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.: IPR2020-00138
U.S. Patent No. RE 47,379E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 47,379E

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

LIST OF EXHIBITS

Exhibit	Description
1201	U.S. Patent No. RE47,379 ("the '379 patent")
1202	File history for U.S. Patent No. 8,292,850
1203	File history for U.S. Patent No. RE47,379
1204	Assignment record of the '379 patent from the USPTO assignment database
1205	Declaration of Doctor Stephen JD Brecker, M.D.
1206	Curriculum Vitae of Doctor Stephen JD Brecker, M.D.
1207	U.S. Patent No. 7,736,355 ("Itou")
1208	U.S. Patent No. 7,604,612 ("Ressemann")
1209	U.S. Patent No. 5,439,445 ("Kontos")
1210	*New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, Catheterization and Cardiovascular Interventions 63: 452-456 (2004) ("Takahashi")
1211	Excerpt of prosecution history of U.S. Patent No. 8,048,032 (Application 11/416,629) (Amendment and Response, April 6, 2009)
1212	Joint Claim Construction Statement in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (January 10, 2018), D.I. 36; D.I. 36-1.
1213	*Markman* Order in *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (October 30, 2018), D.I. 102
1214	Meads, C., et al., *Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review*, Health Technology Assessment 2000 4(23) ("Meads")
1215	Excerpt from Grossman's Cardiac Catheterization, Angiography, and Intervention (6th edition) (2000) (chapters 1, 4, 11, 23-25).
1216	US Patent Publication 2003/0233117 ("Adams '117")
1217	U.S. Patent No. 5,902,290 ("Peacock")

Exhibit	Description
1218	U.S. Patent No. 5,891,056 (“Ramzipoor”)
1219	U.S. Patent No. 6,398,773 (“Bagaoisan”)
1220	Mehan, *Coronary Angioplasty through 4 French Diagnostic Catheters*, Catheterization and Cardiovascular Interventions 30:22-26 (1993) (“Mehan”)
1221	Excerpt of prosecution history for application 11/232,876 (Office Action, 6/20/09)
1222	Cordis, Instructions for Use, CYPHER™ (April 2003)
1223	Medtronic, Summary of Safety and Effectiveness Data, Driver™ Coronary Stent System (October 1, 2003)
1224	Boston Scientific, Summary of Safety and Effectiveness Data, TAXUS™ Express^{2}™ Drug-Eluting Coronary Stent System (March 4, 2004)
1225	U.S. Publication Application No. 2005/0015073 (“Kataishi”)
1226	U.S. Patent No. 5,489,278 (“Abrahamson”)
1227	U.S. Patent No. RE45,776 (“Root”)
1228	Baim, *Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts*, Circulation 105:1285-1290 (2002) (“Baim”)
1229	Limbruno, *Mechanical Prevention of Distal Embolization During Primary Angioplasty*, Circulation 108:171-176 (2003) (“Limbruno”)
1230	U.S. Patent No. 5,413,560 (“Solar ’560”)
1231	Schöbel, *Percutaneous Coronary Interventions Using a New 5 French Guiding Catheter: Results of a Prospective Study*, Catheterization & Cardiovascular Interventions 53:308-312 (2001) (“Schöbel”)
1232	*The sliding rail system (monorail): description of a new technique for intravascular instrumentation and its application to coronary angioplasty*, Z. Kardio. 76:Supp. 6, 119-122 (1987) (“Bonzel”)
1233	U.S. Publication Application No. 2004/0236215 (Mihara)

Exhibit	Description
1234	U.S. Patent No. 5,527,292 (“Adams ’292”)
1235	U.S. Publication Application No. 2004/0010280 (“Adams ’280”)
1236	Williams et al., *Percutaneous Coronary Intervention in the Current Era Compared with 1985-1986*, Circulation (2000) 102:2945-2951.
1237	Dorros, G., et al., *Coronary Angioplasty in Patients with Prior Coronary Artery Bypass Surgery*, Cardiology Clinics 7(4): 791-803 (1989)
1238	Ozaki et al, *New Stent Technologies*, Progress in Cardiovascular Disease 2:129-140 (1996)
1239	Urban et al., *Coronary stenting through 6 French Guiding Catheters, Catheterization and Cardiovascular Diagnosis* (1993) 28:263-266
1240	Excerpt of McGraw-Hill Dictionary of Scientific and Technical Terms (5th edition) (1994) (defining “flexural modulus”)
1241	Excerpt from Kern’s The Interventional Cardiac Catheterization Handbook (2nd edition) (2004) (chapter 1)).
1242	Declaration of Dr. Richard A. Hillstead, Ph.D.
1243	Curriculum Vitae of Dr. Richard A. Hillstead, Ph.D.
1244	U.S. Patent No. 5,961,510 (“Fugoso”)
1245	U.S. Patent No. 6,199,262 (“Martin”)
1246	U.S. Patent No. 6,042,578 (“Dinh”)
1247	WO 97/37713 (“Truckai”)
1248	Terumo Heartrail II product literature
1249	Medtronic Launcher product literature
1250	U.S. Patent No. 5,980,486 (“Enger”)
1251	U.S. Patent No. 5,911,715 (“Berg”)
1252	U.S. Patent No. 5,545,149 (“Brin”)
1253	U.S. Patent No. 5,720,300 (“Fagan”)

Exhibit	Description
1254	U.S. Patent No. 5,120,323 ("Shockey")
1255	Sakurada, *Improved Performance of a New Thrombus Aspiration Catheter*: Outcomes From In Vitro Experiments and a Case Presentation ("Sakurada")
1256	Nordenstrom, *New Instruments for Catheterization and Angiocardiography* ("Nordenstrom")
1257	U.S. Patent No. 5,445,625 ("Voda")
1258	U.S. Patent No. 6,595,952 ("Forsberg")
1259	U.S. Patent No. 6,860,876 ("Chen")
1260	U.S. Patent No. 6,638,268 ("Niazi")
1261	U.S. Patent No. 5,690,613 ("Verbeek")
1262	lserson, *J.-F.-B. Charrière: The Man Behind the "French" Gauge,* The Journal of Emergency Medicine. Vol. 5 pp 545-548 (1987)
1263	U.S. Publication Application No. 2003/0195546 ("Solar '546")
1264	QXMédical, LLC's Opening Claim Construction Memorandum *QXMedical, LLC v. Vascular Solutions, Inc*., D. Minn., No. 17-cv-01969 (March 14, 2018), D.I. 56
1265	U.S. Patent No. 4,000,739 ("Stevens")
1266	EP 0 881 921 B1 ("Lee")
1267	U.S. Patent No. 5,451,209 ("Ainsworth")
1268	Defendants' Memorandum in Opposition to Plaintiff's Summary Judgment Motion and in Support of Defendants' Summary Judgment Motion, *QXMedical, LLC v. Vascular Solutions LLC et al*., 17-cv-01969-PJS-TNL (D. Minn 2019)
1269	Excerpt of prosecution history for application 14/195,435 (Office Action, 10/06/15)
1270	Metz, *Comparison of 6f with 7f and 8f guiding catheters for elective coronary angioplasty: Results of a prospective, multicenter, randomized trial,* American Heart Journal. Vol. 134, Number 1, pp 132-137 ("Metz")

Exhibit	Description
1271	Feldman, *Coronary Angioplasty Using New 6 French Guiding Catheters*, Catheterization and Cardiovascular Diagnosis 23:93-99 (1991) ("Feldman")
1272	U.S. Patent No. 5,704,926 ("Sutton")
1273	Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL
1274	Yokoyama, *Feasibility and safety of thrombectomy with TVAC aspiration catheter system for patients with acute myocardial infarction*, Heart Vessels (2006) 21:1–7 ("Yokoyama")
1275	Excerpt from Plaintiff's infringement allegations in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1276	U.S. Patent No. 5,860,963 ("Azam")
1277	10/16/2019 Deposition of Peter Keith in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760
1278	Sylvia Hall-Ellis's Librarian Declaration
1279	Complaint in *Vascular Solutions, LLC. v. Medtronic, Inc*., D. Minn., No. 19-cv-01760 (October 11, 2019), D.I. 1-14.
1280	U.S. Patent No. 5,061,273 ("Yock")
1281	U.S. RE45,380 ("the '380 patent")
1282	Declaration of Peter Keith in Support of Plaintiffs' Motion for Preliminary Injunction, *Vascular Solutions LLC et al. v. Medtronic, Inc.*, 19:cv-01760-PJS-TNL (July 12, 2019)
1283	Joint Fed. R. C. P. 26(f) Report [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL
1284	Plaintiffs' Objections and Responses to Interrogatories [Excerpt], *Vascular Solutions LLC et al. v. Medtronic, Inc*., 19:cv-01760-PJS-TNL

