UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

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Case No.: IPR2020-00128
U.S. Patent No. RE45,380

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 45,380**

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## I. PRELIMINARY STATEMENT

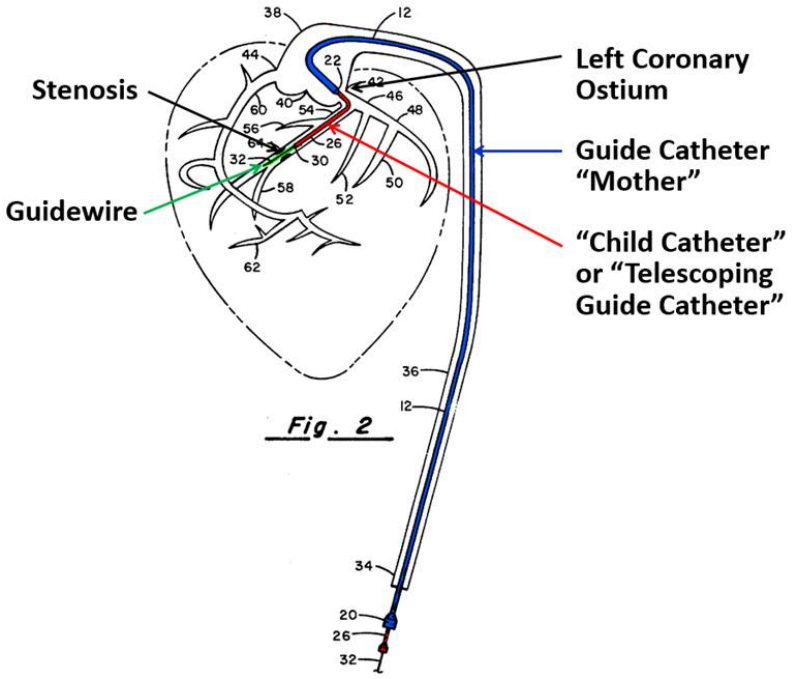
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 1-4, 6-10, 12-21, and 23 ("Challenged Claims") of U.S. Pat. No. RE 45,380 ("the '380 patent," Ex-1001). The '380 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1001, [62])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id.*, [54], [72]. The Challenged Claims were never subject to an Office Action, meaning there is no substantive file history for the '380 patent.

The '380 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 **g**uide **c**atheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id.*, Abstract; Figs. 8, 9. In

[1] The '380 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1005, ¶¶ 75 n.8, 129. A POSITA knew that the "coaxial guide catheter" of the '380 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1009, 5:49-50 (referring to body 12 "as a guide catheter extension").

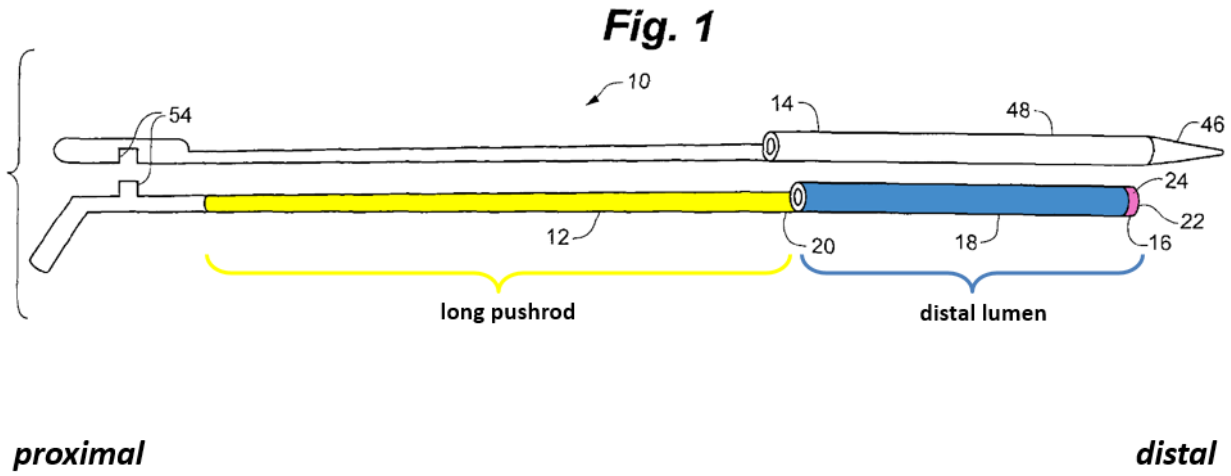
so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id*., 3:1-5; s*ee also id*. 8:19-30.

The '380 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. Ex-1001, 2:40-56 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a "mother-and-child assembly," (Ex-1005, ¶¶ 74-84, 103-104) where the child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. Ex-1005, ¶ 74.



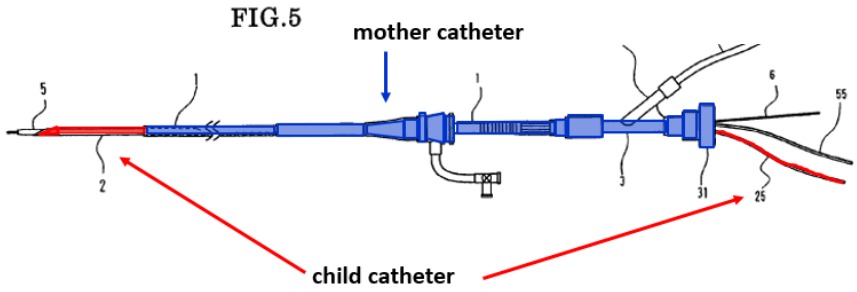

Ex-1054, Fig. 2 (annotation and color added).

The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id*. The '380 patent alleges that such a design had certain drawbacks (Ex-1001, 2:57-67) and modifies the child catheter of the mother-and-child assembly to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



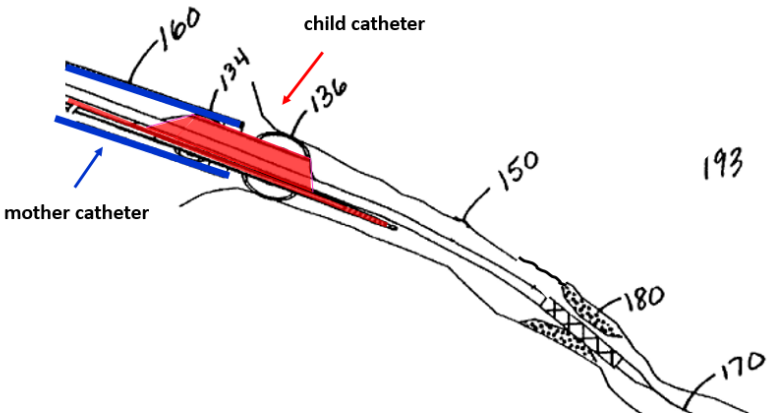

Ex-1001, Fig. 1 (annotations and color added).

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




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

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




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

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the ’380 patent are unpatentable. Accordingly, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the Challenged Claims.

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

### A. Real Party-in Interest

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

### B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the ’380 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 '380 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent). The '850 patent was previously the subject of litigation (i) in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and (ii) at the PTAB in *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (P.T.A.B., terminated Aug. 11, 2014).

Petitioner is also concurrently filing another petition for IPR challenging the '380 patent based on prior art references having different priority dates and disclosures than the references discussed herein, or challenging different claims.

### C. Lead and Backup Counsel

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

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

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

### D. Service Information

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

## III. REQUIREMENTS FOR INTER PARTES REVIEW

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

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the ’380 patent is available for IPR and that Petitioner is not barred or estopped from requesting such review of the ’380 patent on the identified grounds.

### B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 1-4, 6-10, 12-21 and 23 of the ’380 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

| No. | Grounds |
|---|---|
| 1 | Claims 1-4, 6-10, 12-20, and 23 are anticipated by U.S. 7,736,355 (“Itou”). |
| 2 | Claims 3, 14, and 15 are rendered obvious by Itou in view of U.S. 7,604,612 (“Ressemann”) and the knowledge of a POSITA. |
| 3 | Claim 21 is rendered obvious by Itou in view of U.S. 5,911,715 (“Berg”) and the knowledge of a POSITA. |

## IV. BACKGROUND

### A. Overview of the Technology

Coronary artery disease (“CAD”) occurs when plaque buildup narrows the arterial lumen. Ex-1005, ¶¶ 32-36. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id*. In response, physicians developed percutaneous coronary interventional (“PCI”) procedures

[2] This petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1005), and Richard A. Hillstead, PhD (Ex-1042), as experts in the field of the ’380 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1078) to support authenticity and public availability of the documents cited herein.

that use catheter-based technologies inserted through the femoral or radial artery, and thus can treat CAD without the need for open-heart surgery. Ex-1005, ¶¶ 33, 38-44.

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

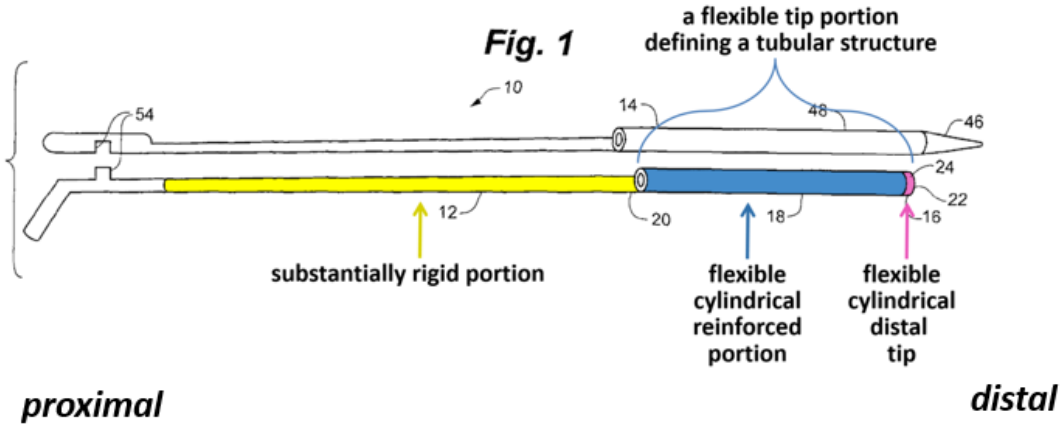
stenosis. Ex-1005, ¶¶ 63-69. This last step—crossing the guidewire and therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium. Ex-1005, ¶¶ 70-71. As discussed above, one way to ameliorate this backward force is to use a mother-and-child catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id.*, ¶¶ 72-84.

### B. The ’380 Patent

The ’380 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:32-33. In particular, the ’380 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends through the lumen of a GC, “beyond the distal end of the guide catheter and insert[s] into [a] branch artery.” *Id.*, Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id.*, 5:23-26; Ex-1005, ¶¶ 129-30.

The ’380 patent explains that the guide extension catheter 12 has a tubular portion that includes a flexible distal tip 16 (pink) and a reinforced portion 18 (blue), as well as rigid portion 20 (yellow). Ex-1001, 3:51-53; 6:34-35; Fig. 1. Color has been added to Figure 1, below, which has been annotated with the

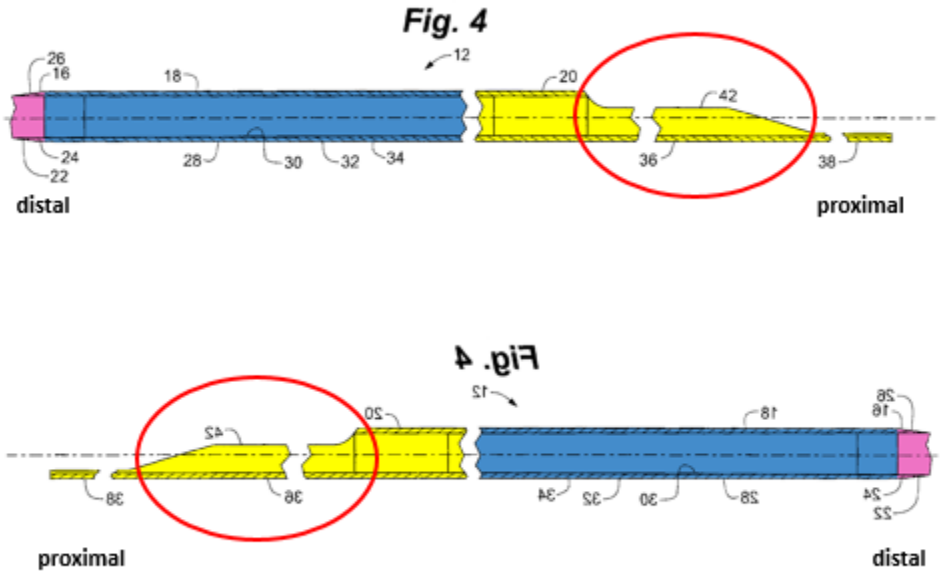
language of claim 1.[3] Ex-1005, ¶ 131.




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

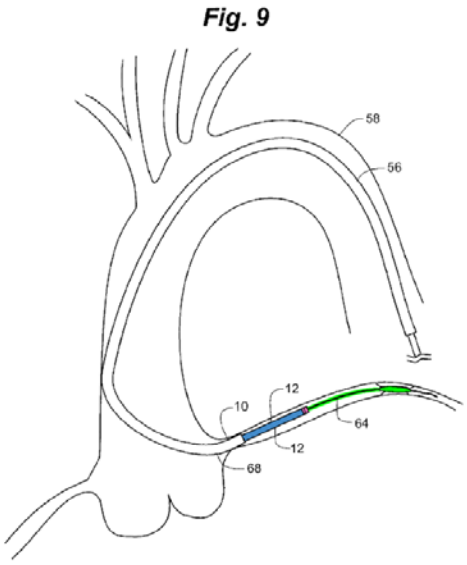
The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "side opening," (red circle), which may have an "inclined slope." *Id*., Figs. 4, 13-16; *see also id.* 6:62-7:11, 8:58-64; claims 3, 26; Ex-1005, ¶ 132.

[3] In claim 1 "a flexible tip portion" defines "a tubular structure." Ex-1001, 10:58. The "tubular structure" in claim 1 further "includes a flexible cylindrical distal tip portion (pink) and a flexible cylindrical reinforced portion (blue)." *Id.*, 11:19-21. Claim 12 describes the guide extension catheter using different language. Specifically, claim 12 recites "a flexible tip portion defining a tubular structure," and a "reinforced portion" that is proximal to the flexible tip portion. *Id.*, 12:17, 29 (corresponding, respectively, to the pink and blue portions of annotated Fig. 1).




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

The ’380 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, ¶ 133.




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

### C. Prosecution History of the ’380 Patent

The parent ’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. The Examiner, however, was not aware of Itou or Ressemann. Patent Owner

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

sought reissuance in 2013, and as with the original prosecution, the claims of the '380 patent issued without an Office Action. Ex-1003.

### D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim that is not supported by a pre-March 16, 2013 application. AIA § 3(n)(1)(A); MPEP § 2159.02. The '380 patent is subject to the AIA first-to-file provisions because it contains at least one claim that lacks written description, and therefore pre-AIA priority. Thus, Patent Owner cannot swear behind Itou in this proceeding. First, no pre-AIA application to which the '380 patent claims priority contains disclosure of "a proximal side opening" outside of the substantially rigid segment, but the independent claims permit the side opening to be in the "flexible tip portion" or "reinforced portion." *Compare* Ex-1001, claims 1, 11 (independent claims not restricting location of side opening) *with id*., claim 3 (dependent claim 3 requiring side opening to be in "tubular portion" of flexible tip portion"). Second, claim 27 requires a side opening with two inclined slopes, while the only alleged support (*See* Ex-1003 at 19 (Preliminary Amendment, November 1, 2013)), Fig 4, discloses an arc and an inclined slope. Third, claim 27 requires a side opening portion with "at least two different inclined slopes," but there is no support for more than two. At best, the '380 patent supports ***only*** two inclined slopes. Ex-1001, Fig. 4.

## V. THE PERSON OF ORDINARY SKILL IN THE ART

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

## VI. CLAIM CONSTRUCTION

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, Patent Owner stipulated to the following constructions:

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1012 at 2)
- "interventional cardiology device(s)": "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters" (*Compare* Ex-1012 (Dkt. 36-1) at 21 (Patent Owner construction), *with* Ex-1064 at 1 n.1 (agreeing to Patent Owner's construction)).

