UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

Case No.: IPR2020-00135
U.S. Patent No. RE45,776

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE45,776

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I. PRELIMINARY STATEMENT

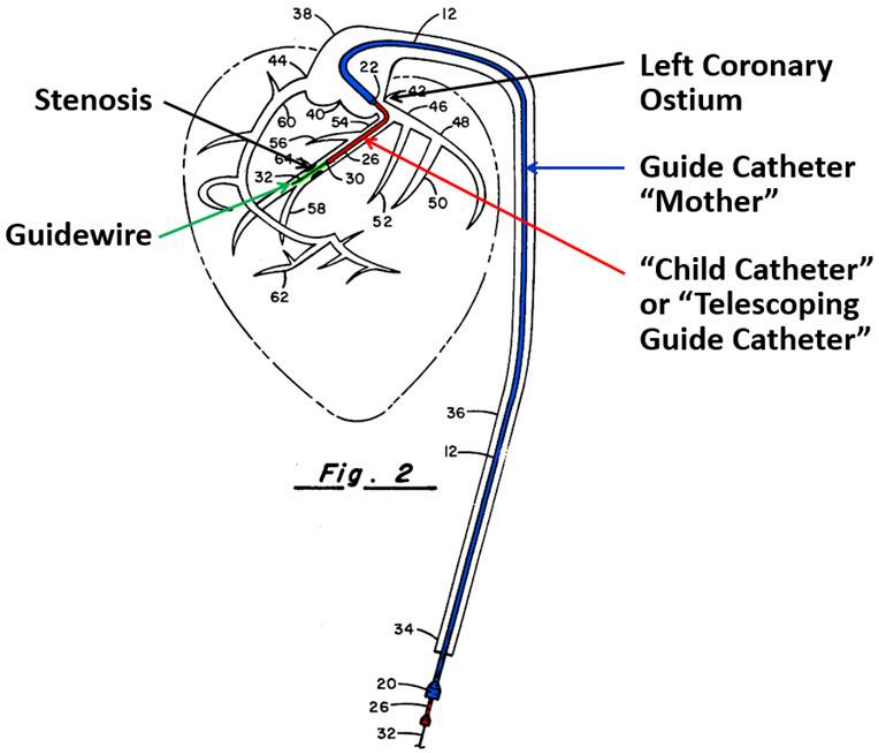
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") request *inter partes* review ("IPR") of claims 25-27, 29-33, 35-39, 41-49, and 52-56 ("Challenged Claims") of U.S. Patent No. RE45,776 ("'776 patent," Ex-1001). The '776 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1001, [60])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id*., [54], [72]. The Challenged Claims were never subject to a prior art based Office Action, meaning there is no substantive file history for the '776 patent.

The '776 patent describes a catheter system that reduces the likelihood of a guide catheter ("GC") dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a GC and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*., Abstract, Figs. 8-9. In so doing,

[1] The '776 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1005, ¶ 131. A POSITA knew that the "coaxial guide catheter" of the '776 patent was commonly understood to be a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id*.; *see also* Ex-1009, 5:49-52 (referring to body 12 "as a guide catheter extension").

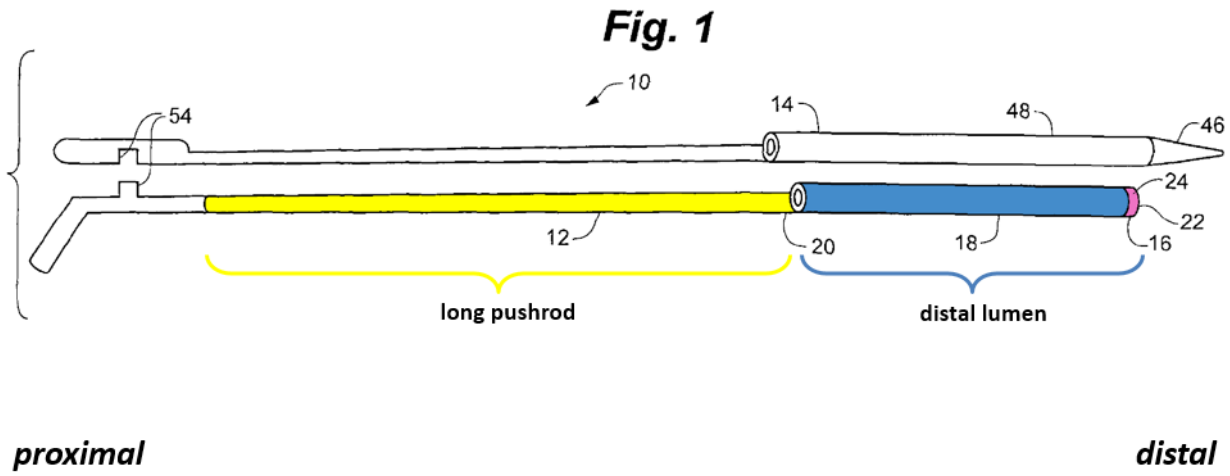
the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id*., 3:7-11, 8:24-35.

The '776 patent admits the use of a guide extension catheter inside an outer GC was known. *Id.*, 2:46-62 (describing as the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a "mother-and-child assembly." Ex-1005, ¶¶ 74-85. The child catheter (red in below figure) (i.e., guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., mother catheter) into the coronary artery. Ex-1005, ¶ 74.



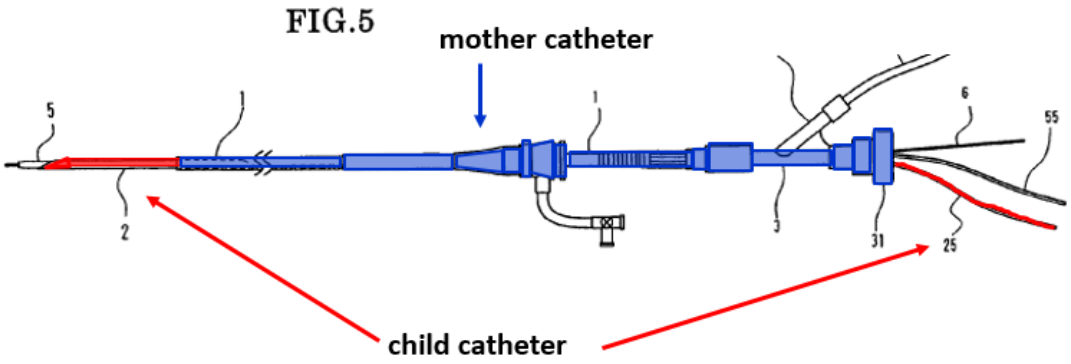
Ex-1054, Fig. 2 (annotations and color added).

The child catheter in the mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id.*; Ex-1005, ¶¶ 74-85. The '776 patent alleges such a design had certain drawbacks (Ex-1001, 2:63-3:6) and modifies the child catheter (of the mother-and-child assembly) to have two parts: (i) a long thin pushrod; (ii) coupled to a short distal lumen (i.e., tube) that is highly flexible so it can extend deep into the coronary artery.



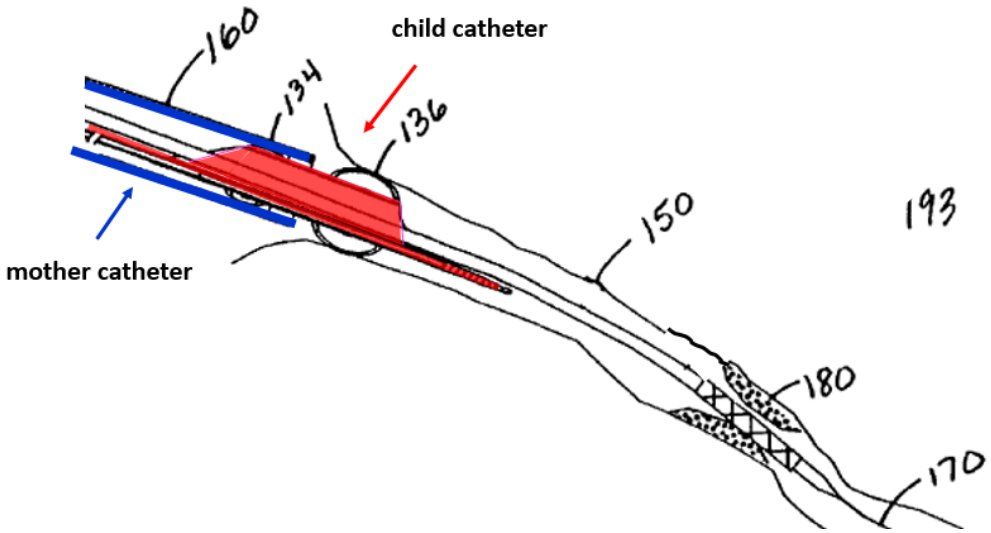
Ex-1001, Fig. 1 (annotations and color added).

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



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

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



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

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the '776 patent are unpatentable. Petitioner respectfully requests institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the Challenged Claims.

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

A. Real Party-in-Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the '776 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 '776 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 '776 patent based on prior art references having different priority dates and

disclosures than the references discussed herein.

C. Lead and Backup Counsel

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

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

D. Service Information

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

III. REQUIREMENTS FOR IPR

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the '776 patent is available for IPR and Petitioner is not barred or estopped from requesting such review.

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 25-27, 29-33, 35-39, 41-49, and 52-56 of the '776 patent and cancellation of those claims as unpatentable based on the following grounds:[2]

No.	Grounds
1	Claims 25-27, 29-33, 35-37, 41-45, and 47-49 are anticipated by Itou.
2	Claims 39 and 46 are rendered obvious by Itou in view of the knowledge of a POSITA.
3	Claims 36-37 and 52-56 are rendered obvious by Itou in view of Kataishi and/or the knowledge of a POSITA.
4	Claims 32, 36-38, 46, 52-56 are rendered obvious by Itou in view of Ressemann and/or the knowledge of a POSITA.
5	Claims 52-56 are rendered obvious by Itou in view of Enger and/or the knowledge of a POSITA.

[2] This Petition is supported by Declarations of Stephen JD Brecker, MD (Ex-1005), and Dr. Richard A. Hillstead (Ex-1042), as experts in the field of the '776 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1078) to support the authenticity and public availability of the documents cited herein.

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.*, ¶ 35. Physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery to treat CAD without the need for open-heart surgery. Ex-1005, ¶¶ 33, 38-44.

PCI was developed over forty years ago. Although its catheter-based technology has advanced, basic PCI components have remained largely unchanged. Ex-1005, ¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature, and a guide catheter ("GC") is 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, 46-62.

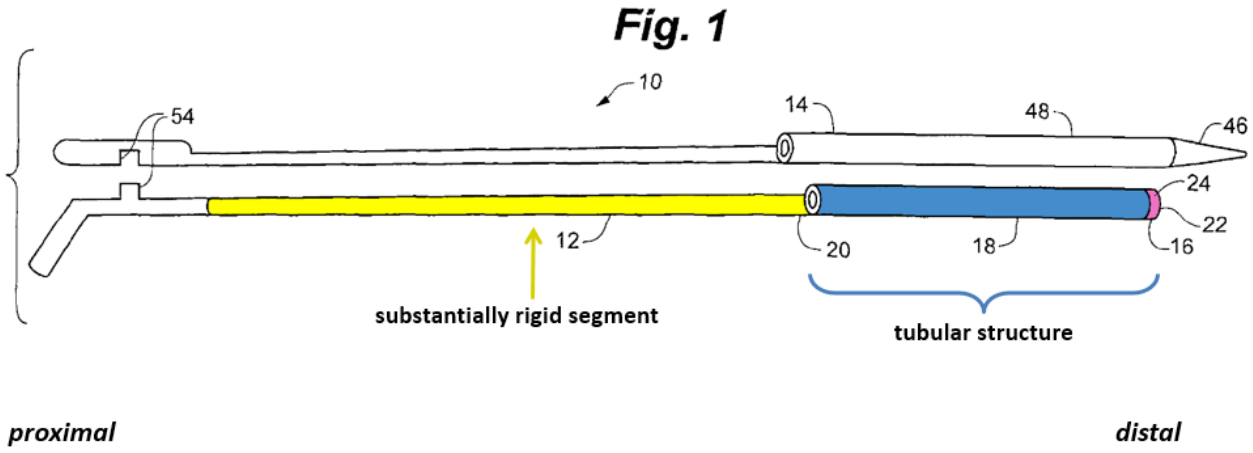
A small diameter flexible guidewire can then be threaded through the lumen of the GC to the target site. Ex-1005, ¶¶ 60-62. This guidewire serves as a guiderail to advance a therapeutic catheter through the GC and to the occlusion. *Id*. The therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. Ex-1005, ¶¶ 63-71. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that

can dislodge the GC from the ostium. Ex-1005, ¶¶ 70-71. As discussed above, one way to ameliorate this backward force is to use a mother-and-child assembly where the child catheter acts as an extension of the GC into the coronary artery. Ex-1005, ¶¶ 72-85.

B. The ’776 Patent

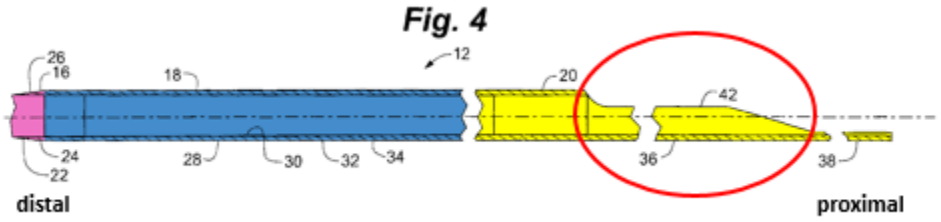
The ’776 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1001, 1:37-38. In particular, the ’776 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends “beyond the distal end of the guide catheter and … into [a] branch artery.” *Id*., Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:30-34, Abstract; Ex-1205, ¶¶ 131-132

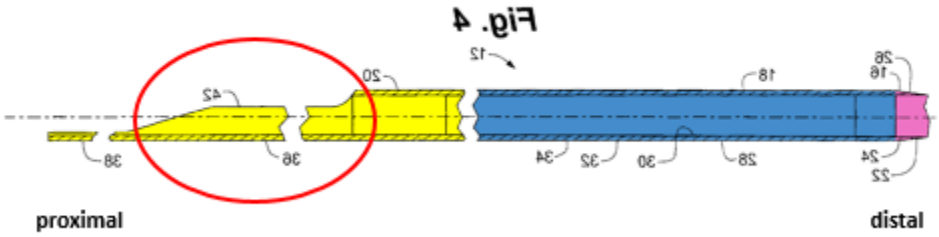
The ’776 patent claims a guide extension catheter 12 that includes a substantially rigid segment (yellow) and a tubular portion (blue).



Ex-1001, 13:36-49, Fig. 1 (annotations and color added). Ex-1005, ¶ 133.

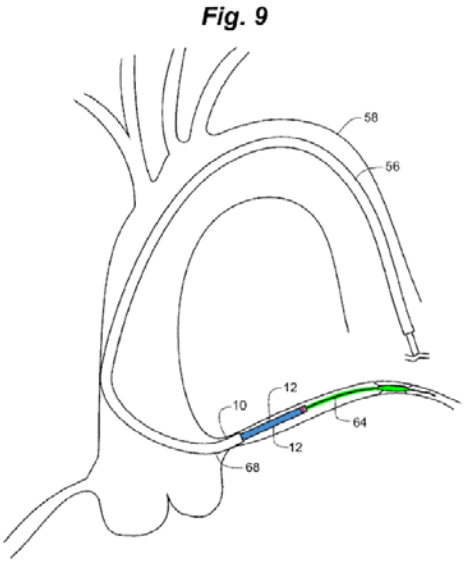
The ’776 patent also recites “a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure.” Ex-1001, 13:36-44 The specification, however, provides no written description support for the placement of this feature, and, as shown below, only describes the partially cylindrical opening (red circle) positioned in the substantially rigid segment 20.





Id., Fig. 4 (annotations and color added); *see* Ex-1005, ¶ 134.

Regardless, the ’776 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 tip (pink) and tubular portion (blue) extend out the distal tip of guide catheter 56. Ex-1005, ¶ 135.



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

C. Prosecution History of the ’776 Patent

The parent ’850 patent issued without Office Action. *See generally* Ex-1002.

Patent Owner sought reissuance in 2014. The claims of the ’776 patent also issued without any substantive Office Action. Ex-1003.

D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim not supported by a pre-March 16, 2013 application or claims priority to any patent or application that is subject to the AIA first-to-file provisions. AIA § 3(n)(1)(A); MPEP § 2159.02. The ’776 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority,[3] and (2) it claims priority to RE45,380 (“the ’380 patent”), which is subject to the AIA first-to-file provisions. Thus, Patent Owner cannot swear behind Itou in this proceeding.

The ’776 patent lacks written description support for at least the following reasons. First, there is no disclosure of “a partially cylindrical opening” that is not part of the substantially rigid segment, but each of independent claim places it between a distal end of the substantially rigid segment and a proximal end of the tubular structure. Ex-1001, 13:36-52. Second, claims 52-53 (*see* Ex-1001, 15:15-16:18) require a partially cylindrical opening with two inclined slopes, while

[3] The ’776 patent shares the same specification as all applications in its priority chain that were filed before March 16, 2013.

the only alleged support Figure 4 (Ex-1003a at 110 (Preliminary Amendment (3/3/14) at 23)), discloses an arc and an inclined region. Third, claims 52-53 call for "at least two" inclined regions, but there is no support for more than two. *See* Ex-1001, 15:15-16:18.

