UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

Case No.: IPR2020-00129
U.S. Patent No. RE45,380

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. RE45,380

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I. PRELIMINARY STATEMENT

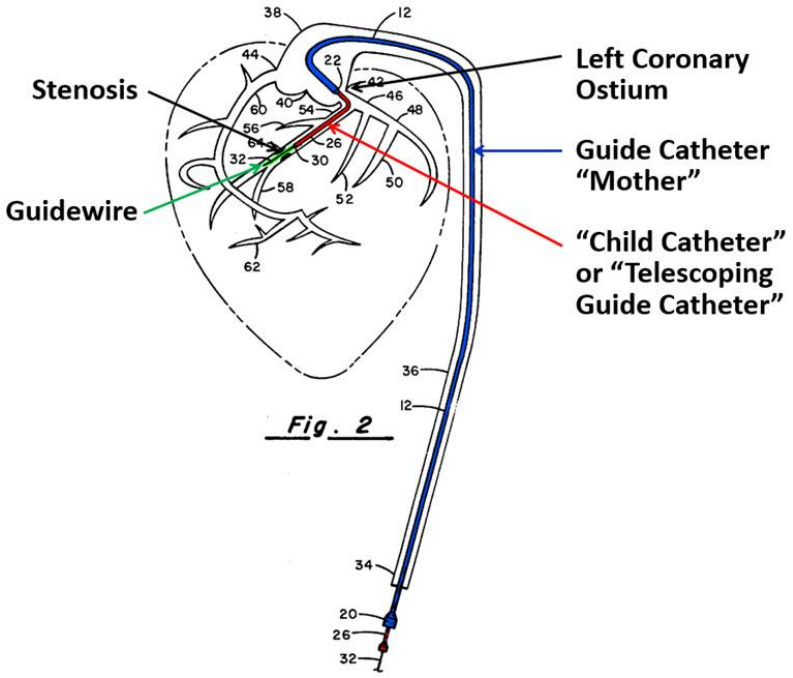
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioners") request *inter partes* review ("IPR") of claims 25-39 ("Challenged Claims") of U.S. Pat. No. RE45,380 ("the '380 patent" Ex-1201). The '380 patent is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root et al. as inventors. *Id*., [54], [72]. The Challenged Claims were never subject to an Office Action, meaning there is no substantive file history for the '380 patent.

The '380 patent describes a catheter system that reduces the likelihood of a guide catheter dislodging from the ostium of a coronary artery during the removal of a coronary stenosis. The purported invention requires a guide catheter ("GC") and a guide extension catheter.[1] The latter is inserted into and extended beyond the distal end of the GC (i.e., into a coronary branch artery). *Id*., 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,"

[1] The '380 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1205, ¶ 129. A POSITA knew that the "coaxial guide catheter" of the '380 patent was commonly understood as a guide extension catheter because it extends the GC further into the coronary artery. *Id*.; *see also* Ex-1209, 5:49-52.

thereby preventing the GC from dislodging from the ostium. *Id*., 3:1-5; *see also id*., 8:19-30.

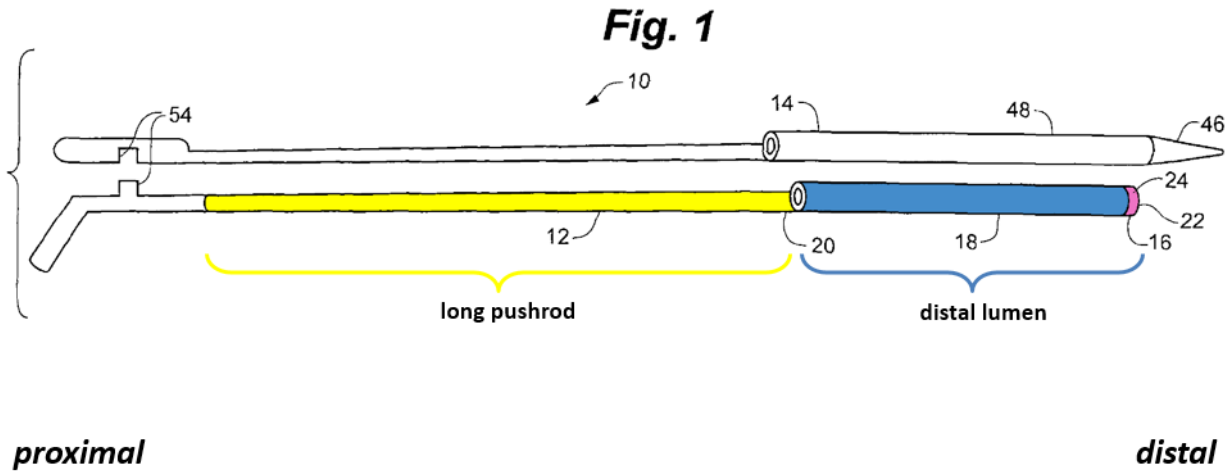
The ’380 patent admits that the use of a guide extension catheter inside an outer GC was known. Ex-1201, 2:40-56 (describing use of a “smaller guide catheter within a larger guide catheter”). Indeed, such a catheter-in-a-catheter assembly—a “mother-and-child assembly”— was well-known. Ex-1205, ¶¶ 74-84. The child catheter (red below) (i.e., the extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue below) (i.e., the mother catheter) into the coronary artery. *Id*., ¶ 74.



Ex-1254, Fig. 2 (annotation and color added).

The child catheter in the mother-and-child assembly had a continuous lumen

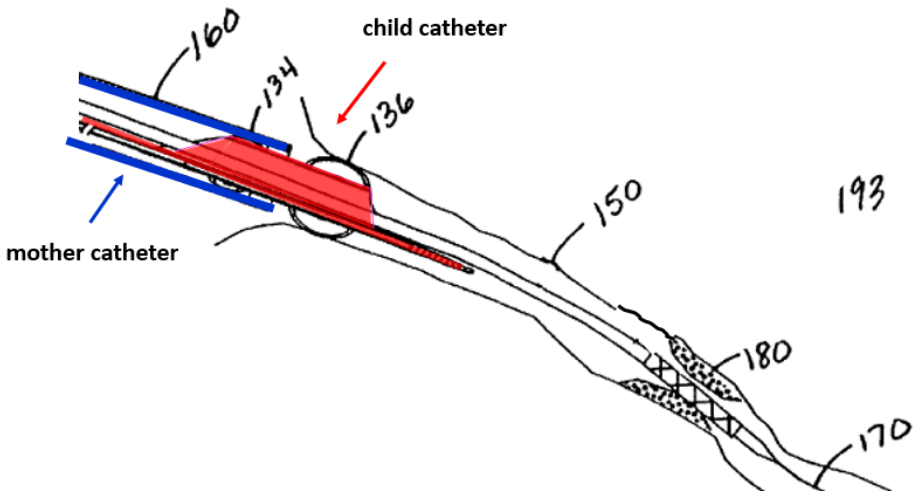
that was longer than the lumen of the guide ("mother") catheter. *Id.*; Ex-1205, ¶¶ 74-84. The '380 patent alleges that such a design had certain drawbacks (Ex-1201, 2:57-67) and modifies the child catheter (of the mother-and-child assembly) to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



Ex-1201, Fig. 1 (annotations and color added).

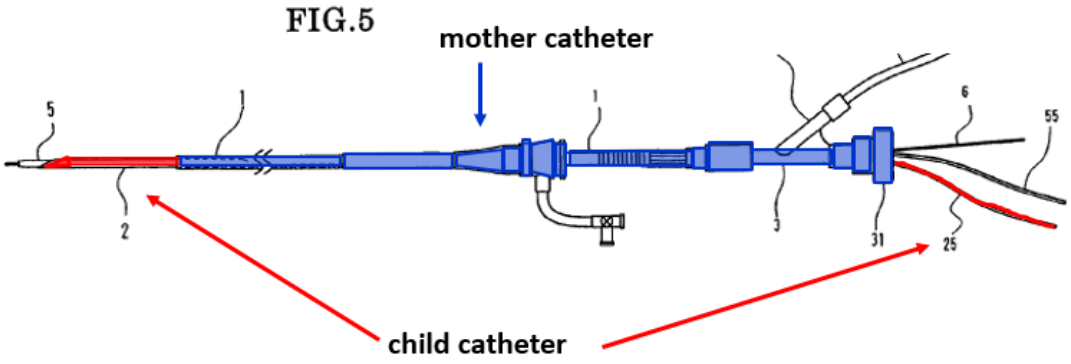
But such child catheters were already well-known, as evidenced by U.S. Patent No. 7,604,612 ("Ressemann") and U.S. Patent No. 7,736,355 ("Itou"), both depicted below.

Ressemann



Ex-1208, Fig. 6E (annotations and color added).

Itou



Ex-1207, Fig. 5 (annotations and color added).

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

A. Real Party-in Interest

Petitioners identify Medtronic, Inc. and Medtronic Vascular, Inc. as the real

parties-in-interest. 37 C.F.R. § 42.8(b)(1). Medtronic plc is the ultimate parent of both entities.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioners identify that the ’380 patent is currently the subject of litigation in two separate actions in the U.S. District Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019); and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) (“QXMedical Litigation”).

Further, the ’380 patent is a reissue of U.S. Pat. No. 8,292,850 (“the ’850 patent”). The ’850 patent was previously the subject of litigation (i) in the U.S. District Court for the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and (ii) at the PTAB in *Boston Scientific Corp. v. Vascular Solutions, Inc.*, IPR2014-00762, IPR2014-00763 (P.T.A.B., terminated prior to institution, Aug. 11, 2014).

Petitioners are also concurrently filing other petitions for IPR challenging the ’380 patent based on prior art references having different priority dates and disclosures than the references discussed herein, or challenging different claims.

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D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

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

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

B. Precise Relief Requested and Asserted Grounds

Petitioners respectfully request review and cancellation of claims 25-39 of the '380 patent as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Claims 25-31, 34-37 and 39 as anticipated by U.S. 7,604,612 ("Ressemann").
2	Claim 27 as obvious over Ressemann in view of the knowledge of a POSITA.
3	Claim 27 as obvious over Ressemann in view of US 2005/0015073 ("Kataishi") and the knowledge of a POSITA.
4	Claim 27 as obvious over Ressemann in view of US 5,980,486 ("Enger") and the knowledge of a POSITA.
5	Claims 32 and 33 as obvious over Ressemann in view of Takahashi and/or the knowledge of a POSITA.
6	Claim 38 as obvious over Ressemann in view of Berg and/or the knowledge of a POSITA.
7	Claims 25-26, 28-30, 32-37 and 39 as anticipated by U.S. 7,736,355 ("Itou").
8	Claim 31 as obvious over Itou in view of the knowledge of a POSITA.
9	Claim 27 as obvious over Itou in view of Kataishi and/or the knowledge of a POSITA.

[2] This petition is supported by the Declarations of Dr. Stephen JD Brecker, MD (Ex-1205), and Richard A. Hillstead, PhD (Ex-1242), as experts in the field of the '380 patent. Petitioners also submit the Declaration of Sylvia D. Hall-Ellis, PhD (Ex-1278) to support the authenticity and public availability of documents cited herein.

No.	Grounds
10	Claim 38 as obvious over Itou in view of Berg and/or the knowledge of a POSITA.

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1205, ¶¶ 32-36. This narrowing, sometimes called stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id*. Physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery to treat CAD without the need for open-heart surgery. Ex-1205, ¶¶ 33, 38-44.

PCI was developed more than forty years ago. Although catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1205, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. A GC is then introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. Ex-1205, ¶¶ 38, 46-62. A hemostatic valve is placed at the proximal end of the GC, remaining outside the patient's body. Ex-1205, ¶¶ 39, 58. The hemostatic valve prevents blood from exiting the patient's artery and keeps air from entering the bloodstream. *Id*.

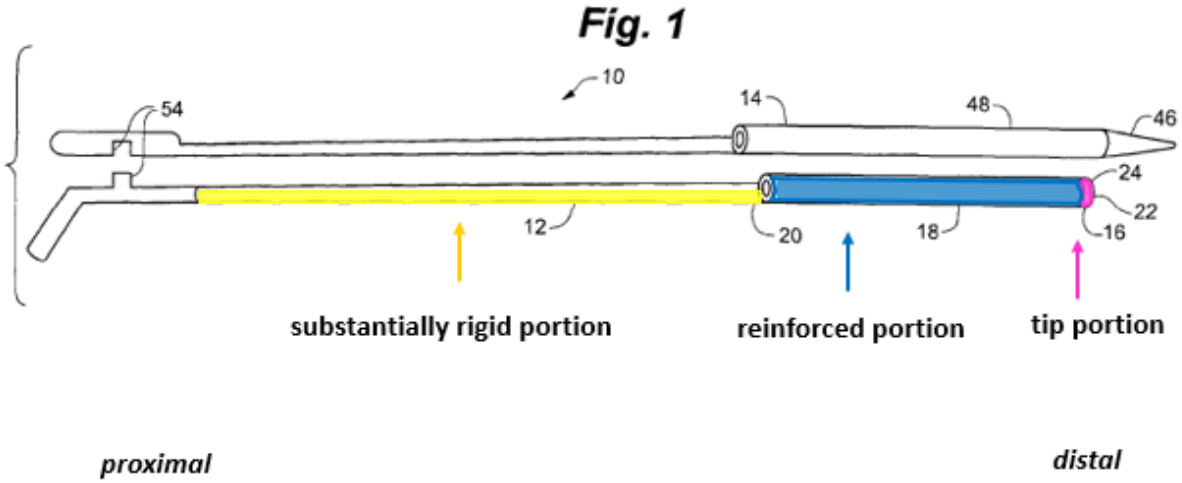
A smaller-diameter, more flexible guidewire can then be threaded through the lumen of the GC to the target site. Ex-1205, ¶¶ 60-62. This guidewire serves as a guiderail to advance a therapeutic catheter through the GC and to the occlusion. *Id*. The therapeutic catheter is typically passed through and beyond the occlusion in order to alleviate the stenosis. Ex-1205, ¶¶ 63-71. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that can dislodge the GC from the ostium. *Id*., ¶¶ 70-71. 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 GC. *Id*., ¶¶ 72-84.

B. The ’380 Patent

The ’380 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1201, 1:31-32. In particular, the ’380 patent discloses a coaxial guide catheter (i.e. 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—“assist[ing] in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:23-27; Ex-1205, ¶¶ 129-30.

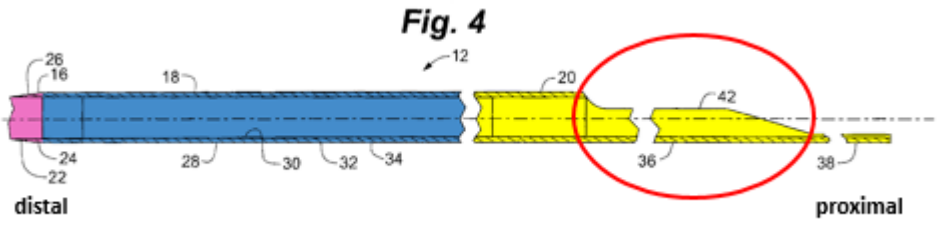
The ’380 patent discloses extension catheter 12 with a tubular portion that includes a flexible distal tip 16 (pink) and a reinforced portion 18 (blue), as well as

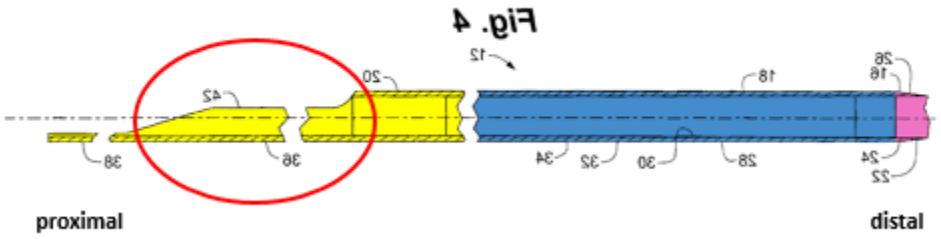
rigid portion 20 (yellow). Ex-1201, 3:51-53, 6:34-35, Fig. 1.



Ex-1201, Fig. 1 (annotations and color added).

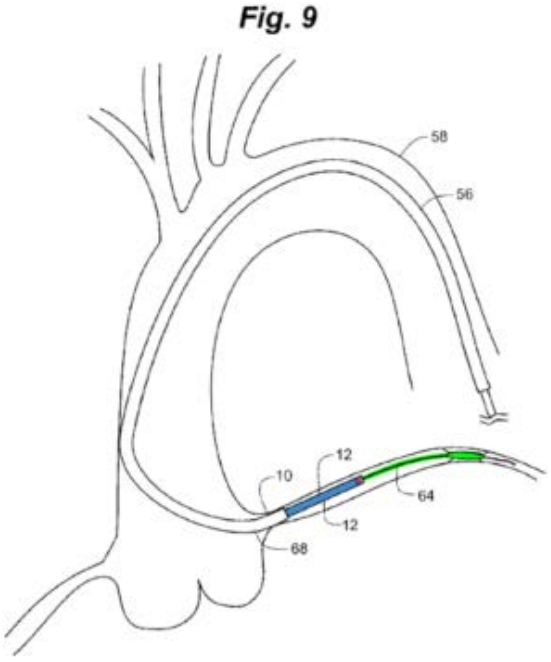
The patent also addresses structural characteristics of the transition at or near the extension catheter's reinforced and rigid portions, sometimes referred to as a "side opening," (red circle), which may have an "inclined slope." *Id*., Figs. 4, 13-16, 6:62-7:11, 8:58-64, 11:33-40, 14:6-7; Ex-1205, ¶¶ 131-132.





Ex-1201, Fig 4 (annotations and color added) (bottom figure inverted).

The ’380 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the distal tip (pink) of the extension catheter. Moving distally to proximally, the extension catheter’s distal tip (pink) and a reinforced portion (blue) extend out of the distal tip of guide catheter 56. Ex-1205, ¶ 133.



Ex-1201, Fig. 9 (color added).

C. Prosecution History of the ’380 Patent

The parent ’850 patent issued without an Office Action. Ex-1202. The Examiner, however, was not aware of Ressemann or Itou.

Patent Owner sought reissuance in 2013. The claims of the ’380 patent also issued without an Office Action. Ex-1203.

D. Priority Date

The ’380 patent is subject to the AIA first-to-file provisions because it contains at least one claim that lacks written description, and therefore pre-AIA priority. AIA § 3(n)(1)(A); MPEP § 2159.02. Thus, Patent Owner cannot swear behind Itou.

First, no pre-AIA application to which the ’380 patent claims priority contains disclosure of “a proximal side opening” outside of the substantially rigid segment, though the independent claims permit the side opening to be in the “flexible tip portion” or “reinforced portion.” *Compare* Ex-1201, claims 1, 11 (independent claims not restricting location of side opening) *with id*., claim 3 (dependent claim 3 requiring side opening to be in “tubular portion” of flexible tip portion).

