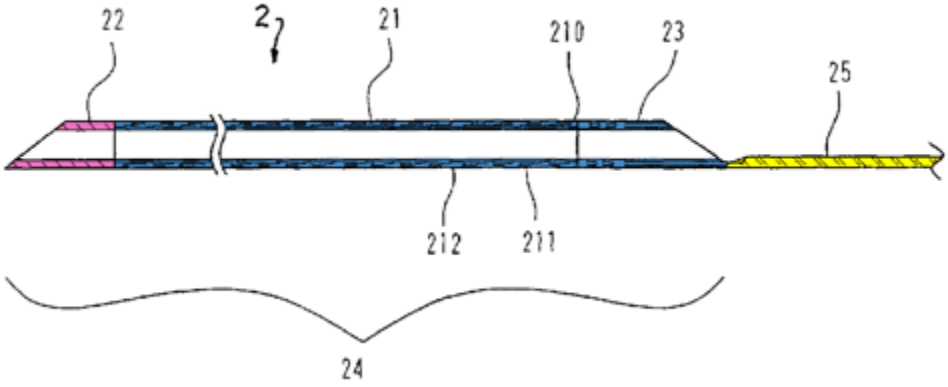


Id., Figs. 3, 4 (color added).

Tubular structure 21 includes resin layers (210) and (212), and a "reinforcing layer 211 made of metal wire." *Id*., 3:50-58. As Dr. Brecker and Dr. Hillstead explain—given the materials that are used to form them— tubular structure (21) and the segment defining the side opening of suction catheter (2) are a "reinforced portion" of suction catheter (2). Ex-1005, ¶ 195; Ex-1042, ¶¶ 72-80.

K. Claim 35: The system of claim 25, wherein the distal end of the guide extension catheter includes a tip portion.

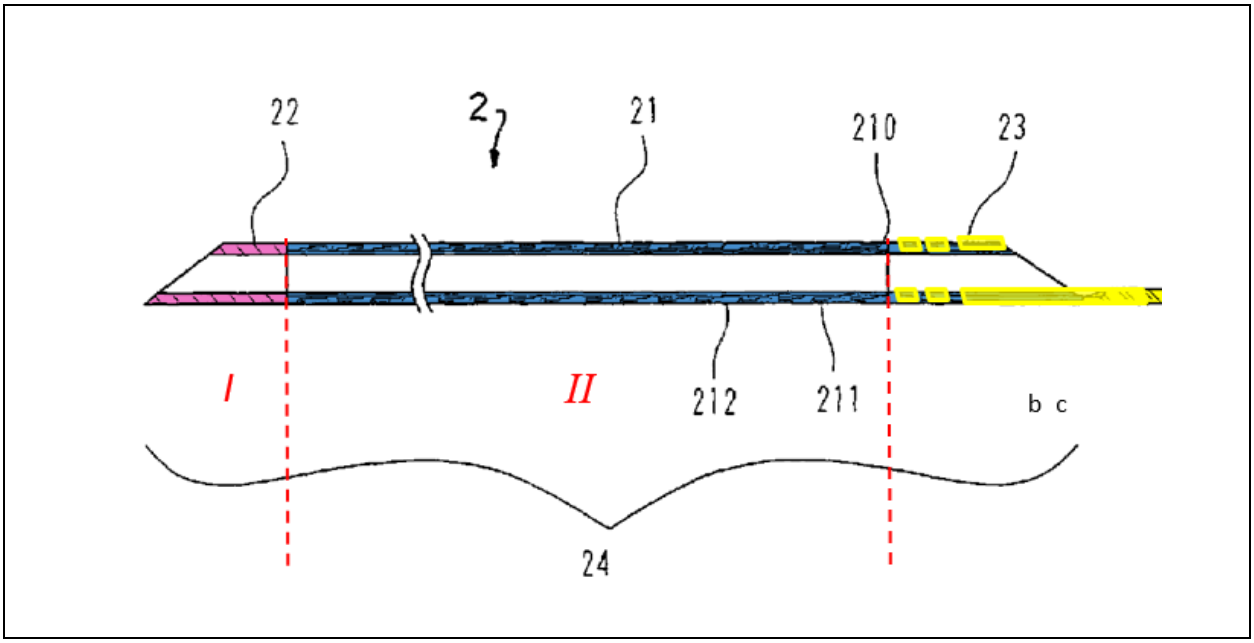
Itou discloses claim 35, Ex-1005, ¶ 196, as it teaches that the "suction catheter has a soft tip whose distal end is flexible in order to reduce the damage to the blood vessel . . . ." Ex-1007, 2:12-18; *and see id*., 3:46-58 (teaching that tip (22) lacks metal wire reinforcing layer 211 that is present in tubular structure (21)).



Id., Fig. 3 (color added, tip 22 shown in pink).

L. Claim 36: The system of claim 35, wherein a flexural modulus of the tubular structure is greater than a flexural modulus of the tip portion.

Itou discloses claim 36. Ex-1005, ¶¶ 197-202. Itou teaches that tip 22 is a "soft tip whose distal end is flexible in order to reduce the damage to the blood vessel." Ex-1007, 2:16-21. As explained by Dr. Brecker and Dr. Hillstead, tip portion (22), shown below in pink, has a first flexural modulus (*I*). Ex-1005, ¶¶ 196-202; Ex-1042, ¶¶ 81-84.



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

Tubular structure (21) has a second flexural modulus (*II*). Ex-1005, ¶¶ 197-202; Ex-1042, ¶¶ 81-84. Itou teaches that tubular portion (21) is proximal to tip (22). It has "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . ." Ex-1007, 3:50-58.

Given the differences in the materials that are used to form tip (22) and reinforced tubular structure (21), the flexural modulus of tubular struture 21 is necessarily greater than the flexural modulus of unreinfoced tip (22). Ex-1005, ¶¶ 197-202; Ex-1042, ¶¶ 81-84.

M. Claim 37: The system of claim 25, wherein the uniform cross-sectional inner diameter of the lumen of the tubular structure is greater than a largest outer dimension of the substantially rigid segment.

As discussed above, the cross-sectional inner diameter of the lumen of tubular structure (21) is (uniformly) 1.5 mm. Ex-1007, Table 1, Fig 3; *supra*, § VII.B.4 (citing Ex-1005 ¶ 171).

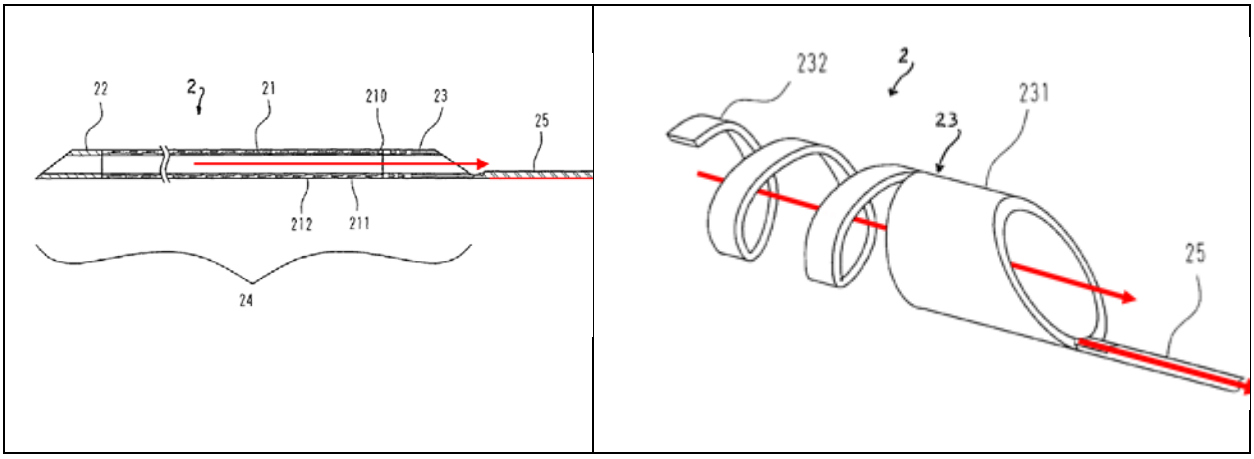
Wire-like portion 25 is the "substantially rigid segment," as discussed above. *Supra*, § VII.B.3. Wire-like portion (25) has a cross sectional outer diameter of 0.45 mm, which is smaller than the cross sectional, 1.5 mm inner diameter of tubular structure (21). Ex-1007, 3:59-63, Table 1; Ex-1005, ¶ 203. Thus, the "largest outer dimension of the substantially rigid segment" [12] in Itou is smaller than the "cross-sectional inner diameter of the lumen of the tubular structure," and claim 37 is disclosed. Ex-1005, ¶ 203.

N. Claim 38: The system of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure.

Itou discloses claim 38. Ex-1005, ¶ 204. The "substantially rigid segment," wire-like portion 25, is eccentrically positioned (not concentric) relative to a cross

[12] Claim 37's language "largest outer dimension" permits, but does not require, the substantially rigid segment to vary in outer dimension. All the claim requires is that the substantially rigid segment cannot be bigger (in cross-sectional dimension) than the inner diameter of the tubular structure.

section taken through "tubular structure" 21. As shown below on the left, tubular structure (21) is part of tubular portion 24, the proximal opening to which is shown below on the right.