V. PERSON OF ORDINARY SKILL IN THE ART

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

VI. CLAIM CONSTRUCTION

A district court's claim constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation, Patent Owner stipulated to

these 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, *with* Ex-1064, 1 n.1).

Patent Owner advanced,[4] and the district court adopted, this construction:

- "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).

The district court provided the following constructions:

- "partially cylindrical opening": "need[s] no construction and will be given [its] plain and ordinary meaning" (Ex-1013 at 25-26)
- "lumen": "the cavity of a tube" (*Id.* at 25)
- "formed from a material more rigid than a material or material combination forming the tubular structure": "formed from matter that is more rigid than the matter forming the tubular structure" (*Id.* at 32)
- "formed from a material having a greater flexural modulus than a flexural

[4] Ex-1012 (Dkt 36-1) includes constructions Patent Owner advanced in the QXMedical Litigation.

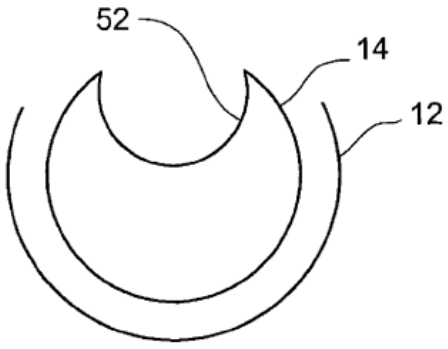
modulus of the tubular structure": "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure" (*Id.*).

Petitioner agrees with the above constructions for purposes of this IPR[5] (Ex-1005, ¶¶ 136-142) and proposes these additional constructions:

A. "concave track" (claim 37)

The '776 patent does not define the claim term "concave track." It mentions that a cutout portion, which supports a track, "may" have certain amounts removed and "may" extend for certain lengths, and later refers to cutout portion 44, which is not labeled in a figure. Ex-1001, 4:24-33, 4:47-49, 7:39-40; Ex-1005, ¶ 143. Figure 6, though, discloses a cross-sectional view of concave track 52. Ex-1001, 7:39-40, Fig. 6.

Fig. 6



[5] Petitioner proposes constructions for purposes of this IPR only, reserving the right to raise different constructions in other forums.

Thus, in the ’776 patent, “concave track” means a “portion that is not fully circumferential.” Ex-1005, ¶ 143.

B. “flexural modulus” (claims 52, 54)

The claim term “flexural modulus” had a known and established meaning by 2006 (Ex-1042, ¶ 30), 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. The ’776 patent admits this provides a coaxial extension catheter with decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1001, 7:31-38; Ex-1005, ¶¶ 144-145.

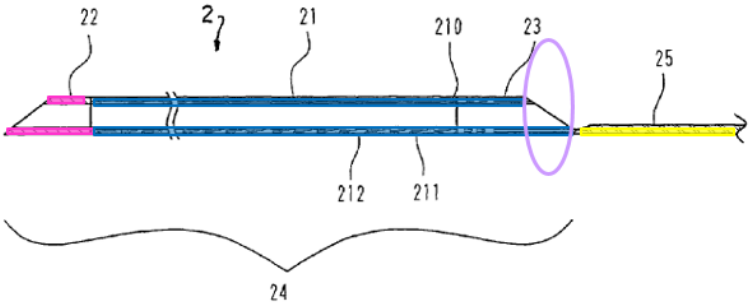
VII. GROUND 1: ITOU ANTICIPATES CLAIMS 25-27, 29-33, 35-37, 39, 41-43, 45, AND 47-49.

A. Itou

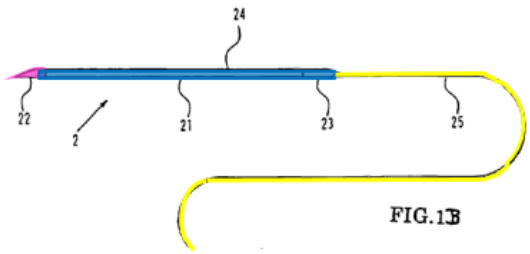
Itou was filed on September 23, 2005 and issued as U.S. Pat. No. 7,736,355 on June 15, 2010. It is prior art under pre-AIA § 102(e) and post-AIA §§ 102(a)(1), and 102(a)(2), and was not cited or considered during prosecutions of either the original ’850 patent, or of the ’776 reissue patent. Exs-1001-1003.

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.*, 1:66-2:5, Abstract, 5:32-34, 7:7-12, and a suction

catheter insertable through the GC. *Id.*, Abstract, Figs 1A-B, 5-6, 3:59-63. Suction catheter (2) has a proximal, solid wire-like portion (25), and a distal tubular portion (24) that includes tubular body portion (21). *Id.*, Abstract, Fig. 3, 1:53-60, 2:12-15, 3:46-50. Tubular portion (24) includes a portion reinforced with a metal layer (211) (blue). *Id.*, 2:18, 3:50-58. The partially cylindrical opening is angled (purple circle).



Id., Fig. 3 (color added); *see also* Ex-1005, ¶¶ 146-148.



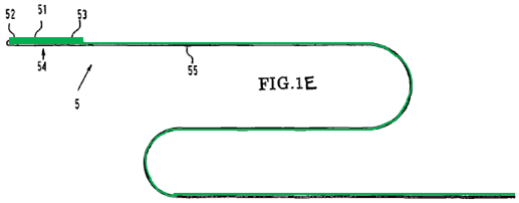
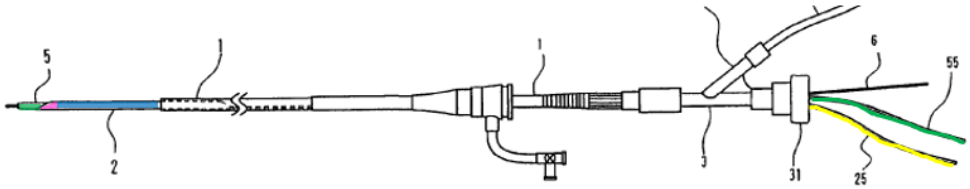


FIG.5



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

Itou also describes "distal end protective catheter" (5), shown above (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, 2:29-38, Figs. 5-6; Ex-1005, ¶¶ 148-149.

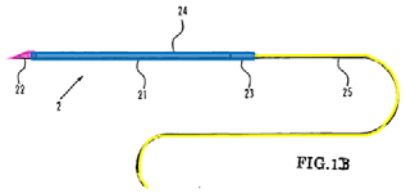
Where a prior art reference contains the claim elements in the same order as the claims it is anticipatory, regardless of whether the prior art and the claimed invention are directed to achieving the same purpose. *Legget & Platt, Inc. v. VUTEK, Inc*., 537 F.3d 1349, 1356 (Fed. Cir. 2008). Regardless, by the time of the alleged invention of the '776 patent, a POSITA knew suction catheters with a structure similar to Itou's may serve a dual purpose. Ex-1005, ¶ 150. An aspiration catheter could be "preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen." Ex-1019, 3:4-6. An aspiration lumen could be used both to remove thrombus from a coronary artery, and to deliver an angioplasty catheter or stent. *Id*., 3:34-36, 12:16-20; Ex-1008, 6:18-34, Figs. 6A-I; Ex-1005, ¶¶ 150-151.

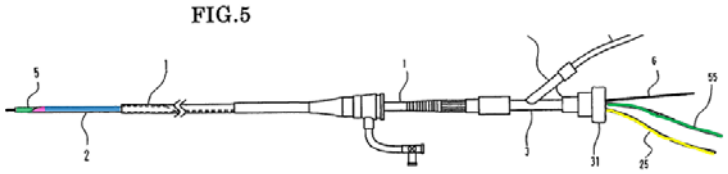
B. Claim 25

1. [25.pre] "A guide extension catheter for use with a guide catheter, comprising:"

To the extent the preamble is limiting, Itou discloses it. Ex-1005, ¶ 152. Itou teaches a combination of guiding catheter (1) and suction catheter (2). Ex-1007,

1:66-2:11, 7:1-23, 7:35-43, Abstract, Figs. 1B, 5-6, 8. Itou also teaches that suction catheter (2) "is disposed in the lumen of guiding catheter 1," *id*. 5:11-17, and suction catheter (2) may be inserted into guiding catheter (1) at its proximal end, to extend from its distal end.



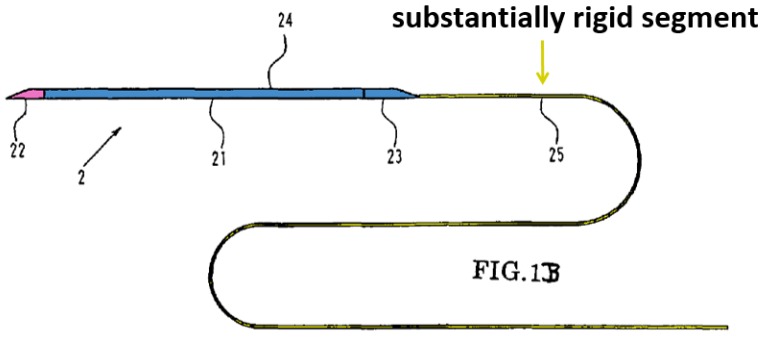


Compare id., Fig. 1B *with id.*, Fig. 5 (color added); *see also id.*, Figs. 6, 8.

Thus, as Dr. Brecker explains, suction catheter (2) may be used as a guide extension catheter. Ex-1005, ¶¶ 153-155.

2. [25.a] "a substantially rigid segment;"

Itou discloses this limitation. Ex-1005, ¶ 156. Guide extension catheter (suction catheter (2)) includes, at its proximal end, wire-like portion (25). Ex-1007, 2:12-15, 3:48-50.

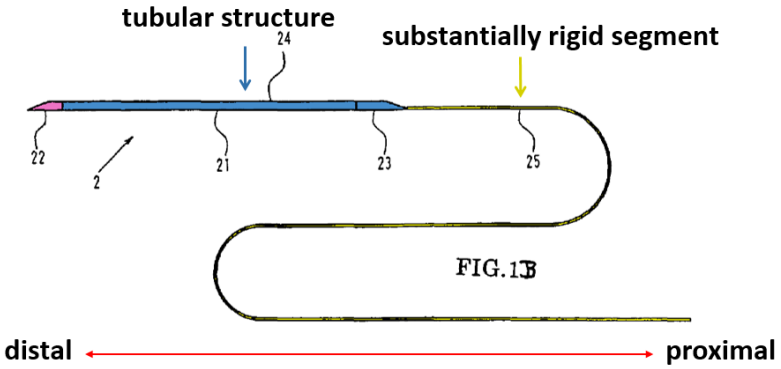


Id., Fig. 1B (annotations and color added).

Wire-like portion (25) is a "substantially rigid" segment because it is used to advance suction catheter (2) through guiding catheter (1). *Id*., 2:32-36, 5:35-46, Abstract, Figs. 5-6. Thus, wire-like portion 25 meets the claim construction of a segment "rigid enough to allow the device to be advanced within the guide catheter." *Supra*, § VI; Ex-1005, ¶ 156.

3. [25.b] "a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and"

Itou's tubular body portion (21) is a tubular structure positioned distal to the substantially rigid segment. Ex-1007, Abstract, 3:47-58, Figs. 3-4.

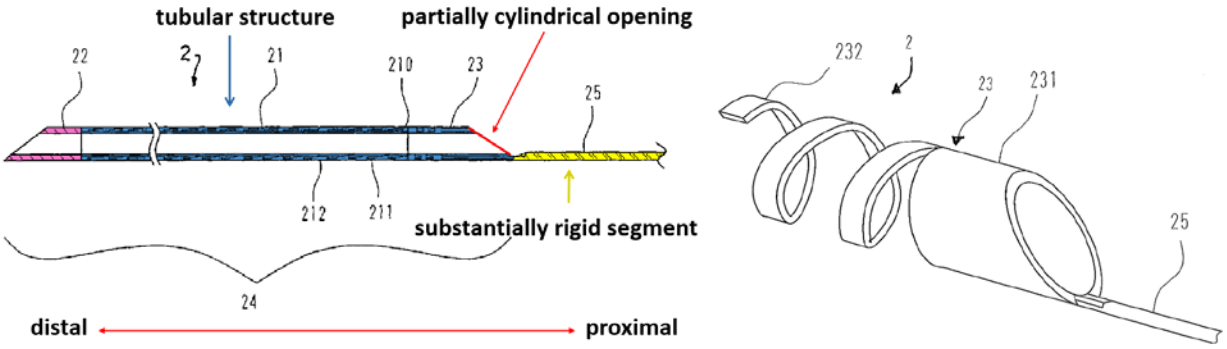


Id., Fig. 1.B (annotations and color added).

Itou also discloses that tubular body portion (21) defines a lumen, into which distal end protective catheter (5) may be inserted. *Id*. 4:48-52, 5:14-15, Figs. 3-4, Table 1 (providing an inner diameter for suction catheter, evidencing a "lumen"); Ex-1005, ¶ 157

4. [25.c.i] "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure,"[6]

Itou discloses a segment defining a partially cylindrical opening. Ex-1007, Fig. 4, 3:47-48, 4:10-11, 4:27-30. The opening is "formed by obliquely cutting one end of a [cylindrical] metal pipe." *Id.*, 4:10-11, 4:27-32, Fig. 4.



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

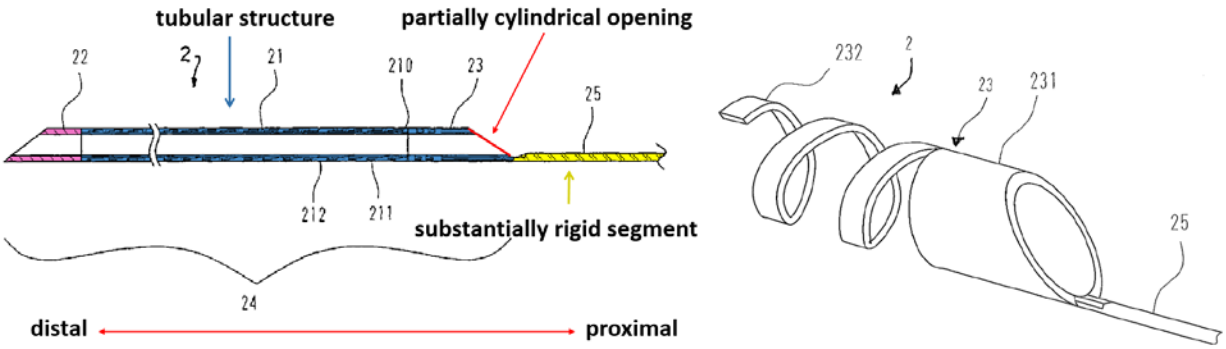
As illustrated above, the partially opening is positioned between a distal end of the substantially rigid segment (wire-like portion (25)) and a proximal end of the

[6] The '776 patent does not disclose a partially cylindrical opening positioned "between" the distal end of the substantially rigid segment and the proximal end of the tubular segment. *See* § IV.B, *supra*. The only disclosure is of an opening in the substantially rigid portion. Despite the claim drafting game Patent Owner has played, it is obvious to have an opening in that location. Mapping these elements to the art is also consistent with Patent Owner's allegations in the district court. Ex-1077, 127:24-128:14, 144:9-22, 145:11-17.

tubular structure (21). Ex-1005, ¶ 158.

5. [25.c.ii] "the segment defining the partially cylindrical opening having an angled proximal end,"

Itou discloses that the opening is "inclined obliquely," and "formed by obliquely cutting one end of a metal pipe," as shown below. Ex-1007, 4:10-11, 4:27-32.

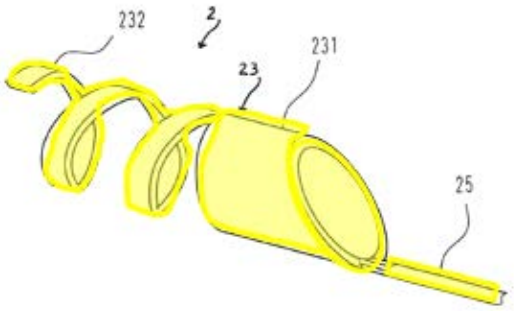


Id., Figs. 3-4 (annotations and color added).

Thus, Itou teaches that the segment defining the partially cylindrical opening has an angled proximal end. *Id.*; Ex-1005, ¶ 159.

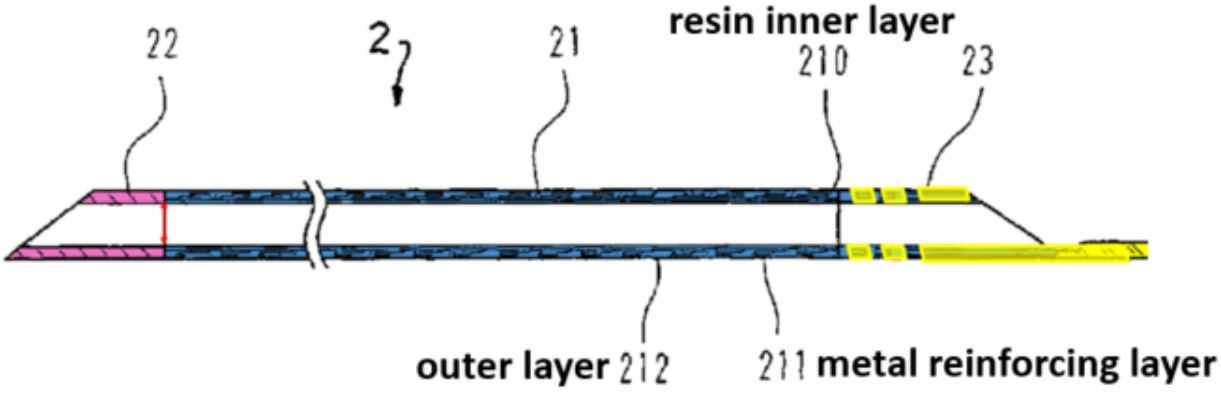
6. [25.c.iii] "formed from a material more rigid than a material or material combination forming the tubular structure,"

Itou discloses that the partially cylindrical opening is "formed by obliquely cutting one end of a metal pipe." Ex-1007, 4:27-30 ("end 231"). The metal pipe is encased in resin layers. *Id.*, 3:45-58, 4:36-38.



