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.: IPR2020-00134
U.S. Patent No. RE 45,760E

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

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I. PRELIMINARY STATEMENT

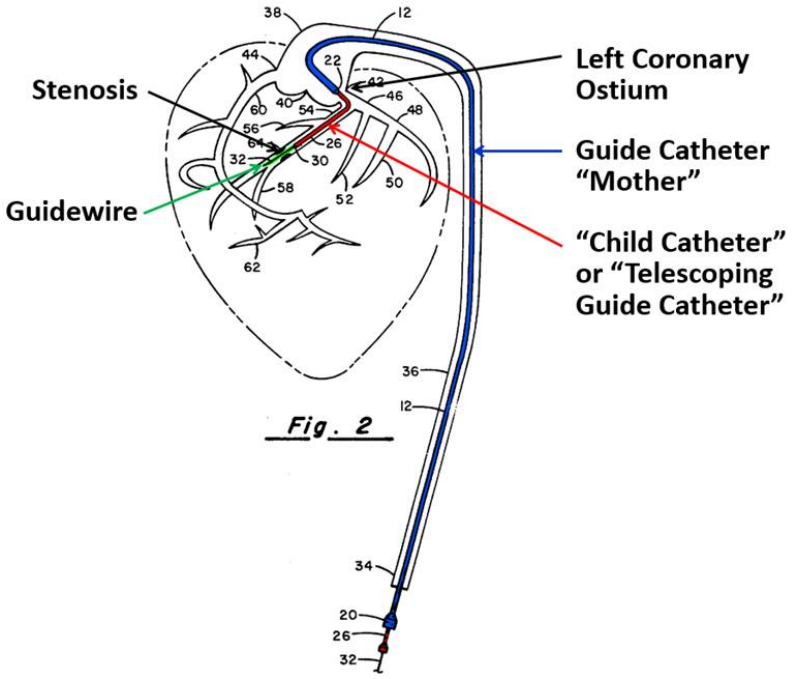
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 48 and 51-53 ("Challenged Claims") of U.S. Pat. No. RE 45,760 ("the '760 patent," Ex-1601). The '760 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1601, [60])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id.*, [54], [72]. The Challenged Claims were issued on a first Office Action, meaning there is no substantive file history for the '760 patent.

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

[1] The '760 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1605, ¶¶ 75 n.8, 129. A POSITA knew that the '760 patent's "coaxial guide catheter" was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1609, 5:49-50 (referring to body 12 "as a guide catheter extension").

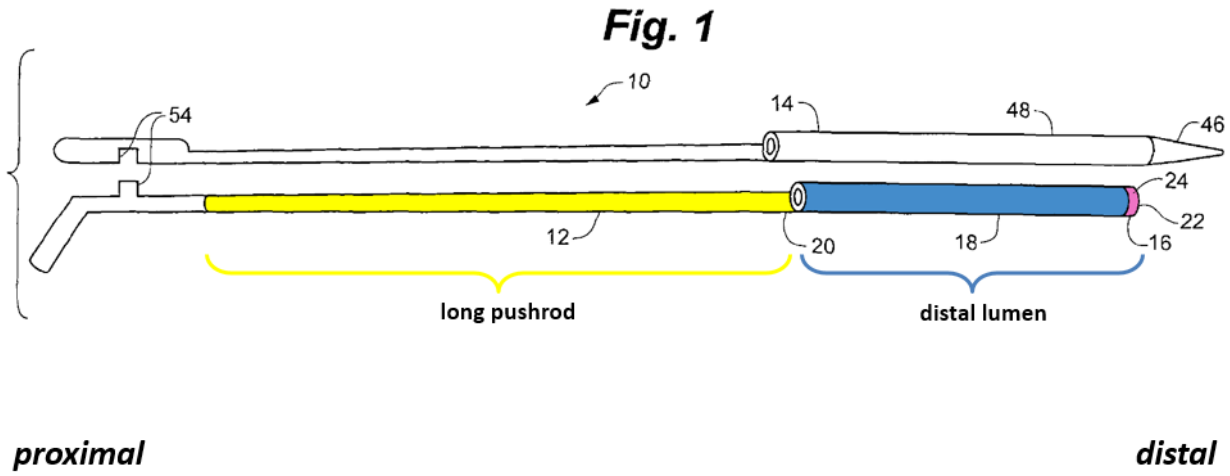
Abstract; Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from the ostium. *Id*., 3:7-11; s*ee also id.*, 8:23-35.

The '760 patent admits that using a guide extension catheter inside an outer guide catheter was known. Ex-1601, 2:46-61 (describing the use of a "smaller guide catheter within a larger guide catheter"). Ex-1605. Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a "mother-and-child assembly," where the child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. Ex-1605, ¶¶ 74-84, 103-104.



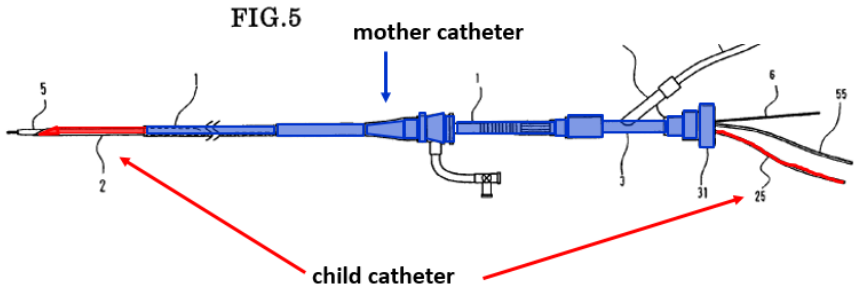
Ex-1654, Fig. 2 (annotation and color added).

The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id*. The '760 patent alleges that such a design had certain drawbacks (Ex-1601, 2:63-3:6) and modifies the child catheter of the mother-and-child assembly to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



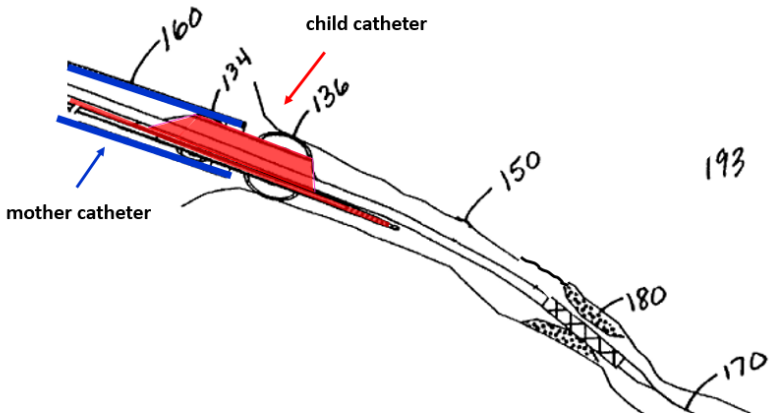
Ex-1601, Fig. 1 (annotation and color added).

But child catheters with short lumen connected to a long thin pushrod were already well-known in the art, evidenced by U.S. Patent No. 7,736,355 ("Itou") (Ex-1607).



Ex-1608, Fig. 6B (annotations and color added); *infra*, §VII.A.

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



Ex-1608, Fig, 6E (annotations and color added); *infra*, §VII.A.

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

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

A. Real Party-in Interest

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

B. Related Matters

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

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

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

Petitioner is also concurrently filing other petitions for IPR challenging different '760 patent claims.

C. Lead and Backup Counsel

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

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D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

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

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

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 48 and 51-53 of the '760 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Itou anticipates claims 48, 51 and 53.
2	Itou renders claims 48, 51 and 53 obvious in view of Ressemann and the knowledge of a POSITA.
3	Itou renders claim 52 obvious in view of the knowledge of a POSITA.
4	Ressemann renders claims 48 and 51-53 obvious in view of the knowledge of a POSITA.

IV. BACKGROUND

A. Technology Overview

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1605, ¶¶ 32-36. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id*. In response,

[2] This petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1605), and Richard A. Hillstead, Ph.D., (Ex-1642), as experts in the '760 patent field. Petitioner also submits Sylvia D. Hall-Ellis, PhD's declaration (Ex-1678) to support authenticity and public availability of the documents cited herein.

physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery, and thus can treat CAD without the need for open-heart surgery. Ex-1605, ¶¶ 33, 38-44.

PCI was developed over 40 years ago, and although its catheter-based technology has advanced, the basic PCI components remain largely unchanged. Ex-1605, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to access the patient's vasculature. Ex-1605, ¶¶ 38, 46-59. A guidewire is introduced into the needle, the needle is removed, and an introducer sheath is inserted over the guidewire and into the artery. Next, a guide catheter is introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the coronary artery ostium. *Id.*, ¶¶ 38, 46-59. At the proximal end, a hemostatic valve is coupled to the guide catheter and remains outside the patient's body. *Id.*, ¶¶ 39, 58. The valve prevents blood from exiting the patient's artery and keeps air from entering the bloodstream. *Id*.

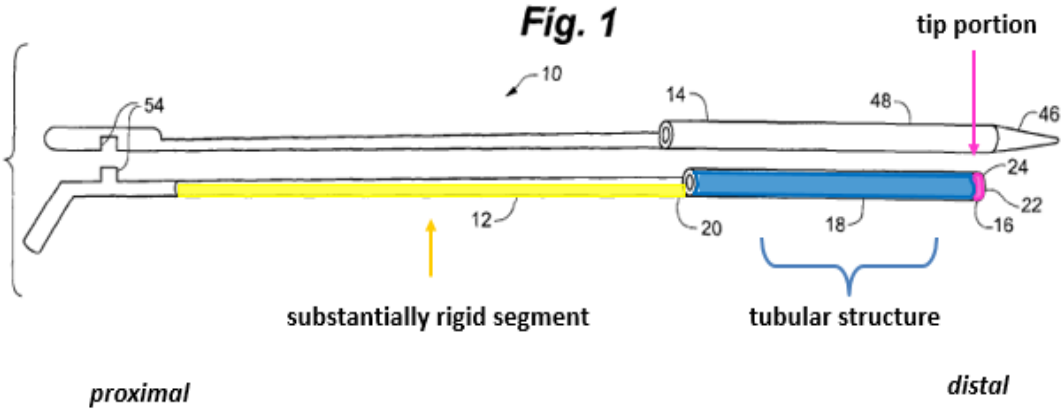
A smaller-diameter, more flexible guidewire is then threaded through the guide catheter to the target site. *Id.*, ¶¶ 60-62. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to the occlusion. *Id*. The guidewire and therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. *Id.*, ¶¶ 63-71. This last

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

B. The ’760 Patent

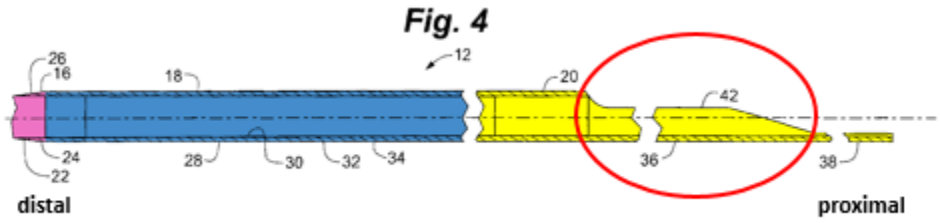
The ’760 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1601, 1:37-38. In particular, the ’760 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends through the lumen of a GC, “beyond the distal end of the guide catheter and insert[s] into [a] branch artery.” *Id*., Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:30-34; Ex-1605, ¶¶ 129-130.

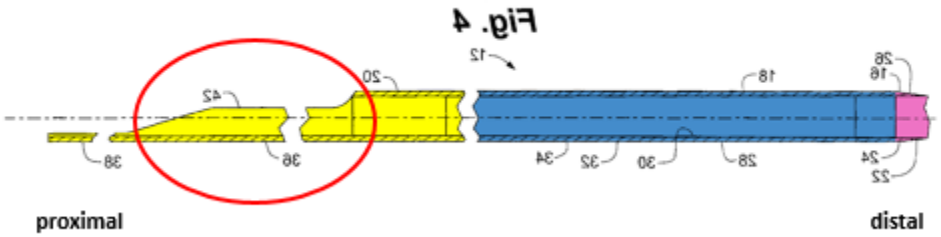
The ’760 patent claims a guide extension catheter 12 that includes a substantially rigid segment (yellow) and a tubular structure (blue) and a tip portion (pink). Ex-1601, 3:58-61, 6:40-41, Fig. 1. Color has been added to Figure 1, below, which has been annotated with the language of claim 51.



Ex-1601, Fig. 1 (annotations and color added).

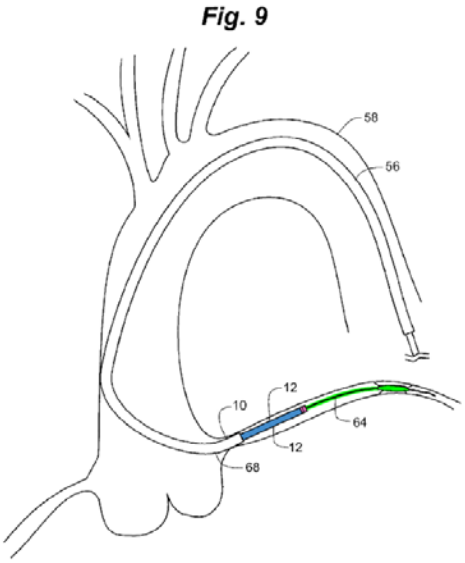
The '760 patent also recites that the extension catheter include "in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure." *Id.*, 15:14-53, 15:60-16:36, 16:39-17:13. The specification, however, provides no written description support for a "side opening" located anywhere other than ***in*** the substantially rigid segment 20, circled in red below." Ex-1601, Figs. 4, 13-16; *see also id.*, 7:1-17, 8:63-9:5.





Ex-1601, Fig 4 (annotations and color added) (bottom figure inverted by Petitioner).

Regardless, the ’760 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the extension catheter’s distal tip (pink). Moving distally to proximally, the extension catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the guide catheter’s distal tip 56. Ex-1605, ¶ 131.



Ex-1601, Fig. 9 (color added).

C. Prosecution History of the ’760 Patent

The predecessor, ’850 patent issued without an Office Action. *See generally* Ex-1602. According to the Examiner, the claims were allowable because “adding a guide catheter to the claimed rail structure[3] with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” Ex-1602 at 83 (Notice of Allowance at 3).

Patent Owner sought reissuance in 2014. The Examiner found the claims were patentable because he found no prior art disclosing “a guide extension catheter which is long enough to extend from both ends of the guide catheter and includes a rigid segment, a segment defining a side opening and a tubular structure, where the lumen of the tubular structure is shorter than the guide catheter.” Ex-1603 at 708 (Non-Final Rejection, December 10, 2014 at 10). In other words, in both the original and reissue prosecutions, the Examiner believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art, but he was not aware of Itou or Ressemann.

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

D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim that is not supported by a pre-March 16, 2013 application or claims priority to any patent or application that is subject to the AIA first-to-file provisions. AIA § 3(n)(1)(A); MPEP § 2159.02. This would prevent, for instance, any attempt by Patent Owner to swear behind the Itou patent. The '760 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority,[4] and (2) it claims priority to RE 45,380 ("the '380 patent"), which is subject to the AIA first-to-file provisions. Thus, Patent Owner cannot swear behind Itou in this proceeding. First, no pre-AIA application to which the '760 patent claims priority contains disclosure of "a side opening portion" that is not part of the substantially rigid segment, but the independent claims allow the side opening to, in the alternative, be in the reinforced segment. *Compare* Ex-1662, 13:36-14:7, *with id.*, 14:31-33.. Second, claim 32 requires a side opening with two inclined slopes, while the only alleged support (*See* Ex-1603 at 163 (Preliminary Amendment, March 3, 2014 at 21)), Figure 4, discloses an arc and an inclined slope. Third, claim 32 requires a side

[4] The '760 patent shares the same specification as all its priority chain's applications filed before March 16, 2013.

opening that includes "at least two" inclined slopes but there is no support for more than two. Fourth, the '380 patent, to which the '760 patent claims priority, is an AIA patent because it includes at least one claim that lacks support in a pre-March 16, 2013 application. Similar to claim 32 of the '760 patent, claim 27 of the '380 patent requires "at least two different inclined slopes." The '760 and '380 patents—at best—support ***only*** two inclined slopes. Ex-1601, Fig. 4; Ex-1681, Fig. 4.

V. THE PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art ("POSITA") was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer, s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and one with an engineering degree might have access to one with a medical degree. Ex-1605, ¶ 31; Ex-1642, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

For IPR proceedings, the Board applies the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). *See* 83 Fed. Reg. 51,340-51,359 (Oct. 11, 2018). Claim terms are typically given their ordinary and customary meanings, as would have been understood by a POSITA at the time of the invention, having taken into consideration the language of the claims, the specification, and the prosecution history of record. *Phillips*, 415 F.3d at 1312-16.

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

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1612 at 2)

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

- "substantially rigid": "rigid enough to allow the device to be advanced

[5] The full list of constructions advanced by Patent Owner in the QXMedical Litigation is found at Ex-1612 (Dkt. 36-1).

within the guide catheter" (*Id.* (Dkt. 36-1) at 2; Ex-1613 at 15)

- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1613 at 20)

Additionally, the district court provided the following construction:

- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (*Id* at 26)

- "lumen": "the cavity of a tube" (*Id.* at 25)
- "wherein a material forming the segment defining the side opening is more rigid than the tubular structure": "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure" (*Id*. at 31).

