UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.

Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00133
U.S. Patent No: RE45,760

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

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I. PRELIMINARY STATEMENT

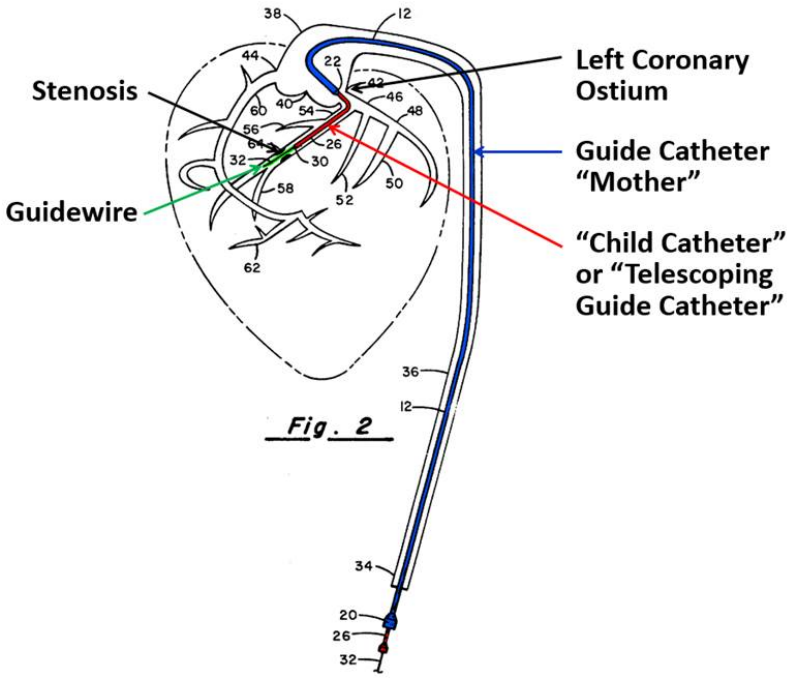
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 25-42, 44, and 47 ("Challenged Claims") of U.S. Pat. No. RE 45,760 ("the '760 patent," Ex-1201). The '760 patent—which claims priority to a patent application filed on May 3, 2006 (Ex-1201, [60])—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id.*, [54], [72]. The Challenged Claims were issued on a first Office Action, meaning there is no substantive file history for the '760 patent.

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

[1] The '760 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1205, ¶¶ 71 n.8, 125-129. A POSITA knew that the '760 patent's "coaxial guide catheter" of the '760 patent was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1209, 5:49-52 (referring to body 12 "as a guide catheter extension").

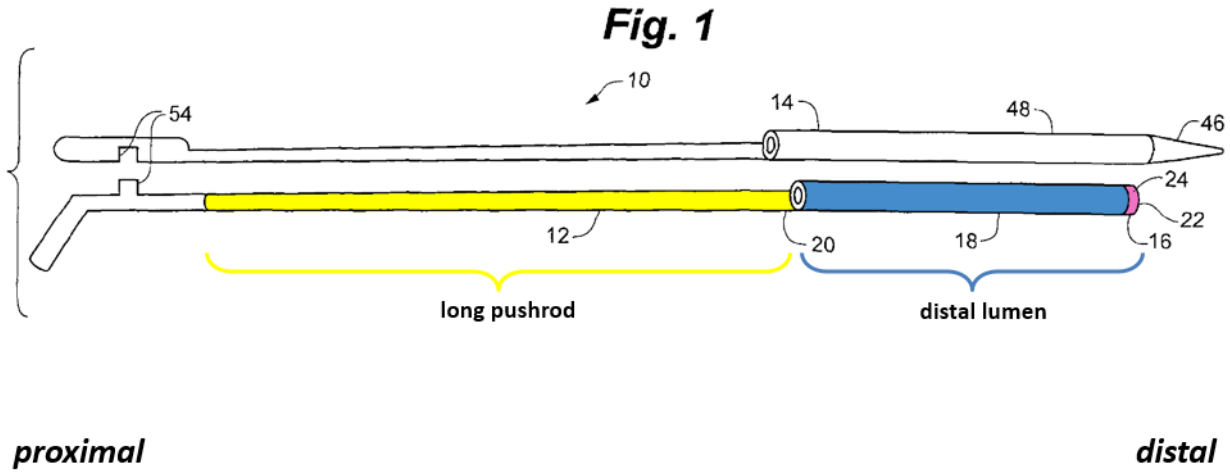
distal end of the GC (i.e., into a coronary branch artery). *Id*., Abstract; Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the GC from dislodging from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

The '760 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. Ex-1201, 2:46-61 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art as a "mother-and-child assembly," where the child catheter (red in below figure) (i.e., the guide extension catheter) is essentially a tube that is inserted into and extends beyond the GC (blue in below figure) (i.e., the mother catheter) into the coronary artery. Ex-1205, ¶¶ 70-80.



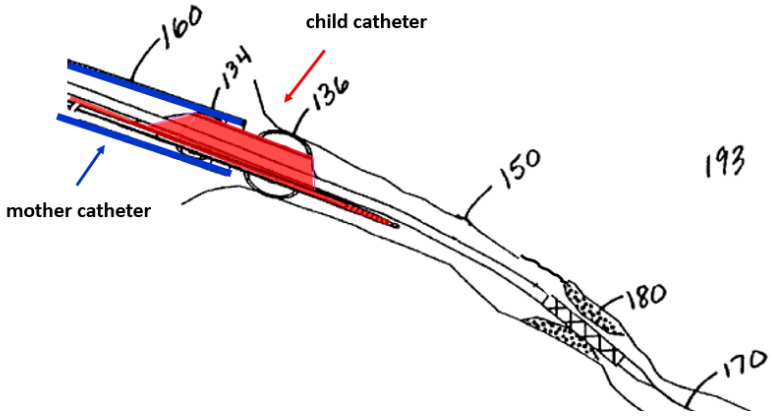
Ex-1254, Fig. 2 (annotations and color added).

The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. *Id*. The '760 patent alleges that such a design had certain drawbacks (Ex-1201, 2:63-3:6) and modifies the child catheter of the mother-and-child assembly to have two parts: (i) a long thin pushrod (ii) coupled to a short distal lumen (i.e., a tube) that is highly flexible so it can extend deep into the coronary artery.



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

But child catheters with a short lumen connected to a long thin push rod were already well-known in the art, as evidenced by U.S. Patent No. 7,604,612 ("Ressemann") (Ex-1208).



Ex-1208, Fig, 6E (annotations and color added); *and see infra*, §VII.A.

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the '760 patent are unpatentable based on the Grounds discussed below. Accordingly, Petitioner respectfully requests institution

of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the Challenged Claims.

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

A. Real Party-in Interest

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

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies that the ’760 patent is currently the subject of litigation in two separate actions in the U.S. District Court for the District of Minnesota: (i) *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al*., No. 19-cv-01760 (D. Minn., filed July 2, 2019); and (ii) *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017) (“QXMedical Litigation”).

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

Petitioner is also concurrently filing other petitions for IPR challenging different claims of the ’760 patent, or based on prior art references having different priority dates and different disclosures than the references discussed herein.

C. Lead and Backup Counsel

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

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D. Service Information

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

III. REQUIREMENTS FOR INTER PARTES REVIEW

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

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

B. Precise Relief Requested and Asserted Grounds

Petitioner respectfully requests review of claims 25-42, 44, and 47 of the '760 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Ressemann renders claims 25-42, 44 and 47 obvious in view of Takahashi and the knowledge of a POSITA.
2	Ressemann renders claim 32 obvious in view of Takahashi, Kataishi and the knowledge of a POSITA
3	Ressemann renders claim 32 obvious in view of Takahashi, Enger and the knowledge of a POSITA

[2] This petition is also supported by the Declarations of Stephen JD Brecker, MD (Ex-1205), and Richard A. Hillstead, Ph.D., (Ex-1242), as experts in the field of the '760 patent. Petitioner also submits the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1278) to support the authenticity and public availability of documents cited herein.

IV. BACKGROUND

A. Overview of the Technology

Coronary artery disease ("CAD") occurs when plaque buildup narrows the arterial lumen. Ex-1205, ¶¶ 28, 30-32. This narrowing, sometimes called a stenosis, restricts blood flow and increases the risk of heart attack or stroke. *Id*. In response, physicians developed percutaneous coronary interventional ("PCI") procedures that use catheter-based technologies inserted through the femoral or radial artery, and thus can treat CAD without the need for open-heart surgery. Ex-1205, ¶¶ 29, 34-40.

PCI was developed over forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1205, ¶¶ 33, 41. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. A guidewire is then introduced into the needle, the needle is removed, and an introducer sheath is inserted over the guidewire and into the artery. Next, a guide catheter can be introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. *Id*., ¶¶ 34, 42-55. At the proximal end, a hemostatic valve is coupled to the guide catheter and remains outside the patient's body. *Id*., ¶¶ 35, 54. The hemostatic valve prevents blood from exiting the patient's artery and keeps air from entering the bloodstream. *Id*.

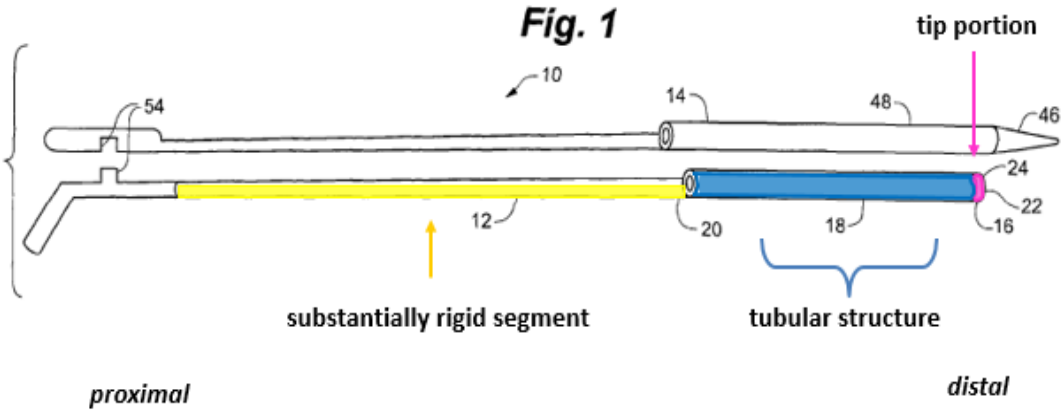
A smaller-diameter, more flexible guidewire can then be threaded through the lumen of the guide catheter to the target site. *Id*., ¶¶ 56-58. This guidewire serves as a guiderail to advance a therapeutic catheter through the guide catheter and to the occlusion. *Id*. The guidewire and therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. *Id*., ¶¶ 59-65. This last step—crossing the guidewire and therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium. *Id*., ¶¶ 66-67. As discussed above, one way to ameliorate this backward force is to use a mother-and-child catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. *Id*., ¶¶ 68-80.

B. The ’760 Patent

The ’760 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1201, 1:37-38. In particular, the ’760 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends through the lumen of a GC, “beyond the distal end of the guide catheter, and insert[s] into [a] branch artery.” *Id*., Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—it “assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.” *Id*., 5:30-34; Ex-1205, ¶ 126.

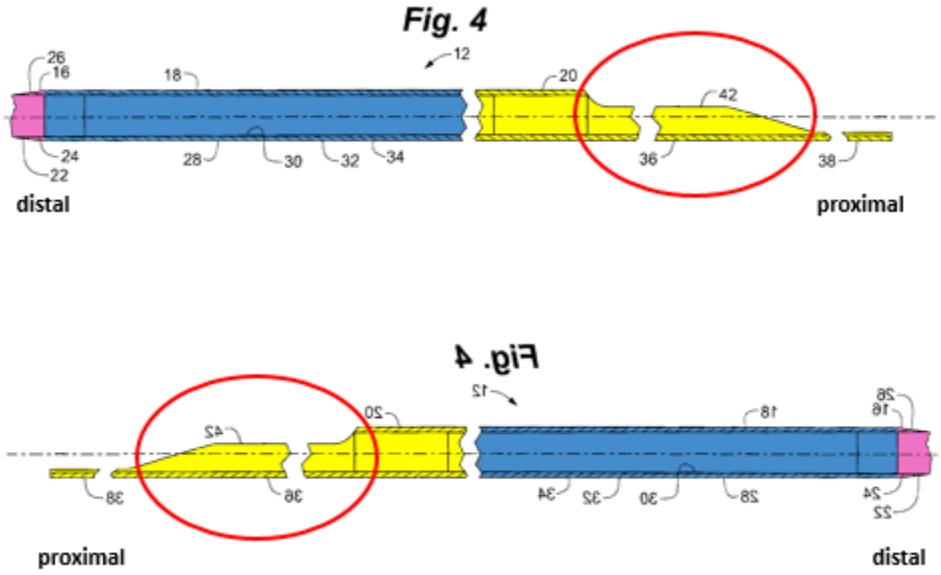
The ’760 patent claims a guide extension catheter 12 that includes a

substantially rigid segment (yellow) and a tubular structure (blue) and a tip portion (pink). Color has been added to Figure 1, below, which has been annotated with the language of claims 25 and 35.



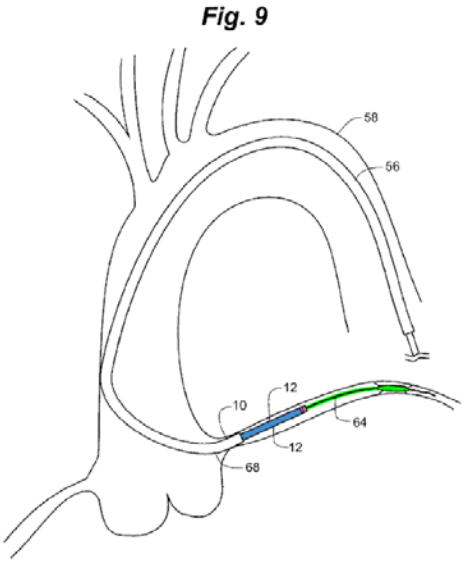
Ex-1201, Fig. 1 (annotations and color added).

The ’760 patent also recites that the extension catheter includes, “in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure.” *Id.*, 15:14-53, 15:60-16:36, 16:39-17:13. The specification, however, provides no written description support for the placement of a “side opening” anywhere other than ***in*** the substantially rigid segment 20, circled in red below. Ex-1201, Figs. 4, 13-16; *see also id.*, 7:1-17, 8:63-9:5.



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

Regardless, the ’760 patent describes that extension catheter 12 is deployed through guide catheter 56 (no color). A guidewire 64 and balloon (green) extend from the 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-1201, Fig. 9 (color added).

C. Prosecution History of the ’760 Patent

The predecessor ’850 patent issued without an Office Action. *See generally* Ex-1202. According to the Examiner, the claims of the ’850 patent were allowable because “adding a guide catheter to the claimed rail structure[3] with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” Ex-1202 at 83 (Notice of Allowance at 3).

Patent Owner sought reissuance in 2014. The Examiner found the claims were patentable because he found no prior art disclosing “a guide extension catheter which is long enough to extend from both ends of the guide catheter and includes a rigid segment, a segment defining a side opening and a tubular structure, where the

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

lumen of the tubular structure is shorter than the guide catheter." Ex-1203 at 708 (Non-Final Rejection, December 10, 2014 at 10). In other words, in both the original prosecution of the '850 patent, and the prosecution of the '760 reissuance, the Examiner believed that a mother-and-child assembly—where the child catheter is characterized by a short distal lumen coupled to a proximally located pushrod—was not described in the art, but he was not aware of Ressemann.