Id., Fig. 4 (color added).

By contrast, Itou discloses that tubular structure (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[.]" *Id.*, 3:50-58.



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

As Dr. Brecker and Dr. Hillstead explain, the partially cylindrical opening formed from a *metal* pipe material is more rigid than the individual *resin* material or *metal* wire material of tubular structure 21 (210), (211), and (212) Ex-1007, 3:54-55, Fig. 3; Ex-1005, ¶ 160; Ex-1042, ¶¶ 66-71. The *metal* pipe material is more rigid than the material combination of the *resin* and *metal* wire material too.

Ex-1005, ¶ 160; Ex-1042, ¶ 72. Given the differences in the materials, under the district court's claim construction, Itou discloses the partially cylindrical opening is "formed from matter that is more rigid than the matter forming the tubular structure." *Supra*, § VI; Ex-1005, ¶ 160; Ex-1042, ¶ 73.

7. [25.c.iv] "and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,"

Itou teaches that suction catheter (2) is long enough so while its distal end is advanced to a target location—distal to the distal end of the guiding catheter (1)—its proximal end remains in guiding catheter (1). Ex-1007, 5:35-42, 6:30-35, Figs. 5-6; Ex-1005, ¶ 161. Thus, Itou discloses the structural limitations of 25.c.iv. *See* § VII.B.7. To the extent Patent Owner suggests anything more is required than the cited disclosure in Itou, it is mistaken. The additional language recites an intended use ("configured to receive one or more interventional cardiology devices therethrough when the positioned within the guide catheter"), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

Regardless, Itou teaches that the tubular portion of Itou's suction catheter (2) has an inner diameter of 1.5 mm and is configured to receive distal end protective catheter (5),[7] which has an outer diameter of 1.35 mm. Ex-1007, Table 1, Fig. 5,

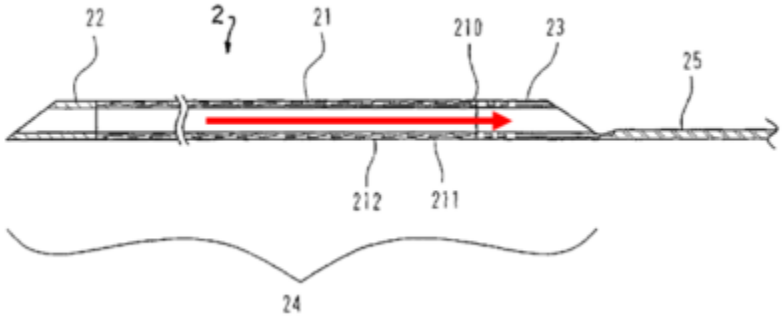
[7] Distal end protective catheter (5) is an "interventional cardiology device." *Supra*, § VI.

4:48-50, 5:15. As catheter (5) "projects from the distal end" of catheter (2), *id*., it follows that catheter (5) is inserted into the proximal end of catheter (2), through the partially cylindrical opening discussed in § VII.B.4, *supra*.

Thus, the partially cylindrical opening of suction catheter (2) is large enough (i.e. "configured") "to receive one or more interventional cardiology devices therethrough when the positioned within the guide catheter." Ex-1005, ¶ 161.

8. [25.d] "wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen."

Itou discloses only a single lumen for the suction catheter (2) (Ex-1007, 5:15, 4:48-50) as shown below.

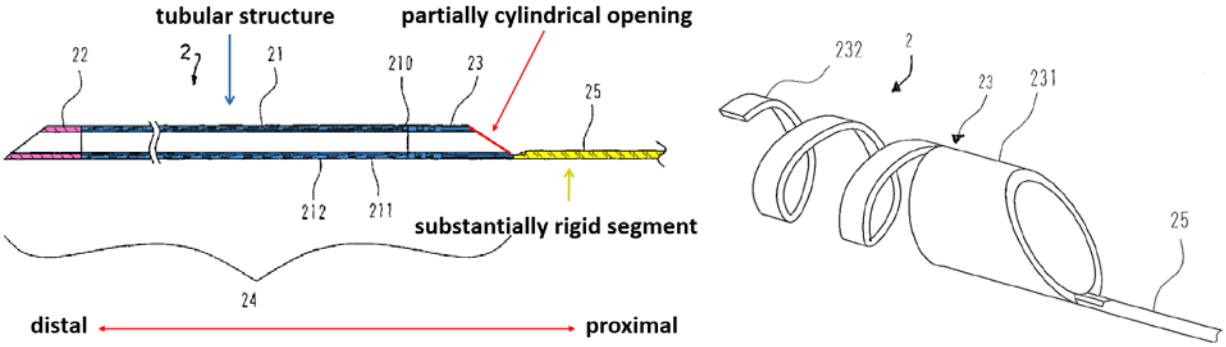


Id., Fig. 3 (arrow added).

Thus, Itou discloses a cross-section at the proximal end of the tubular portion (21) of suction catheter (2) defines a single lumen. Ex-1005, ¶ 162.

C. Claim 26: "The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent the distal end of the substantially rigid segment and extends distally toward the tubular structure."

Itou anticipates claim 26. Ex-1005, ¶ 163. Itou discloses that the partially cylindrical opening formed by proximal end portion (231) "is secured firmly by being welded to the distal end of the wire-like portion 25[.]" Ex-1007, 4:33-34. Figure 3 depicts the angled proximal end of the partially cylindrical opening originating from adjacent the distal end of substantially rigid segment (25). Angled proximal end (231) extends distally toward the tubular structure (21).

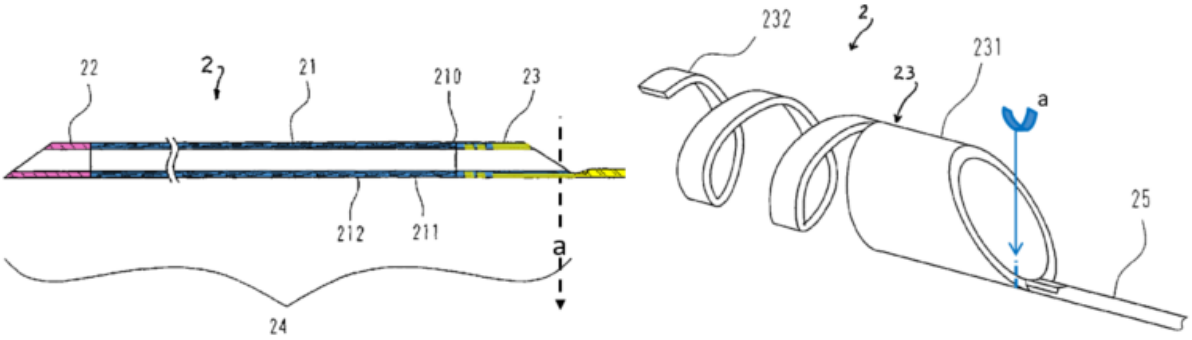


Id., Figs. 3-4 (annotations and color added); Ex-1005, ¶ 163.

D. Claim 27: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape."

Itou anticipates claim 27. Ex-1005, ¶ 164. As illustrated below, the segment defining the partially cylindrical opening necessarily has a portion with an arcuate cross-sectional shape. *Id.* In so doing, a portion of the cylindrical opening necessarily includes an arcuate cross-sectional shape, which, according to the '776

patent, is a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1001, 7:12-14; Ex-1005, ¶ 164.



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

E. Claim 29: "The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of a cross-sectional circumference of a tube."

Itou anticipates claim 29 for the same reasons it anticipates claim 27. Ex-1005, ¶ 165. Indeed, claim 29 adds nothing of patentable weight and merely rephrases claim 27. Claim 29 adds that the arcuate cross-section "radially extends 25% to 40% of a cross-sectional circumference of a tube." But as explained for claim 27, the '776 patent already describes an arcuate cross-sectional shape in this fashion. Ex-1001, 7:12-14. Stated another way, by reciting an arcuate portion in claim 27, Patent Owner necessarily recited a shape that radially extends 25% to 40% of the cross-sectional circumference of a tube. Regardless, Itou discloses this limitation. Ex-1005, ¶ 165.

F. Claim 30: "The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter."[8]

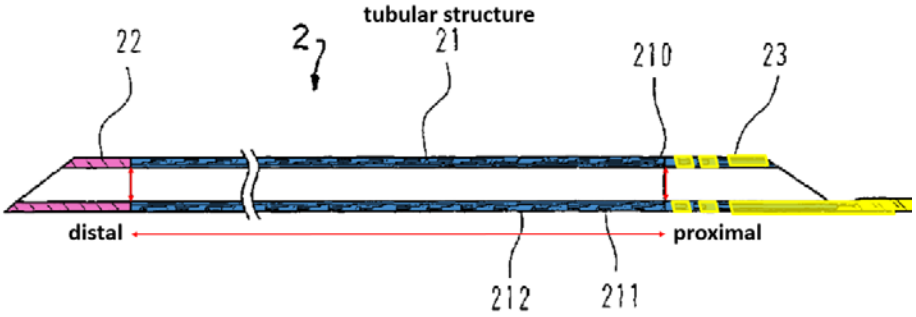
Itou anticipates claim 30. Ex-1005, ¶ 166. Itou discloses that "guiding catheter 1 is formed from a guiding catheter of 6 Fr (2.06 mm) which is used popularly and has an inner diameter of 1.8 mm." Ex-1007, 6:47-50, Table 1. Itou also discloses the lumen of the tubular portion of suction catheter (2) has a cross-sectional inner diameter of 1.5 mm, *id*., Table 1, which is 0.3 mm smaller than the inner diameter of the guiding catheter. And 0.3 mm is "not more than one French

[8] The '776 patent describes only three guide catheters. These guide catheters have an ***outer*** diameter—not an ***inner*** diameter—of 6 French, 7 French, and 8 French. (Ex-1001, 3:36-44). In others words, the '776 patent never describes a guide catheter with a "a cross-sectional inner diameter of six French, seven French or eight French," as claimed. For this reason, Petitioner assumes this was a drafting error, and, for purposes of this Petition, interprets claim 30 as though it recites a French size of the "outer diameter" of the guide catheter, meaning the claim would read as follows: "The guide extension catheter of claim 25, wherein the guide catheter includes a … cross-sectional [outer] diameter of six French, seven French or eight French …."

smaller," because one French is 0.33 mm. Ex-1062, 545; Ex-1005, ¶ 166. Itou explains that its invention "is not limited to the embodiment described above." Ex-1007, 8:36-38. Thus, claim 30 is anticipated by Itou. Ex-1005, ¶ 166.

G. Claim 31: "The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from a proximal end to a distal end of the tubular structure."

Itou anticipates claim 31. Ex-1005, ¶ 167. Itou teaches that the tubular structure lumen is "uniform in size from its proximal end to its distal end" as shown below.



Ex-1007, Fig. 3 (annotations and color added) (showing no taper).

TABLE 1

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

Id., Table 1 (disclosing that the tubular portion of suction catheter (2) has a singular inner diameter of 1.5 mm) (boxes added); Ex-1005, ¶ 167.

H. Claim 32: "The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter."

Itou anticipates claim 32. Ex-1005, ¶ 168. Itou teaches that "[t]he distal end protective catheter 5 is inserted in the lumen of the suction catheter 2 and projects from the distal end of the suction catheter 2." Ex-1007, 4:48-52. Thus, Itou discloses the structural limitations. To the extent Patent Owner suggests it requires anything more than the cited disclosure in Itou, it is mistaken. The additional language recites an intended use ("configured to receive a stent and a balloon catheter"), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

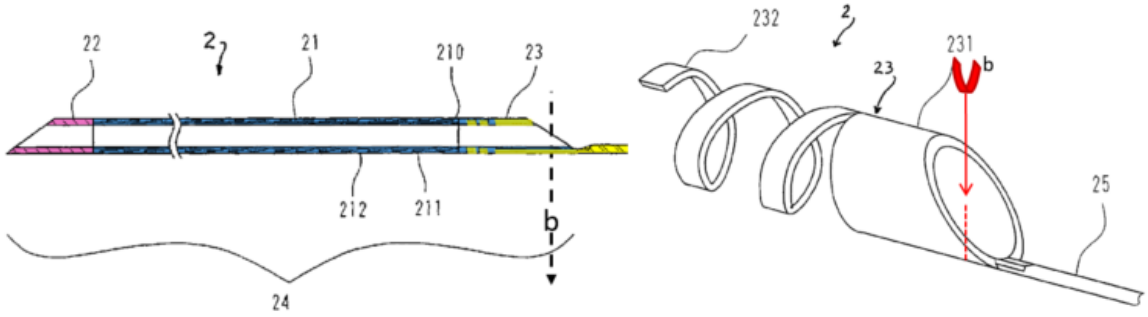
Regardless, Itou teaches that the tubular member of suction catheter (2) (of which tubular structure (21) is a part) has an inner diameter of 1.5 mm, Ex-1007, Table 1, which Dr. Brecker explains is 0.059 inches.[9] This was large enough to accommodate the insertion of a balloon-expandable stent, several of which were available by the time of the purported invention of the '776 patent. Ex-1005, ¶ 168;

[9] This corresponds to the inner diameter of the extension catheter taught in the '776. Ex-1001, 3:51 ("greater than or equal to 0.056 inches ...").

Ex-1022, 3 (requiring a > 0.056 in. (1.4 mm) inner catheter diameter for CYPHER stents between 2.50-3.0 mm on an RX delivery system); Ex-1023, 9 (requiring a minimum, inner catheter diameter of 0.56 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1024, 10 (requiring an inner catheter diameter ≥ 0.058 in. (1.47 mm) for TAXUS Express stents on a monorail delivery system). Thus, tubular structure (21) is large enough (i.e. "configured") "to receive a stent and a balloon catheter." Ex-1005, ¶ 168.

I. Claim 33: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape."

Itou anticipates claim 33. Ex-1005, ¶ 169. As illustrated below, the segment defining the partially cylindrical opening necessarily has a portion with a hemicylindrical cross-sectional shape, which, according to the '776 patent, is a portion that "desirably includes 40% to 70% of the circumference of the tube." Ex-1001, 7:7-8; Ex-1005, ¶ 169.



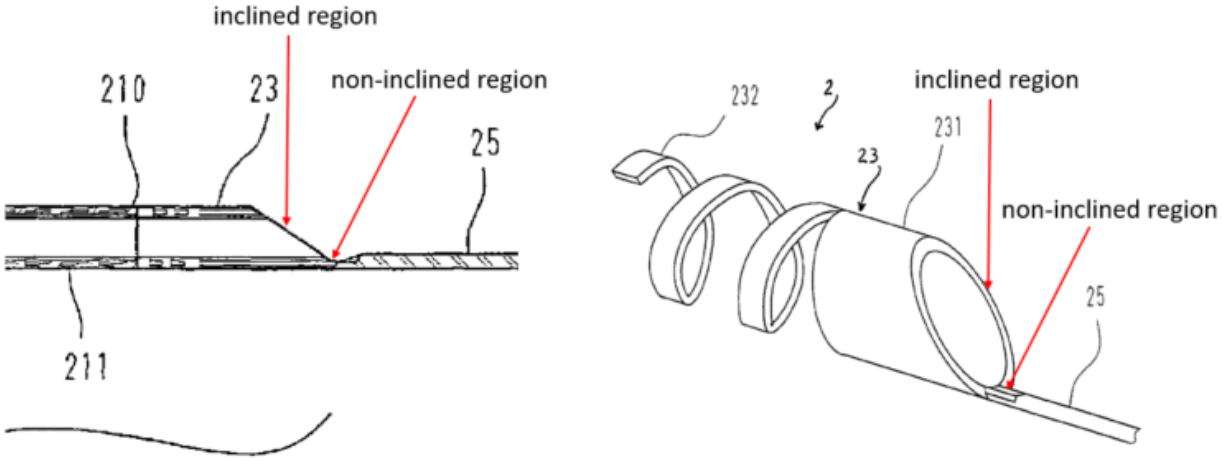
Ex-1007, Figs. 3-4 (annotations and color added).

J. Claim 35: "The guide extension catheter of claim 33, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of a cross-sectional circumference of a tube."