I. PRELIMINARY STATEMENT

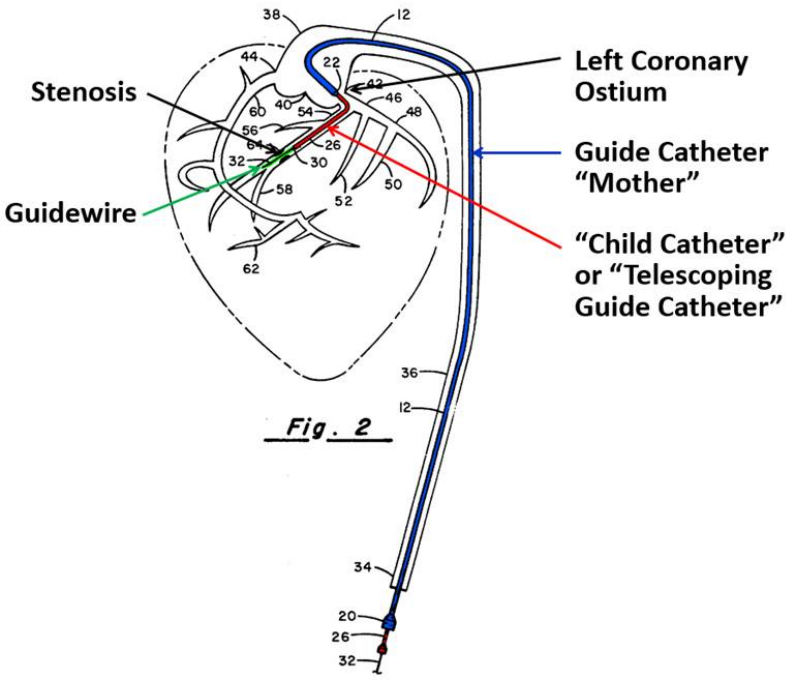
Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioners") requests *inter partes* review ("IPR") of claims 25-26, 29-40, and 42-45 ("Challenged Claims") of U.S. Pat. No. RE47,379 (Ex-1201). The '379 patent—which claims priority to a patent application filed on May 3, 2006—is entitled *Coaxial Guide Catheter for Interventional Cardiology Procedures* and lists Howard Root *et al.* as inventors. *Id*.

The '379 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*. at Abstract, Figs. 8, 9. In so doing, the guide extension catheter delivers "backup support by

[1] The '379 patent refers to the guide extension catheter as a "coaxial guide catheter." Ex-1205, ¶ 75 n.8, ¶ 130. A POSITA would have recognized that the "coaxial guide catheter" of the '379 patent is what was commonly understood as a guide extension catheter because it extends the guide catheter further into the coronary artery. *Id.*; *see also* Ex-1209, 5:49-50 (referring to body 12 "as a guide catheter extension").

providing the ability to effectively create deep seating in the ostium of the coronary artery," thereby preventing the guide catheter from dislodging from the ostium. Ex-1201, 3:18-22; *see also id.* at 8:39-52. Ex-1205, ¶ 131.

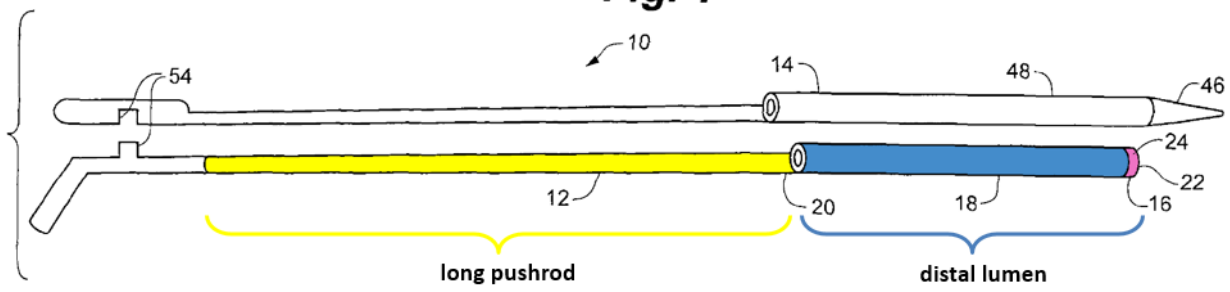
The '379 patent admits that the use of a guide extension catheter inside an outer guide catheter was known. Ex-1201, 2:56-3:6 (describing the use of a "smaller guide catheter within a larger guide catheter"). Indeed, such a catheter-in-a-catheter assembly was well-known in the art and described as a "mother-and-child assembly." Ex-1205, ¶¶ 74-84. 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, ¶ 74.



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

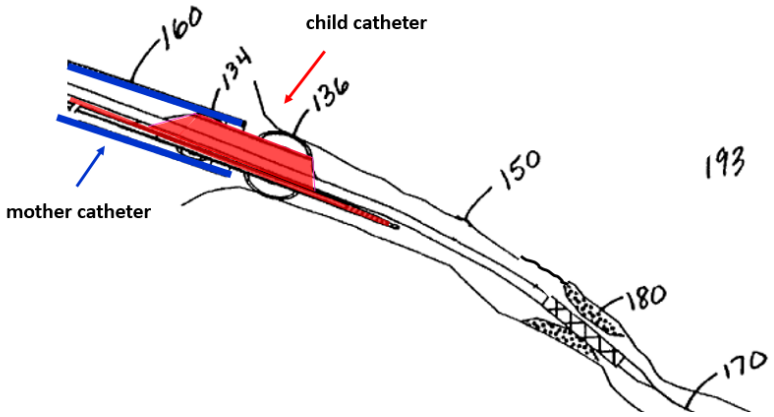
The child catheter in the original mother-and-child assembly had a continuous lumen that was longer than the lumen of the guide ("mother") catheter. Ex-1254, Fig. 2; Ex-1205, ¶¶ 74-84. The '379 patent alleges that such a design had certain drawbacks (Ex-1201, 3:7-17) and modifies the child catheter (of the mother-and-child assembly) to have two parts: a short lumen (i.e., a tube) at the distal end and a long thin pushrod coupled to the short lumen at the proximal end thereof, where the distal most end of the short lumen is highly flexible because it extends deep into the coronary artery.

Fig. 1



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

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



Ex-1208, Fig, 6B (annotations and color added). *See infr*a § VII(A).

For the reasons set forth herein, there is more than a reasonable likelihood that the Challenged Claims of the ’379 patent are unpatentable based on the Grounds discussed below. Accordingly, Petitioners respectfully request institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of claims 25-26, 29-40, and 42-45 of the ’379 patent under 35 U.S.C. §§ 102 and/or 103.

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

A. Real Party-in Interest

The real parties-in-interest are Medtronic, Inc. and Medtronic Vascular, Inc. 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 ’379 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 '379 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).

Petitioners also concurrently file another petition for IPR challenging the '379 patent based on prior art references having different priority dates and disclosures than the references discussed herein, or challenging different claims.

C. Lead and Backup Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioners identify 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. 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 certifies that the ’379 patent is available for IPR and that Petitioners are not barred or estopped from requesting such review of the ’379 patent on the identified grounds.

The ’379 patent issued less than 9 months before the filing of the instant IPR petition. But the prohibition against filing an IPR in the first 9 months of issuance, *see* 35 U.S.C. § 311(c)(1), is inapplicable to the ’379 patent because, *at least on its face*, the ’379 patent is a first-to-invent patent, i.e., it is not subject to the AIA’s first-inventor-to-file provisions. *See* TECHNICAL CORRECTIONS—LEAHY–

SMITH AMERICA INVENTS ACT, PL 112-274, January 14, 2013, 126 Stat 2456, § 1(d)(1); 37 C.F.R. § 42.102(a)(2).

However, as explained below in **Section IV.D**, the first-inventor-to-file provisions of the AIA should apply to the '379 patent. But even then, the '379 patent is eligible for IPR because the 9-month proscription against IPR in § 311(c)(1) does not apply to reissue patents (such as the '379 patent). *See* Changes To Implement the Technical Corrections to the Leahy-Smith America Invents Act as to Inter Partes Review, 78 FR 17871-72; PL 112-274, January 14, 2013, 126 Stat 2456, § 1(d)(2) (striking reissue patents from § 311(c)(1)).

B. Precise Relief Requested and Asserted Grounds

Petitioners respectfully request review of claims 25-26, 29-40, and 42-45 of the '379 patent and cancellation of these claims as unpatentable in view of the following grounds:[2]

No.	Grounds
1	Claims 25-26, 29-31, 36, 38-40, and 42-45 are anticipated by Ressemann

[2] This petition is also supported by the Declarations of Dr. Stephen JD Brecker, MD (Ex-1205), and Dr. Richard A. Hillstead, PhD (Ex-1242), as experts in the field of the '379 patent. Petitioners also submit the declaration of Sylvia D. Hall-Ellis, PhD (Ex-1278) to support the authenticity and public availability of the documents cited herein.

