UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner

Case No.: IPR2020-00137
U.S. Patent No. RE 47,379

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 47,379E

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I. PRELIMINARY STATEMENT

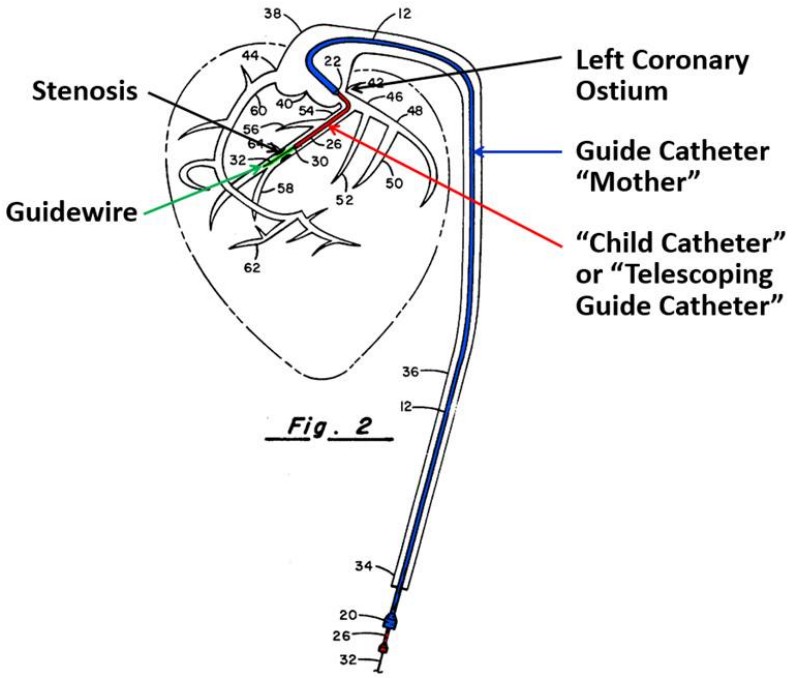
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioners") request *inter partes* review ("IPR") of claims 25-26, 29-40, and 42-45 ("Challenged Claims") of U.S. Pat. No. RE47,379 (Ex. 1001). The '379 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1001)—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id*.

The '379 patent describes a catheter system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a guide catheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*. at Abstract, Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by

[1] The '379 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1005, ¶ 75 n.8, ¶ 130. A POSITA would have recognized that the "coaxial guide catheter" of the '379 patent is what was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1009, 5:49-50 (referring to body 12 "as a guide catheter extension").

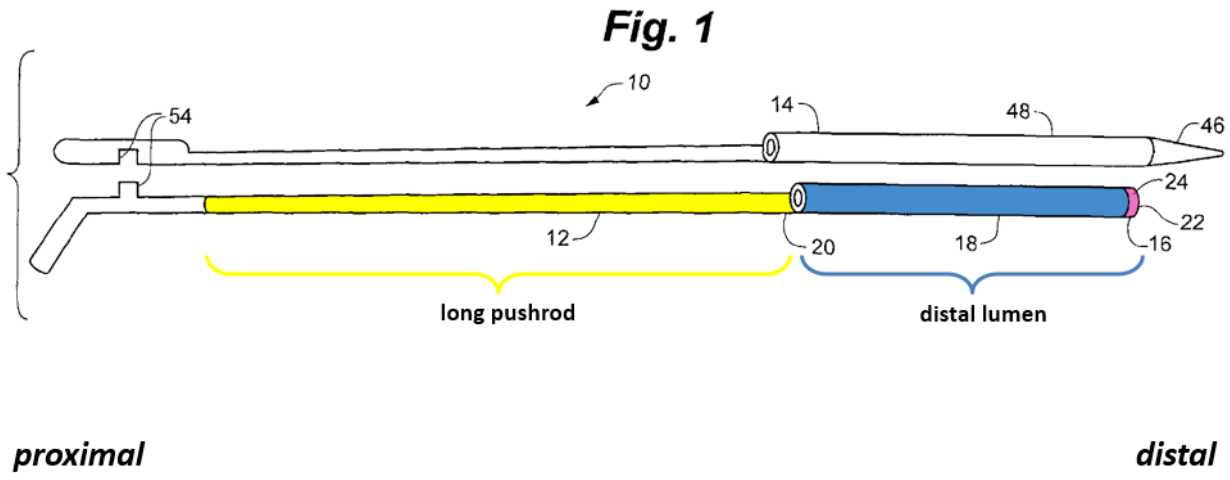
providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. Ex-1001, 3:18-22; *see also id*. at 8:39-52. Ex-1005, ¶ 131.

The '379 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. Ex-1001, 2:56-3:6 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art and described as a "mother-and-child assembly." Ex-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.* at ¶ 74.



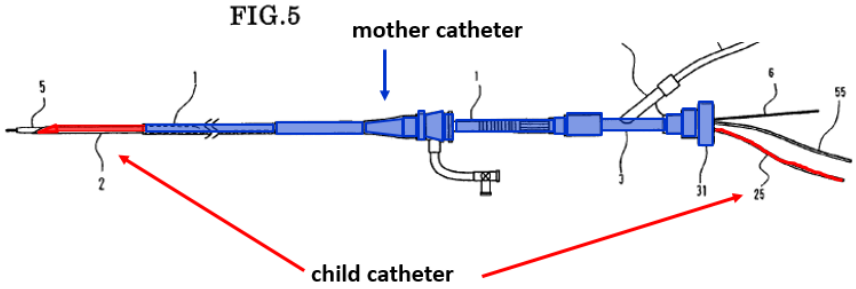
Ex-1054, Fig. 2 (color and labels added).

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. Ex-1054, Fig. 2; Ex-1005, ¶¶ 74-84. The '379 patent alleges that such a design had certain drawbacks (Ex-1001, 3:7-17) and modifies the child catheter (of the mother-and-child assembly) to have two parts: (i) a long thin pushrod coupled to (ii) a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



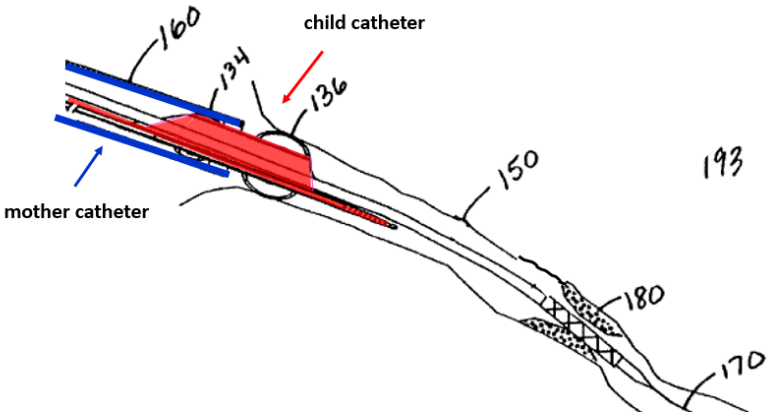
Ex-1001, Fig. 1 (annotations and color added).

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

It was also evidenced by U.S. Patent No. 7,604,612 ("Ressemann") (Ex-1008).



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

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the '379 patent are unpatentable based on the Grounds discussed below. Accordingly, Petitioners respectfully request institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of claims 25-26, 29-

40, and 42-45 of the ’379 patent as unpatentable under 35 U.S.C. §§ 102 and/or 103.

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

A. Real Party-in Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioners identify that the ’379 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 ’379 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).

Petitioners also concurrently file another petition for IPR challenging the

'379 patent based on prior art references having different priority dates and disclosures than the references discussed herein.

C. Lead and Backup Counsel

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

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D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), please direct all correspondence to lead and back-up counsel at the above addresses. Petitioners consent 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, Petitioners certify that the ’379 patent is available for IPR and that Petitioners are not barred or estopped from requesting such review of the ’379 patent on the identified grounds.

The ’379 patent issued less than 9 months before the filing of the instant IPR petition. But the prohibition against filing an IPR in the first 9 months of issuance, *see* 35 U.S.C. § 311(c)(1), is inapplicable to the ’379 patent because, *at least on its face*, the ’379 patent is a first-to-invent patent, i.e., it is not subject to the AIA’s first-inventor-to-file provisions. *See* TECHNICAL CORRECTIONS—LEAHY–SMITH AMERICA INVENTS ACT, PL 112-274, January 14, 2013, 126 Stat 2456, § 1(d)(1); 37 C.F.R. § 42.102(a)(2).

However, as explained below in **Section IV.D**, the first-inventor-to-file provisions of the AIA should apply to the ’379 patent. But even then, the ’379 patent is eligible for IPR because the 9-month proscription against IPR in § 311(c)(1) does not apply to reissue patents (such as the ’379 patent). *See* Changes To Implement the Technical Corrections to the Leahy-Smith America Invents Act as to Inter Partes Review, 78 FR 17871-72; PL 112-274, January 14, 2013, 126 Stat 2456, § 1(d)(2) (striking reissue patents from § 311(c)(1)).

B. Precise Relief Requested and Asserted Grounds

Petitioners respectfully request review of claims 25-26, 29-40, and 42-45 of the '379 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Claims 25-26, 29-31, 33-40, 42, 43 and 45 are anticipated by U.S. 7,736,355 ("Itou").
2	Claims 26, 38-40, 43-45 are rendered obvious by Itou in view of U.S. 7,604,612 ("Ressemann").
3	Claim 32 is rendered obvious by Itou and the common knowledge of a POSITA.
4	Claim 44 is rendered obvious by Itou in view of U.S. 2005/0015073 ("Kataishi") and the common knowledge of a POSITA.
5	Claim 44 is rendered obvious by Itou in view of U.S. 5,980,486 ("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, ¶¶ 32-36. This narrowing, sometimes called a stenosis,

[2] This petition is also supported by the Declarations of Dr. Stephen JD Brecker, MD (Ex. 1005), and Dr. Richard A. Hillstead (Ex. 1042), as experts in the field of the '379 patent. Petitioners also submit 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. *Id.* at ¶¶ 33, 38-44.

PCI was developed more than forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1005, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. *Id.* at ¶¶ 38, 46-59. 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. *Id.* 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.* at ¶¶ 38, 46-59, 64. At the proximal end, a hemostatic valve is coupled to the guide catheter and remains outside the patient's body. *Id.* at ¶¶ 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. Ex-1005, ¶¶ 60-62. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to the occlusion. *Id.* The therapeutic catheter typically must then be

passed through and beyond the occlusion in order to alleviate the stenosis. *Id.* at ¶¶ 63-69. This last step—crossing the guidewire and therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium.[3] *Id.* at ¶¶ 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*. at ¶¶ 72-84.

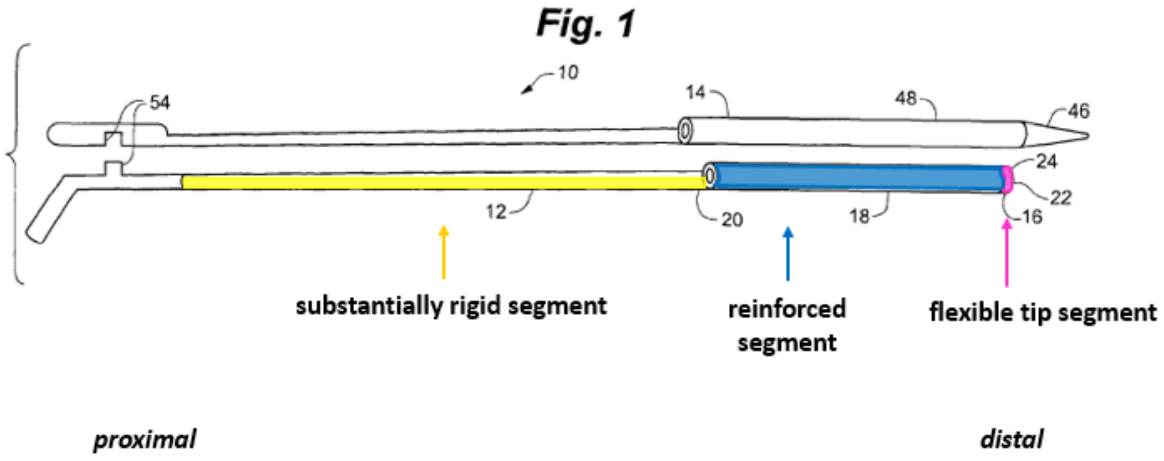
B. Overview of the ’379 Patent

The ’379 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:43-44. In particular, the ’379 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*. at Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—“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*. at 5:41-44; Ex-1005, ¶¶ 130-31.

The ’379 patent explains that the guide extension catheter 12 has a tubular portion that includes a flexible tip segment 16 (pink) and a reinforced segment 18

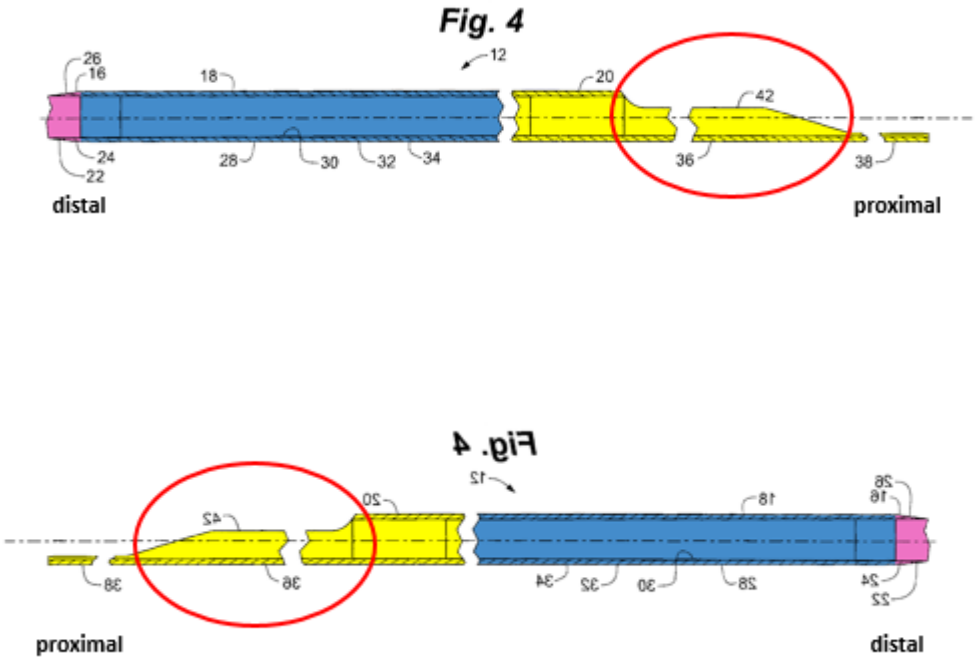
[3] During the PCI process, the proximal end of the guide catheter, guidewire, and therapeutic catheter all remain outside the patient’s body. Ex-1005, ¶¶ 72-84.

(blue), as well as substantially rigid segment 20 (yellow). Ex-1001, 4:2-4, 6:50-51, Fig. 1. Color has been added to Figure 1, below, which has been annotated with the language of claim 25. Ex-1005, ¶ 132.



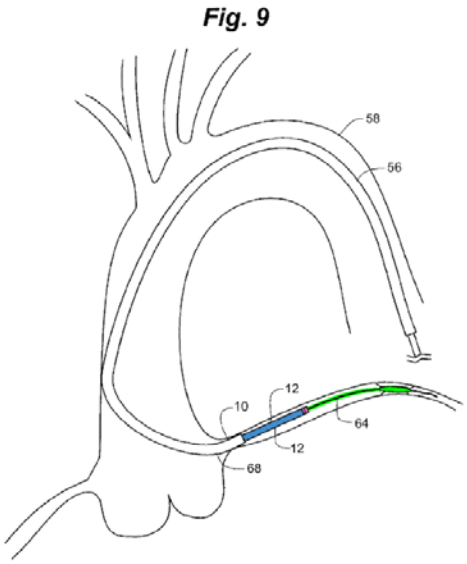
Ex-1001, Fig. 1 (color and annotation added).

The ’379 patent also recites the step of “arranging, in a proximal to distal direction, the substantially rigid segment, the side opening portion, the reinforced segment, and the flexible tip segment.” 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.* at 7:12-16, 9:13-21.



Ex-1001, Fig 4 (annotations and color added).

Regardless, the ’379 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56. Ex-1005, ¶ 134.



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

C. Prosecution History of the '379 Patent

The predecessor '850 patent issued without an Office Action. Ex-1002. According to the Examiner, the claims of the '850 patent were allowable because "adding a guide catheter to the claimed rail structure[4] 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). In other words, he believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art, but he was not aware of Itou or Ressemann.

[4] *See infra*, § VI (construing "rail structure").

Patent Owner sought reissuance in 2015. The Examiner rejected pending claims, finding (in part), that they were anticipated by U.S. Patent 5,527,292 to Adams, and U.S. Patent 5,578,009 to Kraus. Ex-1003 at 175-78 (7/20/17 Non-Final Rejection at 12-15). In response, Patent Owner distinguished the cited art by arguing that it did not teach or suggest "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape" as required by claim 25. Ex-1003 at 225-27 (1/19/18 Applicant Response at 25-27). The Examiner found the reissued claims patentable on this basis (Ex-1003 at 622 (Notice of Allowance at 2)), however, she was unaware of Itou or Ressemann.[5]

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 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

[5] A patent related to Ressemann, U.S. Pat. No. 7,959,603 (Wahr) is cited on the face of the '379 patent, but nowhere discussed and was disclosed after the pending claims were deemed allowable. Ex-1001; Ex-1003 at 617 (10/12/18 Notice of Allowance), 675 (1/11/19 Information Disclosure Statement).

Patent Owner to swear behind the Itou patent. The ’379 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority,[6] 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 ’379 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* claims 25, 38 *with* claim 42. Ex-1001. Second, claim 44 requires a side opening portion with two inclined sidewalls separated by a non-inclined region, while the only alleged support, Fig 4, discloses a non-inclined region (42) that separates an inclined region and an arc. *See* Ex-1003 at 31 (12/30/15 Preliminary Amendment at 24). Third, the ’380 patent, to which the ’379 patent claims priority, is an AIA patent because it includes at least one claim that lacks support in a pre-March 16, 2013 application. Claim 27 recites a side opening that “includes ***at least two*** different inclined slopes,” but the ’380 patent—at best—supports ***only*** two inclined slopes. Ex-1081, Fig. 4.