Itou anticipates claim 35 for the same reasons it anticipates claim 33. Ex-1005, ¶ 170. Indeed, claim 35 adds nothing of patentable weight and merely rephrases claim 33. Claim 35 adds that the hemicylindrical cross-section "radially extends 40% to 70% of a cross-sectional circumference of a tube." But as explained for claim 33, the '776 patent describes a hemicylindrical cross-sectional shape in this fashion. Ex-1001, 7:7-8. By reciting a hemicylindrical portion in claim 33, Patent Owner necessarily recited a portion that extends 40% to 70% of the cross-sectional circumference of a tube. Ex-1005, ¶ 170. Itou discloses this limitation. *Id.*

K. Claim 36: "The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region."

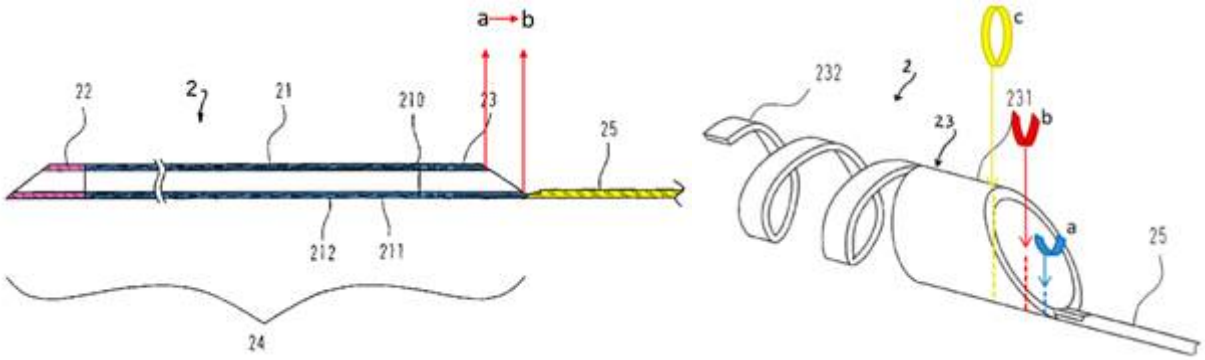
Itou anticipates claim 36. Ex-1005, ¶ 171. Itou discloses that the partially cylindrical opening portion (231) is formed by obliquely cutting one end of a metal pipe. Ex-1007, 4:27-32, Fig 4. As depicted below, the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region. Ex-1005, ¶ 171.



Id., Figs. 3-4 (annotations and arrows added).

L. Claim 37: "The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure."

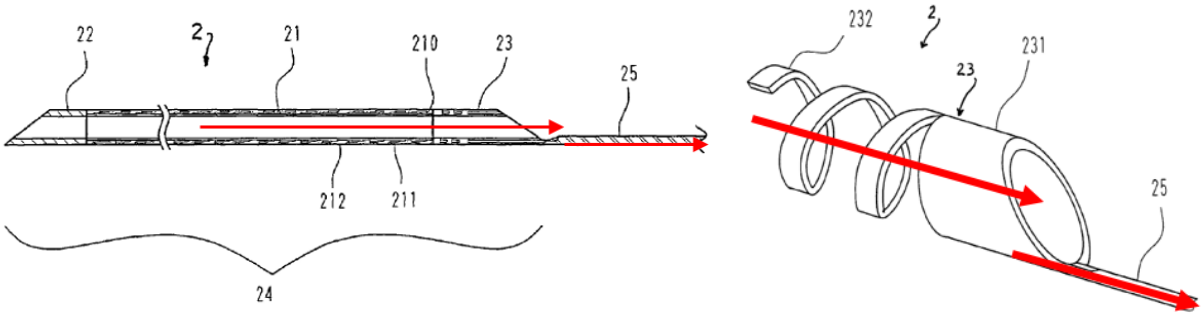
Itou discloses claim 37. Ex-1005, ¶ 172. In the context of the '776 patent, "concave track" refers to a portion that is not fully circumferential. *Supra*, § VI.A. Itou discloses that the partially cylindrical opening 231 includes a portion that is not fully circumferential, and thus, concave. *Supra*, §§ VII.B.4, VII.I (claims 25.c.i and 33). As illustrated below, the partially cylindrical opening defining a concave track is continuous with the lumen of the tubular structure. Ex-1005, ¶ 172.



Ex. 1005, Fig. 3 (not fully cylindrical between "a" and "b"), Fig. 4 (not fully cylindrical, for example, at "a" or "b") (annotations and color added).

M. Claim 41: "The guide extension catheter of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure."

Itou anticipates claim 41. Ex-1005, ¶ 174. As illustrated by the arrows in the figures below, the substantially rigid segment wire-like portion 25 is eccentrically positioned (not concentric) relative to a cross section taken through tubular structure (21). Ex-1005, ¶ 174.



Ex-1007, Figs. 3-4 (arrows added).

N. Claim 42: "The guide extension catheter of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure to be advanced within and partially through the guide catheter while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the substantially rigid segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure."

Itou anticipates claim 42. Ex-1005, ¶¶ 175-179. Itou discloses that the substantially rigid wire-like segment (25) is "formed from a solid metal wire," has

a cross-sectional diameter of 0.45 mm, and is positioned eccentrically relative to a cross-section through tubular structure (21). Ex-1007, 3:47-50, Table 1, Figs. 3-4. Itou also teaches that the substantially rigid segment is used to advance the tubular structure of suction catheter (2) through guiding catheter (1) until the distal portion of suction catheter (2) "projects forwardly beyond the distal side of the guiding catheter." *Id.*, 2:32-36, 5:43-46, Abstract, Figs. 5-6. Itou further teaches that "distal end protective catheter 5 is inserted in the lumen of the suction catheter 2 and projects from the distal end of the suction catheter 2 such that it acts as a protective safety tip upon insertion into a blood vessel," *Id.*, 4:48-63, thereby disclosing "at least partial delivery" of a received interventional cardiology device. As illustrated below, distal end protective catheter (5) (green) is inserted alongside the substantially rigid segment (yellow), through the partially cylindrical opening, and through the lumen of the tubular structure of suction catheter (2).

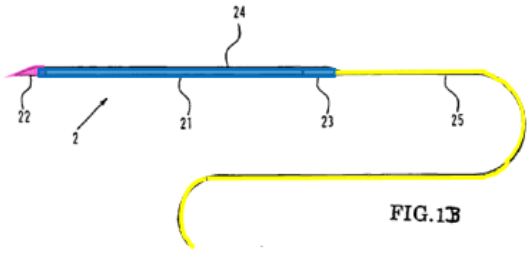


FIG.1B

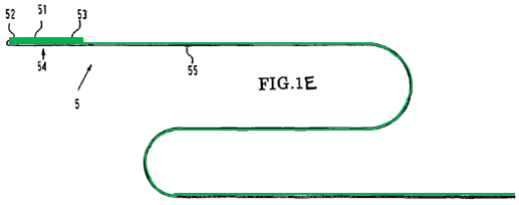
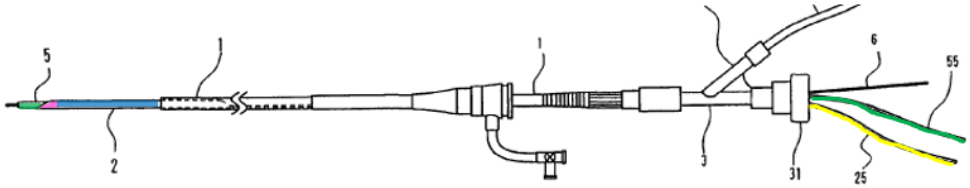


FIG.1E

FIG.5



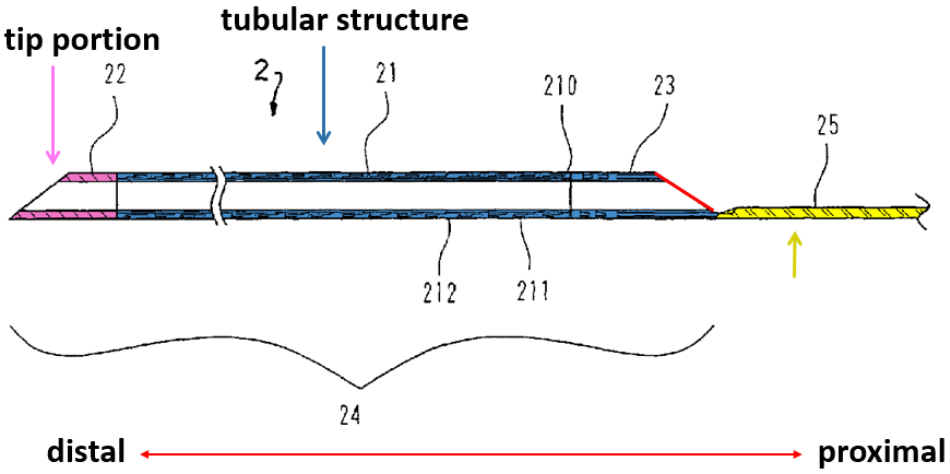
Id., Figs. 1B, 1E, 5 (color added); s*ee also* §§ VII.B.7, VII.G-H, VII.L (claims 25.c.iv, 31-32, 37), *supra*. Thus, claim 42 is anticipated. Ex-1005, ¶¶ 175-179.

O. Claim 43: "The guide extension catheter of claim 25, wherein the substantially rigid segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the substantially rigid segment."

Itou anticipates claim 43. Ex-1005, ¶ 180. Itou discloses an intravascular foreign matter suction assembly, including suction catheter (2) with tubular portion 24 (of which tubular structure (21) is a part) having a lumen with an inner diameter size of 1.5mm, which is greater than the 0.45mm outer diameter size of substantially rigid wire-like portion (25). Ex-1007, Fig. 3, 7:50-66, Table 1; Ex-1005, ¶ 180.

P. Claim 44: "The guide extension catheter of claim 25, further comprising a tip portion positioned distal to the distal end of the tubular structure."

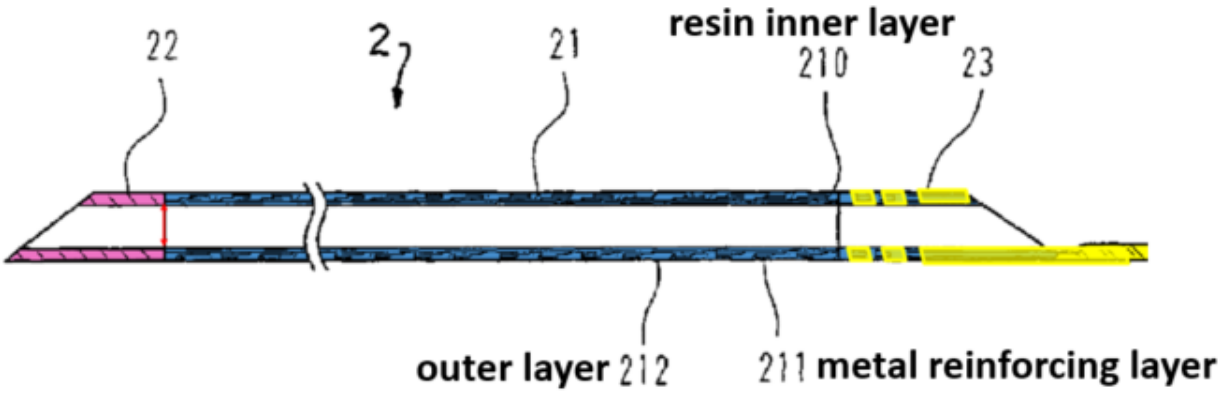
Itou anticipates claim 44. Itou discloses "a distal tip 22 provided at the distal end of the tubular body portion 21." Ex-1007, 3:56-57, Figs. 1B, 3; Ex-1005, ¶ 181. As shown below, distal tip (22) is positioned distal to the distal end of tubular structure 21.



Id., Fig. 3 (annotations and color added); Ex-1005, ¶ 181.

Q. Claim 45: "The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of a length of the tubular structure and surrounded by one or more polymer materials."

Itou anticipates claim 45. Ex-1005, ¶ 182. Tubular structure (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).

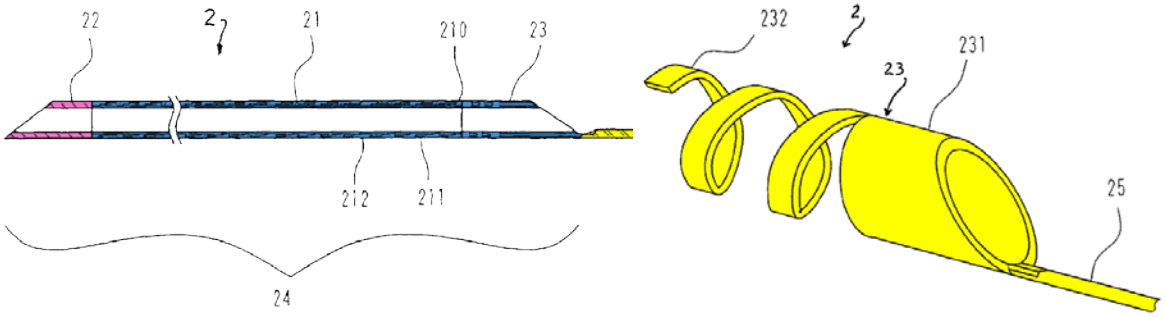


Id., Fig. 3 (annotations and color added).

From Itou's disclosures, it is evident that metal wire (211) is braided or coiled around inner layer 210. Ex-1005, ¶ 182; Ex-1042, ¶ 69. Itou teaches that metal reinforcing layer (211) is encased in layers of resin, which disclose the reinforcing braid or coil. Ex-1005, ¶ 182; Ex-1042, ¶¶ 66-73.

R. Claim 47: "The guide extension catheter of claim 25, wherein the substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.

Itou anticipates claim 47. Ex-1005, ¶ 183. Itou discloses substantially rigid wire-like portion (25) of suction catheter (2) is "formed from a solid metal wire[.]" Ex-1007, 3:47-50. Itou also discloses that the partially cylindrical opening comprises a rigid portion made of an obliquely cut end of a stainless steel metal pipe. *Id.*, 4:25-42, Fig 4; Ex-1005, ¶ 183; Ex-1042, ¶¶ 70, 73. Itou discloses "proximal end portion 231 [of the partially cylindrical opening] is secured firmly by being welded to the distal end of the wire-like portion 25 crushed into a form of a flat place so that it may not be broken during use." *Id.*, 4:33-36.



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

Thus, Itou discloses that "the substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter." Ex-1005, ¶ 183.

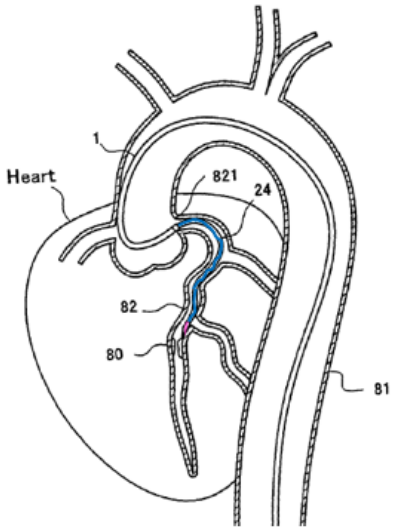
S. Claim 48: "The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter."

Itou discloses claim 48. Ex-1005, ¶ 184. As discussed for claim 45, Itou discloses a reinforced tubular portion (21) with "a reinforcing layer 211 made of a metal wire made of stainless steel or the like." Ex-1007, 3:50-58, 4:27-32, Figs. 3-4; *supra* § VII.Q (claim 45). Itou teaches that the distal portion of proximal tip 23, coil 232, is also a reinforced tubular structure, while the proximal portion of tip 23, opening 231, is a partially cylindrical opening. Thus, Itou discloses that the "partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter." Ex-1005, ¶ 184; Ex-1042, ¶¶ 70, 75, 77.

T. Claim 49: "The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium of a coronary vessel and resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion."

Itou anticipates claim 49. Ex-1005, ¶¶ 185-191. Itou teaches that the distal portion of catheter (2) (tubular member (24)) is advanced through guiding catheter (1) and into the coronary artery. Ex-1007, Abstract, 3:1-3, 5:26-46; Ex-1005,

¶ 185. Itou also teaches that the proximal portion of tubular member (24) remains within the lumen of guiding catheter (1). *Id*., Fig. 6, 3:1-3, 5:26-46.



Id., Fig. 6 (color added, illustrating tip (22) (pink) and a portion of tubular structure (21) (blue)), Abstract, 1:46-65, 5:38-42.

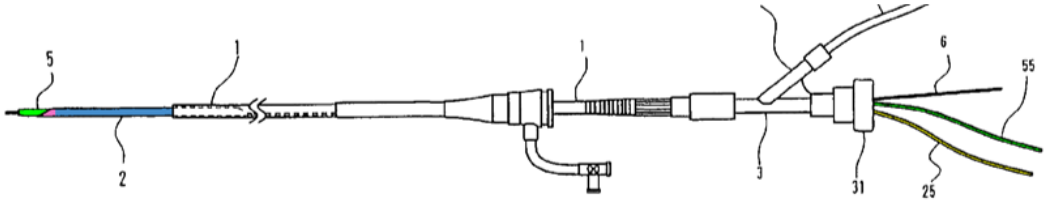
Thus, Itou discloses the structural limitations of claim 49, which is an apparatus claim.[10] Ex-1005, ¶ 185.

[10] Claim 49 includes additional language that the "distal portion of the ***guide extension catheter***" is configured to "anchor within the ostium." That cannot be correct as the '776 patent specification teaches that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter be advanced further into the coronary artery. Ex-1001, Fig. 8. For purpose of this IPR, Petitioner assumes this is a claim drafting error. Similar to the '776 patent, Itou

To the extent Patent Owner suggests claim 49 requires anything more than the cited disclosure in Itou, it is mistaken. Claim 49 additionally recites an intended use ("resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion"), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.")