Petitioner agrees with the above constructions for purposes of this IPR[6] (Ex-1605, ¶¶ 134-40) and proposes construing "flexural modulus" (Ex-1601, 16:39-17:13) as follows. The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1642, ¶ 31), and according to McGraw-Hill Dictionary of

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

Scientific and Technical Terms means "[a] measure of resistance . . . to bending." Ex-1640, 772. In other words, the "flexural modulus" is a measure of a device's rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. Such an understanding is consistent with the '760 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1601, 7:25-30; Ex-1605, ¶¶ 141-142. Stated differently, the extension catheter's resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the distal end (flexible tip) is the most flexible (least rigid).[7]

VII. GROUND 1: ITOU ANTICIPATES CLAIMS 48, 51 AND 53.

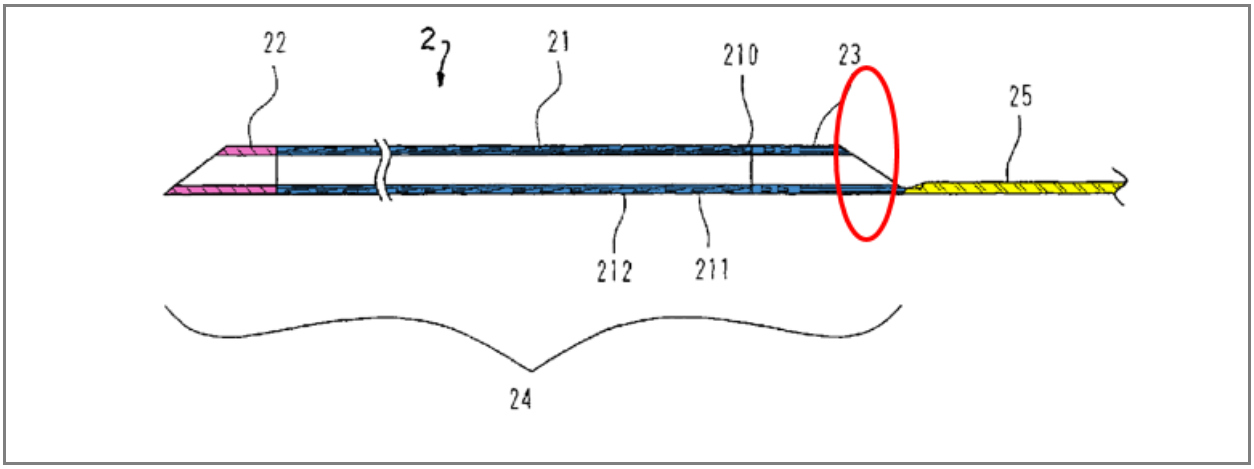
A. Itou

Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. Ex-1605, ¶ 143; Ex-1642 ¶ 67. It is prior art under both pre-AIA §102(e) and post-AIA §102(a)(1), (2), and was not cited or considered during

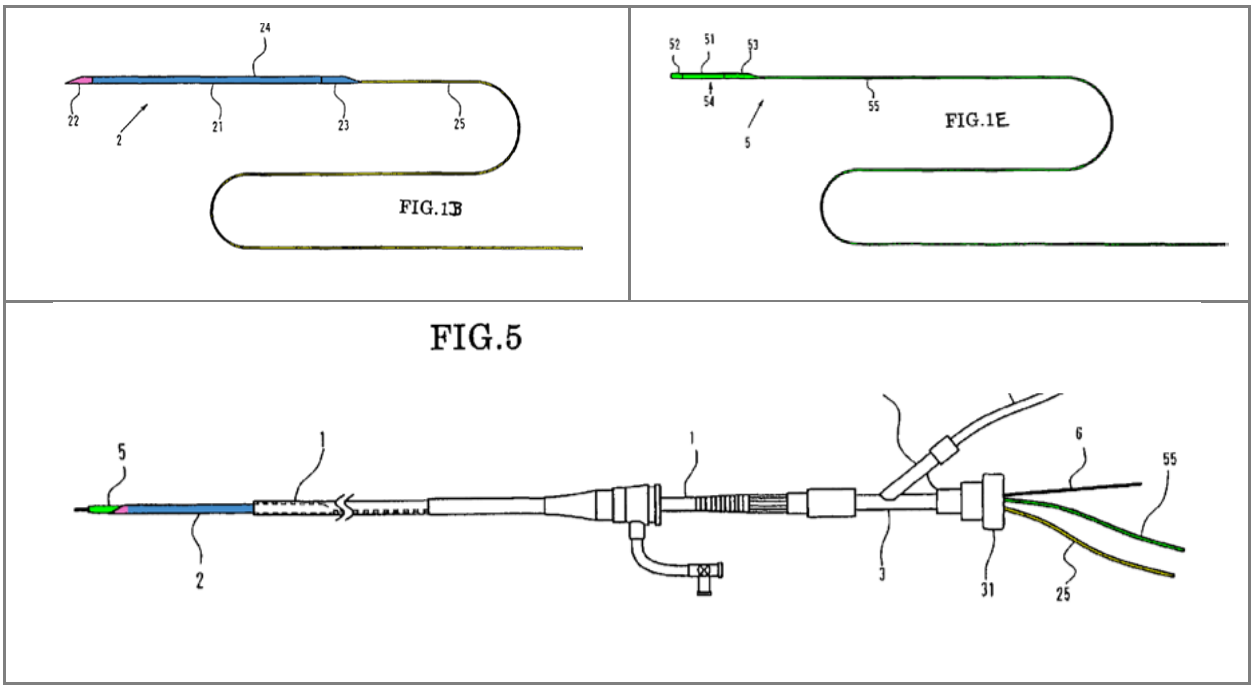
[7] In the QXMedical Litigation, Patent Owner stipulated to following construction of "flexural modulus": "a numeric, dimension-independent material property that captures the tendency of a material to bend." Ex-1612 at 2. It is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

prosecutions of either the original ’850 patent, or of the ’760 reissue patent. Exs-1601-1603.

Itou discloses a catheter assembly for alleviating blood flow obstruction. Ex-1607, 1:13-16; Ex-1642 ¶¶ 21-23. The assembly includes a GC that is inserted into a coronary artery ostium, Ex-1607, 2:2-5, Abstract, 5:32-34, 7:7-11, and a suction catheter that is insertable through the GC. *Id*., Abstract, Figs. 1A, 1B, 5, 6; Ex-1642 ¶¶ 21-23. Suction catheter (2) has a proximal, “solid wire-like portion” (25), shown below in yellow, and a distal, tubular portion (24). *Id*., Abstract, 1:53-60, 2:12-15, 3:46-50 (color added). Tubular member (24) includes a “soft tip whose distal end is flexible in order to reduce the damage to the blood vessel,” (22) (pink), *id*. 2:15-18, and a portion reinforced with a metal layer (211) (blue). *Id*., 2:18, 3:50-56 (color added) (tubular structure 21). Tubular member 24’s proximal opening is angled (red circle).



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



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

Itou also describes a "distal end protective catheter" (5), shown above in green, which is insertable through the suction catheter (2). . Suction catheter (2) may be extended beyond the GC (1)'s

distal end into a coronary artery. *Id.*, Abstract, 2:29-38, Figs 5, 6; Ex-1605, ¶ 144-46, 97-98.

Where a prior art reference contains the claim elements in the same order as the claims it is anticipatory, regardless of whether the prior art and the claimed invention are directed to achieving the same purpose. *Legget & Platt, Inc. v. VUTEK, Inc.*, 537 F.3d 1349, 1356 (Fed. Cir. 2008). Regardless, by the time of the alleged invention of the '760 patent, and as Dr. Brecker explains, a POSITA knew that suction catheters with a structure similar to Itou's may serve a dual purpose.

Ex-1605, ¶¶ 94-102, 147-153, *see also id.* ¶¶120-124. An aspiration catheter could be "preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen." Ex-1619, 3:4-6. An aspiration lumen could be used both to remove thrombus from a coronary artery, as well as to deliver an angioplasty catheter or stent. *Id*., 3:34-36, 12:16-20; Ex-1608, 6:18-34, Figs. 6A-I; Ex-1605, ¶¶ 94-102, 147-153.

B. Claim 48:

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

To the extent the preamble is limiting, Itou discloses it as set forth below. Ex-1605, ¶ 158.

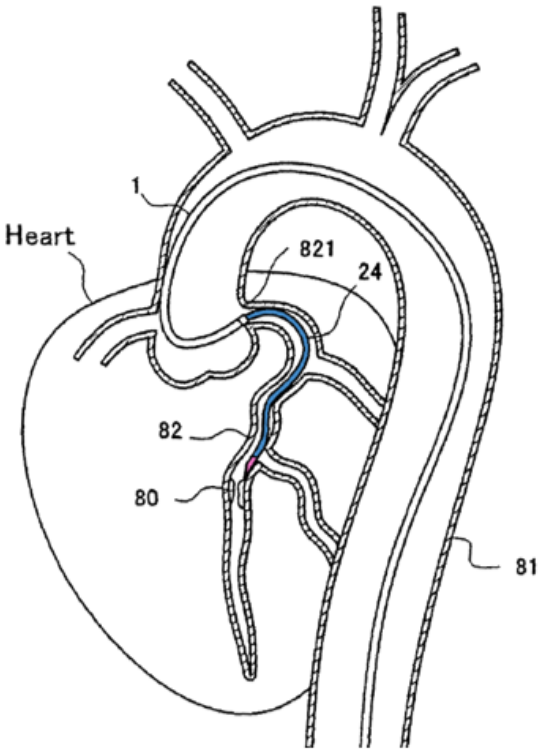
2. [48.a] "a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted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

Itou discloses this limitation. Ex-1605, ¶ 159.

As Dr. Brecker explains, guiding catheter (1) is configured to be advanceable through a main blood vessel (an aorta) to a position adjacent an ostium of a coronary artery. Ex-1607, 5:29-34 (explaining that "guiding catheter 1 is disposed

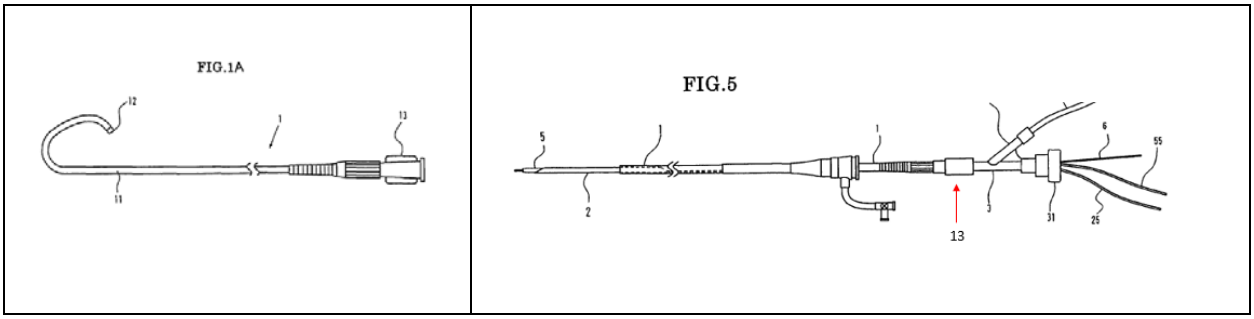
in the aorta," and its distal end is "hooked at an ostium . . . of a coronary artery"), 7:1-10. Ex-1605, ¶ 159.

FIG.6



Id., Fig. 6 (color added).

Itou teaches that guiding catheter (1) has a lumen that extends from a hemostatic valve at its proximal end, to its distal end. Guiding catheter (1) has distal end 12 and body portion (11), which terminates at connector (13). Ex-1607, Fig. 1A; 3:29-37. Connector (13) is coupled to Y-shaped connector (3), which includes main connector portion (31). *Id.*, 5:11-23.



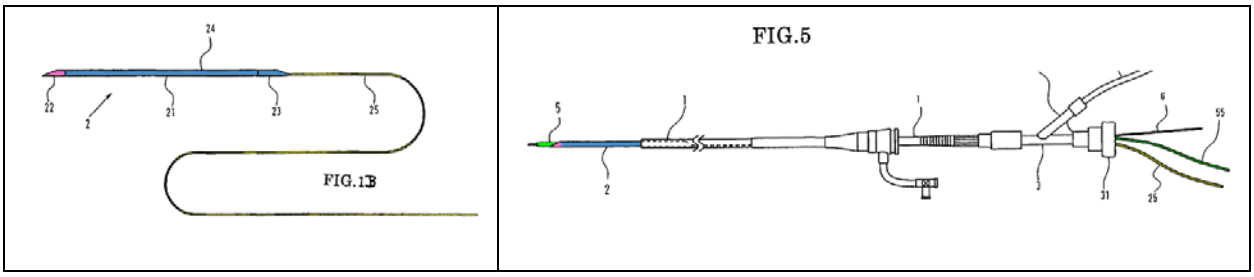
Id., Figs. 1A, 5 (annotation added).

Connector (31) includes a valve, which can close a bore in connector (31) and "selectively clamp and fix the guide wire 6, the wire-like portion 25 or 55 to prevent leakage of the blood." *Id.*, 5:20-23. Thus, guiding catheter (1) has a hemostatic valve (within connector 31 of connector 13 (arrow below)) at its proximal end. Ex-1605, ¶ 159, *see also* ¶¶ 39, 58.[8]

Itou discloses that suction catheter (2) "is disposed in the lumen of guiding catheter 1," Ex-1607, 5:11-17," and additionally teaches that suction catheter (2)

[8] The '760 patent admits a "guide catheter . . . can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter." Ex-1601, 3:29-31. Similarly, Patent Owner's expert explains that a hemostatic valve is sometimes called a Y-connector, Ex-1682, ¶ 18, also known as a Y-adapter. Ex-1605, ¶ 159.

may be inserted into guiding catheter (1) at its proximal end, to extend from its distal end.



Id., *compare* Ex-1607, Fig. 1B *with* Ex-1607, Fig. 5 (color added). Thus, Itou discloses 48.a. Ex-1605, ¶ 159.

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

Itou discloses a guide extension catheter (suction catheter 2), which is configured to be partially advanceable through the guide catheter and into the coronary artery. Ex-1605, ¶ 160.

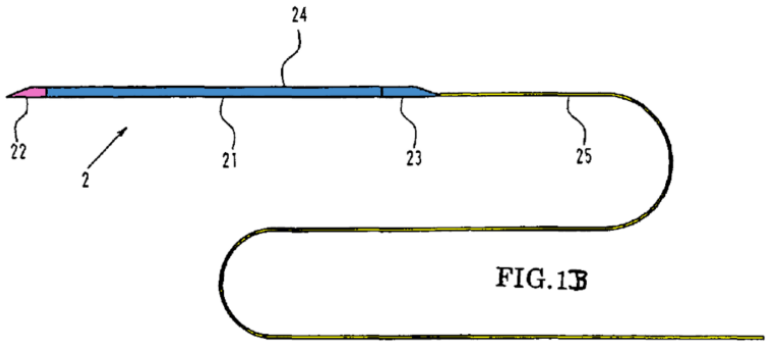
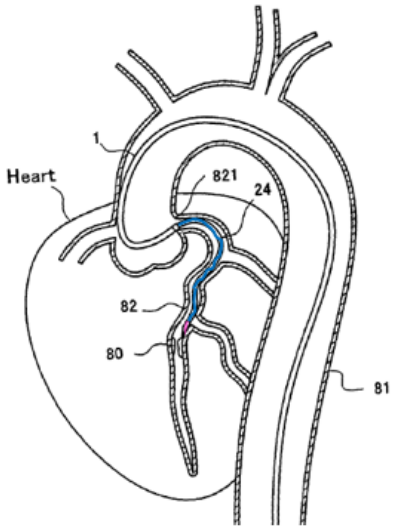


FIG. 1B

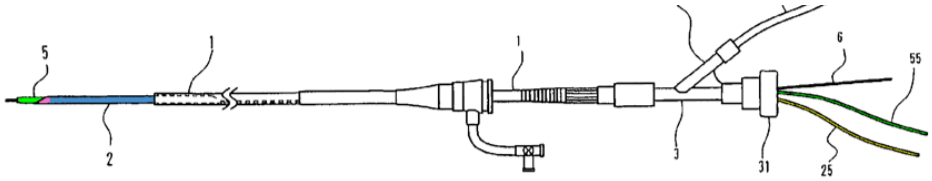
Ex-1607, Fig. 1B (color added); *supra* § VII.B.2.

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



Ex-1607, Fig. 6 (color added, illustrating tip (22) (pink) and a portion of tubular structure (21) (blue) advanced through guiding catheter (1)'s distal end into the coronary artery); *and see id.*, Abstract, 1:47-65 (explaining that "tubular portion [24] is configured to project outwardly beyond the distal end" of guiding catheter (1)), 5:38-42.

Itou also discloses that suction catheter (2) has a length such that when its distal end is extended through the lumen and beyond the distal end of guiding catheter (1) (below, left, colored blue and pink), its proximal end is extendtable through the hemostatic valve at the proximal end of the guide catheter (below, right, colored yellow). Ex-1605, ¶ 160.



Ex-1607, Fig. 5 (color added); *and see id.*, Table 1 (disclosing that suction catheter (2) is 1250 mm long, while guiding catheter (1) is 1000 mm long); *supra*, § VII.B.2 (discussing hemostatic valve located in connector 31 at the proximal end of the guide catheter 1). Thus, as Dr. Brecker explains, Itou discloses 48.b. Ex-1605, ¶ 160.

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

Itou discloses this limitation. Ex-1605, ¶ 161; *see also id.*, ¶¶ 46-59, 63-84. Guide extension catheter (suction catheter 2) includes, at its proximal end, wire-like portion 25 (below, yellow). Ex-1607, 2:12-15, 3:47-50.