Further, Patent Owner advanced,[5] and the district court adopted, the following constructions:

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

Additionally, the district court provided the following construction:

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

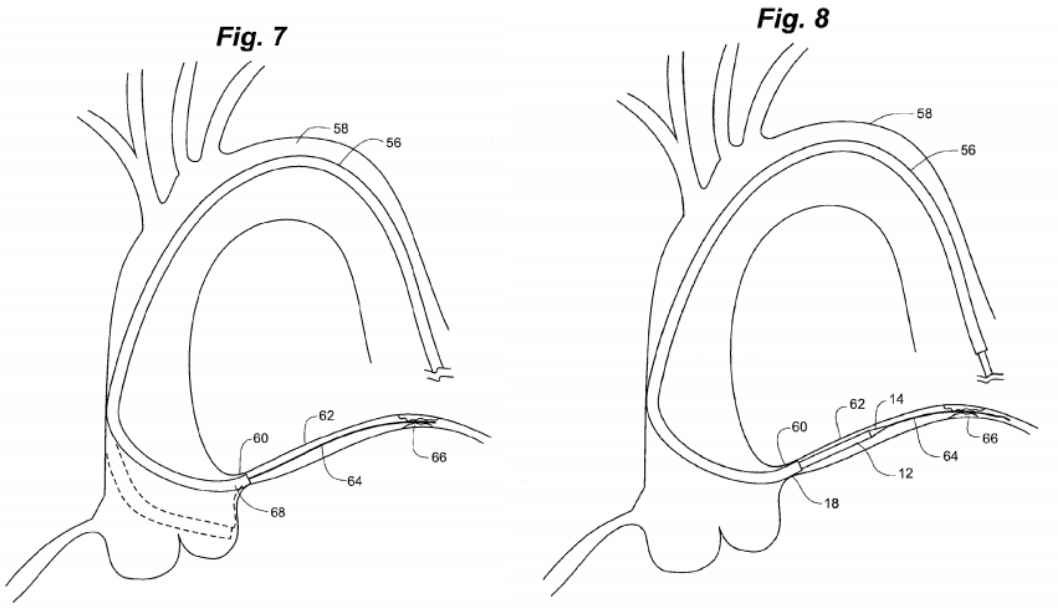
- "side opening": "need[s] no construction and will be given [its] plain and ordinary meaning" (*Id.*, 26)
- "lumen": "the cavity of a tube" (*Id.*, 25).

Petitioner agrees with the above constructions for purposes of this IPR[6] (Ex-1005, ¶¶ 134-40) and proposes the following additional constructions:

**A. "placed in the branch artery" (cl. 1, 12)**

Claims 1 and 12 recite, *inter alia*, "a guide catheter having . . . a distal end adapted to be placed in the branch artery." In the context of the '380 patent, "placed in the branch artery" includes "placement in the ostium of a coronary artery." Ex-1005, ¶¶ 141-46. For instance, the '380 patent notes in its background the well-understood fact that a "guide catheter is typically seated into the . . . ostium of the artery . . . ." Ex-1001, 1:55-59. This is further shown in figures 7 and 8 (reproduced below), and confirmed by other description in the '380 patent. The patent describes that a GC is "inserted into the ostium of a branch artery where it branches off from a larger artery." *Id*., 4:63-64, 5:6-8, 18, 26-27, 7:51-53, 8:8-10, 10:25-32, Figs. 7, 8.

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




It is more common in the art to refer to arteries branching off ***from*** the coronary arteries as branch arteries, rather than to the coronary arteries themselves. Ex-1005, ¶ 143. However the patent explicitly states that "guide catheter 56 is brought into proximity of ostium 60 of a smaller ***branch*** blood vessel, ***such as coronary artery 62***." Ex-1001, 10:1-5 (emphasis added). Thus, to the extent Petitioner's construction deviates from the plain meaning, the inventors acted as their own lexicographers. *Laryngeal Mask Co. v. Ambu, A/S*, 618 F.3d 1367, 1371-72 (Fed. Cir. 2010).

**B. "flexural modulus" (cl. 20, 21)**

The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1042, ¶ 31), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means "[a] measure of resistance . . . to bending." Ex-1040, 772.

In other words, the "flexural modulus" is a measure of a device's rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. This is admitted by the '380 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1001, 7:25-32; Ex-1005, ¶¶ 147-148. Stated differently, the extension catheter's resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the distal end (flexible tip) is the most flexible (least rigid).[7]

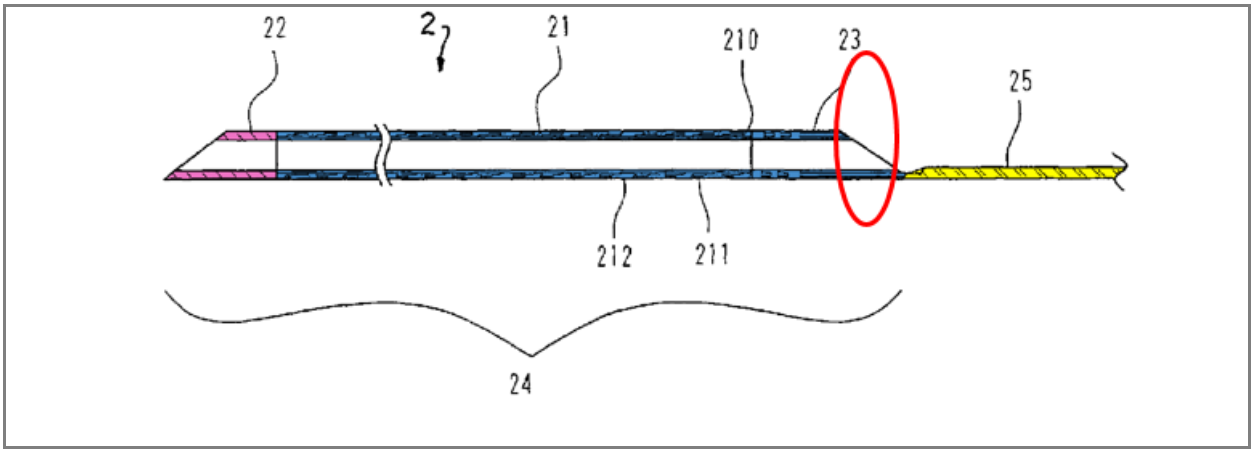
## VII. GROUND 1: ITOU ANTICIPATES CLAIMS 1-4, 6-10, 12-20 AND 23.

### A. Itou

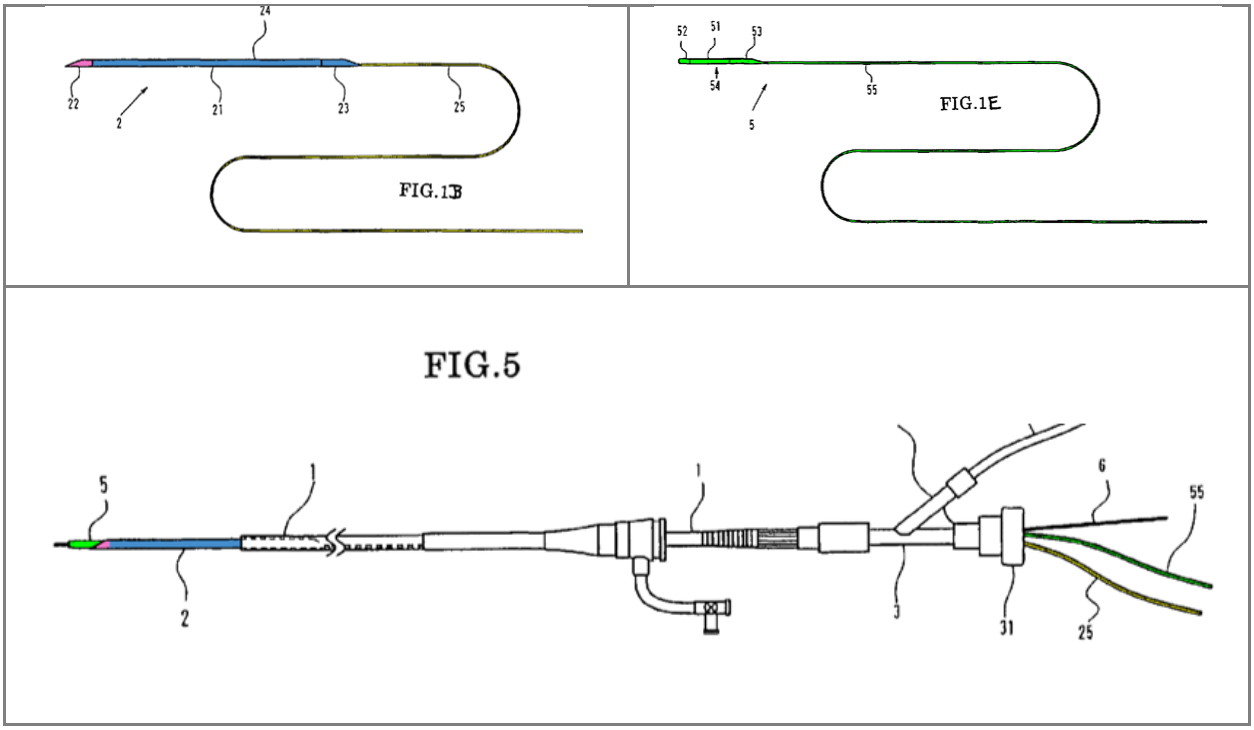
Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. It is prior art under both pre-AIA § 102(e) and post-AIA § 102(a)(1), (a)(2), and was not cited or considered during prosecutions of either the original '850 patent, or of the '380 reissue patent. Ex-1001-1003.

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

Itou discloses a catheter assembly for alleviating the obstruction of blood flow. Ex-1007, 1:13-16. The assembly includes a GC that is inserted into a coronary artery ostium, *id*., 2:2-5, Abstract, 5:32-34, 7:7-10, and a suction catheter that is insertable through the GC. *Id*., 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*., Abstract, 1:53-60, 2:12-15, 3:46-50 (color added). Tubular portion (24) includes a "soft tip whose distal end is flexible in order to reduce the damage to the blood vessel," (22) (pink), *id*. 2:15-18, and a portion reinforced with a metal layer (211) (blue). *Id*., 2:18-21; 3:50-58 (color added). The tubular structure's proximal opening is angled (red circle).




*Id*., Fig. 3; Ex-1005, ¶¶ 94-98, 149-152; Ex-1042, ¶¶ 21-26.




Itou also describes a "distal end protective catheter" (5), shown above in green, which is insertable through the suction catheter (2). *Id*., Figs. 1B, 1E, 5 (color added). Suction catheter (2) may be extended beyond the distal end of the GC (1) into a coronary artery. *Id*., Abstract, 2:27-38; Figs 5, 6; Ex-1005, ¶¶ 160-166, 181.

Where a prior art reference contains the claim elements in the same order as the claims it is anticipatory, regardless of whether the prior art and the claimed invention are directed to achieving the same purpose. *Legget & Platt, Inc. v. VUTEK, Inc*., 537 F.3d 1349, 1356 (Fed. Cir. 2008). Nevertheless, by the time of the alleged invention of the '380 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 main 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*., 3:34-36, 12:16-20; Ex-1008, 6:18-34, Figs. 6A-6I; Ex-1005, ¶¶ 94-102, 149-159.

### B. Claim 1

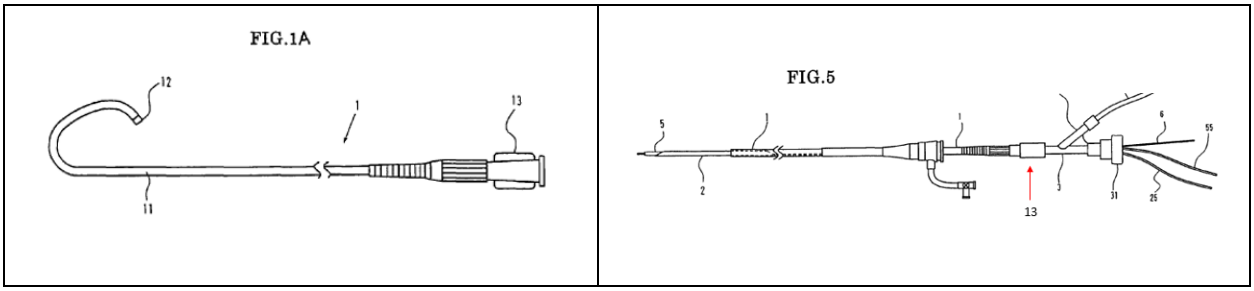
#### 1. [1.pre] "A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:"

To the extent the preamble is limiting, Itou discloses it. Ex-1005, ¶¶ 160-166; Ex-1007, 1:66-2:11; *and see id*., Abstract; 5:32-34; Fig. 6. As discussed herein, Itou discloses a combination of guiding catheter 1 and suction catheter 2 (i.e. "a system") and further discloses the system's use in delivering a protective catheter 5 and a guidewire 6 to the location of a coronary artery occlusion. *Id*., 5:35-38, 43-46, 7:1-23, 35-42, Figs. 5-6, 8. Both protective catheter 5 and guide wire 6 are "interventional cardiology devices," *supra*, § VI, that are adapted to be insertable into a branch artery.

#### 2. [1.a.i] "a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery,"

Itou discloses [1.a.i]. Ex-1005, ¶ 167.

Guiding catheter (1) has distal end (12) and body portion (11), which terminates at connector (13). Ex-1007, Fig. 1A; 3:29-37. Connector (13) is coupled to Y-shaped connector (3), which includes main connector portion (31). *Id*., 5:11-20. Connector (31) includes a valve, which can close a bore in connector (31) and "selectively clamp and fix the guide wire 6, the wire-like portion (25) or (55) to prevent leakage of the blood." *Id*., 5:20-23.




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

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

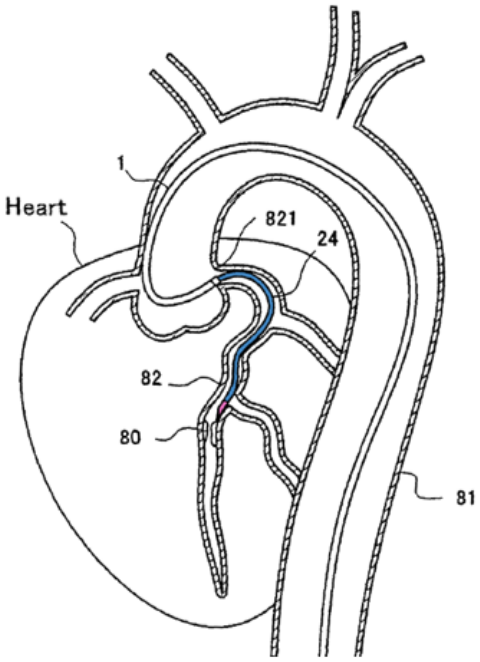
Additionally, the capability of a valve, connected to the proximal end of guiding catheter (1), to prevent a leak indicates that guiding catheter (1) has a continuous lumen (meaning the walls of the guiding catheter (1) are continuous along its length). Ex-1005, ¶ 167. Moreover, a POSITA understands Itou's

teachings to disclose that the proximal end of guiding catheter (1) extends from a hemostatic valve.[8] Ex-1005, ¶ 167; *see also id*. ¶¶ 39, 46-59, 63-84, 141-146.

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

[8] Itou's disclosure reflects what the '380 patent admits, which is that the "guide catheter . . . can be delivered through ***commonly existing hemostatic valves*** used with guide catheters while still allowing injections ***through the existing Y adapter***." Ex-1001, 3:21-24 (emphasis added). Similarly, Patent Owner's expert in the co-pending litigation explains that a hemostatic valve is sometimes called a Y-connector, Ex-1082, ¶ 18; Ex-1005, ¶ 167, which is also known as a Y-adapter.

FIG.6




*Id*., Fig. 6 (color added).

Itou explicitly discloses that the GC may be placed in "an ostium portion of a coronary artery." *Id*., 2:4-5. Thus, Itou teaches placement of guiding catheter (1) that meets the construction of "placed in the branch artery," which includes "placement in the ostium of a coronary artery." *See* § VI.A, *supra*; Ex-1005, ¶ 167.

**3. [1.a.ii] "the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and"**

Itou discloses [1.a.ii]. Ex-1005, ¶ 168.