Regardless, as Dr. Brecker explains, Itou discloses the remainder of claim 49 to a POSITA. Ex-1005, ¶¶ 186-191. First, Itou teaches that distal end protective catheter (5) may be extended through suction catheter (2) and beyond its distal tip. Ex-1007, 1:66-2:11, 4:43-52, Fig. 5; Ex-1005, ¶187.

FIG.5



Id., Fig. 5 (color added).

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teaches that the distal end of guiding catheter (1) "is hooked at ostium 821 of a coronary artery 82." Ex-1007, Fig. 6, 5:32-34.

Second, long before the ’776 patent, those working in the field knew 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-1015a, 548; Ex-1005, ¶ 188. As Dr. Brecker explains, and as taught in Grossman’s Cardiac Catheterization, Angiography and Intervention, the support came from the GC’s shape, the intrinsic stiffness of its material, and from its “deep engagement” with the coronary ostia. Ex-1015, 550; *and see* Ex-1041, 20 (Kern’s The Interventional Cardiac Catheterization Handbook).

The ’776 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, 5:4-34. According to the ’776 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*., 8:23-37. But this is no different than what was already known in the prior art and disclosed in Itou. Ex-1005, ¶ 189.

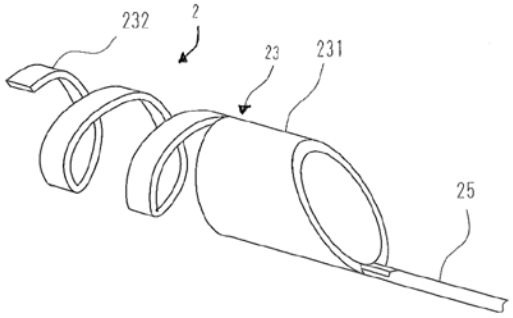
The ’776 patent admits that back-up support is achieved where the differential between the inner diameter of the guide catheter and the inner diameter

of the coaxial catheter is between 0.20 and 0.35 mm (0.008 and 0.014 inches). Ex-1001, 3:31-51. Itou teaches a differential between the inner diameters of guiding catheter (1) and suction catheter (2) within that range: 0.3 mm. Ex-1007, Table 1; Ex-1005, ¶ 190. 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 guide extension catheter that "resist[s] axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion." Ex-1005, ¶ 191.

VIII. GROUND 2: ITOU RENDERS CLAIMS 39 AND 46 OBVIOUS IN VIEW OF THE COMMON KNOWLEDGE OF A POSITA.

A. Claim 39: "The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of stainless steel."

Itou discloses the substantially rigid segment wire-like portion 25 (shown below) is "formed from a solid metal wire[.]" Ex-1005, ¶ 192; Ex-1007, 3:48-50, Figs. 3-4.



Itou further discloses that the partially cylindrical opening formed by proximal end portion (231) "is secured firmly by being welded to the distal end of the wire-like portion 25[.]" *Id.*, 4:33-34. Proximal end portion (231) is "formed by obliquely cutting one end of a metal pipe such as a pipe of stainless steel and a distal end portion 232." *Id.* 4:27-30. Itou renders claim 39 obvious because a POSITA understood that stainless steel was commonly used for monorail style pushrods. Ex-1042, ¶ 78; Ex-1009, 4:58-61, Ex-1050, 5:1-2.

B. Claim 46: "The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm."

Itou renders claim 46 obvious in view of the common knowledge of a POSITA. Ex-1005, ¶¶ 192-196; *supra* § VII.Q. In Itou, the reinforcing braid or coil on tubular structure (21) does not extend "20 to 30 cm," because the length of the tubular portion of the catheter is 150 mm (or 15 cm.). Ex-1007, Table 1; Ex-1005, ¶ 192. Itou, however, explains that the tubular portion can be up to 200 mm in length (or 20 cm). Ex-1007, 6:7-10. In this scenario, at least the distal 2 mm of the suction catheter would not be reinforced, because the catheter tip must be soft and flexible, to avoid damaging the blood vessel. *Id.*, 2:15-18; Ex-1015a, 549.

As Dr. Brecker and Dr. Hillstead explain, a POSITA had motivation to lengthen the tubular portion of Itou's suction catheter (2). Ex-1005, ¶¶ 193-196; Ex-1042, ¶¶ 131-132. As explained herein, a POSITA understood the tubular structure of Itou's catheter (2) was configured so that it could be used to receive a

stent and balloon catheter, and had motivation to use it in this fashion. *Supra*, § VII.H.

By the time of the purported invention of the '776 patent, those working in the field appreciated that interventional cardiologists were attempting to treat "more challenging lesions than in the past" using PCI procedures. Ex-1036, 2949; Ex-1005, ¶ 194. And those in the field knew that in order to "maneuver [a catheter] through a tortuous path to [a] treatment site," the catheter must have "sufficient 'pushability' and 'torqueability' to allow the guiding catheter to be inserted percutaneously into a peripheral artery, moved and rotated in the vasculature to position the distal end of the catheter at the desired site adjacent to a particular coronary artery." Ex-1046, 1:39-44. But also that the catheter's "distal portion should have sufficient flexibility so that it can track over a guidewire and be maneuvered through a tortuous path to the treatment site." *Id*., 1:45-47; Ex-1005, ¶ 194.

In particular, for a catheter to reach a "desired remote location in a bodily passageway, such as a small, tortuous artery," it was advantageous for the "less flexible section ... [with] greater pushability ... to comprise a substantial portion of the length of the catheter," while the more distal and more flexible portion be "preferably about 15-30 cm in length." Ex-1072, 2:38-44. Thus, in the case of Itou's suction catheter (2), a POSITA knew tubular structure (24) could be

increased in length, up to 30 cm, to accommodate reaching lesions located in particularly tortuous vessels. Ex-1005, ¶ 195. And, in this instance, the longitudinal length of the reinforcing braid or coil on catheter (2) would be between 20 to 30 cm. Ex-1042, ¶¶ 133-135; Ex-1005, ¶ 196.

IX. GROUND 3: ITOU RENDERS CLAIMS 36-37 AND 52-56 OBVIOUS IN VIEW OF KATAISHI AND THE COMMON KNOWLEDGE OF A POSITA.

A. Overview of Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under pre-AIA §102(b) and post-AIA §102(a)(1). Ex-1025. During prosecution of the ’776 patent (and the ’850 patent), Kataishi was neither disclosed by Patent Owner nor cited by the Examiner. Exs-1001-1003.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1025, [0001]. It teaches a distal opening with two inclines designed, in part, to improve the catheter’s “crossing ability”— its ability to smoothly reach a desired target site. *Id.*, Abstract, [0001]; Ex-1042, ¶¶ 56-57. In addition to providing flexibility, the two-incline shape of the catheter’s distal opening improves its ability to suction thrombi, Ex-1025, Abstract, [0026]-[0027], Fig. 10 (color added), which corresponds to loading a thrombus into the catheter’s distal end. Ex-1005, ¶¶ 197-198; Ex-1042, ¶¶ 58-62.

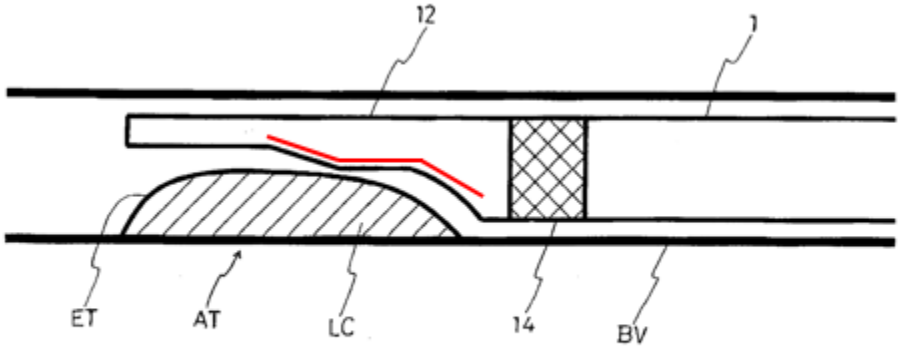


Fig. 10

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

The distal end has an "angled cut surface, in which at least a part on the proximal end side of the angled surface is formed in a concave shape in the angled direction and the distal end side of the cut surface is formed to be flat and flexible...." *Id*., [0010]. The catheter tip is shown below. *Id*., Figs. 2, 12 (color added). Ex-1005, ¶ 199.

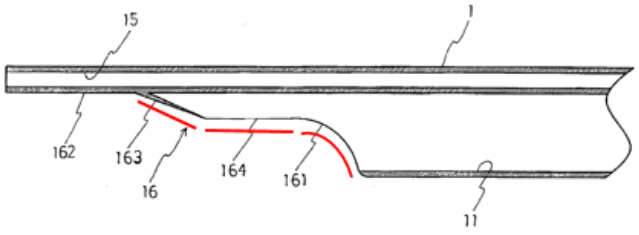


Fig. 2

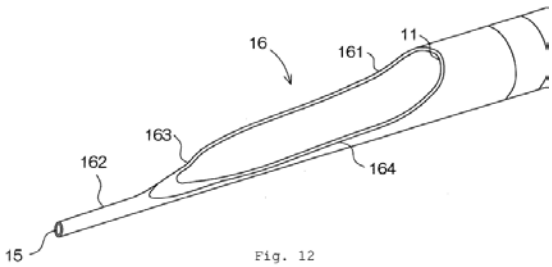


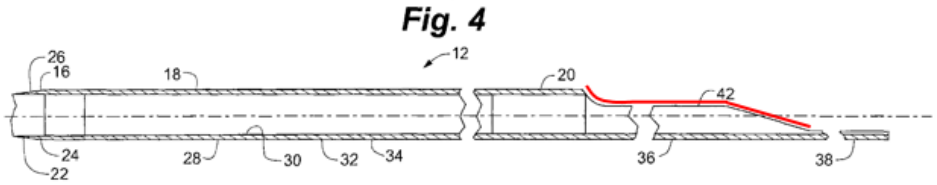
Fig. 12

B. Claim 36

Itou renders claim 36 obvious in combination with Kataishi and/or the knowledge of a POSITA. Ex-1005, ¶¶ 200-205.

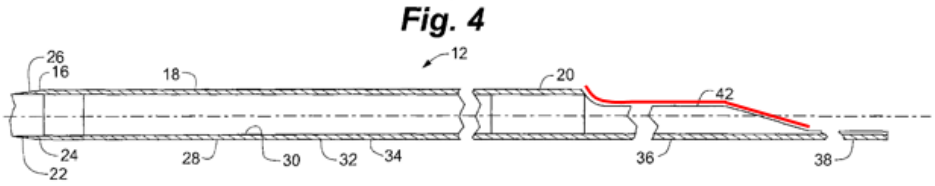
In an attempt to support claim 36, patentee represented to the Examiner that Figure 4 of the ’776 patent showed that the angled proximal end of the partially cylindrical opening includes at least “one inclined region that tapers into a non-inclined region.”

’776 Patent



Ex-1003, at 110 (Preliminary Amendment (3/3/14) at 22) (color added).

Of course, the disclosure in the ’776 patent is no different than what was disclosed in Kataishi.



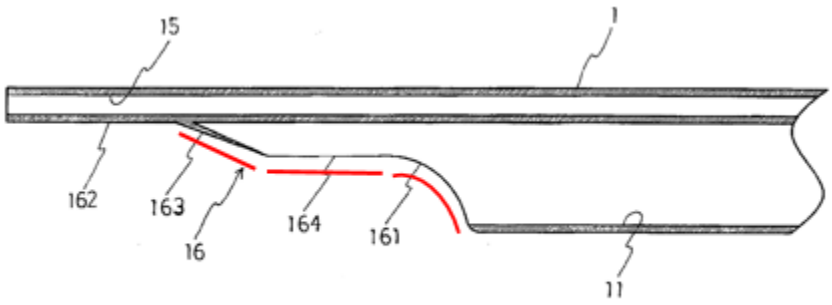


Fig. 2

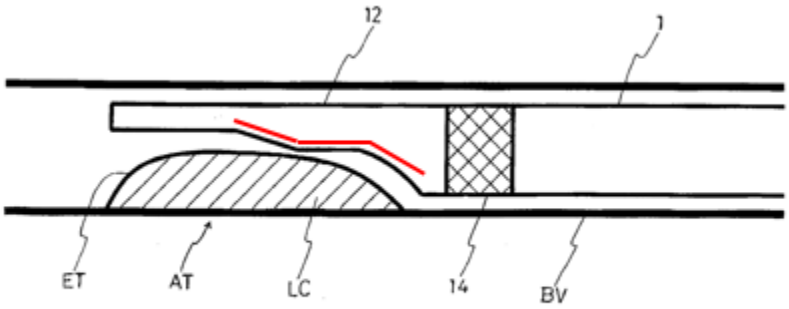


Fig. 10

Compare Ex-1001, Fig. 4 *with* Ex-1025, Figs. 2, 10 (color added); Ex-1005, ¶ 200; Ex-1042, ¶¶ 124-125.

Kataishi teaches a suction catheter with a distal end designed to do two things: 1) improve crossability of the catheter; and 2) provide superior loading of matter (thrombus) into the distal end of the suction catheter. Ex-1042, ¶¶ 117-120. These advantages are accomplished by the shape of Kataishi's distal end. The same improvements apply equally to the proximal end of a catheter, especially catheters such as Itou. Ex-1042, ¶ 121. Thus, it would have been obvious to modify the partially cylindrical opening of Itou's suction catheter (2) to include at least one inclined region that tapers into a non-inclined region from Kataishi. Ex-1005, ¶¶ 201-202. Indeed, Itou

and Kataishi are both directed at the same problem—removing occlusions from coronary arteries. Ex-1008, Abstract; Ex-1025, Abstract; Ex-1005, ¶ 202. A POSITA would be motivated to apply Kataishi's distal opening structure to Itou's partially cylindrical opening for the reasons set forth below. Ex-1005, ¶ 202.

Adding at least one inclined slope that tapers into a non-inclined slope to the angled partially cylindrical opening of Itou's suction catheter (2) would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex-1005, ¶ 203; Ex-1042, ¶ 122. A POSITA had motivation to make this modification because it would allow the catheter to receive a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1025, Abstract [0026-0027], Fig. 10; Ex-1055, 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end). Ex-1005, ¶ 203; Ex-1042, ¶ 122.

Second, a POSITA knew that angled openings in the sidewall of a catheter—located proximal of the catheter's distal end—can "minimize ... kinking ... during insertion[.]" Ex-1026, 3:6-14, 6:5-19, Fig. 2B; Ex-1005, ¶ 204; Ex-1042, ¶ 122. A POSITA had motivation to modify Itou's single incline partially cylindrical opening to include at least one inclined slope that tapers into a non-inclined slope from Kataishi in order to minimize kinking and thus improve the crossability of the device by avoiding drag on the inside of the guide catheter. *Id.*; Ex-1042, ¶¶ 117,

122.

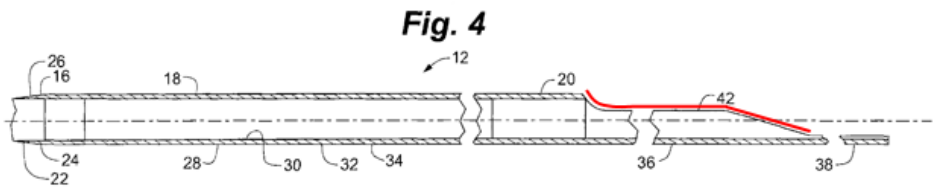
A POSITA had a reasonable expectation of success, as creating at least one inclined slope that tapers into a non-inclined slope in an opening, as disclosed in Kataishi, would have been a routine task in manufacturing an extension catheter. Ex-1042, ¶ 123; Ex-1005, ¶ 205; Ex-1050, Fig. 7; (disclosing double incline opening).

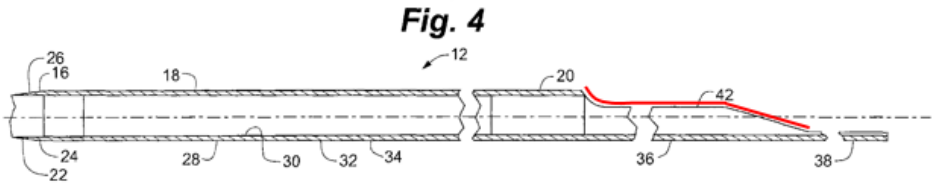
C. Claim 37

Itou renders claim 37 obvious in combination with Kataishi and/or the knowledge of a POSITA. Ex-1005, ¶¶ 206-208.

Patentee represented to the Examiner that Figure 4 of the ’776 patent showed “partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.” Ex-1003, at 110 (Preliminary Amendment (3/3/14) at 23) (color added). The disclosure in the ’776 patent is no different than what was disclosed in Kataishi.