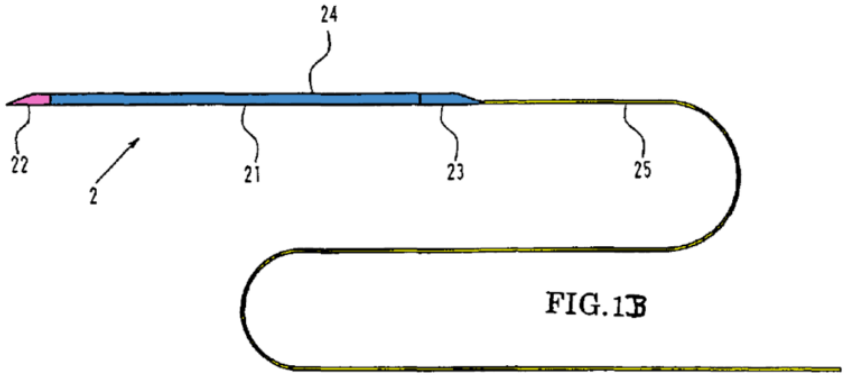
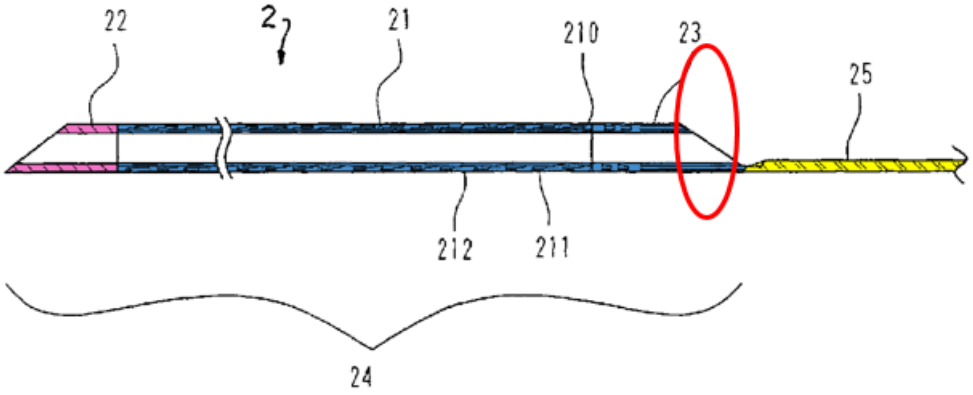


FIG. 1B

Id. (color added).

Wire-like portion 25 is a "substantially rigid" segment because it is used to advance suction catheter (2) through guiding catheter (1) until suction catheter (2)'s distal end "projects forwardly beyond the distal side of the guiding catheter." *Id*., 2:32-38, 5:43-46; *and see id.*, Abstract, Figs. 5, 6. Thus, "wire-like portion 25" meets the prior, district court claim construction of a segment that is "rigid enough to allow the device to be advanced within the guide catheter." *Supra*, § VI; Ex-1665, ¶ 161.

Moving distally, Itou discloses a segment defining a side opening (circled in red) in tubular member 24. Ex-1607, Fig. 4, 3:47-50, 4:10-15, 4:27-30.



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

Distal to the side opening, Itou discloses a tubular structure including tubular portion (21) and tip (22). *Id.*, *and see id.*, 3:47-58. Tubular structure (21, 22) defines a lumen, into which distal end protective catheter (5) may be inserted. *Id*. 4:48-52; *and see id.*, Fig. 5.

TABLE 1

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

Id., Table 1 (providing ***both*** inner and outer diameters for suction catheter, evidencing a "lumen"). [9] Ex-1605, ¶ 161.

[9] The tubular portion of suction catheter 2 is tubular member 24, of which tubular structure [21, 22] is a part. Ex-1607, Figs. 1B, 3.

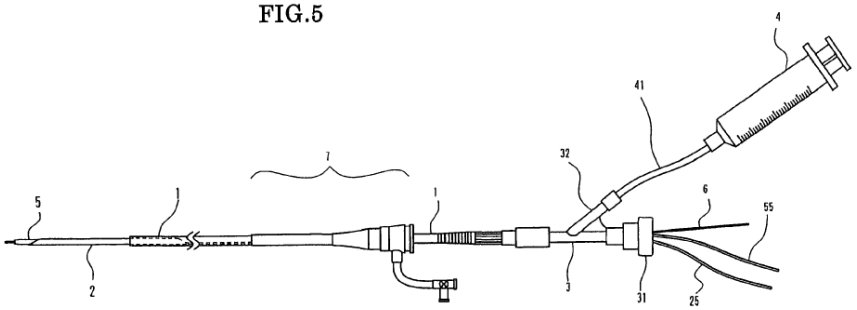
Tubular structure (21, 22)'s lumen is coaxial to the lumen of guiding catheter (1). Ex-1667, Figs. 5, 6, 1:60-62, 2:32-37; Ex-1605, ¶ 161.

As Dr. Brecker explains, the lumen of tubular structure [21, 22] is in fluid communication with the lumen of guiding catheter (1). First, suction catheter (2)'s total length is 1250 mm, while its distal, tubular member is 150 mm in length.

Guiding catheter (1) is 1000 mm. Ex-1607, Table 1. Necessarily, in use, the proximal end of the tubular portion of the suction catheter opens into the lumen of guiding catheter (1), such that fluid may flow between the guiding catheter and the suction catheter. Ex-1605, ¶ 161.

Second, Itou explains that syringe (4) may be used to "recover foreign matter in the blood vessel," such as a thrombus, through the distal opening of suction catheter 2. Ex-1607, 7:13-26.

FIG.5



Id., Fig. 5.

As syringe (4) is not connected to suction catheter (2)—but, instead, attached to guiding catheter (1) through Y-shaped connector (3), *id*., 5:11-25, Fig. 5—the recovery of foreign matter requires that suction catheter (2)'s lumen, including that of tubular structure [21,22], be in fluid communication with guiding catheter (1)'s lumen. Ex-1605, ¶ 161; *see also* Ex-1607, Figs. 9A, 10, 8:2-24 (describing suction of a glycerin solution through the distal tip of suction catheter (2), through guiding catheter (1) and into a tube connected to a Y-shaped connector).

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

Itou discloses this limitation. Ex-1605, ¶ 162.

Itou teaches that tubular structure [21, 22]'s lumen is shorter than guiding catheter 1's lumen. This is necessarily the case because tubular structure [21, 22] is part of longer, tubular member (24), which, itself, is shorter than guiding catheter (1). Ex-1607, Table 1 (disclosing that the tubular member (24) of suction catheter (2) is 150 mm in length, and guiding catheter (1) is 1000 mm in length). Ex-1605, ¶ 162.

Similarly, Itou teaches that tubular structure [21, 22]'s lumen has a "uniform cross-sectional inner diameter. Ex-1607, Fig. 3 (disclosing a longitudinal cross

section through portion 21 with a constant diameter), Table 1 (disclosing that the tubular portion of suction catheter (2) has a (***singular***) inner diameter of 1.5 mm). Ex-1605, ¶ 162.

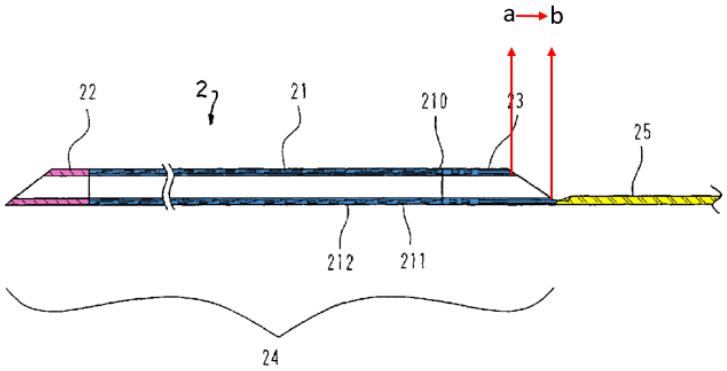
Itou teaches that there is not more than a one French size differential between the cross-sectional diameters of suction catheter (2) (including tubular structure [21, 22]) and guiding catheter (1). Ex-1607, Table 1 (disclosing inner diameters, respectively, of 1.5 and 1.8 mm). As Dr. Brecker explains, a "one French" size differential is 0.33 mm, so the "0.3 mm" size differential between the inner diameters of Itou's guiding and suction catheters is "not more than one French." Ex-1605, ¶ 162; Ex-1662 at 547. Itou discloses this limitation. Ex-1605, ¶ 162.

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

Itou discloses this limitation, disclosing a side opening extending along a longitudinal axis that is accessible from a longitudinal side defined transverse to

the longitudinal axis, and a tubular structure with a lumen. *Supra*, §§ VII.B.4-5; Ex-1605, ¶ 161-74.

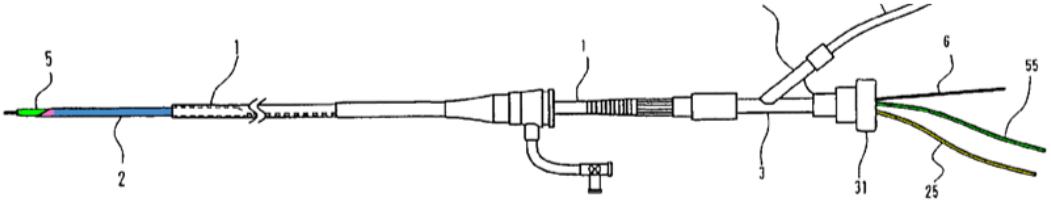
As shown below, the side opening in Itou's suction catheter 2 extends for a distance from (a) to (b) along the catheter's longitudinal axis.



Ex-1607, Fig. 3 (color and annotation added).

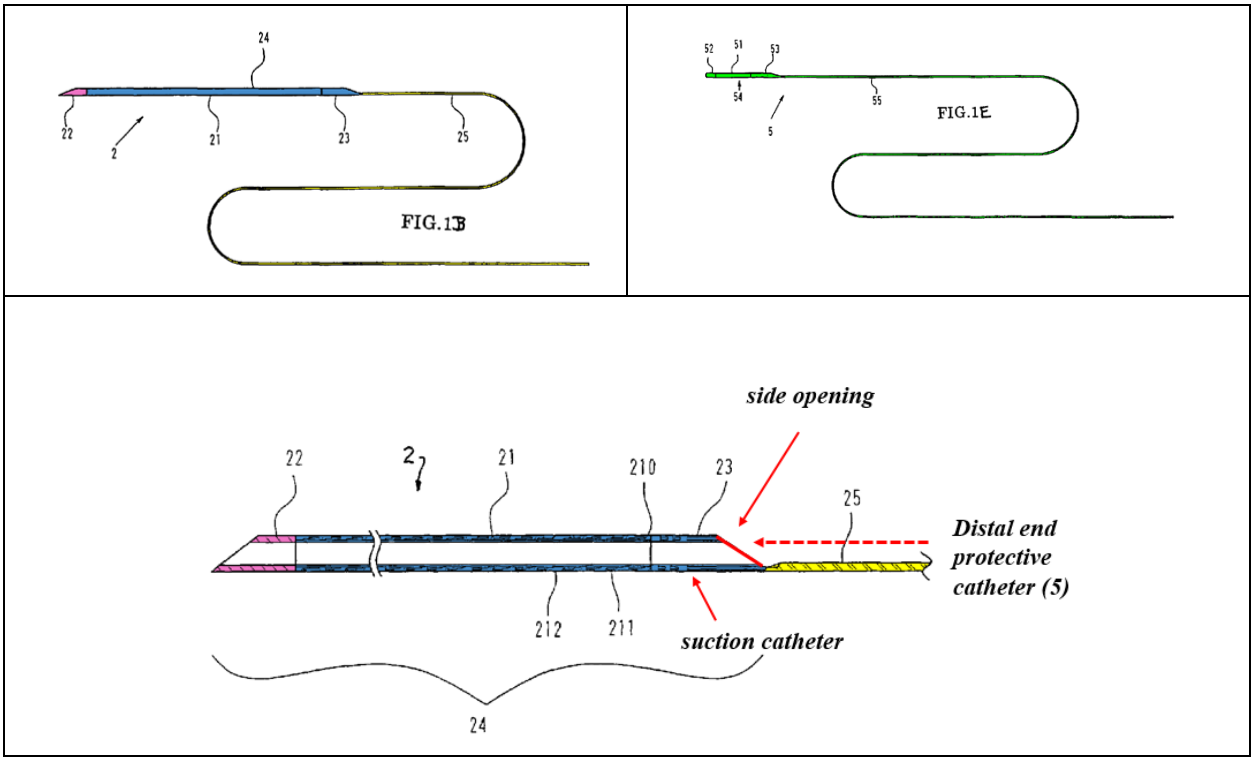
Moreover, Itou teaches that protective catheter (5) is inserted into catheter (2)'s lumen, to project from its distal end. Ex-1607, 4:48-52.

FIG.5



Id., Fig. 5 (color added).

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



Id; Figs. 1B, 1E, 3 (color and annotation added); Ex-1605, ¶ 161-63.

Itou also explicitly teaches that tubular member (24) is long enough so that while its distal end is advanced to a target location—distal to the distal end of the guiding catheter 1—its proximal end remains in guiding catheter 1. Ex-1607, 5:35-42, 6:30-35, Figs. 5, 6. This discloses that "when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter," that the "distal end of the guide extension catheter extends beyond the distal end of the guide catheter." Ex-1605, ¶¶ 162-63.

Thus, Itou discloses the structural limitations of 48.c.iii, and claim 48 is a system claim. To the extent that Patent Owner suggests that 48.c.iii requires anything more than the cited disclosure in Itou, it is mistaken. The additional

language recites an intended use ("configured ***to receive one or more stents or balloon catheters when the segment defining the side opening . . . [is] positioned within the lumen of the guide catheter***") (emphasis added), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d at 1477.

Regardless, Itou explicitly teaches that the tubular member (24) of suction catheter (2) (of which tubular structure [21, 22] is a part) has an inner diameter of 1.5 mm, Ex-1607, Table 1, which Dr. Brecker explains is 0.059 inches.[10] This was large enough to accommodate the insertion of a balloon-expandable stent, several of which were available by the time of the purported invention of the '760 patent. Ex-1605, ¶¶ 165-174; Ex-1622, 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-1623, 9 (requiring a minimum, inner catheter diameter of 0.056 inches (1.4 mm) for Driver™ stents on an OTW or RX delivery system); Ex-1624, 10 (requiring an inner catheter diameter $\geq$ 0.058 in. (1.47 mm) for TAXUS Express^2 stents on a monorail delivery system).

Thus, the proximal side opening of tubular member (24) of suction catheter (2)—and tubular structure [21, 22]—are large enough (i.e. "configured to")

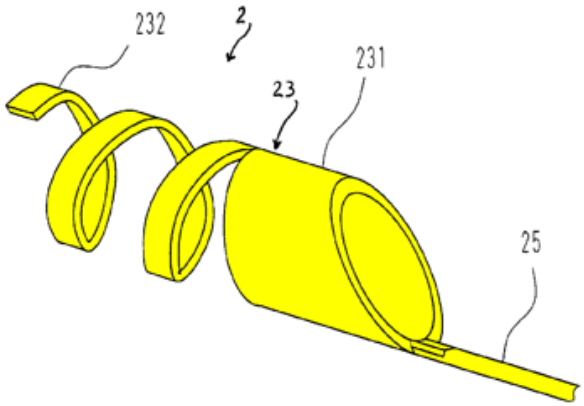
[10] This corresponds to the inner diameter of the extension catheter taught in the '760. Ex-1601, 3:49-51 ("greater than or equal to 0.056 inches . . .").

"receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter," and Itou discloses this limitation Ex-1605, ¶¶ 163-174.

7. [48.d] "wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure."

Itou discloses this limitation. Ex-1605, ¶¶ 175-177.

Itou teaches that the side opening in tubular member (24) is "formed by obliquely cutting one end of a metal pipe." Ex-1607, 4:27-32 (referring to end 231). The metal pipe is encased in resin layers. *Id*., 3:45-58, 4:36-38.



Id., Fig. 4 (color added).

By contrast, tubular structure [21, 22]'s distal end is tip (22), which Itou describes as soft and flexible, in order to avoid damaging the blood vessel.

Ex-1607, 2:15-21, Fig. 3. Unlike tubular structure (21), distal tip (22) lacks metal reinforcing layer 211. *Id*. 3:46-58.

As Dr. Brecker and Dr. Hillstead explain, because side opening 231 is formed by cutting a metal pipe, it is necessarily more rigid than distal tip (22), which Itou teaches is soft and flexible, to avoid damaging a blood vessel. Ex-1607, 2:15-21. Ex-1605, ¶¶ 175-177; Ex-1642, ¶¶ 24, 27, 86-94, *see also* ¶¶82-85.

Given the differences in the materials that are used to form tip (22) and the side opening of tubular member 24, "the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure." Ex-1605, ¶¶ 175-176; Ex-1642, ¶¶ 24, 27, 86-88.

C. Claim 51

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

To the extent the preamble is limiting, Itou discloses it as set forth below. Ex, 1605, ¶ 178.

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

Itou discloses this limitation. *Supr*a, § VII.B.2; Ex, 1605, ¶ 159, 179.

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

Itou discloses this limitation. *Supr*a, § VII.B.3; Ex, 1605, ¶ 160, 180.

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

Itou discloses this limitation. *Supr*a, § VII.B.4; Ex, 1605, ¶ 161, 181.

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

Itou discloses this limitation. *Supr*a, § VII.B.5; Ex, 1605, ¶ 162, 182.