Second, claim 27 requires a side opening with two inclined slopes, while the only alleged support (*see* Ex-1203a at 19 (Preliminary Amendment (11/1/2013) at 17), Fig. 4, discloses an arc and an inclined slope.

Third, claim 27 requires a side opening portion with "at least two different inclined slopes," but there is no support for more than two. At best, the '380 patent supports ***only*** two inclined slopes. Ex-1201, Fig. 4.

V. PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art ("POSITA") was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and a POSITA with an engineering degree may have access to one with a medical degree. Ex-1205, ¶ 31; Ex-1242, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

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

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1212, 2)
- "interventional cardiology device(s)": "devices including, but not limited to, guidewires, balloon catheters, stents, and stent catheters" (*Compare* Ex-1212, 21, *with* Ex-1264, 1 n.1)

Patent Owner advanced,[3] and the district court adopted, this construction:

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (Ex-1212, 2; Ex-1213, 15)

The district court provided the following constructions:

- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (Ex-1213, 26)
- "lumen": "the cavity of a tube" (*Id.*, 25).

Petitioners agree with the above constructions for purposes of this IPR[4] (Ex-1205, ¶¶ 134-139) and proposes the following additional constructions:

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[3] Ex-1212 includes constructions Patent Owner advanced in the QXMedical Litigation.

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

A. Means-Plus-Function Limitations (cl. 25)

Claim 25, and its dependents, recite terms that use the phrase "means for," which presumptively invokes 35 U.S.C. § 112, ¶ 6. *TriMed, Inc. v. Styker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). For "means" claims, a tribunal will first determine the claimed function and then determine the corresponding structures disclosed in the specification that perform that function. *In re Aoyama*, 656 F.3d 1293, 1296-97 (Fed. Cir. 2011). But when a "claim recites sufficient structure for performing the described functions in their entirety, the presumption of § 112, ¶ 6 is overcome—the limitation is not a means-plus function limitation." *TriMed*, 514 F.3d at 1259. "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an ***adequate understanding*** of the structure." *Id.* at 1259-60 (emphasis added).

Claim 25 recites the following "means" terms:

> (i) means for **guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel**; and
>
> (ii) means for **receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel**.

Ex-1201, 13:44-51 (claimed functions bolded).

For "means" term (i), the claim language does not recite sufficient structure to overcome the presumption of means-plus-function. The specification discloses that the structure is a guide catheter. Ex-1201, Figs. 7-9 (depicting "typical guide catheter" at 56), Abstract, 7:50-64; Ex-1205, ¶¶ 140-143.

For "means" term (ii), the structure corresponding to that function is a "coaxial guide catheter." Ex-1201, Figs. 1-6, 8-9 (depicting a "coaxial guide catheter" at 12), Abstract, 5:40-56, 5:61-67, 6:31-37, 8:4-32; Ex-1205, ¶¶ 144-145. The rest of claim 25, however, recites more detailed structure and overcomes the means-plus-function presumption. Ex-1205, ¶ 146. The claim provides that the same "means for receiving" includes:

- "a tip portion, a reinforced portion, a side opening, and a substantially rigid portion" (the basic components of the coaxial guide catheter in the specification and other claims) (Ex-1201, 13:55-56);
- a "length" longer than the guide catheter (*Id*., 13:56-64);
- a size "configured to be passed" through the lumen of the guide catheter. (*Id*., 13:65-14:2); and,
- a "more rigid" side opening and substantially rigid portion than tip portion (*Id*., 14:3-5).

Ex-1205, ¶¶ 147-149. This is more than "adequate understanding" of the structure. *Id*.

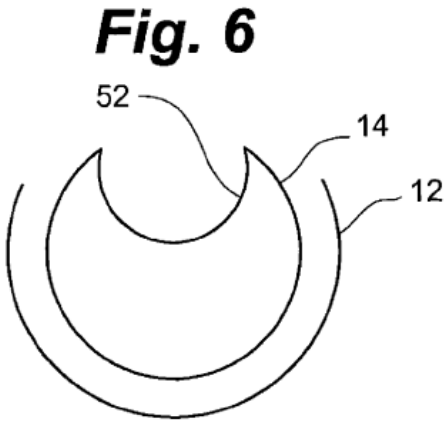
Because claim 25 recites the structural components that make up the disclosed coaxial guide catheter (Ex-1201, 6:34-35)—including their length, size, and relative rigidities—the means-plus-function presumption is overcome. *TriMed*, 514 F.3d at 1260 (finding same when claim recited "size and shape of the claimed holes").

If, however, the Board finds that the presumption is not overcome, Petitioners are unaware of any additional structural component that is appropriately read into the claim. The corresponding structure for the claimed function of receiving and guiding an interventional device deeper into a branch vessel is simply a coaxial guide catheter.[5] Ex-1205, ¶¶ 144-145. The claimed side opening cannot be further limited because the coaxial guide catheter of Figures 2-3 does not have a side opening. Similarly, no further limitations on the substantially rigid portion are appropriate because they are not required by the claimed function and are qualified by the word "may" in the specification. *See, e.g.*, Ex-1201, 6:59-62 ("Rigid portion 20 may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well."). Thus, if the presumption is not rebutted, the only difference is that the prior art need only disclose a coaxial guide catheter *or equivalents*.

[5] Also known as an extension catheter. *See* footnote 1, *supra*.

B. "concave track" (cl. 34)

The '380 patent does not define the claim term "concave track." It mentions that a cutout portion, which supports a track, "may" have certain amounts removed and "may" extend for certain lengths, and later refers to cutout portion 44, which is not labeled in a figure. Ex-1201, 4:7-15, 4:29-31, 7:19-20; Ex-1205, ¶ 150. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex-1201, 7:19-20.



Id., Fig. 6.

Thus, in the '380 patent, "concave track" means a "portion that is not fully circumferential." Ex-1205, ¶¶ 150-151.

C. "flexural modulus" (cl. 38)

The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1242, ¶ 55), and according to McGraw-Hill Dictionary of Scientific and Technical Terms means "[a] measure of resistance ... to bending." Ex-1240, 772.

In other words, the "flexural modulus" is a measure of a device's rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. This is admitted by the '380 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1201, 7:25-32; Ex-1205, ¶¶ 152-153.

VII. GROUND 1: RESSEMANN ANTICIPATES CLAIMS 25-31, 34-37 AND 39.

A. Ressemann

Ressemann was filed on August 9, 2002 and issued on October 20, 2009. It is prior art under pre-AIA § 102(e) and post-AIA §§ 102(a)(1), 102(a)(2). Ressemann was not cited or considered during prosecutions of the original '850 patent or the '380 patent. Exs-1201-1203.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1208, 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, 12:9-12, 12:19-30, 29:56-58.

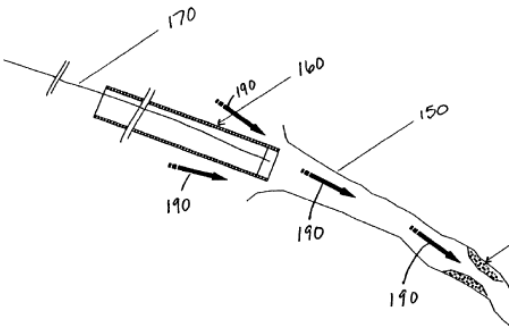


FIG. 6A

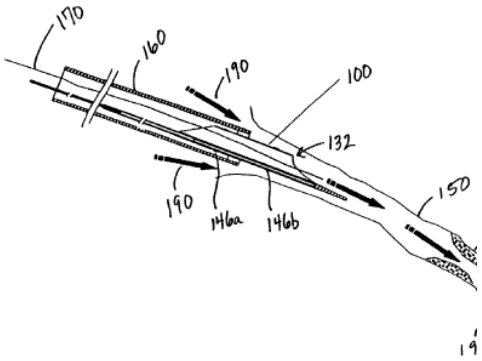


FIG. 6B

Id., Figs. 6A-6B.

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

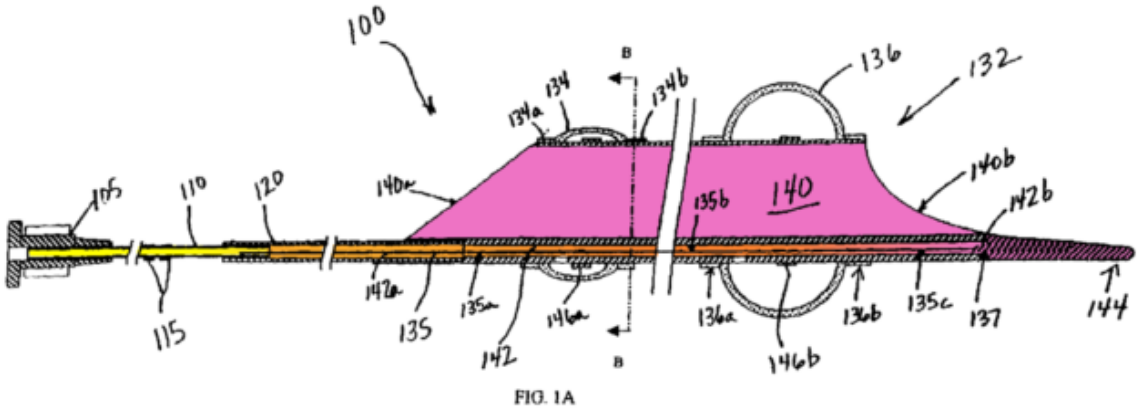


FIG. 1A

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

The shaft includes proximal, intermediate, and distal portions. Proximal shaft 110 (above, yellow) is a hollow tube preferably made of stainless steel. *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, and may include soft distal tip 144 made of a polymer more flexible than the head, so as to ensure atraumatic insertion into blood vessels. *Id*., 11:11-28.

Ressemann also teaches that the evacuation head may include a kink-resistant structure—a coil 139 (yellow lines below)—that may be made of metal ribbon. *Id*., 6:66-7:7, 23:49-60; Ex-1205, ¶¶ 154-158; Ex-1242, ¶¶ 20-26, 73-83.

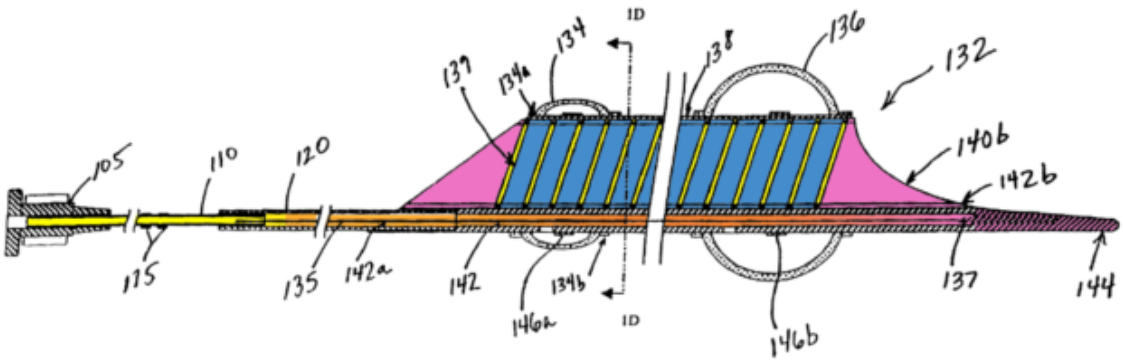


FIG. 1C

Ex-1208, Fig. 1C (color added).

B. Claim 25

1. [25.p] "A system comprising:"

To the extent the preamble is limiting, Ressemann describes guide catheter 160 "may be positioned within the ostium of the target vessel." Ex-1208, 12:9-30, Figs. 5A-5D, 6A-6I, 22:38-45. The guide catheter 160 is used in conjunction with an evacuation assembly 100 and "allow the passage of most therapeutic devices," such as angioplasty and stent delivery catheters, for the treatment of occluded vessels. *Id.*, 6:19-34, 10:17-21, 12:3-8, 12:26-30, Fig. 6E-6F, *see also id*., 28:26-29. The combination of the guide catheter 160 and evacuation assembly 100 discloses the claimed "system." *See* § VII.B(2-7), *infra*; Ex-1205, ¶ 179.

2. [25.a] "means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and"

Ressemann discloses the function of guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel. Ex-1208, Figs. 5a-5d, 6A-6I, *see also id*., 22:38-45; Ex-1205, ¶ 180. As discussed in § VI.A, *supra*, the corresponding structure disclosed in the '380 specification is a guide catheter. Ressemann discloses (i) that guide catheter 160 "may be positioned within the ostium of the target vessel" (Ex-1208, 12:9-30, Figs. 5a-5d, 6A-6I, *see also* 22:38-45, 28:31-32), (ii) that guide catheter 160 is used in conjunction with evacuation assembly 100 that is sized to fit therein

(*id*., 6:18-24, 22:38-45, 28:26-29), and (iii) that evacuation assembly 100 "will allow the passage of most therapeutic devices," such as angioplasty and stent delivery catheters. *Id.*, 10:17-21, 12:9-26, 28:46-49, 28:54-55, Figs. 6B-6F. Thus, Ressemann discloses limitation [25.a]. Ex-1205, ¶ 180. If this limitation is not construed as means-plus-function, Ressemann's same teachings satisfy this limitation. *Id*.

3. [25.b] "means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,"

As discussed in § VI, this is not a means-plus-function limitation.

Ressemann's evacuation assembly 100 receives the interventional device from the distal end of the guide catheter 160 near the ostium of the branch vessel and guides the interventional device deeper into the branch vessel. Ex-1205, ¶ 181; Ex-1208, Figs. 6A-6F, 12:9-14:10, *see also* 27:22-36, 27:51-53, 28:33-46, Fig. 16I. The evacuation assembly 100 of Ressemann includes a lumen 140 with a proximal end opening 140a large enough to "allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, atherectomy catheters . . . ." Ex-1208, 10:17-20, 12:3-4; *see also id.* at 28:54-55. *See supra* § VII(b)(3). It is evident in Ressemann's teaching that after the evacuation sheath is deployed through the GC (such that that its distal end is in the blood vessel), a therapy

catheter is introduced into the GC and advanced through side opening 140a of the evacuation sheath, which is positioned in the GC. The therapy catheter is then advanced into the blood vessel and across a lesion. Ex-1208, 12:19-14:10, Figs. 6B-6F.

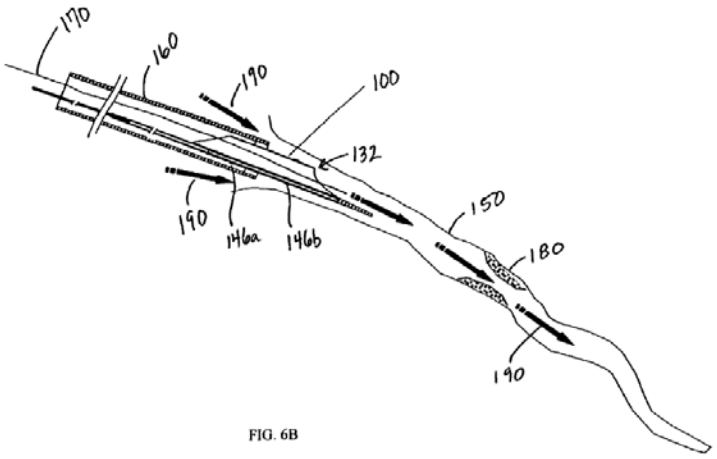


FIG. 6B

Ex-1208, Fig. 6B.

Thus, Ressemann discloses this limitation. Ex-1205, ¶ 181.

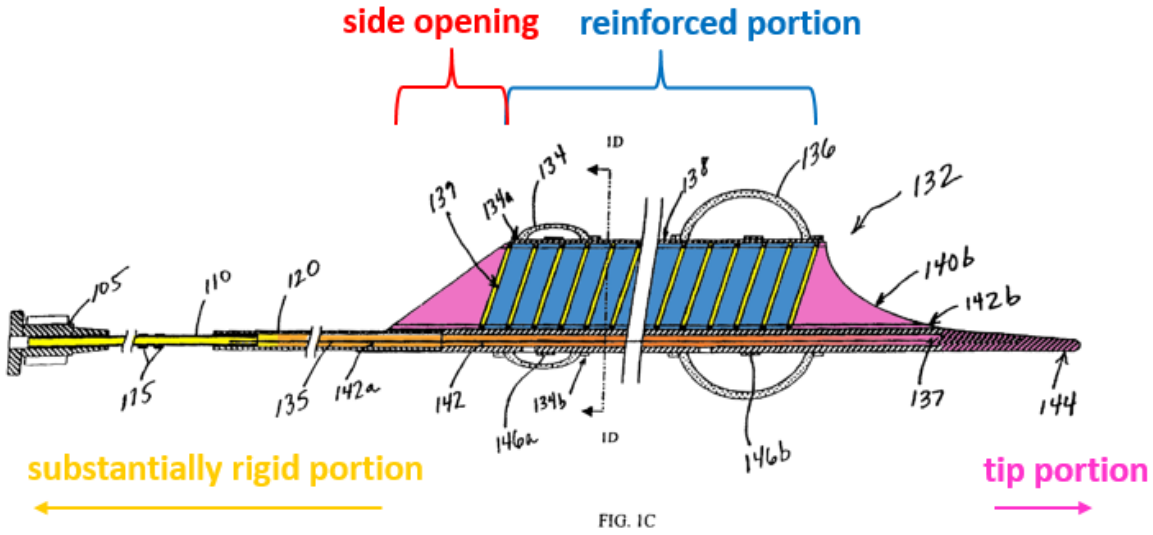
If this is a means-plus-function claim element, Ressemann's evacuation assembly 100 is a "coaxial guide catheter" that performs the claimed function for the same reasons provided herein. *Id*. To be clear, the claim is not limited to "a rail structure without a lumen," which was added by amendment as a further limitation on the substantially rigid portion in other claims like claim 1. Ex-1203, 9. Regardless, a rail structure without a lumen is equivalent to a rail structure with a

lumen for purposes of the claimed function of receiving and guiding an interventional device deeper into a branch vessel. Ex-1205, ¶ 181.

4. [25.c.i] "the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel [25.b] including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion,"

The remainder of claim 25 recites solely structure, meaning that regardless of whether the claim is construed as a means-plus-function limitation, the same disclosures from Ressemann are applicable. Ressemann's evacuation assembly 100 discloses in a distal-to-proximal direction, a tip portion, a reinforced portion, a side

opening, and a substantially rigid portion. Ex-1205, ¶ 182.[6]



Ex-1208, Fig. 1C (color and annotations added); *see also id*., Figs. 16A-C, 16F-G (showing tip portion 2144, reinforced portion (evacuation head 2132 reinforced with coil 2139), side opening (at proximal end 2140a), and substantially rigid portion (proximal shaft 2110 and intermediate shaft 2120)).