’776 Patent





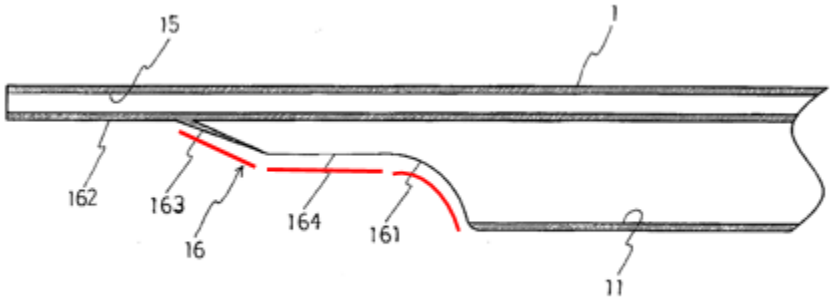


Fig. 2

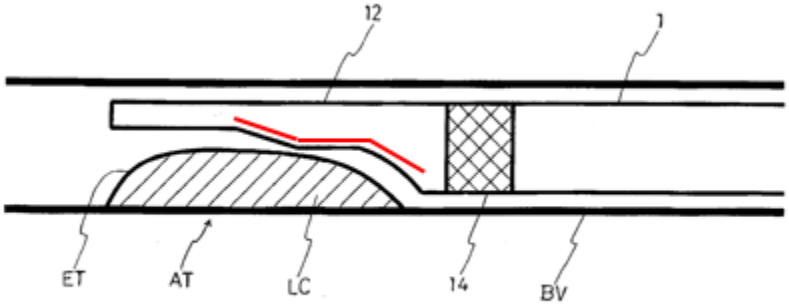
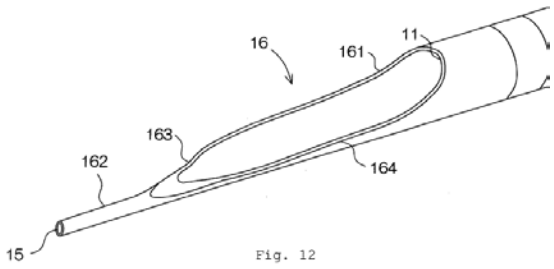


Fig. 10

Compare Ex-1001, Fig. 4 *with* Ex-1025, Figs. 2, 10 (color added)); Ex-1005, ¶ 206; Ex-1042, ¶¶ 124-125. Kataishi discloses a suction catheter with an opening on the distal end that has an "angled cut surface, in which at least a part on the proximal end side of the angled surface is formed in a concave shape[.]" Ex-1025, [0010]. Cut surface 16 has a concave shape 161 that is closest to the fully circumferential portion of catheter lumen 11. The concave shape is adjacent "ledge surface 164," which is parallel to the catheter's longitudinal axis. Moving distally is "cut surface 163 defining an angle with the longitudinal axis of the catheter." *Id*.,

[0027].



Id., Fig. 12. *See* Ex-1005, ¶ 207.

Including those characteristics in Itou would give the partially cylindrical opening of Itou's suction catheter a concave shape too. For the same reasons set forth above for claim 36, a POSITA had motivation to apply the teachings of Kataishi's distal end to the partially cylindrical opening of Itou's suction catheter (2) with a reasonable expectation of success. Ex-1005, ¶¶ 201-205, 208; Ex-1042, ¶¶ 121-122; § IX.B (claim 36), *supra*.

D. Claim 52

Itou in combination with Kataishi renders claim 52 obvious. Ex-1005, ¶¶ 209-224. The limitations in the table below are disclosed by Itou.

Claim Language	Evidence & Corresponding Disclosure (Ground 1)
[52.pre]	[25.pre] (§ VII.B.1, *supra*)
[52.a]	[25.a] (§ VII.B.2, *supra*)
[52.b]	[25.b] (§ VII.B.3, *supra*)
[52.c.i]	[25.c.i] (§ VII.B.4, *supra*)
[52.c.ii]	[25.c.ii] (§ VII.B.5, *supra*)
[52.c.iv]	[25.c.iv] (§ VII.B.7, *supra*)
[52.d]	[25.d] (§ VII.B.8, *supra*)

1. [52.c.iii] "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure,"

Itou teaches this limitation. Ex-1005, ¶ 216. As explained by Dr. Brecker and Dr. Hillstead, tubular structure (21) has a first flexural modulus. Ex-1005, ¶ 216; Ex-1042, ¶¶ 79-80. Itou teaches that 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. The segment defining the partially cylindrical opening is formed by cutting a metal pipe, and it has a second flexural modulus. The partially cylindrical opening (231) is more rigid than tubular structure (21). *Id.*, 3:54-55, Fig. 3; Ex-1005, ¶ 216; Ex-1042, ¶ 80. Given the differences in the materials used to form tubular structure and the partially cylindrical opening, the flexural modulus of the segment defining the partially cylindrical opening is necessarily greater than the flexible modulus of the tubular struture. Ex-1005, ¶ 216; Ex-1042, ¶ 80.

2. [52.e] "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions."

Itou in view of Kataishi renders this limitation of claim 52 obvious, because Kataishi discloses a partially cylindrical opening with two inclined slopes, as shown below. Ex-1005, ¶ 219.

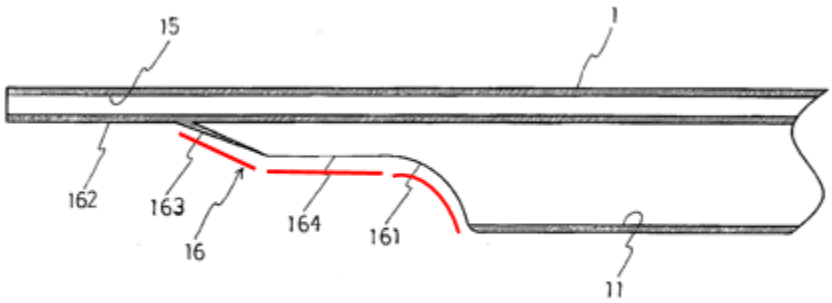


Fig. 2

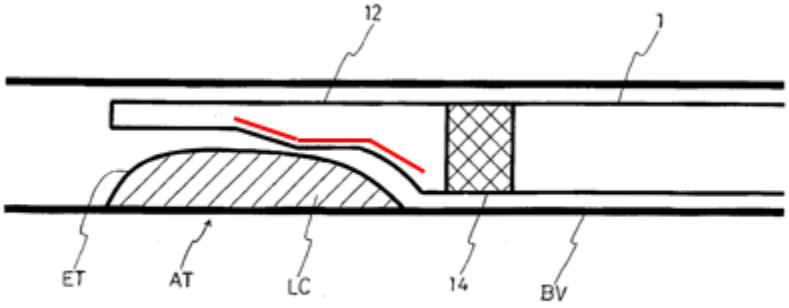
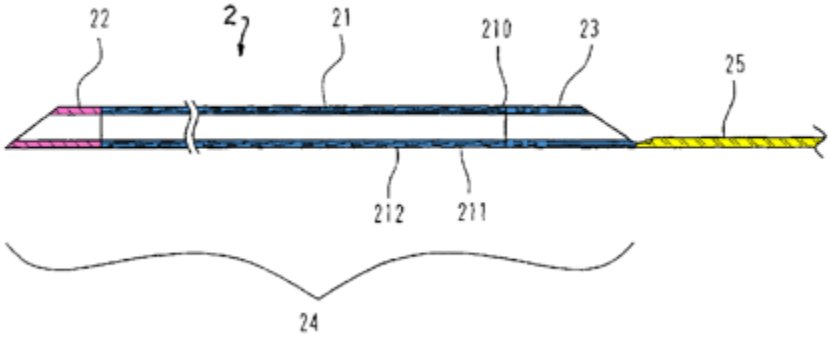


Fig. 10

Compare id., Fig. 4, *with* Ex-1025, Figs. 2, 10 (color added); Ex-1005, ¶ 219; Ex-1042, ¶¶ 124-125.

A POSITA had motivation to modify the partially cylindrical opening of Itou's suction catheter (2) to include at least two inclined regions from Kataishi for the reasons discussed above with respect to claim 36. *See* § IX.B, *supra*.



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

In addition, including a second, inclined slope to Itou's angled partially cylindrical opening would have increased the area of entry for a stent or balloon, without increasing suction catheter (2)'s diameter. The increase in area of entry comes from the ramp created by the two different inclined slopes, and not from an increase in the outer or inner diameters of the suction catheter. Ex-1005, ¶ 221; Ex-1042, ¶ 122. A POSITA had motivation to make this modification because it would increase the ease with which catheter (2) could receive a therapy catheter without impeding its ability to be maneuvered deeper into the coronary vasculature (compared to catheters with larger diameters). Ex-1025, Abstract, [0026]-[0027], Fig. 10; Ex-1055, 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end); Ex-1073, 1, 5 (teaching that the "unique oblique tip" was beneficial because it provided a wide opening area and increased trackability); Ex-1005, ¶¶ 220-222; Ex-1042, ¶¶ 121-123. Those in the field appreciated that a larger area of an opening would be beneficial to Itou's suction function and its capability of receiving a therapy catheter. Ex-1008, 6:52-60 (explaining that a larger angled opening on an aspiration catheter allowed for both "larger deformable particulate matter" to pass through the lumen, and "facilitate[d] smoother passage of other therapeutic devices."). Ex-1005, ¶ 222; Ex-1042, ¶ 122.

Creating at least two different inclined slopes on the partially cylindrical opening of Itou's suction catheter (2) would have been a routine task when manufacturing an extension catheter. Ex-1042, ¶ 123. Thus, a POSITA would have a reasonable expectation of success in modifying Itou's suction catheter to include a partially cylindrical opening with at least two different inclined slopes as disclosed in Kataishi. Ex-1042, ¶ 123.

E. Claim 53

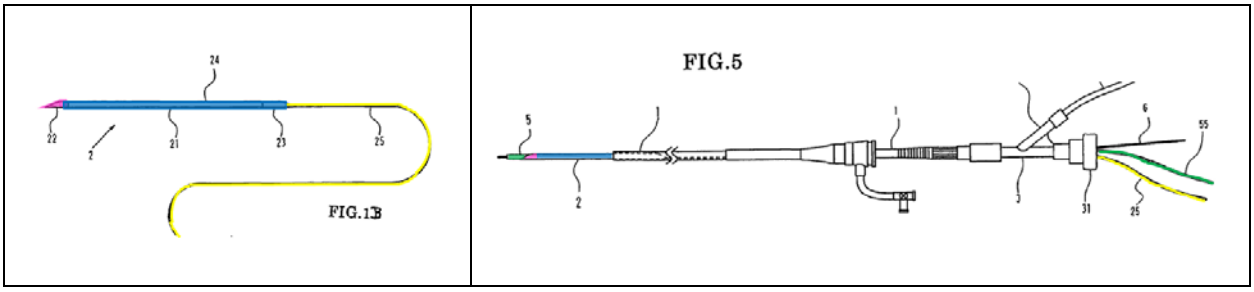
Itou in combination with Kataishi renders claim 53 obvious. Ex-1005, ¶¶ 225-235. The limitations in the table below are disclosed by Itou.

Claim Language	**Evidence & Corresponding Disclosure** (Ground 1)
[53.a]	[25.a] (§ VII.B.2, *supra*)
[53.b.i]	[25.b] (§ VII.B.3, *supra*)
[53.b.ii]	30, 31 (§§ VII.F, VII.G, *supra*)
[53.c.i]	[25.c.i] (§ VII.B.4, *supra*)
[53.c.ii]	[25.c.ii] (§ VII.B.5, *supra*)
[53.c.iii]	[25.c.iv] (§ VII.B.7, *supra*)
[53.c.iv]	[25.d] (§ VII.B.8, *supra*)

1. [53.pre] "A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:"

To the extent the preamble is limiting, Itou discloses it. Ex-1005, ¶¶ 225-227. Itou teaches a combination of guiding catheter (1) and a guide extension catheter (suction catheter (2)). Ex-1007, 1:66-2:11, 7:1-23, 7:35-43, Abstract, Figs. 1B, 5-6, 8. Itou also teaches that suction catheter (2) "is disposed in the lumen of

guiding catheter 1," *id*. 5:11-14," and suction catheter (2) may be inserted into guiding catheter (1) at its proximal end, to extend from its distal end.



Compare id., Fig. 1B *with id.*, Fig. 5 (color added), Figs. 6, 8. The guide catheter in the '776 patent necessarily has a lumen with a cross-sectional inner diameter. *Id.*, Fig. 4, Table 1. Thus, Itou discloses 53.pre. Ex-1005, ¶ 227.

2. [53.d] "wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions."

Itou in view of Kataishi renders this limitation of claim 53 obvious, because a POSITA would have been motivated to include Kataishi's partially cylindrical opening with two different inclined slopes in Itou's suction catheter for the same reasons discussed above for claims 36 and 52. *See* §§ IX.B, IX.D.2, *supra*; Ex-1005, ¶ 235.

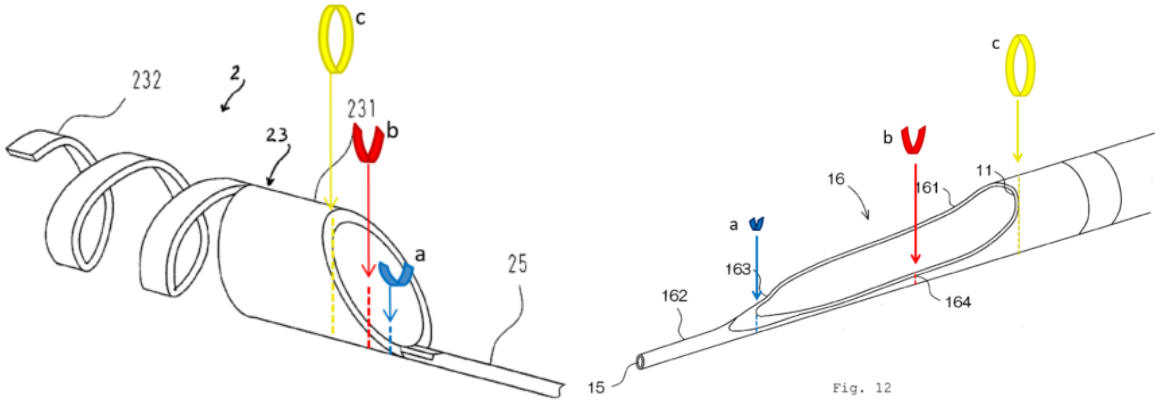
F. Claim 54: "The guide extension catheter of claim 53, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure."

As discussed for claim 52, Itou discloses this limitation, § IX.D.1, *supra*, and the combination of Itou and Kataishi render this claim obvious for the same

reasons discussed above for claims 36, 52-53. *See* §§ IX.B, IX.D-IX.E, *supra*; Ex-1005, ¶ 236.

G. Claim 55: "The guide extension catheter of claim 53, wherein the segment defining the partially cylindrical opening includes portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape."

As discussed for claim limitations 52.e and 53.d, a POSITA had motivation motivated, with a reasonable expectation of success, to implement at least two inclined regions from Kataishi in Itou's partially cylindrical opening. *See* §§ IX.D.2, IX.E.2, *supra*. In so doing, the partially cylindrical opening necessarily includes a cross-sectional shape having a full circumference portion (yellow), a hemicylindrical portion (red), and an arcuate portion (blue) as shown below. Ex-1005, ¶ 237.



Id., Fig. 3; Ex-1025, Fig. 12 (annotations and color added).

Claim 55 depends from claim 53, and is rendered obvious for the same reasons as discussed above. *See* § IX.E (claim 53), *supra*; Ex-1005, ¶ 237.

H. Claim 56: "The guide extension catheter of claim 53, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter."

Itou discloses the additional limitation in dependent claim 56. Ex-1005, ¶ 238. Claim 56 depends on claim 53, and is rendered obvious by Itou and Kataishi for the same reasons as discussed above. *See* § IX.E (claim 53), *supra*; Ex-1005, ¶ 238.

Itou discloses the cross-section of the substantially rigid wire-like segment (25) is 0.45 mm and it is positioned eccentrically relative to a cross-section through tubular structure (21). Ex-1007, Table 1, Figs. 3-4. The substantially rigid segment is used to advance the tubular structure of suction catheter (2) through guiding catheter (1) until the distal portion of suction catheter (2) "projects forwardly beyond the distal side of the guiding catheter" into a coronary artery. *Id*., 2:32-36, 3:1-3, 5:26-46, 5:43-46, Abstract, Figs. 5-6.

Additionally, Itou teaches that placing catheter 2 into guide catheter 1 does not preclude use of guide catheter 1 for delivering distal and protective catheter 5. *Supra*, §§ VII.B, VII.N, *supra*; *see also* Ex-1005, ¶¶ 161, 175-179. Itou discloses a cross section inner diameter of the lumen of the guide catheter of 1.8mm and an outer diameter of the guide extension catheter (suction catheter (2)) of 1.5mm.

Ex-1007, Table 1, Ex-1005, ¶ 238. Thus, space is preserved in the lumen of the guide catheter.

X. GROUND 4: ITOU RENDERS CLAIMS 32, 36-38 AND 52-56 OBVIOUS IN VIEW OF RESSEMANN AND THE COMMON KNOWLEDGE OF A POSITA.

A. Overview of Ressemann

Ressemann was filed on August 9, 2002, issuing as U.S. Pat. No. 7,604,612 on October 20, 2009. It is prior art under pre-AIA §102(e) and post-AIA §§ 102(a)(1), 102(a)(2), and was not cited or considered during prosecutions of the '776 patent. Ex-1001-1003; Ex-1005, ¶ 239.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1008, Abstract. The assembly includes a GC, which "may be positioned within the ostium of a target vessel," *id*., 12:26-27, and an evacuation sheath coaxially insertable through the GC and advanceable beyond the GC's distal end to treat stenosis. *Id*., Abstract, Figs. 6A-F, 6:18-24, 12:9-14:39; Ex-1005, ¶ 240.