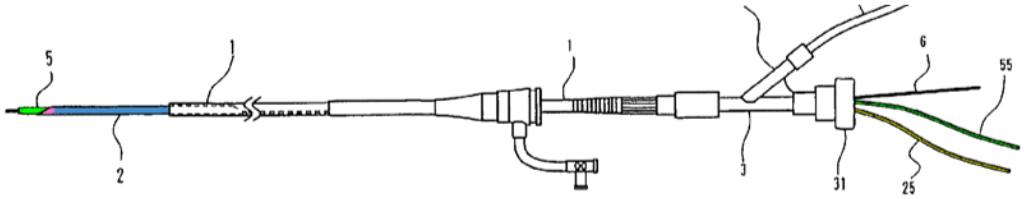
TABLE 1

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

Ex-1007, Table 1.

Because guiding catheter (1) has an "inner ***diameter*** of 1.8 mm," it necessarily has a "circular cross section." Ex-1005, ¶ 168. Distal end protective catheter (5) has a maximal outer diameter of 1.35 mm, and has a lumen of "a size sufficient to receive . . . guidewire (6) . . . ." Ex-1007, Table 1; 4:61-63. Thus, both protective catheter (5) and guidewire (6), which are "interventional cardiology devices, *supra*, § VI, sized to be insertable into and through the lumen of the guiding catheter (1). Ex-1007, 3:59-63, 4:43-52, Fig. 5; Ex-1005, ¶ 168; *see also* ¶¶ 46-59.

FIG.5



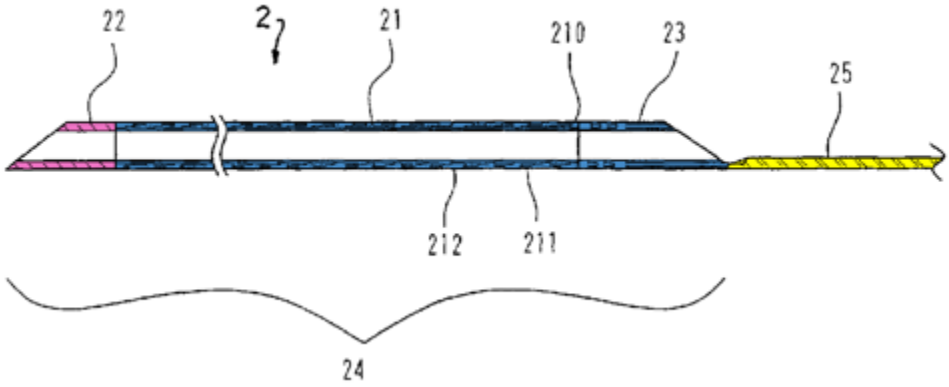

Ex-1007, Fig. 5 (color added).

**4. [1.b] "a device adapted for use with the guide catheter, including:"**

Itou discloses [1.b]. Ex-1005, ¶¶ 161-162, 169. Suction catheter (2) is used with guiding catheter (1). Ex-1007, Abstract; Figs. 1A, 1B, 5, 6; 2:5-11, 27-38; 5:12-17; 5:26-42; 7:7-23.

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

Itou discloses a flexible tip portion defining a tubular structure and having a circular cross-section. Ex-1005, ¶ 170 and n.12. Tubular portion (21) and tip (22) of suction catheter (2) comprise the "flexible tip portion." Ex-1007, 2:12-21; Fig. 3; *see also* § VII.B.7, *infra*.




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

As shown above, "flexible tip portion" [21, 22] is part of tubular member 24. As a cross section through tubular member (24) is necessarily circular, *id*., Table 1 (disclosing an inner ***diamete***r for catheter 2's tubular portion of 1.5mm), *and see id*. Fig. 7B, the same is true for a cross section through portion (21). Ex-1005, ¶ 170.

Because Itou explicitly teaches that tubular portion (24) "is shorter than the guiding catheter," Ex-1007, 2:23-26, flexible tip portion [21, 22] necessarily has "a length that is shorter than the predefined length of the continuous lumen of the guide catheter."

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

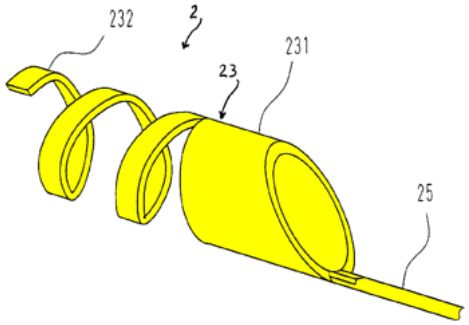
to be insertable through the cross-sectional inner diameter of the continuous lumen of the guiding catheter (1.8 mm). *Id*., Table 1, 1:60-65.

Flexible tip portion [21, 22] defines a lumen that is coaxial to the guiding catheter. *Id*. Figs. 4-6; *and see id*. Table 1 (providing both inner and outer diameters for suction catheter (2)). Finally, protective catheter (5) is an interventional cardiology device insertable through flexible tip portion [21, 22]. *Id*., Table 1, 4:48-52, 7:1-23, Fig. 5. Thus, Itou discloses [1.b.i]. Ex-1005, ¶ 170.

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

Itou discloses [1.b.ii]. Ex-1005, ¶¶ 171-184. Itou's suction catheter (2) has a "substantially rigid portion," which includes solid wire-like portion (25) on the catheter's proximal end that is "formed from a solid metal wire and an outer layer such as a polymer coating." Ex-1007, 3:47-50, Fig. 1B. Wire-like portion (25)'s

distal end is fused to the proximal portion of an obliquely cut metal pipe (231), *id.*, 4:25-36, which is also part of the "substantially rigid" portion. [9] ("Mapping-1"). Ex-1005, ¶ 171.

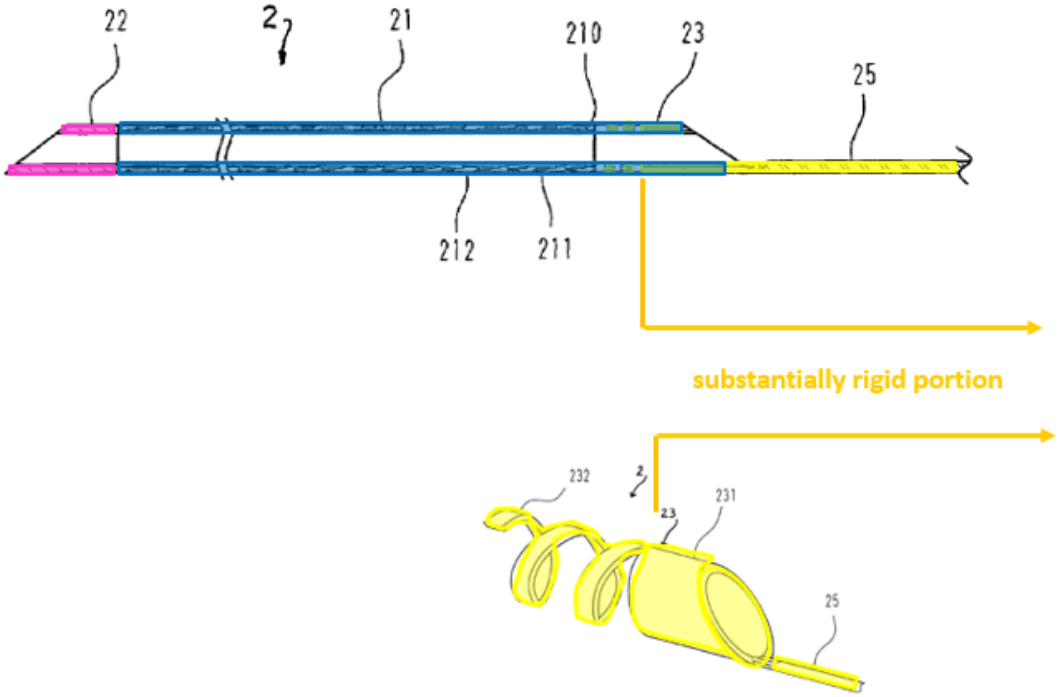



Ex-1007, Fig. 4 (color added).

Wire-like portion (25) and end (231) are used to advance suction catheter (2) to a target location (80), which refers to a location deep in a coronary artery. *Id.*, 2:32-38, 5:35-38, 5:43-46. Thus, wire-like portion (25) and/or end (231) must be

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

"rigid enough to allow the device to be advanced within the guide catheter." *See* § VI (claim construction of "substantially rigid"), *supra*; Ex-1005, ¶ 171.

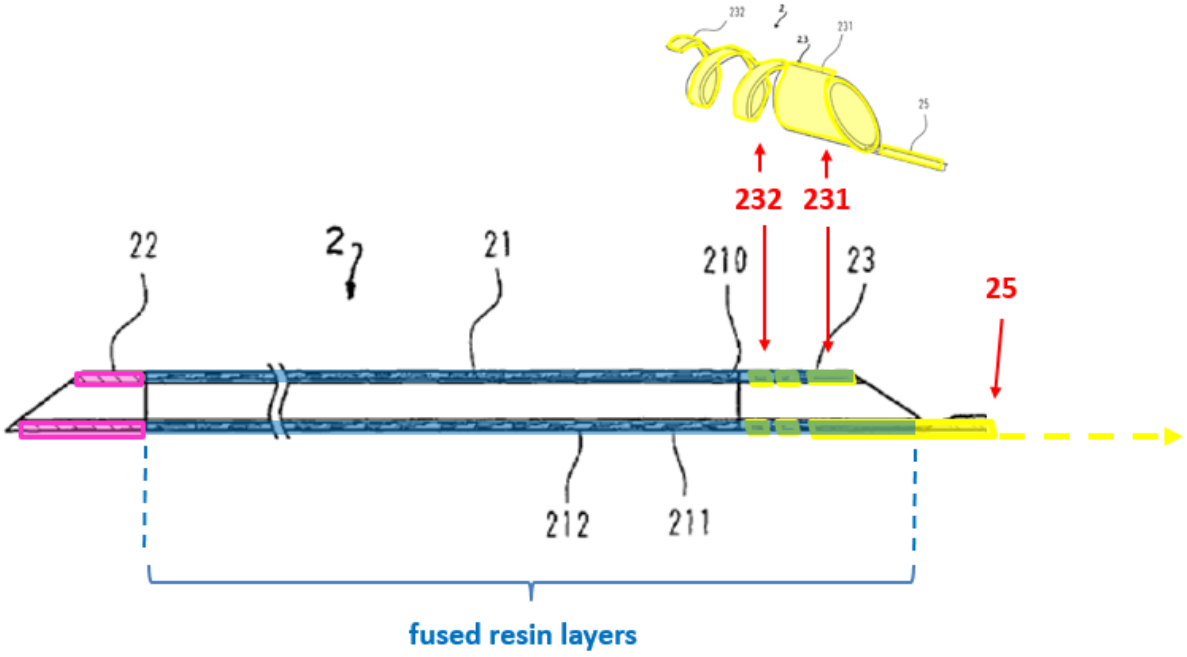



Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).

Under both mappings, Itou's substantially rigid portion [25 and 231, or 25 alone] is operably connected to its flexible tip portion [21, 22].[10] The distal end of wire-like portion (25) is welded to the proximal end of proximal tip (231). *Id*., 4:43-48. End (231) is formed by obliquely cutting the proximal end of a metal pipe, while the distal end of the metal pipe is formed into spiral shape (232). *Id*.,

[10] There is no antecedent basis for a "flexible distal tip portion." The claim only makes sense if it is the same as the "flexible tip portion" claimed in [1.b.i].

4:27-32. Both the inner—and the outer—faces of end (231) and spiral (232) are encased in resin layers, which are fused to the resin layers of tubular portion (21), operably connecting it to portion 25 and 231. *Id.*, 3:50-58, 4:32-33, 4:36-38.




Ex-1007, Figs. 3, 4 (color and annotation added). Ex-1005, ¶ 171.

Each, alternative substantially rigid portion is more rigid along a longitudinal axis than flexible tip portion [21, 22]. First, both 25 and 231 are made of solid metal. *Id.*, 4:27-32. By contrast, the "flexible tip portion" includes tip (22), which is described as soft and "flexible in order to reduce the damage to the blood vessel." Ex-1007, 2:15-21. It also includes tubular body portion (21), which includes an inner layer made of resin (210), such as PTFE, a reinforcing layer made of metal (211), and outer layer (212). *Id.*, 3:50-58.

As Dr. Brecker and Dr. Hillstead explain, based on the known properties of the materials of portions 25 and 231 and flexible tip portion [21, 22], the former are more rigid along a longitudinal axis. Ex-1005, ¶¶ 170-171; Ex-1042, ¶¶ 48-58, 63-72. This is further evidenced by the function Itou discloses for proximal, wire-like portion (25), which is to advance suction catheter (2) to a deep location in the coronary vasculature. Ex-1007, 5:43-46. It was well understood in the art that in order to advance through the coronary vasculature, the proximal portion of a catheter necessarily had to have sufficient rigidity or stiffness (in order to permit the catheter to be pushed through the vasculature), while its distal end was fairly flexible. Ex-1019, 9:30-50; Ex-1072, 2:29-44; Ex-1005, ¶¶ 172-177; Ex-1042, ¶¶ 27-32.

Each mapping includes a "rail structure without a lumen," which is wire-like portion 25.[11] Wire-like portion (25) does not have a "lumen" because it is "formed

[11] Claim 1 (and claim 11) recite numerous limitations on the substantially rigid portion, including "defining a rail structure without a lumen." Thus, while the substantially rigid portion includes a rail structure without a lumen, the claim does not say it is limited to only that structure (Ex-1007, 138:24-139:10), particularly where it is "operably connected to . . . the flexible tip portion." Dependent claims 9

from a ***solid*** metal wire." Ex-1007, 3:47-50; *and see* 2:12-15. Wire-like portion (25) is a "rail structure" because it facilitates the sliding rail delivery of suction catheter (2) through guiding catheter (1). *Id*., Figs. 5, 6, 4:43-52, 5:26-46. Ex-1005, ¶ 178.

Wire-like portion 25 has a cross sectional outer diameter of 0.45 mm, which is smaller than the cross sectional outer diameter of the tubular portion of the suction catheter [including flexible tip portion [21, 22]), which is 1.72 mm. Ex-1007, 3:59-63; Table 1. Thus, the "rail structure without a lumen" in Itou has a "maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion." [12] Ex-1005, ¶ 179.

Wire-like portion (25) is 1100 mm long. Ex-1007, Table 1. This, alone, is longer than the 1000 mm length of the disclosed guiding catheter. *Id*. Thus, the combined length of wire-like portion (25) and flexible distal tip portion [21, 22] is

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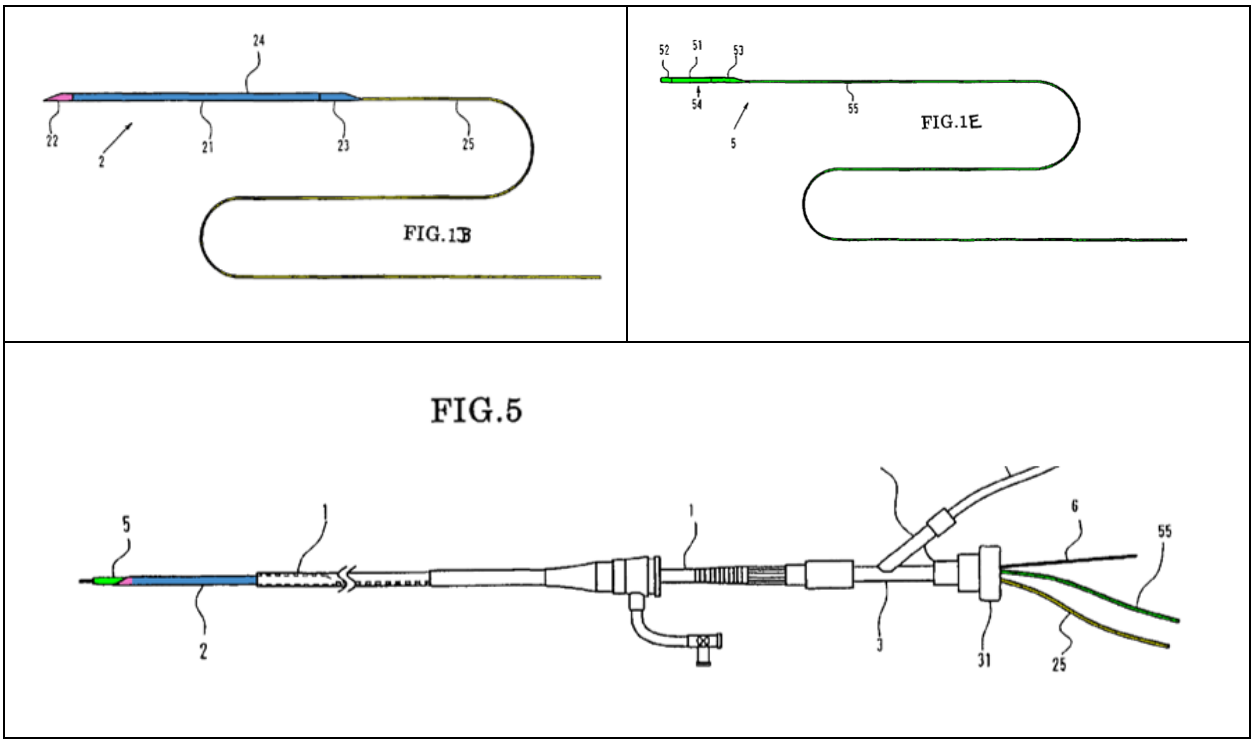
and 14 confirm this reading and require the side opening, which necessarily includes a lumen, to be part of the substantially rigid portion.