Ex-1007, Figs. 3 (left), 4 (right) (annotations added).

As illustrated by the arrows, wire-like portion 25 is eccentrically positioned relative to a cross section through tubular structure 21. Ex-1005, ¶ 204.

O. Claim 41: The system of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be partially advanced through the guide catheter and into the coronary artery without blocking use of the guide catheter.

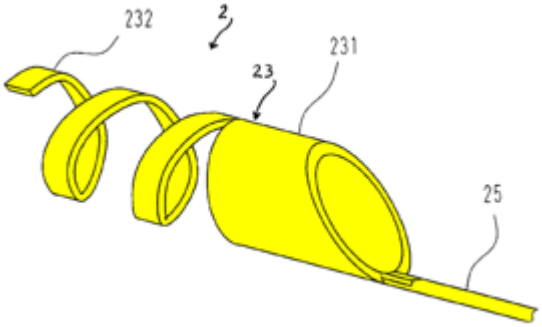
Itou discloses claim 41. Ex-1005, ¶ 205. As discussed above, *supra* §§ VII.M-N, wire-like portion 25 has a cross-sectional diameter of 0.45 mm and is positioned eccentrically relative to a cross section through tubular structure 21. Moreover, Itou discloses that guiding catheter 1 has an inner diameter of more than three times the diameter of the wire-like portion 25. Ex-1007, Table 1 (inner

diameter of guiding catheter is 1.8 mm, which is more than three times 0.45 mm); Ex-1005, ¶ 205. Thus, when tubular structure 21 is partially advanced through guiding catheter 1 into the coronary artery, Ex-1007, Fig. 6, "use of the guide catheter" is not blocked. This is evidenced by Itou's teaching that suction should be applied "to the guiding catheter which is transmitted to the tubular portion [of suction catheter (2)]. *Id*., 2:39-41; *and see, supra*, § VII.B.3 (explaining that the lumen of tubular structure (21) is in fluid communication with the lumen of guiding catheter (1), which necessarily indicates that use of guiding catheter 1 is not blocked). Ex-1005, ¶ 205.

P. Claim 42: The system of claim 25, wherein the substantially rigid segment and the tubular structure are operably coupled at or adjacent to the segment defining the side opening.

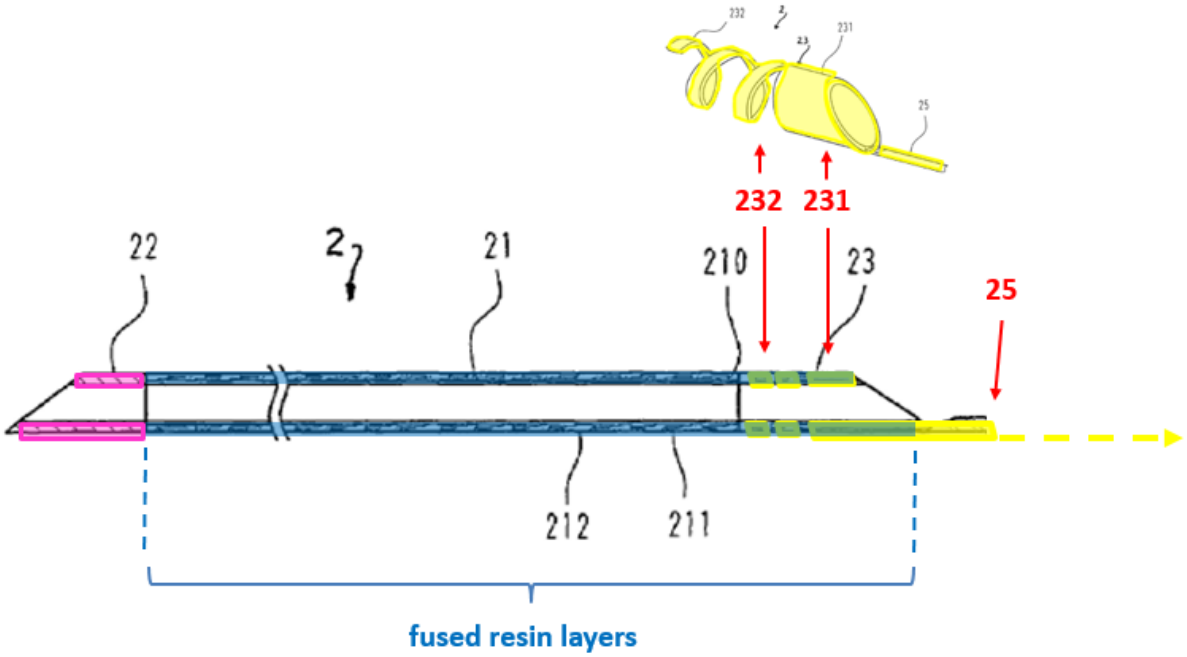
Itou discloses claim 42. Ex-1005, ¶ 206.

Wire-like portion (25) is the substantially rigid segment, *supra*, claim 1, and is welded to proximal end portion 231 ("side opening") of Itou's tubular portion 24. Ex-1007, 4:33-36.



Id., Fig. 4 (color added).

While end (231) is formed by obliquely cutting the proximal end of a metal pipe, 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 fused to the resin layers of tubular portion (21). *Id*., 3:50-55, 4:32-33, 4:36-38.



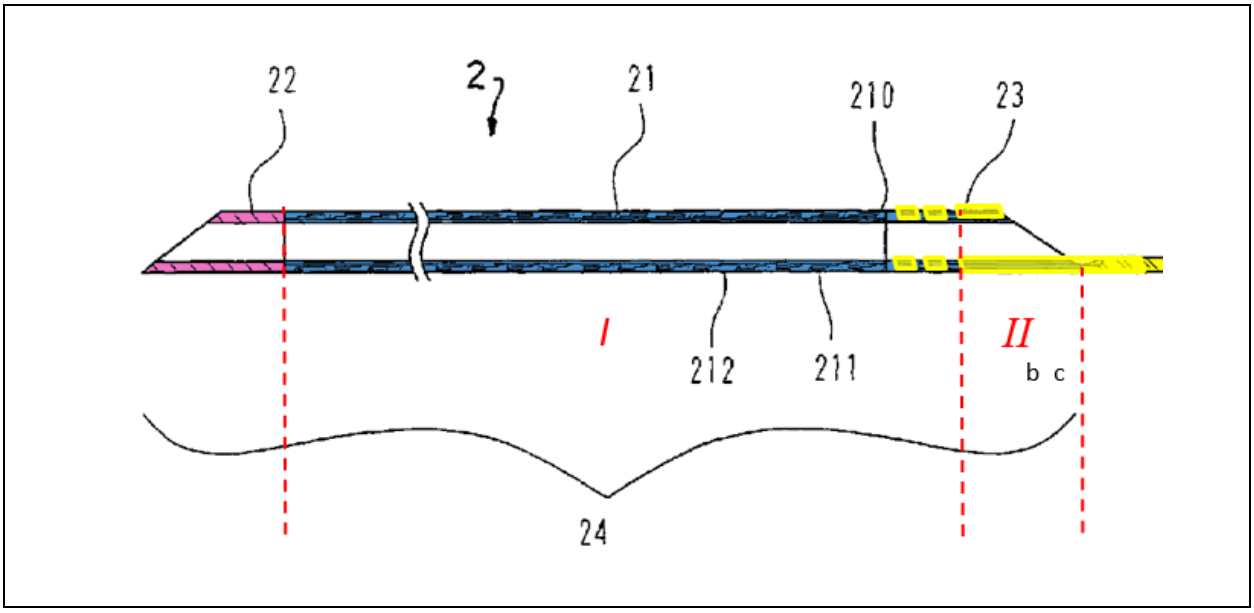
Ex-1007, Figs. 3, 4 (color and annotation added).

Thus, Itou's substantially rigid segment (wire-like portion 25) and Itou's tubular structure (21) are operably coupled at or adjacent to segment (231) defining the side opening. Ex-1005, ¶ 206.

Q. Claim 44: The system of claim 25, wherein a flexural modulus of the segment defining the side opening is greater than a flexural modulus of the tubular structure.

Itou discloses claim 44. Ex-1005, ¶¶ 207-213, *see also* ¶¶ 144-145.

As explained by Dr. Brecker and Dr. Hillstead, tubular structure (21) has a first flexural modulus (*I*). Ex-1005, ¶¶ 207-213; Ex-1042, ¶¶ 70-71, *see also* ¶¶ 64-69. Itou teaches that tubular portion (21) includes "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . ." Ex-1007, 3:50-58.



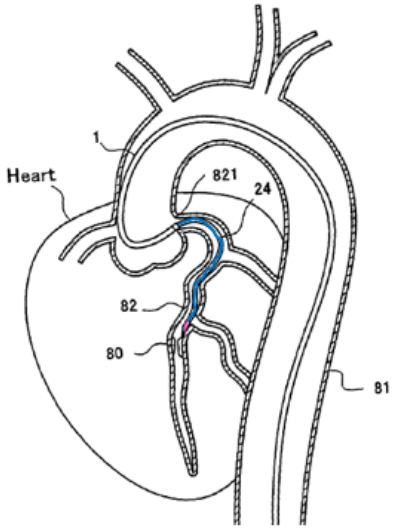
Ex-1007, Fig. 3 (color and annotations added).