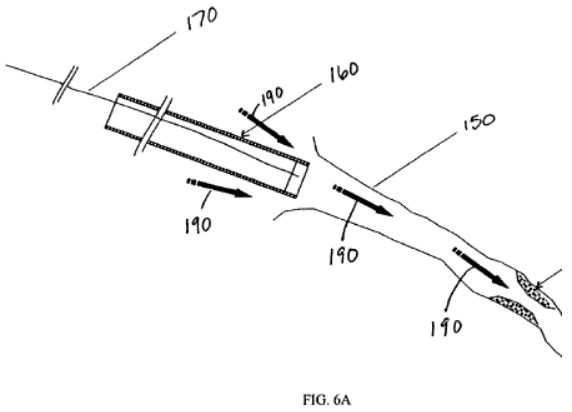


FIG. 6A

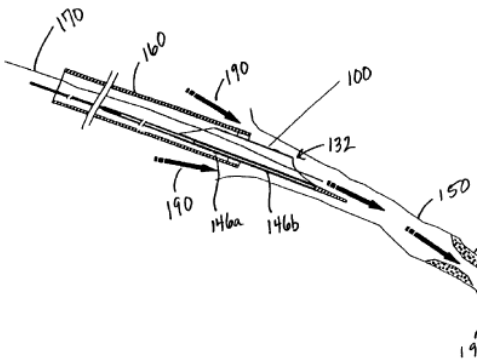


FIG. 6B

Ex-1008, Figs. 6A-B. 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 ¶ 241.

The evacuation sheath includes a distal evacuation head and a shaft. Ex-1008, 6:19-20, Figs. 1A, 1C, 11A. The head (below, pink) is "preferably made of a relatively flexible polymer such as low-density polyethylene, polyurethane, or low durometer Pebax® material." *Id*., 6:36-39; Ex-1005, ¶ 242.

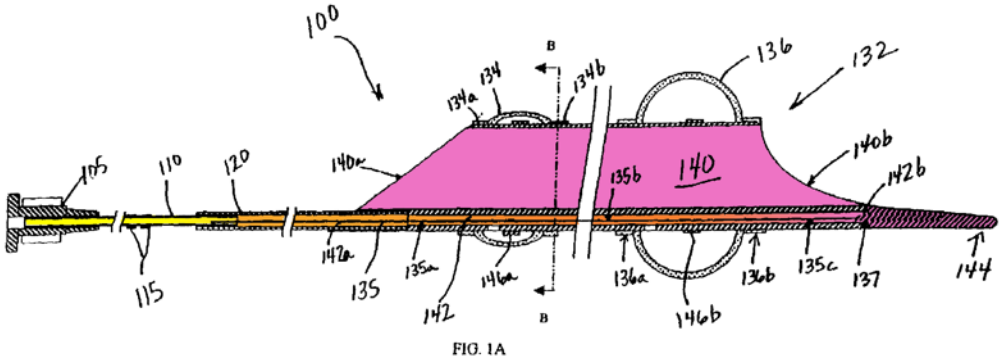


FIG. 1A

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

The shaft includes proximal, intermediate, and distal portions. Proximal

shaft (110) (above, yellow) is a hollow tube preferably made of stainless steel, but which may also be made of polymer and metal composites. Ex-1008, 10:36-42. Intermediate shaft (120) (transitioning to orange)—a hollow "preferably formed of polyethylene or Pebax"—is more flexible than shaft (110). *Id*., 10:63-11:10. Distal shaft (transitioning to pink) includes the evacuation head, *id*. 10:31-35, and an inflation lumen for sealing balloons (134, 136), and may include soft distal tip (144) made of a polymer more flexible than the head so as to ensure atraumatic insertion into blood vessels. *Id*., 11:11-28.

Ressemann teaches that evacuation head 132 should be made of a "relatively flexible polymer." Ex-1008, 6:35-39. Ressemann also teaches that the evacuation head may also include a kink-resistant structure (below), a coil, (139) which may be made of metal ribbon. *Id*., 6:66-7:7, 23:50-60.

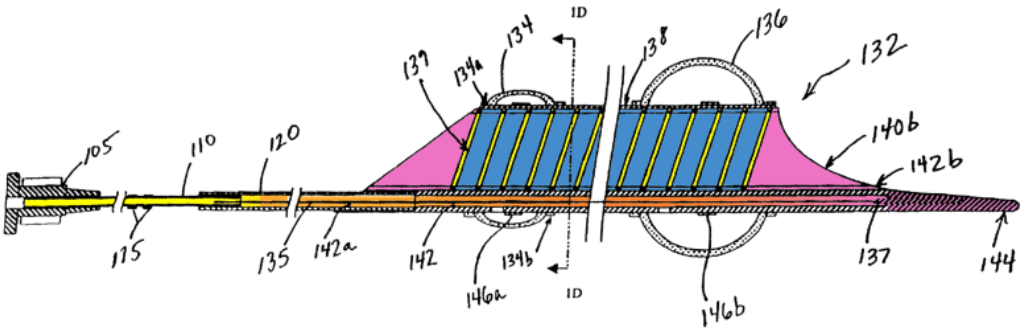


FIG. 1C

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

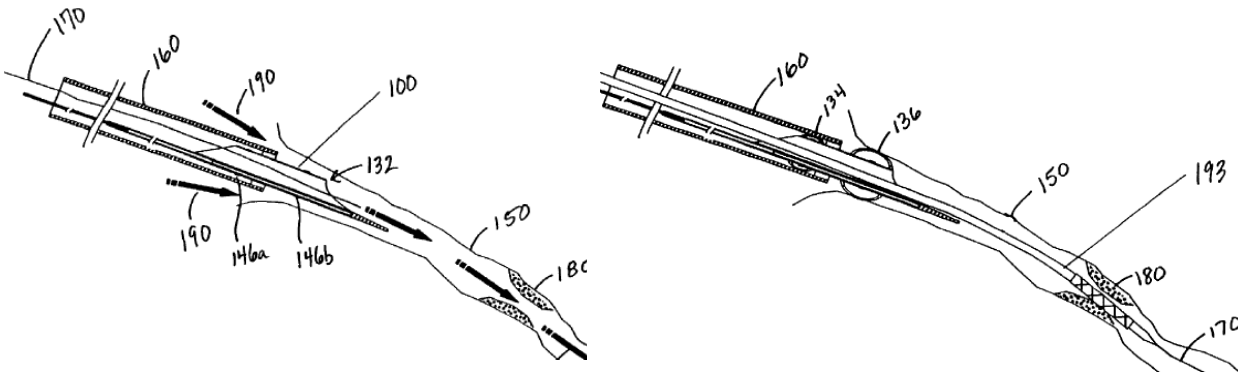
Ressemann also discloses a stiffness transition member 135 that runs longitudinally along the majority of the evacuation sheath's intermediate and distal

shafts, starting at the distal end of the proximal shaft, and terminating toward the distal end at 137. *Id.*, 11:29-35. Member 135's rigidity decreases along its longitudinal axis so it is most flexible at its distal end. *Id*., 11:57-59. Either the decreasing rigidity of member 135 (alone), or the absence of kink-resistant coil 139 at the distal end of the evacuation head made of a flexible polymer (alone), renders the distal end of the evacuation head more flexible than its more proximal regions. Ex-1005, ¶¶ 240-246; Ex-1042, ¶¶ 47-51.

B. Claim 32

Itou discloses the structural limitations recited in claim 32, which is an apparatus claim. *See* § VII.H, *supra*. To the extent Patent Owner argues the intended use of the claimed structure —"to receive a stent and a balloon catheter"— carries patentable weight and is a limitation, Itou in combination with Ressemann renders claim 32 obvious. Ex-1005, ¶ 247.

Ressemann teaches an evacuation head with a diameter large enough to "allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, atherectomy catheters . . . ." Ex-1008, 10:17-20, 12:3-4. Ressemann further teaches that the evacuation sheath should be advanced through a GC until the head's (a) distal end is distal to the distal end of the GC; and (b) proximal end remains in the GC. *Id*., 12:19-26, Fig. 6B (below, left).



Id., Figs. 6B, 6E.

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

A POSITA had motivation to combine the teachings of Itou and Ressemann because of Ressemann's explicit teaching that it was advantageous for an aspiration catheter to include a distal lumen of sufficient diameter for use in delivering an interventional cardiology device. *Supra*, § X.B; Ex-1019, 3:4-6, 3:34-36 (explaining that an aspiration catheter is "preferably sized so as to allow the slidable insertion of a therapy catheter through the main" lumen of the aspiration catheter); Ex-1005, ¶ 248. This is because angioplasty and coronary artery stenting come with a risk of embolization. Ex-1005, ¶ 248; Ex-1028, 1285; Ex-1029, 172, 176.

Those working in the field knew that PCI such as angioplasty or stent delivery "may break free fragments of friable plaque." Ex-1005, ¶ 249; Ex-1015b,

629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was motivation to combine stent delivery with use of an embolic protection device, Ex-1015b, 629-630, and a reasonable expectation of success. Ex-1028, 1285 ("Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire."); Ex-1029, 172, 176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of an embolic protection device in conjunction with stenting); Ex-1005, ¶ 249. Additionally, using a suction catheter large enough to deliver a therapy catheter ensures that a PCI procedure can be completed without having to switch catheters between suction and stenting. Ex-1005, ¶ 250; Ex-1008, 14:29-34 ("In some instances, once the particulate . . . has been removed, additional contrast delivery to the blood vessel may indicate a need for more therapeutic steps, e.g., further dilation of the stent with the balloon. In this case, it is more convenient to have the balloon catheter already in position for any subsequent use.")

The inner lumen of Resseman's sheath is "approximately 0.061 inches," allowing for the "passage of most therapeutic devices such as angioplasty catheters [and] stent delivery catheters . . . ." Ex-1008, 10:17-20. PTCA catheters were insertable through support catheters with an 0.045 inch inner lumen. Ex-1009,

4:46-50, 4:61-64. Angioplasty procedures had been performed through 4 French diagnostic catheters. Ex-1020 ("Mehan"), 22. Ressemann, Kontos and Mehan disclosed prior art catheters, which, respectively, had inner lumen diameters of approximately 1.54 mm, 1.14 mm and under 1.33 mm. Ex-1005, ¶ 251.

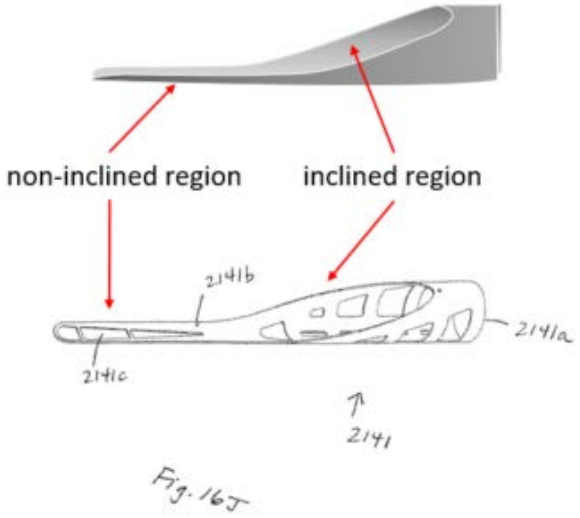
Similarly, Itou taught a suction catheter with an inner diameter of 1.5 mm, Ex-1007, Table 1. By reference to Ressemann, Kontos and Mehan, a catheter with an inner diameter of 1.5 mm is large enough to accommodate the insertion of a therapy catheter. Moreover, an inner diameter of 1.5 mm corresponds to an inner diameter of 0.059 inches. 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 of which were available at the purported time of the '776 invention. *Supra*, §X.B; Ex-1005, ¶ 252.

Indeed, evidence that combining Itou and Ressemann is appropriate exists in Itou's prosecution history. There, the examiner rejected pending claims on a suction assembly based on a prior, angioplasty balloon catheter, because the latter was "capable of being an intravascular foreign matter suction assembly." Ex-1021, 3. Claims were also rejected over the same art in combination with a prior aspiration catheter because—at the time of the invention—the references were analogous art, and it would have been obvious to combine angioplasty with removal of emboli. *Id.*, 4-5; Ex-1005, ¶ 253.

C. Claim 36

Itou renders claim 36 obvious in view of Ressemann. Ex-1005, ¶ 254.

Ressemann discloses a support collar 2141, which includes "an angled proximal end" of a "partially cylindrical opening" that "includes at least one inclined region that tapers into a non-inclined region." Ex-1005, ¶ 254.



Ex-1008, Fig. 16J (annotations and arrows added).

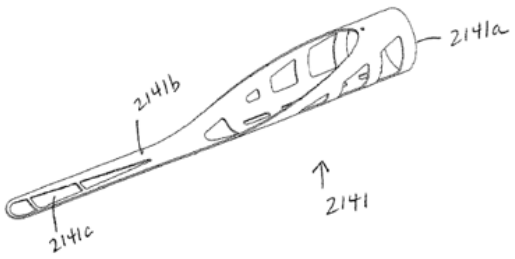
As Dr. Brecker and Dr. Hillstead explain, a POSITA had motivation to replace Itou's proximal tip (23) with Ressemann's support collar 2141, Ex-1007, Figs. 3-4. First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter (2) because s/he understood that it was configured to receive an interventional cardiology device. *See* § VII.B.7, *supra*. By modifying the partially cylindrical opening of Itou's suction catheter (2) with

Ressemann's collar 2141, a larger area for receiving an interventional cardiology device would be achieved. Ex-1005, ¶¶ 255-256; Ex-1042, ¶¶ 96-102, 112.

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.

D. Claim 37

Ressemann's support collar discloses a concave track. In the figure below, the concave track runs from the proximal end of the collar, terminating toward its distal end (i.e. the portion of the collar that becomes "fully circumferential"). *Supra*, § VI.A (construing "concave track"); Ex-1005, ¶ 257.



proximal Fig. 16J ***distal***

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

For the reasons discussed above for claim 36 (§ X.C, *supra*) , a POSITA had motivation to replace the partially cylindrical opening of Itou's suction catheter

(2), Ex-1007, Figs. 3-4, with Ressemann's support collar, Ex-1008, Fig. 16J, and a reasonable expectation of success. Ex-1005, ¶ 258; Ex-1042, ¶¶ 96, 99-102, 112.

A POSITA additionally had motivation to combine Ressemann's support collar with Itou's suction catheter (2) because the concavity of tab 2141b ensures that adding the collar does not impede entry into the proximal end of the suction catheter. 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 an interventional cardiology device such as a balloon or stent catheter into the angled opening of the inflation lumen. The same holds true for adding the collar to the partially cylindrical opening of Itou's suction catheter (2). Ex-1005, ¶ 259; Ex-1042, ¶¶ 105-109.

Thus, Itou in view of Ressemann renders claim 37 obvious. Ex-1005, ¶ 260.

E. Claim 46

Itou in combination with Ressemann renders claim 46 obvious. Ex-1005, ¶ 261. In Itou, the reinforcing braid or coil on tubular structure (21) does not extend "20 to 30 cm," because the entire length of the tubular portion of the catheter is 150 mm (or 15 cm.). Ex-1007, 8:20, Table 1; Ex-1005, ¶ 261.

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

Ressemann discloses an embodiment in Figures 16A and 16B for treatment of vascular stenosis in the coronary arteries. In this embodiment, the evacuation head is taught to be up to 40 cm in length. Ex-1008, 22:38-52. Ressemann also discloses that the length of evacuation head 132 depicted in Fig. 1C "is dependent on the application for which the evacuation sheath assembly 100 is intended to be used." *Id.*, 9:63-65.

A POSITA had motivation to lengthen the tubular portion of Itou's suction catheter (2) as disclosed by Ressemann to be longer than 20 cm, and up to 40 cm in length. *Supra*, § VIII.B; Ex-1005, ¶ 262; Ex-1042, ¶¶ 133-135. As explained herein, a POSITA knew the tubular structure of Itou's suction catheter (2) was configured so it could be used to receive a stent or balloon catheter, and had motivation to use it in this fashion. *Supra*, §§ VII.B, VII.H.

In the case of Itou's suction catheter (2), a POSITA would be aware that tubular structure (24) could be increased in length as disclosed by Ressemann, to accommodate reaching lesions located in particularly tortuous vessels. Ex-1005,

¶ 263. A POSITA had a reasonable expectation of success in using a tubular portion that was 40 cm in length, with a coiled metallic element having a length between 20 cm and 30 cm, because these were well-known lengths for braid or coil elements used in an known manner to treat vascular stenosis to achieve a predictable result of having sufficient length and stability to allow the interventional device to reach the desired area. Ex-1042, ¶¶ 133-135; Ex-1005, ¶ 264; *see supra*, § VIII.B (claim 46).

F. Claim 52

Itou in combination with Ressemann renders claim 52 obvious. Ex-1005, ¶¶ 265-275.