The "tip portion" (soft tip 144) is comprised of "a more flexible polymer secured to the distal end of the . . . [lumen] 138 of the evacuation head 132."[7] *Id.*,

[6] Patent Owner's expert testified that the various portions do not need to overlap or be co-terminus with each other. Ex-1277, 155:13-156:2.

[7] Although not required, the claimed tip portion could also include "distal end 137 of the stiffness transition member 135." Ex-1208, 11:39-44. As demonstrated by

11:20-25, *see also* 24:20-32; Ex-1205, ¶ 182; Ex-1242, ¶¶ 77-78. As shown above in Figure 1C, Ressemann discloses that a portion of the evacuation head 132 may be reinforced with a kink-resistant coil 139. Ex-1208, 6:66-7:18, Fig. 1C, *see also id*., 23:53-67, 24:58-67; Ex-1205, ¶ 182; § VI, *supra* (construing "reinforced portion"). Further, a stiffness transition member 135 runs longitudinally along the majority of the evacuation sheath's intermediate and distal shafts, starting at the distal end of the proximal shaft 110 and terminating toward the distal end 137 and adds additional stiffness to the evacuation head 132. Ex-1208, 11:29-35. For both of these reasons, the portion of evacuation head 132 that includes reinforced coil, and the portion proximal to it, is the reinforced portion. Ex-1242, ¶¶ 75-79.

Proximal end 140(a) is the "side opening" (*see also* proximal end 2140a). Ex-1208, 6:42-53, 23:8-20; Ex-1205, ¶ 182.

The proximal shaft portion 110 and intermediate shaft portion 120, made from (i) stainless steel (or a polymer or metal composite) and (ii) polyethylene or Pebax tube, respectively, are the "substantially rigid portion." Ex-1208, 6:19-24, 12:19-30, Figs. 6A-6F, *see also id*., 27:22-36, 27:51-59. As shown in Figures 6A-

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Patent Owner's infringement positions, it does not matter that distal end 137 lies between tip 144 and the reinforced portion. Ex-1277, 121:16-24.

6F, the "substantially rigid portion" permits the advancement of the evacuation sheath assembly 100 within the guide catheter. *Id.*; *see also id*., 28:46-49; § VI, *supra* (construing "substantially rigid"); Ex-1205, ¶ 182; Ex-1242, ¶¶ 81-83.

5. [25.c.ii] "and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,"

Ressemann teaches that the evacuation assembly 100 is longer than the guide catheter 160. *See* Ex-1208, 22:49-52; Ex-1205, ¶ 183. Ressemann teaches that evacuation head 132 can be positioned distal to the guide catheter 160. Ex-1208, 12:37-40, *see also id*., 22:31-37, 28:46-49. At the same time, at the proximal end "[a] suitable valve [is] attached to the guiding catheter 160 . . . [which] provides a fluid tight seal against . . . the proximal shaft portion" of the evacuation assembly 100 that travels proximally therethrough. *Id.*, 12:45-49, 27:22-36, 28:46-55. In Figure 5A, the guide catheter 160 ends at the valve 184 while the proximal portion of the substantially rigid portion (proximal shaft 110) of the extension catheter extends proximally through the valve. Ex-1208, Fig. 5A; Ex-1205, ¶ 183.

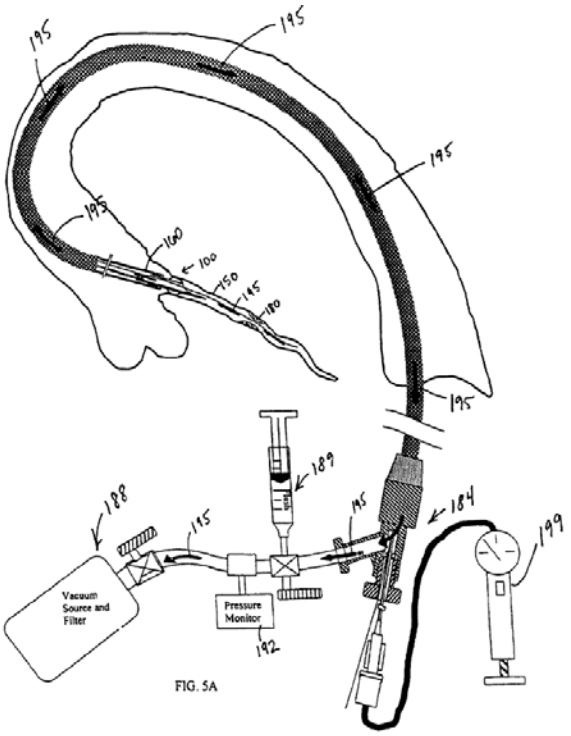


FIG. 5A

Ex-1208, Fig. 5A.

6. [25.d] "wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and"

In Fig. 6B, Ressemann discloses this limitation as the evacuation assembly 100 is "sized to fit inside a guide catheter to advance a distal end of the evacuation sheath assembly into a blood vessel." Ex-1205, ¶ 184; Ex-1208, 6:18-24, 28:46-49.

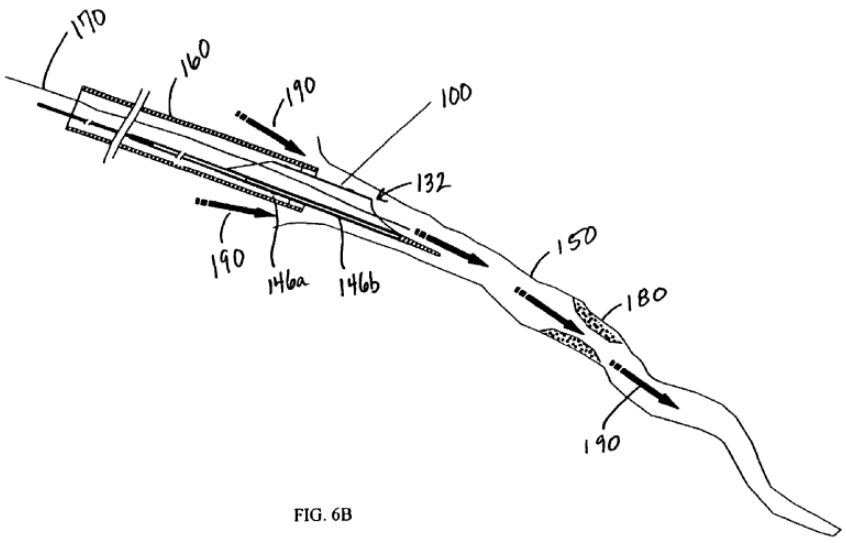


FIG. 6B

Ex-1208, Fig. 6B.

7. [25.e] "the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion."

Ressemann discloses this limitation.[8] Ex-1205, ¶ 185. The "tip portion" (soft tip 144) is comprised of "a more flexible polymer secured to the distal end of the . . . [lumen] 138 of the evacuation head 132." Ex-1208, 11:20-25; *see also id*., 22:54-58, 24:20-32, 24:47-67, Fig. 16J; Ex-1205, ¶ 185. In other words, the "tip portion" (soft tip 144) is more flexible than the proximally located evacuation head

[8] This limitation does not address the relative rigidities of the substantially rigid portion and the side opening.

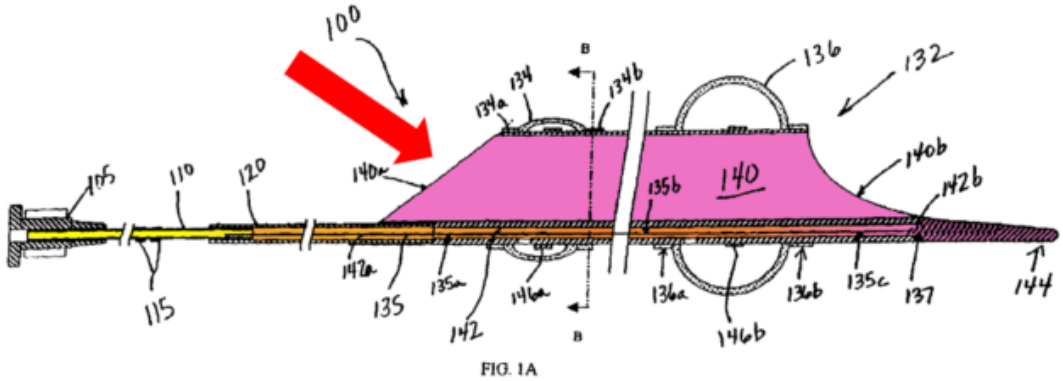
132. Ex-1205, ¶ 185. Thus, the "side opening" (proximal end 140(a)), which is proximal of soft tip 144 and made of the same material as evacuation head 132 (of which it is a part), is more rigid along a length thereof than the tip portion. Ex-1205, ¶ 185; Ex-1242, ¶ 82; *see also* Ex-1242 ¶¶ 73-81.

The "substantially rigid portion" (proximal shaft portion 110 and intermediate shaft portion 120) is made of (i) stainless steel (or a polymer or metal composite) and (ii) polyethylene or Pebax tube, respectively." Ex-1208, 6:19-24, 10:47-11:1, 12:19-30, Figs. 6A-6F, *see also* 27:26-28, 27:51-55. Based on the known material properties, Ressemann discloses that the "substantially rigid portion" is also more rigid along a length thereof than the tip portion. Ex-1205, ¶ 185; Ex-1242, ¶ 83.

Apart from evacuation sheath assembly 100, addressed above, claim 25 is also anticipated by the disclosures related to evacuation sheath assembly 2100. Ex-1208, Figs. 16A-16J, 22:29-29:61. Ressemann states that "[m]any of the elements present in the previous embodiments [such evacuation sheath assembly 100] are also shown in FIGS. 16A-16J and where these elements are substantially the same, similar reference numerals have been used and no detailed description of the element has been provided." *Id.*, 22:33-37. The elements in Ressemann identified above are also found in evacuation sheath assembly 2100, as indicated by the use of similar reference numerals. *Id.,* 22:29-29:61, more particularly 22:29-23:20,

23:53-25:16, 26:41-43, 27:22-56, 28:26-29:61; Ex-1205, ¶¶ 179-185. As such, this embodiment also anticipates claim 25.

C. Claim 26: "The system of claim 25, wherein the side opening includes at least one inclined slope."



Ex-1208, Fig. 1A (color and annotations added).

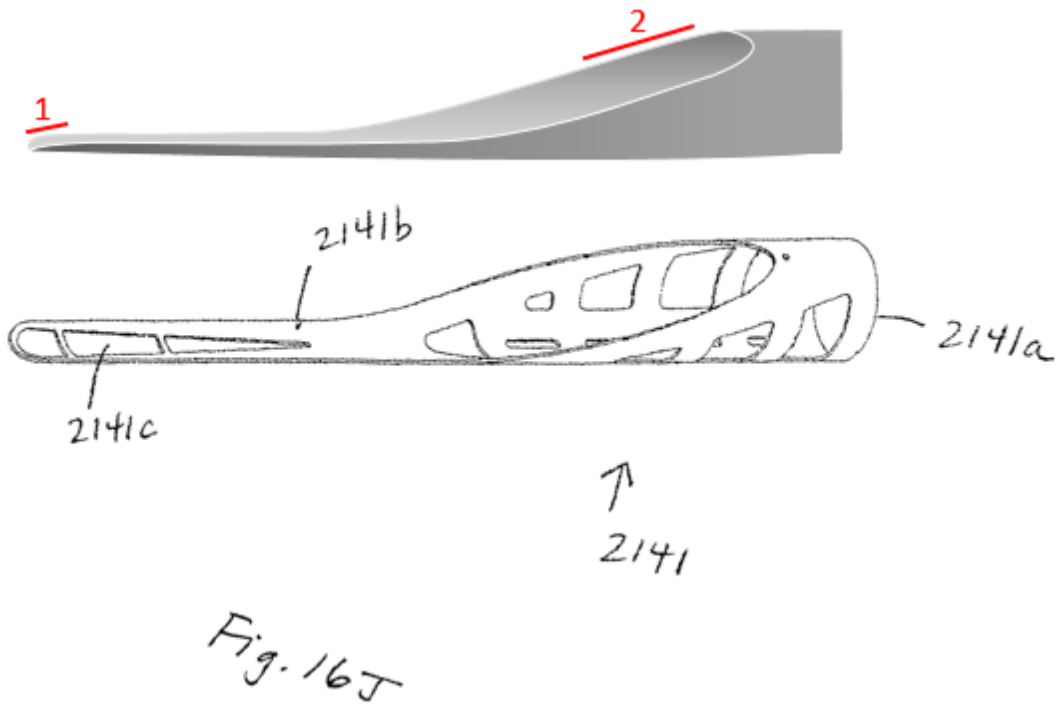
Ressemann discloses that side opening (proximal end 140(a)) includes one inclined slope (red arrow), as shown in Figure 1A. *Id.*; *see also id.*, Fig. 16D; Ex-1205, ¶ 186. Thus, Ressemann anticipates claim 26. Ex-1205, ¶ 186.

Because Ressemann's teachings regarding evacuation sheath 2100 anticipate claim 25, they also anticipate claim 26. This is for the same reasons as Ressemann's teachings regarding sheath 100 anticipate claim 26.

D. Claim 27: "The system of claim 26, wherein the side opening includes at least two different inclined slopes."

Ressemann anticipates claim 27. Ressemann discloses a side opening that has two different inclined slopes. Ex-1205, ¶¶ 187-188; Ex-1242, ¶ 88. Fig. 16J

discloses a support collar 2141 that has a first inclined slope at the proximal end of support collar 2141 ("1" below), a flat, non-inclined region, and a second inclined slope at the distal end of support collar 2141, ("2" below). Ex-1242, ¶ 88-89. These inclined slopes are similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1205, ¶ 187; Ex-1242, ¶ 95.



Ex-1208, Fig. 16J (below) and annotated schematic of Fig. 16J (above).

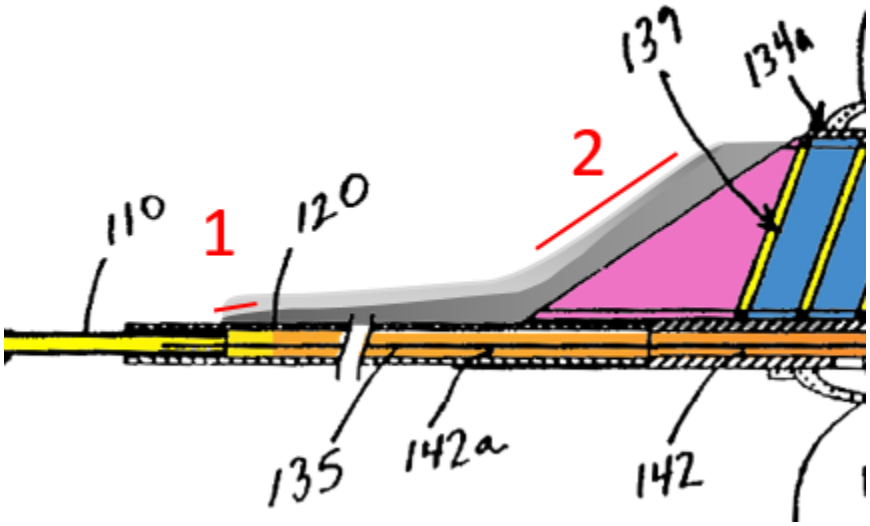
Ressemann explicitly discloses support collar 2141 for use with evacuation sheath 2100. Ex-1208, 24:47-67, 22:38-41, 23:8-20. Specifically, the cylindrical portion of collar 2141a fits into the proximal opening of the evacuation lumen 2140. *Id*., 24:55-58. Tab 2141b extends proximally of the opening of the

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

Because Ressemann's teachings regarding evacuation sheath 2100 anticipate claims 25 and 26, they also (in conjunction with Ressemann's teachings regarding support collar 2141) anticipate claim 27.

Additionally, support collar 2141 and evacuation assembly 100 can be used in conjunction, because the embodiments of Ressemann are the same in material ways. Specifically, evacuation lumen 140 is like lumen 2140 as Ressemann discloses that "***where these elements are substantially the same, similar reference numbers have been used***." Ex-1208, 22:33-37 (emphasis added), 6:44-47 (lumen 140 is for passage of interventional devices), 23:8-11 (lumen 2140 is for passage of interventional devices). Support collar 2141 serves to reinforce the proximal opening of the evacuation lumen "in the presence of deforming forces" in the same way for both evacuation lumens. Ex-1205, ¶ 187; Ex-1242, ¶ 86. Ressemann anticipates claim 27 because a POSITA would envisage using the support collar 2141 with evacuation assembly 100. Ex-1205, ¶ 188; Ex-1242, ¶ 90; *see also Kennametal, Inc. v. Ingersoll Cutting Tool Co*., 780 F.3d 1376, 1381 (Fed. Cir. 2015) (a reference will anticipate if a POSITA would "at once envisage the claimed arrangement or combination").

Ressemann explicitly teaches how to incorporate support collar 2141 into evacuation lumen 100, by fitting cylindrical portion 2141a into proximal opening of evacuation lumen 100 and resting tab portion 2141b adjacent the exterior of shaft 120. Ex-1242, ¶¶ 84-91. In addition, lumen 2140 and lumen 140 must align to allow for passage of the interventional device. Ex-1208, 6:44-47, 23:8-11; Ex-1205, ¶ 190; Ex-1242, ¶ 91; *see also* Ex-1242, ¶¶ 92-94. A schematic of support collar 2141 (shown in gray) combined with evacuation lumen 100 is shown below.



Ex-1208, Fig. 1C, modified with support collar 2141 (gray) (color and annotations added).

E. Claims 28-30

Ressemann anticipates claims 28-30. Ex-1205, ¶¶ 191-193. The limitations of "extending less than 180° of a full circumference" and "extends 25% to 40% of a full circumference," as recited in claims 28 and 29, respectively, add nothing of

patentable weight to these claims. As defined in the '380 patent, arcuate portion means "extends from 25% to 40% of the circumference of the tube." Ex-1201, 7:5-7. Stated another way, by reciting an arcuate portion in claim 28, Patent Owner recited a portion that extends 25% to 40% of the cross-sectional circumference, or between 90° and 144°, which is less than 180°. Ex-1205, ¶ 246. Nonetheless, Ressemann discloses that evacuation head 132 is a tube, and thus the side opening 140a would include a portion of the side opening with each of the cross-sectional shapes recited in claims 28-30. Ex-1208, 6:36; Ex-1205, ¶¶ 191-193.