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

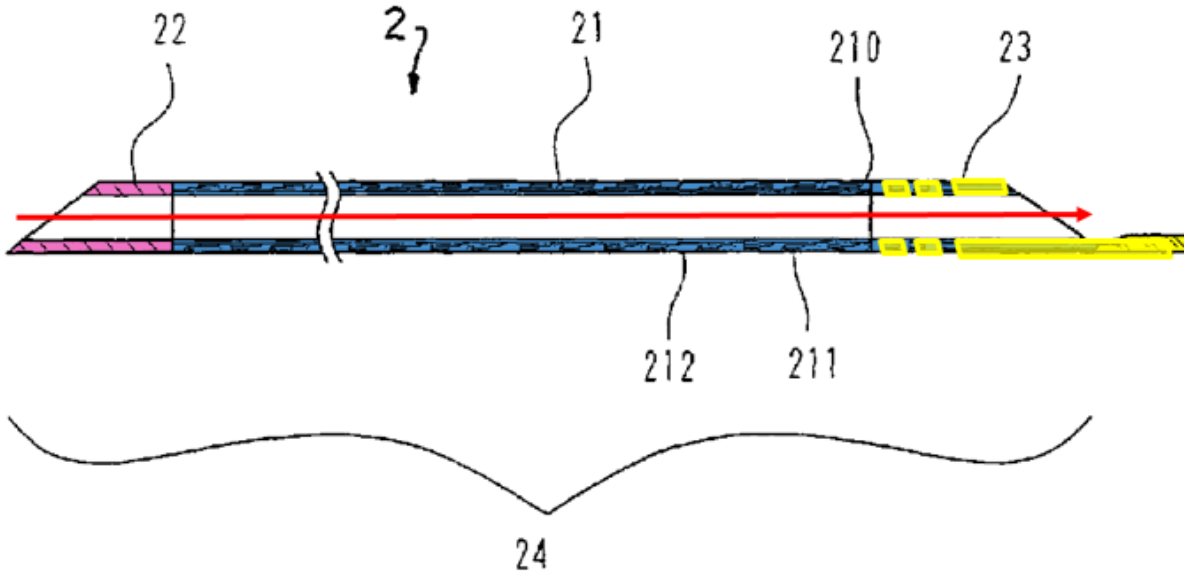
Itou discloses this limitation. *Supr*a, § VII.B.6; Ex, 1605, ¶ 163-77, 183.

7. [51.d] "wherein the tip portion[11] includes an atraumatic bumper formed from a flexible material and having a lumen continuous with the lumen of the tubular structure; and"

Itou discloses this limitation. Ex, 1605, ¶ 184.

Tip 22 is an "atraumatic bumper formed from a flexible material." Itou teaches tubular structure [21, 22]'s tip 22 is "soft" and "flexible in order to reduce the damage to the blood vessel . . . ." Ex-1607, 2:15-21.

[11] There is no antecedent basis for "the tip portion." The claim only makes sense if "tip portion" is understood to refer to the "tip portion" of the "tubular structure" recited in 51.c.i, *supra* § VII.C.4.

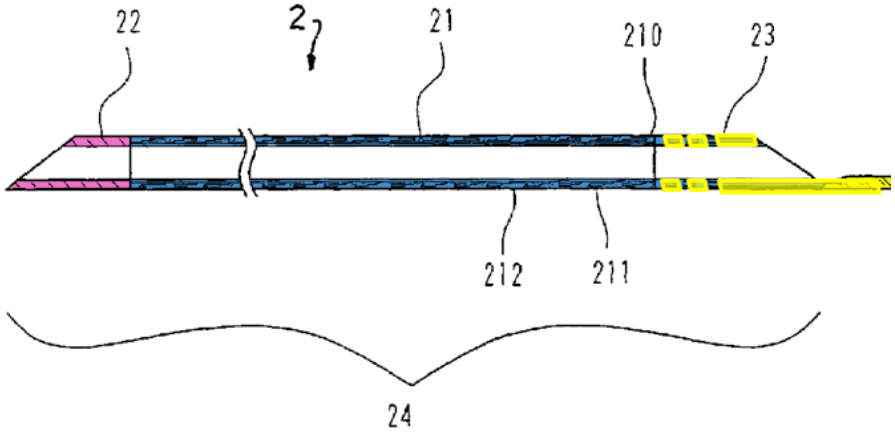


Id., Fig. 3 (color and annotation added, tip 22 shown in pink). As illustrated above by a red arrow, tip 22 has a lumen continuous with tubular structure [21, 22]'s lumen.

8. [51.e] "wherein the tubular structure includes a reinforcing braid or coil, and wherein the tip portion includes a marker band positioned distal to the distal end of the reinforcing braid or coil."

Itou discloses this limitation. Ex, 1605, ¶ 185.

Itou's tubular structure [21, 22] includes a reinforcing braid or coil through tubular portion 21, which 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-1607, 3:50-58.



Id., Fig. 3 (color added).

From Itou's teachings, it is evident that metal wire (211) is braided or coiled around inner layer 210. Ex, 1605, ¶ 185; Ex-1642, ¶¶ 68-71, ¶¶ 36-46.

Itou also teaches a "tip portion" that includes a "marker band positioned distal to the distal end of the reinforcing braid or coil." Tip (22) is not reinforced, and is distal to reinforced tubular portion 21. Ex-1607, 2:12-21, Fig. 3, 3:46-58. Tip (22), itself, forms a "marker band" as it "is formed such that a filler such as tungsten, bismuth oxide or barium sulfate, which are X-ray contrast agents, is mixed by 50 to 70 wt % in a matrix made of a resin . . . it functions as an X-ray contrast marker (radiopaque marker)." Ex-1607, 4:15-20; Ex, 1605, ¶ 185.

D. Claim 53

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

To the extent the preamble is limiting, Itou discloses it as set forth below. Ex- 1605, ¶¶ 158, 178, 186.

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

Itou discloses this limitation. *Supr*a, §§ VII.B.2, VIII.C.2; Ex-1605, ¶¶ 159, 179, 187.

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

Itou discloses this limitation. *Supr*a, §§ VII.B.3, VIII.C.3; Ex-1605, ¶ 160, 180, 188.

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

Itou discloses this limitation. *Supr*a, §§ VII.B.4, VIII.C.4; Ex, 1605, ¶ 161, 181, 189.

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

Itou discloses this limitation. *Supr*a, §§ VII.B.5, VIII.C.5; Ex-1605, ¶ 162, 182, 190.

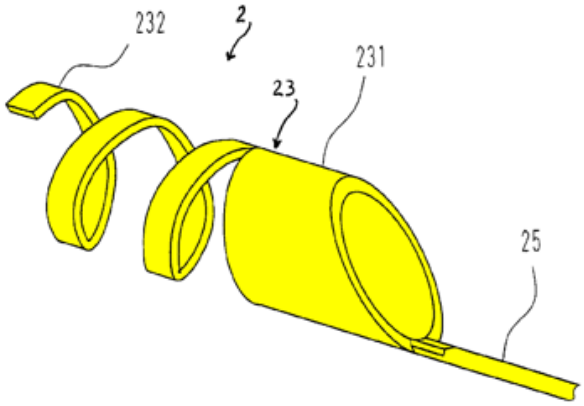
6. [53.c.iii] "the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more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

Itou discloses this limitation. *Supr*a, §§ VII.B.6, VIII.C.6; Ex-1605, ¶ 163, 183, 191.

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

Itou discloses this limitation. Ex-1605, ¶¶ 192-96; *see also id*., ¶¶ 175-177, 184.

Itou teaches that the side opening in tubular member (24) is "formed by obliquely cutting one end of a metal pipe." Ex-1607, 4:27-32 (referring to end 231). The metal pipe is encased in resin layers. *Id*., 3:46-58, 4:36-38.



Id., Fig. 4 (color added); Ex-1642, ¶¶ 68-74; Ex-1605, ¶¶ 192-93, 195.

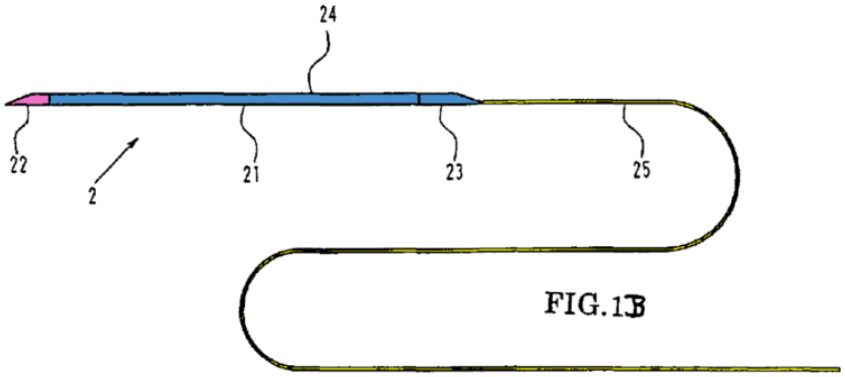
By contrast, tubular structure (21) includes resign layers (210) and (212) and a "reinforcing layer 211 made of metal wire." Ex-1607, 3:50-58, Fig. 3; Ex-1605 ¶¶ 192-94, 195; Ex-1642, ¶¶ 24-26, 68-71.

As Dr. Brecker and Dr. Hillstead explain, because side opening 231 is formed by cutting a metal pipe, it is necessarily more rigid than tubular structure 21, which includes resin layers and a wire reinforcing layer. Ex-1605, ¶ 194; Ex-1642, ¶ 73.

Given the differences in the materials that are used to form tubular structure (21) and tubular member 24's side opening, "a material forming the segment defining the side opening is more rigid than tubular structure." Ex, 1605, ¶¶ 192-96; Ex-1642, ¶¶ 24-26, 68-74; *and see, supra* § VI (construing 53.d to mean "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure).

8. [53.e] "wherein a flexural modulus of the substantially rigid segment is greater than a flexural modulus of the tubular structure."

Itou discloses this limitation. Ex-1605, ¶¶ 197-202. As discussed for claim 48.c.i, Itou's wire-like portion (25) is the "substantially rigid segment," and the tubular structure consisting of tubular portion (21) and tip (22). Ex-1607, 3:50-58.



Ex-1607, Fig. 1B (color added).

Itou teaches that wire-like portion (25) is "formed from a solid metal wire" that has an outer polymer coating. Ex-1607, 3:46-50, 4:33-36. 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 . . . ." *Id*., 3:50-58.

As Dr. Brecker and Dr. Hillstead explain, given the differences in the materials that are used to form wire-like portion (25) and tubular structure [21, 22], they each have a different flexural modulus, and the former's is greater than the latter's. Ex-1642, ¶¶ 24-27, 68-81; Ex-1605, ¶¶ 197-202.

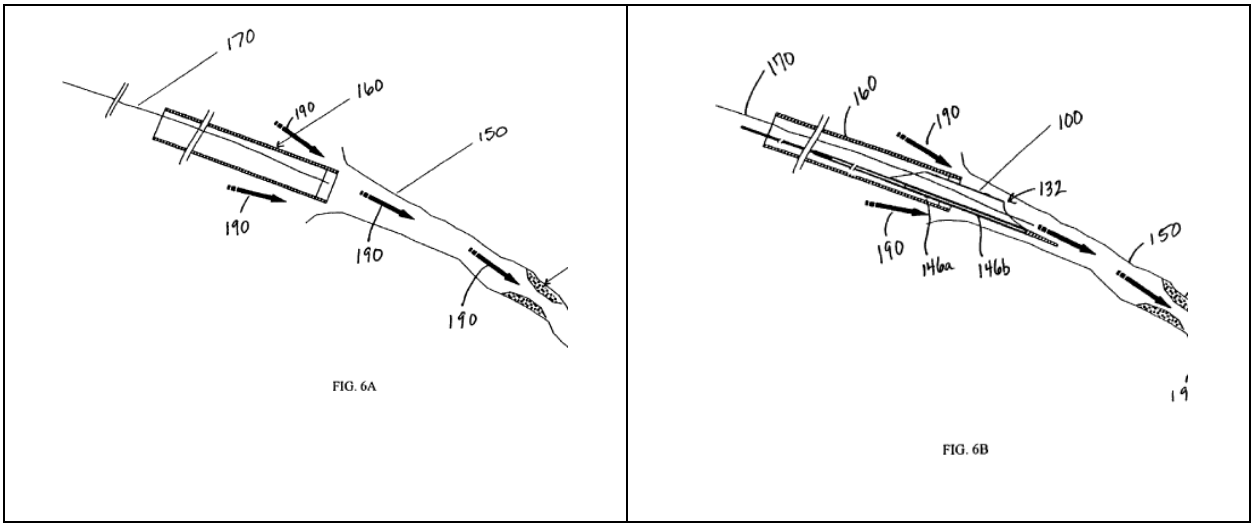
This is further evidenced by the function Itou discloses for proximal, wire-like portion (25), which is to advance suction catheter (2) to a deep location in the coronary vasculature. Ex-1607, 5:43-46. It was well understood in the art that in order to advance through the coronary vasculature, a catheter's proximal portion necessarily had to be sufficient rigid (stiff) to permit the catheter to be pushed through the vasculature, while its distal end was fairly flexible. Ex-1619, 9:30-50; Ex-1672, 2:29-43; Ex-1642, ¶¶ 27-32, 35; Ex-1605, ¶¶ 53-55.

VIII. GROUND 2: ITOU RENDERS CLAIMS 48, 51 AND 53 OBVIOUS IN VIEW OF RESSEMANN AND THE COMMON KNOWLEDGE OF A POSITA.

A. Ressemann

Ressemann was filed on August 9, 2002, issuing as U.S. Pat. No. 7,604,612 on October 20, 2009. It is prior art under both pre-AIA §102(e) and post-AIA § 102(a)(1), (2), and was not cited or considered during prosecutions of the original '850 patent, or the '760 reissue patent. Exs-1601-1603.

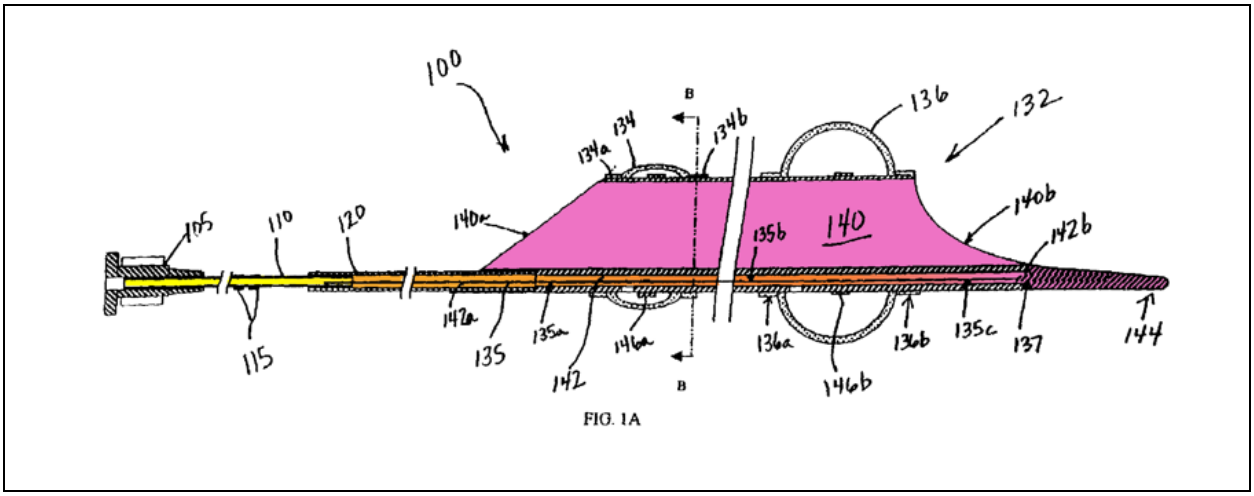
Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1608, Abstract. The assembly includes a GC, which "may be positioned within the ostium of a target vessel," *id*., 12:26-27, and an evacuation sheath that is coaxially insertable through the GC, and advanceable beyond the GC's distal end to treat stenosis. *Id*., Abstract, Figs. 6A-F, 6:18-24, 12:9-14:39.



Id., Fig. 6A-B.

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

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



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

The shaft includes proximal, intermediate, and distal portions. Proximal shaft (110) (above, yellow) is a hollow tube (preferably stainless steel). *Id*., 10:36-42. Intermediate shaft (120) (yellow transitioning to pink) —a hollow, polyethylene or Pebax tube—is more flexible than shaft (110). *Id*., 10:63-11:10. Distal shaft (transitioning to pink) includes the evacuation head, *id*., 10:31-35, as well as an inflation lumen for sealing balloons (134, 136), and may include soft distal tip (144) made of a polymer more flexible than the head, so as to ensure atraumatic insertion into blood vessels. *Id*., 11:11-28; Ex-1605, ¶¶ 99-102, 147-153; Ex-1642, ¶¶ 47-52, 119-129.

As explained in §VII.B.6, Itou's suction catheter (2) has the structure that would allow it to receive "one or more stents or balloon catheters when the segment defining the side opening" is positioned within the guide catheter (claims 48.c.iii, 51.c.iii, 53.c.iii). To the extent Patent Owner argues that Itou's teachings—alone—are insufficient to anticipate claims 48, 51 and 53, then they are rendered obvious by Itou in view of Ressemann and the knowledge of a POSITA. Ex-1605, ¶¶ 203-246.

B. Claims 48, 51, 53

Claim Language	Evidence & Corresponding Disclosure
[48.pre] through [48.c.ii];	*Supra*, §§ VII.B.1-5
[51.pre] through [51.c.ii], [51.d] through [51.e];	*Supra*, §§ VII.C.1-5, VII.C.7-8.
[53.pre] through [53.c.ii], [53.d] through [53.e]	*Supra*, §§ VII.D.1-5, VII.D.7-8.