No.	Grounds
2	Claims 25-26, 29-32, 35-40 and 42-44 are rendered obvious by Ressemann in view of the knowledge of POSITA.
3	Claims 33 and 34 are rendered obvious by Ressemann in view of Takahashi and the knowledge of POSITA.
4	Claim 44 is rendered obvious by Ressemann in view of U.S. 2005/0015073 ("Kataishi") the knowledge of POSITA.
5	Claim 44 is rendered obvious by Ressemann in view of U.S. 5,980,486 ("Enger") and the common 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 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, ¶¶ 33, 38-44.

PCI was developed more than forty years ago, and although its catheter-based technology has advanced, the basic components of PCI have remained largely unchanged. Ex-1205, ¶¶ 37, 45. During PCI, a physician uses a hollow needle to gain access to the patient's vasculature. Ex-1205, ¶¶ 38, 46-59. A guidewire is then introduced into the needle, the needle is removed, and an introducer sheath is inserted over the guidewire and into the artery. *Id.* Next, a

guide catheter can be introduced and advanced along the vasculature until its distal end is placed—by a few millimeters—in the ostium of a coronary artery. Ex-1205, ¶¶ 38, 46-59, 64. A hemostatic valve is placed at the proximal end of the guide catheter, both of which remain 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*.

Another small diameter flexible guidewire can then be threaded through the lumen of the guide catheter to the target site. Ex-1205, ¶¶ 60-62. This guidewire serves as a guiderail to advance the therapeutic catheter to the occlusion. *Id*. The therapeutic catheter typically must then be passed through and beyond the occlusion in order to alleviate the stenosis. Ex-1205, ¶¶ 63-69. This last step—crossing the therapeutic catheter past the occlusion—creates backward force that can dislodge the guide catheter from the ostium.[3] Ex-1205, ¶¶ 70-71. As discussed above, one way to ameliorate this backward force is to use a mother-and-child catheter assembly where the child catheter acts as an extension of the guide catheter into the coronary artery. Ex-1205, ¶ 72-84.

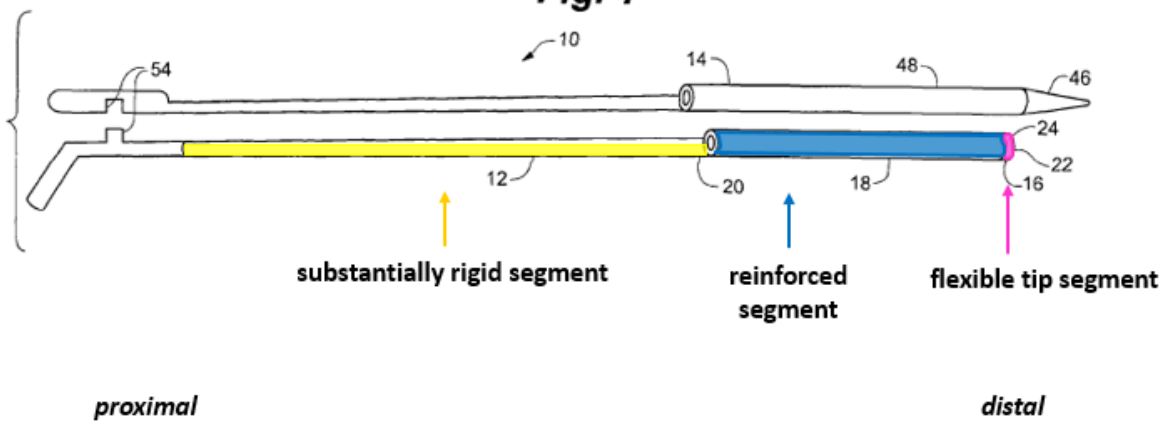
[3] During the PCI process, the proximal end of the guide catheter, guidewire, and therapeutic catheter all remain outside the patient's body. Ex-1205, ¶ 72-84.

B. Overview of the ’379 Patent

The ’379 patent relates “generally to catheters used in interventional cardiology procedures.” Ex-1201, 1:43-44. In particular, the ’379 patent discloses a coaxial guide catheter (also known as an extension catheter) that extends through the lumen of a guide catheter, “beyond the distal end of the guide catheter, and insert[s] into [a] branch artery.” *Id*. at Abstract. The catheter assembly purports to have the benefit of a mother-and-child assembly—“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*. at 5:41-44; Ex-1205, ¶¶ 130-131.

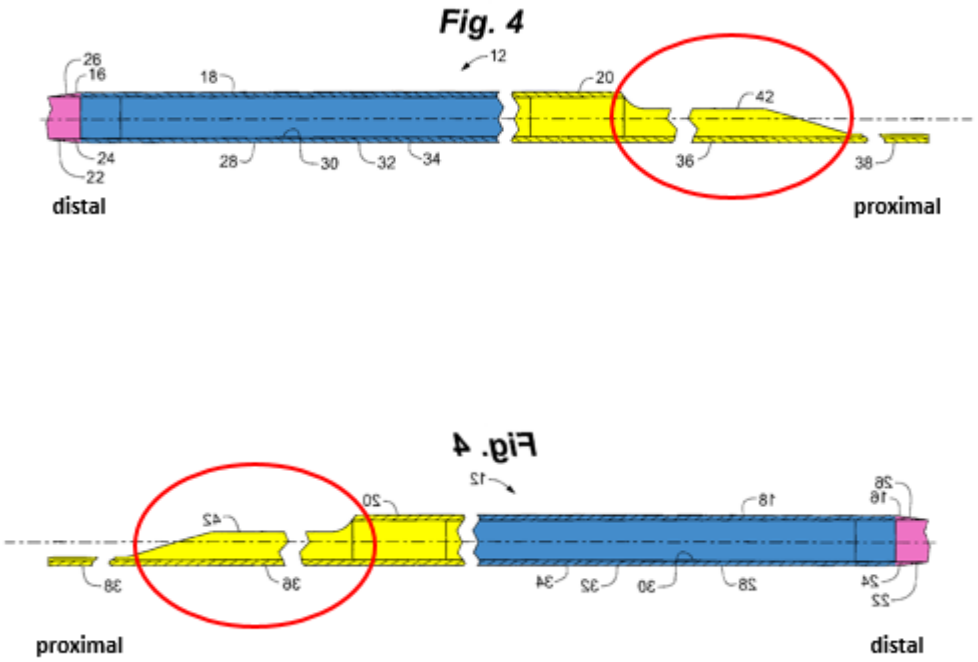
The ’379 patent explains that the guide extension catheter 12 has a tubular portion that includes a flexible tip segment 16 (pink) and a reinforced segment 18 (blue), as well as substantially rigid segment 20 (yellow). *Id*. at 4:2-4, 6:50-51, Fig. 1. Color has been added to Figure 1, below, which has been annotated with the language of claim 25. Ex-1205, ¶ 132.

Fig. 1



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

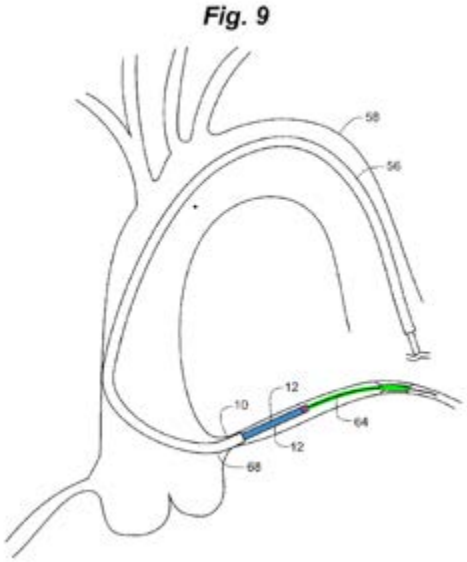
The ’379 patent also recites the step of “arranging, in a proximal to distal direction, the substantially rigid segment, the side opening portion, the reinforced segment, and the flexible tip segment.” The specification, however, provides no written description support for the placement of a “side opening” anywhere other than in the substantially rigid segment 20, circled in red below. Ex-1201, Figs. 4, 13-16; *see also id.* at 7:12-16, 9:13-21.



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

Regardless, the ’379 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, ¶ 134.



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

C. Prosecution History of the '379 Patent

The predecessor '850 patent issued without an Office Action. Ex-1202. According to the Examiner, the claims of the '850 patent were allowable because "adding a guide catheter to the claimed rail structure[4] with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art." Ex-1202 at 83 (Notice of Allowance at 3). In other words, he believed that a mother-and-child assembly—where the child catheter is characterized by a short

[4] *See infra* § VI (construing "rail structure").

distal lumen coupled to a proximally located pushrod—was not described in the art, but he was not aware of Ressemann.