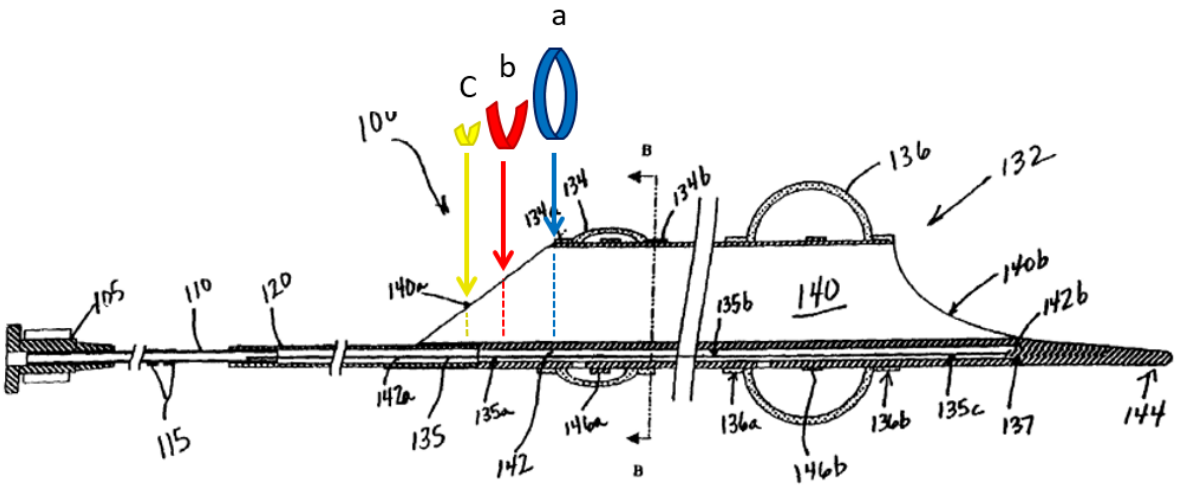


FIG. 1A

Ex-1208, Fig. 1A (annotations added).

Claim	Side Opening Claim Language Bolded	Location in Evacuation Head 132
28	"… wherein a portion of the side opening includes an **arcuate cross-sectional shape extending less than 180° of a full circumference**."	Portion proximal of red line (b)
29	"… wherein the portion of the side opening having the **arcuate cross-sectional shape extends 25% to 40% of a full circumference**."	Portion proximal of yellow line (c)
30	"… wherein the side opening includes a portion having **a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape**."	Portion between blue line (a) and red line (b)

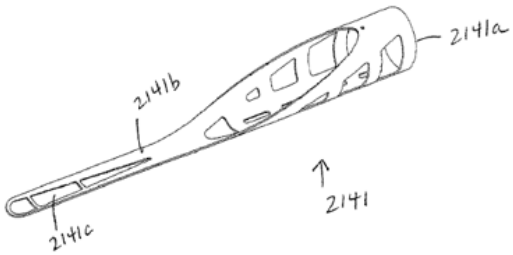
F. Claim 31: "The system of claim 25, wherein the reinforced portion includes one or more braided elements embedded in a polymer."

Ressemann anticipates claim 31. Ex-1205, ¶ 194. Ressemann discloses that the reinforced portion of multi-lumen tube 138 within the evacuation lumen 140 "may be formed around a coil 139 such that the coil 139 is embedded within the multi-lumen tube 138." Ex-1208, 7:4-7, *see also id*., 23:53-66, 24:58-67. Ressemann also teaches using a braid for coil 139, *id.*, 7:14-16, and that "[a] covering of polyurethane can then be applied to contain the coil 139, and secure it in position with the evacuation lumen 140." *Id*., 7:10-12, 23:53-24:14.

G. Claim 34: "The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes a concave track along a portion of a length thereof."

Ressemann anticipates claim 34. Ressemann discloses that evacuation head includes side opening 140a, which includes a portion that is not fully circumferential. Ex-1208, Figs. 1A, 16J. *See supra* § VII.E (claims 28-30). The non-fully circumferential portion of side opening 140a forms a concave track along a portion of a length thereof. Ex-1205, ¶ 195

Further, Ressemann teaches that support collar 2140 includes a non-fully circumferential portion. *See* § VII.D (claim 27), *supra*; Ex-1208, Fig. 16J; Ex-1205, ¶ 195.



Ex-1208, Fig. 16J (annotations added). Like side opening 140a, this non-fully circumferential portion forms a concave track along a portion of a length thereof. *Id.*

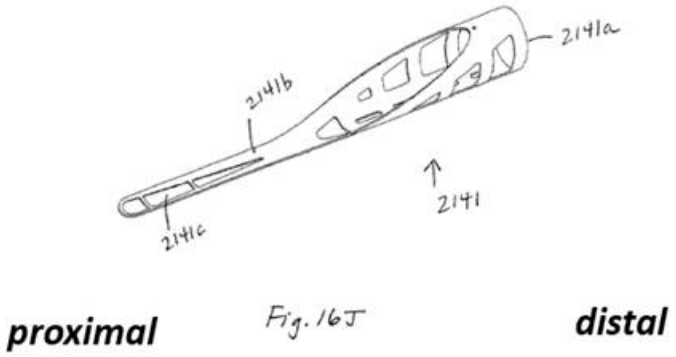
In addition, claim 34 is anticipated by the disclosures related to evacuation

sheath assembly 2100 based on the disclosures included above and the reasons stated in § VII.B. Ex-1205, ¶ 195.

H. Claim 35: "The system of claim 25, wherein the side opening is incorporated with the distal end of the substantially rigid portion."

Ressemann discloses this limitation. Ex-1205, ¶ 196. Side opening 140a is part of the evacuation lumen 140 in evacuation head 132, which includes distal evacuation shaft 130. Ex-1208, 10:30-35. Shaft 130 is secured to intermediate shaft 120, part of the substantially rigid portion, by an "overlapping weld or bond joint." *Id*., 10:60-62, Fig. 1C. Thus, the side opening is incorporated with the distal end of the substantially rigid portion. *Id.*; Ex-1205, ¶ 196.

Ressemann's support collar 2141 is also incorporated with the distal end of the substantially rigid portion. *See* § VII.D (claim 27), *supra*; Ex-1205, ¶ 196. When the support collar is added to evacuation assembly 100, Ressemann teaches that tab 2141b is incorporated with the shaft of the evacuation assembly, which includes intermediate portion 120 and distal portion 110, which comprise the substantially rigid portion disclosed in Ressemann. Ex-1208, 24:62-67; Ex-1242, ¶ 91; Ex-1205, ¶ 196.



Ex-1208, Fig. 16J (annotations added).

In addition, claim 35 is anticipated by the disclosures related to evacuation sheath assembly 2100 based on the disclosures included above and the reasons stated in § VII.B. Ex-1205, ¶ 196.

I. Claim 36: "The system of claim 25, wherein the side opening is incorporated with the proximal end of the reinforced portion."

Ressemann discloses this limitation. Ex-1208, Figs. 1A, 1C. Ressemann discloses that the proximal portion of the evacuation head is reinforced. *See* § VII.B.4 (claim 25.c.i.), *supra*. Thus, side opening 140a is incorporated with the proximal end of the reinforced portion, and Ressemann anticipates claim 36. Ex-1205, ¶ 197.

J. Claim 37: "The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes, starting at the distal end of the tip portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus."

Ressemann discloses this limitation. Ex-1205, ¶ 198; Ex-1242, ¶¶ 97-110. Ressemann discloses that the soft tip 144 is more flexible than the distal end of distal shaft portion 130. Ex-1208, 11:17-25, 11:36-41. Based on their known material properties, Ressemann expressly discloses that intermediate shaft portion 120 is more flexible than proximal shaft portion 110. Ex-1242, ¶ 109; Ex-1208, 11:4-11. As shown below, the proximal shaft portion 110 (region III) has a flexural modulus greater than the flexural modulus of intermediate shaft 120 (region II), and intermediate shaft 120 has flexural modulus greater than the flexural modulus of soft tip 144 (region I). Ex-1205, ¶ 198; Ex-1242, ¶ 110.

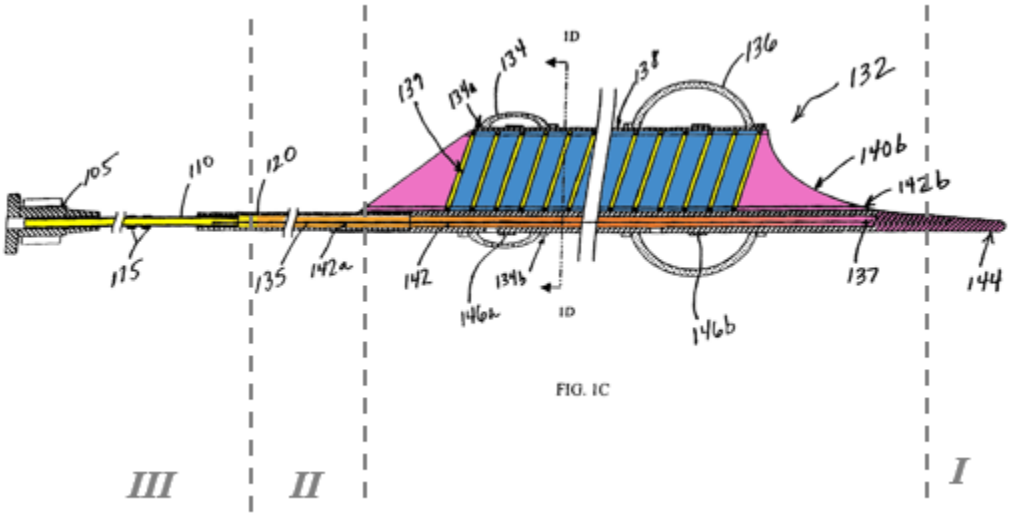


FIG. 1C

Ex-1208, Fig.1C (color and annotations added).

K. Claim 39: "The system of claim 25, wherein a distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received interventional device that would otherwise tend to dislodge the distal portion."[9]

Ressemann teaches that the distal portion of the evacuation assembly 100 is

[9] Patent Owner drafted claim 39 such that the "distal portion" of the extension catheter "anchor[s] within the ostium of the branch vessel." This claim language is nonsensical—if the distal portion of the extension catheter is located in the ostium, it cannot provide backup support—and Petitioner interprets this claim similar to claims 2 and 13.

advanced through guide catheter 160 and into the coronary artery. Ex-1208, Figs. 6B-6E, 12:19-13:64. The proximal portion of the evacuation head remains within the lumen of the guide catheter. *Id*. The evacuation sheath can then be used to deliver a stent across a stenotic lesion 180. *Id*. Fig. 6F, 14:7-10.

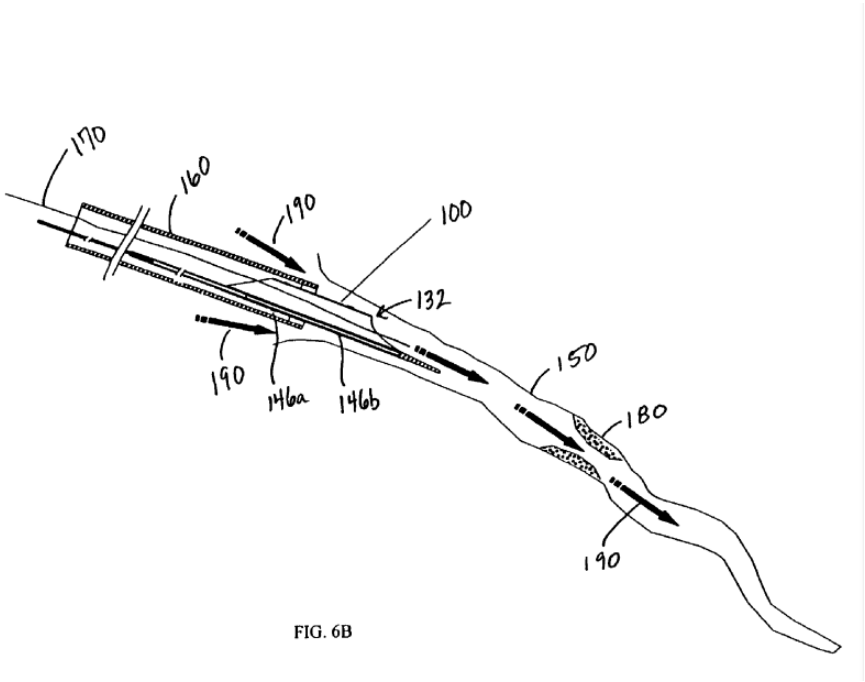


FIG. 6B

Id., Fig. 6B.

Thus, Ressemann discloses the structural limitations of claim 25, which is a system claim.[10] Ex-1205, ¶ 199.

[10] Claim 39 includes additional language that the "distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel" is configured to "anchor within the ostium." That cannot be

To the extent Patent Owner suggests claim 39 requires anything more than the cited disclosure in Ressemann, it is mistaken. Claim 39 recites an intended use ("to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received interventional device that would otherwise tend to dislodge the distal portion"), to which no patentable weight should be given. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.")

Regardless, Ressemann discloses the remainder of claim 39. Ex-1205, ¶¶ 199-207. Ressemann teaches that an interventional device may be extended through the evacuation sheath 100 and beyond its distal tip. Ex-1208, 12:26-30. Before the '380 patent, a POSTIA knew that in order to advance an interventional

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correct as the '380 patent specification teaches that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter be advanced further into the coronary artery. Ex-1201, Fig. 8. For this proceeding, Petitioner assumes this is a claim drafting error. Similar to the '380 patent, Ressemann teaches that the distal end of guide catheter 160 is "positioned within the ostium of the target vessel." Ex-1208, 12:26-30, Figs. 6A-6E.

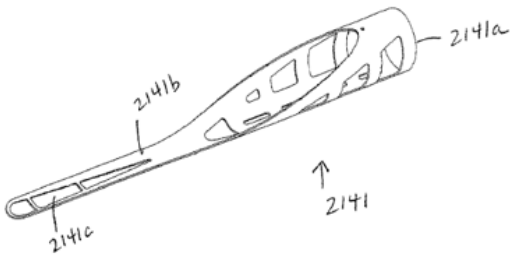
cardiology device through a guide catheter into the coronary vasculature, the guide catheter had to have "sufficient stiffness to offer 'backup' support." Ex-1215, 548; Ex-1205, ¶ 200. The support came from the guide catheter's shape, and the intrinsic stiffness of its material, as well as its "deep engagement" with the coronary ostia. Ex-1215, 549; Ex-1241, 20; Ex-1205, ¶¶ 200-207.

The '380 patent admits that because the disclosed, coaxial extension catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery," it "assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion . . . ." Ex-1201, Abstract, 5:6-27. Thus, it is the combination of a guide catheter ***and*** an extension catheter inserted into a coronary ostium that improves distal anchoring of the system and provides "stiffer back up support" than a guide catheter alone. *Id*., 8:19-32. But this is no different than what was already known in the prior art and disclosed in Ressemann. Ex-1205, ¶¶ 130, 199-207.

VIII. GROUND 2: RESSEMANN IN VIEW OF THE KNOWLEDGE OF A POSITA RENDERS CLAIM 27 OBVIOUS.

Ressemann in view of the knowledge of a POSITA renders claim 27 obvious. It would have been obvious to a POSITA to use Ressemann's support collar disclosed in Fig. 16J with evacuation sheath 100, such that "the side opening

includes at least two different inclined slopes." *Supra*, VII.D; Ex-1205, ¶¶ 189-190.



Ex-1208, Fig. 16J (annotations added).

The shape of the support collar, and the material from which it is made, serve to "reinforce the proximal opening" of the evacuation head. *Id*., 24:47-49. The cylindrical portion 2141a "fits into the proximal opening of the evacuation lumen," providing hoop support. *Id*., 24:55-58. The concave track portion of the collar, referred to as "distal tab 2141b" serves as a "flexibility transition" between the proximal end of the evacuation head and the evacuation sheath's shaft. *Id*., 24:62-67.

A POSITA would have been motivated to add the support collar of Ressemann in Fig. 16J to evacuation sheath assembly 100. Ex-1205, ¶¶ 189-190; Ex-1242, ¶¶ 86-94. The very purpose of the Ressemann support collar is to assist in effectively transmitting force from the proximal end of the evacuation sheath

assembly to its distal end. The collar serves "to reinforce the proximal opening of the evacuation lumen 2140 in the presence of deforming forces, particularly torsional stresses that may be created unintentionally by rotation of the catheter shaft near its proximal end." Ex-1208, 24:49-55. In other words, Ressemann teaches that the support collar would be advantageous for the purpose to which evacuation sheath 100 is directed—advancement through tortuous vasculature to treat a stenosis. Ex-1208, 6:18-24, 6:66-7:4. The proximal and intermediate evacuation shafts of sheath 100 are used to generate and transmit longitudinal force to the distal shaft, which is part of the evacuation head. *Id*., 10:30-35, 11:4-6; Ex-1205, ¶¶ 189-190.

IX. GROUND 3: RESSEMANN IN VIEW OF KATAISHI AND/OR THE KNOWLEDGE OF A POSITA RENDERS CLAIM 27 OBVIOUS.

A. Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under pre-AIA § 102(b) and post-AIA § 102(a)(1). Ex-1225. During prosecution of the '380 patent (and the parent '850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. Ex-1201-1003.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1225, [0001]. It teaches a distal opening with two inclines designed, in part, to improve the catheter's "crossing ability," which is its ability to

smoothly reach a desired target site. *Id*., Abstract, [0001]; *see also* Ex-1205 ¶¶ 113-114, 160. In addition to providing flexibility, the two-incline shape of the catheter's distal opening improves its ability to suction thrombi, Ex-1225, Abstract [0026]-[0027]; Fig. 10 (below, color added), corresponding to loading a thrombus into the catheter's distal end. Ex-1205, ¶¶ 159-162; Ex-1242, ¶¶ 42-49.

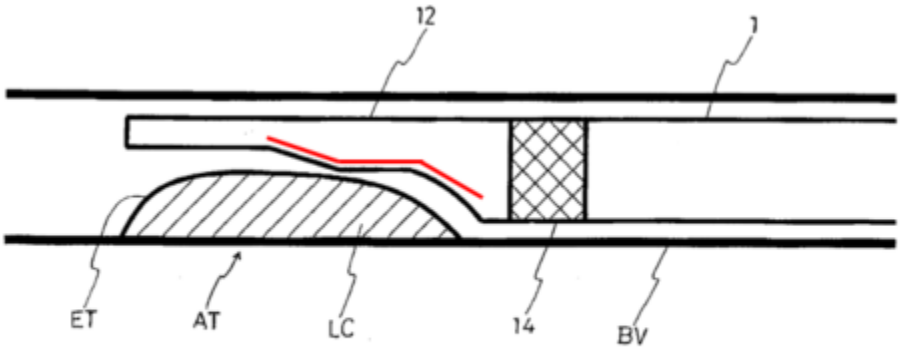
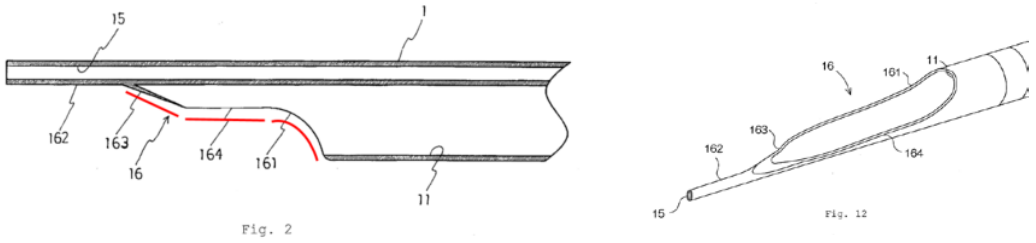


Fig. 10

Ex-1225, Fig. 10 (annotation added).