V. THE PERSON OF ORDINARY SKILL IN THE ART

If a person of ordinary skill in the art ("POSITA") was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist. Alternatively, if a POSITA was an engineer, s/he would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices. Extensive experience and technical training might substitute for education, and advanced degrees might substitute for experience. Additionally, a POSITA with a medical degree may have access to a POSITA with an engineering degree, and one with an engineering degree might have access to one with a medical degree. Ex-1205, ¶ 27; Ex-1242, ¶¶ 18-19.

VI. CLAIM CONSTRUCTION

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

When, as here, claim terms have been construed by a district court, those constructions are properly considered during an IPR. 37 C.F.R. § 42.100(b). In the QXMedical Litigation,[4] Patent Owner stipulated to the following constructions:

- "reinforced portion": "portion made stronger by additional material or support" (Ex-1212 at 2)

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

- "substantially rigid": "rigid enough to allow the device to be advanced within the guide catheter" (*Id.* (Dkt. 36-1) at 2; Ex-1213 at 15)

- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1213 at 20)

[4] The full list of constructions advanced by Patent Owner in the QXMedical Litigation is found at Ex-1212 (Dkt. 36-1).

Additionally, the district court provided the following construction:

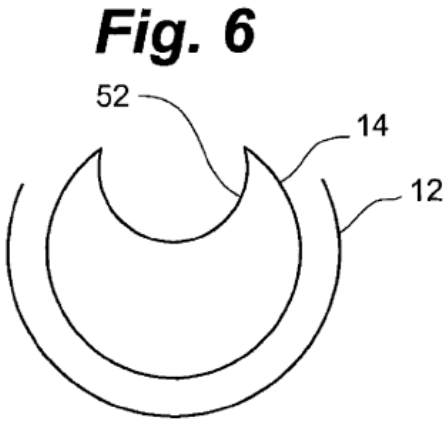
- "side opening": "need no construction and will be given [its] plain and ordinary meaning" (*Id.* at 26)
- "lumen": "the cavity of a tube" (*Id.* at 25)
- "wherein a material forming the segment defining the side opening is more rigid than the tubular structure": "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure" (*Id*. at 31).

Petitioner agrees with the above constructions for purposes of this IPR[5] (Ex-1205, ¶¶ 130-136) and proposes the following additional construction:

A. "concave track" (cl. 30)

The '760 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, 4:11-23, 4:37-39, 7:25-26; Ex-1205, ¶¶ 137-138. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex-1201, 7:25-26.

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



As a result, in the context of the ’760 patent, the claim term “concave track” means a “portion that is not fully circumferential.” Ex-1205, ¶ 139.

B. “flexural modulus” (cl. 36, 44)

The claim term “flexural modulus” had a known and established meaning by 2006 (Ex-1242, ¶ 33), 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. Such an understanding is consistent with the ’760 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1201, 7:25-30; Ex-1205, ¶¶ 140-141. Stated differently, the extension catheter’s resistance to bending is greatest at its proximal end, and decreases along the longitudinal axis moving distally, where the

distal end (flexible tip) is the most flexible (least rigid).[6]

VII. GROUND 1: RESSEMANN RENDERS CLAIMS 25-42, 44, AND 47 OBVIOUS IN VIEW OF TAKAHASHI AND THE COMMON KNOWLEDGE OF A POSITA

A. Ressemann

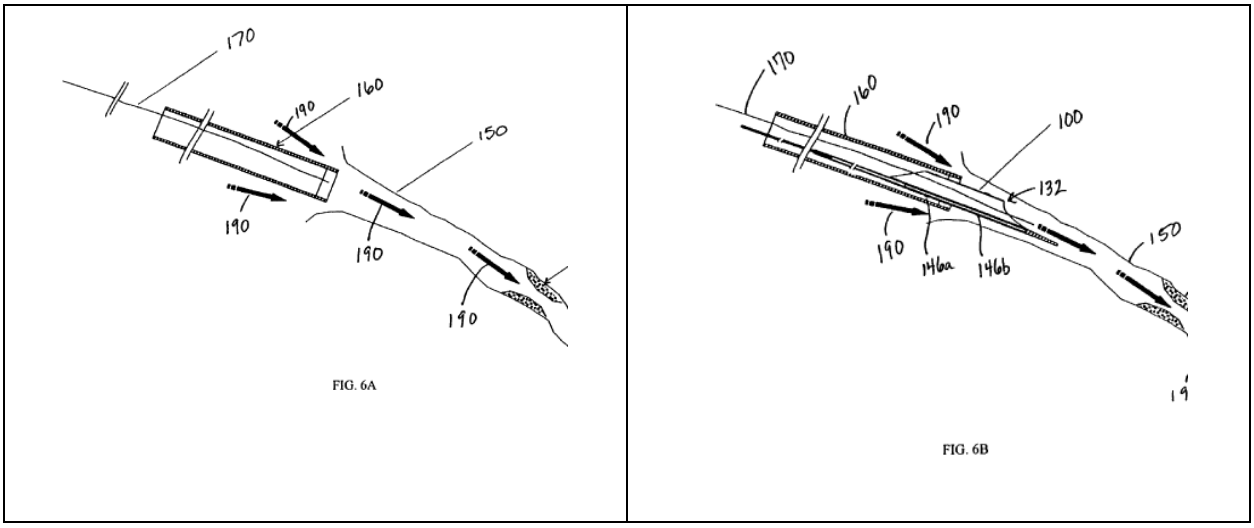
Ressemann was filed on August 9, 2002, issuing as U.S. Pat. No. 7,604,612 on October 20, 2009. It is prior art under both pre-AIA §102(e) and post-AIA §102(a)(1), (2),[7] and was not cited or considered during prosecutions of the original ’850 patent, or the ’760 reissue patent. Exs-1201-03.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1208,

[6] In the QXMedical Litigation, Patent Owner stipulated to following construction of “flexural modulus”: “a numeric, dimension-independent material property that captures the tendency of a material to bend.” Ex-1212 at 2. From this construction, it is unclear if Patent Owner agrees that a high flexural modulus means an increased resistance to bending.

[7] The first-inventor-to-file provisions of the AIA apply to the ’760 patent because, inter alia, at least one claim of the ’760 patent (e.g. claim 32) is not entitled to an effective filing date of March 16, 2013.

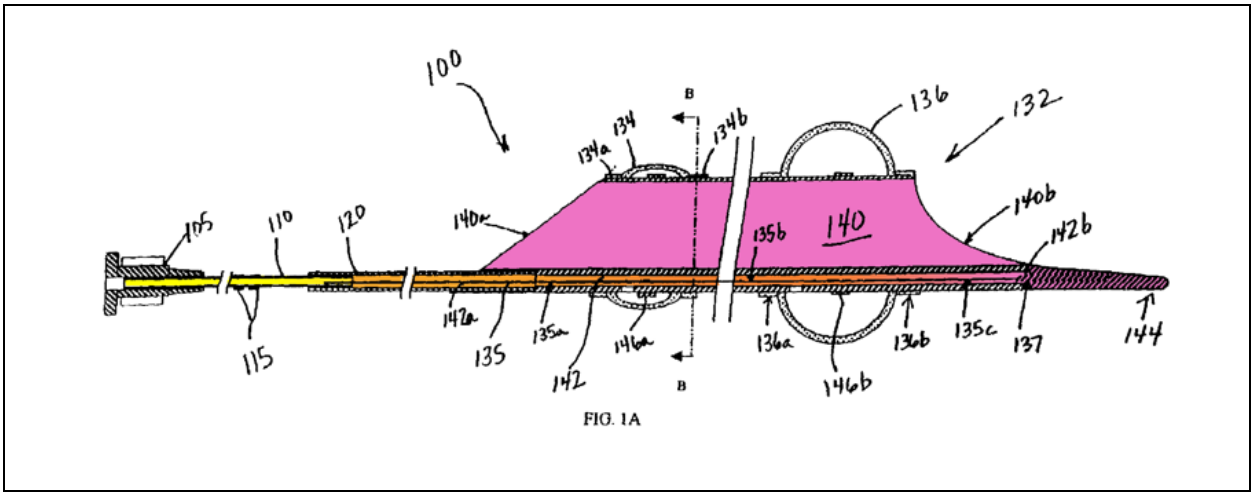
Abstract. The assembly includes a GC, which "may be positioned within the ostium of a target vessel," *id*., 12:26-27, and an evacuation sheath that is coaxially insertable through the GC, and advanceable beyond the GC's distal end to treat stenosis. *Id*., Abstract, Figs. 6A-6F, 6:18-24, 12:9-14:39.



Id., Figs. 6A-B.

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

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



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

The shaft includes proximal, intermediate, and distal portions. Proximal shaft (110) (above, yellow) is a hollow tube preferably made of stainless steel, but which may also be made of polymer and metal composites. *Id*., 10:36-42. Intermediate shaft (120) (yellow transitioning to pink) —a hollow, polyethylene or Pebax tube—is more flexible than shaft (110). *Id*., 10:63-11:10. Distal shaft (transitioning to pink) includes the evacuation head, *id*., 10:31-35, as well as an inflation lumen for sealing balloons (134, 136), and may include soft distal tip (144) made of a polymer more flexible than the head, so as to ensure atraumatic insertion into blood vessels. *Id*., 11:11-28; *see also* Ex-1205, ¶¶ 95-98, 142-146; Ex-1242, ¶¶ 20-26.

B. Takahashi

Takahashi et al. (Ex-1210, "Takahashi") is entitled *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*" and published in 2004,

making it prior art under at least pre-AIA § 102(b) and post-AIA §102(a)(1). Ex-1278, ¶¶ 43-52. Takahashi is cited in the Background of the '760 patent, but was not the basis of an Examiner rejection during prosecution of either the '760 patent or the '850 patent (Exs-1201-03), and thus the Board should decline to exercise its discretion under 35 U.S.C. § 325(d).

Takahashi explains that "[t]he five-in-six system is a method of inserting a 5 Fr guiding catheter . . . into a 6 Fr guiding catheter to increase backup support." Ex-1210, 452; *see also* Ex-1205, ¶¶ 77-80, 147-150; Ex-1242, ¶¶ 39-42. 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-1262, 545.

C. Claim 25

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

To the extent the preamble is limiting, Ressemann discloses it as set forth below. Ex-1205, ¶ 161.

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

Ressemann discloses this limitation. Ex-1205, ¶ 162.

As Dr. Brecker explains, Ressemann teaches a guide catheter 160 that is used with an evacuation sheath assembly 100 sized to fit therein. Ex-1208, Abstract, 6:18-24, 28:26-29. The guide catheter 160 is advanced through a "main blood vessel," the aorta, *id*., Fig. 5A, and its distal end is then "positioned within the ostium of the target vessel," a coronary artery. *Id*., 12:26-30, Fig. 5A, 22:38-45, 28:31-32. At its proximal end, the guide catheter 160 is attached to "[a] suitable valve 184, such as a touhy borst valve." *Id*., Fig. 5A, 12:45-49; *and see id*., 28:32-36.

The guide catheter necessarily has a "lumen extending from a hemostatic valve" (at its proximal end) to its distal end. Ex-1205, ¶ 162.

First, Ressemann discloses that an evacuation sheath assembly fits inside the guide catheter, and is advanced so that the its distal end is extended from the guide catheter's distal end and into a blood vessel to treat a stenosis. Ex-1208, 6:18-24, Fig. 6B, 12:9-30; 22:38-45. Second, Ressemann explains that the valve attached to the proximal end of the guide catheter provides a fluid tight seal against the

proximal end of the evacuation sheath assembly. *Id*., 12:45-52 (describing use of a conventional "Y-adaptor");[8] *and see id.*, 10:47-53, 28:32-36. Third, the "guiding catheter 160 performs an evacuation function in combination with the evacuation lumen 140 [of the evacuation sheath]," and "also maintains a contrast delivery function." *Id*., 9:30-33, *and see id.*, 29:14-16, 29:56-59.

The advancement of the evacuation sheath assembly 100 and the use of guiding catheter (160) for evacuation and contrast delivery functions necessarily evidence a lumen extending from a hemostatic valve at the guide catheter's proximal end to the guide catheter's distal end. Ex-1205, ¶ 162.

[8] Ressemann's disclosure reflects what the '760 patent admits, which is that the "guide catheter . . . can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter." Ex-1201, 3:28-31. Similarly, Patent Owner's expert in the co-pending litigation explains that a hemostatic valve is sometimes called a Y-connector, Ex-1282, ¶ 18, also known as a Y-adapter. Ex-1205, ¶162.

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

Ressemann discloses this limitation. Ex-1205, ¶ 163.

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

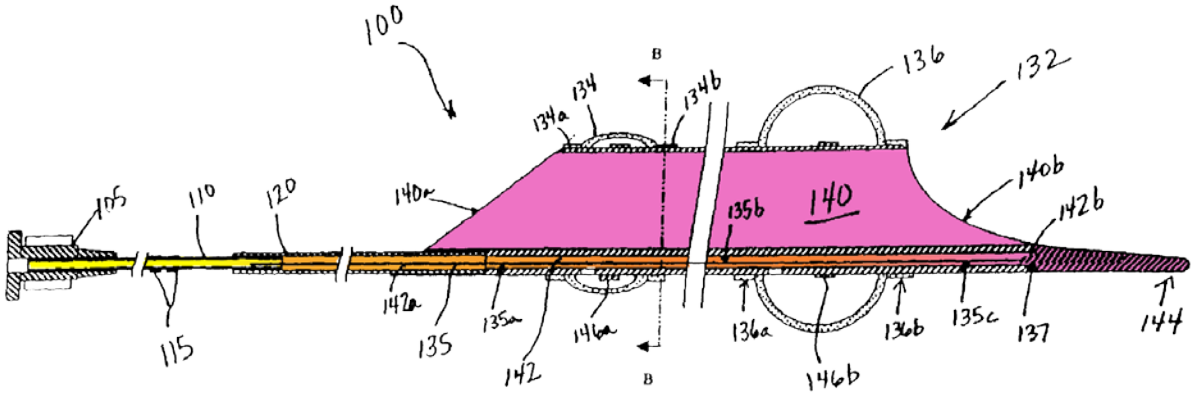


FIG. 1A

Ex-1208, Fig. 1A (color added); *and see id.*, Figs. 16 A-B, 16F-G.