The segment defining the side opening has a second flexural modulus (*II*) that is greater than the flexural modulus of tubular structure (21). As Dr. Brecker and

Dr. Hillstead explain, because side opening of proximal end 231 is formed by cutting a metal pipe, it is more rigid than tubular structure 21. Ex-1007, 3:54-55, Fig. 3; Ex-1005, ¶¶ 207-213; Ex-1042, ¶¶ 70-71, ¶¶ 64-69. Given the differences in the materials that are used to form tubular structure (21) and the side opening of tubular portion 24, the flexural modulus of the segment defining the side opening is necessarily greater than the flexible modulus of tubular struture 21. Ex-1005, ¶¶ 207-213; Ex-1042, ¶¶ 70-71, ¶¶ 64-69.

R. Claim 47: The system of claim 25, wherein a distal portion of the guide extension catheter is configured to anchor within the ostium of the coronary artery and resist axial and shear forces exerted by the one or more received stents or balloon catheters that would otherwise tend to dislodge the distal portion.

Itou discloses claim 47. Ex-1005, ¶¶ 214-228. The distal portion of the guide extension catheter is the tubular portion of Itou's suction catheter (2). Ex-1007, Figs. 1B, 3. Itou teaches that the distal portion of catheter 2 (tubular portion 24) is advanced through guiding catheter 1 and into the coronary artery. Ex- 1007, Abstract, 3:1-3; 5:26-46. Ex-1005, ¶¶ 214-215. Itou also teaches that the proximal portion of tubular portion (24) remains within the lumen of guiding catheter (1). Ex-1007, Fig. 6, 3:1-3, 5:26-46.



Id., Fig. 6 (color added, illustrating tip (22) (pink) and a portion of tubular structure (21) (blue)); Abstract, 1:46-65; 5:38-42. Thus, Itou discloses the structural limitations of claim 47, which is a systems claim.[13] Ex-1005, ¶¶ 214-215.

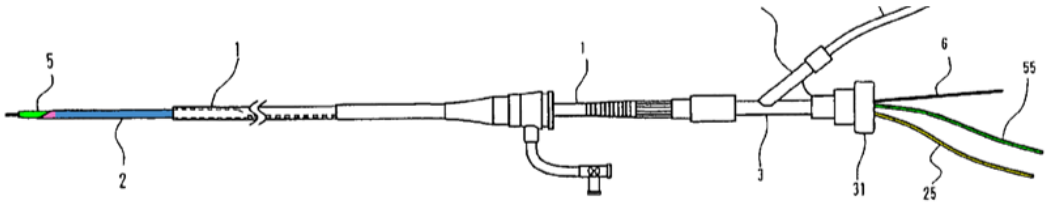
To the extent that Patent Owner suggests that claim 47 requires anything more

[13] Claim 47 includes additional language that the "distal portion of the ***guide extension catheter***" is configured to "anchor within the ostium." That cannot be correct as the '760 patent specification teaches that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter can be advanced further into the coronary artery. Ex-1001, Fig. 8. For purpose of this IPR, Petitioner assumes this is a claim drafting error. Similar to the '760 patent, Itou teaches that the distal end of guiding catheter 1 "is hooked at ostium 821 of a coronary artery 82." Ex-1007, Fig. 6, 5:32-34.

than the cited disclosure in Itou, it is mistaken. Claim 47 additionally recites an intended use ("resist axial and shear forces exerted by the one or more received stents or balloon catheters that would otherwise tend to dislodge the distal portion"), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.")

Regardless, as Dr. Brecker explains, Itou discloses the remainder of claim 47 to a POSITA. Ex-1005, ¶¶ 216-228. First, Itou additionally teaches that distal end protective catheter (5) may be extended through suction catheter (2) and beyond its distal tip. Ex- 1007, 1:66-2:11, 4:43-52, Fig. 5.

FIG.5



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

Second, long before the '760 patent, those working in the field knew that in order to advance an interventional cardiology device through GC into the coronary vasculature, the GC had to have "sufficient stiffness to offer 'backup' support." Ex-1015, 548; Ex-1005, ¶¶ 220-225. As Dr. Brecker explains, and as taught in

Grossman's Cardiac Catheterization, Angiography and Intervention, the support came from the GC's shape, and the intrinsic stiffness of its material, as well as from its "deep engagement" with the coronary ostia. *Id*., 549; *and see* Ex-1041, 20 (Kern's The Interventional Cardiac Catheterization Handbook).

The '760 patent also admits that because the disclosed, coaxial extension catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery," it "assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion . . . ." Ex-1001, Abstract; *and see id.*, 5:14-34. According to the '760 patent's own disclosure, it is the combination of a GC ***and*** an extension catheter inserted into a coronary ostium that improves distal anchoring of the system and provides "stiffer back up support" than a GC alone. *Id*., 8:20-30. But this is no different than what was already known in the prior art and disclosed in Itou. Ex-1005, ¶¶ 226, 228.

The '760 patent further admits that back-up support is achieved where the differential between the inner diameter of the guide catheter and the inner diameter of the coaxial catheter is between 0.20 and 0.35 mm (0.008 and 0.014 inches). Ex-1001, 3:28-43. Itou teaches a differential between the inner diameters of guiding catheter (1) and suction catheter (2) that is precisely within the range taught by the '760: 0.3 mm. Ex-1007, Table 1; Ex-1005, ¶ 227. And Itou's

disclosure of a suction catheter that is extended through a GC (and beyond its distal tip into a branch artery)—and used to deliver a distal end protective catheter—inherently discloses a device that "resist[s] axial and shear forces exerted by the one or more received stents or balloon catheters that would otherwise tend to dislodge the distal portion" of the catheter from the coronary artery. Ex-1005, ¶¶ 214-228; *see also* ¶¶ 72-84.

VIII. GROUND 2: ITOU RENDERS CLAIMS 25, 30, 32, 39 AND 40 OBVIOUS IN VIEW OF RESSEMANN AND THE COMMON KNOWLEDGE OF A POSITA.

A. Ressemann

Ressemann was filed on August 9, 2002, issuing as U.S. Pat. No. 7,604,612 on October 20, 2009. It is prior art under both pre-AIA §102(e) and post-AIA §102(a)(1),(2), and was not cited or considered during prosecutions of the original '850 patent, or the '760 reissue patent. Exs-1001-1003.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1008, Abstract. The assembly includes a GC, which "may be positioned within the ostium of a target vessel," *id*., 12:26-27, and an evacuation sheath that is coaxially insertable through the GC, and advanceable beyond the GC's distal end to treat stenosis. *Id*., Abstract, Figs. 6A-F, 6:18-24, 12:9-14:39.

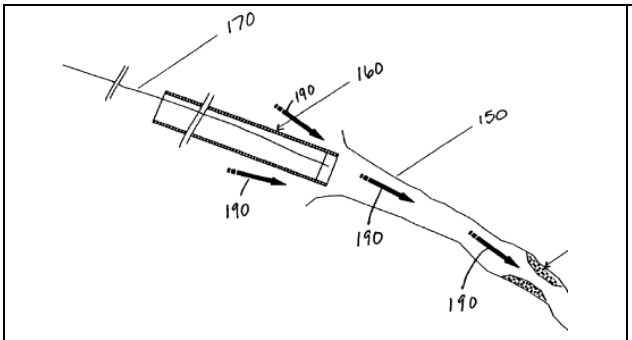


FIG. 6A

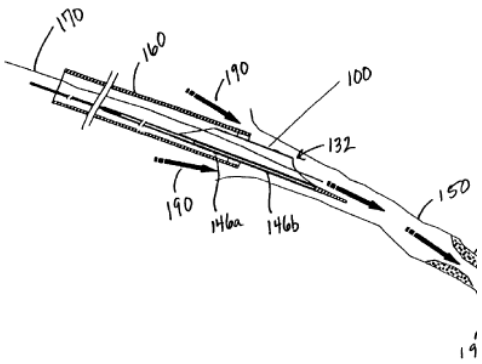
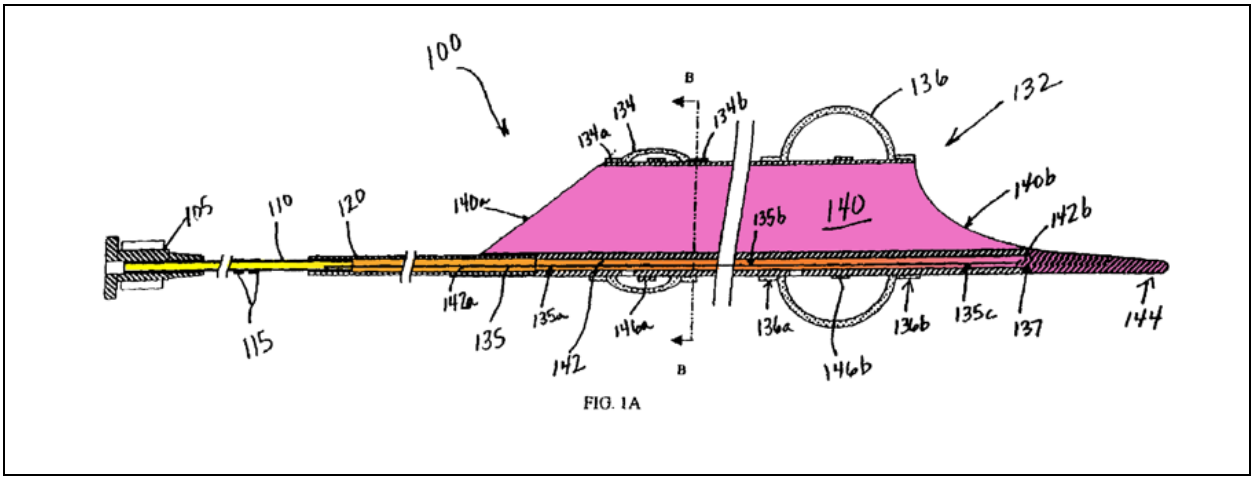


FIG. 6B

Id., Figs. 6A-B.