[6] The ’379 patent shares the same specification as all applications in its priority chain that were filed before March 16, 2013.

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 may 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,[7] 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)

The district court additionally adopted the following construction:

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

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

Petitioners agree with the above constructions[8] (Ex-1005, ¶¶ 135-140) and propose the following additional constructions:

A. "standard guide catheter" (cl. 25, 38)

As of the purported priority date, "standard guide catheter" did not refer to a guide catheter of a specific length (although 100 cm was common (Ex-1001, 3:9-10; Ex-1015, 549)) inner or outer diameter, or rigidity. Ex-1005, ¶ 148; Ex-1010, 454 (showing various "guiding catheter systems"). Further, the patent does not define "standard guide catheter," and, in fact, only uses this term (outside of the claims) once in the background when describing the drawbacks of previous catheter assemblies. Ex-1001, 3:7-8. Finally, in other parts of the patent, the specification instead refers to "typical guide catheter" or references, more simply, "guide catheters." *Id.* at 8:4-12. Thus, "standard guide catheter" does not reference a specific guide catheter and means "one of a variety of catheters used to guide devices or smaller catheters into the coronary vasculature" Ex-1005, ¶ 148.

B. "flexural modulus" (cl. 30, 39)

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

[8] Petitioners propose these constructions for purposes of this IPR only and reserve the right to raise different constructions in other forums.

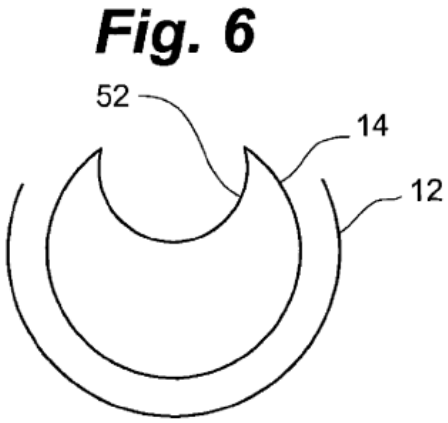
Technical Terms means "[a] measure of resistance . . . to bending." Ex. 1040, 772. In other words, the "flexural modulus" is a measure of a device's rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. Such an understanding is consistent with the '379 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex. 1001, 7:25-31; Ex. 1005, ¶¶141-42; Ex. 1042, ¶ 31. 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).[9]

C. "concave track" (cl. 43)

The '379 patent does not define the claim term "concave track." Ex-1005, ¶ 143. 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, 4:24-33, 4:47-49, 7:39-40;

[9] 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.

Ex-1005, ¶¶ 144-46. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex-1001, 7:39-40.



Ex-1001, Fig. 6.

As a result, in the context of the ’379 patent, the claim term “concave track” means a “portion that is not fully circumferential.” Ex-1005, ¶ 147.

VII. GROUND 1: ITOU ANTICIPATES CLAIMS 25-26, 29-31, 33-40, 42, 43 AND 45.

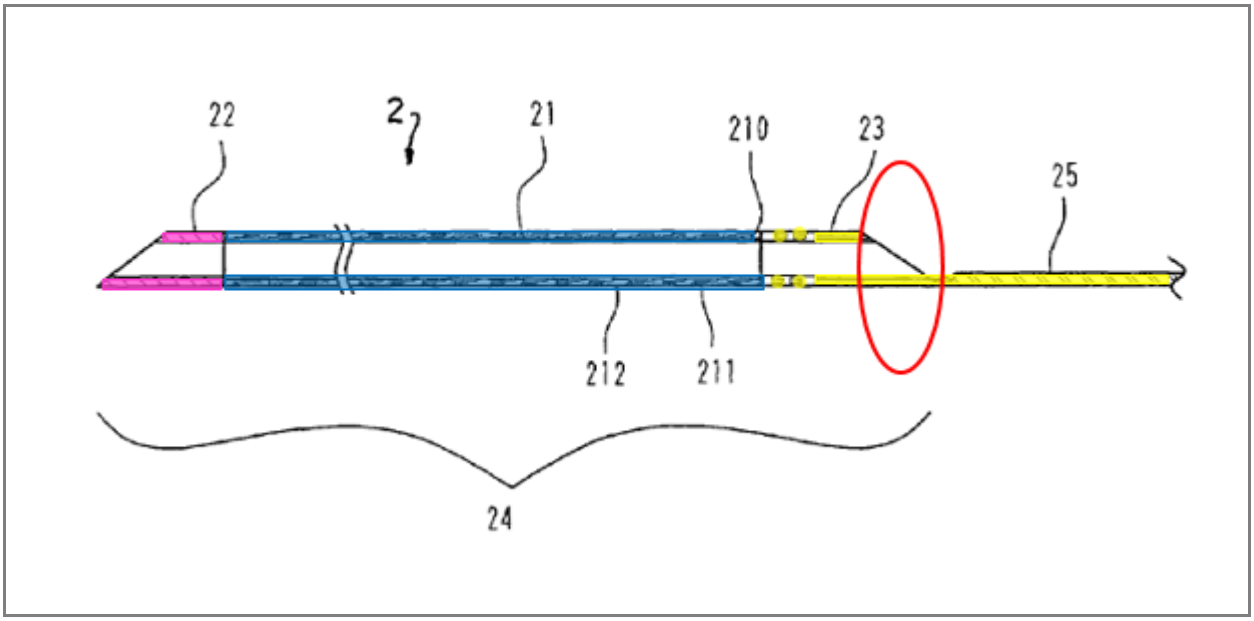
A. Itou

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)[10], and was not cited or considered during prosecutions of either the original

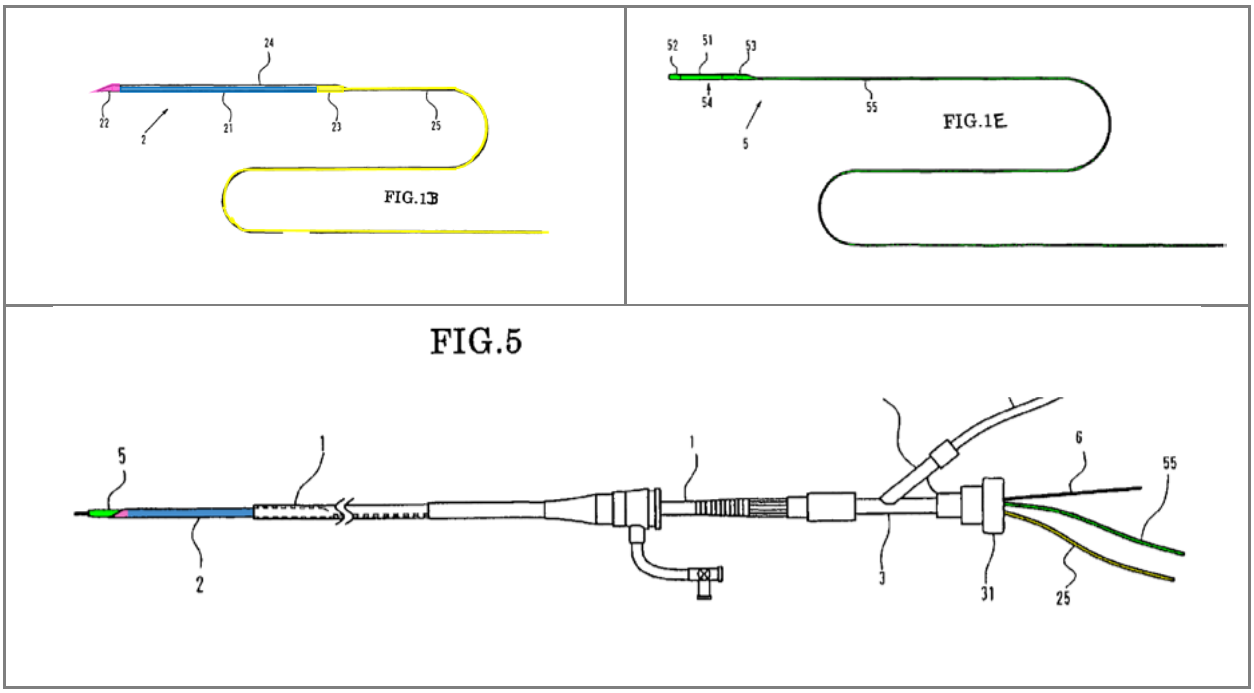
[10] The first-inventor-to-file provisions of the AIA apply to the ‘379 patent because, *inter alia*, at least one claim of the ‘379 patent (e.g., claim 25) is not entitled to an effective filing date prior to March 16, 2013.

’850 patent, or of the ’379 reissue patent. Exs-1001, 1002, 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*. at 2:2-5, Abstract, 5:32-34, 7:7-11) and a suction catheter that is insertable through the GC. *Id*. at Abstract, Figs 1A, 1B, 5, 6, 3:59-61. Suction catheter (2) has a proximal, “solid wire-like portion” (25), shown below in yellow, and a distal, tubular portion (24). *Id*. at Abstract, 1:53-60, 2:12-15, 3:46-50 (color added). Tubular member (24) includes a “soft tip whose distal end is flexible in order to reduce the damage to the blood vessel,” (22) (pink) (*id*. at 2:15-18) and a portion reinforced with a metal layer (211) (blue). *Id*. at 2:18, 3:50-56. Tubular member 24’s proximal opening is angled (red circle).



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



Id. at 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).. Suction catheter (2) may be extended beyond the distal end of the GC (1) into a coronary artery. *Id*. at Abstract, 2:29-38, Figs 5, 6. Ex-1005, ¶¶ 149-152; *see also id.* at ¶¶ 95-98; 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 '379 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, ¶¶ 94-102, 149-159. An aspiration catheter could be "preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen." Ex-1019, 3:3-5. 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*. at 3:34-36, 12:16-20; Ex-1008, 6:18-34, Figs. 6A-6I; Ex, 1005, ¶¶ 94-102, 149-159.

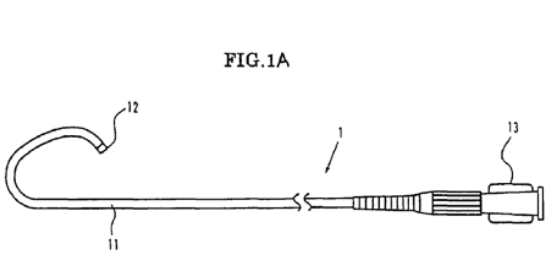
B. Claim 25

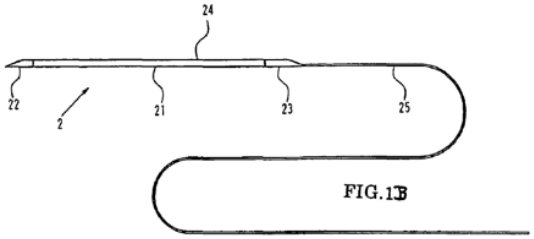
1. [25.pre] "A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:"

To the extent the preamble is limiting, the system of guiding catheter (1) (the "standard guide catheter") and suction catheter (2) ("a device adapted for use with" the same) in Itou, *infra*, 25.a through 25.g, necessarily discloses a method of forming a device according to claim 25.[11] Ex-1005, ¶¶ 173-76.

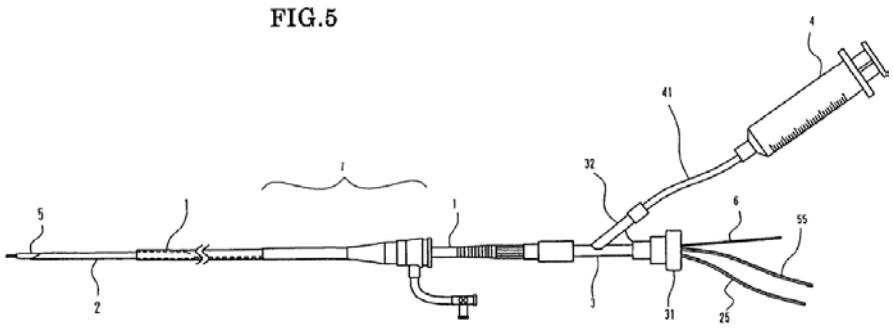
[11] The Challenged Claims are product-by-process claims as they claim "[a] method of forming a device" and then recite various structural elements of the device. Ex-1001, 13:61, 15:7. Such claims are invalid if the product in the product-by-process claims is the same as, or obvious from, a product of the prior art. *In re Brown*, 459 F.2d 531, 535 (CCPA 1972). In other words, "in determining the patentability of

Guiding catheter (1) has a predefined length of 1000 mm. Ex-1007, Fig. 1A, Table 1 (teaching a guiding catheter length of 1000 mm); Ex-1015, 549 (teaching a "standard guiding catheter length" of 100 cm); Ex-1005, ¶ 174. Catheter (1) also necessarily has a "continuous lumen extending" throughout its length, as Itou teaches that suction catheter (2) is inserted through catheter 1. Ex-1007, Abstract, 1:60-65; Ex-1005, ¶ 175.





product-by-process claim, it is not the process steps that are looked to, but rather the product itself, which is analyzed." *Ex Parte Erler*, App. No. 2012-012641, 2014 Pat. App. LEXIS 8753, **11-13 (PTAB Dec. 26, 2014). As discussed herein, the products taught in the prior art disclose the claimed products. Even if such claims are not product-by-process claims, the same disclosures in the prior art disclose the purported inventions.

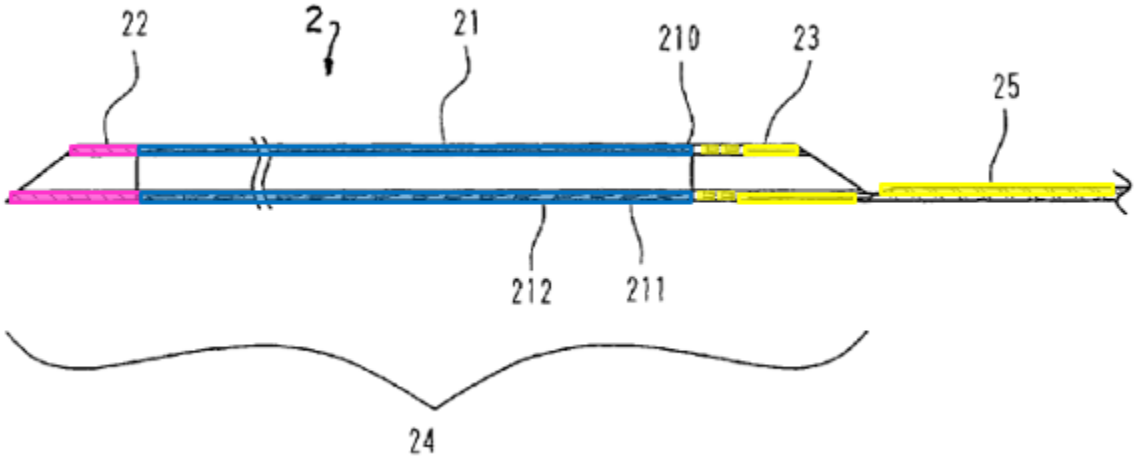


Ex-1007, Figs. 1A, 1B, 5.

Guiding catheter (1) also is used to guide suction catheter (2) into a coronary artery (*id*. at Abstract, Fig. 6, 5:26-51), evidencing that it is a "standard guide catheter." *See supra* § VI; Ex-1005, ¶ 176.

2. **[25.a] "providing a flexible tip segment having a lumen therethrough"**

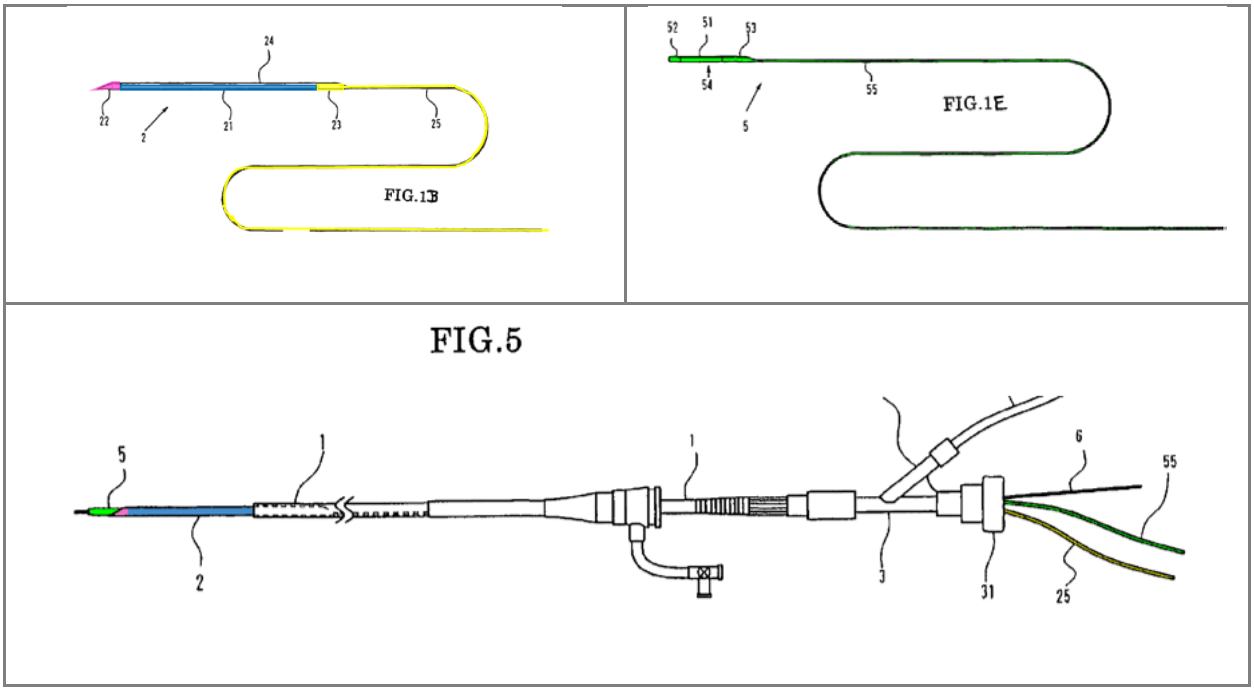
Itou discloses 25.a. Ex-1005, ¶¶ 177-79.