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

necessarily greater than that of the guiding catheter. *Id*., 2:23-26. Ex-1005, ¶ 180.

When at least a distal portion of flexible tip [21, 22] is extended distally of the distal end of the guiding catheter, at least a portion of wire-like portion (25) extends proximally through the hemostatic valve in common with the hemostatic valve through which the distal end protective catheter 5 and guidewire 6 are insertable. Ex-1007, 5:11-23; Ex-1005, ¶¶ 181-183.




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

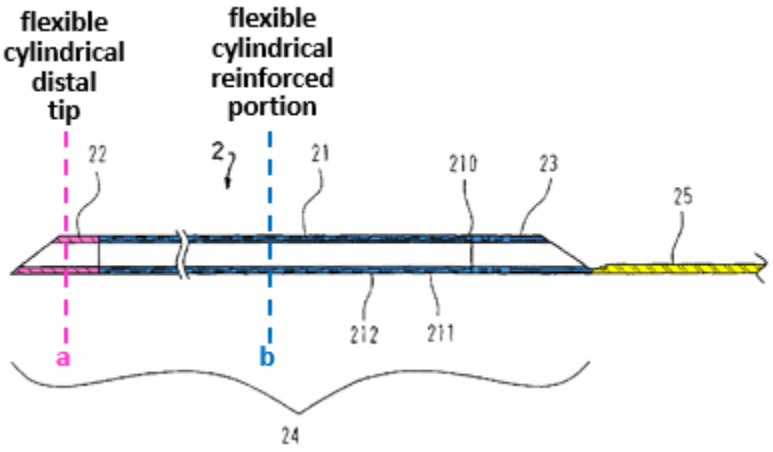
Connector (31) includes a valve, which can close a bore in connector (31) and "selectively clamp and fix the guide wire 6, the wire-like portion 25 or [protective catheter] 55 to prevent leakage of the blood." *Id*., 5:20-23. That the valve may clamp (6), (25), or (55) establishes that all three extend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

through a common hemostatic valve.[13] Ex-1005, ¶ 183. Thus, Itou discloses [1.b.ii]. Ex-1005, ¶¶ 171-184; *see also* ¶¶ 39, 46-59, 63-84, 85-93.

**7. [1.b.iii] "wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion."**

Itou discloses [1.b.iii]. Ex-1005, ¶ 185. Flexible tip portion [21, 22] defines a tubular structure that includes both a (i) flexible cylindrical distal tip (22); and (ii) flexible cylindrical reinforced portion, tubular portion (21), which is proximal to tip (22).

Tip (22) is soft and flexible to reduce the risk of potential blood vessel damage. Ex-1007, 2:12-17; 3:47-50; Ex-1005, ¶ 185; Ex-1042, ¶¶ 24, 53-57, 63.




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

[13] *Supra*, n.8.

Tip 22 (pink) is cylindrical as a cross section taken through line (a) is circular, reflected by tubular portion (24) having an inner ***diameter***. Ex-1007, Table 1; *see also* Fig. 7B; Ex-1005, ¶ 185. Thus, distal tip 22 is both "flexible" and "cylindrical." Ex-1005, ¶ 185.

Tubular portion (21) (blue) is proximal to tip (22). It is also cylindrical, as a cross section taken through line (b) is circular, reflected by tube portion (24) having an inner ***diameter***. Ex-1007, Table 1, *see also* Fig. 7B; Ex-1005, ¶ 185. Tubular portion (21) is reinforced. As discussed above, a "reinforced portion" is a "portion made stronger by additional material or support." *See* § VI, *supra*. Itou teaches that tubular portion (21) includes a reinforcing metal wire layer (211) to prevent kinking, an outer layer (212), and an inner layer (210) made of resin. Ex-1007, 2:15-21, 3:50-58; Ex-1005, ¶ 185; Ex-1042, ¶¶ 24, 53-59, 63.

Itou discloses that reinforced tubular portion (21) is also flexible. First, Itou explicitly teaches that the "***tubular portion*** of said suction catheter ***is more flexible*** than the distal end of said guiding catheter." Ex-1007, 10:4-7 (emphasis added). All the claim element requires is flexibility, so this element is met.

Alternatively, Itou inherently discloses that reinforced tubular portion (21) is flexible. A claim element is inherent when the prior art must "necessarily function[] in accordance with, or include[], the claim[ed] limitations. *Legget & Platt, Inc.*, 537 F.3d at 1354. As Dr. Brecker explains, the distal portion of a

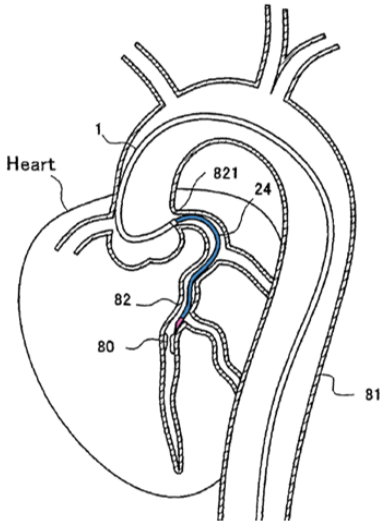
suction catheter must be "fairly flexible," so that the catheter can be "navigated through tortuous blood vessel networks." Ex-1019, 9:35-37, Ex-1005, ¶ 185, *see also* ¶¶ 174-177. Itou is no different. Suction catheter (2) is specifically configured to extend beyond the distal tip of the guide catheter, to remove foreign matter "***positioned at a deep location*** in a coronary artery." Ex-1007, 1:66-2:11 (emphasis added). If reinforced tubular portion (21) lacked flexibility, suction catheter (2) would not be able to reach foreign matter at a "deep location" in a coronary artery. Tubular portion (21)'s location at the distal end of suction catheter (2) means that portion (21) is necessarily flexible. Ex-1005, ¶¶ 174-177, 185; Ex-1042, ¶¶ 21-23, 50, 58; *see also* ¶¶ 27-32. Finally, given that tip (22) is ***not*** reinforced, Ex-1007, Fig. 3, 3:46-58, tip (22) is necessarily more flexible than tubular portion (21). *Id*. Thus, Itou discloses [1.b.iii]. Ex-1005, ¶ 185; *see also* ¶¶ 46-59, 63-84, 85-93.

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

Itou discloses claim 2. Ex-1005, ¶¶ 186-197. Suction catheter (2) may be inserted into the lumen of guiding catheter (1). Ex- 1007, Abstract; Fig. 6; 3:1-3; 5:26-46. As discussed above, flexible tip portion [21, 22] defines a tubular

structure. *See* § VII [1.b.i], *supra*. As illustrated below, the distal portion of the tubular structure is extended beyond the distal tip of guiding catheter (1). The proximal portion of the tubular structure remains within the lumen of guiding catheter (1). *Id*., Figs. 5, 6; 3:1-3; 5:26-46. Thus, Itou discloses the structural limitations of claim 2, which is a systems claim. Ex-1005, ¶ 186.

FIG.6



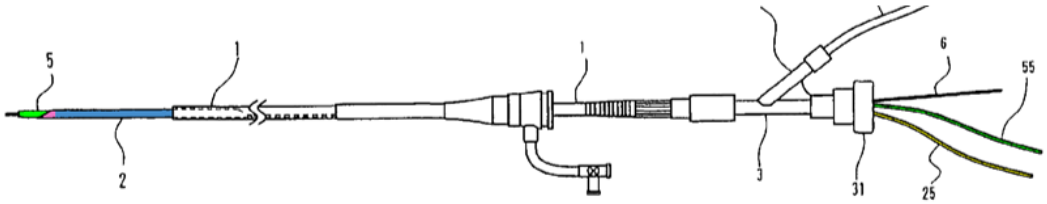

*Id*., Fig. 6 (color added).

To the extent that Patent Owner suggests that claim 2 requires anything more than the cited disclosure in Itou, it is mistaken. Claim 2 additionally recites an intended use ("such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery"), to which no patentable weight should be given. *In re Schreiber*,

128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.").

Regardless, as Dr. Brecker explains, Itou discloses the remainder of claim 2 to a POSITA. Ex-1005, ¶¶ 187-197. First, Itou additionally teaches that distal end protective catheter (5) may be extended through suction catheter (2) and beyond its distal tip. Ex-1007, 1:66-2:11, 4:43-52; *and see* Fig. 6.

FIG.5




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

Second, long before the '380 patent, those working in the field knew that in order to advance an interventional cardiology device through a GC into the coronary vasculature, the GC had to have "sufficient stiffness to offer 'backup' support." Ex-1015, 548; Ex-1005, ¶¶ 188-89. As Dr. Brecker explains, and as taught in Grossman's Cardiac Catheterization, Angiography and Intervention, the support came from the GC's shape, and the intrinsic stiffness of its material, as well as from its "deep engagement" with the coronary ostia. Ex-1005, ¶¶ 190-193; Ex-1015, 549; *and see* Ex-1041, 20 (Kern's The Interventional Cardiac

Catheterization Handbook).

The ’380 patent also admits that because the disclosed, coaxial extension catheter is “extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery,” it “assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion . . . .” Ex-1001, Abstract; *and see* 5:6-27. According to the ’380 patent’s own disclosure, it is the combination of a GC ***and*** an extension catheter inserted into a coronary ostium that improves distal anchoring of the system and provides “stiffer back up support” than a GC alone. *Id*., 8:19-32. But this is no different than what was already known in the prior art and disclosed in Itou. Ex-1005, ¶¶ 186-197.

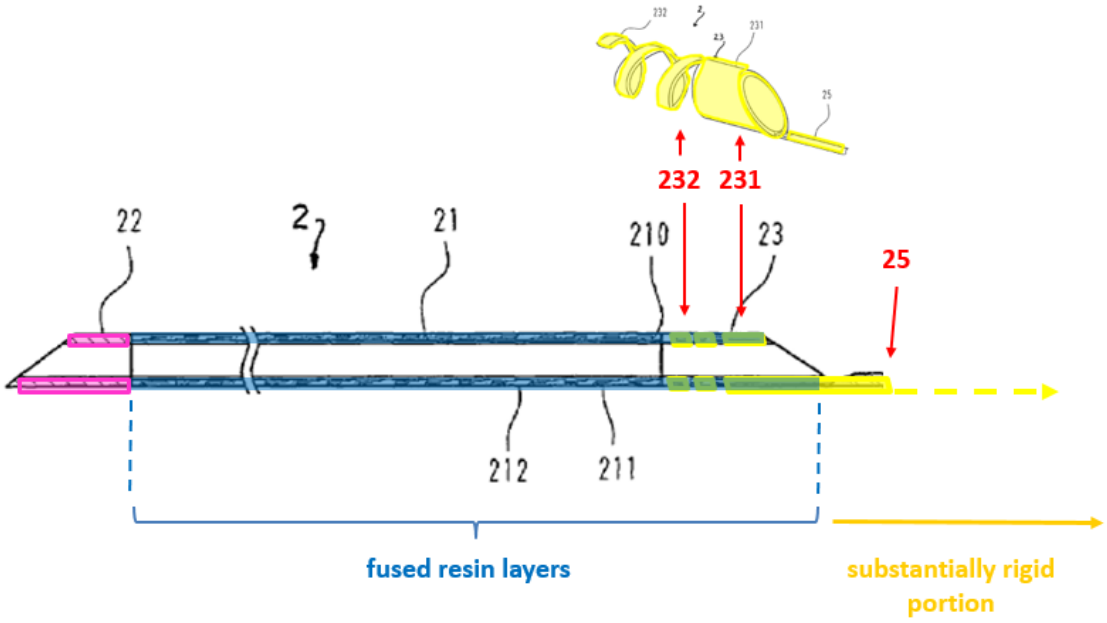
The ’380 patent further admits that back-up support is achieved where the differential between the inner diameter of the guide catheter and the inner diameter of the coaxial catheter is between 0.20 and 0.35 mm. Ex-1001, 3:28-43. Itou teaches a differential between the inner diameters of guiding catheter (1) and suction catheter (2) that is precisely within the range taught by the ’380 patent: 0.3 mm. Ex-1007, Table 1; Ex-1005, ¶ 196. And Itou’s disclosure of a suction catheter that is extended through a GC (and beyond its distal tip into a branch artery)—and used to deliver a distal end protective catheter—inherently discloses a “device assists in resisting axial and shear forces exerted by the interventional cardiology

device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery." Ex-1005, ¶¶ 186-197.

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

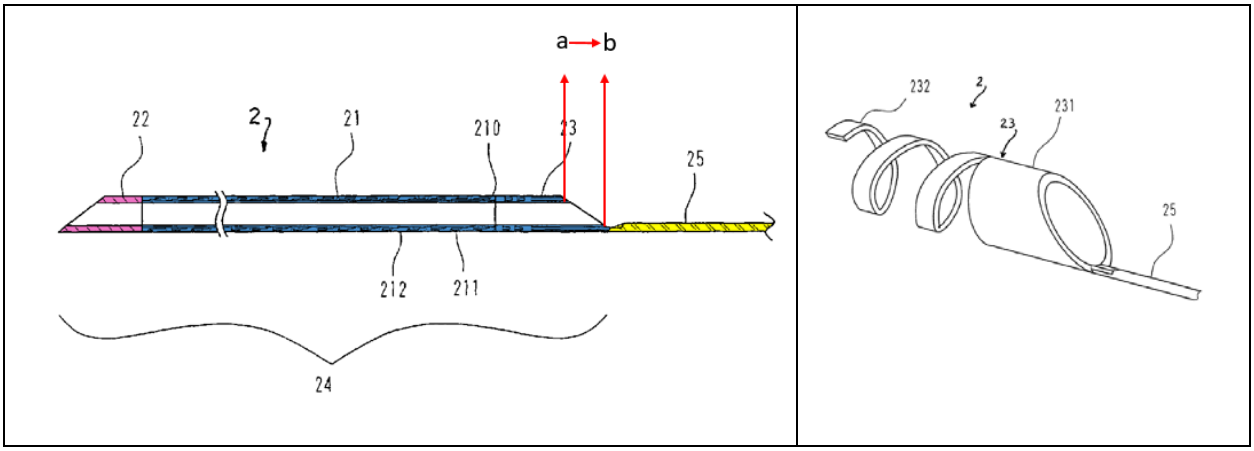
Itou discloses claim 3. Ex-1005, ¶¶ 198 and n. 14, 199-203.

The claimed tubular structure is defined by Itou's flexible tip portion [21, 22]. *See* § VII (claim [1.b.i]), *supra*. Itou discloses that the tubular structure "further comprises structure defining a proximal side opening" because the resin layers of flexible tip portion [21, 22] are fused to the resin layers of proximal tip (23). *See* § VII (claim [1.b.ii]), *supra*.