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.

The evacuation sheath includes a distal evacuation head and a shaft. *Id*., 6:19-20, Figs. 1A, 1C, 11A. The head is "preferably made of a relatively flexible polymer such as low-density polyethylene, polyurethane, or low durometer Pebax® material." *Id*., 6:36-39. (Illustrated below in pink).



Id., Fig. 1A (color added).

The shaft includes proximal, intermediate, and distal portions. Proximal shaft (110) (above, yellow) is a hollow tube preferably made of stainless steel, but which may also be made of polymer and metal composites. *Id*., 10:36-42. Intermediate shaft (120) (yellow transitioning to pink) —a hollow, polyethylene or Pebax tube—is more flexible than shaft (110). *Id*., 10:63-11:10. Distal shaft (transitioning to pink) includes the evacuation head, *id*., 10:31-35, as well as an inflation lumen for sealing balloons (134, 136), and may include soft distal tip (144) made of a polymer more flexible than the head, so as to ensure atraumatic insertion into blood vessels. *Id*., 11:11-28; Ex-1005, ¶¶ 99-102, 152-156; Ex-1042, ¶¶ 47-52.

As explained in §VII, *supra*, Itou's suction catheter (2) has the structure that would allow it to receive "one or more stents or balloon catheters when the segment defining the side opening" is positioned within the guide catheter (claim 25) and includes a "concave track" (claim 30). To the extent Patent Owner argues

that Itou's teachings—alone—are insufficient to anticipate claims 25 and 30, then they are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA.[14] Itou in combination with Ressemann also renders claims 32, 39 and 40 (not discussed in §7) obvious.

B. Claim 25

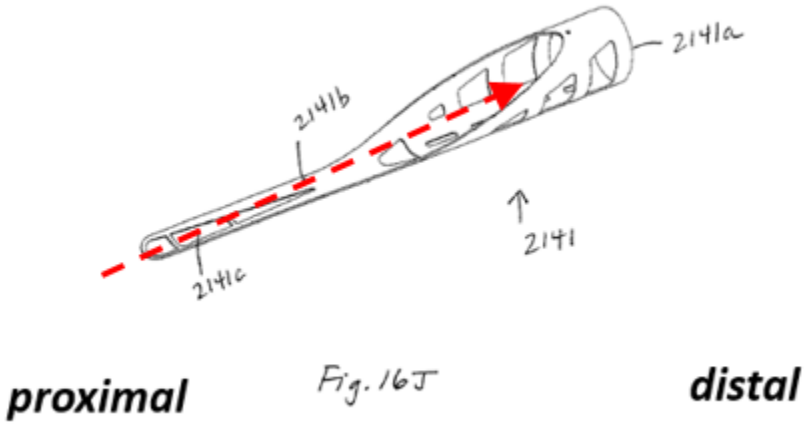
Claim Language	Evidence & Corresponding Disclosure
[25.pre] through [25.c.ii]	*Supra*, §§ VIII.B.1-4. Ex-1005, ¶ 229.

1. [25.c.iii] "the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;"

Itou discloses structure sufficient to meet this limitation. *Supra*, § VII.B.5. In the alternative, Itou and Ressemann render 25.c.iii obvious. Ex-1005, ¶¶ 230-268.

[14] The cited disclosures, references and arguments set forth in §VII are fully incorporated in §VIII.

First, Ressemann discloses a support collar 2141 that defines a side opening that is "accessible from a longitudinal side defined transverse to the longitudinal axis." (dotted arrow below)



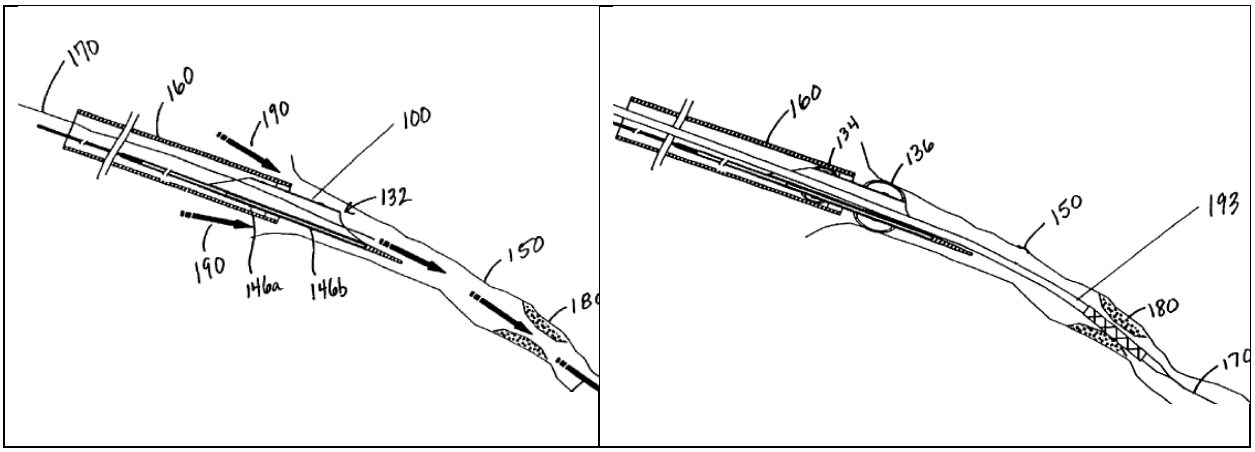
Ex-1008, Fig. 16J (annotation added).

Cylindrical portion 2141a "fits into the proximal opening of the evacuation lumen," providing hoop support. *Id.*, 24:55-58. The concave track portion of the collar, referred to as "distal tab 2141b" serves as a "flexibility transition" between the proximal end of the evacuation head and the evacuation sheath's shaft. *Id.*, 24:62-67.

As discussed for claim 30, *infra* § VIII.C, a POSITA had the motivation to combine the teachings of Itou with those of Ressemann, including to replace Itou's proximal tip (23) with the support collar disclosed in Ressemann. Ex-1005, ¶¶ 267-268; *see also* ¶¶ 269-273.

Ressemann discloses a side opening and lumen of a tubular structure that is "configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter."

Ressemann's evacuation head has a diameter that is large enough to "allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, atherectomy catheters . . . ." Ex-1008, 10:17-21; 12:3-8. Ressemann further teaches that the evacuation sheath should be advanced through a GC until the head's (a) distal end is distal to the distal end of the GC; and (b) proximal end remains in the GC. *Id*., 12:19-26, Fig. 6B (below, left).



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

As Dr. Brecker explains, a POSITA would be motivated to combine the teachings of Itou and Ressemann because of Ressemann's explicit teaching that it was advantageous for an aspiration catheter to include a distal lumen of sufficient diameter for use in delivering an interventional cardiology device. *See also* Ex-1019, 3:4-6, 3:34-36 (explaining that an aspiration catheter is "preferably sized so as to allow the slidable insertion of a therapy catheter through the main" lumen of the aspiration catheter); Ex-1005, ¶¶ 231-240. And this is because angioplasty and coronary artery stenting come with a risk of embolization. *Id*., ¶¶ 241-249; Ex-1028, 1285; Ex-1029, 172, 176.

Those working in the field knew that PCI such as angioplasty or stent delivery "may break free fragments of friable plaque." Ex-1005, ¶ 249; Ex-1015, 629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was a motivation to combine stent delivery with the use of an embolic protection device, Ex-1015, 629-30, and a reasonable expectation of success. Ex-1028, 1285 ("Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire."); Ex-1029, 172, 176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of an embolic protection device in conjunction with stenting); Ex-1005

¶¶ 120-24, 231-49. 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. *Id.*, ¶¶ 239, 250; Ex-1008, 14:29-34 ("In some instances, once the particulate . . . has been removed, additional contrast delivery to the blood vessel may indicate a need for more therapeutic steps, e.g., further dilation of the stent with the balloon. In this case, it is more convenient to have the balloon catheter already in position for any subsequent use.")