Patent Owner sought reissuance in 2015. The Examiner rejected pending claims, finding (in part), that they were anticipated by U.S. Patent 5,527,292 to Adams, and U.S. Patent 5,578,009 to Kraus. Ex-1203 at 175-78 (7/20/17 Non-Final Rejection at 12-15). In response, Patent Owner distinguished the cited art by arguing that it did not teach or suggest "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape" as required by claim 25. Ex-1203 at 225-27 (1/19/18 Applicant Response at 25-27). The Examiner found the reissued claims patentable on this basis (Ex-1203 at 622 (Notice of Allowance at 2)), however, she was unaware of Ressemann.[5]

D. Priority Date

The AIA first-to-file provisions apply to a patent that contains even one claim that is not supported by a pre-March 16, 2013 application or claims priority to any

[5] A patent related to Ressemann, U.S. Pat. No. 7,959,603 (Wahr) is cited on the face of the '379 patent, but nowhere discussed and was disclosed after the pending claims were deemed allowable. Ex-1201; Ex-1203 at 617 (10/12/18 Notice of Allowance), 675 (1/11/19 Information Disclosure Statement).

patent or application that is subject to the AIA first-to-file provisions. AIA § 3(n)(1)(A); MPEP § 2159.02. The '379 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority,[6] and (2) it claims priority to RE 45,380 ("the '380 patent"), which is subject to the AIA first-to-file provisions. First, no pre-AIA application to which the '379 patent claims priority contains disclosure of "a side opening portion" that is not part of the substantially rigid segment, but the independent claims allow the side opening to, in the alternative, be in the reinforced segment. *Compare* claims 25, 38 *with* claim 42. Ex-1201. Second, claim 44 requires a side opening portion with two inclined sidewalls separated by a non-inclined region, while the only alleged support, Fig 4, discloses a non-inclined region (42) that separates an inclined region and an arc. *See* Ex-1203 at 31 (12/30/15 Preliminary Amendment at 24). Third, the '380 patent, to which the '379 patent claims priority, is an AIA patent because it includes at least one claim that lacks support in a pre-March 16, 2013 application. Claim 27 recites a side opening that "includes ***at least two*** different inclined slopes," but the '380 patent—at best—supports ***only*** two inclined slopes. Ex-1281, Fig. 4.

[6] The '379 patent shares the same specification as all applications in its priority chain that were filed before March 16, 2013.

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; 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 may have access to one with a medical degree. Ex-1205, ¶ 31; 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,[7] 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.* at 2; Ex-1213, at 15)
- "rail structure": "structure that facilitates monorail or sliding rail delivery" (Ex-1213, at 20)

The district court additionally adopted the following construction:

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

[7] The full list of constructions advanced by Patent Owner in the QXMedical Litigation are found at Ex-1212.

Petitioners agree with the above constructions for purposes of this IPR[8] (Ex-1205, ¶¶ 135-140) and propose the following additional constructions:

A. "standard guide catheter" (cl. 25, 38)

As of the purported priority date, "standard guide catheter" did not refer to a guide catheter of a specific length (although 100 cm was common (Ex-1201, 3:9-10; Ex-1215, 549)) inner or outer diameter, or rigidity. Ex-1205, ¶ 147; Ex-1210, 454 (showing various "guiding catheter systems"). Further, the patent does not define "standard guide catheter," and, in fact, only uses this term (outside of the claims) once in the background when describing the drawbacks of previous catheter assemblies. Ex-1201, 3:7-8. Finally, in other parts of the patent, the specification instead refers to "typical guide catheter" or references, more simply, "guide catheters." *Id.* at 8:4-12. Thus, "standard guide catheter" does not reference a specific guide catheter and means "one of a variety of catheters used to guide devices or smaller catheters into the coronary vasculature" Ex-1205, ¶ 147.

B. "flexural modulus" (cl. 30, 39)

The claim term "flexural modulus" had a known and established meaning by 2006 (Ex-1242, ¶ 34), and according to McGraw-Hill Dictionary of Scientific and

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

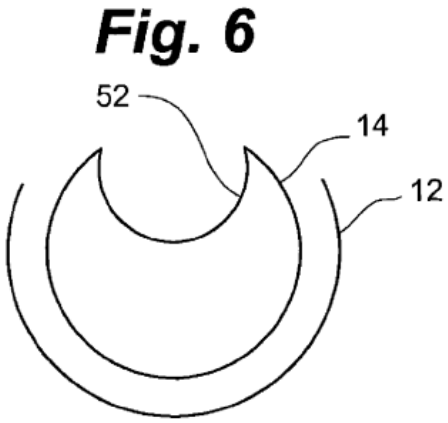
Technical Terms means "[a] measure of resistance . . . to bending." Ex-1240, 772. In other words, the "flexural modulus" is a measure of a device's rigidity. The higher the rigidity (and conversely, lower the flexibility), the higher the flexural modulus. Such an understanding is consistent with the '379 patent, which provides that the coaxial extension catheter has decreasing flexibility and increasing flexural moduli, moving distally to proximally. Ex-1201, 7:45-51; Ex-1205, ¶¶ 141-142; Ex-1242, ¶ 34. 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).[9]

C. "concave track" (cl. 43)

The '379 patent does not define the claim term "concave track." Ex-1205, ¶ 143. 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, 4:24-33, 4:47-49, 7:39-40;

[9] 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.

Ex-1205, ¶ 143. Figure 6, though, discloses a cross-sectional view of a concave track 52. Ex-1201, 7:39-40.



Ex-1201, Fig. 6.

As a result, in the context of the '379 patent, the claim term "concave track" means a "portion that is not fully circumferential." Ex-1205, ¶¶ 144-146.

VII. GROUND 1: RESSEMANN ANTICIPATES CLAIMS 25-26, 29-31, 36, 38, 40, AND 42-45.

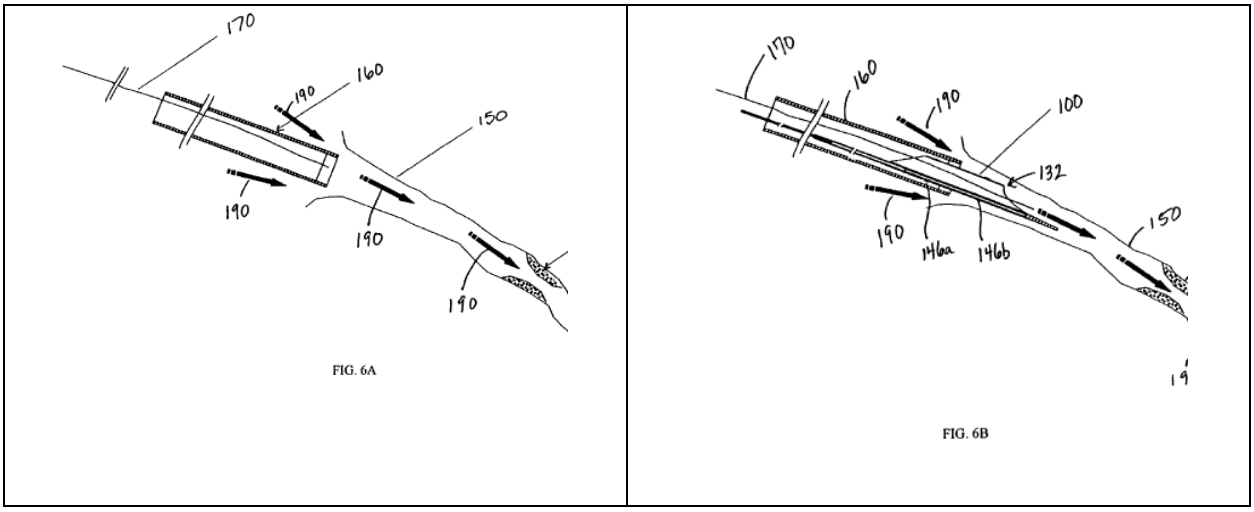
A. Ressemann

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),[10] and was not cited or considered during prosecutions of the

[10] The first-inventor-to-file provisions of the AIA apply to the '379 patent because, inter alia, at least one claim of the '379 patent (e.g. claim 44) is not entitled to an effective filing date prior to March 16, 2013.

original ’850 patent, or the ’379 reissue patent. Exs-1201, 1202, 1003.

Ressemann discloses an evacuation sheath assembly for treating occluded vessels and reducing embolization risk during vascular interventions. Ex-1208, Abstract. The assembly includes a guide catheter, which “may be positioned within the ostium of a target vessel,” (*id*. at 12:26-27) and an evacuation sheath that is coaxially insertable through the guide catheter, and advanceable beyond the guide catheter’s distal end to treat stenosis. *Id*. at Abstract, Figs. 6A-6F, 6:18-24, 12:9-14:39.