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

As shown above, the "flexible tip segment" of suction catheter (2) is distal tip (22) (pink), which is soft and flexible. Ex-1007, 2:15-17, 4:4-5; Ex-1005, ¶ 178.

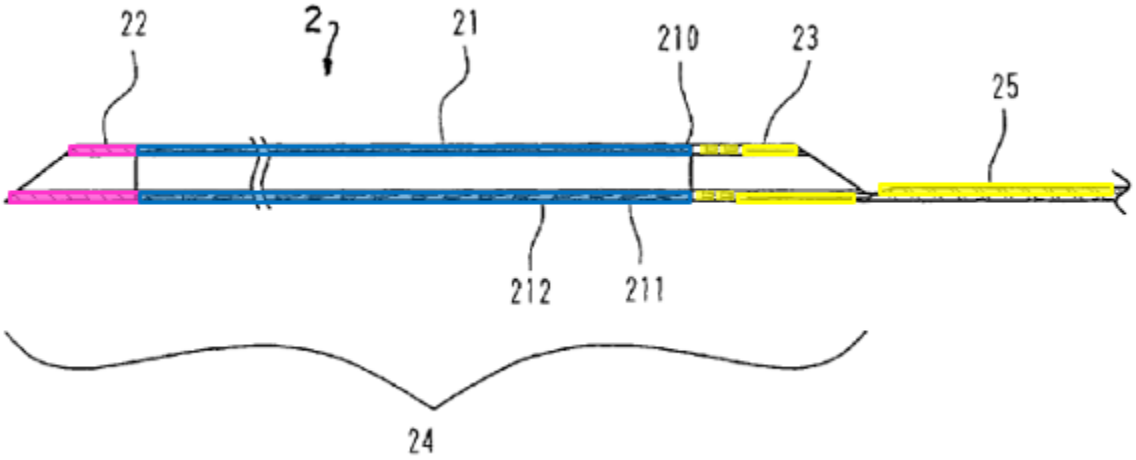
Tip (22) has a "lumen therethrough," evident by Itou's teaching that distal end protective catheter (5) may be "inserted in the lumen of the suction catheter (2) and projects from the distal end" of the same. Ex-1007, 4:48-51; Ex-1005, ¶ 179.



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

3. **[25.b] "providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer, and extending from a proximal end portion to a distal end portion"**

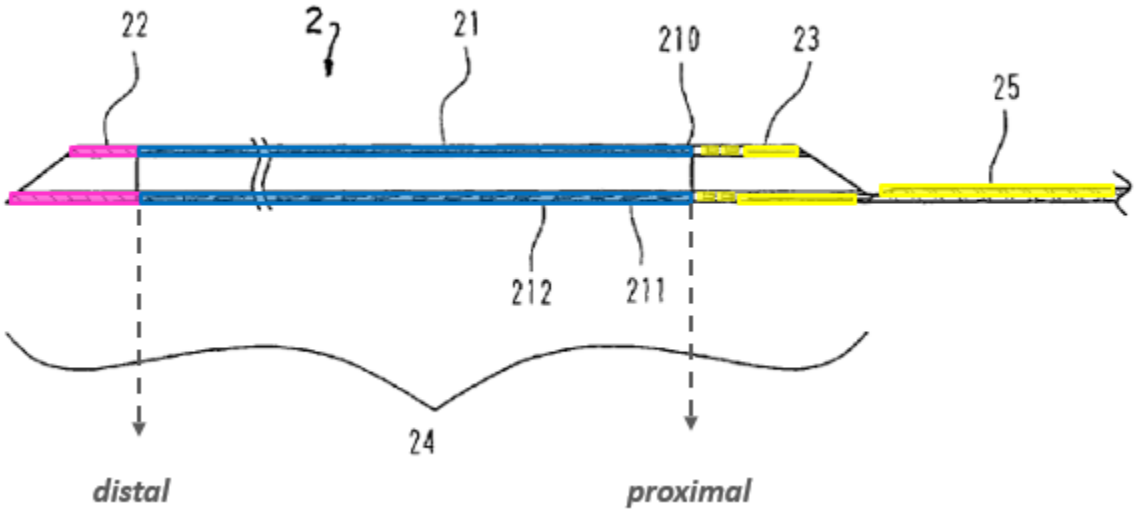
Itou discloses 25.b. Ex-1005, ¶¶ 180-83. The reinforced segment includes tubular body portion (21) (below, blue).



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

Itou teaches that tubular body portion (21) includes "a reinforcing layer 211 made of a metal wire made of stainless steel or the like," which is encased in "an inner layer 210 made of a resin material having a sliding property such as a fluorocarbon resin represented by PTFE" and an outer layer (212). Ex-1007, 3:51-56. As Dr. Brecker and Dr. Hillstead explain, the resin layers that cover layer 211 are polymer. Ex-1005, ¶ 181; Ex-1042, ¶¶ 30, 73-75.

Thus, as illustrated below, the "reinforced segment" extends from a proximal end portion to a distal end portion. Ex-1005, ¶ 182.

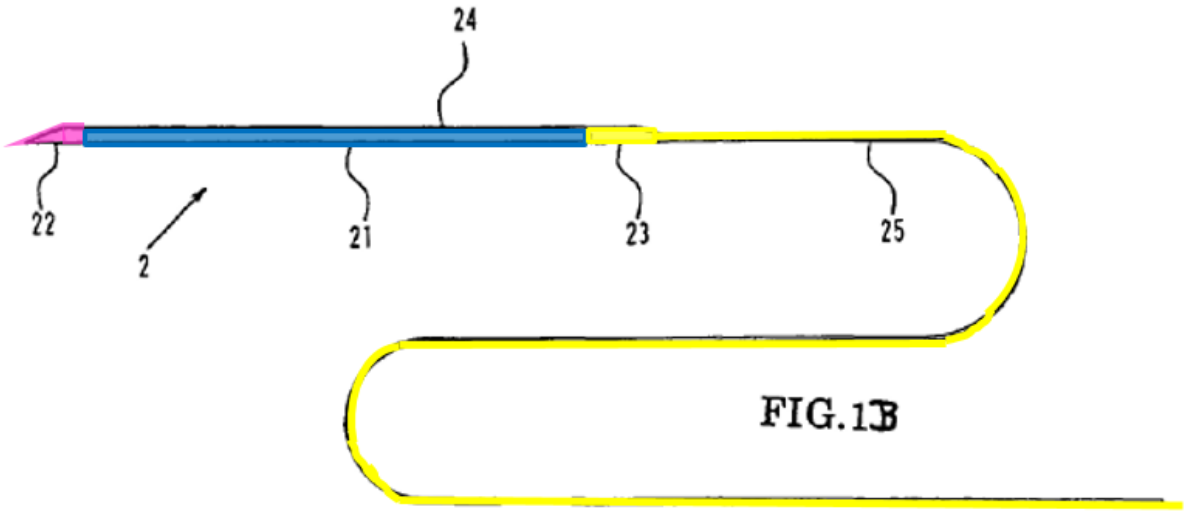


Ex-1007, Fig. 3 (color and annotation added).

Finally, Itou discloses that the reinforced segment has a "lumen therethrough" for the same reasons that tip (22) has a "lumen therethrough." *See supra* § VII ([25.a]). Ex-1005, ¶ 183.

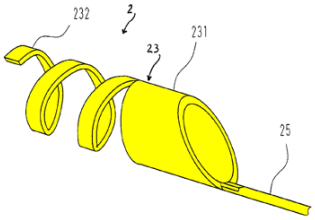
4. **[25.c] "providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment"**

Itou discloses 25.c. Ex-1005, ¶¶ 184-197. The substantially rigid segment includes "wire-like portion 25," (below, yellow), which is formed from a "solid metal wire and an outer layer such as a polymer coating." Ex-1007, 3:49-50.



Ex-1007, Fig. 1B (color added).

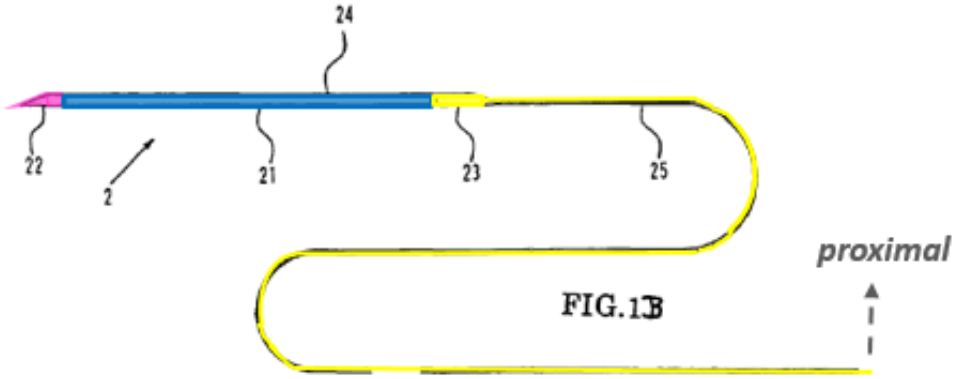
The substantially rigid segment may also include proximal tip (23), which is "formed by obliquely cutting one end of a metal pipe." Ex-1007, 4:27-29. The proximal end of the pipe, end portion (231), is welded to the distal end of wire-like portion (25), while the distal end portion of the pipe, (232), is formed into a spiral shape. *Id*. at 4:27-36.



Id. at Fig. 4 (color added).

Therefore, the claimed "substantially rigid segment" may be mapped to a combination of wire-like portion 25 and proximal tip 23 ("Mapping-1") or, alternatively, to only wire-like portion 25 ("Mapping-2").[12] Ex-1005, ¶ 184.

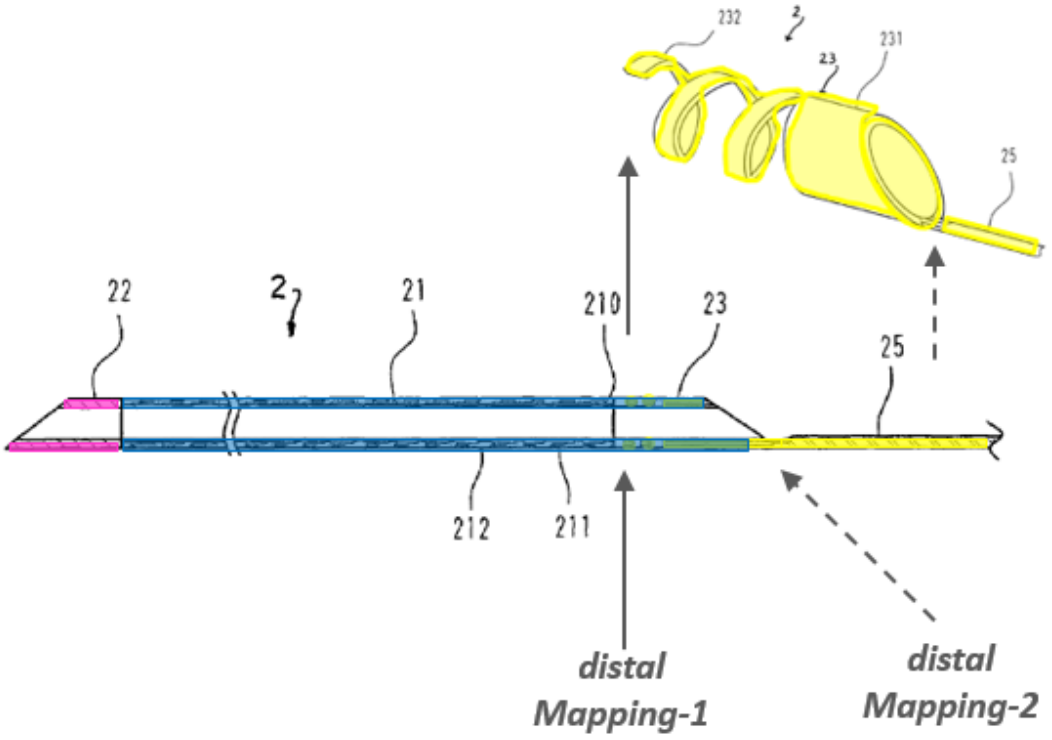
The substantially rigid segment extends ***from*** a proximal end portion, as illustrated below:



Ex-1007, Fig. 1B (color and annotation added). Ex-1005, ¶ 185.

The substantially rigid segment extends ***to*** a distal end portion, as illustrated below:

[12] Mapping-1 is presented to account for the requirements of dependent claim 42, which requires "defining the side opening portion in the substantially rigid segment."



Ex-1007, Figs. 3, 4 (color and annotation added). Ex-1005, ¶¶ 185-86.

Either wire-like portion (25) (alone), or in combination with proximal tip (23), are rigid enough to advance suction catheter (2) within guiding catheter (1), (*see supra* § VI (construing "substantially rigid")) evidenced by their use to insert suction catheter (2) through the lumen of guiding catheter (1) so that catheter (2)'s tubular portion "project[s] outwardly beyond the distal end" of the guiding catheter. Ex-1007, 1:60-63, 2:5-8, 32-37, 5:35-46. Ex-1005, ¶ 187.

FIG.5

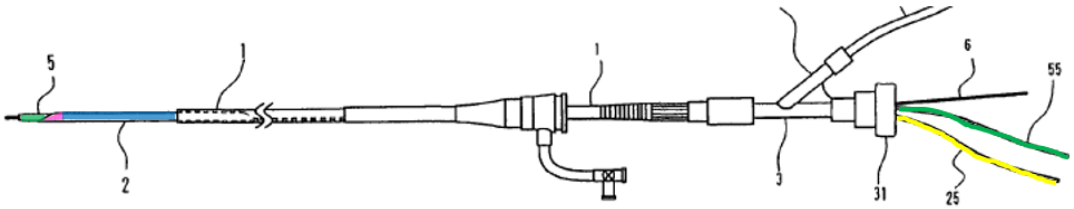
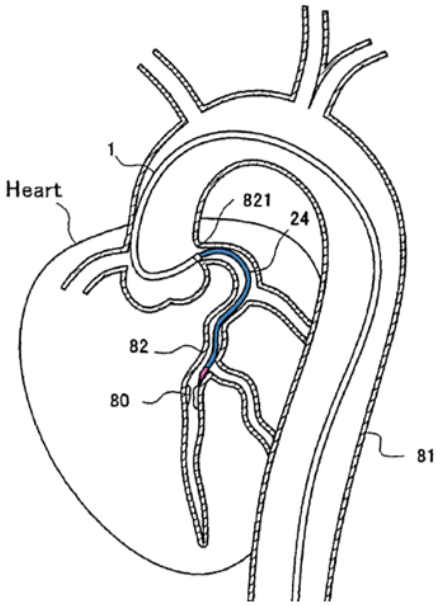
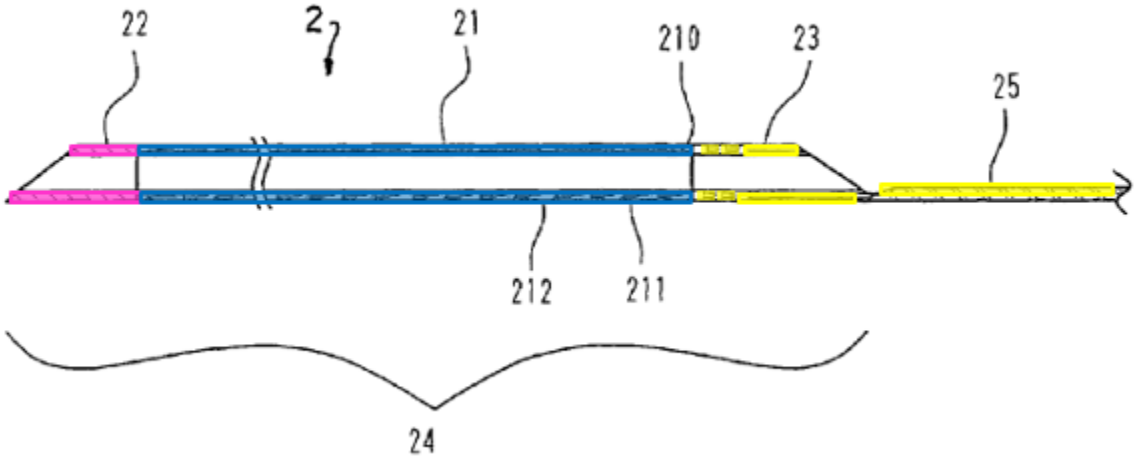


FIG.6



Ex-1007, Figs. 5, 6 (color added).

Both wire-like portion (25) and proximal tip (23) are metal. Ex-1007, 3:49-50, 4:27-32. By contrast, tip (22) is soft and flexible in order to reduce the damage to the blood vessel (*id*. at 2:15-18) and lacks the metal reinforcement layer found in the more proximal tubular body portion (21) of catheter (2). *See supra* § VII ([25.b]). Ex-1005, ¶¶ 188-89



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

As Dr. Brecker and Dr. Hillstead explain, given the differences in the materials that are used to form tip (22) and Itou's "substantially rigid segment" (wire-like portion (25), with or without proximal tip (23)), the latter is more rigid along its longitudinal axis than the former. Ex-1005, ¶ 190; Ex-1042, ¶¶ 64-67; *see also* Ex-1042, ¶¶ 21-31.