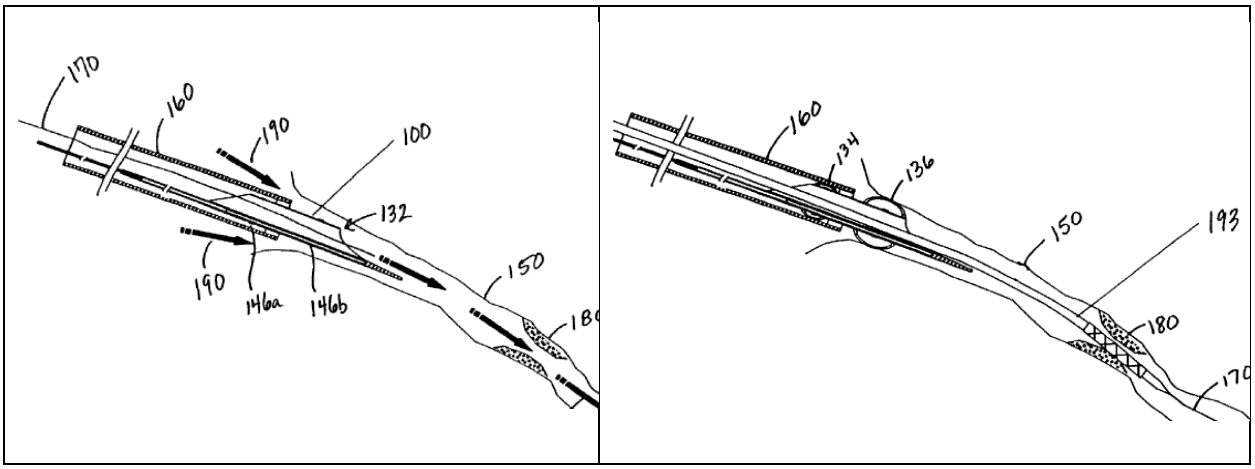
1. 48.c.iii, 51.c.iii, 53.c.iii

Itou discloses structure sufficient to meet this limitation, *supra*, §§ VII.B.1-5; §§ VII.C.1-5, VII.C.7-8; §§ VII.D.1-5, VII.D.7-8.7; alternatively, Itou and Ressemann render it obvious. Ex-1605, ¶¶ 203-246.

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

Ressemann teaches an evacuation head with a diameter that is large enough to "allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, atherectomy catheters . . . ." Ex-1608, 10:17-21, 12:5-8. Ressemann further teaches that the evacuation sheath should be advanced through

a GC until the head's (a) distal end is distal to the distal end of the GC, and (b) proximal end remains in the GC. *Id*.; 12:19-26, Fig. 6B (below, left).



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

As Dr. Brecker explains, a POSITA would be motivated to combine Itou with Ressemann because the latter explicitly explains that it was advantageous for an aspiration catheter to include a distal lumen of sufficient diameter for use in delivering an interventional cardiology device. Ex-1605, ¶¶ 204-212; Ex-1642 ¶¶ 95-100; *and see* Ex-1619, 3:4-6, 3:34-37 (explaining that an aspiration catheter is "preferably sized so as to allow the slidable insertion of a therapy catheter through the main" lumen of the aspiration catheter). And this is because angioplasty and coronary artery stenting come with a risk of embolization. Ex-1605, ¶¶ 213-220; Ex-1628, 1285; Ex-1629, 172, 176.

Those working in the field knew that PCI such as angioplasty or stent delivery "may break free fragments of friable plaque." Ex- 1605, ¶ 221; Ex-1615b, 629. Accordingly, it was beneficial to be able to remove emboli from a coronary artery (or graft) when delivering a stent. Thus, there was a motivation to combine stent delivery with embolic protection, Ex-1615, 629-630, and a reasonable expectation of success. Ex-1628, 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-1629, 172, 176 (explaining that distal embolization during primary PCI is frequent, and reporting the safe and effective use of embolic protection with stenting). 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-1608, 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."); Ex-1605, ¶¶ 204-223.

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

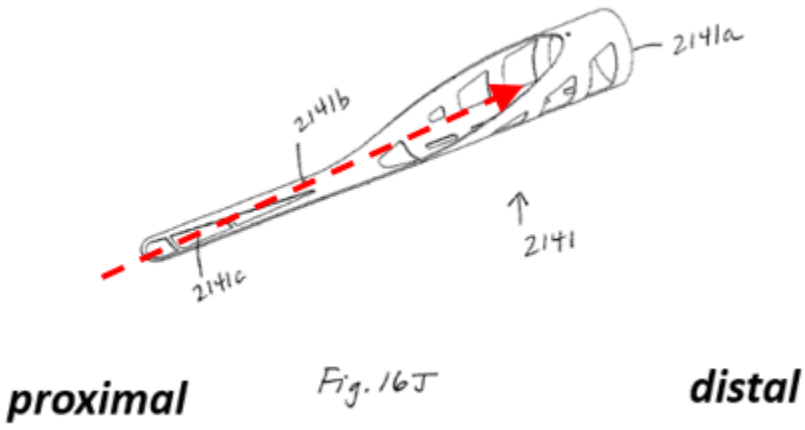
[and] stent delivery catheters . . . .” Ex-1608, 10:17-21, 22:63-23:4. PTCA catheters were insertable through support catheters with an 0.045 inch inner lumen. Ex-1609 (“Kontos”), 4:46-50, 4:61-64. Angioplasty procedures had been performed through 4 French diagnostic catheters. Ex-1620 (“Mehan”), 22. 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-1605, ¶¶ 224-227.

Similarly, Itou taught a suction catheter with an inner diameter of 1.5 mm, Ex-1607, Table 1. By reference to Ressemann, Kontos and Mehan, a catheter with an inner diameter of 1.5 mm is large enough to accommodate 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 such appropriately sized stents were available before the purported invention of the ’760 patent. Ex-1605, ¶¶ 228-234; *supra*, § VII.B.6.

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-1621, 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-1605, ¶¶ 235-238.

Second, Ressemann discloses "a side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis." (dotted arrow below)



Ex-1608, Fig. 16J (annotation added).

Metal collar 2141 includes cylindrical portion 2141a that "fits into the proximal opening of the evacuation lumen," providing hoop support. *Id.*, 24:55-58. "Distal tab 2141b" serves as a "flexibility transition" between the proximal end of the evacuation head and the evacuation sheath's shaft. *Id.*, 24:62-67. As illustrated above, collar 2141 forms a concave track. *Id.*, Fig. 16J; Ex-1605, ¶¶ 109, 239-40; Ex-1642, ¶¶ 98-100.

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

First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because s/he understood that it was large enough to be used to deliver a balloon and stent catheter, as explained above. By modifying the suction catheter (2)'s proximal opening with Ressemann's collar 2141, the area for receiving a stent and/or balloon catheter is larger. Ex-1605, ¶¶ 241-43; Ex-1642, ¶¶ 95-101.

Second, tab 2141b's concavity ensures that adding the collar does not impede entry into the inflation lumen. Ex-1642, ¶¶ 105-06. 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-1608, 6:52-57, 23:17-20. The collar adds material to the lumen opening, as it is .002 inches thick. *Id*., 25:10. And tab 2141b ranges from .020 to .050 inches in width. *Id*., 25:11-13. Because tab 2141b is concave it does not interfere with introducing a balloon or stent catheter into the angled opening of the inflation lumen. The same holds true for adding the collar to the proximal opening of the tubular portion of Itou's suction catheter 2. Ex-1605, ¶¶ 239-243; Ex-1642, ¶¶ 95-112.

A POSITA would have had a reasonable expectation of success because adding Ressemann's collar to Itou's suction catheter 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.

IX. GROUND 3: ITOU RENDERS CLAIM 52 OBVIOUS IN VIEW THE COMMON KNOWLEDGE OF A POSITA.

A. Claim 52. The system of claim 51, wherein a longitudinal length of the reinforcing braid or coil is between 20 to 30 cm.

Claim 52 is obvious. Ex-1605, ¶¶ 247-253. Itou discloses a reinforcing braid or coil, *supra*, § VII.C.8, but it does not extend "between 20 to 30 cm," because the entire length of the catheter's tubular portion (of which only a part is reinforced) is only 150 mm (or 15 cm). Ex-1607, Table 1.

Itou, however, explains that the tubular portion ***can be up to 200 mm in length*** (or 20 cm). Ex-1607, 6:7-10 (emphasis added). In this scenario, though, at least the distal 2 mm of the suction catheter would not be reinforced, because the catheter tip must be soft and flexible, to avoid damaging the blood vessel. *Id*., 2:15-21; Ex-1615, 549 (explaining that guide catheters include "a very soft material in the most distal 2 mm).

As Dr. Brecker and Dr. Hillstead explain, a POSITA had motivation to lengthen the tubular portion of Itou's catheter (2), to be longer than just 20 cm. Ex-1605, ¶¶ 247-253; Ex-1642, ¶¶ 114-118. As explained herein, a POSITA

understood that the tubular structure of Itou's catheter (2) was configured so that it could be used to receive a stent or balloon catheter, and had the motivation to use it in this fashion. *Supra*, §§ VII.B.6, VIII.B.1.

By the time of the '760 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-1636, 2948-49. 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-1646, 1:39-47. 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. In particular, for a catheter to reach a "desired remote location in a bodily passageway, such as a small, tortuous artery," it was advantageous for the "less flexible section . . . [with] greater pushability . . . to comprise a substantial portion of the length of the catheter," while the more distal and more flexible portion could be up to 30 cm in length. Ex-1672, 2:23-44. Thus, in the case of Itou's catheter (2), a POSITA would be aware that tubular structure (24) should be increased in

length, up to 30 cm, to accommodate reaching lesions located in particularly tortuous vessels. And, in this instance, the longitudinal length of the reinforcing braid or coil on catheter (2) would be between 20 to 30 cm. Ex-1605, ¶¶ 247-253; Ex-1642, ¶¶ 114-118.

X. GROUND 4: RESSEMANN RENDERS CLAIMS 48 AND 51-53 OBVIOUS IN VIEW OF TAKAHASHI AND THE COMMON KNOWLEDGE OF A POSITA.

A. Takahashi

Takahashi et al. (Ex-1610, "Takahashi") is entitled *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*" and published in 2004, making it prior art under at least pre-AIA § 102(b) and post-AIA §102(a)(1). Ex-1678, ¶¶ 43-52. Takahashi is cited in the '760 patent's Background, but was not the basis of an Examiner rejection during prosecution (Exs-1601-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d).

Takahashi explains that "[t]he five-in-six system is a method of inserting a 5 Fr guiding catheter . . . into a 6 Fr guiding catheter to increase backup support." Ex-1610, 452; Ex-1605, ¶¶ 154-157; Ex-1642, ¶¶ 53-56. Takahashi states that the inner lumen of the 5 French and 6 French catheters is 0.059 inches and 0.071 inches (Ex-1610, 452), which is less than a 1 French difference in inner diameters. Ex-1662, 545.

B. Claim 48

1. 48.pre

To the extent the preamble is limiting, Ressemann discloses it as set forth below. Ex-1605, ¶ 254.

2. 48.a

Ressemann discloses this limitation. Ex-1605, ¶ 255.

As Dr. Brecker explains, Ressemann teaches a guide catheter 160 that is used with an evacuation sheath assembly 100 sized to fit therein. Ex-1608, Abstract, 6:18-24, 28:26-29. The guide catheter 160 is advanced through a "main blood vessel," the aorta, *id*., Fig. 5A, and its distal end is then "positioned within the ostium of the target vessel," a coronary artery. *Id*., 12:26-30, Fig. 5A, 22:38-45, 28:31-32. At its proximal end, the guide catheter 160 is attached to "[a] suitable valve 184, such as a touhy borst valve." *Id*., Fig. 5A, 12:45-49; *and see id*., 28:32-36.

The guide catheter necessarily has a "lumen extending from a hemostatic valve" (at its proximal end) to its distal end. Ex-1605, ¶ 255.

First, Ressemann discloses that an evacuation sheath assembly fits inside the guide catheter, and is advanced so that the its distal end is extended from the guide catheter's distal end and into a blood vessel to treat a stenosis. Ex-1608, 6:18-24,

Fig. 6B, 12:9-30, 22:38-45. Second, Ressemann explains that the valve attached to the guide catheter's proximal end provides a fluid tight seal against the proximal end of the evacuation sheath assembly. *Id*., 12:45-52 (describing use of a conventional "Y-adaptor"), [12] *and see id.*, 10:47-53, 28:32-36. Third, the "guiding catheter 160 performs an evacuation function in combination with the evacuation lumen 140 [of the evacuation sheath]," and "also maintains a contrast delivery function." *Id*., 9:30-33; *and see id*., 29:14-16, 29:56-59.

Advancing sheath 100 through guiding catheter 160 into the vasculature, as well as the use of the GC for evacuation and contrast delivery functions necessarily evidence a lumen extending from a hemostatic valve at the guide catheter's proximal end to the guide catheter's distal end. Ex-1605, ¶ 255.

[12] Ressemann's disclosure reflects what the '760 patent admits, which is that the "guide catheter . . . can be delivered through ***commonly existing hemostatic valves*** used with guide catheters while still allowing injections ***through the existing Y adapter***." Ex-1601, 3:28-31. Similarly, Patent Owner's expert in the co-pending litigation explains that a hemostatic valve is sometimes called a Y-connector. Ex-1682, ¶ 18, which is also known as a Y-adapter. Ex-1605, ¶ 255.

3. 48.b

Ressemann discloses this limitation. Ex-1605, ¶ 256.

As illustrated below, evacuation sheath assembly (100)—the claimed "guide extension catheter"—includes a distal tip (144) (pink), a distal opening (140b) to head (132)'s evacuation lumen (140), and a shaft that includes proximal shaft (110) (yellow). *Id*., 6:35-57, 10:47-53; *and see id.*, 23:8-20, 24:20-32, 27:22-36, 27:51-53.

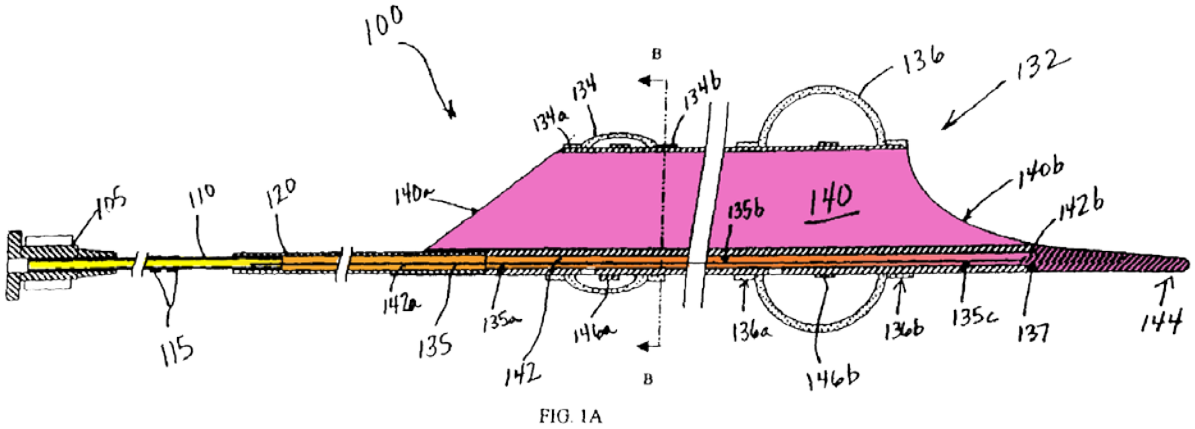


FIG. 1A

Ex-1608, Fig. 1A (color added); *and see id.*, Figs. 16 A-B, 16F-G.

Ressemann teaches that sheath (100)'s distal end may be partially advanced through guiding catheter (160) into the coronary artery. *Id*., Figs. 5A, 6A-C, 6:18-24, 12:9-49; *and see id.*, 21:42-51, 29:56-59.

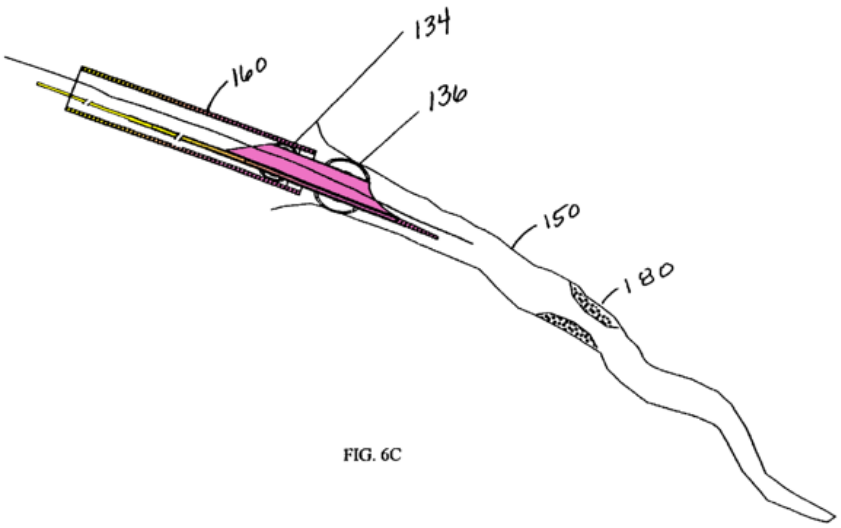


FIG. 6C

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

Ressemann also explains that the proximal portion of proximal shaft (110) extends through the valve at guiding catheter 160's proximal end. *Id*., 12:45-53, Fig. 5A; *and see id.*, 27:22-36, 28:50-55.