Ex-1208, Figs. 6A, 6B.

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

The evacuation sheath includes a distal evacuation head and a shaft. *Id*. at 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*. at 6:36-39. (Illustrated below in pink).

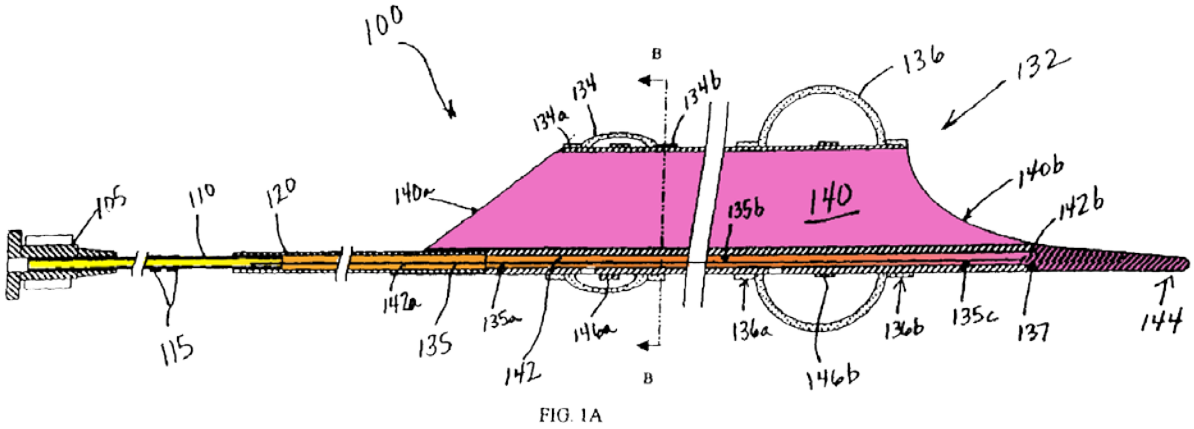


FIG. 1A

Ex-1208, 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*. at 10:36-42. Intermediate shaft 120 (yellow shading to pink) —a hollow, polyethylene or Pebax tube—is more flexible than shaft 110. *Id*. at 10:63-11:10. Distal shaft (shading to pink) includes the evacuation head (*id*. at 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*. at 11:11-29. Ex-1205, ¶¶ 99-102, 148-152. Ex-1242, ¶¶ 20-26.

B. Claim 25[11]

1. [25.p] "A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:"

To the extent the preamble is limiting, the system of a GC and evacuation sheath in Ressemann, *infra*, 25.a through 25.g, discloses a method of forming a device according to claim 25. Ex-1205, ¶ 167.

For example, Ressemann discloses a device adapted for use with a "standard guide catheter" as construed in § VI. Ex-1208, Abstract (teaching an "evacuation

[11] The Challenged Claims are product-by-process claims as they claim "[a] method of forming a device" and then recite various structural elements of the device. Ex-1201, 13:61, 15:7. Such claims are invalid if the product in the product-by-process claims is the same as, or obvious from, a product of the prior art. *In re Brown*, 459 F.2d 531, 535 (CCPA 1972). In other words, "in determining the patentability of product-by-process claim, it is not the process steps that are looked to, but rather the product itself, which is analyzed." *Ex Parte Erler*, App. No. 2012-012641, 2014 Pat. App. LEXIS 8753, **11-13 (PTAB Dec. 26, 2014). As discussed herein, the products taught in the prior art disclose the claimed products. Even if such claims are not product-by-process claims, the same disclosures in the prior art disclose the purported inventions.

sheath assembly," 100, and advancing the same into the blood vessel through a guide catheter 160). The guide catheter 160 necessarily has a continuous lumen extending for a predefined length. Ex-1205, ¶ 167.

The same disclosure regarding advancement of evacuation sheath assembly 100 through guide catheter 160 into a blood vessel is evidence that guide catheter 160 is a "standard guide catheter." Ex-1208, Fig. 5A, 6:18-24, 12:9-30, 22:38-45, 28:26-36, 28:46-49, Fig. 16I; *see supra* § VI; Ex-1205, ¶ 167; *see also id.* at ¶¶ 32-69.

2. **[25.a] "providing a flexible tip segment having a lumen therethrough"**

Ressemann discloses 25.a. Ex-1205, ¶ 168.

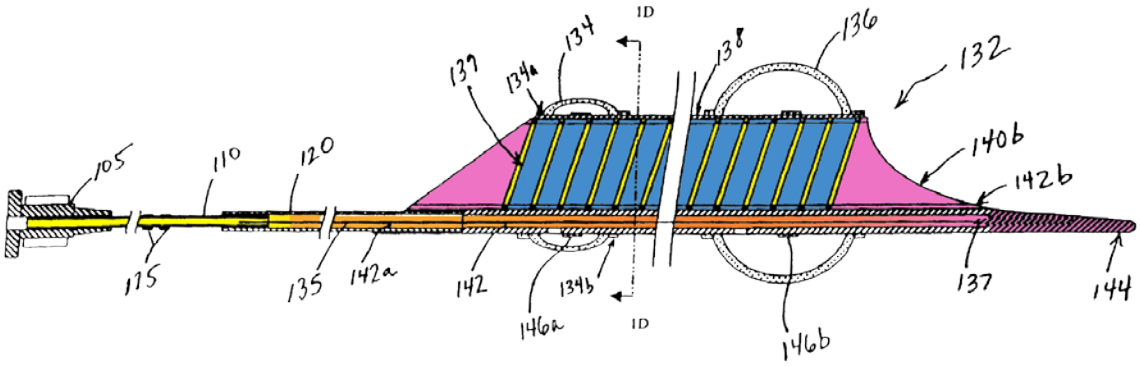


FIG. 1C

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

As shown above, evacuation head 132 includes an evacuation lumen 140 that has a distal end 140b. Evacuation lumen 140 is part of multi-lumen tube 138 that is "preferably made of a relatively flexible polymer." Ex-1208, 6:36-60, 6:66-

7:7, Fig. 1C; *see also id.* at 24:20-26. Evacuation lumen has a distal end 140b. *Id.* at 6:35-60.

Portion 140b has a lumen therethrough as evacuation lumen 140 extends through the evacuation head from 140b to 140a. *Id.* at Figs. 1C, 1D, 3:21-25, 6:35-47, 6:66-7:7; *see also id.* at 23:8-15, Fig. 16F; Ex-1205, ¶ 168. As shown below, distal tip 140b at the red cross-sectional line has a lumen therethrough, similar to the cross section shown in Fig. 1D.

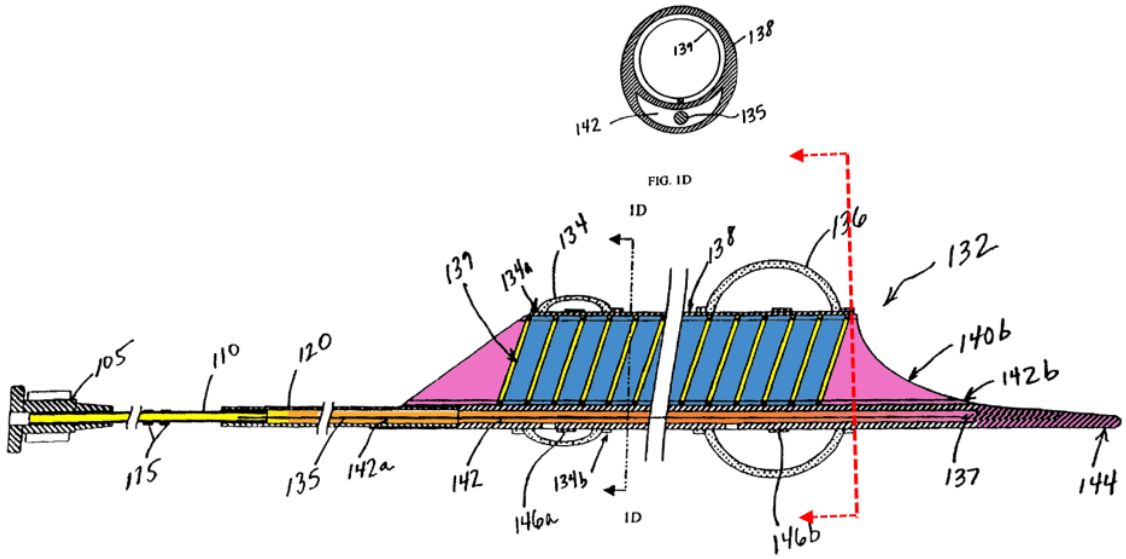


FIG. 1C

Ex-1208, Figs. 1C (color and annotation added), 1D.