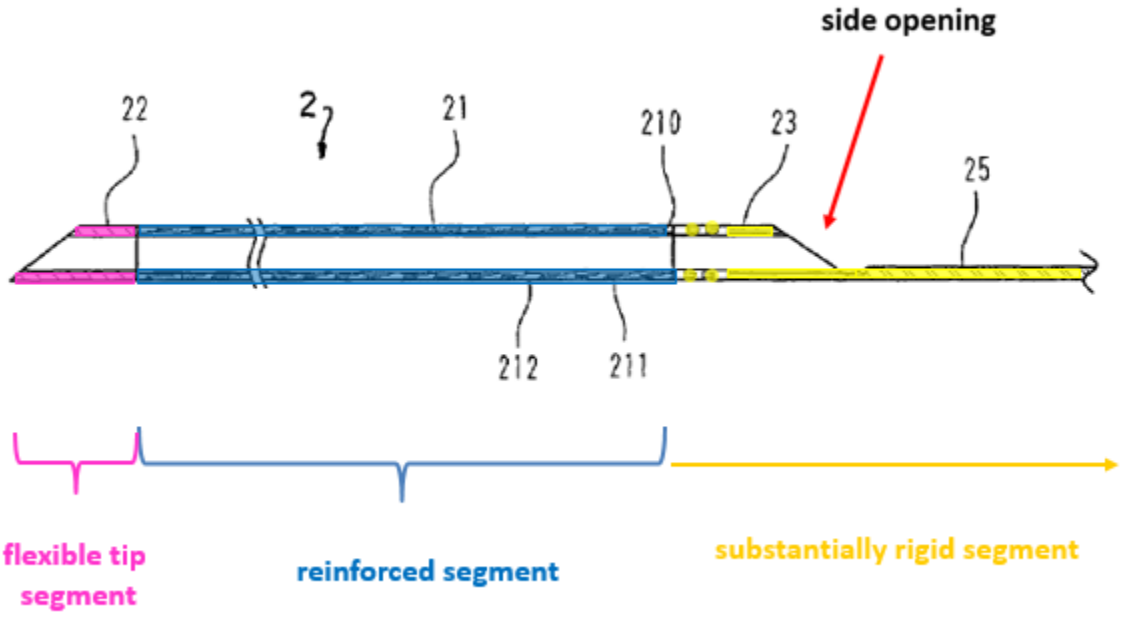
Moreover, the difference in the rigidities is reflected in the functions that Itou describes. A substantial portion of the "substantially rigid segment," proximal wire-like portion (25), advances suction catheter (2) to a deep location in the coronary vasculature. Ex-1007, 5:43-46. Distal tip 22, however, is soft and flexible, so as to avoid damaging a blood vessel. *Id*. at 2:15-18; *see supra* § VII ([25.a]). As Dr. Brecker explains, this necessarily discloses to a POSITA that Itou's "substantially rigid segment" is more rigid along its longitudinal axis than

tip (22), as it was well understood that the proximal portion of a catheter necessarily had to be more rigid than the distal-most portion in order to advance the catheter through the coronary vasculature. Ex-1042, ¶¶ 27-38; Ex-1005, ¶¶ 191-97; *see also* Ex.-1019, 9:30-50 (teaching an aspiration catheter with a stiffer proximal region and more flexible distal end); Ex-1076, 1:28-44 (teaching a guide catheter with a stiff, main body portion for "pushability" and "torqueability" and a more flexible distal portion); Ex-1072, 2:38-40 (teaching an infusion catheter with a more rigid proximal region for pushability and a more flexible distal portion).

5. **[25.d] "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape"**

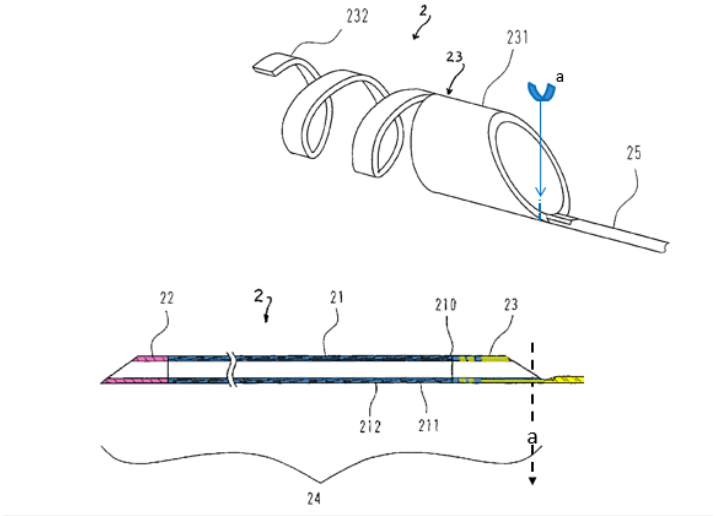
Itou discloses 25.d. Ex-1005, ¶¶ 198-200.

Suction catheter (2) includes a side opening.



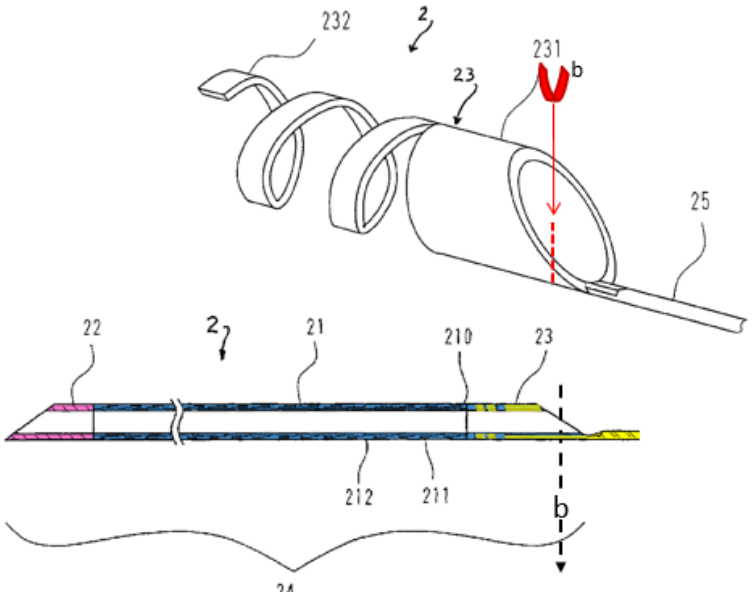
Ex-1007, Fig. 3 (color and annotation added).

As shown below, the side opening includes an arcuate cross sectional shape, which, according to the ’379 patent is a portion that “extends from 25% to 40% of the circumference of the tube.” Ex-1001, 7:25-26. Ex-1005, ¶ 199.



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

Moving distally, as shown below, the side opening also includes a hemicylindrical cross-sectional shape (cross section at "b"), which, according to the '379 patent is a portion that "desirably includes 40% to 70% of the circumference of a tube." Ex-1001, 7:19-20. Ex-1005, ¶ 200.



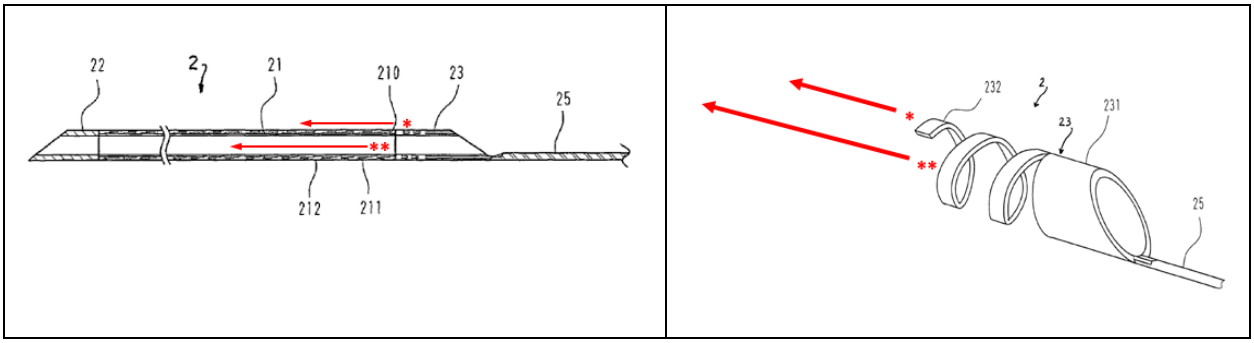
Ex-1007, Figs. 4, 3 (color and annotation added).

6. **[25.e] "eccentrically positioning the distal end portion of the substantially rigid segment relative to a longitudinal axis of the proximal end portion of the reinforced segment; and"**

Itou discloses 25.e under either Mapping-1 or Mapping-2. Ex-1005, ¶ 201.

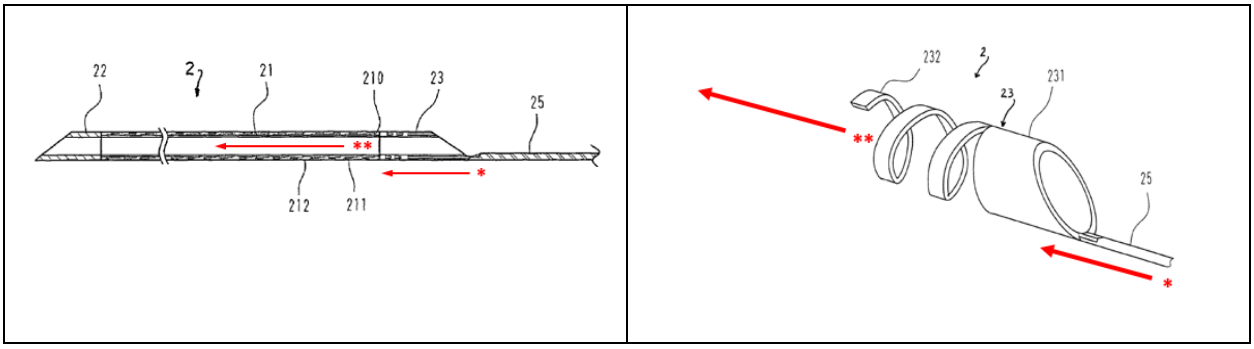
Under Mapping-1, the distal end portion of the substantially rigid segment is the distal tip of (232) (indicated with an * below), which is eccentrically positioned

relative to the longitudinal axis of the proximal portion of the reinforced segment indicated with ** below). Ex-1005, ¶ 201.



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

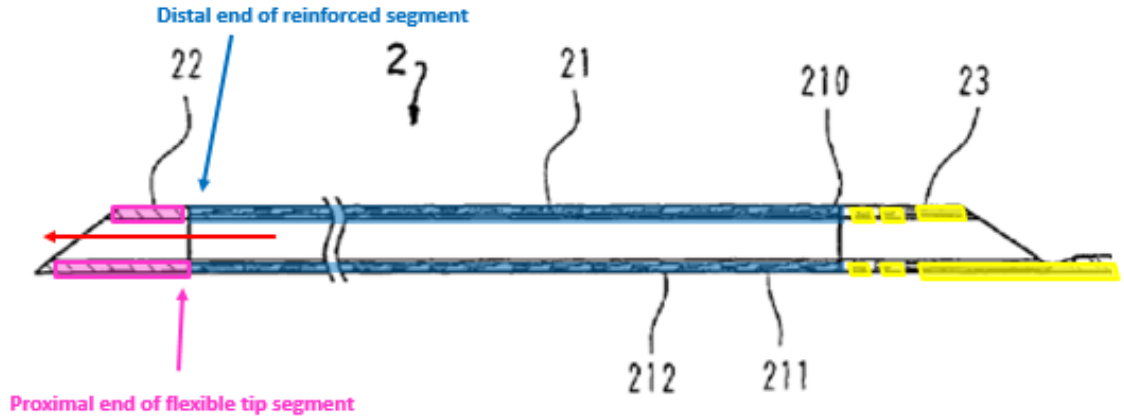
Under Mapping-2, the distal end portion of the substantially rigid segment is the distal tip of wire-like portion (25) (indicated with an * below), which is also eccentrically positioned relative to the longitudinal axis of the proximal portion of the reinforced segment indicated with ** below). Ex-1005, ¶ 201.



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

7. **[25.f] coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment;**

Itou discloses 25.f. Ex-1005, ¶ 202. As illustrated below, the distal end portion of the reinforced segment (tubular body portion 21) is coaxially aligned (red arrow) with the proximal end portion of the flexible tip segment (tip 22).

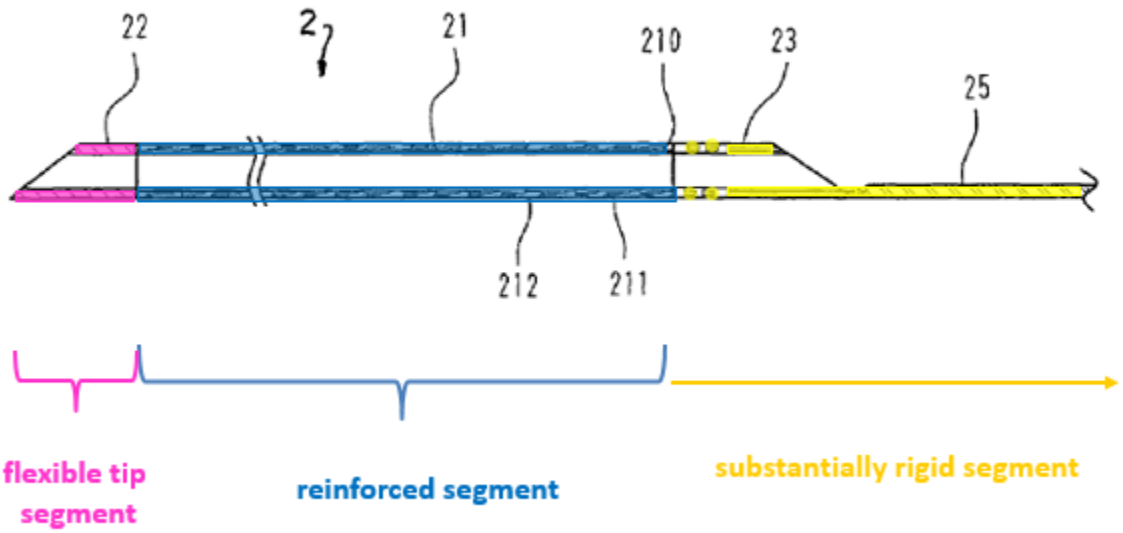


Ex-1007, Fig. 3 (color and annotation added).

8. **[25.g] "wherein providing the substantially rigid segment, the reinforced segment and the flexible tip segment includes forming a device length that is longer than the predefined length of the continuous lumen of the guide catheter such that when a distal end portion of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter."**

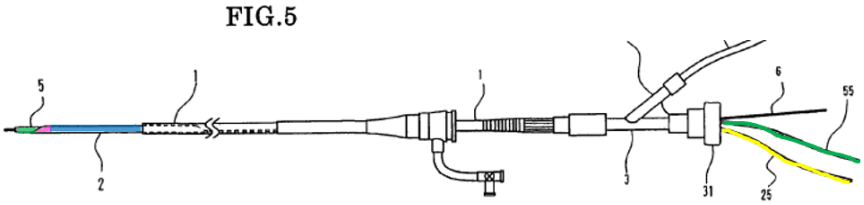
Itou discloses 25.g. Ex-1005, ¶¶ 203-06.

As shown below, together the substantially rigid segment, the reinforced segment and the flexible tip segment form a device with a length that is longer than the predefined length of the continuous lumen of the guide catheter.



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

Itou teaches that the length of suction catheter (2) is 1250 mm, wherein the length of guiding catheter (1) is 1000 mm. *Id*. at Table 1. Itou additionally teaches that suction catheter (2) may be inserted into guiding catheter (1) such that the when the distal end of the flexible tip segment (pink) extends distally of the distal end of the guide catheter, the proximal end of the substantially rigid portion extends proximally of the proximal end of the guide catheter. *Id*. at 1:60-63, 2:5-8, 32-37, 5:35-46. Ex-1005, ¶¶ 205-06.

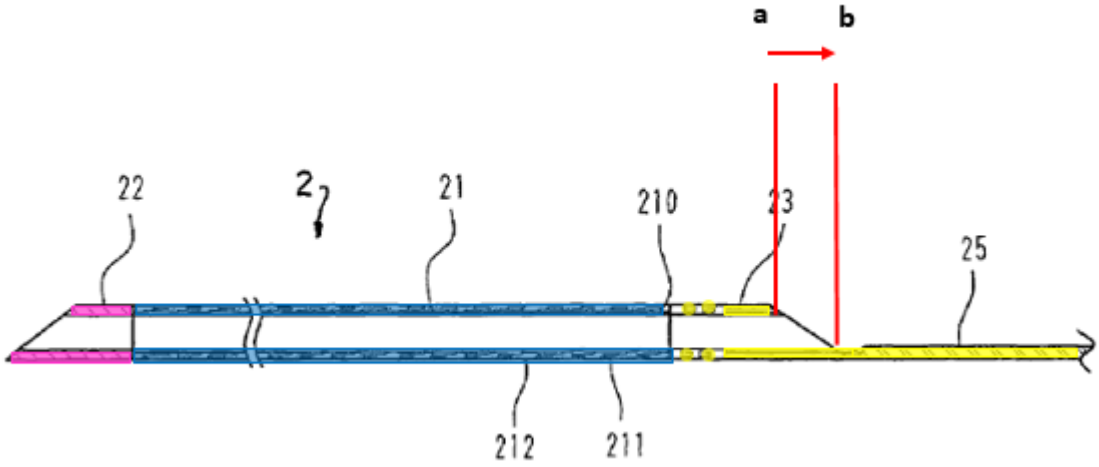


Ex-1007, Fig. 5 (color added).

C. Claim 26: The method of claim 25, further comprising extending the side opening portion for a distance along a longitudinal axis of the device, such that the side opening portion is accessible from a longitudinal side, defined transverse to the longitudinal axis, along the distance.

Itou discloses claim 26. Ex-1005, ¶¶ 207-211.

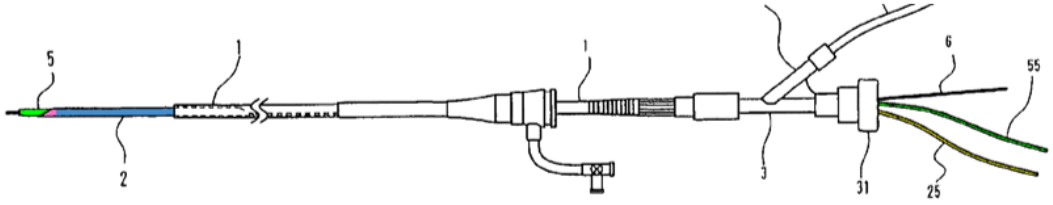
As shown below, the side opening in Itou's suction catheter 2 extends for a distance from (a) to (b) along the catheter's longitudinal axis. Ex-1005, ¶ 208.



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, 4:48-51. Ex-1005, ¶¶ 209-210.

FIG.5



Ex-1007, 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." Ex-1005, ¶ 211.