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

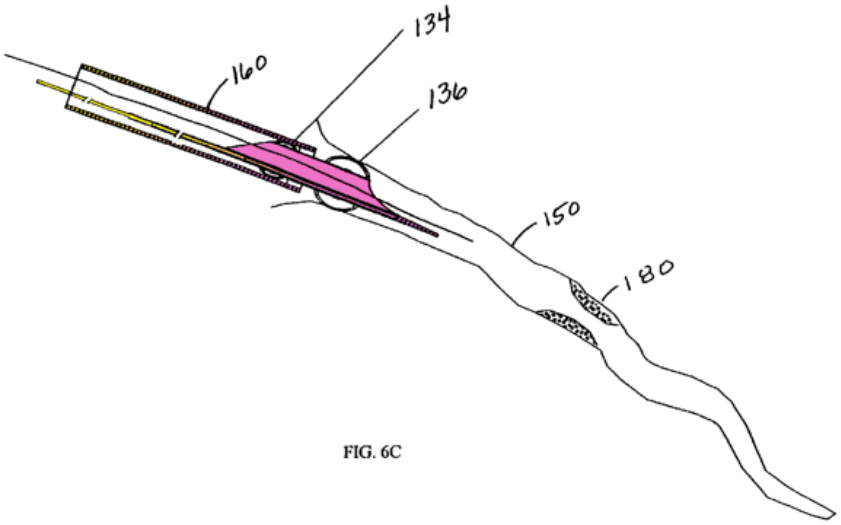


FIG. 6C

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

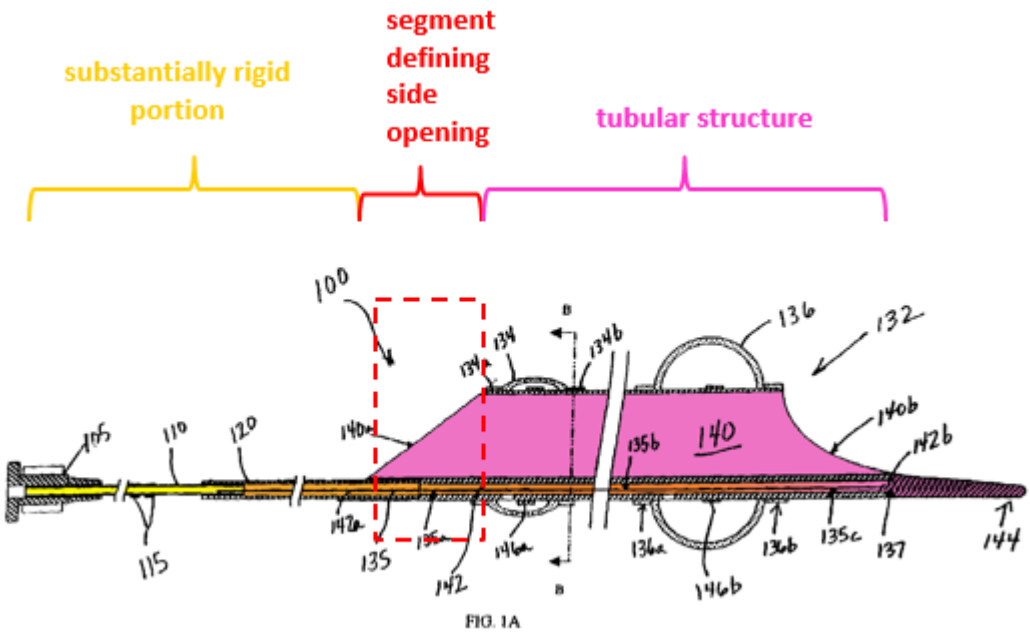
Ressemann also explains that the proximal portion of proximal shaft (110) extends through the valve at the proximal end of the guide catheter. *Id*. 12:45-53, Fig. 5A; *and see id.*, 27:22-36, 28:50-55.

Thus, evacuation assembly (100) necessarily is long enough so that when its distal end is "extendable through the lumen and beyond the distal end of the guide catheter," its proximal end is "extendable through the hemostatic valve at the proximal end of the guide catheter." Ex-1205, ¶ 163.

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

Ressemann discloses this limitation. Ex-1205, ¶ 164.

At its proximal end, sheath assembly (100) includes proximal shaft (110) (below, yellow) and intermediate shaft (120) (yellow transitioning to pink), which form a "substantially rigid segment" because they are used to advance the evacuation sheath through a guide catheter so that the sheath's distal end is extended into a vessel to treat a stenosis. Ex-1208, 6:18-24, 10:47-11:14, 11:52-56; *and see id.*, 27:22-36, 27:51-53; Ex-1205, ¶ 164. Thus, shaft (110) and shaft (120) are sufficiently rigid to allow evacuation sheath (100) to be advanced within the guide catheter, as shown in Figures 6A-F. *Supra*, § VI (construing "substantially rigid"); Ex-1205, ¶ 164.



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

Moving distally, Ressemann discloses a segment defining a side opening, shown above in a dotted red box. That segment is a portion of evacuation head

132. It includes 140a, which is the proximal opening to the evacuation lumen 140. *Id*., 6:35-60. Because head 132 includes distal shaft 130, *id*.. 10:31-35, the segment defining a side opening also includes the portion of shaft 130 that is adjacent 140a.

Distal to opening 140a is a tubular structure, "multi-lumen tube 138," which defines evacuation lumen 140. *Id*., 6:35-47. The claimed "tubular structure" is the portion of the evacuation lumen 140 that is distal to 140a. [9] Ex-1205, ¶ 164.

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

[9] As Patent Owner's expert witness, Peter Keith testified, "just because something is proximal to something else doesn't mean that it has to be ***entirely*** proximal." Ex-1277, 293:13-2943 (emphasis added).

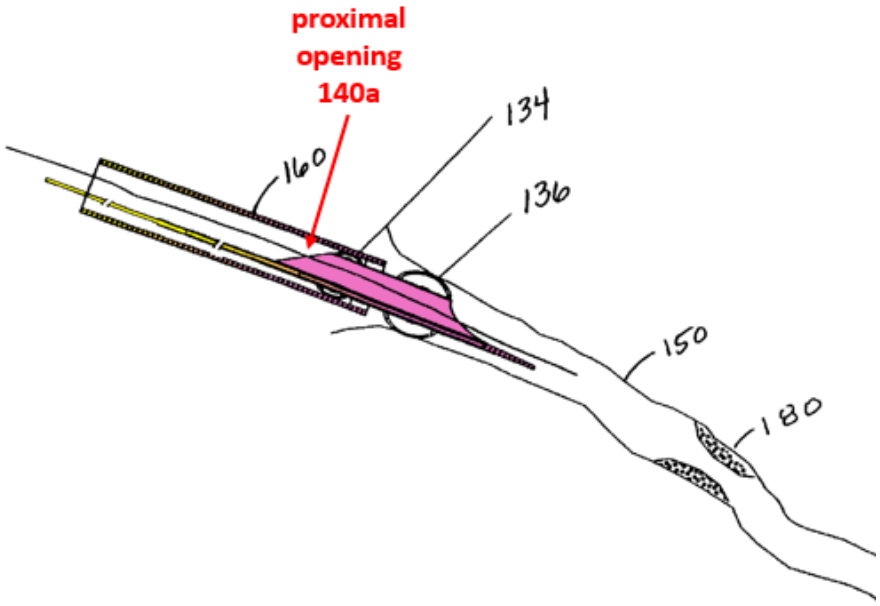


FIG. 6C

Ex-1208, Fig. 6C (color and annotation added); *and see id.*, Figs. 16 A-B, 16F-G; 29:56-59.

The fluid communication between the guide catheter lumen and the evacuation lumen of sheath assembly (100) is confirmed by Ressemann's teaching that guiding catheter (160) "performs an evacuation function in combination with lumen 140." It is also confirmed by Ressemann's explanation that evacuation head (132) is intended to "isolate fluid communication of the internal lumen of guide catheter 160 to the blood vessel" into which the assembly is inserted. *Id.*, 9:30-36; *and see id.*, 22:38-46, 23:11-16, 29:26-28, 29:56-58; Ex-1205, ¶ 164.

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

Ressemann renders this limitation obvious in view of Takahashi and the common knowledge of a POSITA. Ex-1205, ¶ 165.

Ressemann teaches that the lumen of the tubular structure is shorter than the lumen of guiding catheter (160). The tubular structure that is formed by evacuation lumen 140 is part of evacuation head (132), which—for native, coronary artery applications—may be up to 20 cm in length. Ex-1208, 10:11-12; *see id.*, 22:45-47 (disclosing an embodiment with an evacuation head that may be up to 40 cm in length). Thus, the tubular structure in Ressemann is not longer than 20-40 cm in length.

Ressemann is silent on the length of guiding catheter (160). But, as Dr. Brecker explains, the "standard guiding catheter length" was 100 cm. Ex-1215, 549; *and see* Ex-1210, 452 (Takahashi, describing guiding catheters that are 120 cm and 100 cm); Ex-1205, ¶ 165. And it would only be common sense to leverage a well-known technology, *Perfect Web Techs., Inc. v. Info USA, Inc.*, 587 F.3d 1324, 1328 (Fed. Cir. 2009), such as a GC of a commonly used length—as disclosed in Takahashi—with Ressemann's evacuation sheath 100. Thus,

Ressemann discloses that the lumen of the tubular structure has a length that is shorter than the length of the lumen of the guide catheter.

Ressemann also teaches that the tubular structure has a "uniform cross-sectional inner diameter," as there is no taper shown in Figures 1A, 1C. Ex-1208, Figs. 1A, 1C; *and see id.*, Figs. 1B, 1D, 16 A-B, E-G; Ex-1205, ¶ 165.

Ressemann does not, however, teach that the lumen of the tubular structure is "not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter." Ressemann explains that the evacuation lumen has a diameter of 0.061 inches, which is 1.54 mm. Ex-1208, 10:17-21. It also teaches use of the assembly with a guiding catheter that is "8 French" with an inner diameter of 0.090 inches, which is 2.28 mm. Ex-1208, 10:14-17. This is a size differential of 0.74 mm, which is greater than a "one French" differential of 0.33 mm. Ex-1262, 545; Ex-1205, ¶ 165.

Takahashi, however, discloses a lumen of a guide extension catheter that is "not more than one French size smaller than the cross-sectional inner diameter of the lumen of a guide catheter." Specifically, Takahashi teaches inserting a 5 Fr catheter into a 6 Fr guiding catheter to increase backup support. Ex-1210, 452. Takahashi also states that the inner lumen of the 5 Fr and 6 Fr catheters is, respectively, 0.059 inches and 0.071 inches. *Id*. This is a differential of 0.012 inches, or 0.30 mm, which is less than 1 Fr. Ex-1205, ¶ 165; Ex-1262, 454.

As Dr. Brecker explains, bases on the teachings of Takahashi, a POSITA would have been motivated to modify Ressemann to achieve a differential between the inner diameter of evacuation lumen 140 and the inner diameter of a guide catheter that was not more than one French, Ex-1205, ¶ 165, and a POSITA would have been capable of achieving such a difference with a reasonable expectation of success.

Ressemann teaches that catheter (100) may be used to both aspirate embolic material (Ex-1208, Abstract, 12:9-13:34) ***and*** to deliver an angioplasty balloon or stent. *Id*., 6:25-34; *and see id.*, 23:8-20. By the time of the alleged invention of the '760 patent, a POSITA had the motivation to modify the evacuation assembly of Ressemann to remove the sealing balloons. Ex-1242, ¶¶ 81-87. Ressemann could be modified for use solely as an extension catheter, and not as an aspiration catheter. Ex-1205, ¶ 165; Ex-1242, ¶¶ 54-58.

First, the use of extension catheters—with GC—was known in the art. *See* Ex-1209; Ex-1234. Second, modifying Ressemann's assembly 100 so that it did not have sealing balloons would have simplified the manufacturing process. Ex-1242, ¶ 58. Third, the modification would have decreased the outer diameter of assembly 100. *Id*.

As Dr. Brecker and Dr. Hillstead explain, 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-1205, ¶ 165; Ex-1242, ¶ 58. And using guide catheters smaller than the 8 French GC disclosed in Ressemann would have allowed PCI procedures to be performed via access through the radial artery instead of the femoral artery. Ex-1215, 91-92, 549; Ex-1205, ¶ 165. This is desirable because bleeding is easier to control and patients are immediately ambulatory. Ex-1205, ¶ 165.

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. Specifically, 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.

Thus, Ressemann in view of Takahashi renders this limitation obvious. Ex-1205, ¶ 165.

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

Ressemann discloses this limitation. Ex-1205, ¶¶ 166-75.

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

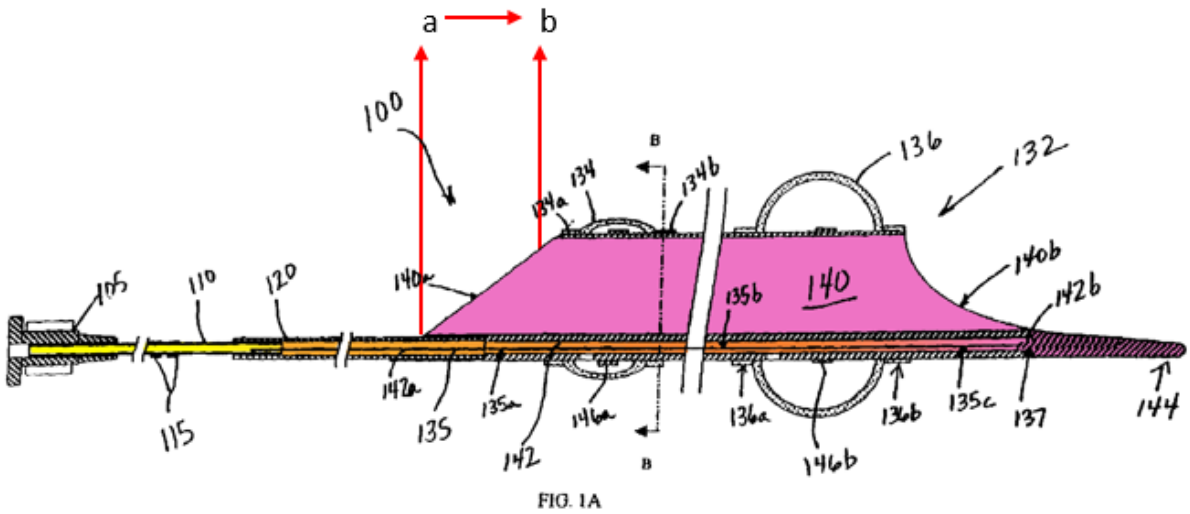
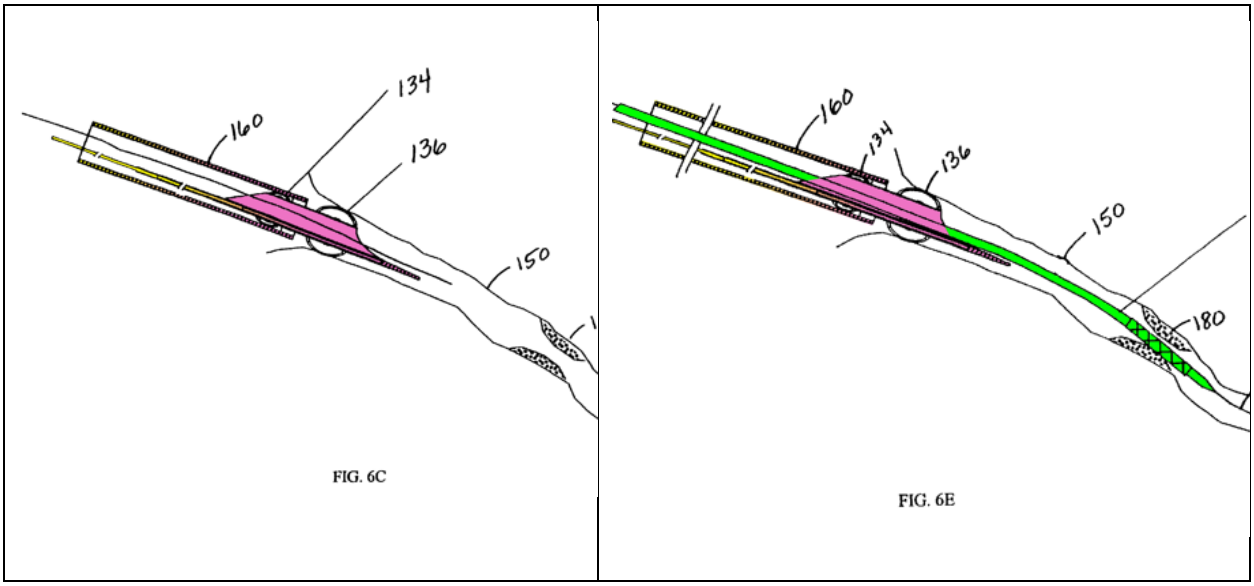


FIG. 1A

Ex-1208, Fig. 1A (color and annotation added); *and see id.*, Fig. 16A (2140a).