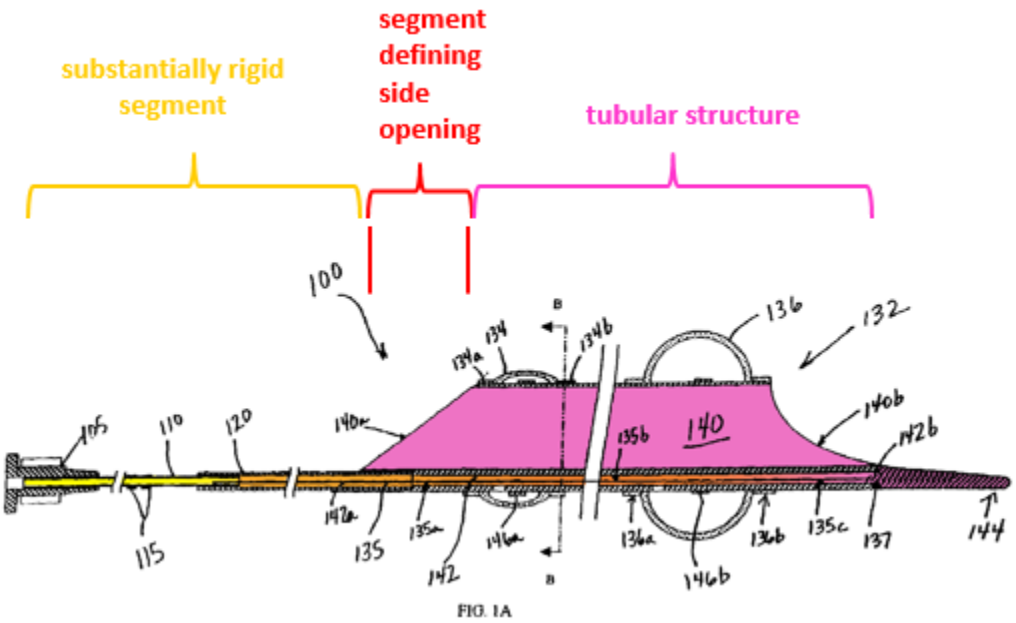
Thus, evacuation assembly (100) necessarily is long enough so that when its distal end is "extendable through the lumen and beyond the distal end of the guide catheter," its proximal end is "extendable through the hemostatic valve at the proximal end of the guide catheter." Ex-1605, ¶ 256.

4. 48.c.i

Ressemann discloses this limitation. Ex-1605, ¶ 257.

At its proximal end, sheath assembly (100) includes proximal shaft (110) (below, yellow) and intermediate shaft (120) (yellow transitioning to pink), which

form a "substantially rigid segment" because they are used to advance the evacuation sheath through a guide catheter so that the sheath's distal end is extended into a vessel to treat a stenosis. Ex-1608, 6:18-24, 10:47-11:14; *and see id.*, 27:22-36, 27:51-53. Thus, shaft (110) and shaft (120) are sufficiently rigid to allow evacuation sheath (100) to be advanced within the guide catheter, as shown in Figs. 6A-F. *Supra*, §6 (construing "substantially rigid"). Ex-1605, ¶ 257.



Ex-1608, Fig. 1A (color and annotation added).

Moving distally, Ressemann discloses a segment defining a side opening, shown above in a dotted red box. That segment is a portion of evacuation head 132. It includes 140a, which is the proximal opening to the evacuation lumen 140. *Id.*, 6:35-60. Because head 132 includes distal shaft 130, *id.*, 10:31-35, the segment defining a side opening also includes the portion of shaft 130 that is adjacent 140a.

Distal to opening 140a is a tubular structure, "multi-lumen tube 138," which defines evacuation lumen 140. *Id*., 6:35-47. The claimed "tubular structure" is the portion of the evacuation lumen 140 that is distal to 140a. [13] Ex-1605, ¶ 257.

As Dr. Brecker explains, lumen (140) is coaxial and in fluid communication with guiding catheter (160)'s lumen. As illustrated below, sheath assembly 100 is coaxial to guiding catheter (160), and side opening 140a of lumen 140 opens into guiding catheter (160)'s lumen, such that fluid may flow between the catheters.

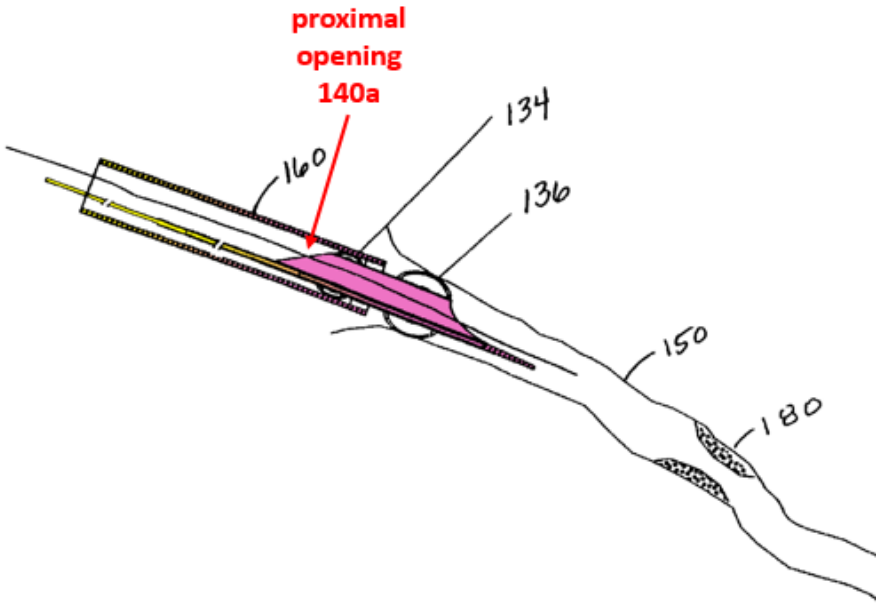


FIG. 6C

[13] As Patent Owner's expert witness, Peter Keith testified, "just because something is proximal to something else doesn't mean that it has to be ***entirely*** proximal." Ex-1677, 293:13-294:3 (emphasis added).

Id., Fig. 6C (color and annotations added); *see id.*, Figs. 16A-B, 16F-G; 29:56-59.

The fluid communication between the guide catheter lumen and the evacuation lumen of sheath assembly (100) is confirmed by Ressemann's teaching that guiding catheter (160) "performs an evacuation function in combination with lumen 140." It is also confirmed by Resseman's explanation that evacuation head (132) is intended to "isolate fluid communication of the internal lumen of guide catheter 160 to the blood vessel" into which the assembly is inserted. *Id*., 9:30-36; *and see id.*, 22:38-46, 23:11-16, 29:26-28, 29:56-59; Ex-1605, ¶ 257.

5. 48.c.ii

Ressemann renders this limitation obvious in view of Takahashi and the common knowledge of a POSITA. Ex-1605, ¶ 258.

Ressemann teaches that the lumen of the tubular structure is shorter than the lumen of guiding catheter (160). The tubular structure that is formed by evacuation lumen 140 is part of evacuation head (132), which—for native, coronary artery applications—may be up to 20 cm in length. Ex-1608, 10:11-12; *see id.*, 22:45-47 (disclosing an embodiment with an evacuation head that may be up to 40 cm in length). Thus, the tubular structure in Ressemann is not longer than 20-40 cm in length.

Ressemann is silent on the length of guiding catheter (160). But, as Dr. Brecker explains, the "standard guiding catheter length" was 100 cm. Ex-1615, 549; *and see* Ex-1610, 452 (Takahashi, describing guiding catheters that are 120 cm and 100 cm). And it would only be common sense to leverage a well-known technology, *Perfect Web Techs., Inc. v. Info USA, Inc*., 587 F.3d 1324, 1328 (Fed. Cir. 2009), such as a GC of a common length—as disclosed in Takahashi—with Ressemann's evacuation sheath 100. Thus, Ressemann discloses that a tubular structure with a lumen that has a length that is shorter than the length of the guide catheter's lumen.

Ressemann also teaches that the tubular structure has a "uniform cross-sectional inner diameter," as there is no taper shown in Figures 1A, 1C. Ex-1608, Figs. 1A, 1C; *and see id.*, Figs. 1B, 1D, 16 A-B, 16E-G.

Rressemann does not, however, teach that the tubular structure's lumen is "not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter." Ressemann explains that the evacuation lumen has an 0.061 inch diameter, which is 1.54 mm. Ex-1608, 10:17-21; Ex-1605, ¶ 258. It also teaches use of the assembly with a guiding catheter that is "8 French" with an 0.090 inch inner diameter, which is 2.28 mm. Ex-1608, 10:14-17. This is a size differential of 0.74 mm, which is greater than a "one French" differential of 0.33 mm. Ex-1662, 545. Ex-1605, ¶ 258.

Takahashi, however, discloses a guide extension catheter lumen that is "not more than one French size smaller than the cross-sectional inner diameter of the lumen of a guide catheter. Takahashi teaches inserting a 5 Fr catheter into a 6 Fr guiding catheter to increase backup support. Ex-1610, 452. Takahashi also states that the inner lumen of the 5 Fr and 6 Fr catheters is, respectively, 0.059 inches and 0.071 inches. *Id*. This is a differential of 0.012 inches, or 0.30 mm, which is less than 1 Fr. Ex-1605, ¶ 258; Ex-1662, 454.

As Dr. Brecker explains, based on Takahashi's teachings, a POSITA would have been motivated to modify Ressemann to achieve a differential between the inner diameter of evacuation lumen 100 and the inner diameter of a guide catheter that was not more than one French, Ex-1605, ¶ 258, and a POSITA would have been capable of achieving such a difference with a reasonable expectation of success.

Ressemann teaches that catheter (100) may be used to both aspirate embolic material (Ex-1608, Abstract, 12:9-13:34) ***and*** to deliver an angioplasty balloon or stent. *Id*., 6:25-34; *and see id.*, 23:8-20. By the time of the'760 patent, a POSITA had the motivation to modify the evacuation assembly of Ressemann to remove the sealing balloons. Ressemann could be modified for use solely as an extension catheter, and not as an aspiration catheter. Ex-1605, ¶ 258, Ex-1642, ¶¶ 150-154.

First, extension catheters were known in the art. *See* Ex-1609; Ex-1634. Second, modifying Ressemann's assembly 100 so that it did not have sealing balloons would have simplified the manufacturing process. Ex-1642, ¶ 154. Third, the modification would have decreased the outer diameter of assembly 100. Ex-1642, ¶ 154.

As Dr. Brecker and Dr. Hillstead explain, decreasing the outer diameter of assembly 100 would have been advantageous because it would have allowed assembly 100 to be used with smaller GCs. Ex-1605, ¶ 258, Ex-1642, ¶ 154. And using guide catheters smaller than the 8 French GC disclosed in Ressemann would have allowed PCI procedures to be performed via access through the radial artery instead of the femoral artery. This is desirable because bleeding is easier to control and patients are immediately ambulatory. Ex-1615, 91-92; Ex-1605, ¶ 258.

Moreover, a POSITA had the motivation to choose a guide catheter such that the inner diameter of the modified Ressemann assembly 100 was "not more than one French size smaller" than the cross-sectional inner diameter of the lumen of the guide catheter for the following reason. Takahashi explicitly taught that using a child catheter with a lumen "not more than one French size smaller" provides better back-up support for the guide catheter, and assists in deploying an angioplasty catheter across chronic total occlusions. Ex-1610, 452, 454, 456.

Thus, Ressemann in view of Takahashi renders this limitation obvious. Ex-1605, ¶ 258.

6. 48.c.iii

Ressemann discloses this limitation. Ex-1605, ¶¶ 259-268.

First, side opening 140a in assembly 100 extends for a distance from (a) to (b) along the catheter's longitudinal axis.

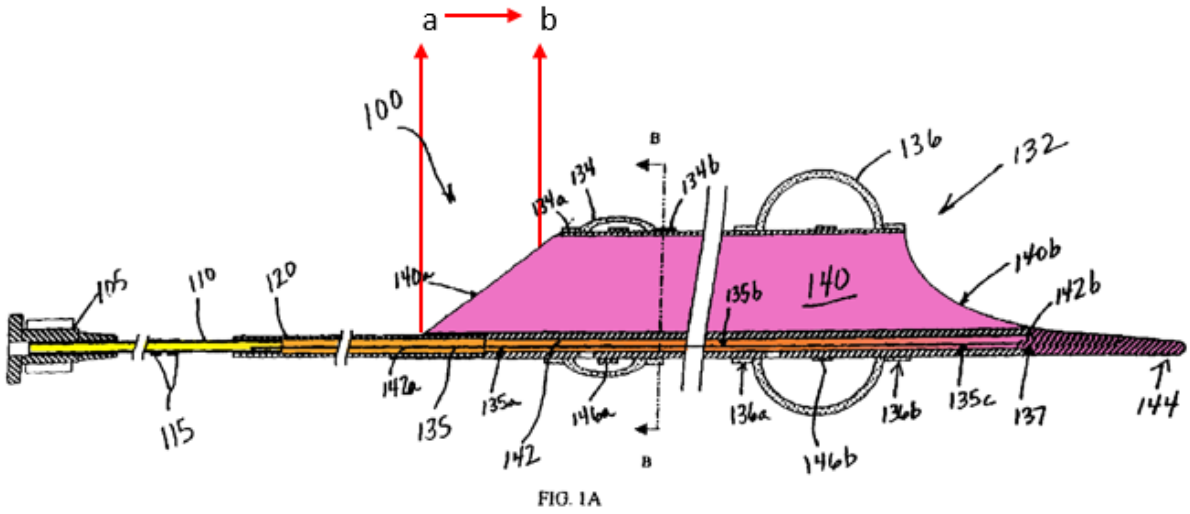


FIG. 1A

Ex-1608, Fig. 1A (color and annotation added); *and see id.*, Fig. 16A (2140a).

Moreover, Ressemann explicitly discloses that the side opening is "accessible from a longitudinal side defined transverse to the longitudinal axis," and that the

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

Ressemann teaches that lumen (140) "is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters." Ex-1608, 6:44-47; *and see id.*, 23:8-20. It also explicitly discloses inserting a balloon catheter and stent (193, below green) into assembly 100's side opening when it —and a proximal part of the assembly— remain within guiding catheter (160), while the assembly's distal end extends past the GC's distal end. Ex-1608, Figs. 6A-F, 12:9-14:10; *and see id.*, 29:56-59.

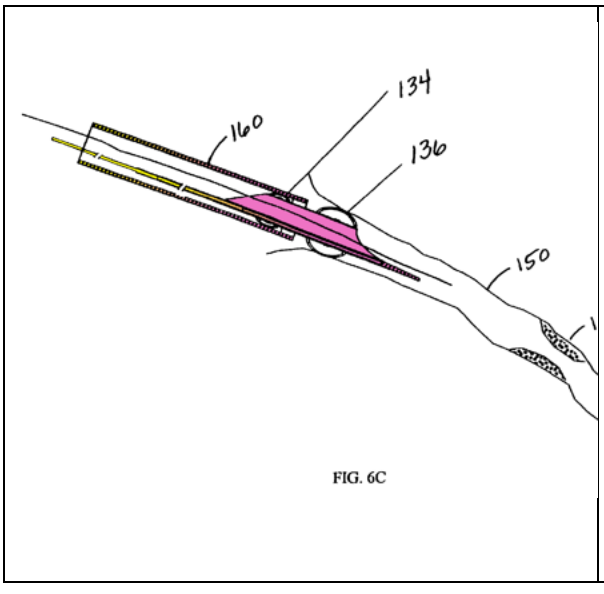


FIG. 6C

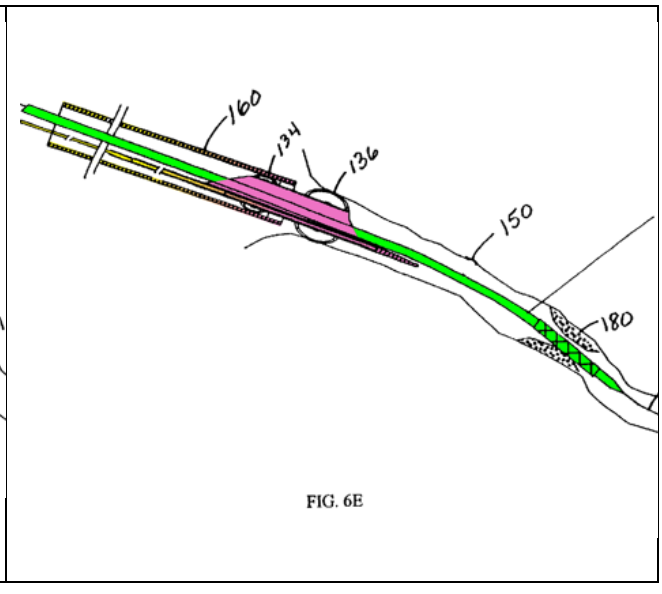
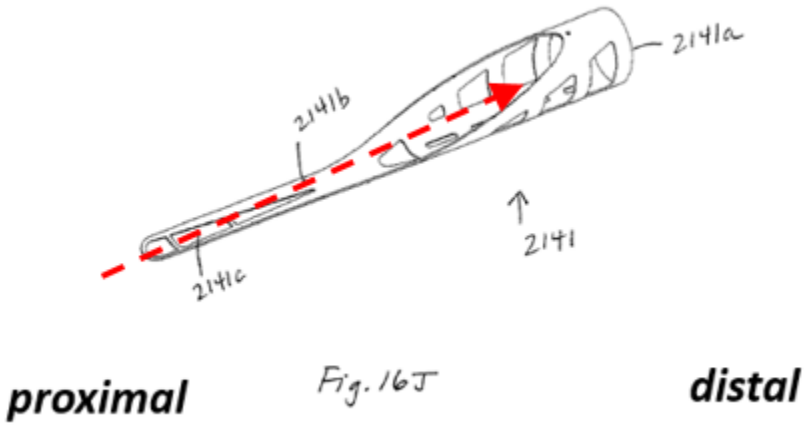


FIG. 6E

Id., Figs. 6C, 6E (color added).