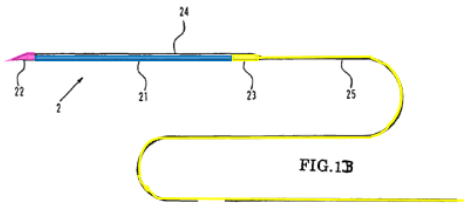


FIG.1B

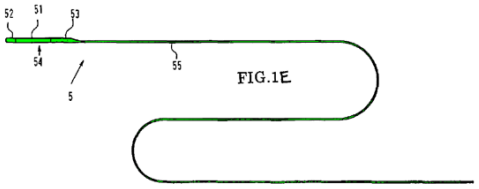
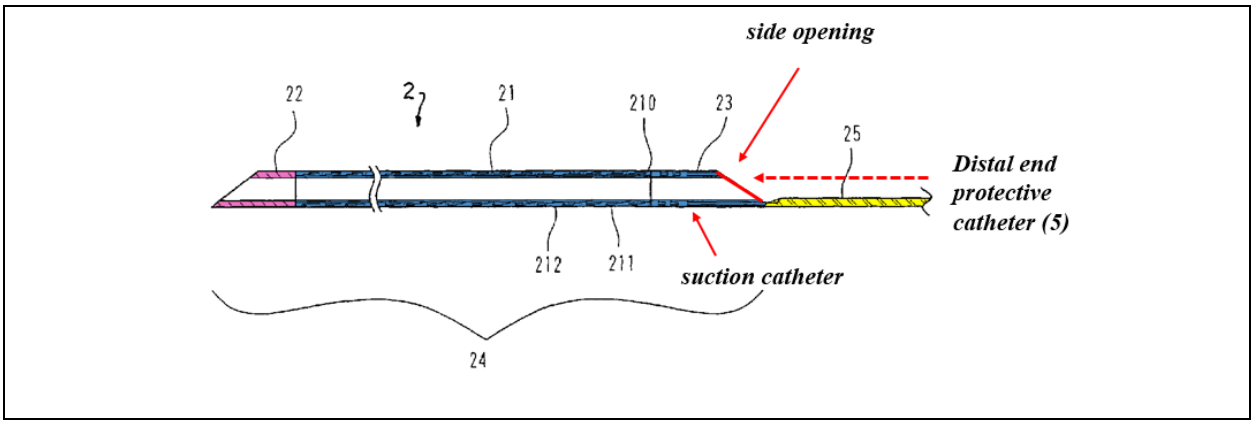


FIG.1E



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

D. Claim 29: The method of claim 25, wherein providing the substantially rigid segment includes forming or obtaining a hypotube or a metal rail structure.

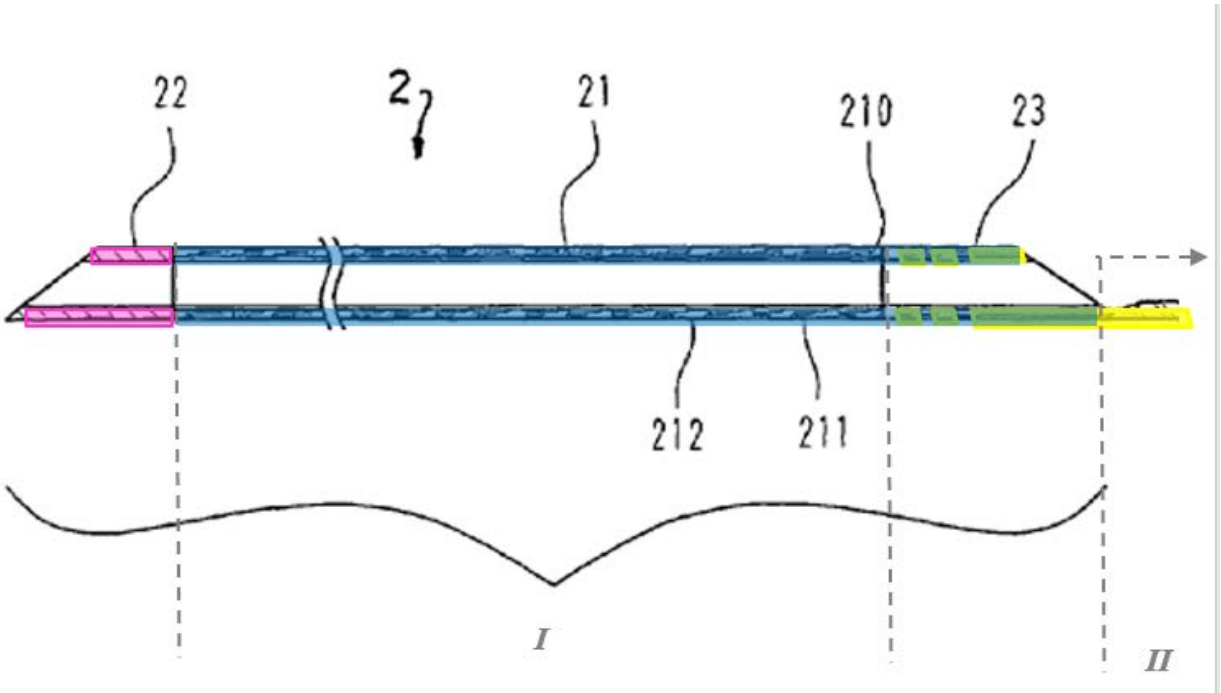
Itou discloses claim 29. Ex.-1005, ¶ 212. The substantially rigid segment of suction catheter (2) is metal-wire like portion (25) and proximal tip (23). *See supra* § VII ([25.c]). Wire (25) is a rail structure (*see supra* § VI) because it may be used to facilitate monorail delivery of suction catheter (2). *See* Ex-1007, Abstract, Figs. 5, 6, 5:35-46.

E. Claim 30: The method of claim 25, wherein providing the substantially rigid segment and the reinforced segment includes, starting at the distal end portion of the reinforced segment and moving proximally toward the proximal end portion of the substantially rigid segment, forming or obtaining at least a first device portion having a first flexural modulus and a second device portion having a second flexural modulus, the second flexural modulus greater than the first flexural modulus.

Itou discloses claim 30. Ex-1005, ¶¶ 213-17, which requires at least two different portions within the reinforced and substantially rigid segments that each

have a distinct flexural modulus. The claim also requires that the at least two flexural moduli increase in the distal to proximal direction. Ex-1005, ¶ 214.

Itou teaches that the reinforced segment, tubular portion (21) (*see supra* § VII ([25.b])) has "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . ." Ex-1007, 3:50-58. Tubular portion (21) is a first device portion having a first flexural modulus, (*I*). Ex-1005, ¶ 215; Ex-1042, ¶¶ 79-80.



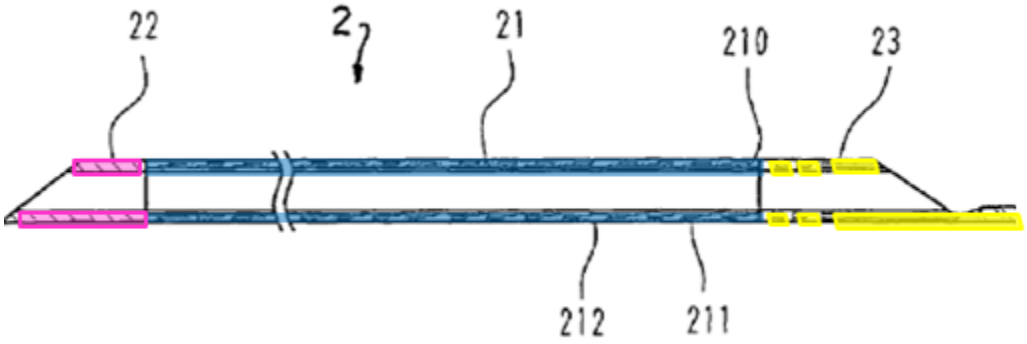
Ex-1007, Fig. 3 (color and annotation added).

Itou also teaches that the substantially rigid segment includes wire-like portion (25) (*see supra* § VII ([25.c])), which is a second device portion having a second flexural modulus (*II*). Ex.-1005, ¶ 216; Ex.-1042, ¶¶79, 84.

As Dr. Brecker and Dr. Hillstead explain, given the differences in the materials that are used to form tubular structure (21) and wire-like portion (25), and the function of proximal wire-like portion (25) (*see supra* § VII ([25.c])), flexural modulus (*II*) is necessarily greater than flexural modulus (*I*). Ex-1005, ¶ 217; Ex-1042, ¶¶ 85-86.

F. Claim 31: The method of claim 25, wherein providing the reinforced segment includes covering one or more braided or coiled metallic elements with the polymer.

Itou discloses claim 31. Ex.-1005, ¶ 218. As discussed, *supra* for claim 25.b, the reinforced segment of suction catheter (2) is tubular structure (21), which has a ***reinforcing layer (211) made of a metal wire*** that is encased in polymer layers (210) and (212).

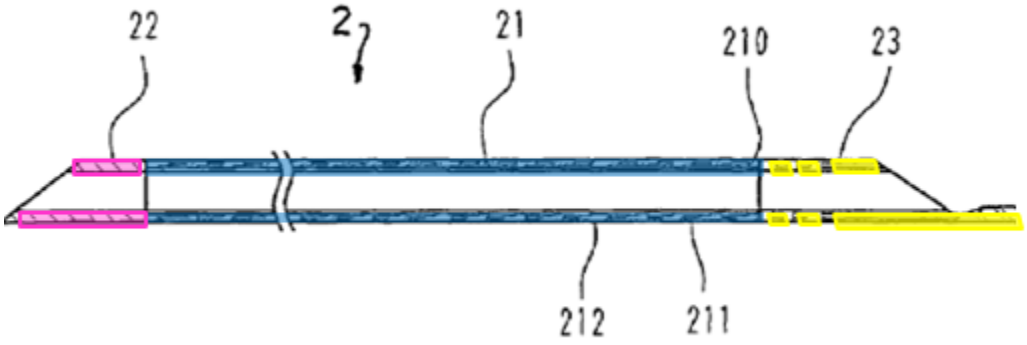


Ex-1007, Fig. 3 (color added).

From the disclosure of Itou, it is evident that reinforcing metal wire (211) is braided or coiled around inner layer (210). Ex-1005, ¶ 218; Ex-1042, ¶¶ 35-46, 70, 73-75.

G. Claim 33: The method of claim 25, where providing the reinforced segment includes forming or obtaining a reinforced segment including a lumen having a uniform inner diameter that is about one French smaller than an inner diameter of the continuous lumen of the guide catheter.

Itou discloses claim 33. Ex-1005, ¶ 218. The reinforced segment of Itou's suction catheter (2) is illustrated below. *See supra* § VII ([25.b]).



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

Itou teaches that the reinforced segment has a lumen with a "uniform inner diameter." Ex-1007, Fig. 3 (disclosing a longitudinal cross section with a constant diameter), Table 1 (disclosing that the tubular portion of suction catheter (2), of which tubular structure (21) is a part, has a (***singular***) inner diameter of 1.5 mm); Ex-1005, ¶ 218.

Itou teaches that there is about a one French size differential between the inner diameter of the reinforced segment and the inner diameter of 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 "about one French." Ex-1005, ¶ 118; Ex-1062, 545.

H. Claim 34: The method of claim 33, wherein the lumen of the reinforced segment is greater than or equal to 0.056 inches and the continuous lumen of the guide catheter is greater than or equal to 0.070 inches.

Itou discloses claim 34 for the same reason it discloses claim 33. Ex-1005, ¶ 218. The inner diameter (lumen) of the reinforced segment of suction catheter (2) is 1.5 mm, or 0.059 inches, which is greater than 0.056 inches. Ex-1007, Table 1; Ex-1005, ¶ 218. The inner diameter of the continuous lumen of guiding catheter (1) is 1.8 mm, or 0.070 inches. Ex-1007, Table 1; Ex-1005, ¶ 218.

I. Claim 35:The method of claim 25, wherein providing one or both of the reinforced segment and the flexible tip segment includes lining the lumens thereof with polytetrafluoroethylene.

Itou discloses claim 35, Ex-1005, ¶ 218, as it teaches that the tubular portion of Itou's suction catheter (2) (which includes the reinforced segment, *supra*, [25.b]) "includes an inner layer 210 made of a resin material having a sliding property such as a fluorocarbon resin represented by PTFE." Ex-1007, 3:52-54. As Dr. Brecker and Dr. Hillstead explain, "PTFE" is an acronym for "polytetrafluoroethylene." Ex-1005, ¶ 218; Ex-1042, ¶ 76.

J. Claim 36: The method of claim 25, wherein providing the flexible tip segment includes providing an atraumatic bumper formed of a polymer or an elastomeric material.

Itou discloses claim 36. Ex-1005, ¶ 218.

Tip (22) is made from a resin, and lacks the metal reinforcement that is found in the more proximal tubular structure (21). Ex-1007, 4:19; *see supra* § VII ([25.a]-[25.c]). As Dr. Brecker and Dr. Hillstead explain, tip (22) is necessarily "formed of a polymer or elastomeric material." Ex-1005, ¶ 218; Ex-1042, ¶¶ 77-78. Further, Itou discloses that tip (22) is soft and flexible "in order to reduce the damage to the blood vessel," Ex-1007, 2:16-17, teaching that it functions as an atraumatic bumper. Ex-1005, ¶ 218; Ex-1042, ¶¶ 77-78.

K. Claim 37: The method of claim 36, wherein providing the flexible tip segment includes covering a marker band with the polymer or the elastomeric material.

Itou discloses claim 37, Ex-1005, ¶ 218.

Itou teaches that tip (22) is "formed such that a filler such as tungsten, bismuth oxide, or barium sulfate, which are X-ray contrast agents" are mixed in a matrix made of resin, and function "as an X-ray contrast marker (radiopaque marker)." Ex-1007, 4:15-20. As Dr. Brecker and Dr. Hillstead explain, the X-ray contrast agents form a "marker band," and are necessarily "covered" by the polymer or elastomeric material which comprises tip (22). Ex-1005, ¶ 218; Ex-1042, ¶¶ 77-78.

L. Claim 38:

1. **[38.pre] A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:"**

Itou discloses 38.pre. *See supra* § VII ([25.pre]).

2. **[38.a] "providing a flexible tip segment having a lumen therethrough"**

Itou discloses 38.a. *See supra* § VII ([25.a]). Ex-1005, ¶ 219.

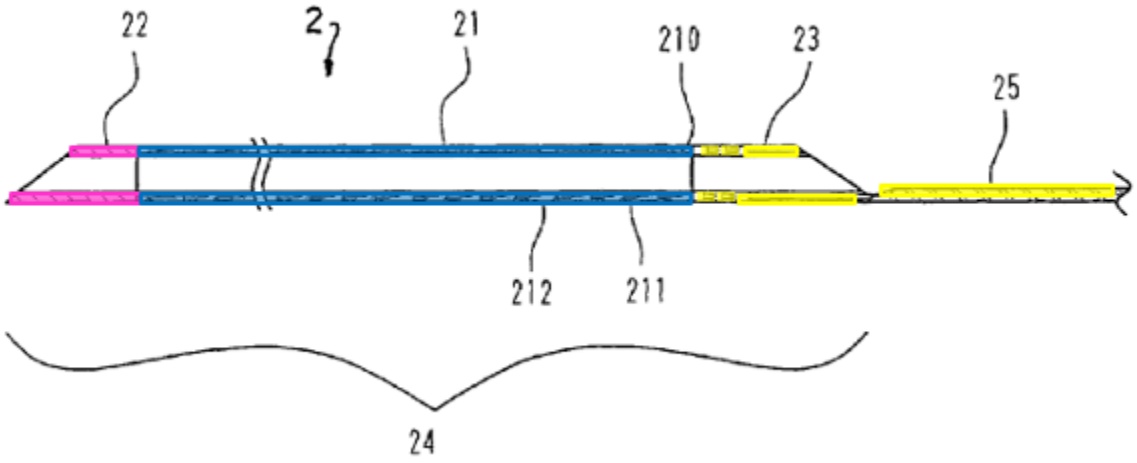
3. **[38.b] "providing a reinforced segment including one or more metallic elements covered with a polymer and having a lumen for coaxial alignment with the lumen of the flexible tip segment;"**

Itou discloses 38.b. *See supra* § VII ([25.b]). Itou additionally teaches coaxial alignment of the lumens of the reinforced and flexible tip segments. *See supra* § VII ([25.f]). Ex-1005, ¶ 219.

4. **[38.c] "providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment"**

Itou discloses 38.c. *See supra* § VII ([25.c]). Ex-1005, ¶¶ 219-220.

Under Mapping-1, the substantially rigid segment includes wire-like portion 25 and proximal tip (23).



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

5. **[38.d.i.] "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape"**

Itou discloses 38.d.i. *See supra* § VII ([25.d]). Ex-1005, ¶ 221.

6. **[38.d.ii] "the side opening portion extending for a distance along a longitudinal axis of the device such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive a balloon catheter and stent;" and**

Itou discloses this limitation, disclosing a side opening portion extending for a distance along a longitudinal axis of the device such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis. *See supra* § VII (claim 26). Ex-1005, ¶¶ 221-26.

Thus, Itou discloses the structural limitations recited in 38.d.ii, and claim 38 is a method of manufacturing a device with those limitations. To the extent that Patent Owner suggests that 38.d.ii requires anything more than the cited disclosure in Itou, it is mistaken. The additional language recites an intended use of the device that is manufactured according to the claimed method. ("***to receive a balloon catheter and stent***") (emphasis added), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Regardless, Itou explicitly teaches that the inner diameter of suction catheter (2)'s tubular structure is 1.5 mm, Ex-1007, Table 1, which Dr. Brecker explains is

0.059 inches.[13] Ex-1005, ¶ 227. Necessarily, the side opening of suction catheter (2) is at least as wide as the lumen.

A catheter with an inner diameter of 1.5 mm 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 '379 patent. Ex-1005, ¶¶ 228-234; 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, 2 (requiring an inner catheter diameter $\geq$ 0.058 in. (1.47 mm) for TAXUS Express^2 stents on a monorail delivery system).

Thus, the side opening of the tubular member of suction catheter (2) is large enough "to receive a balloon catheter and stent." Ex-1005, ¶ 235.

[13] This corresponds to the inner diameter of the extension catheter taught in the '379. Ex. 1001, 3:60-61 ("greater than or equal to 0.056 inches . . .").