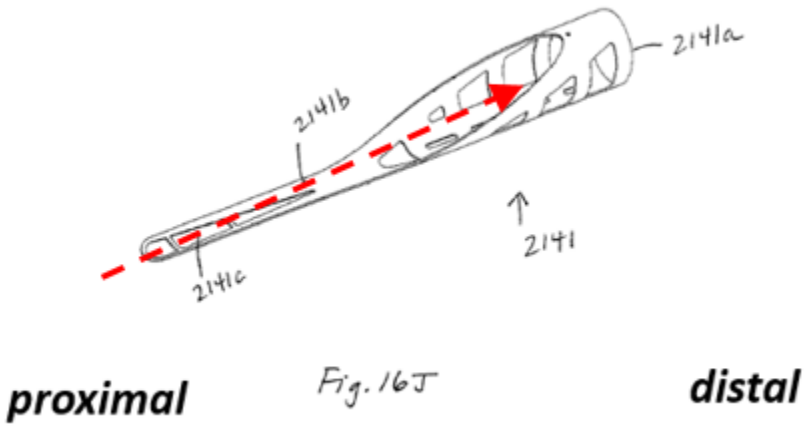
Moreover, Ressemann explicitly discloses that the side opening is "accessible from a longitudinal side defined transverse to the longitudinal axis," and that the "the side opening and the lumen of the tubular structure" are "configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter." Ex-1205, ¶ 166.

Ressemann teaches that lumen (140) "is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters." Ex-1208, 6:44-47; *and see id.*, 23:8-20. It also explicitly discloses the insertion of a balloon catheter with a stent (193, below green) into the side opening of the evacuation assembly when the side opening and a proximal part of the assembly remain within guiding catheter (160), and the distal end of the assembly extends beyond the guide catheter's distal end. Ex-1208, Figs. 6A-F, 12:9-14:10; *and see id.*, 29:56-59.



Id., Figs. 6C (left), 6E (right) (color added); Ex-1205, ¶¶ 167-168.

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



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

Ressemann explicitly discloses support collar 2141 for use with evacuation sheath 2100. Ex-1208, 24:47-67, 22:38-42, 23:8-20; Ex-1205, ¶¶ 103-105. Specifically, the cylindrical portion of collar 2141a fits into the proximal opening of the evacuation lumen. *Id*., 24:55-58. Tab 2141b extends proximally of the opening of the evacuation lumen and provides a flexibility transition between the evacuation head and shaft. *Id*., 24:58-67.[10] Ex-1205, ¶¶ 105, 169; Ex-1242, ¶¶ 71-73.

A POSITA would expect that support collar 2141 and evacuation assembly 100 (with evacuation head 132) are used together. Ex-1205, ¶¶ 170-175; Ex-1242, ¶¶ 75-77. And this is because Ressemann illustrates the use of support collar 2141 with an evacuation sheath assembly 2100 (including evacuation head 2132), explaining that "[m]any of the elements present in the previous embodiments are also shown in Figures 16A-J and ***where these elements are substantially the same, similar reference numbers have been used***." Ex-1208, 22:33-36 (emphasis

[10] Just as Ressemann's teachings regarding evacuation sheath 100 render claim 25 obvious, so, too, do its teachings regarding sheath 2100. *Supra*, §§ VII.C.1-6; *infra*, § VII.C.7 (*citing* Ex-1208, Figs. 16 A-B, 16E-G; *see generally id.*, 22:1-29:67).

added). Accordingly, lumen 140 in evacuation sheath 100 (Figs. 1A-D) is substantially the same as lumen 2140 in evacuation sheath 2100 (Figs. 16A-J). And Ressemann teaches that support collar 2141 serves to reinforce the proximal opening of the evacuation lumen "in the presence of deforming forces" in the same way for both evacuation lumens. Ex-1205, ¶¶ 170-175; Ex-1242, ¶¶ 75-77. Thus, Ressemann provides explicit motivation to modify the proximal opening of lumen 140 with collar 2141. And—whether the support collar 2141 is added to the proximal opening of lumen 2140 in assembly 2100, or to the proximal opening of lumen 140 in assembly 100—limitation 25.c.iii is disclosed. Ex-1205, ¶¶ 169-175.

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

Ressemann discloses this limitation. Ex-1205, ¶ 176.

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

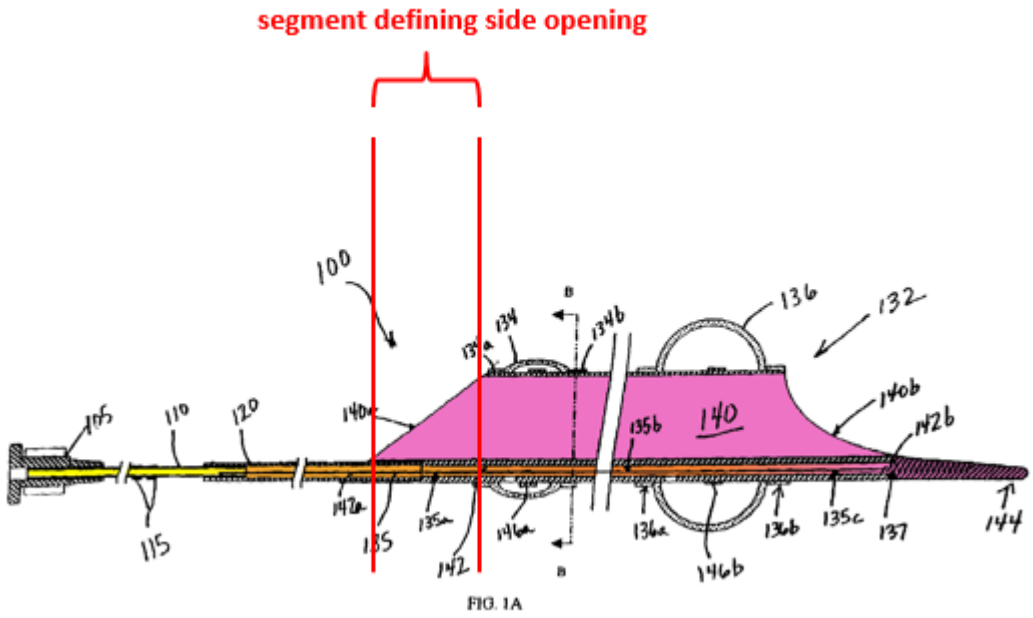
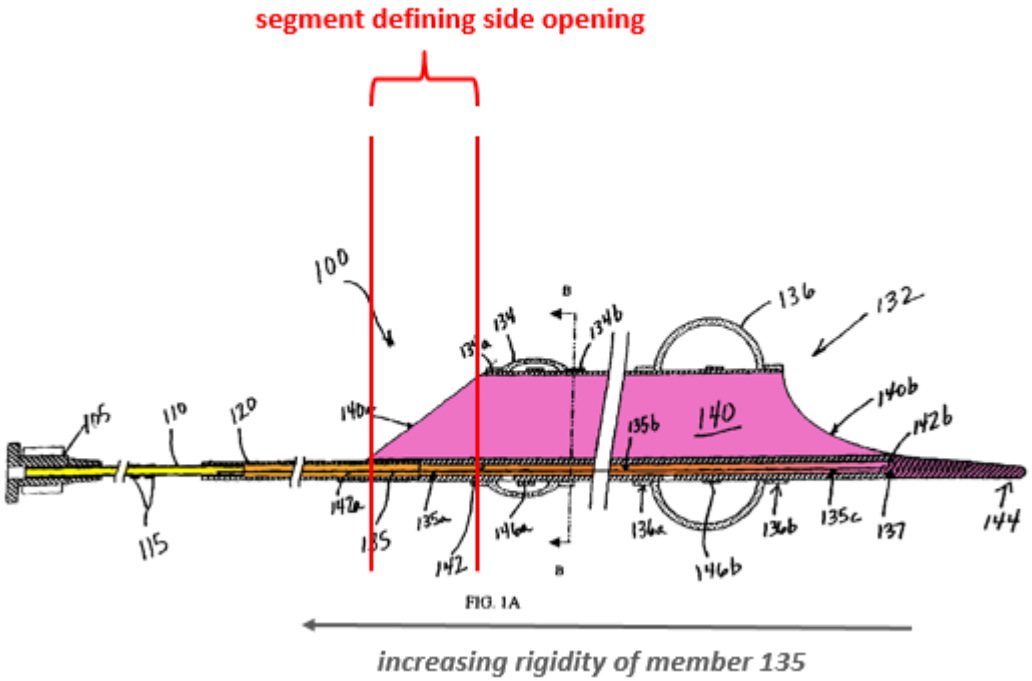


FIG. 1A

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

The segment defining the side opening includes the proximal opening, 140a, of the evacuation lumen 140. Evacuation lumen 140 is part of a multi-lumen tube that is "made of a relatively flexible polymer such as low density polyethylene, polyurethane, or low durometer Pebax® material." Ex-1208, 6:35-39; *and see id.*, 22:54-58, 24:20-32. The segment defining the side opening also includes the portion of distal shaft (130) that is adjacent opening 140a. *Id.*, 10:30-35; *and see id.*, Figs. 16 A-B, 16E, 23:21-40.



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

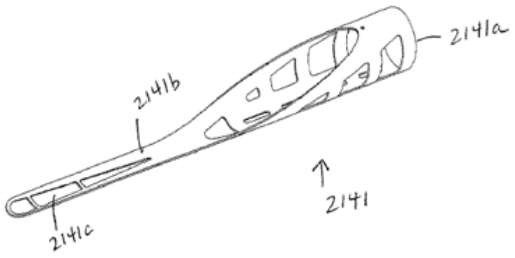
Distal shaft (130) contains an inflation lumen in which stiffness transition member (135) is located. Member (135) is "preferably made of stainless steel." *Id.*, 11:29-39. Ressemann teaches that the rigidity of member (135) increases gradually from its distal end (adjacent tip 144) to its proximal end.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

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

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

Given the difference in the materials that form the "segment defining the side opening" compared to the matrial that forms evacuation lumen 140, the former is necessarily more rigid than the latter. Ex-1205, ¶ 176; Ex-1242, ¶¶ 59-68, *see also* ¶¶ 29-38; *and see, supra* § VI (construing 25.d to mean "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure).

Additionally, Ressemann also discloses support collar 2141, which may be inserted into the proximal opening of the evacuation lumen, as discussed above. *Supra*, § VII.C.6. Circumferential portion 2141a "fits into the proximal opening of the evacuation lumen" in order to "provide hoop support." Ex-1208, 24:55-58.



proximal Fig. 16J **distal**

Ex-1208, Fig. 16J (annotated).

Proximal end tab 2141b "provides a flexibility transition" between the proximal end of the evacuation head and the shaft. *Id*., 24:62-67. Collar 2141 is "fabricated from a thin walled metallic tube," or "any material with suitable rigidity to prevent kinking" of tab 2141b. *Id*., 25:1-16.

With the addition of collar 2141, proximal side opening 140a of assembly 100 is lined with metal, or another material that is suitably rigid. *Supra*, § VII.B.3. By contrast, the more distal portion of lumen 140 lacks the support of collar 2141. This, too, results in the "segment defining the side opening" of assembly 100 being more rigid than the tubular structure. Ex-1205, ¶ 176; Ex-1242, ¶¶ 69-80, *see also* ¶¶ 29-38.

D. Claim 26: The system of claim 25, wherein the segment defining the side opening includes a portion having an arcuate cross-sectional shape.

Ressemann discloses claim 26. Ex-1205, ¶ 177. The segment defining the side opening includes proximal opening 140a to evacuation lumen 140. *Supra*, § VII.C.4. Lumen 140 has a circular cross section:

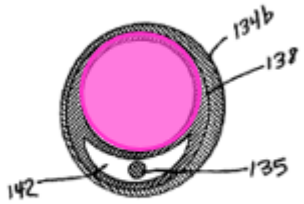


FIG. 1B

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

As shown below, in a cross section through opening 140a, the segment defining the side opening has a portion with an arcuate cross sectional shape, which, according to the '760 patent is a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1201, 7:12-13.

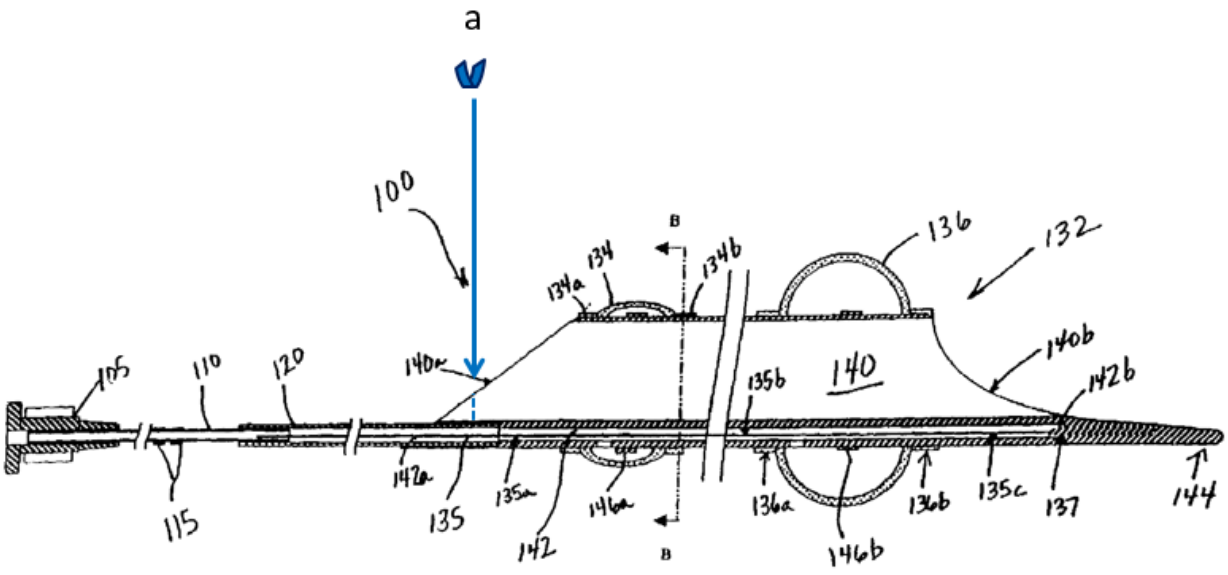


FIG. 1A

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

E. Claim 27. The system of claim 25, wherein the segment defining the side opening includes a portion having a hemicylindrical cross-sectional shape.

Ressemann discloses claim 27. Ex-1205, ¶ 178. As shown below, in a cross section through opening 140a, the segment defining the side opening has a portion with a hemicylindrical cross sectional shape, which, according to the '760 patent is a portion that "desirably includes 40% to 70% of the circumference of the tube." Ex-1201, 7:7-8.