Additionally, Ressemann discloses a support collar 2141, which, as shown below, ***also*** forms a "side opening and accessible from a longitudinal side defined transverse to the longitudinal axis." (dotted arrow).



Ex-1608, Fig. 16J (annotations added).

Ressemann explicitly discloses support collar 2141 for use with evacuation sheath 2100. Ex-1608, 24:47-67, 22:38-44, 23:8-20. Specifically, the cylindrical portion of collar 2141a fits into the proximal opening of the evacuation lumen. *Id*., 24:55-58. Tab 2141b extends proximally of the opening of the evacuation lumen

and provides a flexibility transition between the evacuation head and shaft. *Id*., 24:58-67.[14]

A POSITA would expect that support collar 2141 and evacuation assembly 100 (with evacuation head 132) are used together. And this is because Ressemann illustrates the use of support collar 2141 with an evacuation sheath assembly 2100 (including evacuation head 2132), explaining that "[m]any of the elements present in the previous embodiments are also shown in Figs. 16A-16J and ***where these elements are substantially the same, similar reference numbers have been used***." Ex-1608, 22:33-36 (emphasis added). Accordingly, lumen 140 in evacuation sheath 100 (Figs. 1A-D) is substantially the same as lumen 2140 in evacuation sheath 2100 (Figs. 16A-J). And Ressemann teaches that support collar 2141 serves to reinforce the evacuation lumen's proximal opening "in the presence of deforming forces" in the same way for both evacuation lumens. Ex-1605, ¶¶ 262-267; Ex-1642, ¶¶ 130-143. Thus, Ressemann provides explicit motivation to modify lumen 140's proximal opening with collar 2141. And—whether support collar

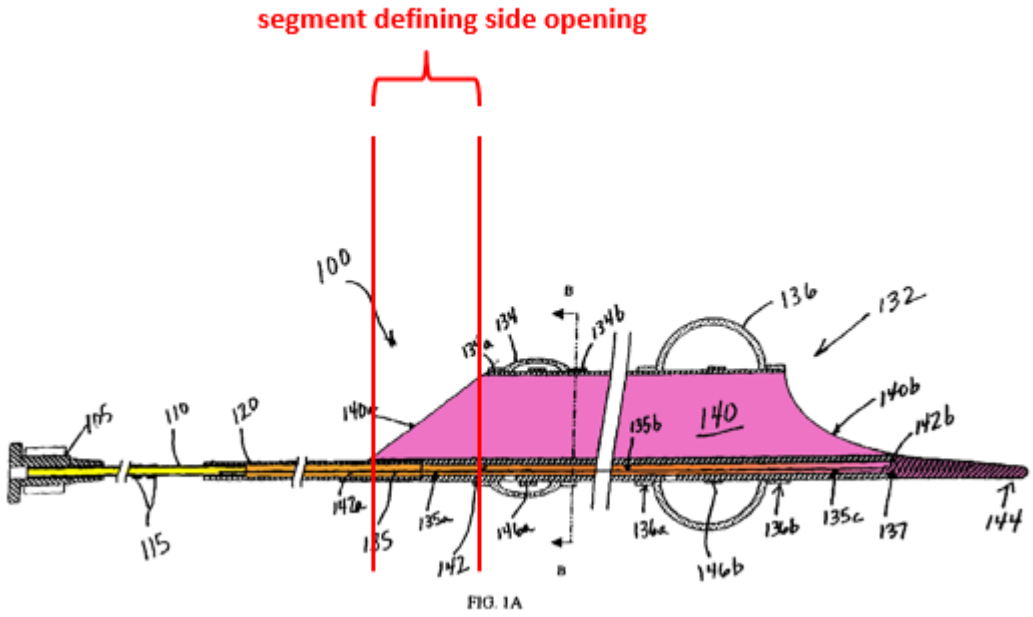
[14] Just as Ressemann's teachings regarding evacuation sheath 100 render claim 48 obvious, so, too, do its teachings regarding sheath 2100. *Supra*, §§ X.B.1-6; *infra*, § X.B.7 (*citing* Ex-1608, Figs. 16 A-B, 16E-G; *see generally id.*, 22:1-29:67).

2141 is added to assembly 2100, or to assembly 100—limitation 48.c.iii is disclosed. Ex-1605, ¶¶ 259-268.

7. 48.d

Ressemann discloses this limitation. Ex, 1605, ¶ 269.

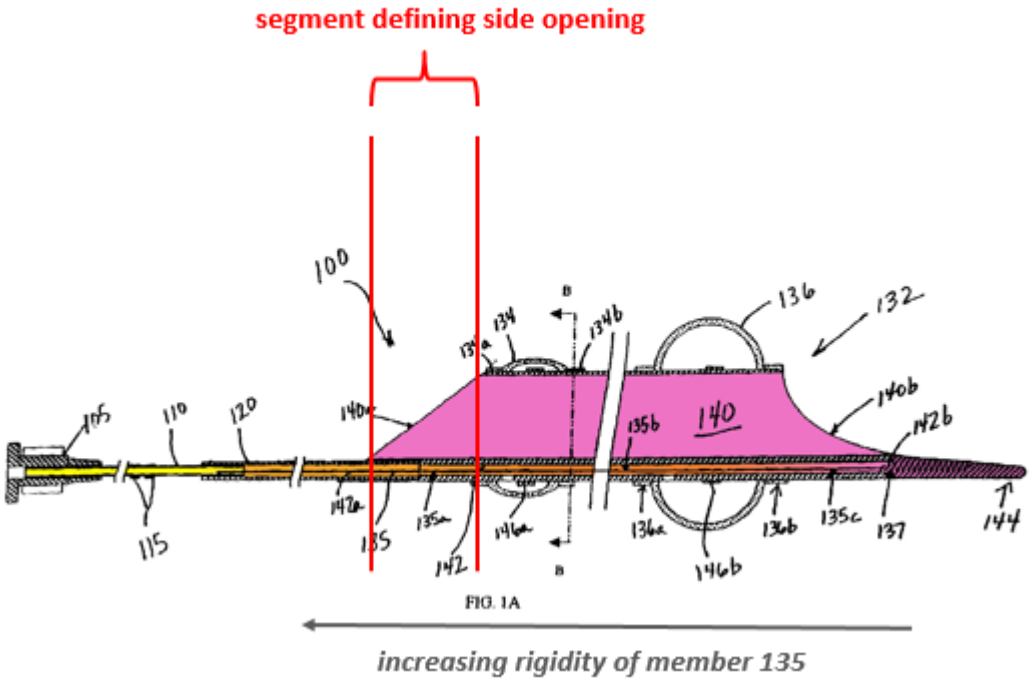
First, as discussed for 48.c.i, the "segment defining the side opening" is illustrated below.



Ex-1608, Fig. 1A (color and annotation added).

The segment defining the side opening includes the proximal opening, 140a, of evacuation lumen 140, which is part of a multi-lumen tube "made of a relatively flexible polymer such as low density polyethylene, polyurethane, or low durometer Pebax® material." Ex-1608, 6:35-39; *and see id.*, 22:54-58, 24:20-32.

The segment defining the side opening also includes the portion of distal shaft (130) that is adjacent opening 140a. *Id.*, 10:30-35; *and see id.*, Figs. 16 A- B, 16E, 23:21-40.



Ex-1608, Fig. 1A (color and annotations added).

Distal shaft (130) contains an inflation lumen in which stiffness transition member (135) is located. Member (135) is "preferably made of stainless steel." *Id.* 11:29-39. Ressemann teaches that the member (135)'s rigidity increases gradually from its distal end (adjacent tip 144) to its proximal end. *Id.*, 11:29-40. The change in stiffness is preferably accomplished by "reducing the cross sectional area" of

member 135 so that its diameter decreases from 135a to 135b to 135c. *Id.*, 11:59-63.

Thus, Ressemann discloses that the "segment defining the side opening" includes both a relatively flexible polymer as well as a portion of a shaft and stiffness transition member, where the stiffness transition member is more rigid than it is along more distal portions of the evacuation head. By contrast, the tubular structure's distal end portion is made of soft polymer. *Supr*a, § X.B.4.

Given the difference in the materials that form the "segment defining the side opening" compared to the matrial that forms evacuation lumen 140, the former is necessarily more rigid than the latter. Ex-1605, ¶ 269; Ex-1642, ¶¶ 119-127, 144-149.

Additionally, Ressemann discloses a support collar 2141. Ex-1608, 24:47-25:16. As discussed for 48.c.iii, § X.B.6, *supra*, a POSITA would expect that support collar 2141 and evacuation assembly 100 (including evacuation lumen 140) are used in conjunction. Adding collar 2141 to assembly 100's proximal side opening 140a adds a metal lining (or a lining with another, suitably rigid material). By contrast, the more distal portion of lumen 140 lacks the support of collar 2141. This, too, results in the "segment defining the side opening" of assembly 100 being more rigid than the tubular structure. Ex-1605, ¶ 269; Ex-1642, ¶¶ 130-143.

C. Claim 51

1. 51.pre

To the extent the preamble is limiting, Ressemann discloses it as set forth below (and for claim 48). *Supra* § X.B.1; Ex-1605, ¶ 254, 270.

2. 51.a

Ressemann discloses this limitation. *Supr*a, § X.B.2; Ex-1605, ¶¶ 255, 271.

3. 51.b

Ressemann discloses this limitation. *Supr*a, § X.B.3; Ex-1605, ¶¶ 256, 272.

4. 51.c.i

Ressemann discloses this limitation. *Supr*a, § X.B.4; Ex-1605, ¶¶ 257, 273.

5. 51.c.ii

Ressemann discloses this limitation. *Supr*a, § X.B.5; Ex-1605, ¶¶ 258, 274.

6. 51.c.iii

Ressemann discloses this limitation. *Supr*a, § X.B.6; Ex-1605, ¶¶ 259-68, 275.

7. 51.d

Ressemann renders this limitation obvious. *Supra*, § X.B.7; Ex-1605, ¶¶ 269, 276-81.

Assembly 100 includes soft tip 144, which allows it "to be placed atraumatically into the blood vessel, even if the blood vessel exhibits tortuosity." Ex-1608, 11:25-28. Tip 144 is made of a more flexible polymer than the tubular

structure of evacuation head 132, for example a "low durometer polyurethane or Pebax." *Id*., 11:22-25.

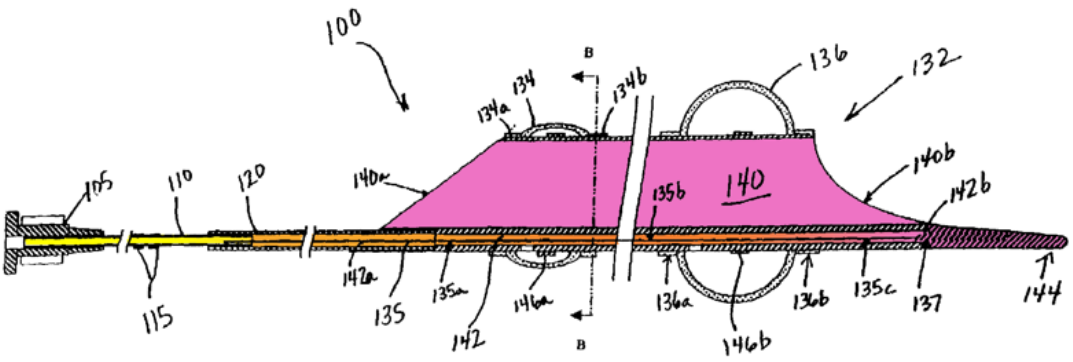


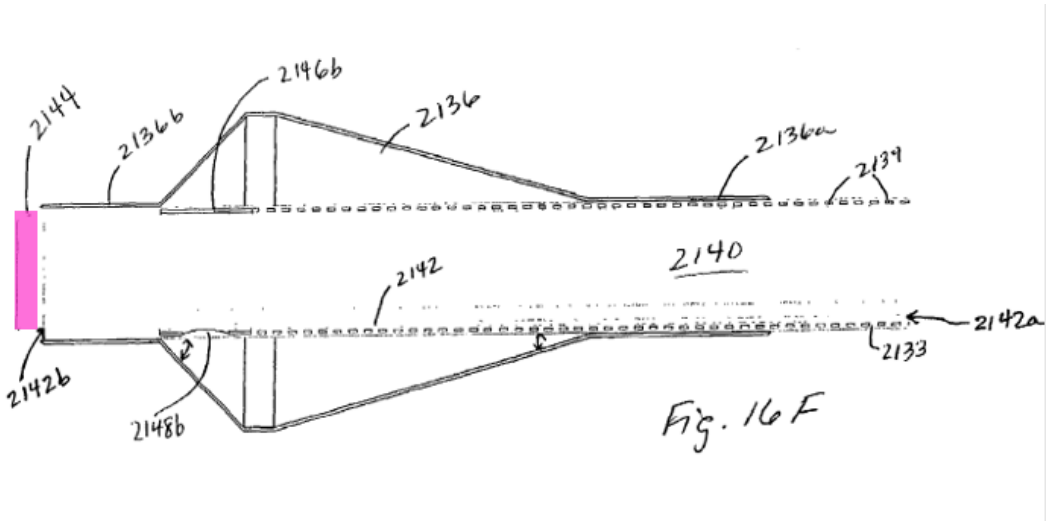
FIG. 1A

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

Thus, Ressemann teaches a "tip portion" that "includes an atraumatic bumper formed from a flexible material." Tip 144 does not, however, have a lumen that is continuous with Ressemann's evacuation lumen 140.

Ressemann teaches an alternative embodiment to the embodiments shown in Figures 1A-D, in which the evacuation lumen's distal end is made of soft polyurethane and is not cut at an angle, but, instead, cut perpendicularly (2144) to the longitudinal axis of the lumen (2140). Ex-1608, 24:20-29. Just as Ressemann's teachings regarding evacuation sheath 100 render claim 51 obvious, so, too, do its teachings regarding sheath 2100. *See supra*, §§ X.B.1-7 (citing Ex-1608, Figs. 16A-B, 16E-G; *see generally id*., 22:1-29:67). In this embodiment 2100,

Ressemann's atraumatic tip 2144 has a lumen that is co-extensive with lumen 2140. And, like the embodiments disclosed in Figs. 1A-D, the embodiment in Fig. 16F may be used to both aspirate embolic material (Ex-1608, Abstract, 12:9-13:34) ***and*** to deliver an angioplasty balloon or stent. *Id*., 28:44-49.



Id., Fig. 16F (color added).

While Ressemann teaches that a perpendicular distal tip 2144 is "useful when the anatomy is such that an angled distal end would contact the vessel wall in such a way that would limit fluid flow through the evacuation lumen 2140, *id*., 24:29-32, a POSITA would also be motivated to use a perpendicular tip even if, for the reasons discussed above, s*upr*a, § X.B.5, Ressemann were modified for use solely as an extension catheter. Ex-1642, ¶¶ 155-63; Ex-1605, ¶¶ 276-81.

As Dr. Brecker and Dr. Hillstead explain, catheters used to deliver therapy catheters typically included a "very soft material in the most distal 2 mm of the catheter to reduce the chance of vessel trauma." Ex-1615a, 549; *see* Ex-1654, 2:37-40 (teaching to include a "soft tip" that is "appropriately rounded to avoid sharp edges" on a child catheter); Ex-1605, ¶ 280; Ex-1642, ¶ 159.

Including an atraumatic bumper at the tip of the tubular structure in the form of 2144 would simplify the manufacturing of the assembly because it would eliminate the step of having to secure tip 144 to the distal end of tube 138. Ex-1608, 11:20:22; Ex-1605, ¶ 281; Ex-1642, ¶ 160.

Thus, Ressemann and the common knowledge of a POSITA render this limitation obvious. Ex, 1605, ¶ 276-281.

8. 51.e

Ressemann renders this limitation obvious. Ex, 1605, ¶ 282-85.

Ressemann teaches that tube (138) may be reinforced with a kink-resistant structure, coil (139). Ex-1608, 6:66-7:7. Ressemann also discloses radiopaque marker bands 146b towards assembly 100's distal end. *Id*., 7:23-26, 9:36-38. These markers are not, however, positioned "distal to the distal end" of the reinforcing coil. They are placed at the locations of the distal sealing balloon. *Id*., 9:17-20

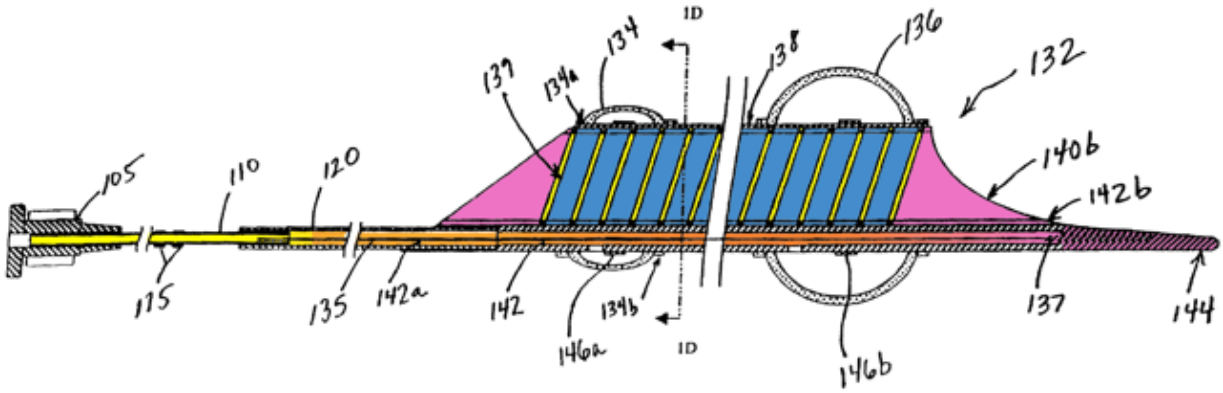
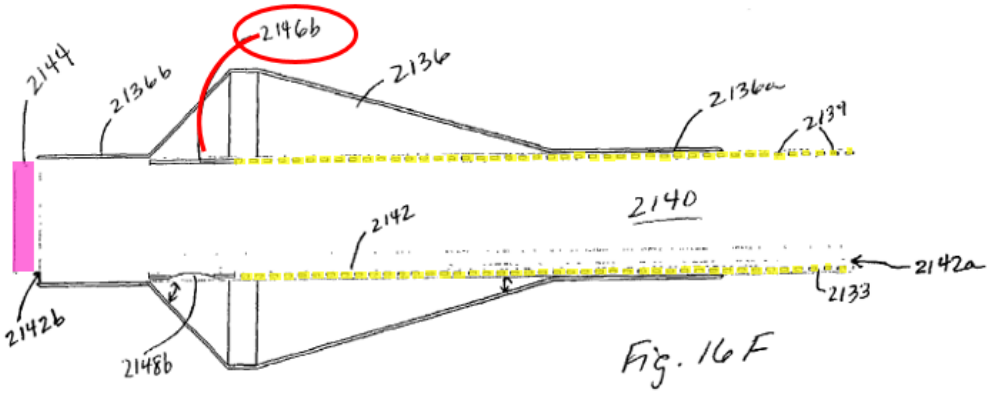


FIG. 1C

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

Ressemann discloses an alternative embodiment, in Fig. 16F, in which radiopaque marker bands are placed distal of coil 2139. *Id*., 23:55-24:2.