7. **[38.d.iii.] "arranging, in a proximal to distal direction, the substantially rigid segment, the side opening portion, the reinforced segment, and the flexible tip segment such that when the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter and the side opening portion is positioned within the continuous lumen of the guide catheter."**

Itou discloses 38.d.iii, as illustrated below. Ex-1005, ¶¶ 236-240.

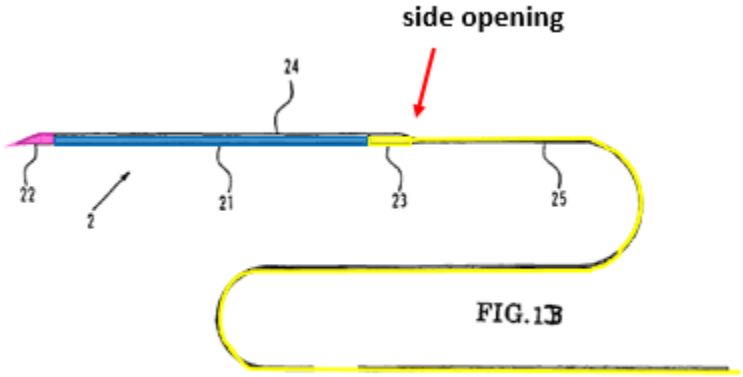
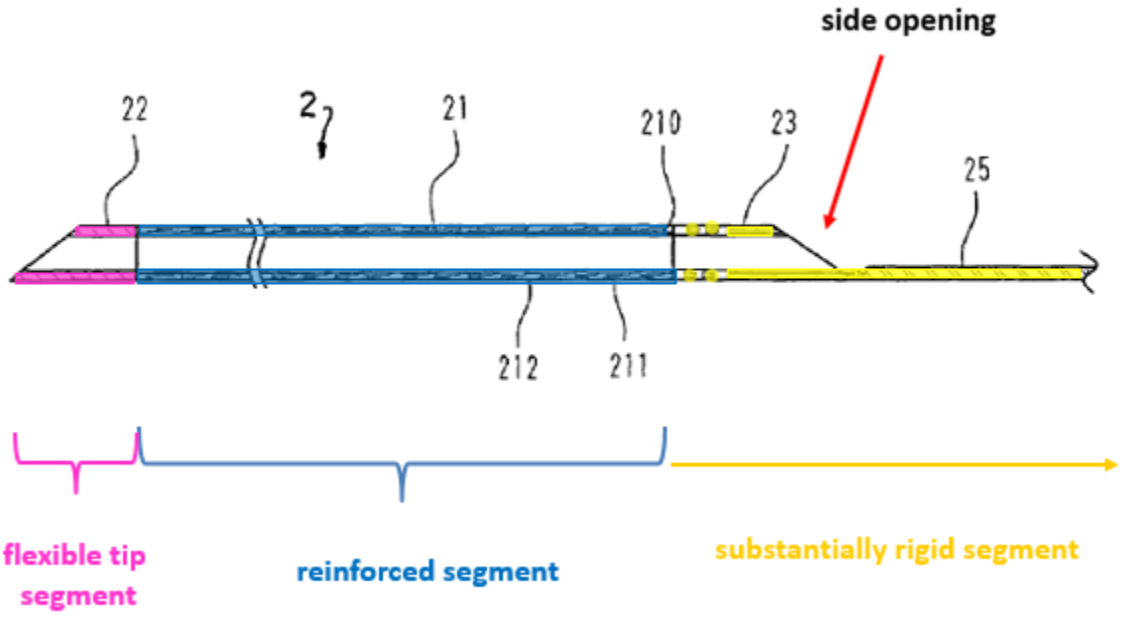


FIG. 13



Ex-1007, Figs. 1B (top), 3 (bottom) (color and annotation added).

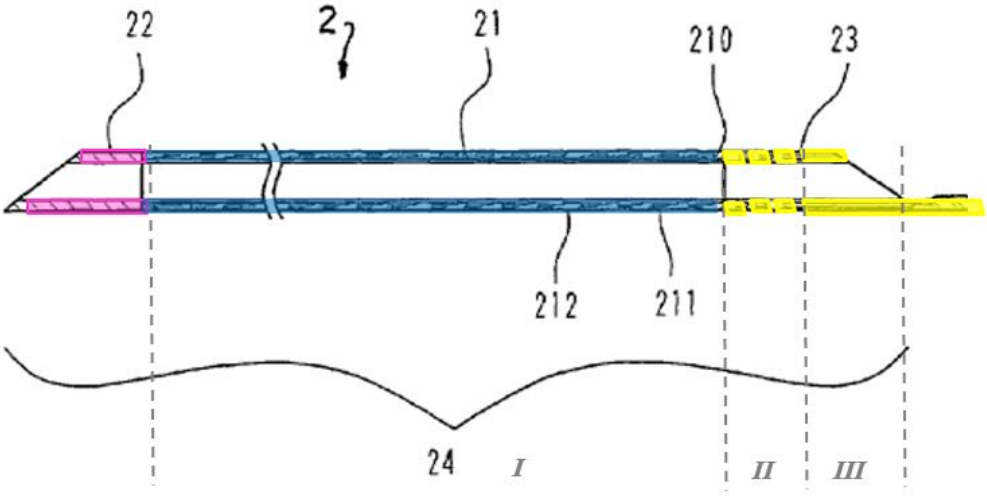
The "side opening" is within the distal portion of Itou's substantially rigid segment. That the side opening is not entirely distal of the "substantially rigid segment" comports with the only disclosure in the '379 patent. *See supra* § IV(B). Additionally, as Patent Owner's expert witness, Peter Keith testified, "just because something is proximal to something else doesn't mean that it has to be ***entirely*** proximal." Ex-1077, 294:1-3 (emphasis added). Ex-1005, ¶ 238.

The remaining limitations of claim 38.d.iii are met for the same reasons the limitations of claim 25.g are met. Ex-1005, ¶¶239-240.

M. Claim 39: The method of claim 38, wherein providing the substantially rigid segment, defining the side opening, and providing the reinforced segment includes, starting at a distal end portion of the reinforced segment and moving proximally toward the proximal end portion of the substantially rigid segment, forming or obtaining at least a first device portion having a first flexural modulus, a second device portion having a second flexural modulus greater than the first flexural modulus, and a third device portion having a third flexural modulus greater than the second flexural modulus.

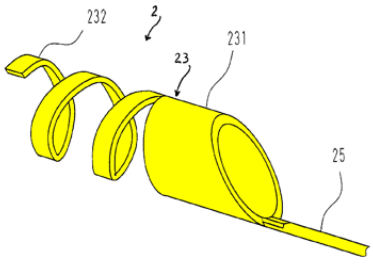
Itou discloses claim 39, Ex.-1005, ¶¶ 240-47, which requires at least three different portions within the reinforced segment, the side opening, and the substantially rigid segment, each having a distinct flexural modulus. The claim also requires that the at least three flexural moduli increase in the distal to proximal direction.

Itou teaches that tubular portion (21), which is part of the reinforced segment (*see supra* § VII ([25.b])) has "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . ." Ex-1007, 3:50-58. Tubular portion (21) is a first device portion with a first flexural modulus, (*I*). Ex-1005, ¶ 242; Ex-1042, ¶¶ 79-80.



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

Itou teaches that the substantially rigid segment is proximal of the reinforced segment, and that it includes (moving distally to proximally) proximal tip 23 and wire-like portion 25. *See supra* § VII ([25.b], [25,c]). The distal end of tip (23) is metal pipe shaped into a spiral ("coil") (232). Ex-1007, 4:27-37. Ex-1005, ¶¶ 243-44.



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

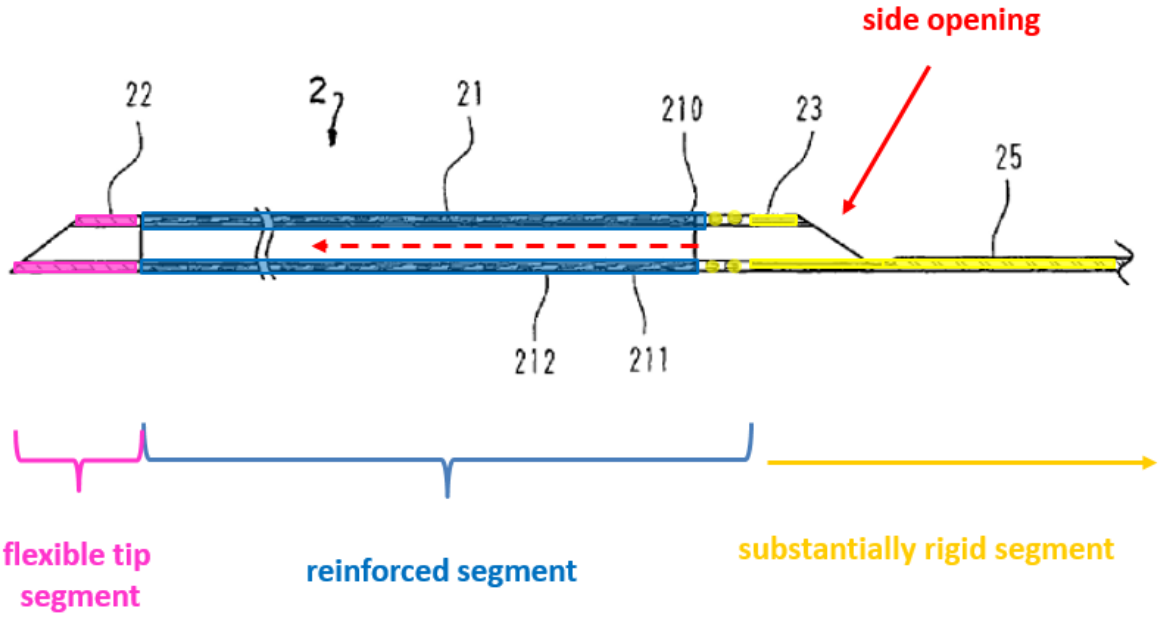
Portion 232 is a second device portion with a second flexural modulus (*II*). Ex.-1005, ¶ 245; Ex.-1042, ¶¶ 79, 81.

The proximal end of tip (23) is an obliquely cut metal pipe, portion (231). Ex-1007, 4:27-29; *see supra* § VII ([38.c]). Portion 231 is a third device portion with a third flexural modulus (*III*). Ex.-1005, ¶ 246; Ex.-1042, 79, 82-83. As Dr. Brecker and Dr. Hillstead explain, given the differences in the materials that are used to form tubular structure (21), portion (232) and portion (231), flexural modulus (*II*) is necessarily greater than flexural modulus (*I*), and flexural modulus (*III*) is necessarily greater than flexural modulus (*II*). Ex-1005, ¶ 247; Ex-1042, ¶¶85-86.

N. Claim 40: The method of claim 38, wherein defining the side opening portion includes providing an angled entrance into the lumen of the reinforced segment.

Itou discloses claim 40. Ex-1005, ¶ 248.

As shown below, the proximal side opening on the tubular portion of suction catheter (2) is angled.



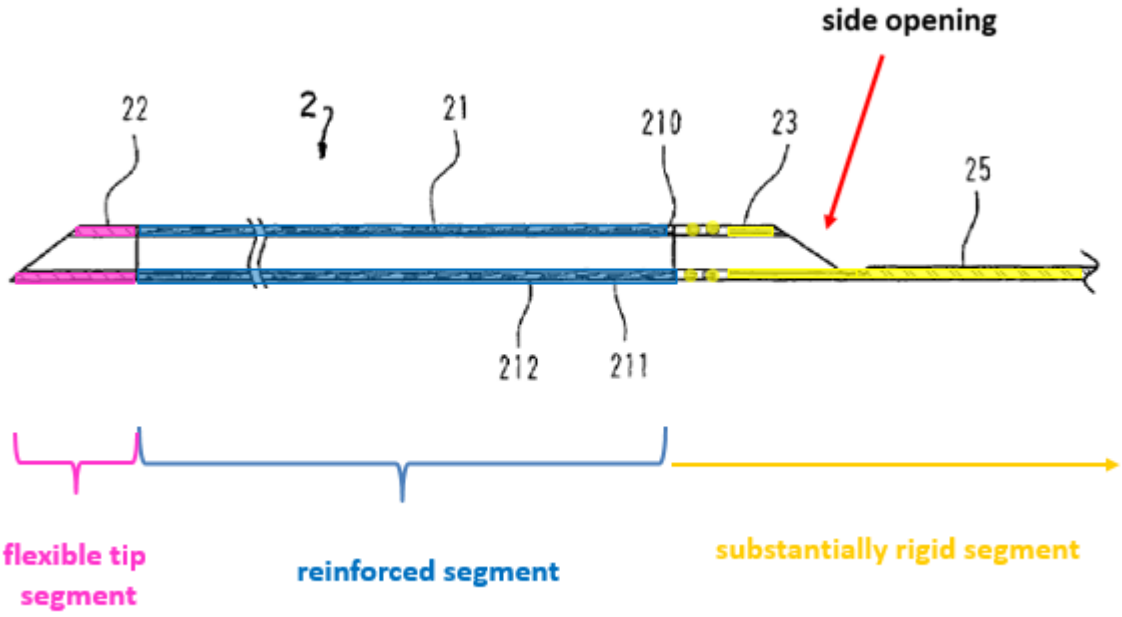
Ex-1007, Fig. 3 (color and annotation added).

Itou also discloses that the proximal side opening on the tubular portion of suction catheter (2) provides an entrance into the lumen of the reinforced segment of catheter (2) at its proximal end (i.e. the transition between tubular structure (21) and portion (232) (red dotted arrow)). *See supra* § VII ([25.b], 26, [38.b]). Thus, Itou discloses claim 40. Ex-1005, ¶ 248.

O. Claim 42: The method of claim 25, further comprising defining the side opening portion in the substantially rigid segment.

Itou discloses claim 42. Ex-1005, ¶ 248.

As discussed in 25.c, the substantially rigid segment includes wire-like portion (25) and proximal tip (23) under Mapping-1.



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

As illustrated above, the side opening portion is defined in the substantially rigid segment.

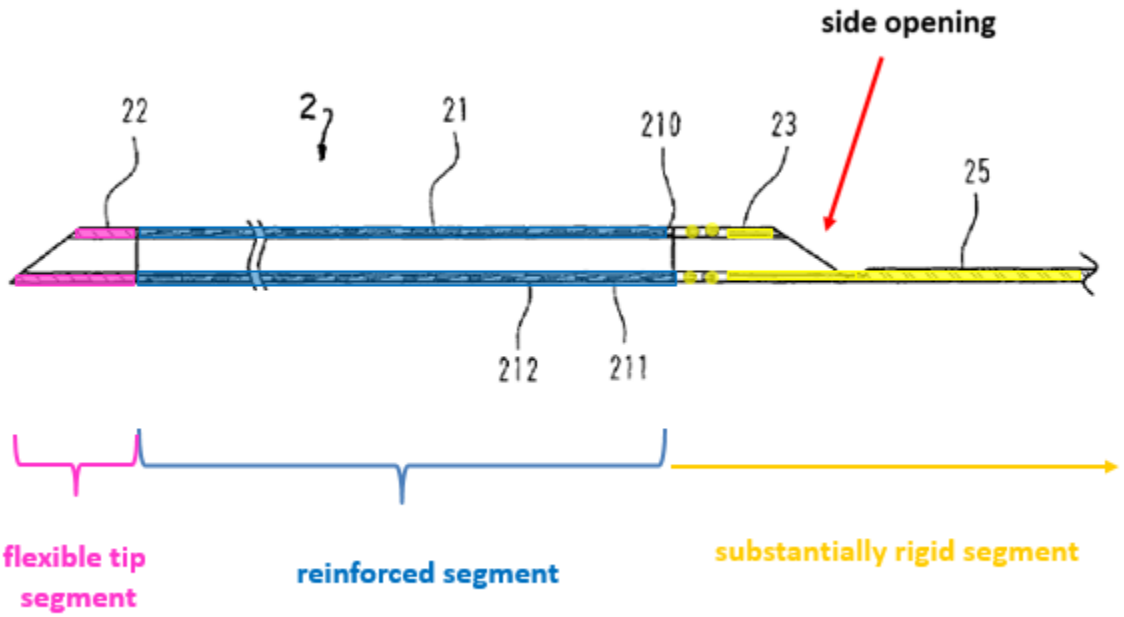
P. Claim 43: The method of claim 38, wherein defining the side opening portion includes forming a concave track.

Itou discloses claim 43. Ex-1005, ¶ 248. In the context of the '379 patent, "concave track" refers to a portion that is not fully circumferential. *See supra* § VI. Itou discloses that side opening 231 includes a portion that is not fully circumferential. *See supra* § VII ([25.d], [38.d.i]). 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 38.d.ii.

Q. Claim 45: The method of claim 38, wherein providing the substantially rigid segment, defining the side opening portion, providing the reinforced segment, and providing the flexible tip segment includes forming a device cross-sectional size and shape configured to be passed, at least in part, into the continuous lumen of the guide catheter.

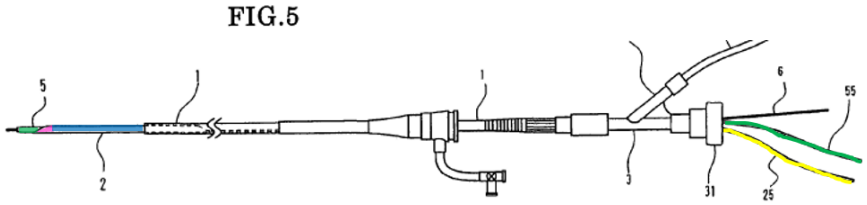
Itou discloses claim 45. Ex-1005, ¶¶ 248-49.

As discussed herein, Itou's suction catheter (2) includes a substantially rigid segment, a side opening portion, a reinforced segment and a flexible tip segment. *See supra* § VII (claim 38).



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

Itou additionally teaches that suction catheter (2) has a cross-sectional size and shape such that it is configured to be passed into the continuous lumen of guiding catheter 1. Ex-1005, ¶ 249.



Ex-1007, Fig. 5 (color added); *see also id.* at Table 1, Fig. 6; *see supra* § VII (claims 25, 33, 34).