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



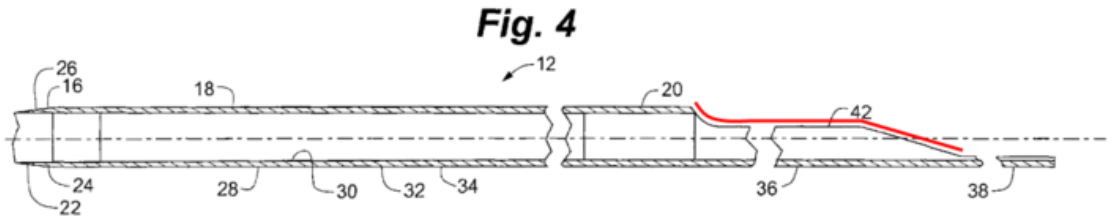
Ex-1225, Figs. 2 (annotation added), 12.

B. Claim 27

Ressemann (*see* § VII.D, *supra*) in view of Kataishi renders claim 27 obvious. Ex-1205, ¶¶ 208-213.

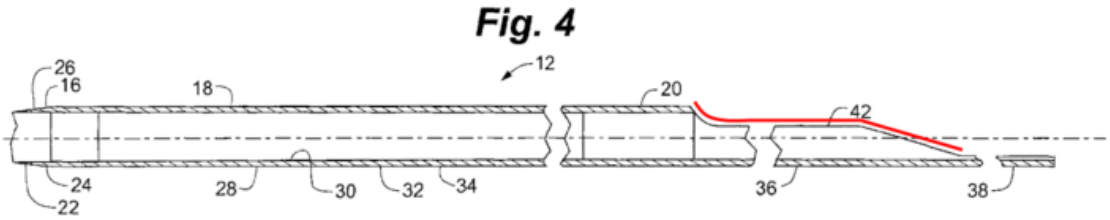
In an attempt to support claim 27, patentee represented to the Examiner that Figure 4 of the ’380 patent showed two different inclined slopes in the side opening.

’380 Patent



Ex-1203a at 19 (Preliminary Amendment (11/1/2013) at 17) (annotation added).

But the disclosure in the ’380 patent is no different than Kataishi.



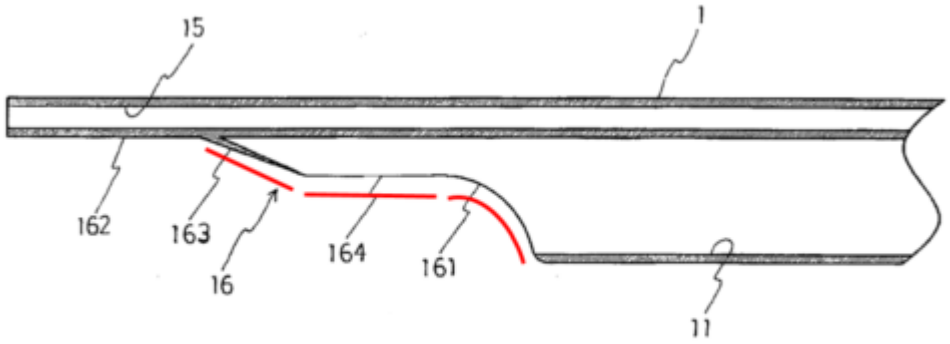


Fig. 2

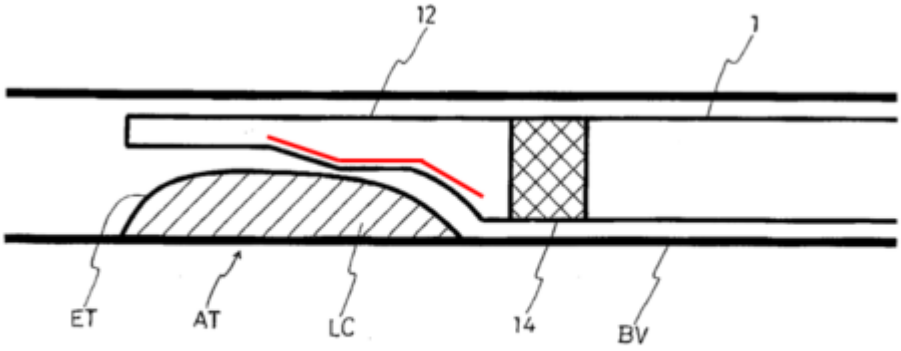


Fig. 10

C*ompare* Ex-1208, Fig. 4 (annotation added), *with* Ex-1225, Figs. 2, 10 (annotations added)); Ex-1205, ¶ 208; Ex-1242, ¶¶ 124-125.

A POSITA would have been motivated to modify the proximal opening of Ressemann's evacuation head 132 to include Kataishi's two different inclined

slopes. Ex-1242, ¶ 111-123; Ex-1205, ¶ 209. Ressemann and Kataishi are both directed at the same problem—removing occlusions from coronary arteries. Ex-1208, Abstract; Ex-1225, Abstract; Ex-1242, ¶ 112; Ex-1205, ¶ 209. Both Ressemann and Kataishi are directed at using a guide catheter and a therapy catheter, such as a balloon catheter, to remove occlusions. Ex-1205, ¶ 209.

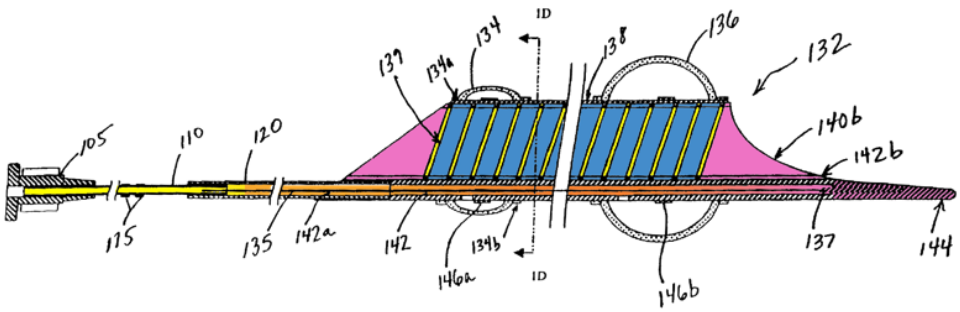


FIG. 1C

Ex-1208, Fig. 1C (color added).

Kataishi teaches a suction catheter with a distal end designed to do two things: 1) improve crossability of the catheter; and 2) provide superior loading of matter (thrombus) into the distal end of the suction catheter. Ex-1205, ¶ 210; Ex-1242, ¶¶ 113, 116. These advantages are accomplished by the shape of Kataishi's distal end. These same considerations—crossability, and the ability to load something into a catheter opening—apply equally to the proximal end of a catheter, especially catheters such as Ressemann in which loading is not just of thrombus, but of stents. Ex-1242, ¶ 118.

A POSITA would have been motivated to apply Kataishi's distal opening structure to the proximal opening, 140a, of Ressemann. Ex-1205, ¶ 210. First, adding a second, inclined slope to the angled, proximal side opening 140a of Ressemann would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex-1205, ¶ 211; Ex-1242, ¶¶ 113-115, 119. This modification would allow the catheter to receive a therapy catheter and still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1225, Abstract, [0026]-[0027], Fig. 10; Ex-1255, 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end); Ex-1205, ¶¶ 107-109, 112, 211; Ex-1242, ¶¶ 113-115, 119.

Second, a POSITA was aware that angled openings in the sidewall of a catheter—located proximal of the catheter's distal end—can "minimize . . . kinking . . . during insertion." Ex-1226, 3:6-14, 6:5-19, Fig. 2B; Ex-1205, ¶ 212; Ex-1242, ¶ 120-122. While Kataishi discloses two different inclined slopes on the distal end, a POSITA would be motivated to modify Ressemann's single incline side opening 140a to include two different inclined slopes for side opening 140a to minimize kinking and improve the crossability of the device. Ex-1205, ¶ 212, Ex-1242, ¶¶ 120-122.

A POSITA would have a reasonable expectation of success in modifying Ressemann's catheter with the two-inclined, proximal side opening disclosed in

Kataishi. Ex-1205, ¶ 213. Creating two different inclined slopes in the side opening would have been a routine task when manufacturing an extension catheter. Ex-1242, ¶ 123; Ex-1250, Fig. 7 (disclosing double incline, proximal side opening).

X. GROUND 4: RESSEMANN IN VIEW OF ENGER RENDERS CLAIM 27 OBVIOUS.

A. Enger

U.S. Pat. No. 5,980,486 to Enger issued on November 9, 1999. Ex-1250. It is prior art under pre-AIA § 102(b) and post-AIA §§ 102(a)(1), 102(a)(2), and was not cited or considered during prosecution of the ’850 patent. Ex-1202. It is cited on the face of the ’380 patent, but was not discussed during prosecution. Ex-1201, Ex-1203. Enger discloses a balloon catheter for use in a coronary artery. Ex-1250, Abstract. Ex-1205, ¶¶ 85-93, 163-168; Ex-1242, ¶¶ 70-71.

B. Claim 27

Ressemann (*see* § VII.D, *supra*) in view of Enger renders claim 27 obvious. Ex-1205, ¶¶ 214-216.

Like Ressemann, Enger is directed to a catheter system for treating occluded coronary arteries. Ex-1250, Abstract, 1:13-15. Like Ressemann’s evacuation assembly 100, Enger’s angioplasty catheter is inserted through a GC and into the coronary artery. Ex-1250, 3:25-29. And like Ressemann’s evacuation assembly 100, Enger’s angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*., 3:8-12.

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

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

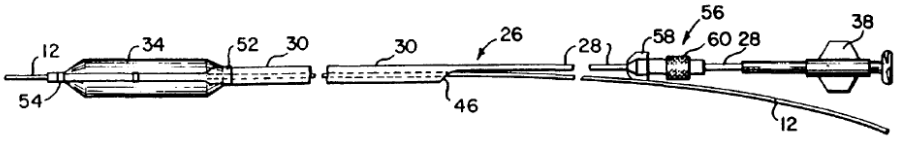


Fig. 1

Id., Fig. 1.

The catheter has a short, distally located guidewire lumen incorporated into the intermediate and distal catheter segments. *Id*., 3:8-11, 5:33-40.

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

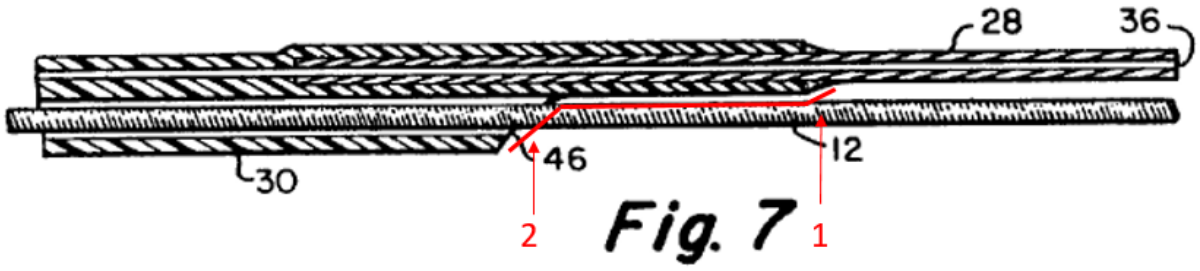
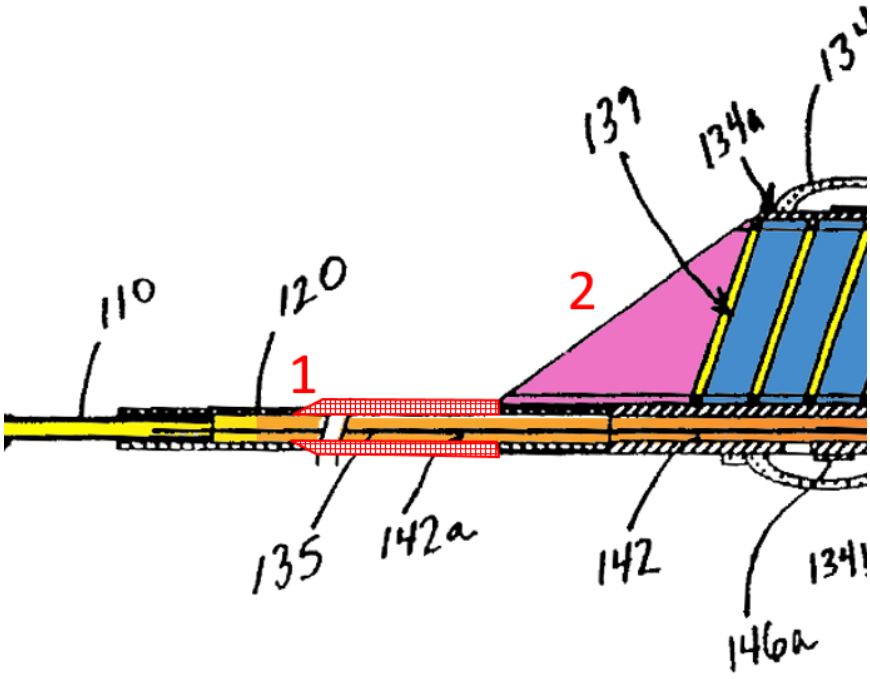


Fig. 7

Id., Fig. 7 (annotation added).

Enger's incline #1 functions as a start of an incline ramp to the entry port located at incline #2. This incline functions to guide the interventional device (in this case a guidewire) into its designated lumen. A POSITA would have had motivation to provide a first incline to function as an "on-ramp" to guide interventional devices such as distal end protective device or stent and balloon catheter into the lumen of evacuation sheath 132. Ex-1205, ¶¶ 118, 215; Ex-1242, ¶ 132.

The first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1242, ¶ 130. A POSITA would have understood that the first incline of Enger could be incorporated into Ressemann's evacuation assembly 100 by using a similarly inclined polymer collar to grip shaft 120. This would result in a two-incline opening as shown below. Ex-1242, ¶¶ 127-132; Ex-1205, ¶ 216.



Ex-1208, Fig. 1C (modified with teaching of Enger and illustrating two-incline opening, color and annotations added).

XI. GROUND 5: RESSEMANN IN VIEW OF TAKAHASHI RENDERS CLAIMS 32 AND 33 OBVIOUS.

A. Takahashi

Takahashi et al. ("Takahashi"), published in 2004, is entitled *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*." Takahashi is prior art under at least pre-AIA § 102(b) and post-AIA §§ 102(a)(1). Ex-1278, ¶¶ 43-52. Takahashi is cited in the Background of the '380 patent, but was not the basis of a rejection during prosecution of either the '380 patent or the '850 patent. Exs-1201-1203.

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-1210, 452. Takahashi states that the inner lumen of the 5 French and 6 French catheters is 0.059 inches and 0.071 inches (*id.*), which is less than a 1 French difference in inner diameters. Ex-1205, ¶¶ 169-172. *See also* Ex-1242, ¶¶ 36-41.

B. Claim 32: "The system of claim 25, wherein a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is not more than one French smaller than a second inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel."

Ressemann renders claim 32 obvious in view of Takahashi and the knowledge of a POSITA. Ex-1205, ¶¶ 217-221. Ressemann does not teach the not-more-than-one French differential, but Takahashi discloses using an extension catheter that had an inner diameter of the lumen that was not more than one French smaller than the inner lumen of the guide catheter. Ex-1210, 452-54; Ex-1205, ¶ 217.

A POSITA had the motivation to modify the structures disclosed in Ressemann to eliminate the sealing balloons and the inflation lumen of the disclosed evacuation assembly 100. Ex-1205, ¶ 218. The evacuation assembly's shaft includes an inflation lumen to allow for the expansion of sealing balloons on the evacuation head. Ex-1208, 8:15-21, 11:13-17. A POSITA, however, had the

motivation to modify Ressemann because it teaches that inner catheter 100 may be used to both aspirate embolic material (Ex-1208, Abstract, 12:9-13:34) ***and*** to deliver an angioplasty balloon or stent. *Id*., 6:25-34, 23:8-20; Ex-1205, ¶ 218. As such, a POSTIA would be motivated to remove the sealing balloons and to replace the inflation lumen with a solid pushrod or wire, such that Ressemann could be used as an extension catheter. Ex-1205, ¶ 219; Ex-1242, ¶¶ 134-136.

First, the use of extension catheters—with a guide catheter—was known in the art. Ex-1209, Abstract; Ex-1234, Abstract. Second, modifying Ressemann's assembly 100 so that it did not have sealing balloons would have simplified the manufacturing process. Ex-1242, ¶ 137. Third, the modification would have decreased the outer diameter of assembly 100. Ex-1242, ¶ 137; Ex-1205, ¶ 220.

Decreasing the size of the outer diameter of assembly 100 would have been advantageous because it would have allowed assembly 100 to be used with smaller guide catheters. Ex-1242, ¶ 137; Ex-1205, ¶ 220. And using guide catheters smaller than the 8 French guide catheter disclosed in Ressemann would have allowed PCI procedures to be performed via access through the radial artery instead of the femoral artery, which allows for easier bleeding control and immediately ambulatory patients. Ex-1215, 91-92, 549; Ex-1205, ¶ 220. A POSITA would have a reasonable expectation of success in making this combination because it involves removing parts of the catheter assembly in a

routine manner. Ex-1242, ¶ 137; Ex-1205, ¶ 221.

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" than the lumen of the guide catheter was beneficial because using a 5 French child catheter in a 6 French guide catheter provides better back-up support for the guide catheter, and assists in deploying an angioplasty catheter across chronic total occlusions. Ex-1210, 452, 454, 456; Ex-1205, ¶¶ 220-221.

C. Claim 33: "The system of claim 32 wherein the lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to receive a stent and a balloon catheter."

Ressemann teaches using the lumen of evacuation assembly 100 to receive a stent and a balloon catheter. Ex-1208, Figs. 6E-6G, 13:55-14:19, 23:8-20. Thus, Ressemann renders claim 33 obvious in view of Takahashi and the knowledge of a POSITA. Ex-1205, ¶ 222.