The inner lumen of Resseman's sheath is "approximately 0.061 inches," allowing for the "passage of most therapeutic devices such as angioplasty catheters [and] stent delivery catheters . . . ." Ex-1008, 10:17-21, 22:63-23:4. PTCA catheters were insertable through support catheters with an 0.045 inch inner lumen. Ex-1009 ("Kontos"), 4:46-50, 4:61-64. Angioplasty procedures had been performed through 4 French diagnostic catheters. Ex-1020 ("Mehan"), 22. Ressemann, Kontos and Mehan disclosed prior art catheters, which, respectively, had inner lumen diameters of approximately 1.54 mm, 1.14 mm and under 1.33 mm. Ex-1005, ¶¶ 251-255.

Similarly, Itou taught a suction catheter with an inner diameter of 1.5 mm, Ex-1007, Table 1. By reference to Ressemann, Kontos and Mehan, a catheter with an inner diameter of 1.5 mm is large enough to accommodate the insertion of a therapy catheter. Ex-1005, ¶¶ 256-257.

Moreover, an inner diameter of 1.5 mm corresponds to an inner diameter of 0.059 inches. As Dr. Brecker explains, the suction catheter could be inserted into guiding catheter (1), and—as taught by Ressemann—used to receive a balloon-expandable stent. Several such stents, of the appropriate size, were available at the time of the purported invention of the '760. Ex-1022, 3 (requiring a > 0.056 in. (1.4 mm) inner catheter diameter for CYPHER stents between 2.50-3.0 mm on an RX delivery system); Ex-1023, 9 (requiring a minimum, inner catheter diameter of 0.56 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1024, 10 (requiring an inner catheter diameter $\geq$ 0.058 in. (1.47 mm) for TAXUS Express stents on a monorail delivery system). Ex-1005, ¶¶ 258-262.

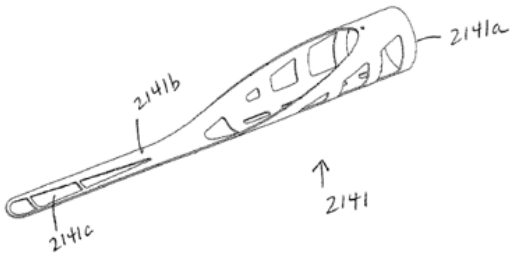
Indeed, evidence that combining Itou and Ressemann is appropriate exists in Itou's prosecution history. There, the examiner rejected pending claims on a suction assembly based on a prior angioplasty balloon catheter because the latter was "capable of being an intravascular foreign matter suction assembly." Ex-1021, 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, ¶¶ 263-266.

Claim Language	Evidence & Corresponding Disclosure
[25.d]	*Supra*, §VII.B.6. Ex-1005, ¶ 268.

C. Claim 30: The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

To the extent that Patent Owner argues that Itou's suction catheter does not meet the limitations of claim 30, *supra*, §VII.G, Itou and Ressemann (alternatively) render claim 30 obvious. Ex-1005, ¶¶ 269-273.

Ressemann discloses a support collar 2141, which includes a concave track. In the figure below, the concave track runs from the proximal end of the collar, terminating toward its distal end (i.e. the portion of the collar that becomes "fully circumferential"). Ex-1005, ¶¶ 267-269; Ex-1042, ¶ 88; *Supra*, §6 (construing "concave track").



proximal Fig. 16J **distal**

Ex-1008, Fig. 16J (annotated).

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

First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because s/he understood that it was configured to receive one or more stents or balloon catheters. *Supra*, 25.c.iii. And by modifying the proximal opening of suction catheter (2) with Ressemann's collar 2141, a larger area for receiving a stent and/or balloon catheter would be achieved. Ex-1005, ¶¶ 271-272; Ex-1042, ¶¶ 85-91, 94-95.

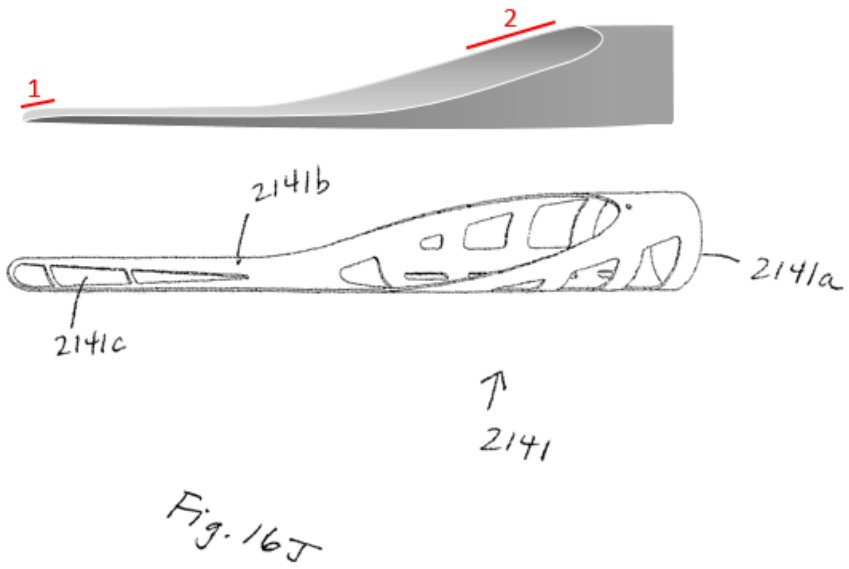
Second, the concavity of tab 2141b ensures that adding the collar does not impede entry into the evacuation lumen. Ressemann teaches that the advantage to having an angled opening is that it "facilitate[s] smoother passage of other therapeutic devices" through the lumen. Ex-1008, 6:52-57, 23:17-20; Ex-1005, ¶ 109. The collar adds material to the opening of the lumen, with a wall thickness of 0.002 inches and a width of between 0.020 and 0.050 inches. Ex-1008, 25:8-13. However, because tab 2141b is concave, it does not interfere with introducing a balloon or stent catheter into the angled opening of the inflation lumen. Ex-1005, ¶ 273; Ex-1042, ¶¶ 91, 94-95. The same holds true for adding the collar to the proximal opening of the tubular portion of Itou's suction catheter 2.

D. Claim 32: The system of claim 25, wherein the segment defining the

side opening includes at least two inclined slopes.

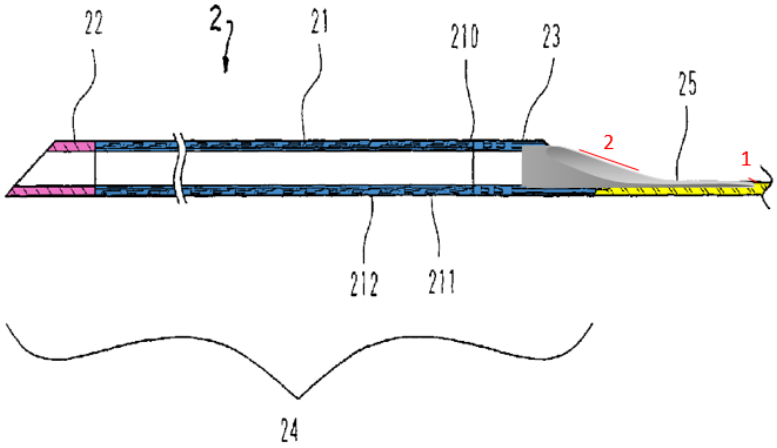
As discussed above, a POSITA had the motivation to add Ressemann's support collar, Ex-1008, Fig. 16J, to the proximal opening of Itou's suction catheter (2). *Supra*, § VIII.B-C. In addition to rendering claims 25 and 30 obvious, this combination also renders claim 32 obvious. Ex-1005, ¶¶ 274-277.

Ressemann's support collar 2141 has a first inclined slope at its proximal end (shown as "1" below), a flat, non-inclined region, and a second inclined slope at its distal end (shown as "2" below). Ex-1005, ¶ 274; Ex-1042, ¶¶ 92-93, *see also* ¶¶ 96, 98-102. These inclined slopes are similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1005, ¶ 274; Ex-1042, ¶ 103.



Ex-1008, Fig. 16J (annotated and colored).

Thus, adding support collar 2141 to Itou's suction catheter 2 discloses a side opening according to claim 32, which includes "at least two inclined slopes." Ex-1005, ¶¶ 275-277.



Ex-1007, Fig. 3 (color added) (modified with support collar 2141 (shown in gray)).

Thus, Itou in view of Ressemann renders claim 32 obvious. Ex-1005, ¶¶ 274-277.