Claim Language	**Evidence & Corresponding Disclosure** (Ground 1)
52.pre	[25.pre] (§ VII.B.1, *supra*)
52.a	[25.a] (§ VII.B.2, *supra*)
52.b	[25.b] (§ VII.B.3, *supra*)
52.c.i	[25.c.i] (§ VII.B.4, *supra*)
52.c.ii	[25.c.ii] (§ VII.B.5, *supra*)
52.c.iv	[25.c.iv] (§ VII.B.7, *supra*)
52.d	[25.d] (§ VII.B.8, *supra*)

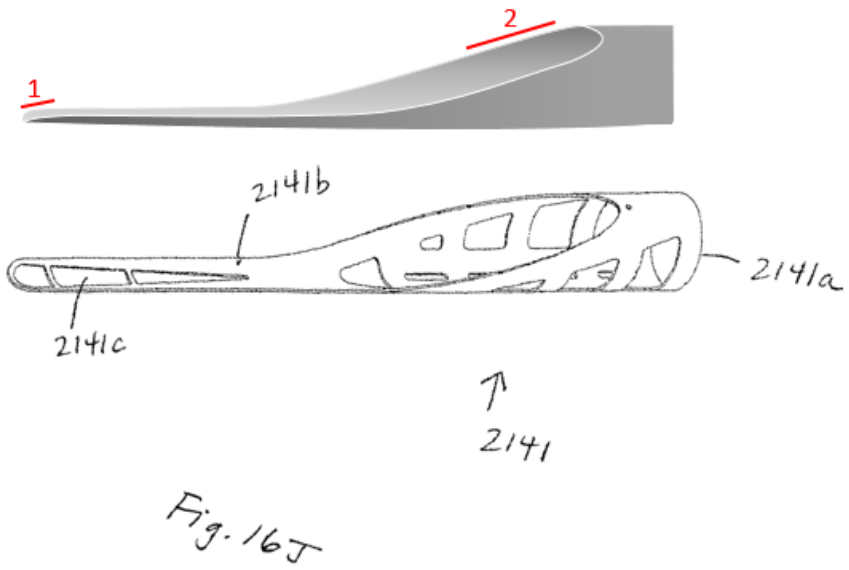
Claim Language	**Evidence & Corresponding Disclosure** (Ground 3)
[52.c.iii]	[52.c.iii] (§ IX.D.1, *supra*)

1. [52.e]

Ressemann's support collar 2141 has a first inclined slope at its proximal end, a flat, non-inclined region, and a second inclined slope at its distal end, as discussed and shown above for claim 36. *Supra* § X.C; Ex-1005, ¶ 275; Ex-1042,

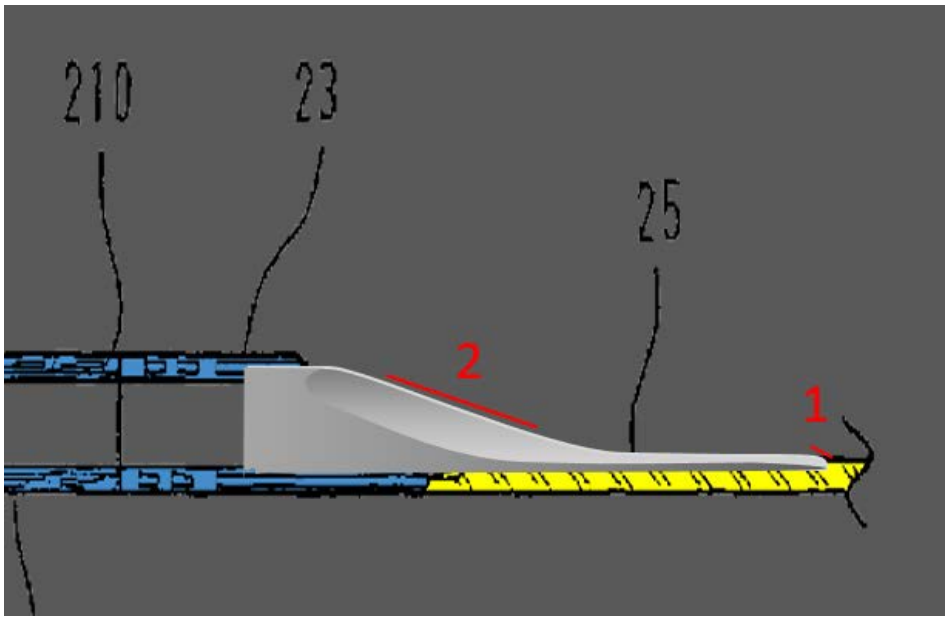
¶¶ 103-104, 110-111. These inclined slopes are similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1075, 10-11.

A POSITA had motivation to modify Itou's partially cylindrical opening with Ressemann's support collar for several reasons including: 1) such modification increases the area for receiving an interventional device, such as Itou's distal end protection device (5); 2) incline #1 provides an on-ramp to guide interventional devices into entry port at incline #2; 3) the tab portion provides a flexibility transition between the proximal end of tubular portion 24 and wire-like portion (25); and 4) the support collar reinforces the opening of the lumen. Ex-1042, ¶¶ 101, 113-116; Ex-1005, ¶¶ 276-277.



Ex-1008, Fig. 16J (annotations and color added).

A POSITA would look to the teaching of Ressemann for how to incorporate support collar 2141 into Itou's design. Ex-1042, ¶¶ 105-109. Support collar 2141 would be fit into the proximal opening of suction catheter (2) and tab portion 2141b would lie adjacent the exterior of wire-like portion (25). *Id.* A representation of how Ressemann's collar would be incorporated into Itou's suction catheter (2) is shown below. *Id.*



Ex-1007, Itou Fig. 3 modified with Ressemann's support collar 2141.

For the reasons discussed for claim 36, a POSITA had motivation to combine Ressemann's support collar, Ex-1008, Fig. 16J, with the proximal opening on the tubular structure of Itou's suction catheter (2), Ex-1007, Figs. 3-4, and a reasonable expectation of success. *See* § X.C, *supra*; Ex-1005, ¶ 278.

G. Claim 53

Itou in combination with Ressemann renders claim 53 obvious. Ex-1005, ¶¶ 279-289.

Claim Language	**Evidence & Corresponding Disclosure** (Ground 3)
[53.pre]	[53.pre] (§ IX.E.1, *supra*)

Claim Language	**Evidence & Corresponding Disclosure** (Ground 1)
[53.a]	[25.a] (§ VII.B.2, *supra*)
[53.b.i]	[25.b] (§VII.B.3, *supra*)
[53.b.ii]	[30, 31] (§§ VII.F, VII.G, *supra*)
[53.c.i]	[25.c.i] (§VII.B.4, *supra*)
[53.c.ii]	[25.c.ii] (§VII.B.5, *supra*)
[53.c.iii]	[25.c.iv] (§VII.B.7, *supra*)
[53.c.iv]	[25.d] (§VII.B.8, *supra*)

1. [53.d]

For the reasons discussed for claims 36 and 52 (*see* §§ X.C, X.F, *supra*), a POSITA had motivation to combine the two inclined regions of Ressemann's support collar, Ex-1008, Fig. 16J, with the partially cylindrical opening on the tubular structure of Itou's suction catheter (2), Ex-1007, Figs. 3-4, and a reasonable expectation of success. Ex-1005, ¶ 289.

H. Claim 54

Itou discloses the additional limitation in dependent claim 54 as discussed above. *See supra* § IX.F; Ex-1005, ¶ 290. A POSITA had motivation to combine Ressemann and Itou for the reasons discussed above. *See* §§ X.C, X.F-X.G, *supra*; Ex-1005, ¶ 290.

I. Claim 55

Itou discloses the additional limitation in dependent claim 55 as discussed above. *See* § IX.G, *supra*; Ex-1005, ¶ 291. A POSITA had motivation to combine Ressemann and Itou for the reasons discussed above. *See* §§ X.C, X.F-X.G (claims 36, 52-53), *supra*; Ex-1005, ¶ 291.

J. Claim 56

Itou discloses the additional limitation in dependent claim 56 as discussed above. *See* § IX.H, *supra*; Ex-1005, ¶ 292. A POSITA had motivation to combine Ressemann and Itou for the reasons discussed above. *See* §§ X.C, X.F-X.G (claims 36, 52-53), *supra*; Ex-1005, ¶ 292.

XI. GROUND 5: ITOU RENDERS CLAIMS 52-56 OBVIOUS IN VIEW OF ENGER AND THE COMMON KNOWLEDGE OF A POSITA.

A. Enger

Enger issued as U.S. Pat. No. 5,980,486 on November 9, 1999. Ex-1050. It is prior art under pre-AIA §102(b) and post-AIA §§ 102(a)(1), 102(a)(2), and was not cited or considered during prosecutions of the ’850 patent. Ex-1002. It is cited on the face of the ’776 patent, but was not discussed during prosecution.[11] Exs-

[11] Enger was not discussed in any Office Action or considered in combination with Itou, and thus this Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36

1001, Ex-1003. Enger discloses a balloon catheter for use in a coronary artery. Ex-1050, Abstract; Ex-1005, ¶¶ 293-295.

B. Claim 52

Enger renders claim 52 obvious. *See* Ex-1005, ¶¶ 295-305.

Claim Language	**Evidence & Corresponding Disclosure** (Ground 1)
52.pre	[25.pre] (§ VII.B.1, *supra*)
52.a	[25.a] (§ VII.B.2, *supra*)
52.b	[25.b] (§ VII.B.3, *supra*)
52.c.i	[25.c.i] (§ VII.B.4, *supra*)
52.c.ii	[25.c.ii] (§ VII.B.5, *supra*)
52.c.iv	[25.c.iv] (§ VII.B.7, *supra*)
52.d	[25.d] (§ VII.B.8, *supra*)

Claim Language	**Evidence & Corresponding Disclosure** (Ground 3)
[52.c.iii]	[52.c.iii] (§ IX.D.1, *supra*)

1. [52.e]

(P.T.A.B. Jan. 17, 2019) (explaining that a reference that "was neither applied against the claims nor discussed by the Examiner" does not weigh in favor of exercising discretion under § 325(d)); *Shenzhen Zhiyi Tech Co. v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (P.T.A.B. Apr. 2, 2018) (declining to apply § 325(d) when the reference was merely cited in a Notice of Reference Cited on face of patent-in-question).

Like Itou, Enger is directed to a catheter system for treating occluded coronary arteries. *See* § XI.A, *supra*; Ex-1050, Abstract, 1:13-15. Like Itou's suction catheter (2), Enger's angioplasty catheter is inserted through a guide catheter and into the coronary artery. Ex-1050, 3:25-27. And, like Itou's suction catheter, Enger's angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*., 3:9-12; Ex-1005, ¶ 306.

Enger explains that prior art balloon angioplasty catheters that did not have a guidewire lumen running along their entire length presented a risk in that the portion of the catheter that did not have guidewire support tended to "buckle" within the guide catheter. *Id*., 2:31-38. This would result in friction between the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy. *Id*., 2:38-49; Ex-1005, ¶ 306.

To address the problems of prior art catheters, Enger's angioplasty catheter includes an "elongate proximal segment" (28), an intermediate segment (30), and a distal segment to which the dilation balloon (34) is mounted. Ex-1050, 4:66-5:11.

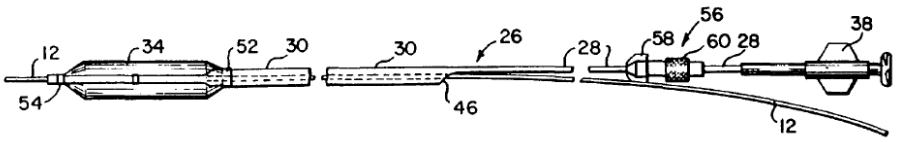


Fig. 1

Id., Fig. 1.

The catheter is designed to have a short, distally located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*., 3:9-13, 5:34-40; Ex-1005, ¶ 306.

The proximal opening to the guidewire lumen has at least two inclined slopes.[12]

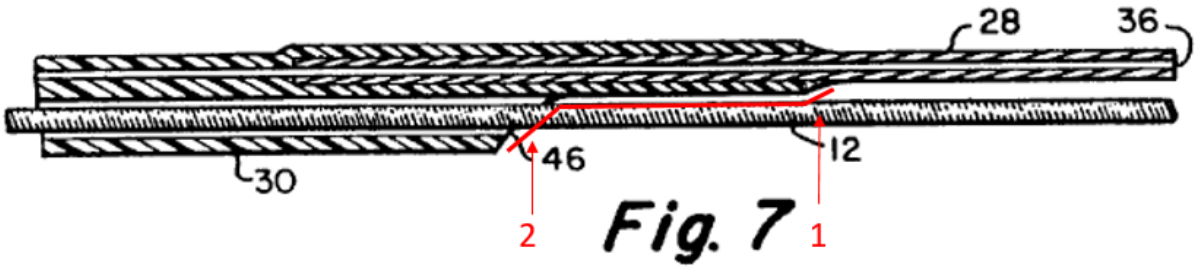


Fig. 7

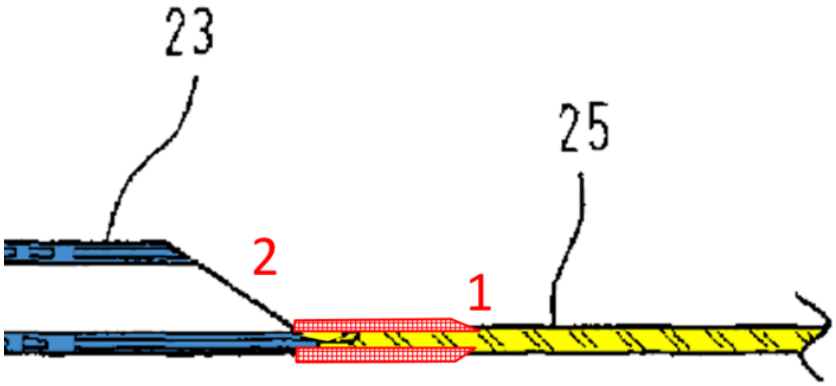
Ex-1050, Fig. 7 (annotations and color added).

Incline slope #1 is similar to Patent Owners infringement allegations. Ex-1075, 10-11.

[12] Enger teaches that enclosing the guidewire in a lumen in the distal and intermediate segments of the catheter (over a 35-45 cm length) is advantageous because it allows those segments to be "supported by the guidewire" that extends through the lumen. *Id*., 3:9-10, 3:21-24. This ensures the catheter "does not tend to bind up" in the GC, facilitating advancement of the distal end of the catheter "into more distal regions of a patient's coronary anatomy." *Id*., 3:25-29.

As Dr. Hillstead explains, Enger's incline #1 functions as a start of an incline to the entry port located at incline #2. This incline functions to guide the interventional device (in this case a guidewire) into its designated lumen. A POSITA had motivation to provide a first incline to function as an "on-ramp" to guide interventional devices such as distal end protective device or stent and balloon catheter (5) into the lumen of Itou's suction catheter (2).

As Dr. Hillstead explains, the first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1042, ¶¶ 126-130; *see also* Ex-1005, ¶ 307. A POSITA would understand that the first incline of Enger could be incorporated into Itou's suction catheter (2) by using a similarly inclined polymer collar to grip substantially rigid wire-like segment (25). This would result in a two-incline opening as shown schematically in modified Figure 3 of Itou. Ex-1005, ¶ 308.



Ex-1007, Fig. 3 (Itou modified with teaching of Enger and illustrating two-incline opening).

Thus, claim 52 is obvious. Ex-1005, ¶¶ 296-308.

C. Claim 53

Itou in combination with Enger renders claim 53 obvious. Ex-1005, ¶¶ 309-319.

Claim Language	**Evidence & Corresponding Disclosure** (Ground 3)
[53.pre]	[53.pre] (§ IX.E.1, *supra*)

Claim Language	**Evidence & Corresponding Disclosure** (Ground 1)
[53.a]	[25.a] (§ VII.B.2, *supra*)
[53.b.i]	[25.b] (§ VII.B.3, *supra*)
[53.b.ii]	30, 31 (§§ VII.F, VII.G, *supra*)
[53.c.i]	[25.c.i] (§ VII.B.4, *supra*)
[53.c.ii]	[25.c.ii] (§ VII.B.5, *supra*)
[53.c.iii]	[25.c.iv] (§ VII.B.7, *supra*)
[53.c.iv]	[25.d] (§ VII.B.8, *supra*)

1. [53.d]

Itou in view of Enger renders this limitation of claim 53 obvious, because a POSITA had motivation to include Enger's two different inclined slopes in Itou's suction catheter (2) for the same reasons discussed above for claim 52.e. *See* § XI.B.1, *supra* (claim 52.e); Ex-1005, ¶ 319.

D. Claim 54

Itou discloses the additional limitation in dependent claim 54 as discussed above. *See* § IX.F, *supra*; Ex-1005, ¶ 320. A POSITA had motivation to combine

Enger and Itou for the reasons discussed above. *See* § XI.B (claim 52), *supra*; Ex-1005, ¶ 320.

E. Claim 55

Itou discloses the additional limitation in dependent claim 55 as discussed above. *See* § IX.G, *supra*; Ex-1005, ¶ 321. A POSITA had motivation to combine Enger and Itou for the reasons discussed above. *See* § XI.B (claim 52), *supra*; Ex-1005, ¶ 321.

F. Claim 56

Itou discloses the additional limitation in dependent claim 56 as discussed above. *See* § IX.H, *supra*; Ex-1005, ¶ 322. A POSITA had motivation to combine Enger and Itou for the reasons discussed above. *See* § XI.B (claim 52), *supra*; Ex-1005, ¶ 322.

XII. SECONDARY CONSIDERATIONS

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.

XIII. CONCLUSION

Petitioner respectfully requests institution of a trial and cancellation/invalidation of claims 25-27, 29-33, 35-39, 41-49, and 52-56 of the '776 patent.

XIV. PAYMENT OF FEES

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

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 14, 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 13,847 words, excluding any Mandatory Notices. I further certify that, in preparation of this 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 14, 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 14, 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