XII. GROUND 6: RESSEMANN IN VIEW BERG AND/OR KNOWLEDGE OF POSITA RENDERS CLAIM 38 INVALID AS OBVIOUS.

A. Berg

Berg issued on June 15, 1999 and is prior art under at least pre-AIA § 102(b) and post-AIA §§ 102(a)(1), 102(a)(2). Berg is listed in the "References Cited" on the '380 patent. Ex-1201, [56]. Berg was not the basis of a rejection during prosecution of either the '380 patent or the '850 patent. Exs-1201-1203.

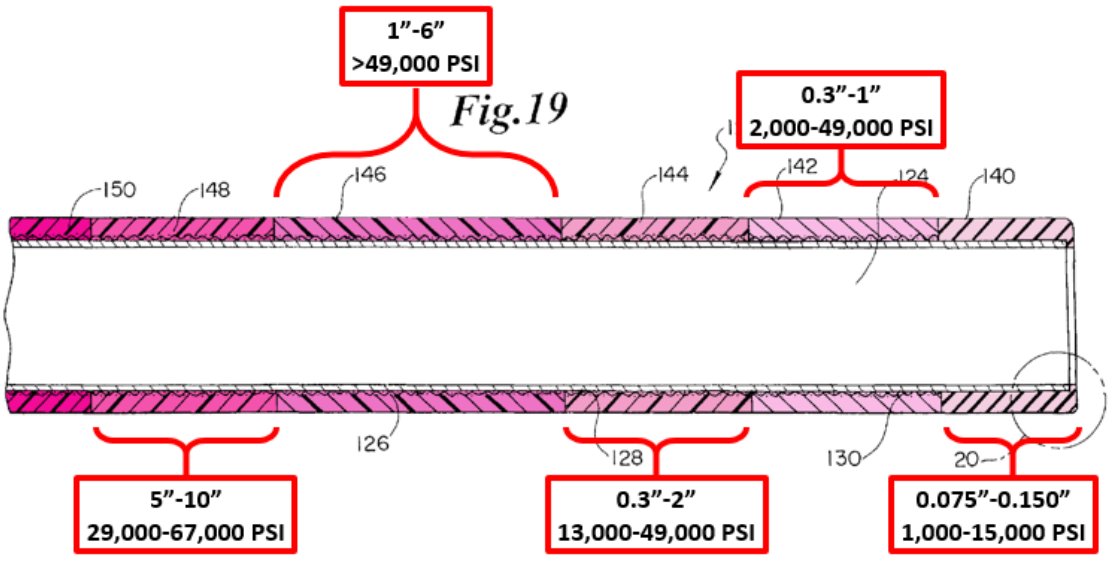
Berg teaches a guide catheter that has a distal tip, the most flexible portion, and, moving distal to proximal, the catheter increases in rigidity. Ex-1251, 2:66-3:9. In particular, the "soft tip zone of flexural modulus [is] between 1 and 15 Kpsi." *Id.*, 3:3-9. The second and third flexural modulus is between 2 and 49 Kpsi and 13 and 49 Kpsi. *Id. See also* Ex-1242, ¶¶50-58.

B. Claim 38: "The system of claim 37, wherein the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third flexural modulus is about 49,000 PSI plus or minus 10,000 PSI."

Ressemann in combination with Berg and the knowledge of a POSITA renders claim 38 obvious. Ex-1205, ¶¶ 223-229. As discussed above for claim 37, Ressemann has at least three regions of flexural moduli. *See* § VII.J, *supra.* Ressemann does not disclose the PSI of those regions. Ex-1242, ¶ 142.

Berg, however, teaches a guide catheter with at least three different specific flexural moduli. Ex-1251, 2:66-3:9. The distal soft tip has a flexural modulus

between "1 to about 15 Kpsi," or 1,000 to 15,000 PSI, which "provide[s] an atraumatic end ... for navigating vasculature" Ex-1251, 13:66-14:7, Fig. 19; Ex-1205, 223; Ex-1242, ¶ 142. Berg also teaches that—just proximal to the soft tip—the catheter should be increasingly rigid in a distal to proximal direction, including a portion with a flexural modulus "between about 2 and about 49 Kpsi" or 2,000 to 49,000 psi. Ex-1251, 14:21-28; Ex-1205, ¶ 223; Ex-1242, ¶ 143. This second flexural modulus assists in the positioning of the catheter tip. . Ex-1251, 14:21-28; Ex-1205, ¶ 223; Ex-1242, ¶ 143. Finally, Berg teaches that the next most proximal segment should have a flexural modulus "between about 13 and about 49 Kpsi" or 13,000 to 49,000 psi, and then a portion with a flexural modulus of greater than 49,000 psi. Ex-1251, 14:35-51; Ex-1205, ¶ 223; Ex-1242, ¶ 144.



Ex-1251, Fig. 19 (color and annotations added).

A POSITA would have been motivated to modify Ressemann to the flexural moduli enumerated by Berg. Ex-1205, 224; Ex-1242, ¶ 145. In particular, it was known that coronary catheters should have "a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions." Ex-1244, 1:36-38; *see also* Ex-1205, ¶¶ 223-227; Ex-1242, ¶¶ 138-147. Indeed, Ressemann teaches that the evacuation sheath assembly should have regions with distinctly different rigidities to promote pushability. Ex-1208, 11:4-10. The guide catheter of Berg likewise discloses that "the present invention allows for flexibility of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out." Ex-1251, 2:37-39. Although Berg's teachings are directed to a guide catheter, and not an extension catheter, a POSITA would have an expectation of success, as both are part of the same catheter assembly and need to traverse the same vasculature. Ex-1205, ¶¶ 227-228; Ex-1242, ¶¶ 146-147.

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

The three regions of flexural moduli taught by Berg overlap with the claimed range. Ex-1205, ¶ 229. Thus, the claimed range would have been obvious.

In re Harris, 409 F.3d 1339, 1341 (Fed. Cir. 2005) ("[A] prima facie case of obviousness arises when the ranges of a claimed composition overlap the ranges disclosed in the prior art.").

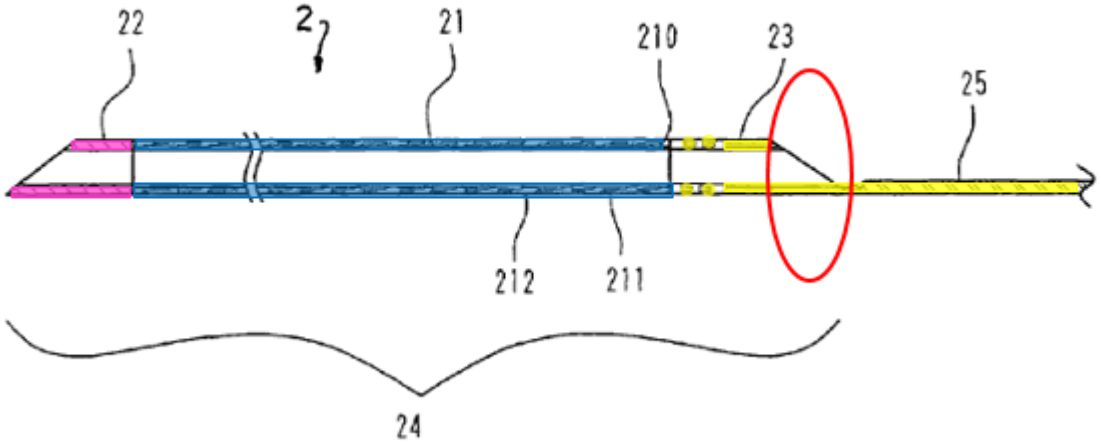
XIII. GROUND 7: ITOU ANTICIPATES CLAIMS 25-26, 28-30, 32-37, AND 39.

A. Itou

Itou was filed on September 23, 2005, issuing as U.S. Pat. No. 7,736,355 on June 15, 2010. It is prior art under pre-AIA § 102(e) and post-AIA §§ 102(a)(1), 102(a)(2), and was not cited or considered during prosecutions of either the original '850 patent or of the '380 reissue patent. Ex-1201-1203.

Itou discloses a catheter assembly for alleviating the obstruction of blood flow. Ex-1207, 1:13-16. The assembly includes a guide catheter that is inserted into a coronary artery ostium, *id*., 1:66-2:5, Abstract, 5:32-34, 7:7-12, and a suction catheter that inserted through the guide catheter. *Id*., Abstract, Figs 1A-1B, 5-6 6, 3:59-63. Suction catheter 2 has a proximal, "solid wire-like portion" 25, shown below in yellow, and a distal, tubular portion 24. *Id*., Abstract, 1:53-60, 2:12-15, 3:46-50. Tubular member 24 includes a "soft tip whose distal end is flexible in order to reduce the damage to the blood vessel," 22 (pink), *id*. 2:15-21, and a portion reinforced with a metal layer 211 (blue). *Id*., 2:18, 3:50-58 (color added) (tubular structure 21). Tubular member 24's proximal opening is angled (red

circle).



Id., Fig. 3 (color and annotation added); *see also* Ex-1205, ¶¶ 173-174.

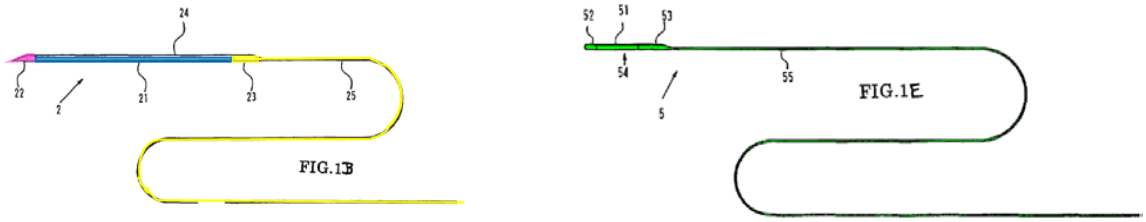
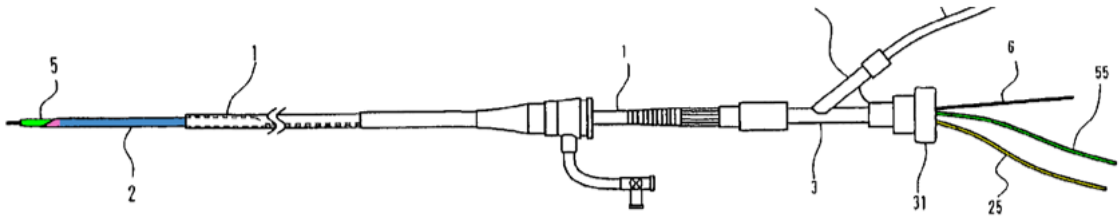


FIG.5



Ex-1207, Figs. 1B, 1E, 5 (color added).

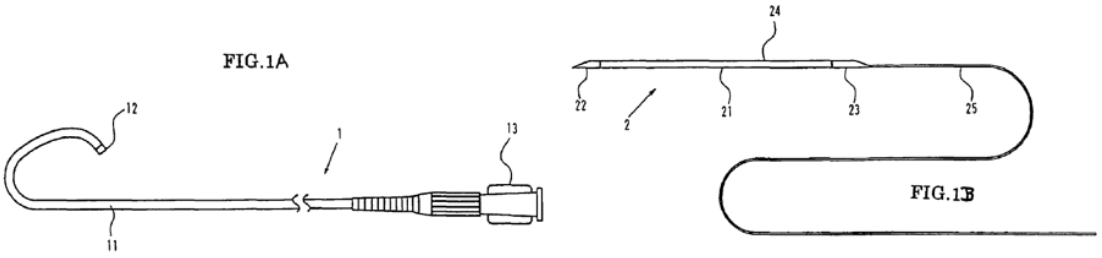
Itou describes a "distal end protective catheter" 5, shown above in green, which is insertable through the suction catheter 2. *Id*. Suction catheter 2 may be

extended beyond the distal end of the guide catheter 1 into a coronary artery. *Id*., Abstract, 2:29-38, Figs 5-6; Ex-1205, ¶ 176; Ex-1242, ¶ 31. By the time of the alleged invention of the ’380 patent, a POSITA knew that suction catheters with a structure similar to Itou’s may serve a dual purpose. Ex-1205, ¶¶ 94-102, 120-121, 124, 177-178. An aspiration catheter could be “preferably sized so as to allow the slideable insertion of a therapy catheter through the aspiration lumen...” Ex-1219, 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-1208, 6:18-34, Figs. 6A-6I; Ex-1205, ¶¶ 94-102, 173-178. *See also* Ex-1242, ¶¶ 30-35.

B. Claim 25

1. [25.pre]

To the extent the preamble is limiting, Itou describes a guide catheter, guiding catheter 1, which is used to guide suction catheter 2 into a coronary artery. Ex-1207, Abstract, Fig. 6, 5:26-51.



Id., Figs. 1A, 1B.

The combination of guiding catheter 1 and suction catheter 2 discloses the claimed "system." *See*, § XIII.B(2-7), *infra*; Ex-1205, ¶ 230.

2. [25.a]

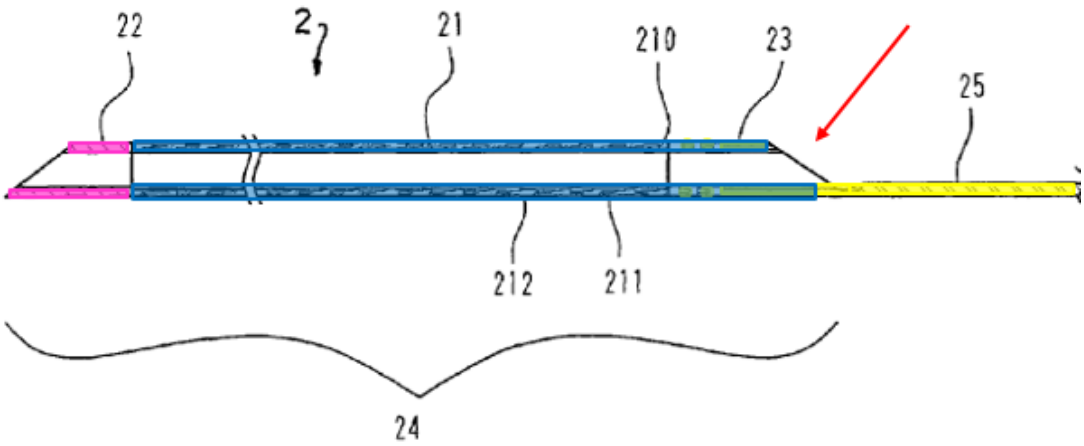
Itou discloses the function of guiding an interventional device, distal end protective catheter 5 from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel. Ex-1207, Fig. 6, 5:26-46, 7:7-18. *See supra* § VI.A (construing means plus function limitations).

The corresponding structure disclosed in the '380 specification is a guide catheter. Itou discloses that (i) guiding catheter 1's distal end is "hooked at an ostium" of a coronary artery (Ex-1207, 5:32-34; *and see id*., 1:66-2:5, Fig. 6), (ii) guiding catheter 1 is used in conjunction with suction catheter 2 that is sized to fit therein (*id*., Abstract, Figs. 1A-1B, 5-6, 2:29-38, 5:11-17; Table 1), and (iii) suction catheter 2 is sized to accommodate insertion of distal end protective catheter 5. *Id*., Figs. 1B, 1E, 5, 4:43-52, 5:11-17, Table 1. Thus, Itou discloses this limitation. Ex-1205, ¶ 231. If this limitation is not construed as means-plus-function, Itou's same teachings satisfy this limitation. *Id*.

3. [25.b]

As discussed in § VI, *supra*, this is not a means-plus-function limitation. Itou teaches that suction catheter 2 may be inserted into guiding catheter 1 after the latter has already been advanced into the vasculature. Ex-1207, 2:29-38. Itou

explains that when a "distal side of the tubular portion projects forwardly beyond the distal side of the guiding catheter," the "proximal side of the tubular portion is disposed inside of the guiding catheter." *Id*., 2:32-38. The proximal side of Itou's tubular portion is an angled opening (arrow below).



Ex-1207, Fig. 3 (color and annotation added).

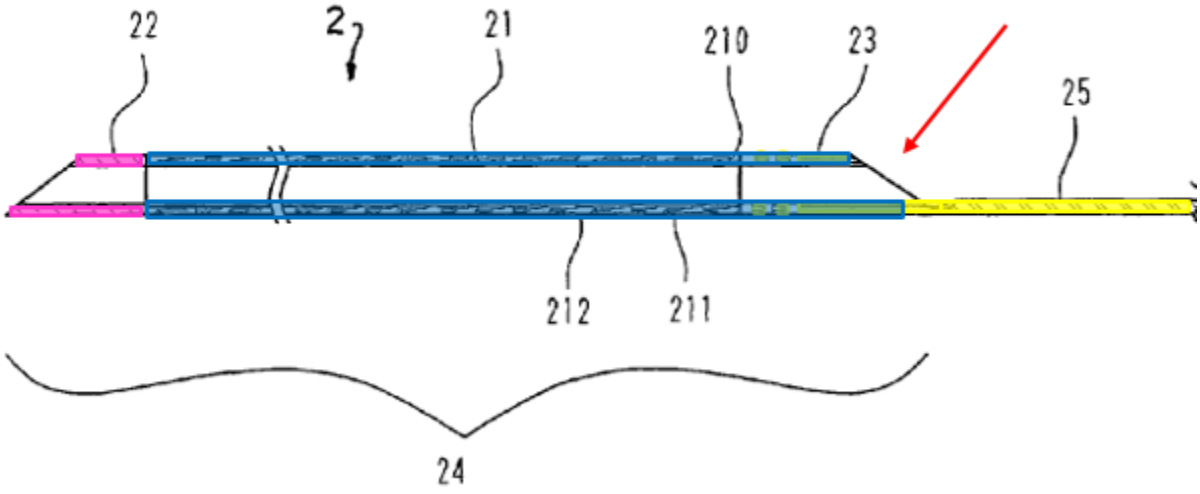
As discussed in 25.a, *supra*, the angled, proximal opening of tubular structure 24 is configured to receive distal end protective catheter 5. Itou also teaches that distal end protective catheter 5 is introduced into the coronary vasculature in conjunction with suction catheter 2, and that both devices are positioned deeper in the vasculature than guiding catheter 1. Ex-1207, 5:29-46, Fig. 6; *see also* § XIII.F (Claim 33), *infra*. Thus, Itou explicitly teaches structure that performs the claimed function. Ex-1205, ¶ 232.

If this is a means-plus-function claim element, Itou's suction catheter 2 is a "coaxial guide catheter" that performs the claimed function for the same reasons provided herein. *Id*.

4. [25.c.i]

The remainder of claim 25 recites solely structure, so the same disclosures in Itou are applicable regardless of whether the claim is construed as a means-plus-function claim.

Itou's suction catheter 2 discloses in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion (yellow). Ex-1205, ¶ 233.



Ex-1207, Fig. 3 (color and annotation added).