VIII. GROUND 2: ITOU RENDERS CLAIMS 26, 38-40, AND 43-45 OBVIOUS IN VIEW OF RESSEMANN AND THE COMMON KNOWLEDGE OF A POSITA.

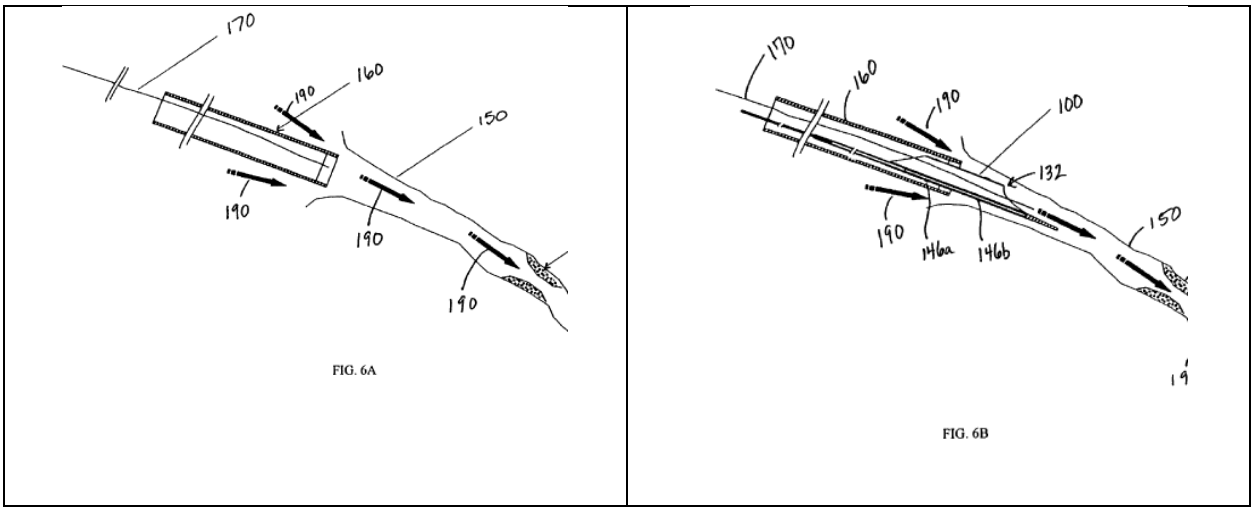
A. Ressemann

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 ’379 reissue patent.[14] Exs-100, 1002, 1003.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex. 1008,

[14] A patent related to Ressemann, U.S. Pat. No. 7,959,603 (Wahr) is cited on the face of the ’379 patent, but nowhere discussed and was disclosed after the pending claims were deemed allowable. . Ex-1001; Ex-1003 at 617 (10/12/18 Notice of Allowance), 675 (1/11/19 Information Disclosure Statement).

Abstract. The assembly includes a GC, which "may be positioned within the ostium of a target vessel" (*id*. at 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*. at Abstract, Figs. 6A-6F, 6:18-24, 12:9-14:39.



Ex-1008, Figs. 6A, 6B.

Sheath assembly is described for use in aspirating embolic material (*id*. at Abstract, 12:9-13:34) and for stent or balloon delivery. *Id*. at 6:25-34, 12:3-8.

The evacuation sheath includes a distal evacuation head and a shaft. *Id*. at 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*. at 6:36-39.

(Illustratehttps://www.ptonline.com/knowledgecenter/profile-extrusion/glossary-of-termsd below in pink).

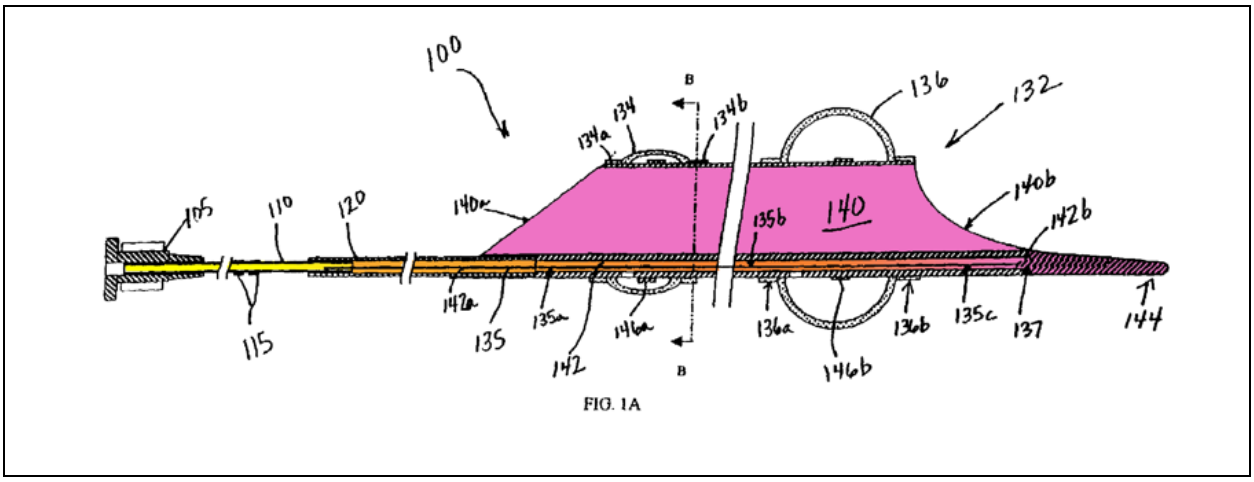


FIG. 1A

Ex-1008, 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*. at 10:36-42. Intermediate shaft (120) (yellow transitioning to pink) —a hollow, polyethylene or Pebax tube—is more flexible than shaft (110). *Id*. at 10:63-11:10. Distal shaft (transitioning to pink) includes the evacuation head, (*id*. at 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*. at 11:11-29. Ex-1042, ¶¶ 47-52; *see also* Ex-1005, ¶¶ 99-102, 155-59.

As explained in § VII, Itou's suction catheter (2) has the structure that meets the limitations in the following claims:

- Claims 26 and 38 (and dependents 39, 40, 43, 44, and 45), reciting that the "side opening [portion] is accessible from a longitudinal side, defined transverse to the longitudinal axis," and claim 38 (and dependents) additionally reciting "to receive a balloon catheter and stent;" and
- Claim 43, reciting a "concave track."

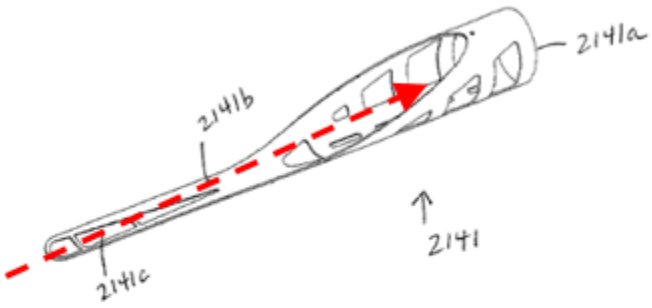
To the extent Patent Owner argues that Itou's teachings—alone—are insufficient to anticipate claims 26, 38-40, 43-45, then they are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA.[15] Itou in combination with Ressemann also renders claim 44 (not discussed in § VII) obvious.

B. Claim 26

Itou discloses the structural limitations recited in claim 26, which is a method of manufacturing a device with those limitations. *See supra* § VII. In the alternative, Itou and Ressemann render claim 26 obvious. Ex-1005, ¶¶ 250-54.

Ressemann discloses a support collar 2141 that includes "extending the side opening portion for a distance along a longitudinal axis of the device, such that the side opening portion is accessible from a longitudinal side, defined transverse to the longitudinal axis, along the distance." (dotted arrow below)

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



Ex-1008, Fig. 16J (annotation added). Ex-1005, ¶ 252.

Cylindrical portion 2141a "fits into the proximal opening of the evacuation lumen," providing hoop support. Ex-1008, 24:55-57. 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*. at 24:64-67. Ex-1005, ¶ 253.

As discussed for claim 43, *infra*, 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, ¶ 254.

C. Claim 38:

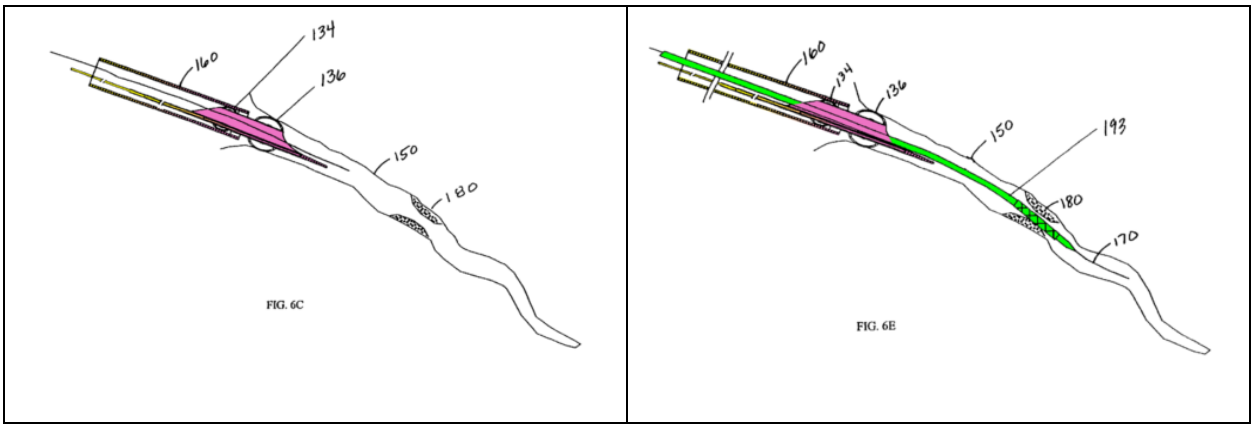
Claim Language	Evidence & Corresponding Disclosure
[38.pre]- [38.d.i];	*Supra* § VII

1. **[38.d.ii]**

Itou discloses the structural limitations recited in 38.d.ii, and claim 38 is a method of manufacturing a device with those limitations. *See supra* § VII. In the alternative, Itou and Ressemann render claim 38.d.ii obvious. Ex-1005, ¶¶ 255-280.

First, Ressemann discloses a support collar 2141 that includes a "side opening portion extending for a distance along a longitudinal axis of the device such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis." *See supra* §VIII(B) (claim 26). A POSITA had the motivation to replace Itou's proximal tip (23) with Ressemann's collar 2141 for the reasons discussed for claim 43, *infra*. Ex-1005, ¶ 257; Ex-1042, ¶¶ 93-97.

Second, Ressemann explicitly discloses using "the side opening portion" that "extend[s] for a distance along a longitudinal axis" of evacuation sheath (100), "such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive a balloon catheter and stent." Ex-1008, 12:9-14:10. Ex-1005, ¶ 258. This is illustrated below.



Ex-1008, Fig. 6C (left), Fig. 6E (right) (color added).

A POSITA had the motivation to use "the side opening portion extending for a distance along a longitudinal axis of the device such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis" of Itou's catheter (2) (*see supra* § VII ([38.d.ii])) to "receive a balloon catheter and stent" for the reasons below. Ex-1005, ¶ 259-260.

Ressemann explicitly teaches that it was advantageous to use an aspiration catheter with a distal lumen of sufficient diameter to deliver an interventional cardiology device. *See supra* § VIII(A); *see also* Ex-1019, 3:3-5, 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, ¶262. And this is because angioplasty and coronary artery stenting come with a risk of embolization. Ex-1005, ¶¶ 261, 265. 274; 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, ¶ 261; Ex-1015, 629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was a motivation to combine stent delivery with the use of an embolic protection device, Ex-1015, 629-630, and a reasonable expectation of success. Ex-1028, 1285 ("Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire."); Ex-1029, 172-176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of an embolic protection device in conjunction with stenting). Ex-1005, ¶¶ 264-273. Additionally, using a suction catheter large enough to deliver a therapy catheter ensures that a PCI procedure can be completed without having to switch catheters between suction and stenting. Ex-1005, ¶ 275; Ex-1008, 14:29-34 (" In some instances, once the particulate . . . has been removed, additional contrast delivery to the blood vessel may indicate a need for more therapeutic steps, e.g., further dilation of the stent with the balloon. In this case, it is more convenient to have the balloon catheter already in position for any subsequent use.")

The inner lumen of Ressemann's sheath is "approximately 0.061 inches," allowing for the "passage of most therapeutic devices such as angioplasty catheters

[and] stent delivery catheters . . . .” Ex-1008, 10:17-20. PTCA catheters were insertable through support catheters with an 0.045 inch inner lumen. Ex-1009 (“Kontos”), 4:46-50, 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, ¶ 263.

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, ¶ 263.

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 ’379. Ex-1005, ¶¶ 227-28, 276; 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, 2 (requiring an inner catheter diameter

≥ 0.058 in. (1.47 mm) for TAXUS Express[2] stents on a monorail delivery system). Ex-1005, ¶¶ 229-235.

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. Ex-1005, ¶¶ 277-78. 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. Ex-1021, 4-5. Ex-1005, ¶¶ 279-280.

Claim Language	Evidence & Corresponding Disclosure
[38.d.iii]	*Supra* § VII

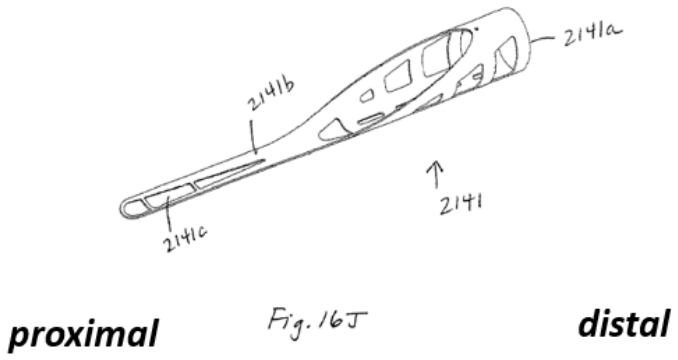
D. Claims 39-40

Claims 39-40 depend from claim 38. To the extent Patent Owner argues that Itou, alone, does not disclose claim 38, Itou and Ressemann render claim 38 (and its dependents, claims 39 and 40) obvious. *See supr*a § VIII (claim 38). Ex-1005, ¶¶ 281-82.

E. Claim 43: The method of claim 38, wherein defining the side opening portion includes forming a concave track.

To the extent Patent Owner argues that Itou, alone, does not disclose claims 38 and 43, claim 38 is obvious. *See supr*a § VIII (claim 38). Itou and Ressemann additionally render claim 43 obvious. Ex-1005, ¶¶ 283-87.

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"). *See supra* § VI (construing "concave track"); Ex-1005, ¶ 284.



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. Ex-1005, ¶ 285. *See also* Ex-1042, ¶¶ 87-105.

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 a balloon catheter and stent. *See supra* § VIII ([38.d.ii]). 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, ¶ 286; Ex-1042, ¶¶ 91-93, 101.

Second, the concavity of tab 2141b ensures that adding the collar does not impede entry into the inflation lumen. Ressemann teaches that the advantage to having an angled opening is that it "facilitate[s] smooth passage of other therapeutic devices" through the lumen. Ex-1008, 6:52-57, 23:17-20. The collar adds material to the opening of the lumen, as it is .002 inches thick. *Id*. at 25:10. And tab 2141b ranges from.020 to .050 inches in width. *Id*. at 25:11-12. Because tab 2141b is concave it does not interfere with introducing a balloon or stent catheter into the angled opening of the inflation lumen. The same holds true for adding the collar to the proximal opening of the tubular portion of Itou's suction catheter 2. Ex-1005, ¶ 287; Ex-1042, ¶¶ 92-93, 97-98.

A POSITA would have had a reasonable expectation of success because adding the support collar of Ressemann to the suction catheter of Itou is nothing more than combining prior art elements according to known methods to yield predictable results. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

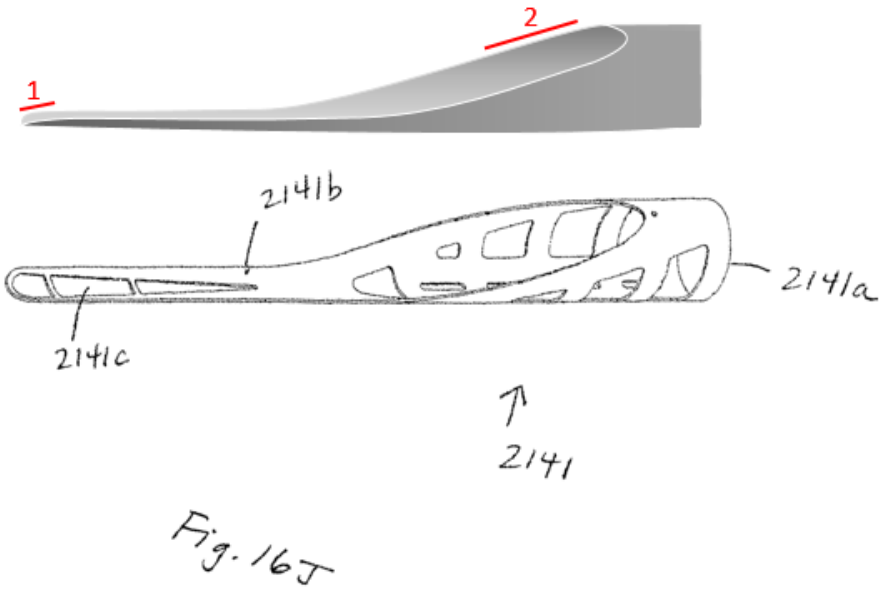
Thus, Itou in view of Ressemann renders claim 43 obvious.

F. Claim 44: The method of claim 38, where defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

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). *See supr*a § VIII (claim 43).