E. Claim 39: The system of claim 38, further comprising a stent releasably joined to the distal end of the elongate balloon catheter.[15]

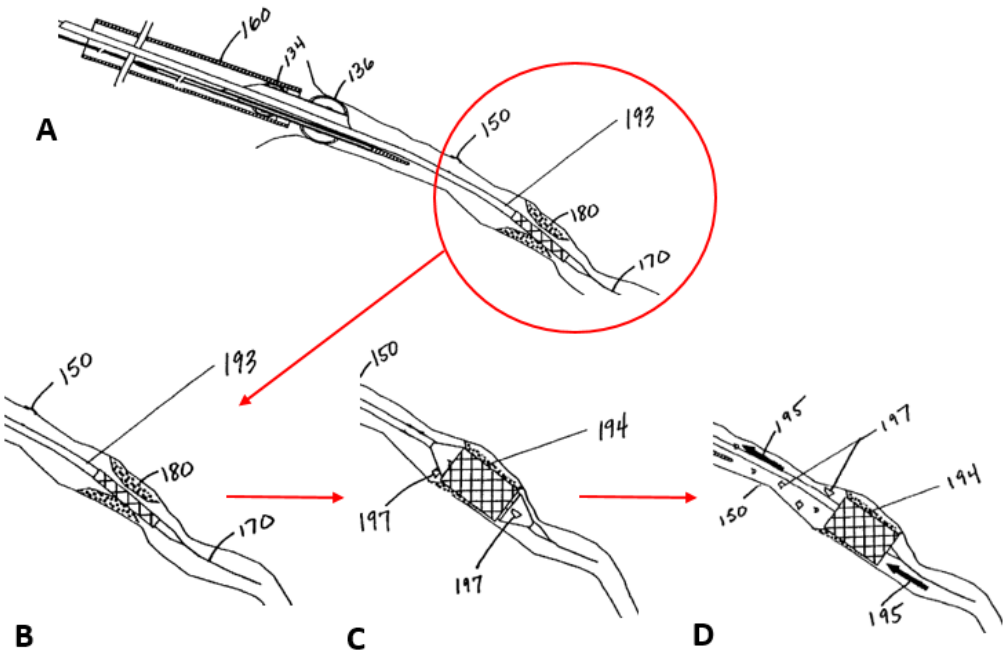
[15] There is no antecedent basis for "the elongate balloon catheter." The claim only makes sense if the elongate balloon catheter refers to one of the "one or more stents or balloon catheters" recited in claim 25.

Itou discloses claim 38. *Supra*, §VII.N. Itou in combination with Resseman renders claim 39 obvious. Ex-1005, ¶¶ 278-280.

Both Itou and Ressemann teach catheters that are extended past the distal end of a GC and into a coronary artery for the purpose of treating an occlusion. Ex-1007, Figs 1A, 1B, 5, 6, Abstract, 1:13-18, 1:66-2:5, 3:59-63, 5:32-34, 7:7-10; Ex. 1008, Figs. 6A-F, Abstract, 6:18-24, 12:9-14:39. Moreover, the structure of Itou's suction catheter (2) is similar to that of Ressemann's evacuation sheath (100). *Compare* Ex-1007, Figs. 1B, 3 *with* Ex-1008, Fig. 1; *and see supra*, §§VII.A, VIII.A, *infra*, § VII.F.

Itou discloses a distal end protective catheter (5) may be inserted through suction catheter (2), and, additionally, that suction catheter (2) is large enough to accommodate insertion of a balloon or stent catheter. *See, e.g.*, *supra*, §VIII.B. While Itou does not disclose "a stent releasably joined to the distal end of [an] elongate balloon catheter," Ressemann does.

Ressemann teaches an "elongate balloon catheter," stent delivery system 193, which is used to deliver a stent across a stenosis 180. Ex-1008, 13:57-14:16; Figs. 6E-G.



Id., Figs. 6E-G (color and annotations added).

As illustrated above, in Figure 6E (panels A, B), a "stent delivery system" is advanced across stenosis (180). *Id*., 13:57-60. Figure 6F (panel C) shows "a stent delivery balloon is inflated to expand a stent 194 against the vessel wall." *Id*., 14:7-10. Figure 6G (panel D) shows the deflation of the balloon after the stent is in place, *id*., 14:14-16, demonstrating that stent 194 is "releasably joined" to the distal end of "elongate balloon catheter" 193. Ex-1005, ¶¶ 278-280.

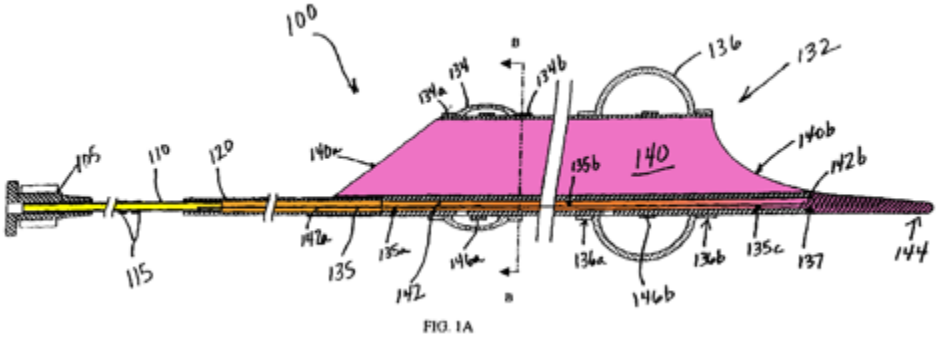
As Dr. Brecker explains—and as set forth, *supra*, §§ VII.B.5, VIII.B.1—a POSITA would be motivated to combine the disclosure in Ressemann of a balloon-deliverable stent (i.e. a stent releasably joined to the distal end of the elongate

balloon catheter) with Itou's suction catheter (2), and have a reasonable expectation of success. Ex-1005, ¶¶ 278-280.

F. Claim 40: The system of claim 25, further comprising an elongate balloon catheter partially insertable within the guide catheter alongside the substantially rigid segment, through the side opening, and through the lumen of the tubular structure.

For the same reasons that Itou in combination with Ressemann renders claim 39 obvious, claim 40 is also obvious. Ex-1005, ¶¶ 281-282.

Just like Itou, *supra*, §VII.B, Ressemann discloses a guide extension catheter that has a substantially rigid segment, a side opening, and a tubular structure with a lumen.



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

In Ressemann, the "substantially rigid" segment of evacuation sheath (100) is the evacuation shaft, specifically proximal shaft (110) and intermediate shaft (120), which is used to advance the evacuation sheath through a guide catheter so that the sheath's distal end is extended into a vessel to treat a stenosis. Ex-1008, 6:19-24,

10:47-11:14; Ex-1005, ¶¶ 281-282.

Thus, the evacuation shaft (110) and (120) is sufficiently rigid to allow evacuation sheath (100) to be advanced within the guide catheter, as shown in Figures 6A-F, and meets the limitation. *Supra*, §VI (construing "substantially rigid"). Ressemann also discloses a side opening, (140a), and a "tubular structure with a lumen," evacuation head (132). Ex-1008, 6:35-47, 6:52-57; Ex-1005, ¶¶ 281-282.

As illustrated below, elongate balloon catheter (139) (green) is partially insertable within guiding catheter (160) alongside the evacuation sheath's shaft (yellow), through side opening (140a), and through lumen 140 (pink) of evacuation head (132).