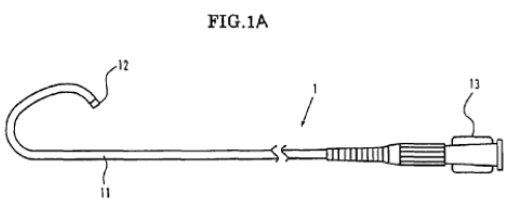
By reference to the annotated Figure above, the "tip portion" is distal tip 22 (pink), which Itou teaches is soft and flexible to avoid damaging the vasculature.

Id., 2:15-21. The reinforced portion is tubular body portion 21 (blue), which includes an inner resin layer 210, a reinforcing layer made of metal wire 211, and an outer layer 212. *Id*., 3:50-58. The side opening is the angled, proximal opening of tubular body 24, *id*., 4:25-32, and the "substantially rigid portion" is wire-like portion 25 (yellow) made of solid metal. *Id*., 3:47-50. Ex-1205, ¶ 233; Ex-1242 ¶¶ 34, 150.

Wire-like portion 25 is "substantially rigid" because Itou describes that it is used to advance suction catheter 2 through guiding catheter 1 and into the coronary vasculature. Ex-1207, 2:32-38, 5:35-46, Abstract, Figs. 5-6. Thus, it satisfies "substantially rigid" as construed. *See* § VI; Ex-1205, ¶ 233.

5. [25.c.ii]

Itou discloses 25.c.ii. Ex-1205, ¶¶ 234-235. Itou teaches that suction catheter 2 is long enough to extend from both the proximal and distal ends of guiding catheter 1. As illustrated below, catheter 2's wire-like portion 25 (yellow) extends proximal of guiding catheter 1's proximal end, and the distal part of its tubular structure (pink, blue) extends distal of guiding catheter 1's distal end.



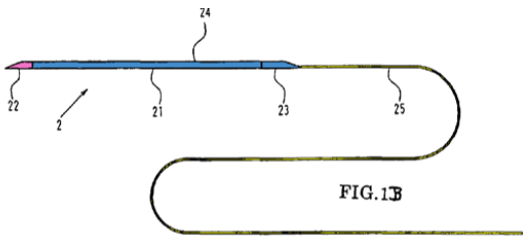
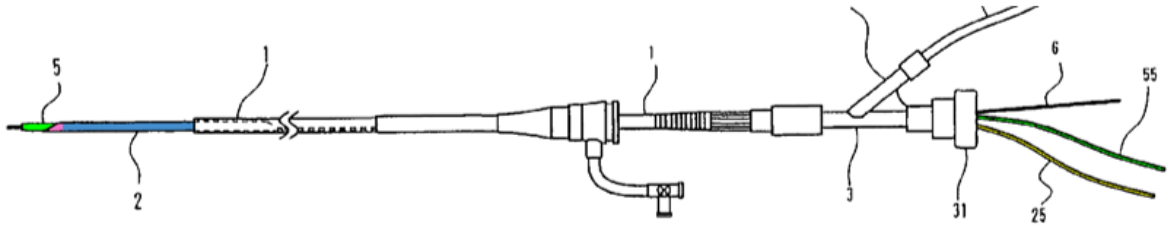


FIG.5

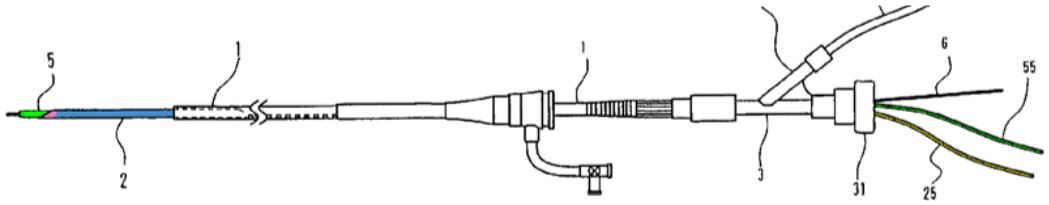


Ex-1207, Figs. 1A, 1B, 5 (color added).

6. [25.d]

Itou discloses 25.d. As shown in Figure 5, suction catheter 2 is configured to be passed, at least in part, into the lumen of guide catheter 1. Ex-1205, ¶ 236. Ex-1207, Fig. 5, 5:11-17.

FIG.5



Ex-1207, Fig. 5 (color added).

7. [25.e]

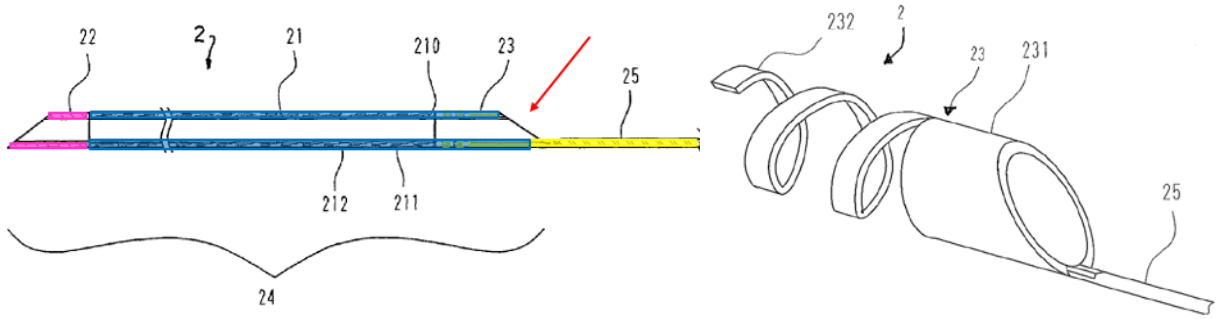
Itou discloses 25.e. First, the side opening is formed by "obliquely cutting one end of a metal pipe." Ex-1207, Figs. 3-4; 4:25-32. Second, the substantially rigid portion is made of "a solid metal wire" and an outer polymer coating. *Id*.,

3:47-50. By contrast, tip 22 is soft and flexible. *See* § XIII.B.4 (claim 25.c.i), *supra*.

Based on the known properties of the materials of catheter 2's side opening and substantially rigid portion, and its flexible tip portion, the former are more rigid along a length than tip 22. Ex-1205, ¶ 237; Ex-1242, ¶¶ 148-157. 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-1207, 5:43-46; Ex-1205, ¶ 238. It was known that in order to advance through the coronary vasculature, the proximal portion of a catheter had to have sufficient rigidity or stiffness (in order to permit the catheter to be pushed through the vasculature), while its distal end was fairly flexible. Ex-1219, 9:30-50; Ex-1272, 2:29-44; Ex-1205, ¶ 239-243; Ex-1242, ¶ 152; *see also* Ex-1242, ¶¶ 51-56, 148-157.

C. Claim 26

Itou discloses that side opening 231 is "inclined obliquely," and "formed by obliquely cutting one end of a metal pipe," as shown below, to form at least one inclined slow (red arrow). Ex-1207, 4:10-15, 4:27-32.

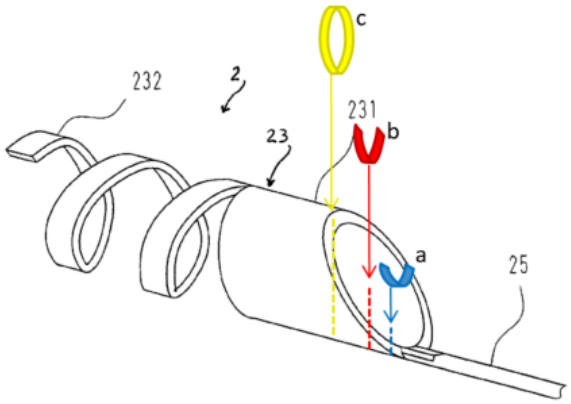


Id., Figs. 3 (color and annotation added), 4.

Thus, Itou anticipates claim 26. Ex-1205, ¶ 244.

D. Claims 28-30

The limitations of "extending less than 180° of a full circumference" and "extends 25% to 40% of a full circumference," as recited in claims 28 and 29, respectively, add nothing of patentable weight. As defined in the '380 patent, arcuate portion means "extends from 25% to 40% of the circumference of the tube." Ex-1201, 7:5-7. Stated another way, by reciting an arcuate portion in claim 28, Patent Owner necessarily recited a portion that extends 25% to 40% of the cross-sectional circumference, or between 90° and 144°, which is less than 180°. Ex-1205, ¶¶ 245-247. Nonetheless, as discussed above, *supra* XIII.C, Itou discloses a side opening 231 features each of the cross-sectional shapes recited in claims 28-30. Ex-1205, ¶¶ 245-248.



Ex-1207, Fig. 3 (annotations added).

Claim	Side Opening Claim Language Bolded	Location in Side Opening 231
28	"… wherein a portion of the side opening includes an **arcuate cross-sectional shape extending less than 180° of a full circumference**."	Portion proximal of red line (b)
29	"… wherein the portion of the side opening having the **arcuate cross-sectional shape extends 25% to 40% of a full circumference**."	Portion proximal of blue line (a)
30	"… wherein the side opening includes a portion having **a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape**."	Portion between red line (b) and yellow line (c)

E. Claim 32

Itou anticipates claim 32. Ex-1205, ¶ 250. "[G]uiding catheter 1 is formed from a guiding catheter of 6 Fr (2.06 mm) which is used popularly and has an inner diameter of 1.8 mm." Ex-1207, 6:47-50, Table 1. Catheter 2's tubular portion 24

(and therefore the "tubular structure defined by flexible tip portion [21, 22]) has an inner diameter of 1.5 mm, *id*., Table 1, which is 0.3 mm smaller than the inner diameter of the guide catheter. And 0.3 mm is "not more than one French smaller," because one French is 0.33 mm. Ex-1262. Ex-1205, ¶ 250.

F. Claim 33

Itou anticipates claim 33. Ex-1205, ¶ 251. Itou teaches that the lumen of suction catheter 2 is a means for receiving an interventional device, distal end protective catheter 5, and guiding it deeper into the branch vessel.

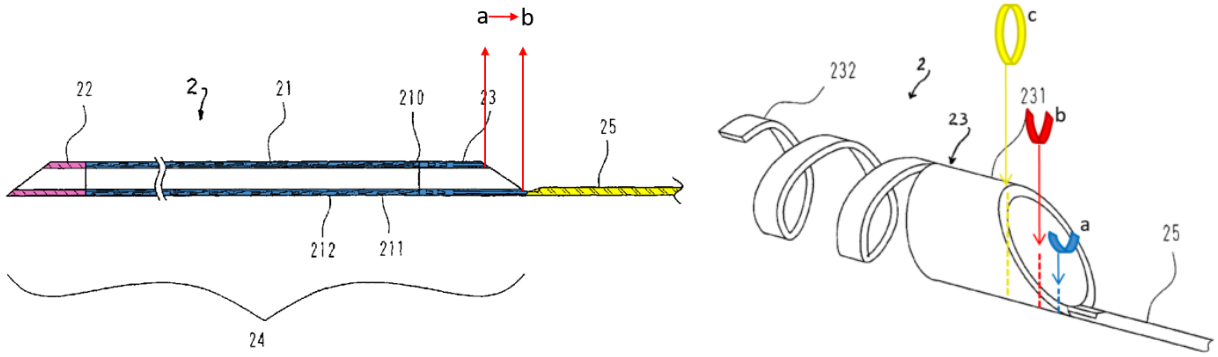
Itou additionally teaches that the lumen of catheter 2 is "configured to receive a stent and a balloon catheter." The inner diameter of catheter 2 is 1.5 mm, Ex-1207, Table 1, which is 0.059 inches.[11] This was large enough to accommodate the insertion of a balloon-expandable stent, several of which were available by the time of the purported invention of the '380 patent. Ex-1205, ¶ 251; Ex-1222, 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-1223, 2 (requiring a minimum, inner catheter diameter of 0.56 inches (1.4 mm) for Driver™ stents on

[11] This corresponds to the inner diameter of the extension catheter taught in the '380. Ex-1201, 3:43 ("greater than or equal to 0.056 inches ...").

an OTW or RX delivery system); Ex-1224, 2 (requiring an inner catheter diameter ≥ 0.058 in. (1.47 mm) for TAXUS Express[2] stents on a monorail delivery system).

G. Claim 34

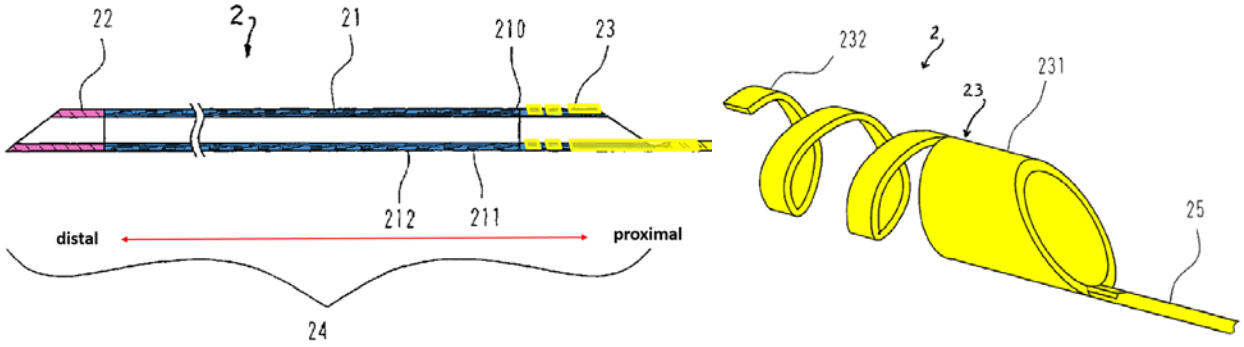
Itou teaches that the lumen of suction catheter 2 is a means for receiving an interventional device, distal end protective catheter 5, and guiding it deeper into the branch vessel. *See* §§ XIII.B.4 (claim 25.c.i), XIII.F (claim 33), *supra*. Itou discloses that suction catheter 2 includes a portion of its length that is not fully circumferential, and thus, forms a concave track along a portion of its length. Ex-1205, ¶ 252.



Ex-1207, Fig. 3 (not fully cylindrical between "a" and "b") (annotations and color added), Fig. 4 (not fully cylindrical, for example, at "a" or "b") (annotations and color added).

H. Claim 35

Itou discloses that proximal end portion 231 "is secured firmly by being welded to the distal end of the wire-like portion 25 crushed into a form of a flat place so that it may not be broken during use." Ex-1207, 4:33-36.

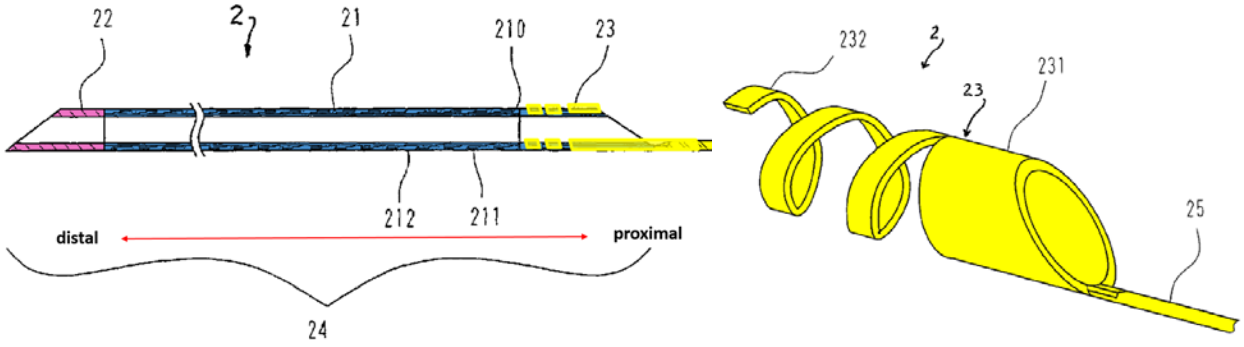


Id., Figs. 3-4 (annotations and color added).

Thus, Itou discloses the side opening is incorporated with the distal end of the substantially rigid segment and anticipates claim 35. Ex-1205, ¶ 253.

I. Claim 36

Itou discloses that reinforced tubular portion 21 contains "the proximal tip 23 includ[ing] a body which in turn includes a proximal end portion 231," as shown below. Ex-1207, 4:27-32.



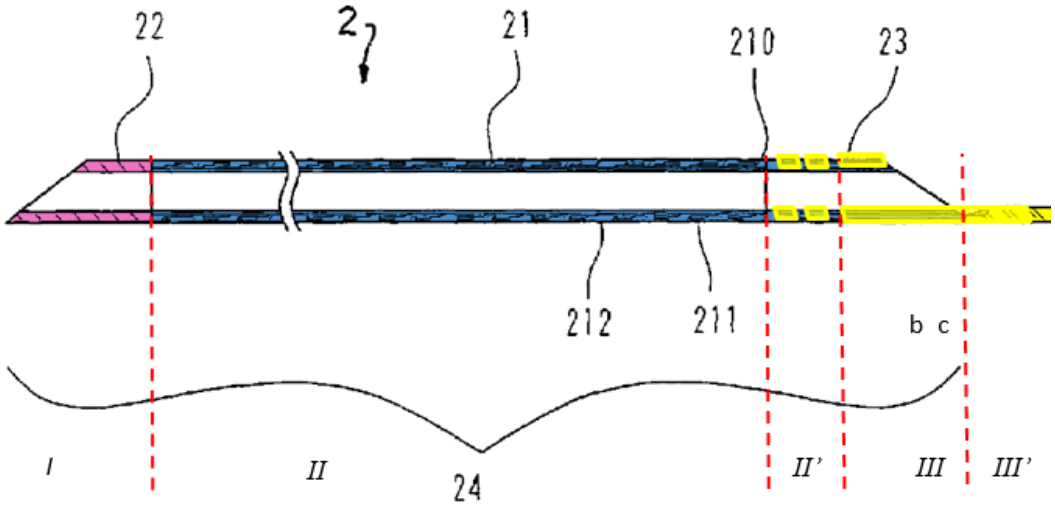
Id., Figs. 3-4 (annotations and color added).

Itou also discloses that "resin layers which cover the inner and outer faces of the proximal tip 23 are secured to the tubular body portion 21 by fusion." *Id.*, 4:36-38. Thus, Itou discloses a side opening incorporated with the proximal end of the reinforced portion 21 and anticipates claim 36. Ex-1205, ¶ 254.

J. Claim 37

Itou anticipates claim 37. Ex-1205, ¶ 255. Itou discloses at least five different portions of the elongate structure of suction catheter 2, each with a different flexural modulus.

Distal tip (22) (pink below) is described as soft and flexible. Ex-1207, 2:12-21. Tip 22 has a first flexural modulus. Ex-1205, ¶ 255; Ex-1242, ¶¶ 163-164. Thus, tip 22 is a "first portion having a first flexural modulus." (Below, *I*).



Ex-1207, Fig. 3 (annotations and color added).