Ex-1007, Figs. 3, 4 (color and annotation added). [14]

Tip (23) includes a proximal side opening (231) that is "inclined obliquely," and formed by cutting one end of a metal pipe. Ex-1007, 4:10-15, 27-32, Figs. 3, 4. The proximal opening extends for a distance from (a) to (b) along the longitudinal axis of catheter (2), which forms a "side opening."

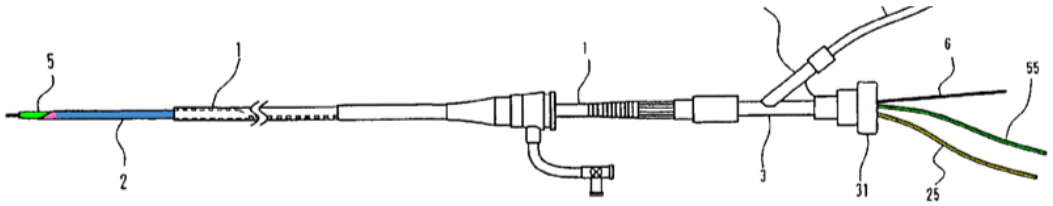



*Id.*, Fig. 3 (color and annotation added), Fig. 4.

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

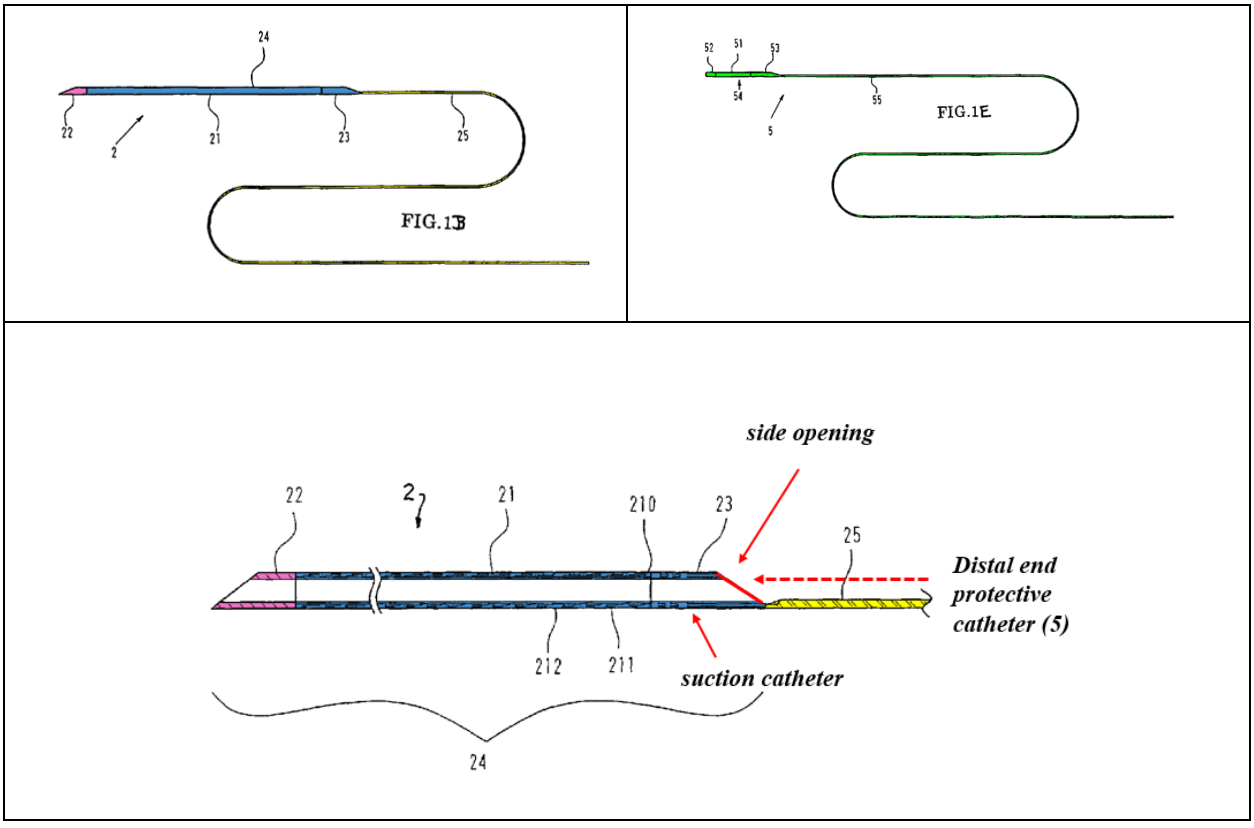
[14] *Supra*, n.9. As discussed for claim 1, there are two possible mappings for the "substantially rigid" portion claimed in [1.b.ii]. Mapping-2, in which the "substantially rigid portion" consists solely of Itou's wire-like portion (25), applies to claims 3 and 4. Ex-1005, ¶ 171 and n.13.

FIG.5




*Id.*, Fig. 5 (color added).

This necessarily requires that protective catheter (5) pass through proximal side opening (231), which is "accessible from a longitudinal side defined transverse to the longitudinal axis."




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

Thus, Itou discloses the structural limitations of claim 3, which is a systems claim. Ex-1005, ¶¶ 198-99.

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

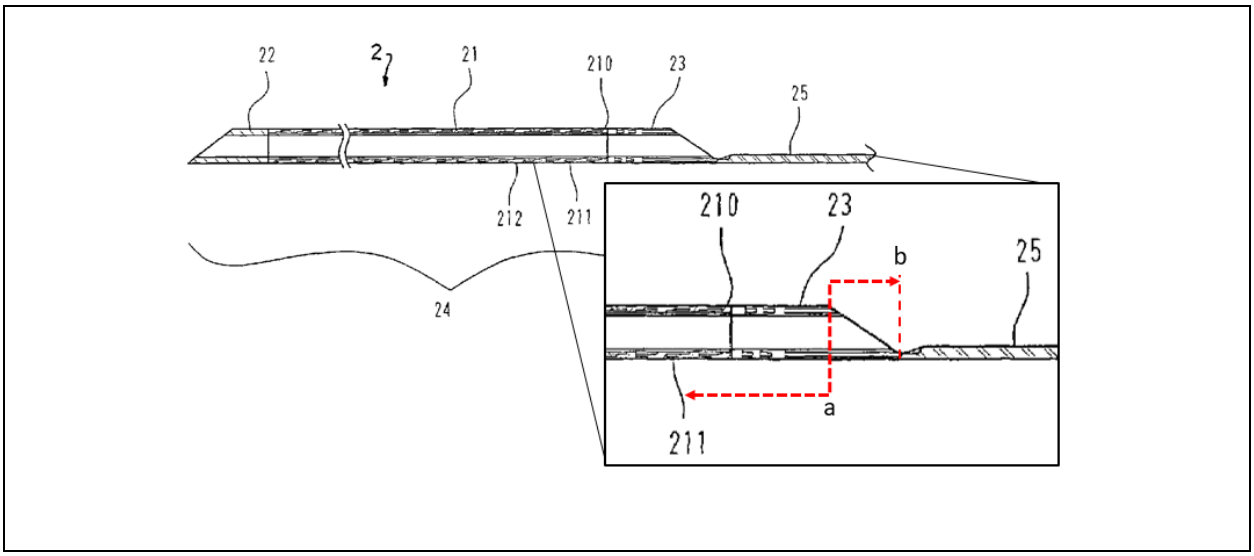
Regardless, Itou explicitly teaches that suction catheter (2) is long enough so that while its distal end is advanced to a target location—distal to the distal end of the GC—its proximal end (and side opening (231)) remains in the GC. Ex-1007, 5:35-42, 6:30-35. And, the tubular portion of suction catheter (2) has an inner diameter of 1.5 mm,[15] as well as a side opening through which a distal end protective catheter with an outer diameter of 1.35 mm can be received. Ex-1007, 4:47-52, Fig. 5, Table 1. Thus, catheter (2), which includes the "proximal portion" of the claimed "tubular structure," necessarily has an inner diameter that is large enough to "receive . . . interventional cardiology devices into the coaxial lumen

[15] This corresponds to the inner diameter of the extension catheter taught in the '380 patent. Ex-1001, 3:41-43 ("greater than or equal to 0.056 inches").

while the proximal portion remains within the lumen of the guide catheter." And Itou, either explicitly or inherently, discloses claim 3. Ex-1005, ¶¶ 200-203.

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

Itou discloses claim 4. Ex-1005, ¶ 204. As illustrated below, a cross section through line (a) of proximal tip 23 (and to the left) defines a full circumference portion, and a cross section taken through a portion to the right of line (a) and the left of line (b) defines a partially cylindrical portion.

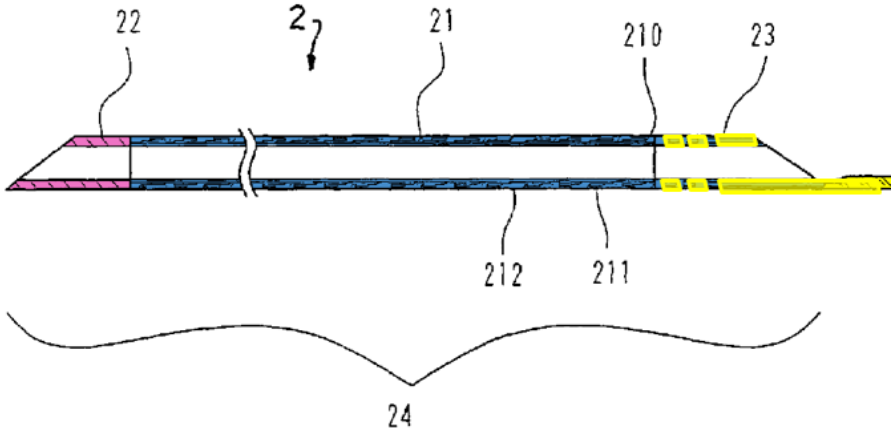



Ex-1007, Fig. 3 (color and annotation added), *and see* Fig. 4.

**F. Claim 6: The system of claim 1, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern**.

Itou discloses claim 6. Ex-1005, ¶ 205. Tubular portion (21) has "an inner layer (210) made of a resin material . . . ***a reinforcing layer (211)*** made of a metal

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




*Id*., Fig. 3 (color added).

From the disclosure of Itou, it is evident that reinforcing metal wire (211) is braided or coiled around inner layer 210. Ex-1005, ¶ 205; Ex-1042, ¶¶ 59-62; *see also* ¶¶ 36-46.

### G. Claim 7: The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

Itou discloses claim 7, teaching that tip (22) “is formed such that a filler such as tungsten, bismuth oxide or barium sulfate, which are X-ray contrast agents, is mixed by 50 to 70 wt % in a matrix made of a resin . . . it functions as an X-ray contrast marker (radiopaque marker).” Ex-1007, 4:15-20 Thus, Itou discloses a “radiopaque marker” that is part of (and therefore “proximate to”) the distal tip of the device. *Id*., Ex-1005, ¶ 206.

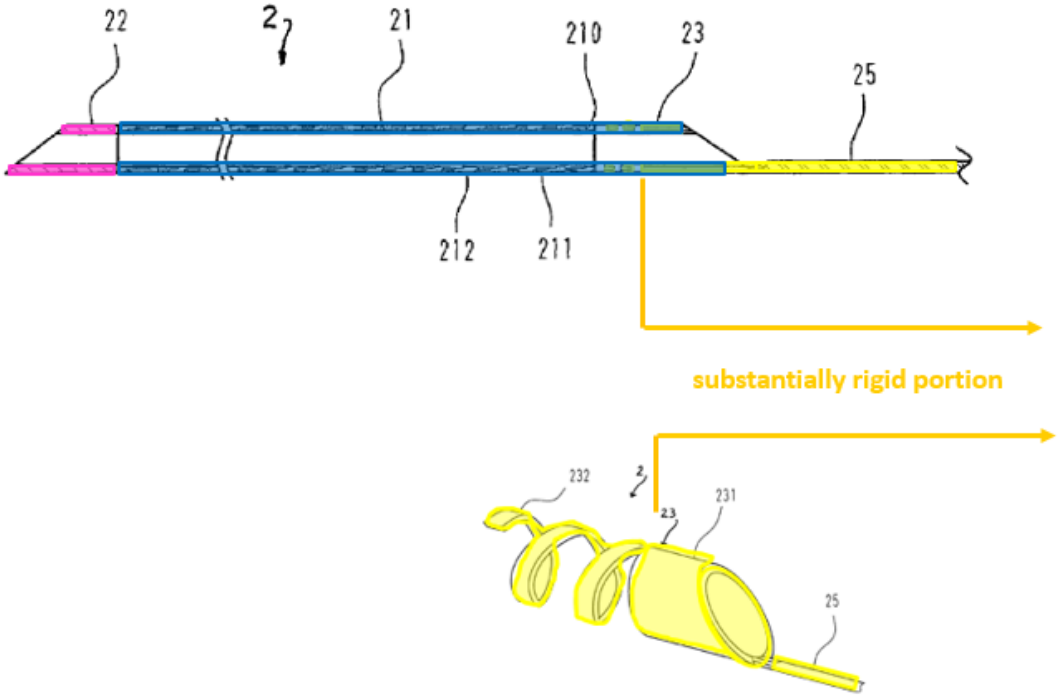
### H. Claim 8: The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

Itou discloses claim 8. Ex-1005, ¶ 207. "[G]uiding catheter 1 is formed from a guiding catheter of 6 Fr (2.06 mm) which is used popularly and has an inner diameter of 1.8 mm." Ex-1007, 6:47-50, Table 1. Catheter (2)'s tubular portion (24) (and therefore the "tubular structure defined by flexible tip portion [21, 22]) has an inner diameter of 1.5 mm, *id*. Table 1, which is 0.3 mm smaller than the inner diameter of the GC. And 0.3 mm is "not more than one French smaller," because one French is 0.33 mm. Ex-1062, 545; Ex-1005, ¶ 207.

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

Itou discloses claim 9. Ex-1005, ¶ 208. The "substantially rigid portion" of Itou's suction catheter (2) includes both wire-like portion (25) and end (231).

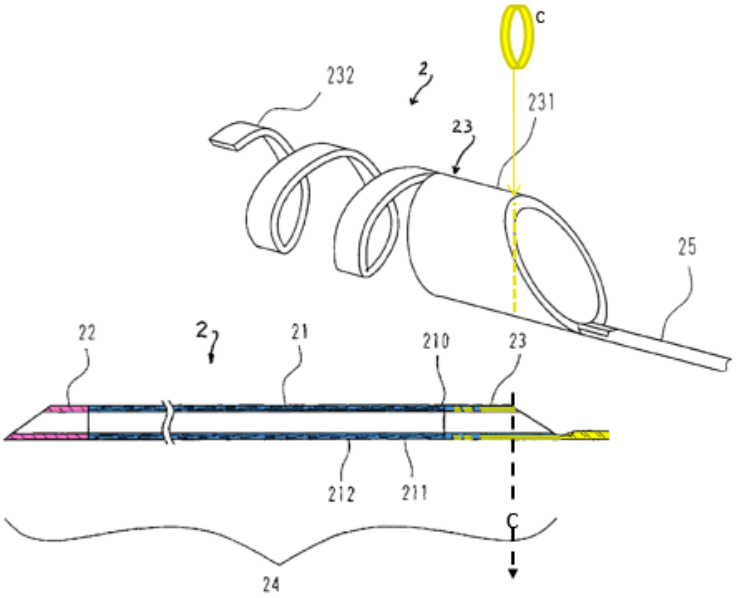
[16] For purposes of consistency between claims 1 and 9, Petitioner notes that the "substantially rigid portion" must include a "rail structure without a lumen," but may also include structure in addition to the rail structure, such as the full circumference portion of claim 9.