Id., Fig. 16F (color and annotation added).

A POSITA had the motivation to modify Ressemann to use solely as an extension catheter, and not also as an aspiration catheter, for reasons discussed above. *Supra*, § X.B.5. Given this modification, a POSITA would have moved the

distal marker bands disclosed on the embodiment shown in Figure 1C so that they were positioned further distally, as shown in Figure 16F. Ex-1605, ¶ 285; Ex-1642, ¶¶ 162-63. As Dr. Brecker and Dr. Hillstead explain, those of ordinary skill in the art were accustomed to having radiopaque marker bands on catheter distal ends, including on extension catheters. Ex-1634, 7:9-12 (explaining that radiopaque markers assist in positioning a child catheter relative to a guide catheter).

Thus, Ressemann and the common knowledge of a POSITA render this limitation obvious. Ex-1605, ¶ 282-285.

D. Claim 52

As discussed herein, Ressemann renders obvious claim 51, including disclosing a longitudinal length of reinforcing coil, coil 139. which extends along the majority of the length of evacuation head 132.

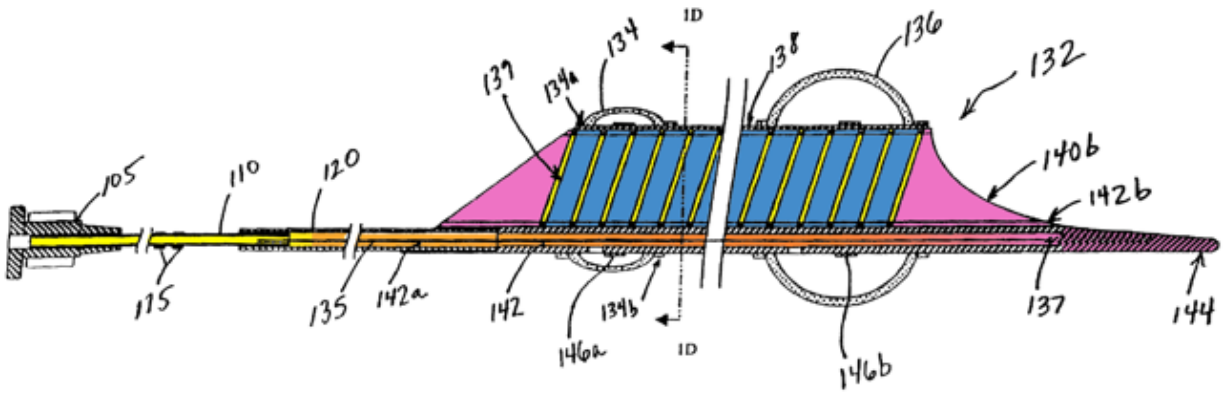


FIG. 1C

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

Ressemann teaches that evacuation head 132's length (in embodiment 100) is up to 20 cm in length, but also that the head's length is dependent on application. Ex-1608, 9:63-65, 10:11-12. Ressemann additionally teaches another embodiment, 2100, with a head length of up to 40 cm. *Id*., 22:45-47. Ex, 1605, ¶¶ 288-290.

For the reasons articulated in Ground 3, a POSITA would be motivated to make evacuation head (132) longer, increasing its length up to 30-40 cm to accommodate reaching lesions located in particularly tortuous vessels. Ex-1605, ¶¶ 247-53; Ex-1642, ¶¶ 114-18. And, in this instance, the longitudinal length of braid or coil would extend along the majority of that length, and therefore be in a range of 20 cm to 30 cm. Thus, claim 52 is rendered obvious. Ex, 1605, ¶¶ 286-292.

E. Claim 53

1. 53.pre

To the extent the preamble is limiting, Ressemann discloses it as set forth below and for claim 48. *Supra* § X.B.1; Ex-1605, ¶¶ 254, 270, 293.

2. 53.a

Ressemann discloses this limitation. *Supra* § X.B.2; Ex-1605, ¶¶ 255, 271, 294.

3. 53.b

Ressemann discloses this limitation. *Supra* § X.B.3; Ex-1605, ¶¶ 256, 272, 295.

4. 53.c.i

Ressemann discloses this limitation. *Supra* § X.B.4; Ex-1605, ¶¶ 257, 273, 296.

5. 53.c.ii

Ressemann discloses this limitation. *Supra* § X.B.5; Ex-1605, ¶¶ 258, 274, 297.

6. 53.c.iii

Ressemann discloses this limitation. *Supra* § X.B.6; Ex-1605, ¶¶ 259-68, 275, 298.

7. 53.d

Ressemann discloses this limitation. *Supra* § X.B.7; Ex-1605, ¶¶ 269, 276-81, 299.

First, as discussed for § X.B.4, *supra*, the "segment defining the side opening" is illustrated below.

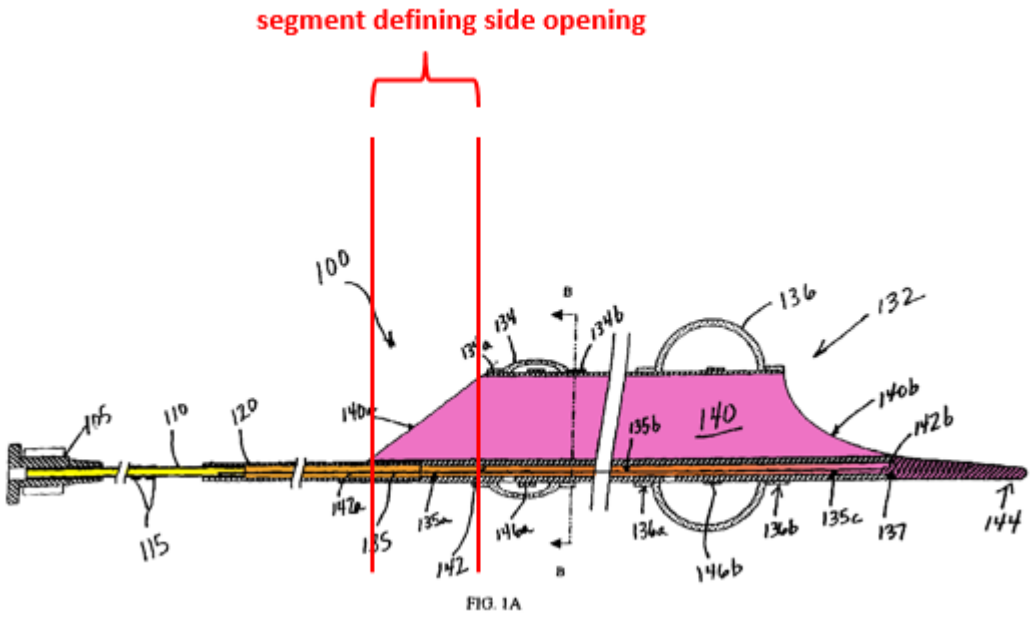
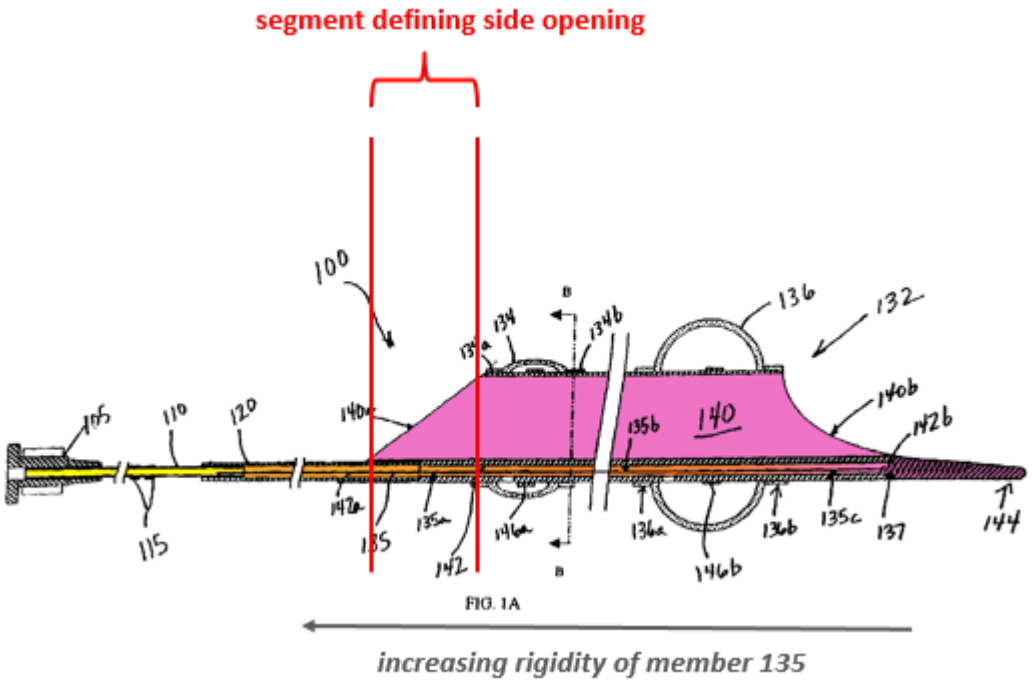


FIG. 1A

Ex-1608, Fig. 1A (color and annotation added).

The segment defining the side opening includes evacuation lumen 140's proximal opening, 140a. Lumen 140 is part of a multi-lumen tube that is "made of a relatively flexible polymer such as low density polyethylene, polyurethane, or low durometer Pebax® material." Ex-1608, 6:35-39; *and see id.*, 22:53-58, 24:20-32. The segment defining the side opening also includes the portion of distal shaft (130) that is adjacent opening 140a. *Id.*, 10:31-35; *and see id.*, Figs. 16 A-B, 16E, 23:21-40.



Ex-1608, Fig. 1A (color and annotation added).

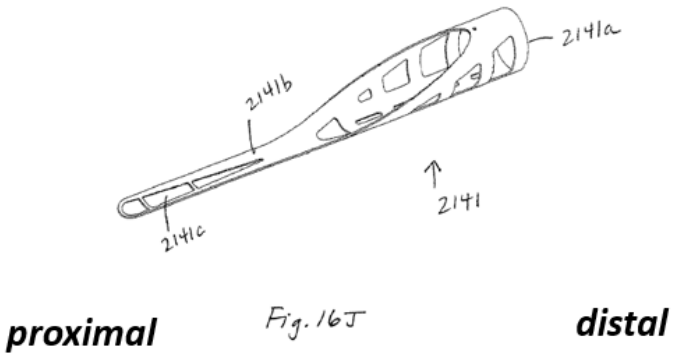
Distal shaft (130) contains an inflation lumen in which stiffness transition member (135) is located. Member (135) is "preferably made of stainless steel." *Id.* 11:29-39. Ressemann teaches that member (135)'s rigidity increases gradually from its distal end (adjacent tip 144) to its proximal end. *Id.*, 11:29-40. The change in stiffness is preferably accomplished by "reducing the cross sectional area" of member 135 so that its diameter decreases from 135a to 135b to 135c. *Id.*, 11:59-63.

Thus, Ressemann discloses that the "material forming the segment defining the side opening" includes both a relatively flexible polymer as well as a portion of a shaft and stiffness transition member, where the stiffness transition member is

more rigid than it is along more distal portions of the evacuation head. By contrast, the tubular structure is the portion of evacuation lumen 140 that is distal to 140a, and is made of soft polymer. *Supr*a, §§ X.B.4, 7.

Given the difference in the materials that form the "segment defining the side opening" compared to the matrial that forms evacuation lumen 140, the former is necessarily more rigid than the latter. Ex-1605, ¶ 299; Ex-1642, ¶¶ 144-149.

Additionally, Ressemann also discloses support collar 2141, which may be inserted into the proximal opening of the evacuation lumen, as discussed above. *Supra*, § X.B.6. Circumferential portion 2141a "fits into the proximal opening of the evacuation lumen" in order to "provide hoop support." Ex-1608, 24:55-58.



Ex-1608, Fig. 16J (annotated).

Proximal end tab 2141b "provides a flexibility transition" between the proximal end of the evacuation head and the shaft. *Id*., 24:62-67. Collar 2141 is

"fabricated from a thin walled metallic tube," or "any material with suitable rigidity to prevent kinking" of tab 2141b. *Id*., 25:1-16.

Adding collar 2141 to assembly 100's proximal side opening 140a adds a metal lining (or a lining with another, suitably rigid material). *Supra*, § X.B.7. By contrast, the more distal portion of lumen 140 lacks the support of collar 2141. This, too, results in the "segment defining the side opening" of assembly 100 being more rigid than the tubular structure. Ex-1605, ¶ 299; Ex-1642, ¶¶ 130-143.

8. 53.e

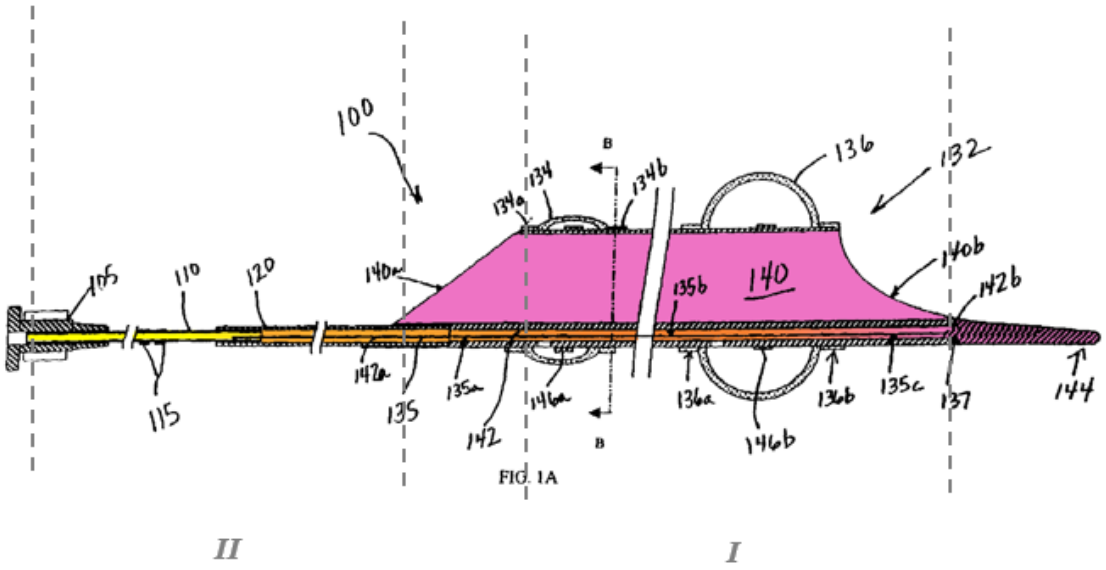
Ressemann discloses this limitation, Ex-1605, ¶ 300, teaching that evacuation sheath 100 has a substantially rigid segment and a reinforced segment. *Supra*, §§ X.B.3-4.

Proximal shaft 110 is part of the "substantially rigid segment," is preferably made of stainless steel. *Supra*, § X.B.4; Ex-1608, 10:36-42, 11:6-10. Proximal shaft 120 is also part of the "substantially rigid segment" and is "preferably formed of polyethylene or Pebax. Ex-1608, 10:63-11:1.

By contrast, the tubular structure is made of a relatively flexible polymer such as low density polyethylene, polyurethane, or low durometer Pebax® material." *Supra*, § X.E.7.

As Dr. Brecker and Dr. Hillstead explain, and as discussed herein (§§ X.B.4, 7), given the differences in the materials that are used to form

Ressemann's subtantially rigid segment and Ressemann's tubular structure, they each have a different flexural modulus, and the flexural modulus of the former (*II*) is greater than the latter (*I*). Ex-1605, ¶ 300; Ex-1642, ¶¶ 165-169.



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

IX. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1673. The "Facts" section states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioner launched a "copycat" product. *Id.*, 2, 5, 9. Patent Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it

has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

XI. CONCLUSION

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

XII. 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 13, 2019
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WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 13,816 words, excluding any Mandatory Notices. I further certify that, in preparation of this Corrected Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 13, 2019

/ Cyrus A. Morton /

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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:

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

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