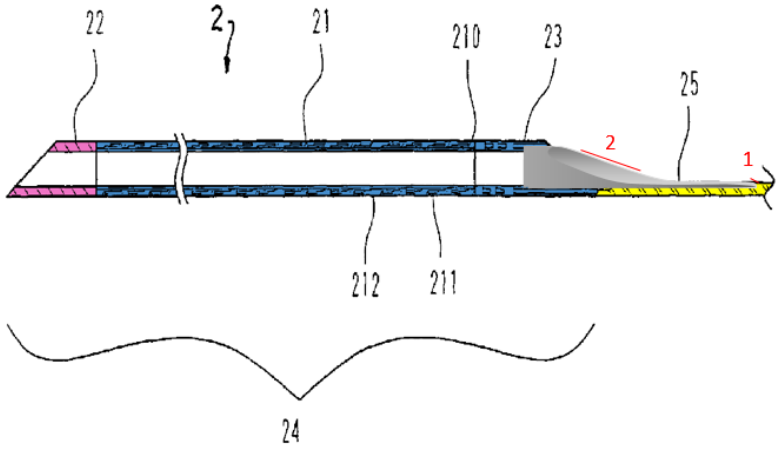
In addition to rendering claim 43 obvious, this combination also renders claim 44 obvious. Ex-1005, ¶¶ 288-292. *See also* Ex-1042, ¶¶ 87-105.

Collar 2141 has a first inclined slope at the proximal end of support collar 2141 (shown as "1" below), a flat, non-inclined region, and a second inclined slope at the distal end of support collar 2141, (shown as "2" below). Ex-1005, ¶ 290; Ex-1042, ¶ 93, 98-100. These inclined slopes are similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1005, ¶ 291; Ex-1075, 11; Ex-1042, ¶ 105.



Ex-1008, Fig. 16J and schematic of Fig. 16J.

Thus, adding support collar 2141 to Itou's suction catheter (2) discloses a side opening according to claim 44, which includes "a first inclined sidewall," "a second inclined sidewall," and "separating the first inclined sidewall and the second inclined sidewall by a non-inclined region." Ex-1005, ¶ 292; Ex-1042, ¶¶ 98-104.



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

Thus, Itou in view of Ressemann renders claim 44 obvious.

G. Claim 45

Claim 45 depends from claim 38. To the extent Patent Owner argues that Itou, alone, does not disclose claim 38, Itou and Ressemann render claim 38 (and its dependent, claim 45) obvious. *See supr*a § VIII (claim 38). Ex-1005, ¶¶ 293-94.

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

A. Claim 32: The method of claim 31, wherein a length of the one or more braided or coiled metallic elements is in a range of 20 centimeters to 30 centimeters.

Itou renders claim 32 obvious. Ex-1005, ¶¶ 295-303. As discussed in § VII, Itou anticipates claim 31. In Itou, the reinforced segment that includes one or more braided or coiled metallic elements covered with the polymer

does not extend "between 20 to 30 cm" because the entire length of the tubular portion of the catheter is only 150 mm (or 15 cm). Ex-1007, Table 1; Ex-1005, ¶ 296.

Itou, however, explains that the tubular portion ***can be*** up to 200 mm in length (or 20 cm). Ex-1007, 6:7-10 (emphasis added). In this scenario, though, at least the distal 2 mm of the suction catheter would not be reinforced, because the catheter tip must be soft and flexible, to avoid damaging the blood vessel. *Id*., at 2:15-18; Ex-1015, 549 (explaining that guide catheters include "a very soft material in the most distal 2 mm). Ex-1005, ¶ 297.

As Dr. Brecker and Dr. Hillstead explain, a POSITA had motivation to lengthen the tubular portion of Itou's catheter (2), to be longer than just 20 cm. Ex-1005, ¶¶ 298-303; Ex-1042, ¶¶ 106-110. As explained herein, a POSITA understood that the tubular structure of Itou's catheter (2) was configured so that it could be used to receive a stent or balloon catheter, and had the motivation to use it in this fashion. *See supra* §§ VII, VIII. Ex-1005, ¶ 299.

By the time of the purported invention of the '379 patent, those working in the field appreciated that interventional cardiologists were attempting to treat "more challenging lesions than in the past" using PCI procedures. Ex-1036, pp. 2948-49; Ex-1005, ¶ 300. And those in the field knew that in order to "maneuver [a catheter] through a tortuous path to [a] treatment site," the catheter must have

"sufficient 'pushability' and 'torqueability' to allow the guiding catheter to be inserted percutaneously into a peripheral artery, moved and rotated in the vasculature to position the distal end of the catheter at the desired site adjacent to a particular coronary artery." Ex-1046, 1:39-44. But also that the catheter's "distal portion should have sufficient flexibility so that it can track over a guidewire and be maneuvered through a tortuous path to the treatment site." *Id*. at 1:45-47; Ex-1005, ¶ 301. In particular, for a catheter to reach a "desired remote location in a bodily passageway, such as a small, tortuous artery," it was advantageous for the "less flexible section . . . [with] greater pushability . . . [to] comprise[] a substantial portion of the length of the catheter," while the more distal and more flexible portion could be up to 30 cm in length. Ex-1072, 2:24-25, 2:38-44. Thus, in the case of Itou's catheter (2), a POSITA would be aware that tubular structure (24) should be increased in length, up to 30 cm, to accommodate reaching lesions located in particularly tortuous vessels. Ex-1005, ¶ 302. And, in this instance, the

longitudinal length of the reinforcing braid or coil on catheter (2) would be between 20 to 30 cm.[16] Ex-1042, ¶ 110; Ex-1005, ¶ 303.

X. GROUND 4: ITOU RENDERS CLAIM 44 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)(1). Ex-1025. During prosecution of the '379 patent (and its previous iteration, the '850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. Exs-1001, 1002, 1003.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1025, [0001]. 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*. at 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*. at Abstract, [0026-0027], Fig. 10),

[16] As Patent Owner's expert witness, Peter Keith testified, "just because something is proximal to something else doesn't mean that it has to be ***entirely*** proximal." Ex-1077, 294:1-3 (emphasis added).

which corresponds to loading a thrombus into the catheter's distal end. Ex. 1005, ¶¶ 163-64; Ex-1042, ¶¶ 54-60.

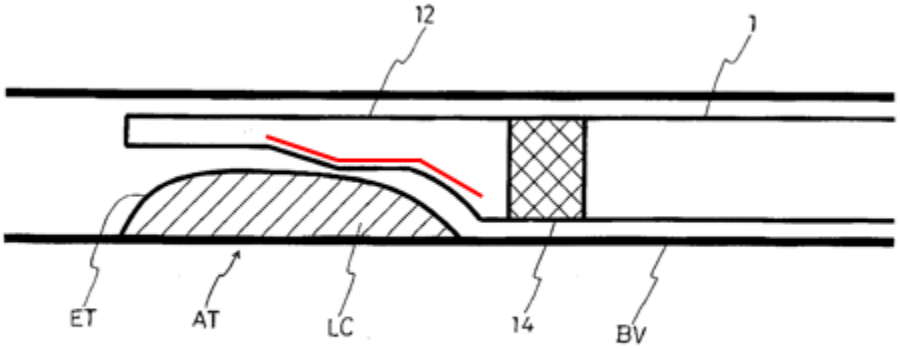


Fig. 10

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 . . . ." Ex-1025, [0010]. The catheter tip is shown below. Ex-1005, ¶ 165.

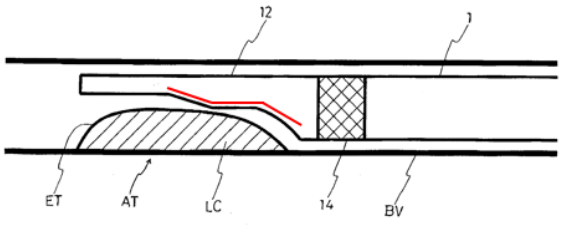


Fig. 10

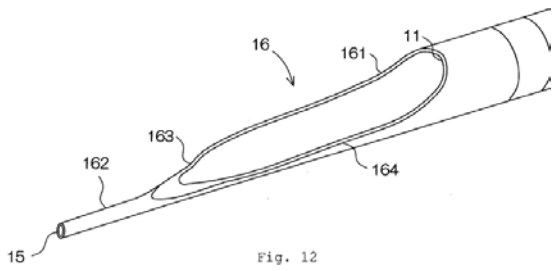


Fig. 12

Ex-1025, Fig. 10 (left, annotation added), Fig. 12 (right).

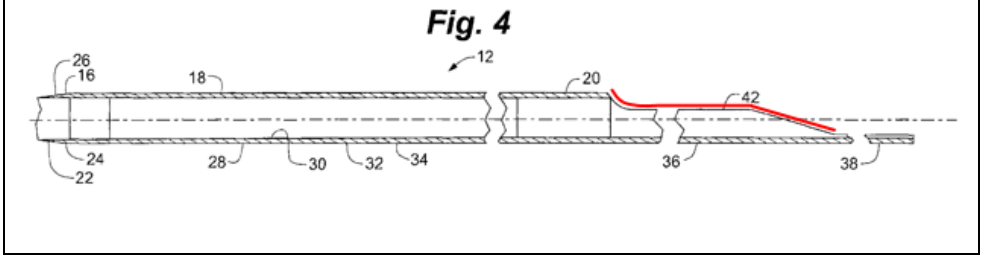
Cut surface 16 has a concave shape 161 that is closest to the fully circumferential portion of catheter lumen 11. The concave shape is adjacent "ledge surface 164," which is parallel to the catheter's longitudinal axis. Moving distally, "cut surface 163 defin[es] an angle with the longitudinal axis of the catheter." *Id*. at [0027]. Ex-1005, ¶¶ 166-67, *see also id.* at ¶¶ 113-117.

B. Claim 44: The method of claim 38, wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

As discussed in §§ VII and VIII, Itou anticipates claim 38, or renders it obvious in view of Ressemann. Claim 44 is also rendered obvious by Itou in view of Kataishi and the common knowledge of a POSITA. Ex-1005, ¶¶ 304-314.

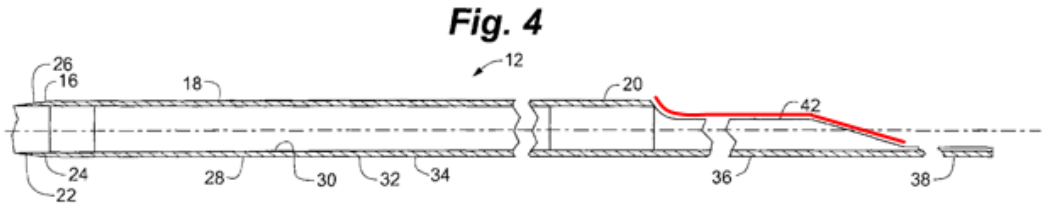
In an attempt to support claim 44, patentee represented to the Examiner that Fig. 4 of the '379 patent showed two different inclined slopes in the side opening.

'379 Patent



Ex-1003 at 31 (12/30/15 Preliminary Amendment at 24) (annotation added).

Of course, the disclosure in the ’379 patent is no different than what was disclosed in Kataishi,



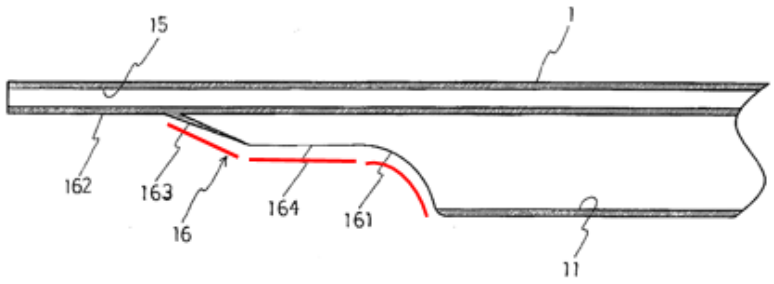


Fig. 2

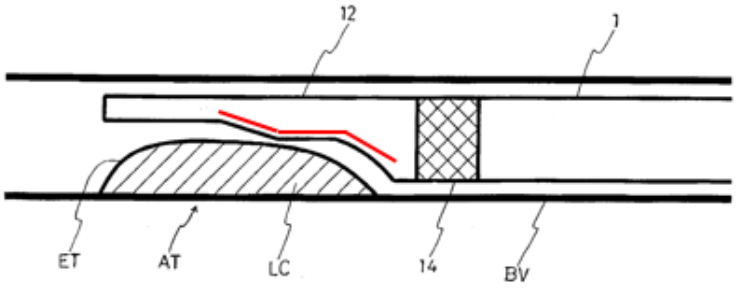


Fig. 10

Compare Ex-1001, Fig. 4 (annotation added), *with* Ex-1025, Figs. 2, 10 (annotation added). Ex-1005, ¶¶ 304-05; Ex-1042, ¶¶ 118-119.

A POSITA had the motivation to modify the proximal opening of the tubular structure of Itou’s suction catheter so that it was configured to include two

different inclined slopes and a non-inclined region in Kataishi. Itou and Kataishi are both directed at the same problem, which is removing occlusions from coronary arteries. Ex-1008, Abstract; Ex-1025, Abstract. Ex-1005, ¶ 306.

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. *See supra* §§ VII, VIII. 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-1005, ¶¶ 307-08, 312; Ex-1042, ¶¶ 112-16.

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-1005, ¶ 309; Ex-1042, ¶¶ 112-14. 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. Ex-1005, ¶ 310; Ex-1042, ¶ 115. 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. Ex-1005, ¶ 311.

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, ¶ 312; Ex-

1042, ¶ 116. 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, ¶ 116; Ex-1042, ¶¶ 111, 116.

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-1005, ¶ 313; Ex-1042, ¶ 116-19; 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. Claim 44 is obvious. Ex-1005, ¶ 314.

XI. GROUND 5: ITOU RENDERS CLAIM 44 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 prosecution of the '850 patent. Ex-1002. It is cited on the face of the '379 patent, but was not discussed during

prosecution.[17] Exs-1001, 1003. Enger discloses a balloon catheter for use in a coronary artery. Ex-1050, Abstract. Ex-1005, ¶¶ 168-172. *See also* Ex-1042, ¶¶ 61-62.

B. Claim 44

As discussed in §§ VIII and X, Itou renders claim 44 obvious, either in view of Ressemann, or in view of Kataishi. Claim 44 is also rendered obvious by Itou in view of Enger. Ex-1005, ¶¶ 315-325.

Like Itou, Enger is directed to a catheter system for treating occluded coronary arteries. *See supra* § VII; Ex-1050, Abstract, 1:13-15. Like Itou's suction catheter, Enger's angioplasty catheter is inserted through a guide catheter and into

[17] 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).

the coronary artery. Ex-1050, 3:25-27. And, like Itou's suction catheter, Enger's angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*. at 3:9-12. Ex-1005, ¶ 315.

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 the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy. Ex-1050, 2:38-49. Ex-1005, ¶ 316.

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. Ex-1050, 4:66-5:11. Ex-1005, ¶ 317.

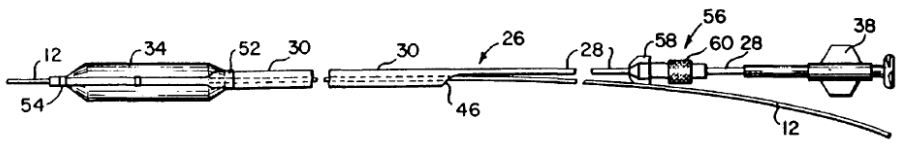


Fig. 1

Ex-1050, Fig. 1.

The catheter is designed to have a short, distally located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*. 3:9-10, 5:34-40. Ex-1005, ¶ 318.

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

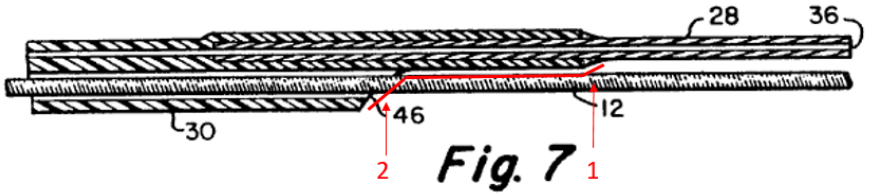


Fig. 7

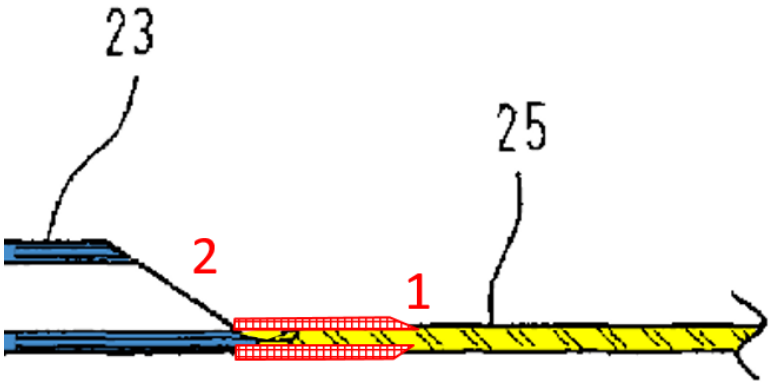
[18] Enger teaches that enclosing the guidewire in a lumen in the distal and intermediate segments of the catheter (over a 35-45 cm length) is advantageous because it allows those segments to be "supported by the guidewire" that extends through the lumen. Ex-1050, 3: 9-10, 21-24. This ensures that the 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*. at 3:25-29. Ex-1005, ¶ 319.

Ex-1050, Fig. 7 (annotation added). Ex-1005, ¶ 320.

As Dr. Hillstead explains, Enger's incline #1 functions as a start of an incline 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, ¶¶ 120-22; Ex-1005, ¶ 321. A POSITA would be motivated to provide a first incline to function as an "on-ramp" to guide interventional devices such as distal end protective device or stent and balloon catheter (5) into the lumen of Itou's suction catheter (2). Ex-1005, ¶ 322.

As Dr. Hillstead explains, the first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1042, ¶ 122; Ex-1005, ¶ 323. 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, ¶¶ 123-24; Ex-1005, 324.

This would result in a two-incline opening as shown schematically in modified Figure 3 of Itou. Ex-1005, ¶ 325.



Ex. 1007, Fig. 3, modified by Petitioners with teaching of Enger and illustrating two-incline opening.

Thus, Itou in view of Enger renders claim 44 obvious.

XII. 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 Petitioners launched a "copycat" product. *Id.* at 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.

XIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the claims 25-26, 29-40, and 42-45 of the ’379 patent as unpatentable under 35 U.S.C. §§ 102 or 103.

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

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

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 12, 2019
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WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 13,085 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 word count.

Dated: November 12, 2019

/ Cyrus A. Morton /

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CERTIFICATE OF SERVICE

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

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

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