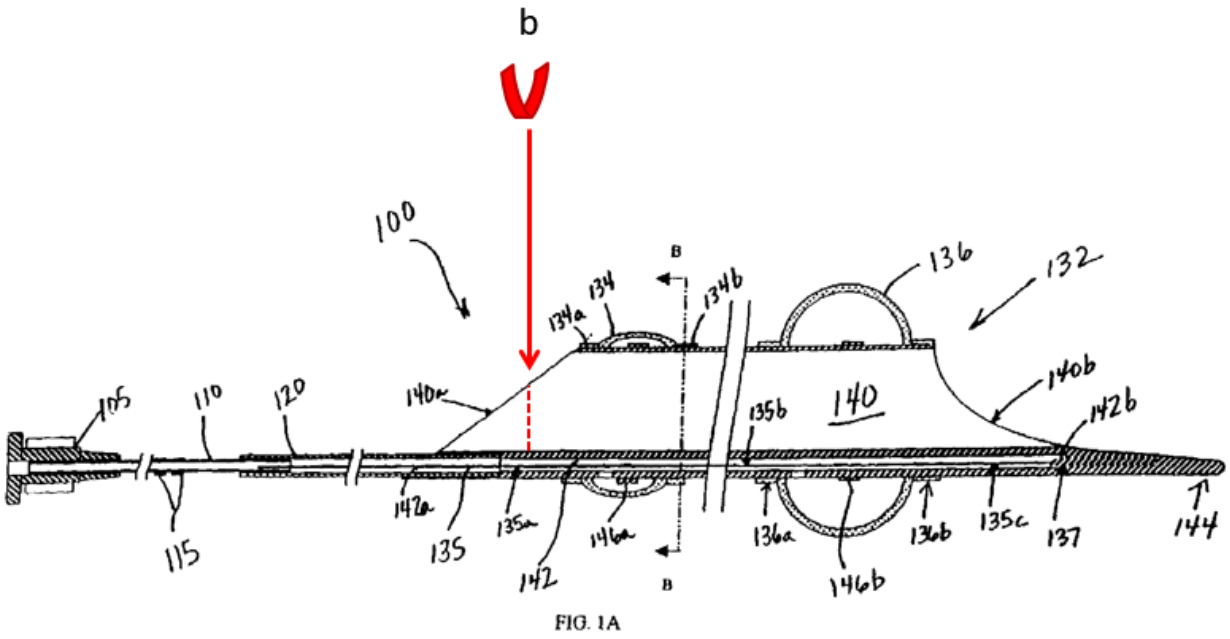


FIG. 1A

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

F. Claim 28: The system of claim 25, wherein the segment defining the side opening includes a portion having a full circumference cross-sectional shape.

Ressemann discloses claim 28. Ex-1205, ¶ 179. As shown below, in a cross section through opening 140a, the segment defining the side opening has a portion with a full circumference cross sectional shape.

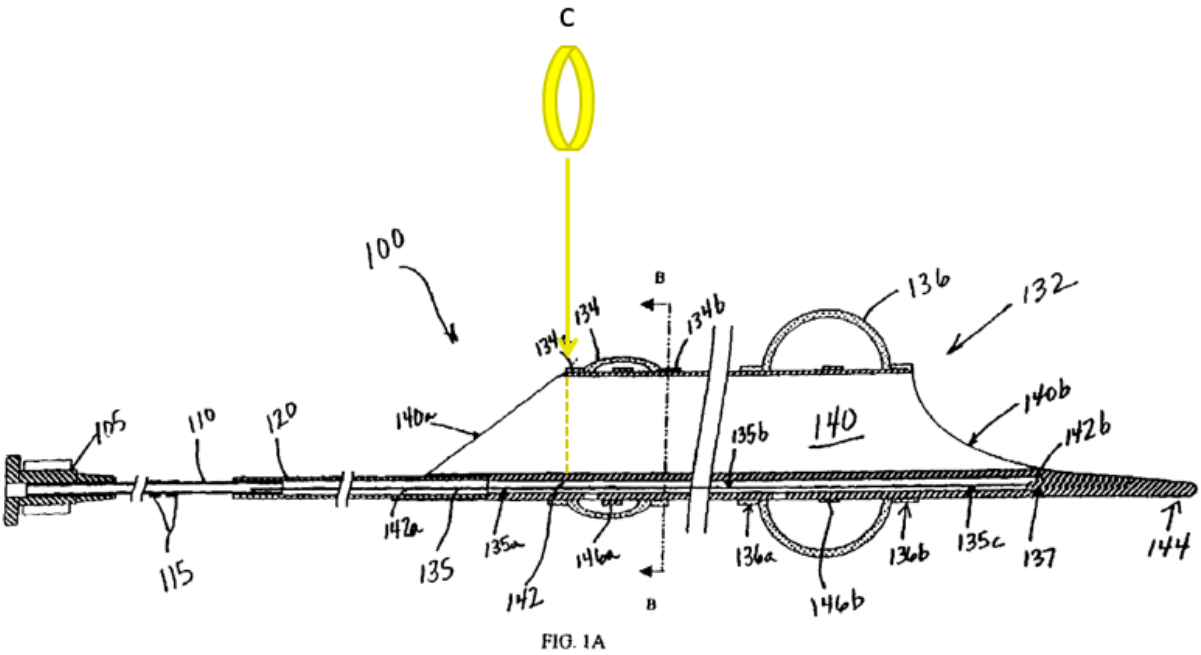


FIG. 1A

Ex-1208, Fig. 1A (color and annotation added); *see also* Fig. 1B.

G. Claim 29: The system of claim 28, wherein the cross-section of the guide extension catheter at the portion of the segment defining the side opening having the full circumference cross-sectional shape includes a single lumen.

Ressemann renders this limitation obvious in view of Takahashi and the common knowledge of a POSITA. Ex-1205, ¶ 180.

A cross section through assembly 100 at the "portion of the segment defining the side opening having the full circumference cross-sectional shape" discloses ***more than one lumen***, evacuation lumen 140 and inflation lumen 142. Ex-1208, 6:35-65; *and see* Fig. 1B.

As explained for 25.c.ii, however, a POSITA had the motivation to modify Ressemann to remove the sealing balloons, so that assembly 100 could be used solely as an extension catheter with a smaller guide catheter, and achieve a "not more than one French size differential" between the inner diameter of the tubular structure and the inner diameter of the guide catheter. *See* § VII.C.5, *supra*.

Absent sealing balloons (134) and (136), there would be no reason to include an inflation lumen in the shaft. A solid shaft could be used instead, Ex-1230, 4:38-40, and were well known alternatives to shafts that included a lumen. *Id.*,

4:38-40; Ex-1205, ¶ 180; Ex-1242, ¶¶ 81-87.

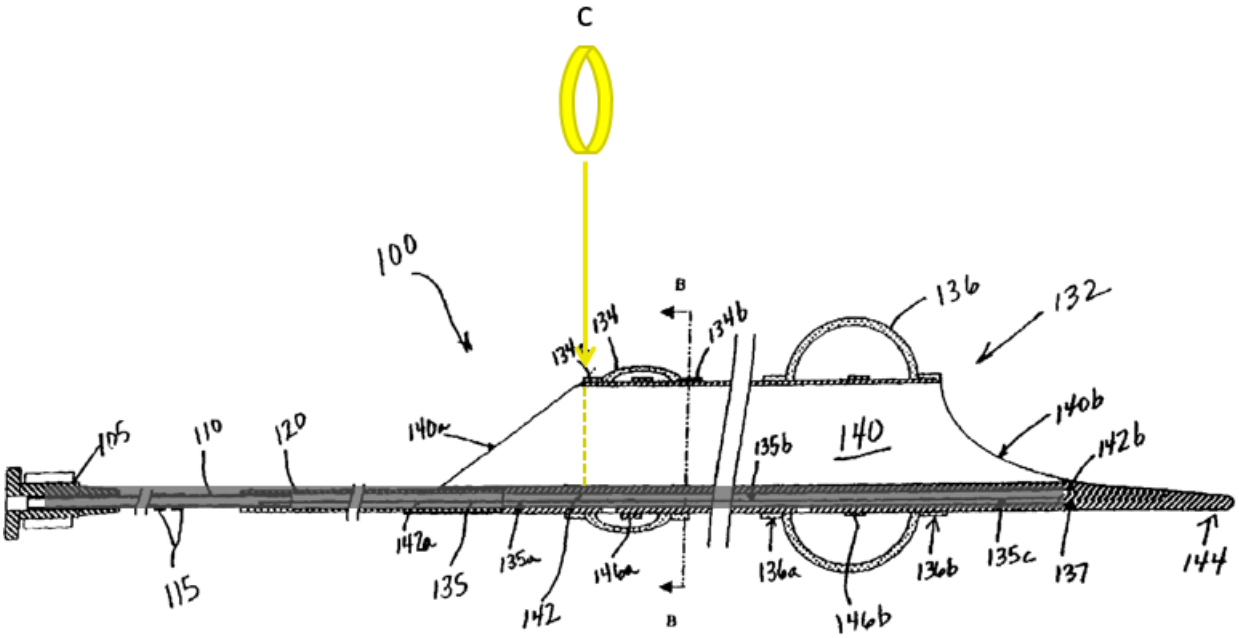


FIG. 1A

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

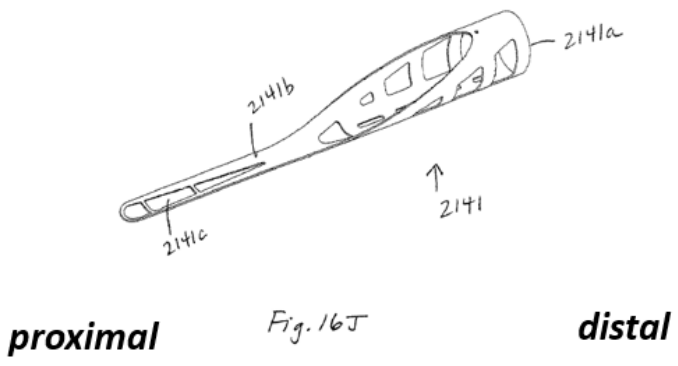
Absent an inflation lumen, a cross section through assembly 100 at the "portion of the segment defining the side opening having the full circumference cross-sectional shape" would include a "single lumen." Claim 29 is obvious. Ex-1205, ¶ 180.

H. Claim 30: The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

Ressemann discloses claim 30. Ex-1205, ¶ 181. In the context of the '760 patent, "concave track" refers to a portion that is not fully circumferential. *Supra*, § VI. Ressemann discloses that the side opening includes portions that are not fully

circumferential. *Supra*, §§ VII.D-E. Ressemann additionally discloses that the concave track is "configured to guide the one or more stents or balloon catheters along a length of the concave track" for the reasons set forth for claim 25.c.iii. *Supra*, § VII.C.6.

Additionally, and as explained above for claim 25 (25.c.iii, 25.d), a POSITA would be motivated to use collar 2141 with assembly 100. §§ VII.C.6-7. Collar 2141 includes a concave track that runs from the proximal end of the collar, 2141c, terminating toward its distal end (i.e. the portion of the collar that becomes "fully circumferential"). Ex-1205, ¶ 181.



Ex-1208, Fig. 16J (annotated).

I. Claim 31: The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.

Ressemann discloses claim 31. Ex-1205, ¶¶ 182-183. The segment defining the side opening includes at least one inclined slop, indicated below by the red arrow.

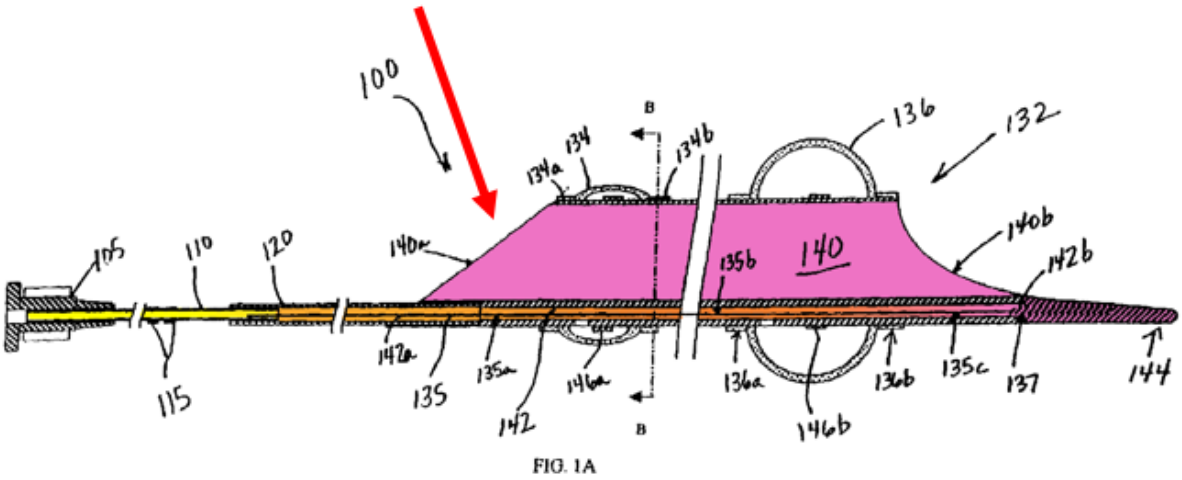


FIG. 1A

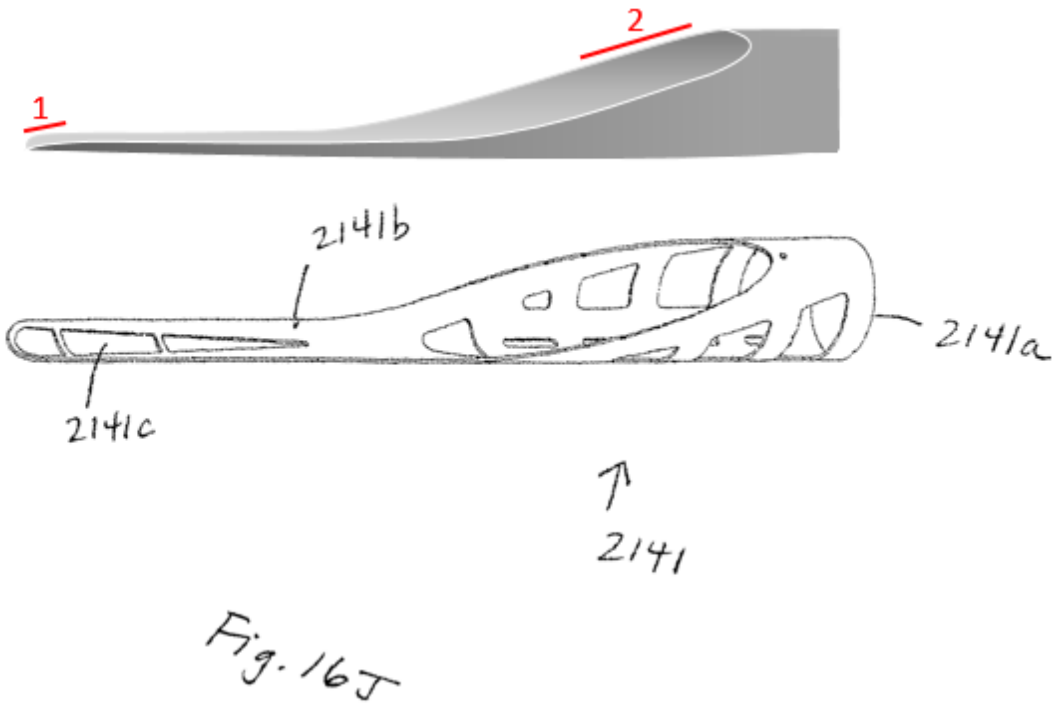
Ex-1208, Fig. 1A (color and annotation added).