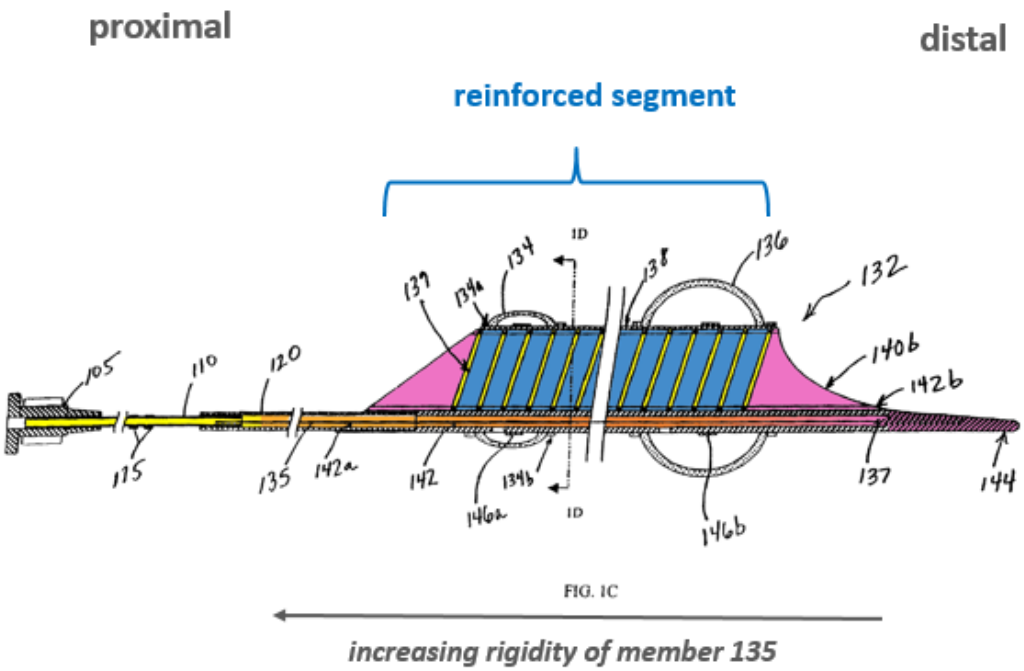
The "flexible tip segment" also includes tip 144, which Ressemann teaches is comprised of a more flexible polymer than lumen 140. For example, if the latter is "fabricated of high density polyethylene," then the former "may be fabricated of

a low durometer polyurethane or Pebax." *Id*. at 10:20-21, 11:22-25; *see also id.* at 22:53-58, 24:20-29. Ex-1205, ¶ 168; *see also id.* at ¶¶ 46-59, 63-84, 85-93.

3. **[25.b] "providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer, and extending from a proximal end portion to a distal end portion"**

Ressemann discloses a reinforced segment having a lumen therethrough. First, evacuation head 132 (including evacuation lumen 140), includes a kink-resistant structure, coil 139 which may be made of metal ribbon. Ex-1208, 6:66-7:17, 23:50-60*; see also id.* at 23:53-66, 24:58-67. Ressemann additionally teaches a stiffness transition member 135 that runs longitudinally along the majority of the evacuation sheath's intermediate and distal shafts, starting at the distal end of the proximal shaft, and terminating toward the distal end at 137. Ex-1208, 11:29-35. Member 135's rigidity decreases along its longitudinal axis so that it is most flexible at its distal end. *Id*. at 11:57-59. Ex-1205, ¶ 169.

Either the increasing rigidity of member 135 (alone), or the addition of kink-resistant coil 139 to the evacuation head, results in a "reinforced segment" in Ressemann's evacuation sheath. Ex-1205, ¶ 169; Ex-1242, ¶¶ 60-66; *see also id.* at ¶¶ 21-24.



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

Ressemann discloses that lumen 140 ***extends through*** evacuation head 132. Ex-1208, 6:44-60; *see also id.* at 22:53-63. Ex-1205, ¶ 169. Also, Ressemann discloses that metal coil 139 is covered with polymer, explaining that a "covering of polyurethane 133 is then applied to contain the coil 139." Ex-1208, 7:6-39; *see also id.* at 23:53-24:14. Ex-1205, ¶ 169. Ressemann further discloses that "[t]he polyurethane may be applied by a solvent casting of polyurethane in an appropriate solvent." Ex-1208, 7:12-14; s*ee also id.* at 23:53-24:14. Ex-1205, ¶ 169. Thus, Ressemann teaches "a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer." Ex-1205, ¶ 169.

Lastly, the reinforced segment extends from a proximal end portion to a

distal end portion, as shown above in Fig. 1C. *See also* Ex-1208, Figs. 16A-B; Ex-1205, ¶ 169.

4. **[25.c] "providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment"**

Ressemann discloses this limitation. Ex-1205, ¶¶ 170-176.

Evacuation sheath 100 includes proximal and intermediate shaft portions, 110 and 120, which forms 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, 6:19-24, 10:47-11:14; *see also id.* at 28:46-49. Ex-1205, ¶ 170. Thus, proximal shaft 110 and intermediate shaft 120 are sufficiently rigid to allow evacuation sheath 100 to be advanced within the guide catheter, as shown in Figs. 6A-F. *See supra* § VI (construing "substantially rigid"); Ex-1205, ¶ 170.

Ressemann also teaches that the substantially rigid segment is more rigid along its longitudinal axis than the flexible tip segment. Ex-1205, ¶ 170-171; Ex-1242, ¶¶ 67-70. Proximal shaft 110 is a "hollow tube preferably made of stainless steel," which is secured to intermediate shaft 120 (formed from a polymer, or polymer metallic composite). Ex-1208, 10:36-42, 60-65; *see also* 27:26-28. Intermediate shaft 120 (made of "polyethylene or Pebax," or another "polymer or polymer metallic composite) additionally includes stiffness transition member 135,

which is preferably made of stainless steel. *Id*. at 10:63-65, 11:29-38, 27:51-53; *see supra* § VII ([25.b]). By contrast, the "flexible tip segment" (*see supra* § VII ([25.a])) is made of flexible polymer. Ex-1208, 6:36-39, 7:49-51; *see also id.* at Fig. 1A; 22:54-58, 24:20-32, 24:47-67, Fig. 16J.

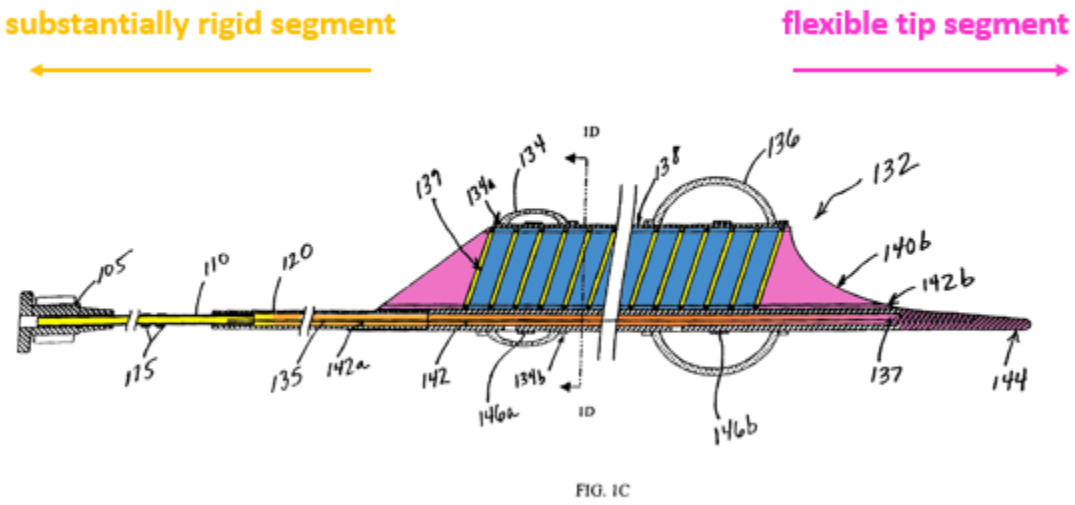


FIG. 1C

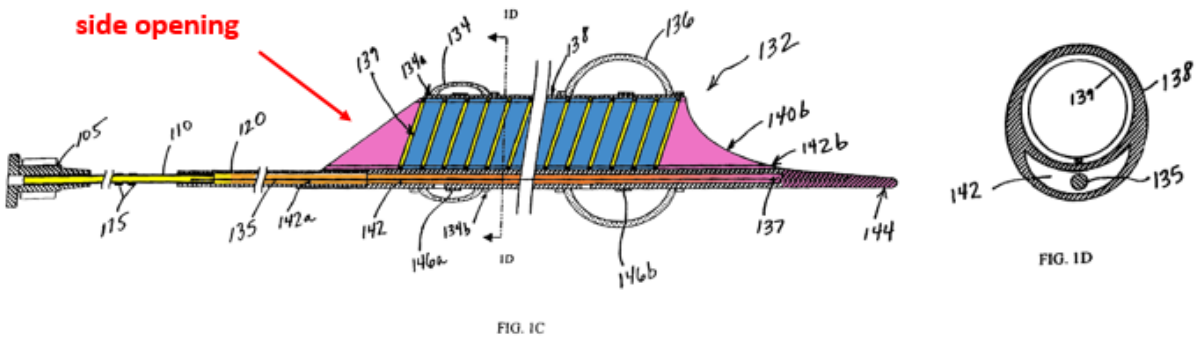
Ex-1208, Fig. 1C (color and annotation added).