Itou teaches that tubular portion 21 is proximal to tip 22, and has "a reinforcing layer 211 made of a metal wire made of stainless steel or the like...." Ex-1207, 3:50-58. Tubular portion 21 is a reinforced portion relative to flexible distal tip 22. Ex-1207, 2:15-21, 3:50-58; Ex-1205, ¶ 255; Ex-1242, ¶ 165. Tubular portion 21 has a second flexural modulus, greater than the first flexural modulus of tip 22. Ex-1205, ¶ 255; Ex-1242, ¶ 165. Thus, tubular portion 21 is a "second portion having a second flexural modulus greater than the first flexural modulus." Ex-1205, ¶ 255. (Above, *II*).

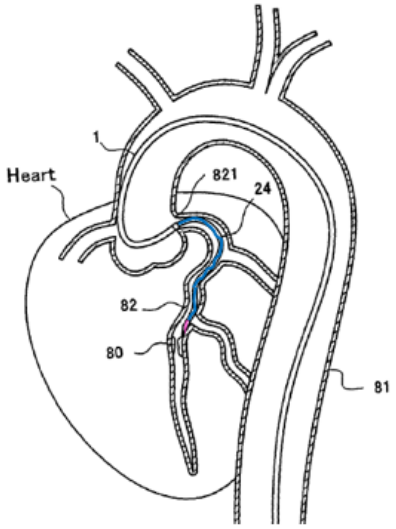
Proximal end portion 231 is ***not*** cut into a spiral shape. Ex-1207, Fig. 4. The portion of the elongate structure that includes proximal end portion 231 has a third flexural modulus that is greater than either the first flexural modulus of tubular portion 21, or the second flexural modulus of the portion of suction catheter 2 that includes spiral shape 232. Ex-1205, ¶ 255; Ex-1242, ¶¶ 166-168. Thus, the portion of the elongate structure that includes proximal end 231 is a "third portion having a third flexural modulus greater than the second flexural modulus." Ex-1205, ¶ 255. (Above, *III*).

Itou teaches that tubular portion 24 is attached to solid metal wire 25. Ex-1207, 3:47-50, 4:33-36. Metal wire 25 has a third flexural modulus that is greater than the second flexural modulus of tubular portion 21, or the second flexural modulus of the portion of suction catheter 2 that includes spiral shape 223. Ex-

1205, ¶ 255; Ex-1242, ¶¶ 169-170. Thus, metal wire 25 is also a "third portion having a third flexural modulus greater than the second flexural modulus." Ex-1205, ¶ 255. (Above, *III'*).

K. Claim 39

Itou teaches that the distal portion of suction catheter 2 (tubular member 24) is advanced through guiding catheter 1 and into the coronary artery. Ex-1207, Abstract, 3:1-3, 5:26-46; Ex-1205, ¶ 256. Itou also teaches that the proximal portion of tubular member 24 remains within the lumen of guiding catheter 1. The suction catheter 2 is used to deliver an interventional device (protective catheter 5) deeper into the vasculature to a target location 80. Ex-1207, Fig. 6, 3:1-3, 5:26-46.



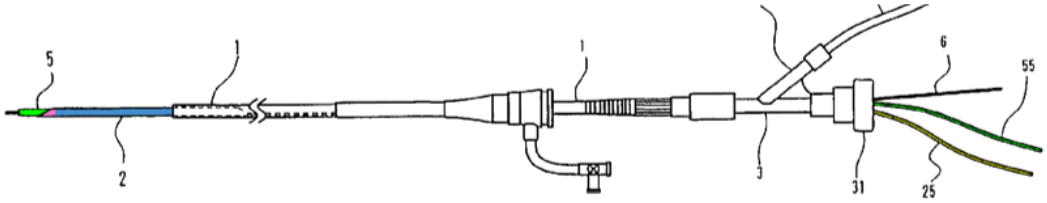
Ex-1207, Fig. 6 (color added, illustrating tip (22) (pink) and a portion of tubular structure (21) (blue)), Abstract, 1:47-65, 5:38-42.

Thus, Itou discloses the structural limitations of claim 39, which is a system claim.[12] Ex-1205, ¶ 256.

To the extent Patent Owner suggests claim 39 requires anything more than the cited disclosure in Itou, it is mistaken. As discussed in Ground 1, the intended use recited in claim 39 should not be given patentable weight. Regardless, Itou discloses the remainder of claim 39 to a POSITA. Ex-1205, ¶¶ 257-262.

First, Itou teaches that protective catheter 5 may be extended through suction catheter 2 and beyond its distal tip. Ex-1207, 1:66-2:11, 4:43-52, Fig. 5.

FIG.5



Id., Fig. 5 (color added).

Second, and as discussed in Ground 1, a POSITA knew that a GC had to have "sufficient stiffness to offer 'backup' support." Ex-1215, 548-49; Ex-1205, ¶ 257-262; *and see* Ex-1241, 20 (Kern's The Interventional Cardiac Catheterization Handbook).

[12] *See supra* note 11 (discussing apparent drafting error in claim 39).

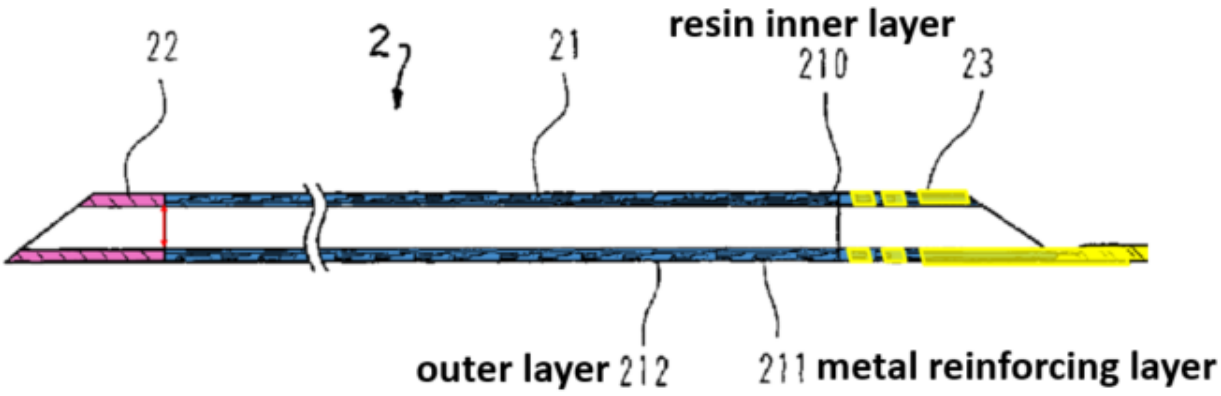
As discussed in Ground 1, the '380 patent discloses that it is the combination of a guide catheter and an extension catheter inserted into a coronary ostium that provides "stiffer back up support" than a guide catheter alone, and this was disclosed in Itou. Ex-1205, ¶ 260-62; Ex-1201, 4:63-5:27, 8:17-32.

The '380 patent admits that back-up support is achieved where the differential between the inner diameter of the guide catheter and the inner diameter of the coaxial catheter is between 0.20 and 0.35 mm. Ex-1201, 3:24-43; Ex-1205, ¶ 261. Itou teaches a differential between the inner diameters of guiding catheter 1 and suction catheter 2 within that range: 0.3 mm. Ex-1207, Table 1; Ex-1205, ¶ 261. And Itou's disclosure of a suction catheter that is extended through a guide catheter (and beyond its distal tip into a branch artery)—and used to deliver a distal end protective catheter—inherently discloses a guide extension catheter that "resist[s] axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion." Ex-1205, ¶ 262.

XV. GROUND 8: ITOU IN VIEW OF THE KNOWLEDGE OF A POSITA RENDERS CLAIM 31 OBVIOUS.

Itou in view of the common knowledge of a POSITA renders claim 31 obvious because a POSITA would understand that the reinforcing layer 211 of Itou's reinforced portion could include one or more braided elements. Ex-1205, ¶

249. Itou's reinforced portion (tubular body portion 21 (blue)) includes "an inner layer 210 made of a resin material . . . a reinforcing layer 211 made of a metal wire made of stainless steel or the like, and an outer layer 212 for covering the reinforcing layer 211 . . . ." Ex-1207, 3:50-58.



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

It was common in the art to reinforce a catheter with braided or coiled metallic elements. Ex-1242, ¶¶ 59-69. Braiding, in particular, provides an advantage over coiling, as braided reinforcing elements allow catheters to have a relatively small outer diameter. Ex-1242, ¶¶ 64-69; Ex-1205, ¶ 272. A POSITA would have been motivated, and had a reasonable expectation of success, to reduce the outer diameter of suction catheter 2, as this would allow for coronary access via the radial artery instead of the femoral artery, and would in turn allow for the use of a relatively small guide catheter 1. Ex-1205, ¶ 220; Ex. 1215, 91-92 (describing advantages of performing PCI procedures radially). Thus, a POSITA would have

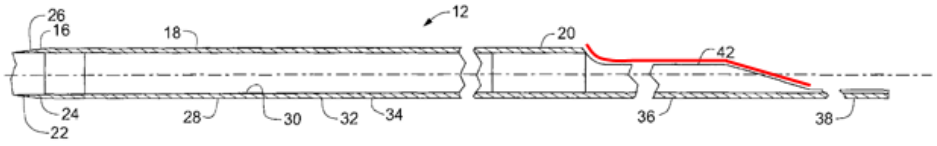
been motivated to include one or more braided elements in the metal reinforcing layer 211 of Itou's suction catheter 2. *See* Ex-1242, ¶¶ 158-162.

XVI. GROUND 9: ITOU IN VIEW OF KATAISHI RENDERS CLAIM 27 OBVIOUS.

Itou in view of Kataishi renders claim 27 obvious because Kataishi discloses a side opening with two inclined slopes. Ex-1205, ¶¶ 263-267.

As discussed in Ground 3, patentee represented to the Examiner that Figure 4 of the '380 patent showed a side opening with "at least two inclined regions." This is no different than what was disclosed in Kataishi. The two-inclined shape of Kataishi's distal end results in 1) improve crossability of the catheter; and 2) provide superior loading of matter (thrombus) into the distal end of the suction catheter. Ex-1242, ¶¶ 171-174. The same improvements apply equally to the proximal end of a catheter, especially catheters such as Itou, because Itou and Kataishi are both directed to the same problem. Ex-1242, ¶ 175. Ex-1207, Abstract; Ex-1225, Abstract; Ex-1205, ¶ 264.

Fig. 4



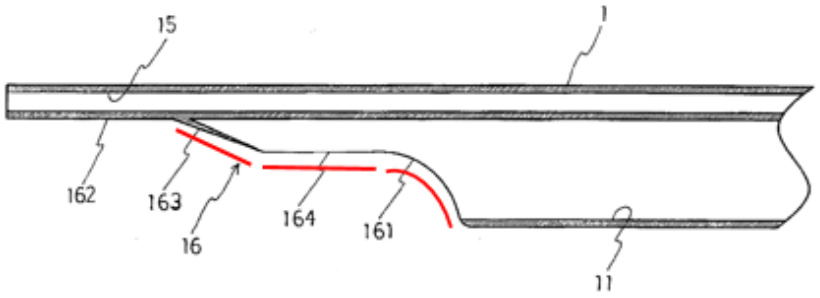


Fig. 2

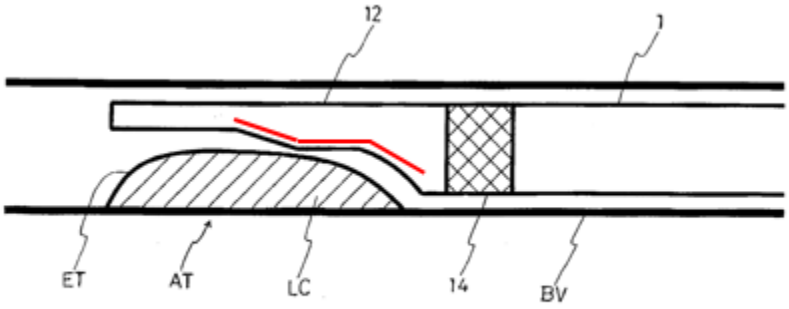


Fig. 10

Compare Ex-1207, Fig. 4 (annotation added), *with* Ex-1225, Figs. 2, 10 (annotations added); Ex-1205, ¶ 263; Ex-1242, ¶¶ 178-179.

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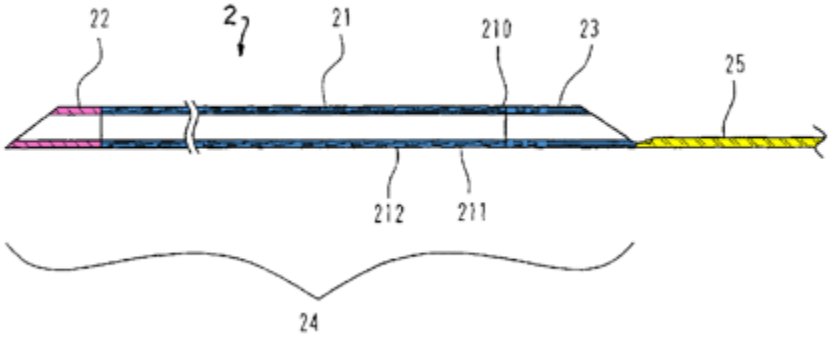


Ex-1207, Fig. 3 (color added).

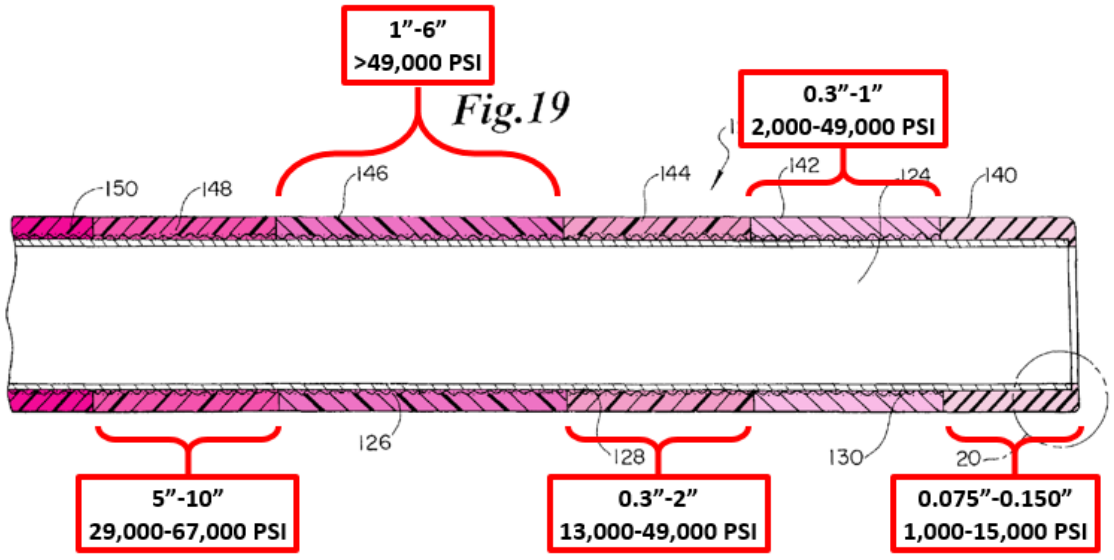
A POSITA would have been motivated to apply Kataishi's distal opening structure to Itou's side opening because including a second inclined slope to Itou's side opening would have increased the area of entry for a stent or balloon, without increasing suction catheter 2's diameter. The increase in area of entry comes from the ramp created by the two different inclined slopes, and not from an increase in the outer or inner diameters of the suction catheter. Ex-1205, ¶ 264-266; Ex-1242, ¶ 176. A POSITA had motivation to make this modification because it would increase the ease with which catheter 2 could receive a therapy catheter without impeding its ability to be maneuvered deeper into the coronary vasculature (compared to catheters with larger diameters). Ex-1225, Abstract, [0026]-[0027], Fig. 10; Ex-1255, 300, 304; Ex-1273, 1, 5; Ex-1205, ¶¶ 115-117, 265; Ex-1242, ¶¶ 172, 176. A larger area of an opening would be beneficial to Itou's suction function and its capability of receiving a therapy catheter. Ex-1207, 6:35-60. Ex-1205, ¶ 265; Ex-1242, ¶¶ 173, 176.

Creating at least two different inclined slopes on the side opening of Itou's suction catheter 2 would have been a routine task when manufacturing an extension catheter. Ex-1205, ¶ 266; Ex-1242, ¶ 177. Thus, a POSITA would have a reasonable expectation of success in modifying the side opening of Itou's catheter to include at least two different inclined slopes as disclosed in Kataishi. Ex-1205, ¶¶ 266-267; Ex-1242, ¶ 177.

XVII. GROUND 10: ITOU IN VIEW OF BERG RENDER CLAIM 38 OBVIOUS.

Itou in view of Berg and the common knowledge of a POSITA renders claim 38 obvious. Ex-1205, ¶¶ 268-279.

It was known that coronary catheters for PCI should have "a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions." Ex-1244, 1:36-38; *see also* Ex-1219, Abstract (explaining that an aspiration catheter should have varying degrees of flexibility along its length); Ex-1205, ¶¶ 269-273.



Ex-1251, Fig. 19 (color and annotations added).

As discussed in Ground 6, Berg teaches a guide catheter with the flexural moduli shown above. Ex-1251, 14:1-7, 14:26-30, 14:35-51. Ex-1205, ¶¶ 274-276; Ex-1242, ¶¶ 180-186.

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

As discussed in Ground 6, three regions of flexural moduli taught by Berg overlap with the claimed ranges. As a result, and the claimed ranges would have been obvious. Ex-1205, ¶¶ 277-279. *In re Harris*, 409 F.3d at 1341.

A POSITA would be motivated to modify Itou to include segments with flexural moduli in the above ranges (known to a POSITA, as evident in Berg's teachings) because Itou explicitly teaches that suction catheter (2) was designed to reach "deep location[s] in a coronary artery," Ex-1207, 1:66-2:5, 5:38-42. Being able to advance a catheter to distal locations in the coronary vasculature often requires that the catheter be maneuvered through tortuous portions of the coronary vasculature. Ex-1242, ¶¶ 187-188; Ex-1205, ¶¶ 277-278; *and see* Ex-1245, 1:39-44. This renders claim 38 obvious. Ex-1205, ¶ 279.

XVIII. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Patent Owner filed a preliminary injunction motion. Ex-1273. The "Facts" section states that Patent Owner's catheters solved a long-standing problem, are successful, and that Petitioners 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.

XIX. CONCLUSION

Petitioners respectfully request institution of a trial and cancellation/invalidation of the claims 25-39 of the '380 patent.

XX. PAYMENT OF FEES

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

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 14, 2019
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/ Cyrus A. Morton /
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Medtronic, Inc.

WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 13,957 words, excluding any Mandatory Notices. I further certify that, in preparation of this Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

Dated: November 14, 2019 */ Cyrus A. Morton /*

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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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