J. Claim 32: The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

Ressemann discloses. Ex-1205, ¶¶ 184-188.

A POSITA would be motivated to use collar 2141 with assembly 100. *Supra*, §§ VII.C.6-7, VII.H. As shown in Figure 16J below, support collar 2141 has a first inclined slope at the proximal end of support collar 2141 (shown as "1" below), a flat, non-inclined region, and a second inclined slope at the distal end of support collar 2141, (shown as "2" below). Ex-1242, ¶¶ 71-79.These inclined slopes are

similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1205, ¶ 184; Ex-1242, ¶138.



Ex-1208, Fig. 16J (annotated and colored).

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, ¶ 79 (citing Ex-1208, 24:55-67). 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, ¶¶ 184-188; Ex-1242, ¶¶127-138. Thus, Ressemann in view of knowledge of POSITA renders claim 32 obvious. Ex-1205, ¶¶ 184-188.

K. Claim 33: The system of claim 25, wherein the side opening is formed by a cutout portion of a cylindrical tubular structure.

Ressemann discloses claim 33, Ex-1205, ¶ 189, explaining that the proximal end of the tube that forms the evacuation lumen may be "cut at an angle" with respect to the longitudinal axis of the evacuation sheath. Ex-1208, 24:33-38 (referring to Fig. 16D, tube 2138 and evacuation lumen 2140). This teaching is equally applicable tube 138 and lumen 140 in Figs. 1A-1D for reasons discussed above. *Supra*, § VII.C.7.

L. Claim 34: The system of claim 25, wherein the segment defining the side opening and the tubular structure comprise a reinforced portion of the guide extension catheter.

Ressemann discloses claim 34. Ex-1205, ¶¶ 190-193. As discussed for claim 25.d, the "segment defining a side opening" is reinforced with stiffness transition member (135). Ex-1242, ¶¶ 88-91. Additionally, and as explained above, Ressemann also teaches the addition of a support collar, 2141, to reinforce side opening 140a. *Supra*, §§ VII.C.6-7, H. Ex-1205, ¶¶ 190-192; Ex-1242, ¶¶ 92-96.

As discussed in 25.c.i., the tubular structure is the portion of the evacuation lumen 140 that is distal to 140a. § VII.C.4, *supra*. Ressemann explains that the evacuation lumen is part of evacuation head 132, which includes an inflation

lumen with a stiffness transition member 135. *Supra*, § VII.C.7. Thus, Ressemann teaches that lumen 140 is reinforced because it has been "made stronger by additional material or support." Supra, § VI (construing "reinforced portion").

M. Claim 35: The system of claim 25, wherein the distal end of the guide extension catheter includes a tip portion.

Ressemann discloses claim 35. Ex-1205, ¶ 194. As discussed for claim 34, sheath assembly (100) has a distal tip (144), which is the "tip portion."

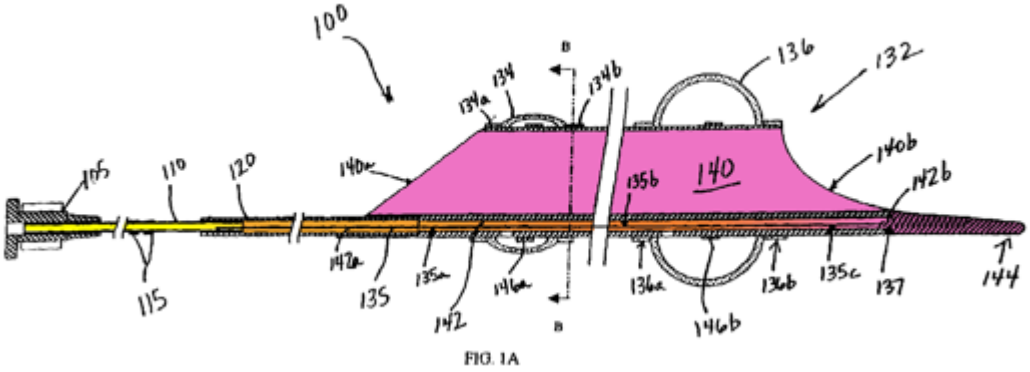


FIG. 1A

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

N. Claim 36: The system of claim 35, wherein a flexural modulus of the tubular structure is greater than a flexural modulus of the tip portion.

Ressemann discloses claim 36. Ex-1205, ¶¶ 195-199. As Dr. Brecker and Dr. Hillstead explain, tip portion (144), shown below in pink, has a first flexural modulus (*I*). *Id*; Ex-1242, ¶¶ 97-99.

Ressemann teaches that tip (144) is made of a more flexible polymer than

tubular structure (140) Ex-1208, 11:20-22. Tip (144) allows the assembly "to be placed atraumatically into the blood vessel, even if the blood vessel exhibits tortuosity." *Id*., 11:25-28. Accordingly, if multi--lumen tube 138 (and evacuation lumen 140) is "fabricated of high density polyethylene," then "soft tip 144 may be fabricated of low durometer polyurethane or Pebax." *Id*., 11:22-24.

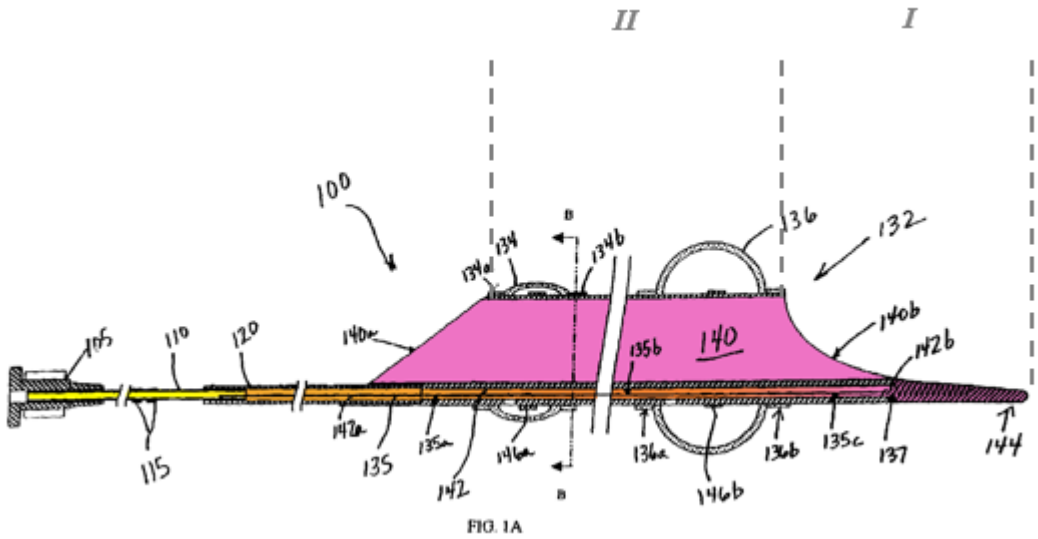


FIG. 1A

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

Given the differences in the materials that are used to form tip (144) and tubular structure 140, the flexural modulus of the tubular structure (*II*) is necessarily greater than that of the tip portion (*I*). Ex-1205, ¶¶ 195-199; Ex-1242, ¶¶ 97-99.

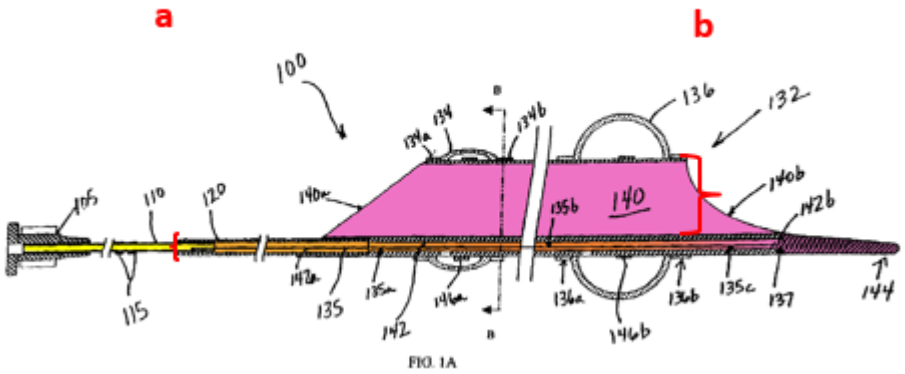
O. Claim 37: The system of claim 25, wherein the uniform cross-sectional inner diameter of the lumen of the tubular structure is greater than a largest outer dimension of the substantially rigid segment.

Ressemann discloses claim 37. Ex-1205, ¶ 200.

As discussed for claim 25.c.ii, the tubular structure of assembly 100 (lumen 140) has a uniform cross-sectional inner diameter of 0.061 inches, which is 1.54 mm. Ex-1208, 10:17-21. The "substantially rigid segment" is the shaft's proximal (110) and intermediate (120) portions. *Supra*, § VII.C.4.

Ressemann teaches that the diameter of the tubular structure (b) is greater than the "largest outer dimension of the substantially rigid segment" (a),[11] as illustrated below.

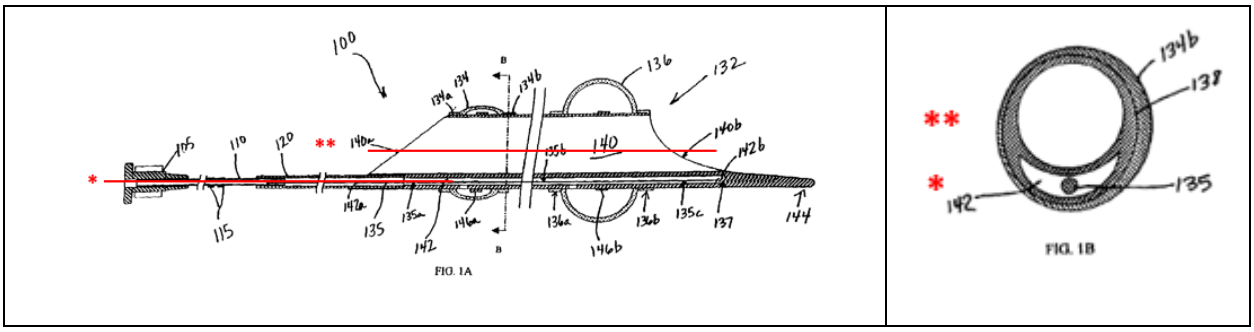
[11] Claim 37's "largest outer dimension" language permits, but does not require, the substantially rigid segment to vary in outer dimension. All the claim requires is that the substantially rigid segment cannot be bigger (in cross-sectional dimension) than the inner diameter of the tubular structure.



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

P. Claim 38: The system of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure.

Ressemann discloses claim 38. Ex-1205, ¶¶ 201-203. The "substantially rigid segment" (proximal and intermediate shafts (110, 120) is eccentrically positioned (not concentric) relative to a cross section taken through the tubular structure of assembly (100).



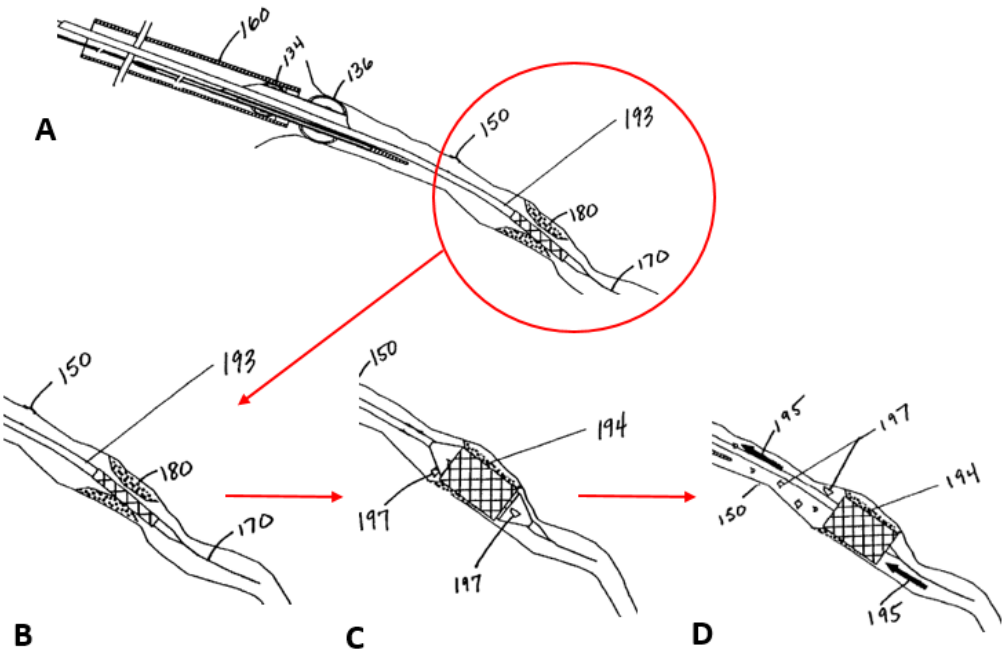
Ex-1208, Figs. 1A (left), 1B (right) (annotations added, where an asterisk discloses the positioning of the substantially rigid segment and a double asterisk discloses the positioning of a cross-section of the tubular structure).

Q. Claim 39: The system of claim 38, further comprising a stent releasably joined to the distal end of the elongate balloon catheter.[12]

Ressemann discloses claim 39. *Supra*, § VII.P. Ex-1205, ¶¶ 204-207.

Ressemann teaches an "elongate balloon catheter," stent delivery system 193, which is used to deliver a stent across a stenosis 180. Ex-1208, 13:57-14:16, Figs. 6E-G.

[12] There is no antecedent basis for "the elongate balloon catheter." The claim only makes sense if the elongate balloon catheter refers to one of the "one or more stents or balloon catheters" recited in claim 25.



Id., Figs. 6E-G (color and annotation added).

As illustrated above, in Figure 6E (panels A, B), a "stent delivery system" is advanced across stenosis (180). *Id.*, 13:57-60. Figure 6F (panel C) shows "a stent delivery balloon is inflated to expand a stent 194 against the vessel wall." *Id.*, 14:7-9. Figure 6G (panel D) shows the deflation of the balloon after the stent is in place. *Id.*, 14:14-15, demonstrating that stent 194 is "releasably joined" to the distal end of "elongate balloon catheter" 193. Ex-1205, ¶¶ 204-207.

R. Claim 40: The system of claim 25, further comprising an elongate balloon catheter partially insertable within the guide catheter alongside the substantially rigid segment, through the side opening, and through the lumen of the tubular structure.

Ressemann discloses claim 40. Ex-1205, ¶¶ 208-210.

As illustrated below, the evacuation sheath's "substantially rigid segment" is proximal shaft 110 (yellow) and intermediate 120 (yellow transitioning to pink) shafts). *Supra*, § VII.C.4.