Based on the known properties of these disclosed materials and the stiffness transition member, Ressemann discloses that the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment. Ex-1205, ¶ 170; Ex-1242, ¶ 70.

5. **[25.d] "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape"**

Ressemann discloses this limitation. Ex-1205, ¶ 177.

The segment defining the side opening portion includes the proximal opening to evacuation lumen 140 (Ex-1208, 6:52-60; *see also id.* at 24:33-41), which has a circular cross section, similar to the cross section shown below.



Id. at Figs. 1C, 1D (color and annotation added).

As shown below, through cross section (a), the side opening portion includes an arcuate cross sectional shape, which, according to the '379 patent is a portion that "extends from 25% to 40% of the circumference of the tube." Ex-1201, 7:25-26.

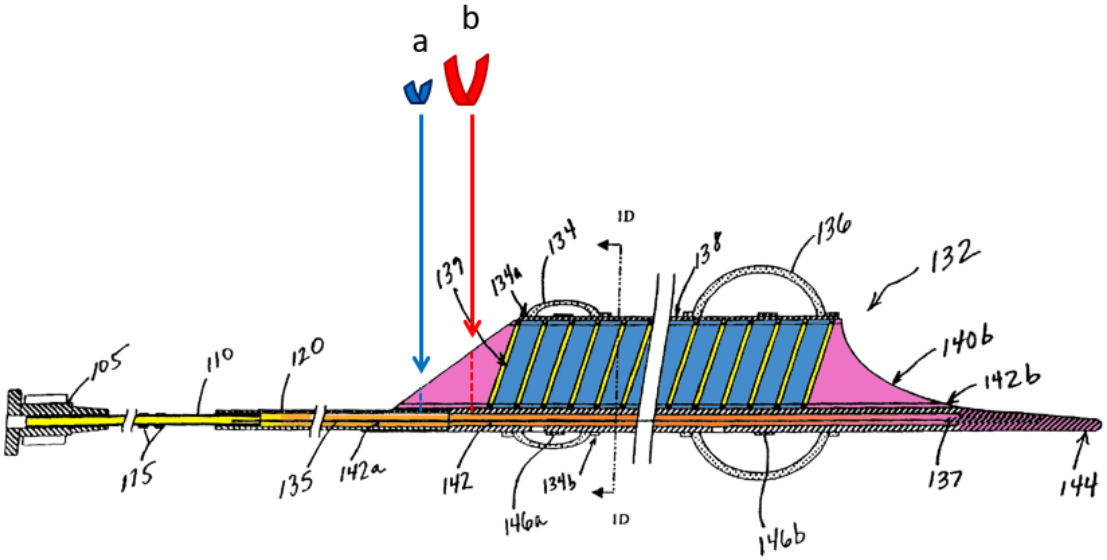


FIG. 1C

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

Moving distally, through cross section (b), the side opening portion includes a hemicylindrical cross sectional shape, which, according to the '379 patent is a portion that "extends from 40% to 70% of the circumference of the tube." Ex-1201, 7:20-21; Ex-1208, 23:17-20, Figs. 16A, 16J.

6. **[25.e] "eccentrically positioning the distal end portion of the substantially rigid segment relative to a longitudinal axis of the proximal end portion of the reinforced segment; and"**

Ressemann discloses this limitation. Ex-1205, ¶ 178.

As illustrated below, left, distal portion of the "substantially rigid segment (proximal shaft (110) and intermediate shaft (120)) (*) is eccentrically positioned (arrows) relative to the proximal end portion of the longitudinal axis of the reinforced segment (**). *Id*.

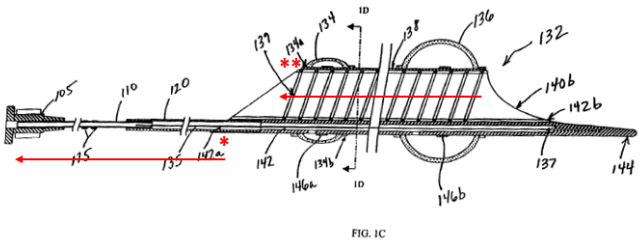


FIG. 1C

FIG. 1D

Ex-1208, Fig. 1C (left), 1D (right) (annotation added); *see also id.* at Figs. 16A-16B, 16D.

7. **[25.f] "coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment,"**

Ressemann discloses 25.f. Ex-1205, ¶ 179. As illustrated below, the distal end portion of the reinforced segment is coaxially aligned (red arrow) with the proximal end portion of the flexible tip segment. *See supra* § VII ([25.a], [25.b]).

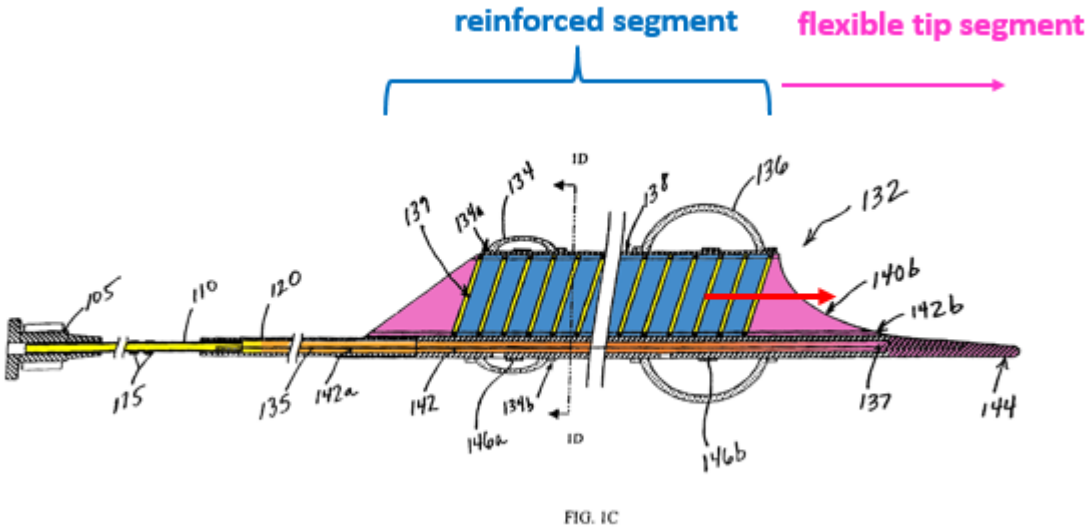


FIG. 1C

Ex-1208, Fig. 1C (color and annotation added), *see also* Figs. 16A-16B, 16D.

8. **[25.g] "wherein providing the substantially rigid segment, the reinforced segment, and the flexible tip segment includes forming a device length that is longer than the predefined length of the continuous lumen of the guide catheter such that when a distal end portion of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter."**

Ressemann discloses 25.g. Ex-1205, ¶ 180.

As shown below, together the substantially rigid segment, the reinforced segment and the flexible tip segment (*see supra* § VII ([25.c], [25.b], [25.a])) form Ressemann's evacuation sheath 100; *see also id.* at Figs. 16A, 22:38-24:45, 27:21-28:2 (regarding sheath 2100). Ex-1205, ¶ 180.