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

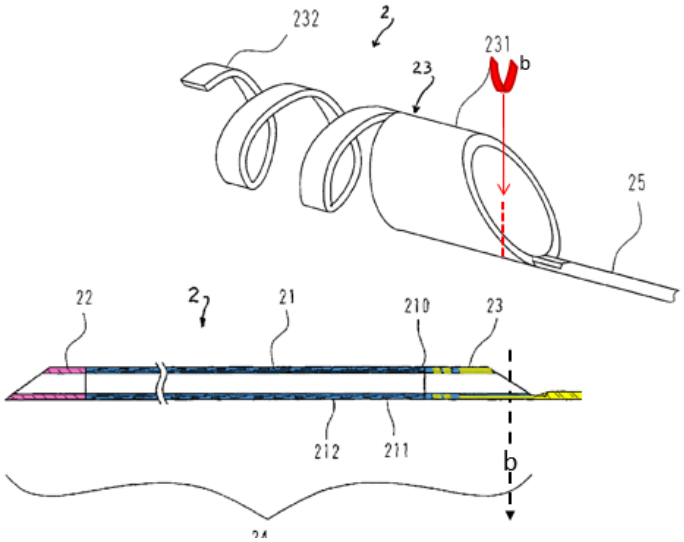
The substantially rigid portion necessarily includes a cross-sectional shape having a full circumference portion (shown by line (c)). Ex-1005, ¶ 208.

[17] Mapping-1 for the "substantially rigid portion" applies to claim 9. *Supra*, n.9.



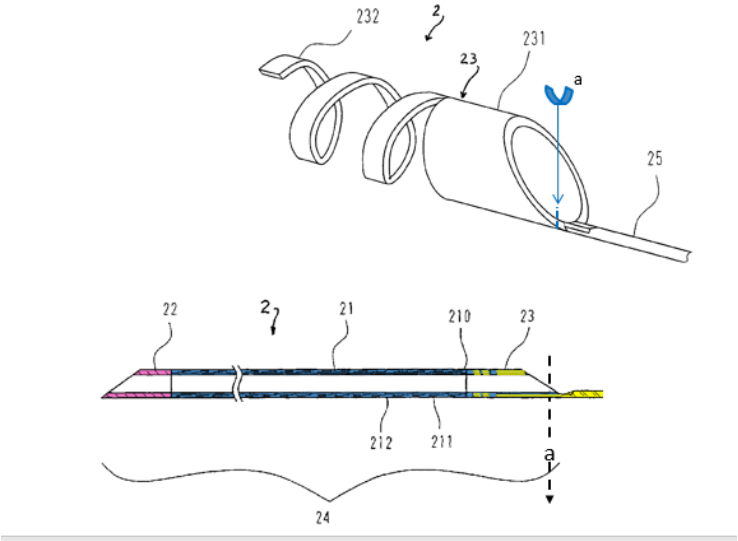

Ex-1007, Figs. 4 (top), 3 (bottom) (color and annotation added).

Moving distally, and as shown below, the substantially rigid portion has a hemicylindrical cross-sectional shape (cross section at "b"), Ex-1005, ¶ 208, which, according to the '380 patent is a portion that "desirably includes 40% to 70% of the circumference of a tube." Ex-1001, 7:1-2.



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

Finally, the side opening includes an arcuate cross sectional shape (cross section at "a"), Ex-1005, ¶ 208, which, according to the '380 patent is a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1001, 7:6-7.




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

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

Itou discloses claim 10. Ex-1005, ¶ 209. The guiding catheter 1 preferably has dimensions equal to those of a guiding catheter used in ordinary catheter operation. As a standard length of a guiding catheter used normally, the total length is approximately 1,000 mm, or 100 cm. Ex-1007, 5:65-6:1. The total length of catheter 2 is the (tubular portion) plus (wire-like portion), which is 15 cm + 110 cm, respectively, equaling 125 cm. Ex-1007, Table 1.

### K. Claim 12

#### 1. [12.pre] "A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:"

Itou discloses [12.pre], to the extent this is a limitation. *See* § VII ([1.pre]), *supra*; Ex-1005, ¶ 210.

#### 2. [12.a] "a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and,"

This language differs from claim 1 only insofar as claim 12 recites a "circular cross section." This additional language is taught by Itou for the same reason it teaches a circular cross-sectional inner diameter of the guide catheter. *See* § VII ([1.a.i], [1.a.ii]), *supra*; Ex-1005, ¶ 211.

#### 3. [12.b] "a device adapted for use with the guide catheter, including:"

Itou discloses [12.b]. *See* § VII ([1.b]), *supra*; Ex-1005, ¶ 212. The "device adapted for use with the guide catheter" is suction catheter (2).

#### 4. [12.b.i] "an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:"

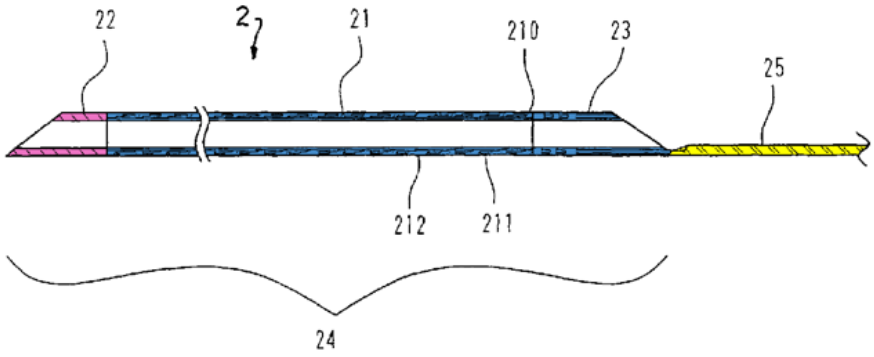
Itou discloses [12.b.i]. *See* § VII ([1.b.i], [1.b.ii]), *supra*; Ex-1005, ¶ 213.

The "elongate structure" is the "device adapted for use with the guide catheter," suction catheter (2). Ex-1007, Fig. 3. The combined length of its tubular portion (24) and wire-like portion (25) is greater than that of guiding catheter (1). *Id*., 2:23-26; *and see* 5:67-6:18; *see also* § VII (claim 10), *supra*; Ex-1005, ¶ 211.

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

Itou discloses [12.b.ii]. Ex-1005, ¶ 214. Suction catheter (2) has a tubular portion (24), which includes distal tip (22), which is the "**flexible tip portion**."[18]

[18] In general, use of the same words in different claims mean the same thing. In claim 1, however, Patent Owner used "flexible tip portion" to include both the "flexible cylindrical distal tip" and the "reinforced portion." *See* § VII (claim [1.b.iii]), *supra*. But in claim 12 that is not the case, as Patent Owner separately recites "a reinforced portion proximal to the flexible tip portion." *Compare* Ex-1001, 12:17-28, *with*, *id*. 12:29-30.




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

Itou explains that the distal tip of catheter (2) is soft and flexible. Ex-1007, 2:12-21. A cross section through tip (22) at line (a) is necessarily circular. *Id*., Table 1 (inner ***diamete***r of tubular portion (24) is 1.5mm). Ex-1005, ¶ 214.

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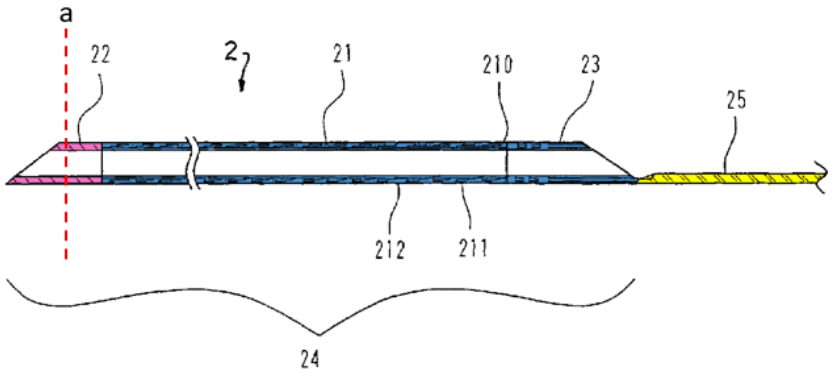
Patent Owner also drafted claim 12 such that the substantially rigid portion is "connected to" the flexible tip portion. The only disclosure in the specification, though, is an indirect connection, such that the flexible tip portion is connected to the reinforced portion, which is connected to the substantially rigid portion. For purposes of this IPR, and not for district court litigation, Petitioner assumes that claim 12 allows for an indirect connection, because the claim would otherwise not make sense. Under any interpretation, this is simply an example of poor claim drafting and there is no inventive concept here worthy of patent protection in light of the prior art presented.



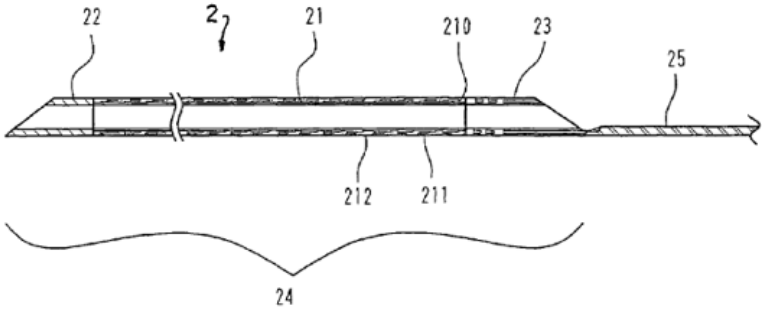

Ex-1007, Fig. 3 (color and annotation added).

Tip (22) is shorter in length than tubular portion (24), which "is [itself] shorter than the guiding catheter." Ex-1007, 2:23-26; Fig. 3. Tip (22) is therefore necessarily shorter than guiding catheter (1). Ex-1005, ¶ 214.

Tip (22) has an outer diameter of 1.72 mm, so is sized to be insertable through the cross-sectional inner diameter (1.8 mm) of the continuous lumen of the guiding catheter. Ex-1007, Table 1, 1:60-65. Tip (22) is also coaxial to the guiding catheter and defines a lumen. *Id*., Figs. 5, 6. Finally, both protective catheter (5) and guide wire (6) are insertable through tip (22), *id*., Table 1, 4:48-52, 7:1-23, Fig. 5, and each meets the construction of "interventional cardiology device." *See* §§ VI, VII (claim [1.a.ii]), *supra*.

**6. [12.b.iii] "a reinforced portion proximal to the flexible tip portion;"**

Itou discloses [12.b.iii]. Ex-1005, ¶ 215. Tubular portion (21) is proximal to tip (22).

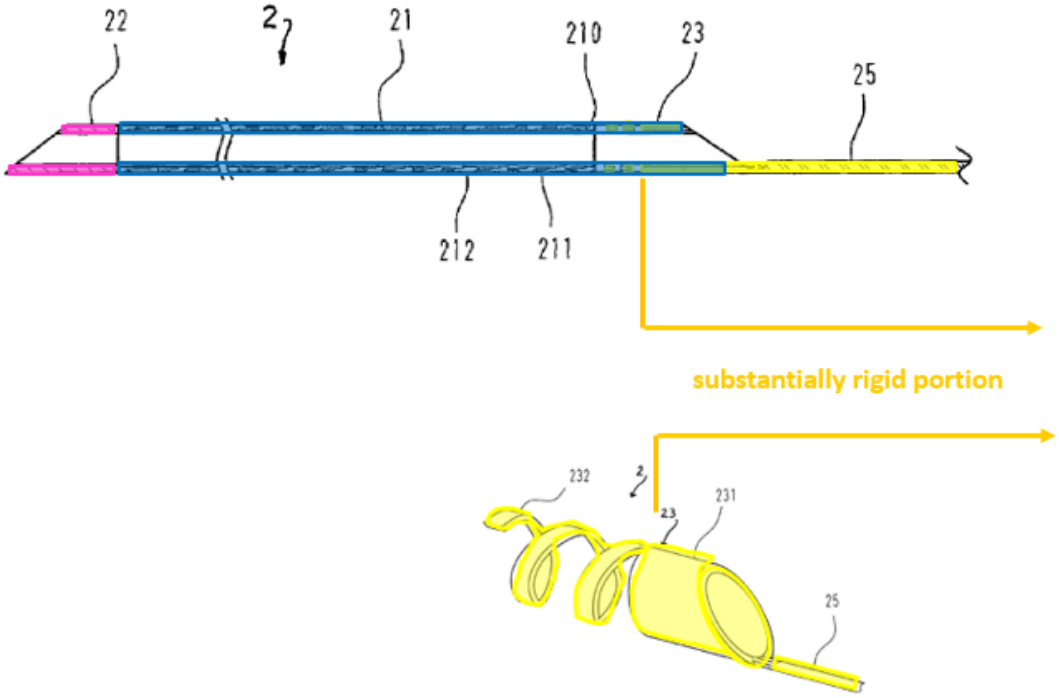



Ex-1007, Fig. 3.

Tubular portion (21) is reinforced. As discussed above, a "reinforced portion" is a "portion made stronger by additional material or support." *See* § VI, *supra*. Itou teaches that tubular portion (21) includes a reinforcing metal wire layer (211) to prevent kinking, an outer layer 212, and an inner layer 210 made of resin. Ex-1007, 2:15-21, 3:50-58; Ex-1005, ¶ 215; Ex-1042, ¶¶ 50, 55-56, 59-60.

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

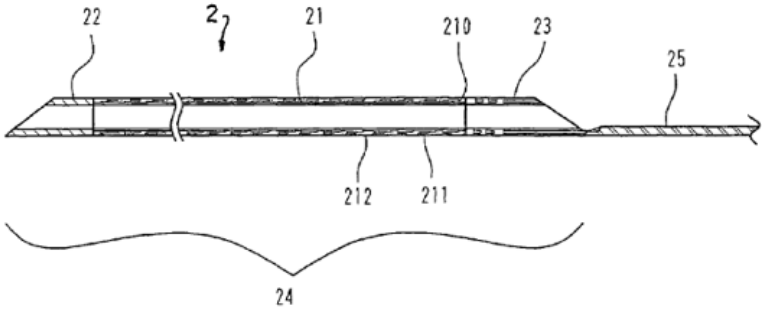
Itou discloses [12.b.iv]. Ex-1005, ¶ 216. The "substantially rigid portion" of Itou's suction catheter (2) is wire-like portion (25) and tip (231) ("Mapping-1").[19] *See* § VII, [1.b.ii], *supra*.




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

[19] Because Mapping-1 (wire-like potion (25) and tip (231)) necessarily encompasses Mapping-2 (wire-like portion (25)), Petitioner analyzes Mapping-1 for claim 12, but the analysis is equally applicable should Mapping-2 apply. *See* Footnote 9, *supra*.

The "substantially rigid portion" is connected to and proximal of distal tip (22) ("flexible tip portion").[20]




Ex-1007, Fig. 3.

Wire-like portion (25) is more rigid along a longitudinal axis than tip (22). As discussed in claim 1, tip (22) is soft and "flexible in order to reduce the damage to the blood vessel" (Ex-1007, 2:15-18) and is less rigid than the proximally-located wire-like portion (25). Ex-1005, ¶ 171; Ex-1042, ¶¶ 55, 64-71. Wire-like portion (25) is the "rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion (22), such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of

[20] *Supra*, n. 17.

the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter" for the reasons set forth above. *See* § VII [1.b.ii], *supra*; Ex-1005, ¶ 216; *see also* Ex-1007, Figs. 1B, 1E, 5, 5:11-23.

**8. [12.b.v] "wherein the flexible tip portion is more flexible than the reinforced portion."**

Itou discloses [12.b.v]. Ex-1005, ¶ 217. Tip (22) is described as soft and flexible, and is not reinforced. Ex-1007, 2:12-21; Fig. 3, 3:46-58. By contrast, tubular portion (21) is reinforced with a reinforcing metal wire layer (211), *supra*, § VII, [1.b.iii], so it is necessarily less flexible than tip (22). Ex-1005, ¶ 217; Ex-1042, ¶¶ 53-57.