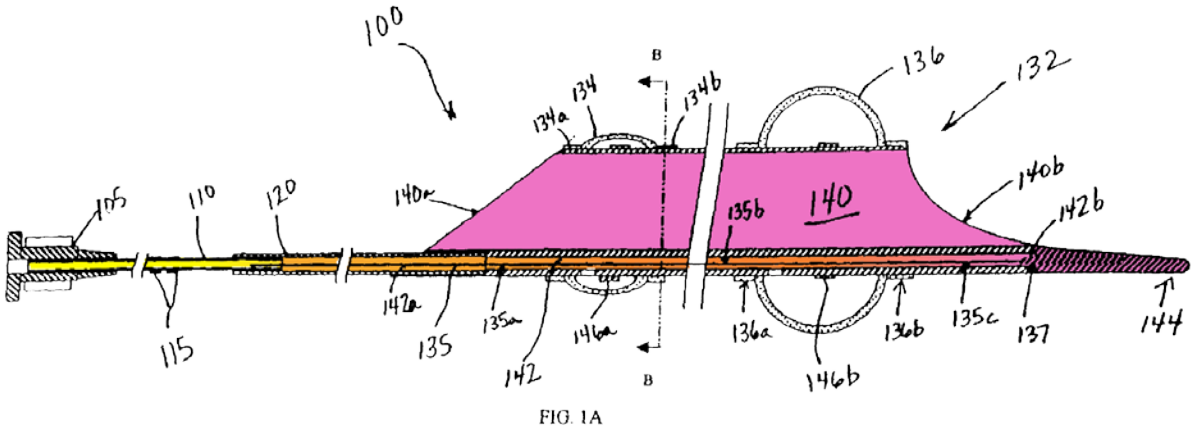


FIG. 1A

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

Elongate balloon catheter (193) (green), *supra* § VII.Q, is partially insertable within guiding catheter (160) alongside the evacuation sheath's substantially rigid segment, through side opening (140a), and through lumen 140 (pink) of evacuation head (132). Ex-1205, ¶¶ 208-210.

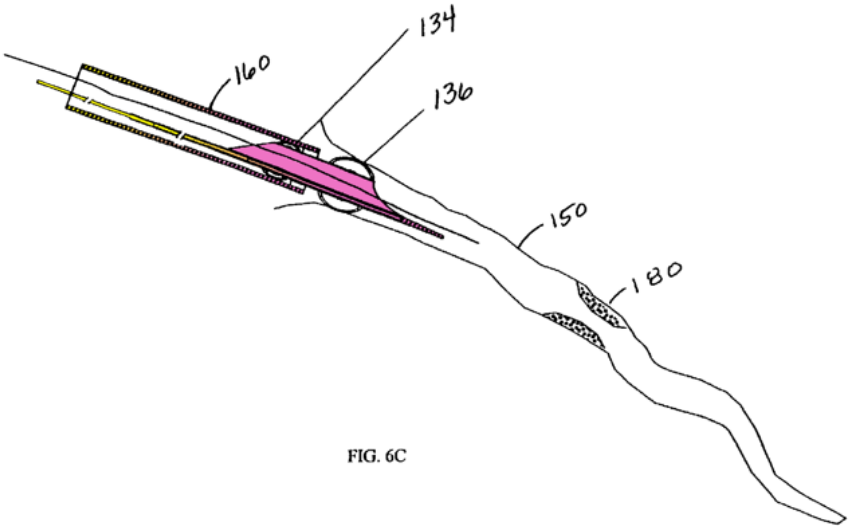


FIG. 6C

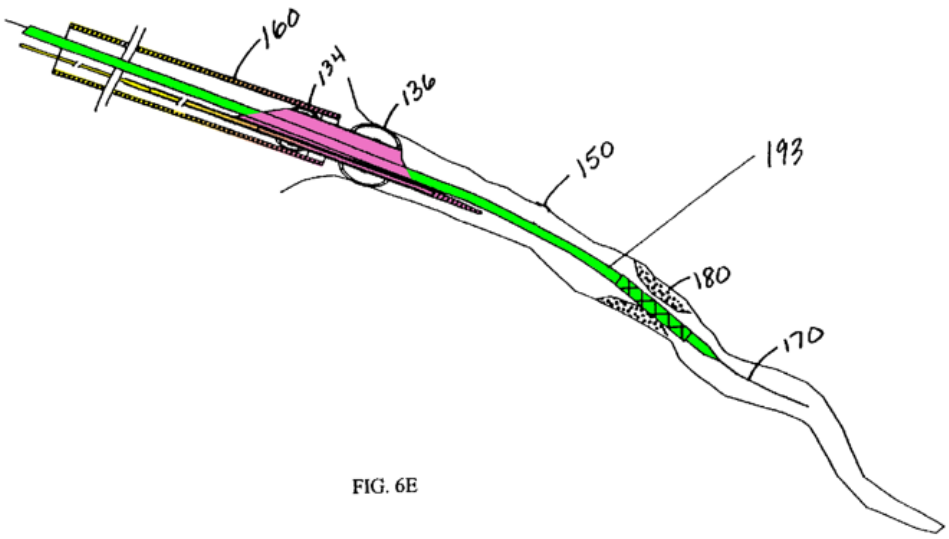


FIG. 6E

Ex-1208, Figs. 6C, 6E (color added).

S. Claim 41: The system of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be partially advanced through the guide catheter and into the coronary artery without blocking use of the guide catheter.

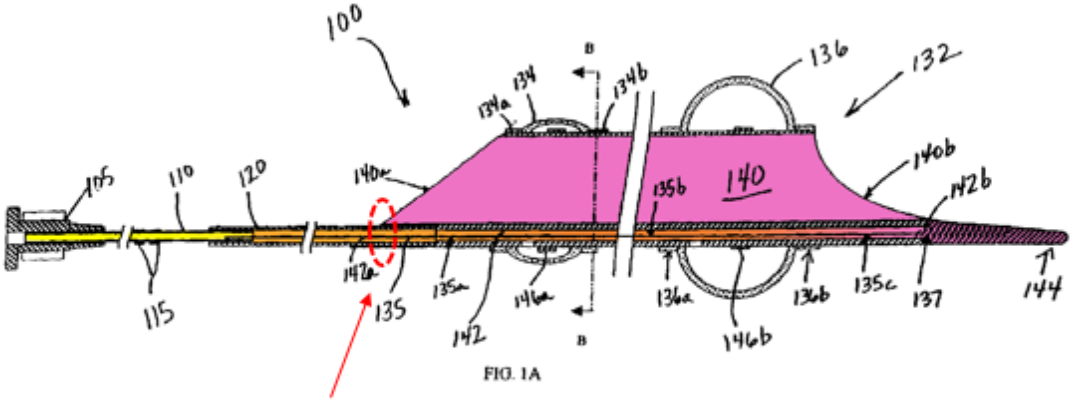
Ressemann discloses claim 41. Ex-1205, ¶ 211. As discussed above, *supra* §§ VII.O-P, the "substantially rigid segment" (proximal and intermediate shafts (110, 120) has a smaller cross sectional diameter than the tubular structure (tube 138 with lumen 140), and is positioned eccentrically relative to a cross section through the same. Moreover, Ressemann teaches that the guide catheter has a diameter that is larger than that of evacuation head (132) including its shaft. *Supra*, §VII.C.

Thus, when the tubular structure of assembly 100 is partially advanced through guiding catheter 160 into the coronary artery, "use of the guide catheter" is not blocked. Ex-1208, Figs. 6A-F, 6:18-24, 12:9-14:39. This is further evidenced by Ressemann's teaching that the guide catheter lumen is in fluid communication with the evacuation lumen of sheath assembly (100). *Supra*, § VII.C.4; Ex-1205, ¶ 211.

T. Claim 42: The system of claim 25, wherein the substantially rigid segment and the tubular structure are operably coupled at or adjacent to the segment defining the side opening.

Ressemann discloses claim 42. Ex-1205, ¶ ¶ 212-215.

The substantially rigid segments are proximal and intermediate portions of shaft, (110, 120). *Supra*, § VII.C.4. Ressemann teaches that proximal, intermediate and distal shaft portions are joined together by overlapping welds or bond joints. Ex-1208, 10:60-62.



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

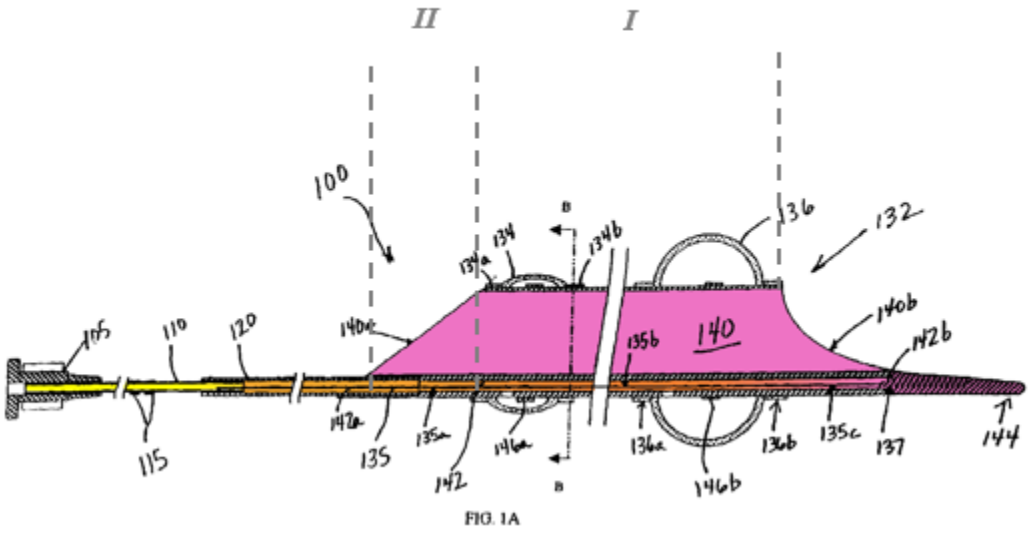
Ressemann also teaches that distal shaft portion (130) includes evacuation head (132), *id*.10:34-35, which, as discussed above, § VII.C.4, includes tubular structure (138) with lumen (140).

As illustrated above. The weld or bond joint between intermediate shaft (120) and distal shaft (130) is adjacent proximal opening 140a. Thus, Ressemann's substantially rigid segment and its tubular structure are operably coupled adjacent to the segment defining the side opening, (140a). Ex-1205, ¶ ¶ 212-215.

U. Claim 44: The system of claim 25, wherein a flexural modulus of the segment defining the side opening is greater than a flexural modulus of the tubular structure.

Ressemann discloses claim 44. Ex-1205, ¶ ¶ 216-223. As explained by Dr. Brecker and Dr. Hillstead, and for the reasons stated in 25.d, the tubular structure

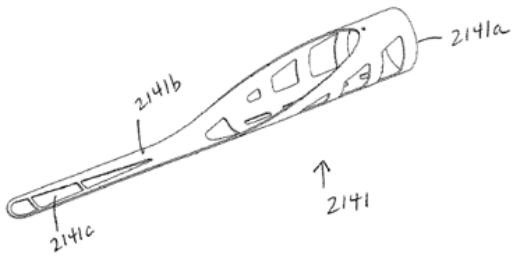
has a first flexural modulus (*I*), and the segment defining the side opening has a second flexural modulus. *Id*.; Ex-1242, ¶¶ 59-80; *supra* § VII.C.7.



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

Given the differences in the materials that are used to form them, the flexural modulus of the segment defining the side opening (*II*) is necessarily greater than that of the tubular structure (*I*). Ex-1205, ¶ ¶ 216-223; Ex-1242, ¶¶ 59-80; *see also* Ex-1242, ¶¶ 29-38.

Additionally, as explained for claims 25 (§§ VII.C.6-7, *supra*), 30 (§VII.H, *supra*) and 32(§ VII.J, *supra*), the side opening of assembly 100 is additionally more rigid than the tubular structure of the evacuation lumen because Ressemann teaches that a support collar 2141 should be used to reinforce the proximal opening of the evacuation lumen. Ex-1208, 24:55-58.



Id., Fig. 16J (annotated).

Collar 2141 is "fabricated from a thin walled metallic tube," or "any material with suitable rigidity," resulting in side opening 140a having a greater flexural modulus than the tubular structure 140.

Thus, the flexural modulus of the segment defining the side opening (*II*) is greater than the flexural modulus of the tubular structure (*I*). Ex-1205, ¶ ¶ 216-223.

V. Claim 47: The system of claim 25, wherein a distal portion of the guide extension catheter is configured to anchor within the ostium of the coronary artery and resist axial and shear forces exerted by the one or more received stents or balloon catheters that would otherwise tend to dislodge the distal portion.

Ressemann discloses claim 47. Ex-1205, ¶ ¶ 224-237.

The distal portion of the guide extension catheter (assembly 100) is advanced distal of the distal tip of the guide catheter and into a coronary artery. *Supra*, § VII.C. Ressemann also teaches that the proximal portion of evacuation head

(132) remains within the lumen of guiding catheter (160). Ex-1208, Figs. 6A-F, 12:9-14:10. Thus, Ressemann discloses the structural limitations of claim 47, which is a systems claim.[13]

To the extent that Patent Owner suggests that claim 47 requires anything more than the cited disclosure in Ressemann, it is mistaken. Claim 47 additionally recites an intended use ("resist axial and shear forces exerted by the one or more received stents or balloon catheters 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

[13] Claim 47 includes additional language that the "distal portion of the ***guide extension catheter***" is configured to "anchor within the ostium." That cannot be correct as the '760 patent specification teaches that the distal portion of the ***guide catheter*** anchors in the ostium, while the guide extension catheter can be advanced further into the coronary artery. Ex-1201, Fig. 8. For purpose of this IPR, Petitioner assumes this is a claim drafting error. Similar to the '760 patent, Ressemann teaches that the distal end of guiding catheter 160 "may be positioned within the ostium of the target vessel," and evacuation sheath assembly 100 "may be advanced through the catheter and beyond a major side branch of the target vessel." Ex-1208, 12:26-30.

use for an old product does not make a claim to that old product patentable.")

Regardless, as Dr. Brecker explains, Ressemann discloses the remainder of claim 47 to a POSITA. Ex-1205, ¶ ¶ 224-237. Ressemann explicitly teaches using assembly (100) to deliver a balloon-expandable stent across a stenotic lesion. Ex-1208, Figs. 6A-F, 12:9-14:10.

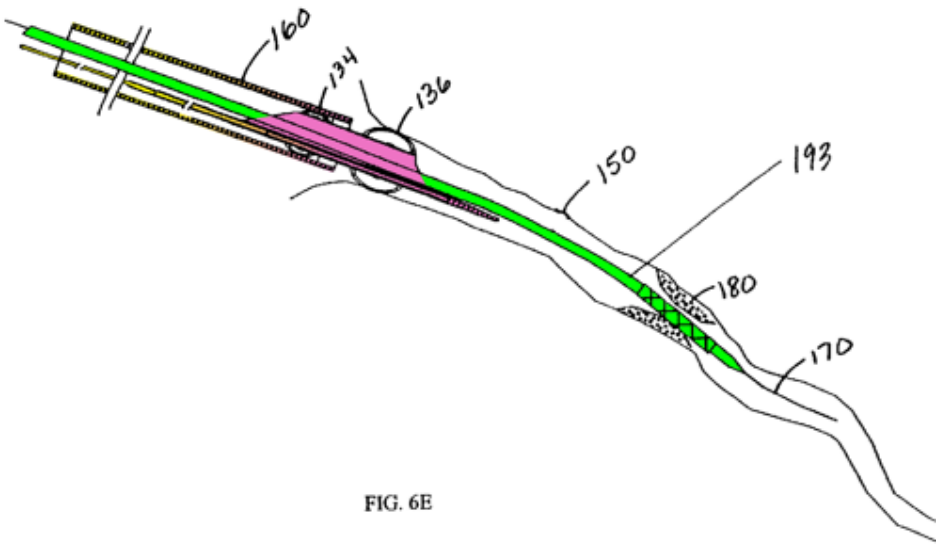


FIG. 6E

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

Long before the '760 patent, those working in the field knew that in order to advance an interventional cardiology device through a GC into the coronary vasculature, the GC had to have "sufficient stiffness to offer 'backup' support." Ex-1215a, 548. As Dr. Brecker explains, and as taught in Grossman's Cardiac Catheterization, Angiography and Intervention, the support came from the GC's shape, and the intrinsic stiffness of its material, as well as from its "deep

engagement" with the coronary ostia. *Id*., 549-50; *and see* Ex-1241, 20.