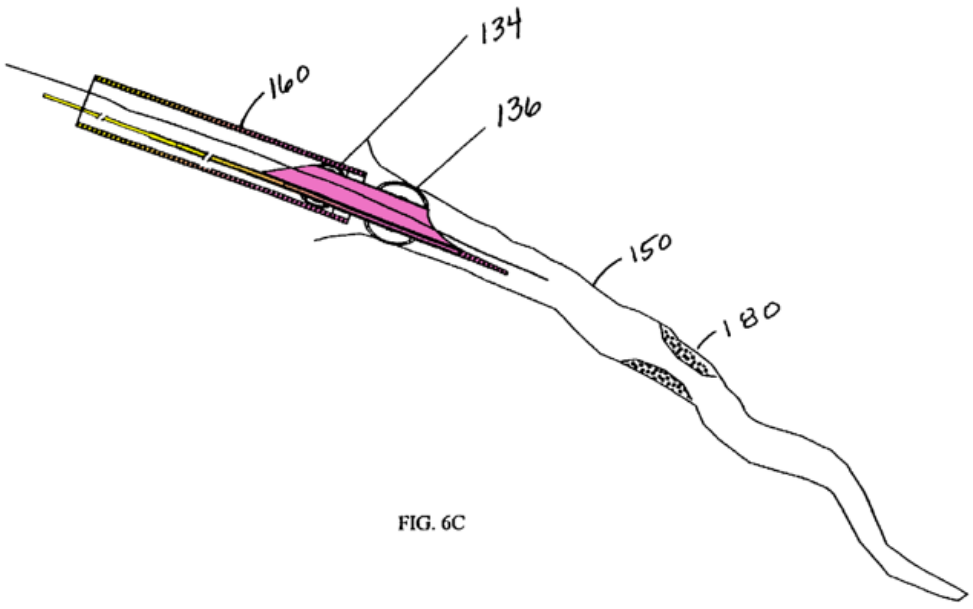


FIG. 6C

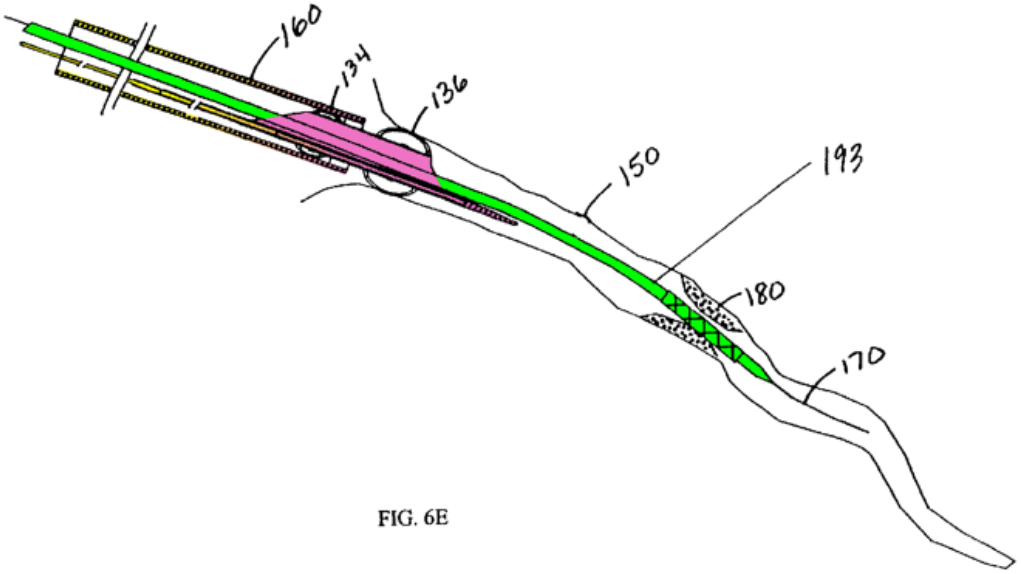


FIG. 6E

Ex-1008, Figs. 6C, 6E (color added).

For the reasons set forth above, *supra*, §VIII.B.1, D, Itou in combination with Ressemann renders claim 40 obvious. Ex-1005, ¶¶ 281-282.

IX. GROUND 3: ITOU RENDERS CLAIM 32 OBVIOUS IN VIEW OF KATAISHI AND THE COMMON KNOWLEDGE OF A POSITA.

A. Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under pre-AIA §102(b) and post-AIA §102(a)(2). Ex-1025. During prosecution of the ’760 patent (and its previous iteration, the ’850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. Exs-1001-1003.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1025, [0001]; Ex-1005, ¶¶ 157-61. It teaches a distal opening with two

inclines designed, in part, to improve the catheter's "crossing ability," which is its ability to smoothly reach a desired target site. *Id.*, Abstract, [0001]. In addition to providing flexibility, the two-incline shape of the catheter's distal opening also improves its ability to suction thrombi, *id.*, Abstract [0026]-[0027], Fig. 10, which corresponds to loading a thrombus into the catheter's distal end. Ex-1005, ¶¶ 113-117, 285, 287, 289; Ex-1042, ¶¶ 53-60, 104,105.

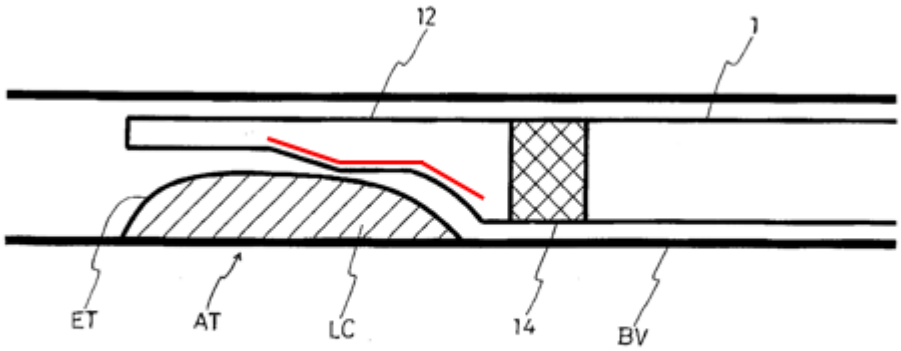
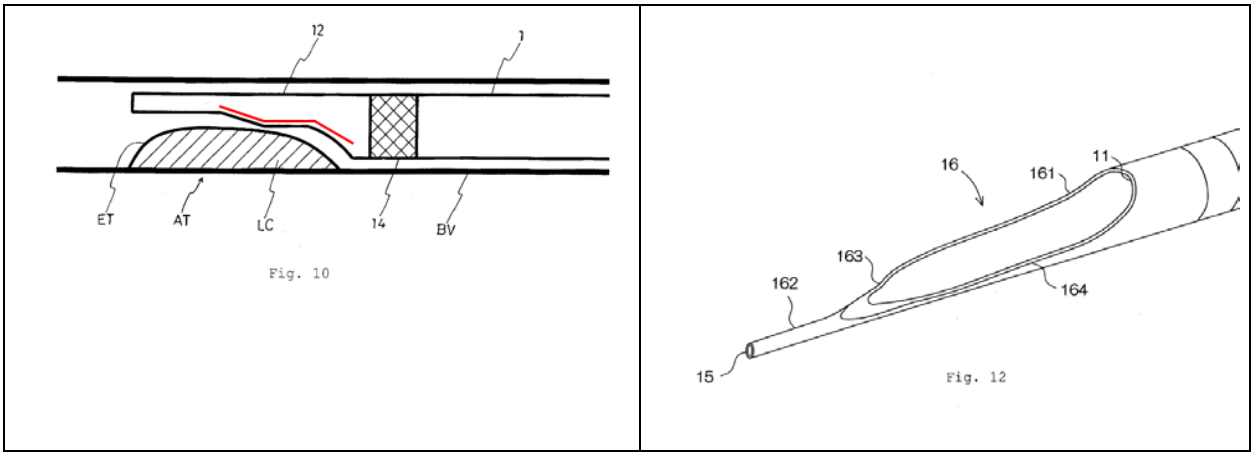


Fig. 10

Ex-1025, Fig. 10 (annotation added).

The distal end has an "angled cut surface, in which at least a part on the proximal end side of the angled surface is formed in a concave shape in the angled direction and the distal end side of the cut surface is formed to be flat and flexible . . . ." *Id.*, [0010]. The catheter tip is shown below. *Id.*, Figs. 2, 12 (annotation added).

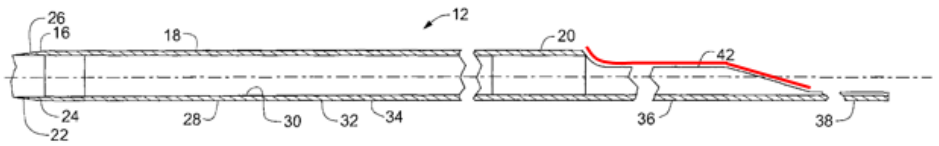


Cut surface 16 has a concave shape 161 that is closest to the fully circumferential portion of catheter lumen 11. The concave shape is adjacent "ledge surface 164," which is parallel to the catheter's longitudinal axis. Moving distally, "cut surface 163 defining an angle with the longitudinal axis of the catheter." *Id*., [0027]; Ex-1042, ¶¶ 106-107; Ex-1005, ¶ 283.

B. Claim 32: The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

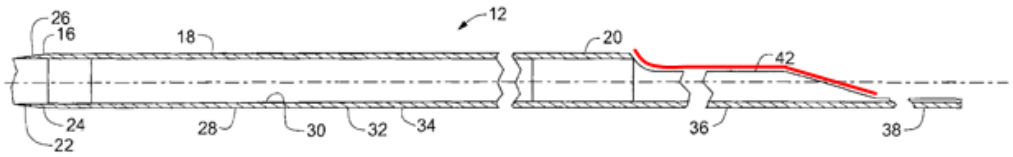
As discussed in § VII.D, Itou in view of Ressemann renders claim 32 obvious. Itou in view of Kataishi also renders claim 32 obvious. Ex-1005, ¶¶ 283-291.

In an attempt to support claim 32, patentee represented to the Examiner that Figure 4 of the '760 patent showed two different inclined slopes in the side opening. Ex-1003 at 112 (Preliminary Amendment March 3, 2014 at 18).

’760 Patent
Fig. 4 

Ex-1001, Fig. 4 (annotation added).

Of course, the disclosure in the ’760 patent is no different than what was disclosed in Kaitishi.

Fig. 4 

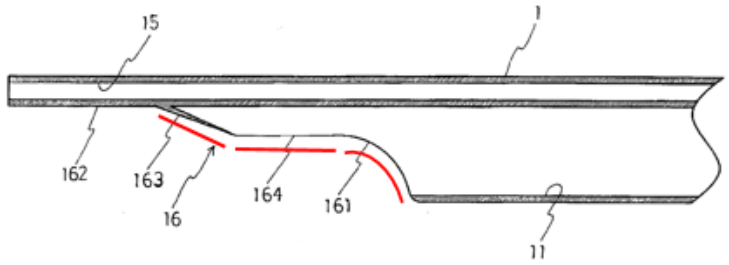


Fig. 2

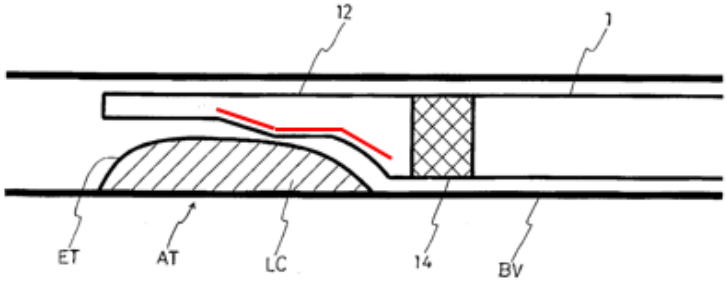


Fig. 10

(*Compare* Fig. 4 (color added), *with* Ex-1025, Figs. 2, 10; (color added)); Ex-1005, ¶ 283; Ex-1042, ¶ 112.