**L. Claim 13: The system of claim 12, wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.**

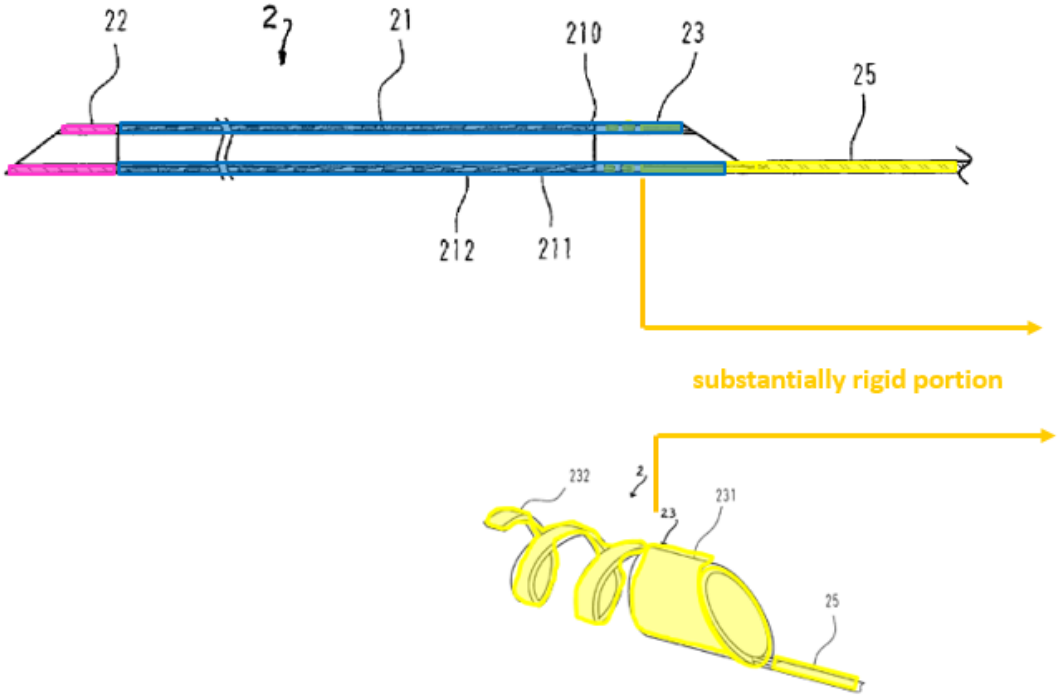
Itou discloses claim 13. Ex-1005, ¶ 218. Itou discloses that a distal portion of tip 22 ("flexible tip portion") is insertable through the continuous lumen of GC (1) and extends beyond the distal end of GC (1). Ex-1007, Abstract, 2:29-38, Figs. 5-6. When tip 22 extends beyond the distal end of GC (1) into the coronary artery, the device assists in resisting axial and shear forces as claimed. *See* § VII (claim 2),

*supra*; Ex-1005, ¶ 218.

**M. Claim 14: The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.**

Itou discloses claim 14. Ex-1005, ¶ 219.

As discussed for claim [12.b.iv], the "substantially rigid" portion includes both wire-like portion (25) and end (231).



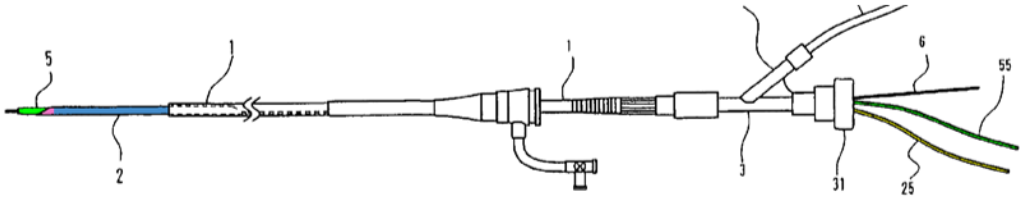

Ex-1007, Figs. 3 (top), 4 (bottom) (color and annotation added).

As discussed for claim 9, the substantially rigid portion includes a "partially cylindrical portion defining an opening." The opening also extends for a distance along a side thereof defined transverse to a longitudinal axis, as explained for claim 3. Moreover, Itou teaches the remainder of claim 14, which is that the side opening is "extend[s] for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion" for the reasons discussed for claim 3. Ex-1005, ¶ 219.

**N. Claim 15: The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.**

Itou discloses claim 15. Ex-1005, ¶ 219. Itou teaches a device (suction catheter 2), which may be inserted into a guide catheter (guiding catheter 1) to present an overall length of a coaxial lumen through which an interventional cardiology device may be inserted using only a single hemostatic valve. *See* § VII (claims [1.a.ii], 2), *supra*.

FIG.5




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

To the extent that Patent Owner suggests that claim 15 requires anything more than the cited disclosure in Itou, it is mistaken. Claim 15 additionally recites an intended use, which is that there be an absence of "any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter," to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

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

catheter 2 has an inner diameter (1.5 mm) large enough to receive distal end protective catheter (1.35 mm), *id*., 4:48-52; Fig. 5; Table 1, as well as a proximal side opening into which the distal end protective catheter can be inserted. *Id*., Fig. 5. Thus, Itou, either explicitly or inherently, discloses claim 15. Ex-1005, ¶ 219.

### O. Claims 16-19

| | |
|---|---|
| 16. The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion. | Itou discloses claim 16. *Supra*, § VII (claim 7); Ex-1005, ¶ 220. |
| 17. The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern. | Itou discloses claim 17. *Supra*, § VII (claim 6); Ex-1005, ¶ 220. |
| 18. The system of claim 12, wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion[21] is not more than one French smaller than the cross-sectional inner diameter of the guide catheter. | Itou discloses claim 18. *Supra*, § VII (claim 8); Ex-1005, ¶ 220. |
| 19. The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion. | Itou discloses claim 19. *Supra*, § VII (claim 9 and n.14); Ex-1005, ¶ 220. |

### P. Claim 20: The system of claim 12, wherein the elongate structure includes, starting at the distal portion of the flexible distal portion,[22] at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the

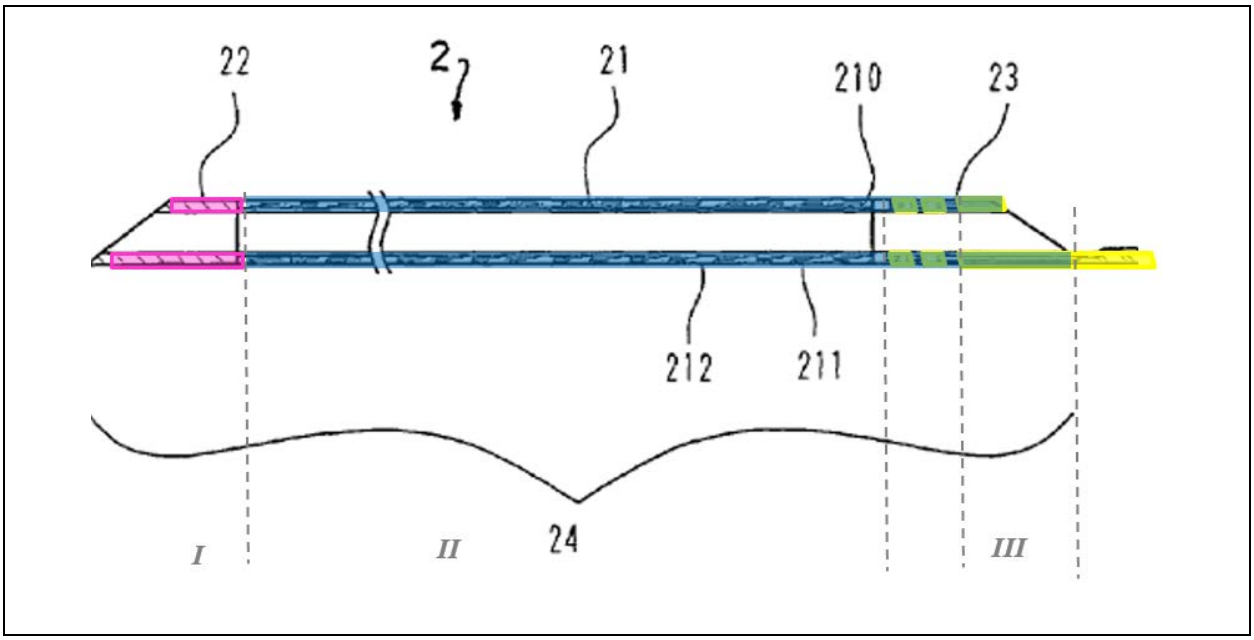
[21] There is no antecedent basis for a "flexible distal portion" in claim 18, or in claim 20, neither of which make sense unless it is the same as the "flexible tip portion" claimed in [12.b.ii].

[22] *Supra*, n. 16.

**first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.**

Itou discloses claim 20, Ex-1005, ¶¶ 221-227, which requires at least three different portions in the elongate structure, each with a distinct flexural modulus. The claim also requires that the at least three flexural moduli increase in the distal to proximal direction. This is disclosed in Itou's suction catheter (2), which is the "elongate structure." *See* § VII, (claim [12.b.i]), *supra*.

Distal tip (22) is soft and flexible. *See* § VII, (cl. [1.b.i] and [1.b.iii]), *supra*. As explained by Dr. Brecker and Dr. Hillstead, tip (22)—shown below in pink—has a first flexural modulus. Ex-1005, ¶ 224; Ex-1042, ¶¶ 53-57, 64-72. Thus, tip (22) is a "first portion having a first flexural modulus." Ex-1007, Fig. 3 (below, *I*).




Itou teaches that tubular portion (21) is proximal to tip (22). It has "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire

made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . .” Ex-1007, 3:50-58. Tubular portion (21) is flexible, but reinforced relative to flexible distal tip (22). *See* § VII (claims [1.b.iii], 6), *supra*. Tubular portion (21) has a second flexural modulus, greater than the first flexural modulus of tip (22). Ex-1005, ¶ 225; Ex-1042, ¶¶ 53-57, 64-72. Thus, tubular portion (21) is a “second portion having a second flexural modulus greater than the first flexural modulus” (above, *II*). Ex-1005, ¶ 225.

Itou also teaches that—proximal to tip (22) and tubular portion (21)—catheter (2) includes a metal pipe.

At its proximal end, the metal pipe is cut obliquely into end (231). Ex-1007, Fig. 4. The portion of the elongate structure that includes (231) has a third flexural modulus that is greater than the second flexural modulus of tubular portion (21). Ex-1005, ¶ 226; Ex-1042, ¶¶ 53-57, 64-72. Thus, the portion of the elongate structure that includes metal pipe (231) is a “third portion having a third flexural modulus greater than the second flexural modulus” (above, *III*). Ex-1005, ¶ 226.

**Q. Claim 23: The system of claim 12, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.**

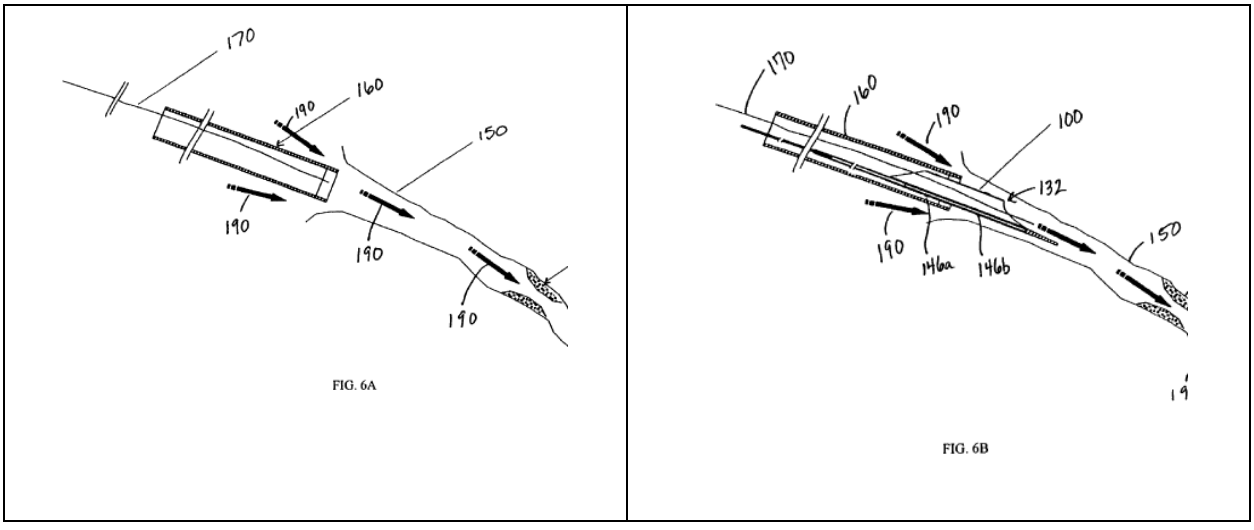
Itou discloses claim 23. *See* § VII.J (claim 10), *supra*; Ex-1005, ¶ 228.

## VIII. GROUND 2: ITOU RENDERS CLAIMS 3, 14, AND 15 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), (a)(2), and was not cited or considered during prosecutions of the original ’850 patent or the ’380 reissue patent. Ex-1001-1003.

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




Ex-1008, Figs. 6A (left), 6B (right).

Sheath assembly is described for use in aspirating embolic material, *id*.,

Abstract; 12:9-13:34, and for stent or balloon delivery. *Id*., 6:25-34; 12:3-8; Ex-1005, ¶¶ 99-102, 109, 153-159; Ex-1042, ¶¶ 83-88.

As explained in § VII, *supra*, Itou's suction catheter (2) has the structure that would allow it to receive an interventional cardiology device into its coaxial lumen while its proximal portion remains within the lumen of the guide catheter (claim 3), as well as to present an "overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter" (claim 15). To the extent Patent Owner argues that Itou's teachings—alone—are insufficient to anticipate claims 3, 14 or 15, then they are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA.[23]

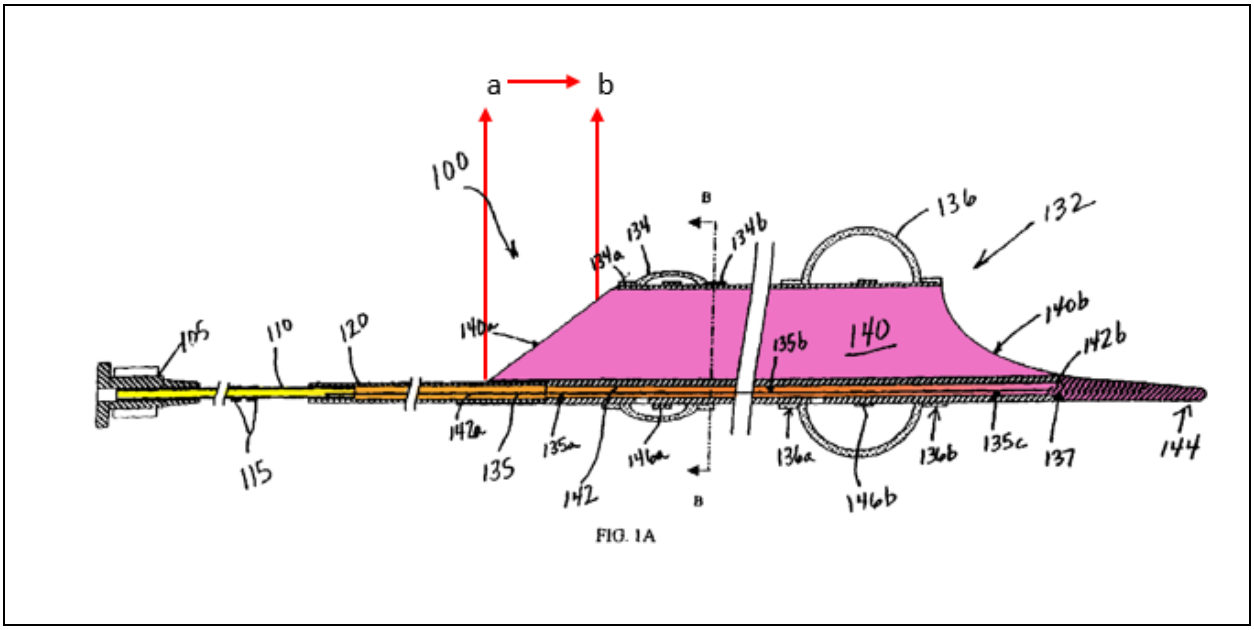
**B. Claim 3**

To the extent that Patent Owner argues that the intended use of the claimed structure—"to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"—carries patentable weight and is a limitation, Itou discloses structure sufficient to

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

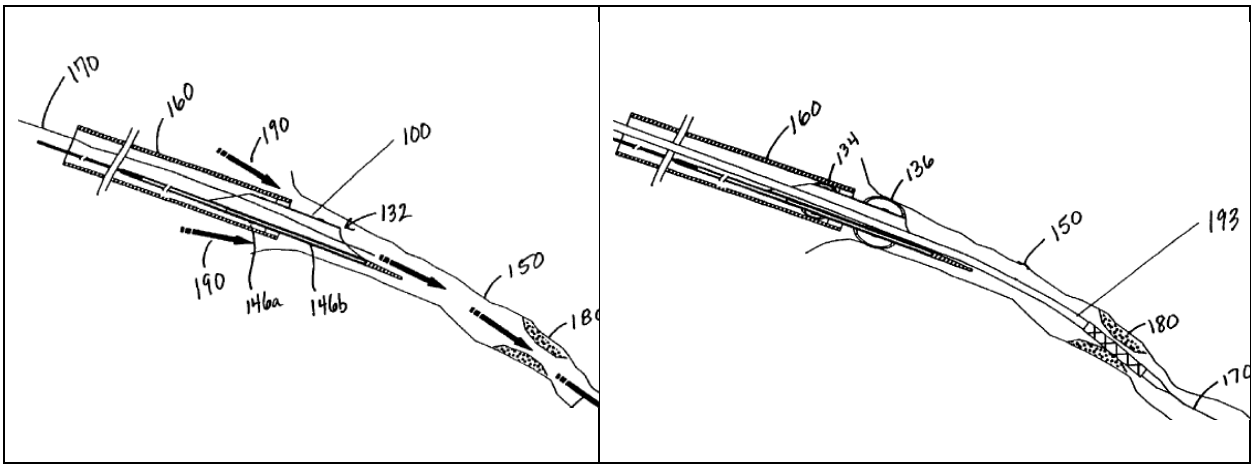
meet this limitation. *See* § VII, *supra*. In the alternative, Itou and Ressemann render claim 3 obvious.[24] Ex-1005, ¶¶ 229-65; *see also* ¶¶ 99-102, 153-59.