The '760 patent also admits that because the disclosed, coaxial extension catheter is "extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery," it "assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion . . . ." Ex-1201, Abstract; *and see id.*, 5:14-34. According to the '760 patent's own disclosure, it is the combination of a GC ***and*** an extension catheter inserted into a coronary ostium that improves distal anchoring of the system and provides "stiffer back up support" than a GC alone. *Id*., 8:20-30. But this is no different than what was already known in the prior art and disclosed in Ressemann. Ex-1205, ¶ ¶ 224-237.

Ressemann's disclosure of a catheter that is extended through a GC (and beyond its distal tip into a coronary artery)—and used to deliver a balloon-expandable stent—inherently discloses a device that "resist[s] axial and shear forces exerted by the one or more received stents or balloon catheters that would otherwise tend to dislodge the distal portion" of the catheter from the coronary artery. Ex-1205, ¶ ¶ 224-237.

VIII. GROUND 2: RESSEMANN RENDERS CLAIM 32 OBVIOUS IN VIEW OF TAKAHASHI, KATAISHI AND THE COMMON KNOWLEDGE OF A POSITA.

A. Kataishi

Kataishi is a U.S. Patent Application published on January 20, 2005, and is prior art under pre-AIA §102(b) and post-AIA §102(a)(2). Ex-1225. During prosecution of the ’760 patent (and its previous iteration, the ’850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. Exs-1201-03.

Kataishi discloses a suction catheter for removing a thrombus from a coronary artery. Ex-1225, [0001]; Ex-1205, ¶¶ 109-113. 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]. In addition to providing flexibility, the two-incline shape of the catheter’s distal opening also improves its ability to suction thrombi, *id*., Abstract [0026]-[0027], Fig. 10, which corresponds to loading a thrombus into the catheter’s distal end. Ex-1205, ¶¶ 109-114; Ex-1242, ¶¶ 43-50.

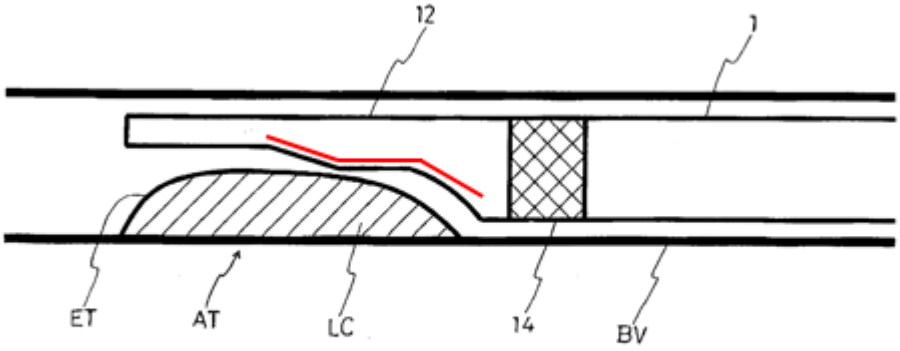


Fig. 10

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

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

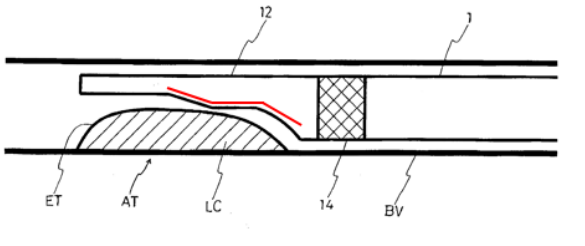


Fig. 10

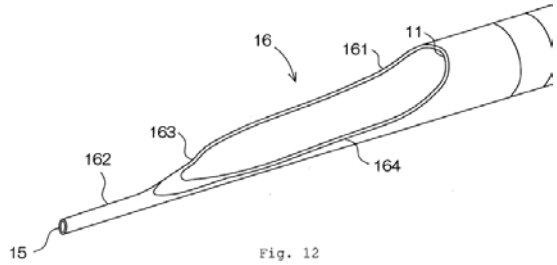


Fig. 12

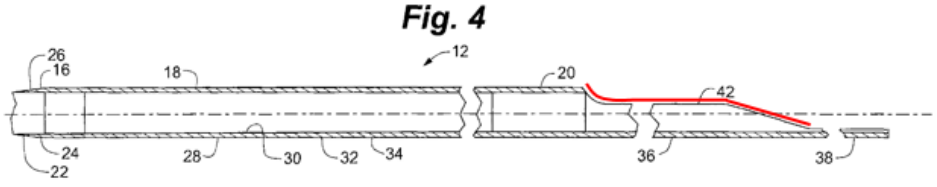
Cut surface 16 has a concave shape 161 that is closest to the fully circumferential portion of catheter lumen 11. The concave shape is adjacent "ledge surface 164," which is parallel to the catheter's longitudinal axis. Moving distally, "cut surface 163 defining an angle with the longitudinal axis of the catheter." *Id*., [0027]; Ex-1205, ¶¶ 151-155; Ex-1242, ¶¶ 43-50.

B. Claim 32: The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

As discussed in § VII.J, *supra*, Ressemann in view of Takahashi renders claim 32 obvious. Ressemann in view of Takahashi and Kataishi also renders claim 32 obvious. Ex-1205, ¶¶ 238-245.

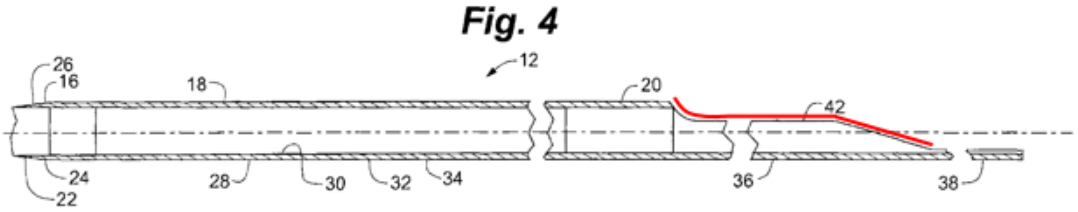
In an attempt to support claim 32, patentee represented to the Examiner that Figure 4 of the '760 patent showed two different inclined slopes in the side opening. Ex-1203 at 112 (Preliminary Amendment March 3, 2014 at 18).

'760 Patent



Ex-1201, Fig. 4 (annotation added).

Of course, the disclosure in the '760 patent is no different than what was disclosed in Kaitishi.



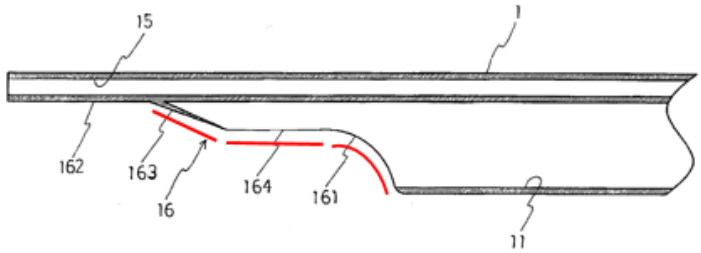


Fig. 2

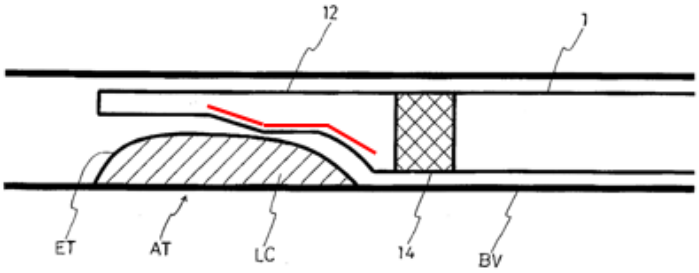


Fig. 10

Compare Fig. 4 (color added), *with* Ex-1225, Figs. 2, 10 (color added). Ex-1205, ¶ 238; Ex-1242, ¶¶ 152-153.

A POSITA had the motivation to modify proximal opening 140a of Ressemann so that it was configured to include two different inclined slopes, as disclosed in Kataishi. Ressemann and Kataishi are both directed at the same problem, which is removing occlusions from coronary arteries. Ex-1208, Abstract; Ex-1225, Abstract.

As Dr. Brecker and Dr. Hillstead explain, a POSITA had the motivation to modify the proximal opening of Ressemann's evacuation lumen because a POSITA knew that it was configured to receive a stent or balloon catheter. *Supra*, § VII.J.

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-1242, ¶¶ 139-148. 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. *Id*. As such, POSITA would be motivated to apply Kataishi's distal opening structure to the proximal opening, 140a, of Ressemann for the reasons set forth below.

Adding a second, inclined slope to the angled, proximal side opening of Ressemann would have increased the area of entry for the stent or balloon, without increasing the catheter's outer diameter. Ex-1205, ¶ 243; Ex-1242, ¶ 147. A POSITA would be motivated to make this modification because it would allow the catheter to receive a therapy catheter, but still be advanced to distal locations into the coronary vasculature (compared to catheters with larger diameters). Ex-1225, Abstract [0026]-[0027], Fig. 10; Ex-1255 at 300, 304 (disclosing a better ability to load because of two different inclined slopes on the end).

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-1242, ¶¶ 149-150. While Kataishi discloses two different inclined slopes on the distal end, a POSITA would be motivated to modify Ressemann's single incline side opening to two different inclined slopes in order to minimize kinking and thus improve the crossability of the device by avoiding drag on the inside of the guide catheter. Ex-1242, ¶¶ 149-150.

A POSITA would have a reasonable expectation of success, as creating two different inclined slopes in the side opening would have been a routine task when manufacturing an extension catheter. Ex-1242, ¶ 151; Ex-1250, Fig. 7 (disclosing double incline, proximal side opening). As such, a POSITA would have a reasonable expectation of success in modifying Ressemann's proximal opening 140a to have the two-inclined side opening disclosed in Kataishi. Thus, claim 32 is obvious. Ex-1205, ¶¶ 238-245.

IX. GROUND 3: RESSEMANN RENDERS CLAIM 32 OBVIOUS IN VIEW OF TAKAHASHI, ENGER AND THE COMMON KNOWLEDGE OF A POSITA.

A. Enger

U.S. Pat. No. 5,980,486 to Enger issued on November 9, 1999. Ex-1250. It is prior art under pre-AIA §102(b) and post-AIA §102(a)(2) and was not cited or

considered during prosecutions of the ’850 patent. Ex-1202. It is cited on the face of the ’760 patent, but was not discussed during prosecution.[14] Ex-1201-03. Enger discloses a balloon catheter for use in a coronary artery. Ex-1250, Abstract; Ex-1205, ¶¶ 81-89, 156-160.

B. Claim 32: The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

[14] Enger was not discussed in any Office Action and was not considered in combination with Ressemann, and thus this Board should decline to exercise its discretion under 35 U.S.C. § 325(d). *See Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019) (explaining that a reference that “was neither applied against the claims nor discussed by the Examiner” does not weigh in favor of exercising discretion under § 325(d)); *Shenzhen Zhiyi Tech Co. v. iRobot Corp.*, IPR2017-02137, Paper 9 at 9-10 (P.T.A.B. Apr. 2, 2018) (declining to apply § 325(d) when the reference was merely cited in a Notice of Reference Cited on face of patent-in-question).

As discussed in §§ VII.J, VIII.B, *supra*,[15] Ressemann, in view of Takahashi, renders claim 32 obvious. Ressemann in view of Takahashi and Enger also renders claim 32 obvious. Ex-1205, ¶¶ 246-250.

Like Ressemann, Enger is directed to a catheter system for treating occluded coronary arteries. *Supra*, § VII.J; Ex-1250, Abstract, 1:13-15. Like Ressemann's catheter assembly 100, Enger's angioplasty catheter is inserted through a guide catheter and into the coronary artery. Ex-1250, 3:25-29. And, like Ressemann, 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 in that the portion of the catheter that did not have guidewire support tended to "buckle" within the guide catheter. *Id*., 2:31-38. This would result in friction between the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy. *Id*., 2:38-49.

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

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

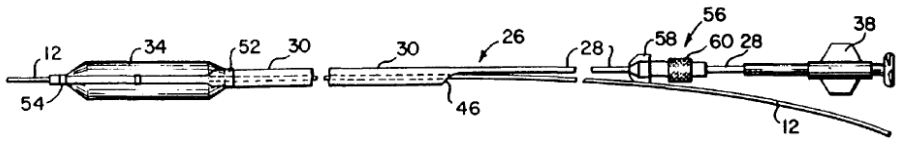


Fig. 1

The catheter is designed to have a short, distally located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*., 3:8-12, 5:34-40.

The proximal opening to the guidewire lumen has at least two inclined slopes.[16]

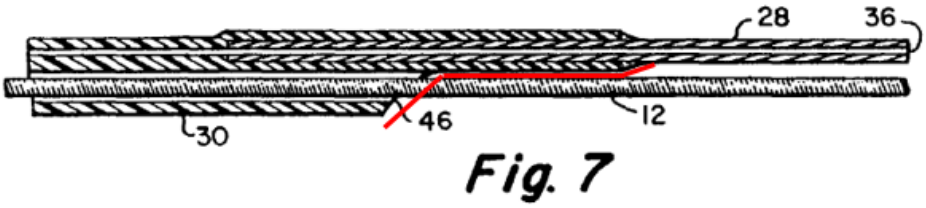


Fig. 7

Ex-1250, Fig. 7 (color added).

As Dr. Hillstead explains, 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. Ex-1242, ¶¶ 154-159. A POSITA would be motivated to provide a first incline to guide interventional devices such as a stent and balloon catheter into Ressemann's evacuation lumen. Ex-1205, ¶¶ 246-250.

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

As Dr. Hillstead explains, the first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1242, ¶¶ 154-159. POSITA would understand that the first incline of Enger could be incorporated into Resseman's proximal opening by using a similarly inclined polymer collar to grip intermediate shaft 120. *Id*. This would result in a two-incline opening to the proximal end of Ressemann's evacuation lumen. Thus, claim 32 is obvious. Ex-1205, ¶¶ 246-250.

X. 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 Petitioner launched a "copycat" product. *Id.*, 2, 5, 9. Patent Owner does not, however, allege secondary considerations in the section on validity and makes no attempt to satisfy any of the requirements for establishing secondary considerations, including nexus. Thus, Patent Owner cannot assert that it has met its burden of production, and secondary considerations—should they be raised later—are a matter for the trial phase.

XI. CONCLUSION

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

XIII. PAYMENT OF FEES

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

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 13, 2019

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WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 11,105 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 13, 2019

/ Cyrus A. Morton /

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition and supporting evidence. was served on November 13, 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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