A POSITA had the motivation to modify the proximal opening of the tubular structure of Itou's suction catheter (2) so that it was configured to include two different inclined slopes, as disclosed in Kataishi. Itou and Kataishi are both directed at the same problem, which is treating occlusions in coronary arteries. Ex-1007, Abstract; Ex-1025, Abstract; Ex-1005, ¶ 286; Ex-1042, ¶ 104.

A POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because a POSITA would understand it was configured to receive a stent and balloon catheter. *Supra*, §§ VII.H, VIII.D. And, by modifying the proximal opening of Itou's suction catheter with the teaching of Kataishi, a larger area for receiving a stent and balloon catheter would be achieved. Ex. 1042, ¶¶ 108-109; Ex-1005, ¶¶ 287-289.

Kataishi teaches a suction catheter with a distal end that provides superior loading of matter (thrombus) into the distal end of the suction catheter. Ex-1042, ¶ 105; Ex-1005, ¶ 285. This advantage is accomplished by the shape of Kataishi's distal end. This same consideration—the ability to load something into a catheter opening—applies equally to the proximal end of a catheter, especially a catheter such as Itou. As such, POSITA would be

motivated to apply Kataishi's distal opening structure to the proximal opening of Itou for the reason set forth below.

Adding a second, inclined slope to the angled, proximal side opening of Itou's suction catheter (2) would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex-1005, ¶ 289; Ex-1042, ¶109. A POSITA would be motivated to make this modification because it would allow the catheter to receive a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1025, Abstract [0026]-[0027], Fig. 10; Ex-1055 at 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end). Ex-1005, ¶ 289; Ex-1042, ¶109.

A POSITA would have a reasonable expectation of success, as creating two different inclined slopes in the side opening would have been a routine task when manufacturing an extension catheter. Ex-1042, ¶ 110-11; Ex-1050, Fig. 7 (disclosing double incline, proximal side opening). As such, a POSITA would have a reasonable expectation of success in modifying Itou's suction catheter with the two-inclined side opening disclosed in Kataishi. Ex-1042, ¶ 110; Ex-1005, ¶ 290; Thus, claim 32 is obvious. Ex-1005, ¶¶ 284-290.

X. GROUND 4: ITOU RENDERS CLAIM 32 OBVIOUS IN VIEW OF ENGER AND THE COMMON KNOWLEDGE OF A POSITA.

A. Enger

U.S. Pat. No. 5,980,486 to Enger issued on November 9, 1999. Ex-1050. It is prior art under pre-AIA §102(b) and post-AIA §102(a)(1),(2), and was not cited or considered during prosecutions of the '850 patent. *See generally* Ex-1002. It is cited on the face of the '760 patent, but was not discussed during prosecution.[16] Ex-1001; Ex-1003. Enger discloses a balloon catheter for use in a coronary artery. Ex-1050, Abstract. Ex-1005, ¶¶ 118-19, 162-66, 291; Ex-1042, ¶¶ 61-62.

[16] Enger was not discussed in any Office Action and was not considered in combination with Itou, and thus this Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019) (explaining that a reference that "was neither applied against the claims nor discussed by the Examiner" does not weigh in favor of exercising discretion under § 325(d)); *Shenzhen Zhiyi Tech Co. v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (P.T.A.B. Apr. 2, 2018) (declining to apply § 325(d) when the reference was merely cited in a Notice of Reference Cited on face of patent-in-question).

B. Claim 32: The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

As discussed in §§ VIII.D, IX.B,[17] Itou in view of Ressemann, and Itou in view of Kataishi renders claim 32 obvious. Claim 32 is also rendered obvious by Itou in view of Enger. Ex-1005, ¶¶ 291-296.

Like Itou, Enger is directed to a catheter system for treating occluded coronary arteries. *Supra*, § VII.A; Ex-1050, Abstract, 1:13-15. Like Itou's suction catheter, Enger's angioplasty catheter is inserted through a guide catheter and into the coronary artery. Ex-1050, 3:25-29. And, like Itou's suction catheter, Enger's angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*., 3:8-12; Ex-1042, ¶¶ 113-114; Ex-1005, ¶¶ 291, 294.

Enger explains that prior art balloon angioplasty catheters that did not have a guidewire lumen running along their entire length presented a risk in that the portion of the catheter that did not have guidewire support tended to "buckle" within the guide catheter. Ex-1050, 2:31-38. This would result in friction between

[17] The cited disclosures, references and arguments set forth in § IX are fully incorporated in § X.

the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy. *Id*., 2:38-49. Ex-1005, ¶ 118, 291, 295; Ex-1042, ¶¶ 61-62.

To address the problems of prior art catheters, Enger's angioplasty catheter includes an "elongate proximal segment" (28), an intermediate segment (30), and a distal segment to which the dilation balloon (34) is mounted. *Id*., 4:66-5:11, Fig. 1.

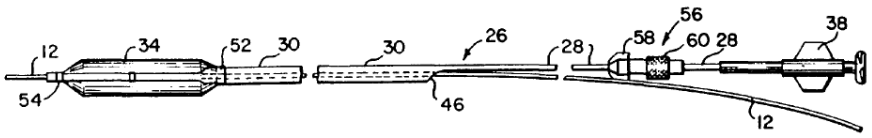


Fig. 1

The catheter is designed to have a short, distally located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*. 3:8-12, 5:34-41.

The proximal opening to the guidewire lumen has at least two inclined slopes.[18]

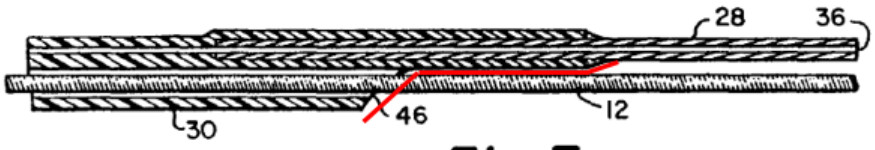


Fig. 7

Ex-1050, Fig. 7 (color added).

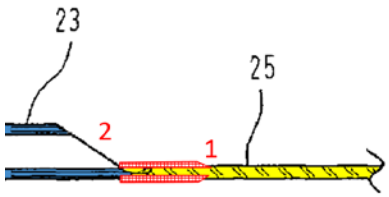
As Dr. Hillstead explains, Enger's incline #1 functions as a start of an incline ramp to the entry port located at incline #2. This incline functions to guide the interventional device (in this case a guidewire) into its designated lumen. Ex-1042, ¶ 115; Ex-1005, ¶ 296. A POSITA would be motivated to provide a first incline to function as an "on-ramp" to guide interventional devices such as distal end

[18] Enger teaches that enclosing the guidewire in a lumen in the distal and intermediate segments of the catheter (over a 35-45 cm length) is advantageous because it allows those segments to be "supported by the guidewire" that extends through the lumen. *Id*., 3:8-12, 3:21-25. This ensures that the catheter "does not tend to bind up" in the GC, facilitating advancement of the distal end of the catheter "into more distal regions of a patient's coronary anatomy." *Id*., 3:25-29.

protective device or stent and balloon catheter (5) into the lumen of Itou's suction catheter (2). Ex-1005, ¶¶ 291-296.

As Dr. Hillstead explains, the first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1042 ¶ 115. POSITA would understand that the first incline of Enger could be incorporated into Itou's suction catheter 2 by using a similarly inclined polymer collar to grip wire-like pushrod 25. Ex-1042, ¶¶ 113-117.

This would result in a two-incline opening as shown schematically in modified Figure 3 of Itou.



Ex-1007, Fig. 3 (color added and modified by Petitioner with teaching of Enger and illustrating two-incline opening).

Thus, Itou in view of Enger renders claim 32 obvious. Ex-1005, ¶¶ 291-296.

XI. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1073. The "Facts" section states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioner launched a "copycat" product *Id.*, 2, 5, 9. Patent

Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

XII. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the claims 25-42, 44, 47, 48, and 51-53 of the ’760 patent as unpatentable under 35 U.S.C. §§ 102 or 103.

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

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

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 13, 2019
800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
612.349.8500

/ Cyrus A. Morton /
Cyrus A. Morton

Attorney for Petitioner
Medtronic, Inc.

WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 12,557 words, excluding any Mandatory Notices. I further certify that, in preparation of this Corrected Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 13, 2019

/ Cyrus A. Morton /

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

Attorney for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence. was served on November 13, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

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

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

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

/ Cyrus A. Morton /

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

Attorney for Petitioners