The evacuation head of Ressemann has a proximal opening 140a that extends for a distance from (a) to (b) along the longitudinal axis of the evacuation sheath. Ex-1008, Figs. 1A, 11A. This is a side opening. Ex-1005, ¶ 232.




[24] A POSITA would look to Ressemann when modifying Itou because both references disclose devices that address the same problem in the same way—removing coronary vessel occlusions by using an aspiration catheter, the distal end of which is extended past a GC's distal end, into a coronary artery. Ex-1005, ¶¶ 95-102, 149-159, 231; Ex-1007, Abstract; 1:13-16; 2:2-5, 29-38; 3:59-63; 5:32-34;; Figs. 1A, 1B, 5, 6; Ex-1008, Abstract, 6:18-24; 12:9-12, 19-30; Figs. 6A, 6B.

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




Ressemann also explains that a stent delivery system should be advanced through the evacuation sheath and then across a stenotic lesion. *Id*., 13:15-16, 57-60; Fig. 6E (above, right); Ex-1005, ¶¶ 233-34.

A POSITA would be motivated to combine the teachings of Itou and Ressemann because s/he knew that it was advantageous for an aspiration catheter to include a distal lumen of sufficient diameter for use in delivering an interventional cardiology device. Ex-1005, ¶¶ 235-39; Ex-1042, ¶¶ 89-94; Ex-1019, 3:4-6; 34-36 (explaining that an aspiration catheter is "preferably sized so as

to allow the slidable insertion of a therapy catheter through the main" lumen of the aspiration catheter). And this is because angioplasty and coronary artery stenting come with a risk of embolization. Ex-1005, ¶¶ 240-48; Ex-1028, 1285; Ex-1029, 172, 176.

As Dr. Brecker explains, those working in the field knew that PCI such as angioplasty or stent delivery "may break free fragments of friable plaque." Ex-1005, ¶ 248; Ex-1015, 629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was a motivation to combine stent delivery with the use of an embolic protection device, Ex-1015, 629-30, and a reasonable expectation of success. Ex-1028, 1285 ("Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire."); Ex-1029, 172, 176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of an embolic protection device in conjunction with stenting); Ex-1005, ¶¶ 249-50. 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-1008, 14:29-34 (" In some instances, once the particulate . . . has been removed, additional contrast delivery to the blood vessel may indicate a need for more therapeutic

steps, e.g., further dilation of the stent with the balloon. In this case, it is more convenient to have the balloon catheter already in position for any subsequent use.").

The inner lumen of Ressemann's sheath is "approximately 0.061 inches," allowing for the "passage of most therapeutic devices such as angioplasty catheters [and] stent delivery catheters . . . ." Ex-1008, 10:17-21. PTCA catheters were insertable through support catheters with an 0.045 inch inner lumen. Ex-1009 ("Kontos"), 4:46-50, 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, ¶¶ 251-54.

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, ¶¶ 255-56.

Moreover, an inner diameter of 1.5 mm corresponds to an inner diameter of 0.059 inches. Ex-1005, ¶ 255. 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 '380 patent. Ex-1022 at 3 (requiring a > 0.056 in. (1.4 mm) inner catheter diameter for CYPHER stents between 2.50-3.0 mm on an RX delivery system); Ex-1023 at 9 (requiring a minimum, inner catheter diameter of 0.56 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1024 at 10 (requiring an inner catheter diameter $\geq$ 0.058 in. (1.47 mm) for TAXUS Express$^2$ stents on a monorail delivery system); Ex-1005, ¶¶ 256-61.

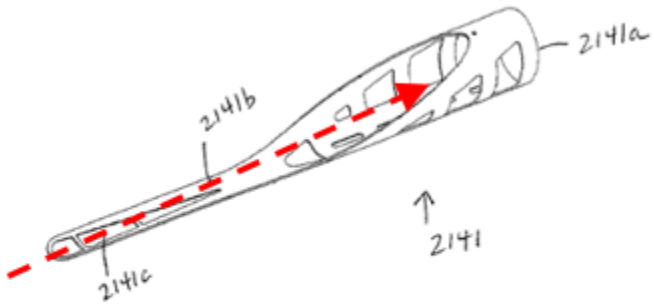
Indeed, evidence that combining Itou and Ressemann is appropriate exists in Itou's prosecution history. There, the examiner rejected pending claims on a suction assembly based on a prior, angioplasty balloon catheter, because the latter was "capable of being an intravascular foreign matter suction assembly." Ex-1021 at 3. Claims were also rejected over the same art in combination with a prior aspiration catheter because—at the time of the invention— the references were analogous art, and it would have been obvious to combine angioplasty with removal of emboli. *Id*., 4-5; Ex-1005, ¶¶ 261-65.

### C. Claim 14

Itou discloses claim 14. *See* § VII, *supra*. In the alternative, Itou in view of Ressemann also renders claim 14 obvious. Ex-1005, ¶¶ 266-74.

Ressemann discloses "wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance

along a side thereof defined transverse to a longitudinal axis [dotted arrow below] . . . the opening extending substantially along at least a portion of a length of the substantially rigid portion."




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

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

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

First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because s/he understood that it was large enough to be used to deliver a balloon and stent catheter, as explained above. By modifying the proximal opening of suction catheter (2) with Ressemann's collar 2141, a larger area for receiving a stent and/or balloon catheter would be achieved. Ex-1005, ¶¶ 270-72; Ex-1042, ¶¶ 23-25, 94, 96.

Second, the concavity of tab 2141b ensures that adding the collar does not impede entry into the inflation lumen. Ex-1042, ¶¶ 102-103. Ressemann teaches that the advantage to having an angled opening is that it "facilitate[s] smoother passage of other therapeutic devices" through the lumen. Ex-1008, 6:52-57, 23:17-20. The collar adds material to the opening of the lumen, as it is 0.002 inches thick. *Id*., 25:10. And tab 2141b ranges from 0.020 to 0.050 inches in width. *Id*., 25:11-12. Because tab 2141b is concave it does not interfere with introducing a balloon or stent catheter into the angled opening of the inflation lumen. Ex-1005, ¶ 273; *see also* ¶¶ 109-19; Ex-1042, ¶ 102. The same holds true for adding the collar to the proximal opening of the tubular portion of Itou's suction catheter 2.

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.*, 550 U.S. at 417.

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

Thus, Itou in view of Ressemann renders claim 3 obvious. Ex-1005, ¶¶ 229-74.

**D. Claim 15**

To the extent it is determined that the language in claim 15 requiring an absence of "any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter" is entitled to patentable weight, Itou discloses structure sufficient to meet this limitation. *See* § VII, *supra*. In the alternative, Itou and Ressemann render claim 15 obvious. Ex-1005, ¶¶ 275-76; *and see* § VII, *supra*.

Itou teaches a device (suction catheter 2), which may be inserted into a guide catheter (guiding catheter 1) to present an overall length of a coaxial lumen through which an interventional cardiology device may be inserted using only a single hemostatic valve. *See* § VII (claims [1.a.ii], 2), *supra*. Itou does not, however, explicitly teach actually inserting an interventional cardiology device "without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter." It instead teaches that protective

catheter (5) should be inserted into catheter (2)—i.e., "preassembled"—before the combination of catheter (2) and protective catheter (5) is inserted into guiding catheter (1). Ex-1007, 7:13-15.

By contrast, Ressemann teaches that evacuation sheath assembly (100) should be positioned in the guide catheter ***before*** an interventional cardiology device (a stent delivery system) is advanced into guide catheter (160) and through the evacuation head. Ex-1008, 12:9-14:10; *and see* § VII (claim 3), *supra*. In other words, Ressemann explicitly discloses there ***not be*** "any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter." A POSITA would be motivated to use the device of Itou as taught by Ressemann for the reasons set forth for claim 3. Ex-1005, ¶¶ 229-74.

Additionally, inserting the suction catheter into the guide catheter without a telescoping preassembly would allow the suction catheter to be used for extraction purposes prior to placement of a therapy device. Ex-1005, ¶ 276.

## IX. GROUND 3: ITOU RENDERS CLAIM 21 OBVIOUS IN VIEW OF BERG AND THE COMMON KNOWLEDGE OF A POSITA.

### A. Berg

Berg issued as U.S. Pat. No. 5,911,715 on June 15, 1999. It is prior art under both pre-AIA § 102(b) and post-AIA § 102(a)(1), (a)(2). Berg was cited, but not discussed, during prosecution of the '380 patent. Exs-1001-1003.

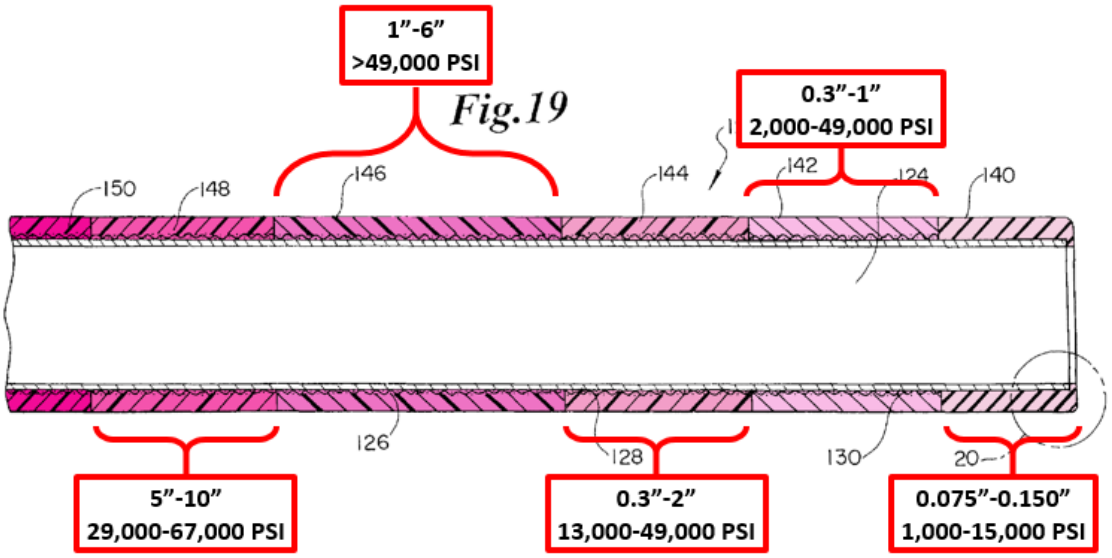
Berg discloses a "guiding catheter for use in coronary angioplasty and other cardiovascular interventions which incorporates a plurality of segment (sic) of selected flexural modulus in the shaft of the device." Ex-1051, Abstract. Berg explains that in order to place a catheter at a correct location in a vessel, a physician "must apply longitudinal and rotational forces," and that the catheter must be "rigid enough to push through the blood vessel, but yet flexible enough to navigate the bends in the blood vessel." *Id*., 1:49-55. Moreover, "[i]t is preferable to have a soft tip or flexible section engage the ostium," so "it is advantageous to have the proximal section be rigid to transmit the forces applied, but to have the distal end more flexible to allow for better placement of the guide catheter." *Id*., 1:65-2:2. Additionally, a more flexible, distal section causes less trauma to the blood vessel. *Id*., 2:2-4.

### B. Claim 21: The system of claim 20, in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

Itou in view of Berg renders claim 21 obvious in view of the common knowledge of a POSITA. Ex-1005, ¶¶ 277-89; *see also* 46-59, 63-84, 120-124.

By the time of the alleged invention of the '380 patent it was known that coronary catheters for PCI should have "a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions." Ex-1044,

1:36-38; *see also* Ex-1019, Abstract (explaining that an aspiration catheter should have varying degrees of flexibility along its length); Ex-1005, ¶¶ 279-84; Ex-1042, ¶¶ 27-46.




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

Berg teaches a guide catheter with a soft tip with a flexural modulus of between 1,000 and 15,000 PSI. This was desirable because it "provide[d] an atraumatic end . . . for navigating vasculature . . . ." Ex-1051, 14:1-7. Berg also teaches that the catheter should be increasingly rigid in a distal to proximal direction, including a portion— just proximal to the soft tip—with a flexural modulus of between 2,000 and 49,000 PSI, which assists in positioning the catheter tip. *Id.*, 14:27-30. Berg additionally teaches that the next most proximal segments should be a portion with a flexural modulus of between 13,000 and 49,000 PSI, and then a portion with a flexural modulus of greater than 49,000 PSI. This

configuration ensured both that the catheter had sufficient stiffness and backup support, as well as a smooth and flexible transition to the more flexible, distal portions. *Id*., 14:35-51. Ex-1005, ¶¶ 279-86; Ex-1042, ¶¶ 33-34, 73-82.

| | **PSI known to a POSITA** | **PSI claimed in the '380** |
|---|---|---|
| ***first portion*** | 1,000-15,000 | 13,000 +/- 5,000 |
| ***second portion*** | 2,000-49,000 | 29,000 +/- 10,000 |
| ***third portion*** | 13,000-49,000 and >49,000 | 49,000 +/- 10,000 |

Thus, three regions of flexural moduli taught by Berg overlap with the claimed range. Ex-1005, ¶¶ 286-87. As a result, the claimed range would have been obvious. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005) ("[A] prima facie case of obviousness arises when the ranges of a claimed composition overlap the ranges disclosed in the prior art."). A POSITA would have had the motivation to modify Itou to include segments with flexural moduli in the above ranges (known to a POSITA, as evident in Berg's teachings) because Itou explicitly teaches that suction catheter (2) was designed to reach "deep location[s] in a coronary artery," Ex-1007, 2:1-2, 5:35-38. As Dr. Brecker and Dr. Hillstead explain, being able to advance a catheter to distal locations in the coronary vasculature often requires that the catheter be maneuvered through tortuous portions of the coronary vasculature.

Ex-1042, ¶¶ 27-46, 73-82; Ex-1005, ¶¶ 279-89; *and see* Ex-1045, 1:39-44. This renders claim 21 obvious.

## X. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1073. The "Facts" section states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioner launched a "copycat" product *Id.*, 2, 5, 9. Patent Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

## XI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the claims 1-4, 6-10, 12-21, and 23 of the '380 patent as unpatentable under 35 U.S.C. §§ 102 and/or 103.

## XIII. 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

*/ Cyrus A. Morton /*
Cyrus A. Morton

800 LaSalle Ave, Suite 2800
Minneapolis, MN 55402
612.349.8500

Attorney for Petitioner
Medtronic, Inc.

## WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 13,806 words, excluding any Mandatory Notices. I further certify that, in preparation of this Corrected Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 12, 2019

*/ Cyrus A. Morton /*

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

*Attorney for Petitioner*

## CERTIFICATE OF SERVICE

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

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

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

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

*/ Cyrus A. Morton /*

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

*Attorney for Petitioners*