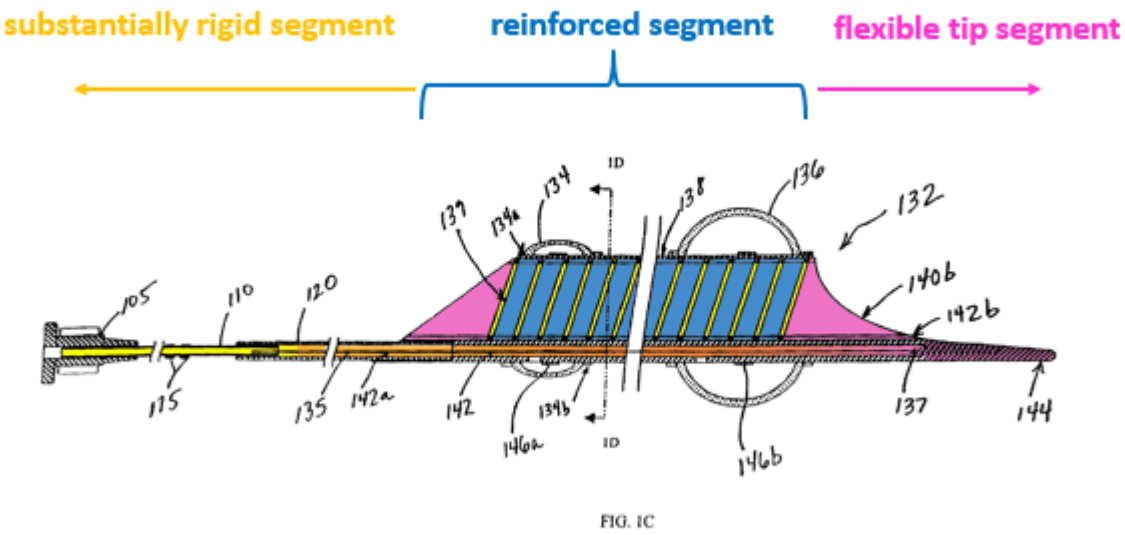


FIG. 1C

Ex-1208, Fig. 1C (color and annotation added); *see also id.* at 22:50-52, Figs. 16A-B.

Ressemann discloses that the length of the device that includes the "substantially rigid segment, the reinforced segment and the flexible tip segment" (i.e., evacuation sheath 100) is longer than "the predefined length of the continuous lumen of the guide catheter such that when a distal end of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid portion extends proximally of a proximal end of the guide catheter." Ex-1205, ¶ 180.

Ressemann teaches that the distal end of evacuation sheath 100 is advanced ***into the blood vessel*** through a guide catheter 160. Ex-1208, Abstract, 6:20-24; Fig. 5A; Figs. 6A-6C. And, while its distal end is in the blood vessel (and its

proximal end is in the GC), a valve attached to the proximal end of guide catheter 160 provides a fluid tight seal against ***both*** the guide wire and the proximal end of proximal shaft portion 110. Ex-1208, 12:37-38, 12:45-49; *see also id.* at 28:46-49. Ressemann additionally teaches that the distal end of sheath 100 may be advanced into a blood vessel, while a balloon catheter and stent is introduced into its proximal end, to be advanced therethrough into a blood vessel. *Id*. at Figs. 6B-6F, 12:19-14:10; *see also id.* at 28:46-49 (regarding sheath 2100). Thus, Ressemann discloses that evacuation sheath 100 is long enough so that when the "distal end of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid portion extends proximally of a proximal end of the guide catheter." Ex-1205, ¶ 180.

Apart from evacuation sheath assembly 100, addressed above, claim 25 is also anticipated by the disclosures related to evacuation sheath assembly 2100. Ressemann states that "[m]any of the elements present in the previous embodiments [such as evacuation sheath assembly 100] are also shown in FIGS. 16A-J and where these elements are substantially the same, similar reference numerals have been used and no detailed description of the element has been provided." Ex-1208, 22:33-38. The disclosed elements in Ressemann identified above demonstrating anticipation of claim 25 are also found in evacuation sheath assembly 2100, as indicated by the use of similar reference numerals. Ex-1208,

22:29-29:61, more particularly 22:29-23:20, 23:53-25:16, 26:41-43, 27:22-56, 28:26-29:61, Figs. 16A-J; Ex-1205, ¶ 181. As such, this embodiment in Ressemann also anticipates claim 25.

C. Claim 26: The method of claim 25, further comprising extending the side opening portion for a distance along a longitudinal axis of the device such that the side opening portion is accessible from a longitudinal side, defined transverse to the longitudinal axis, along the distance.

Ressemann discloses claim 26. Ex-1205, ¶¶ 182-185.

The evacuation head of Ressemann has a proximal opening 140a that extends for a distance from (A) to (B) along the longitudinal axis of the evacuation sheath. Ex-1208, Figs. 1A, 1C, 11A; *see also id.* at Figs. 16A-16B, 16D; Ex-1205, ¶182.

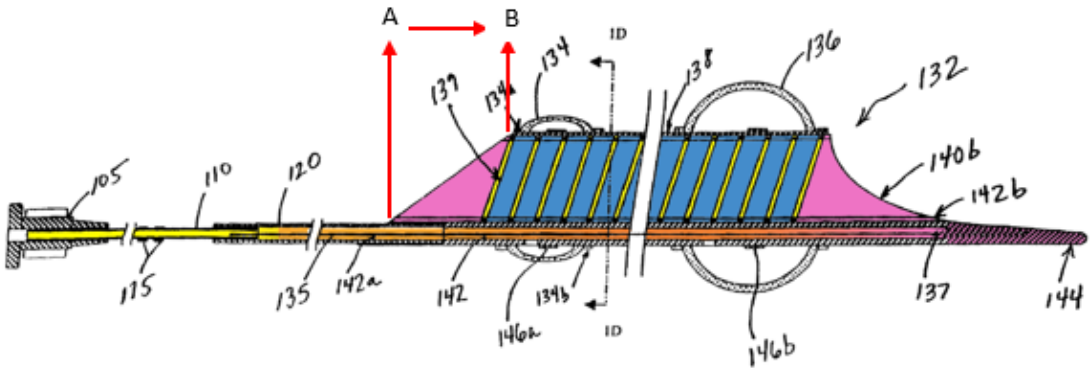
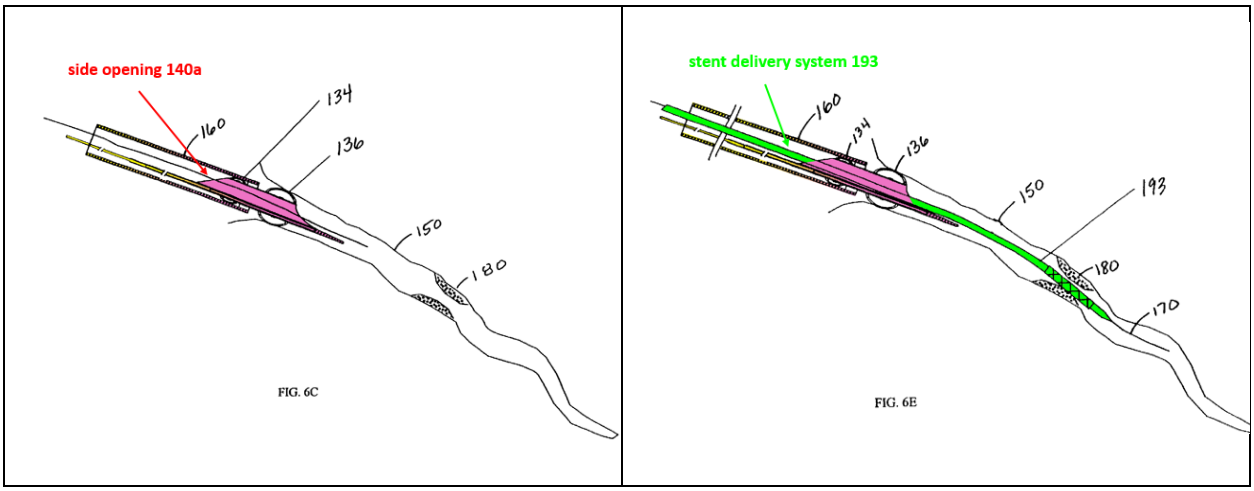


FIG. 1C

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

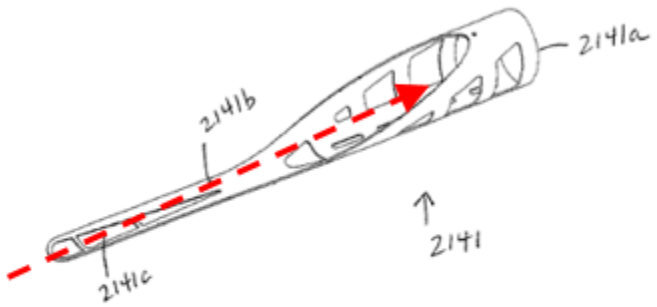
Side opening 140a's diameter is large enough to "allow the passage of most

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. Side opening 140a is “accessible from a longitudinal side, defined transverse to the longitudinal axis, along the distance,” evident in Ressemann’s teaching that after the evacuation sheath is deployed through the GC, so 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.



Ex-1208, *compare* Fig. 6C *with* Fig. 6E (color and annotation added); *see also id.* at 28:46-49.

Additionally, Ressemann discloses a support collar 2141, which, as shown below, forms a "side opening portion for a distance along a longitudinal axis of the device such that the side opening portion is accessible from a longitudinal side, defined transverse to the longitudinal axis, along the distance." (dotted arrow).



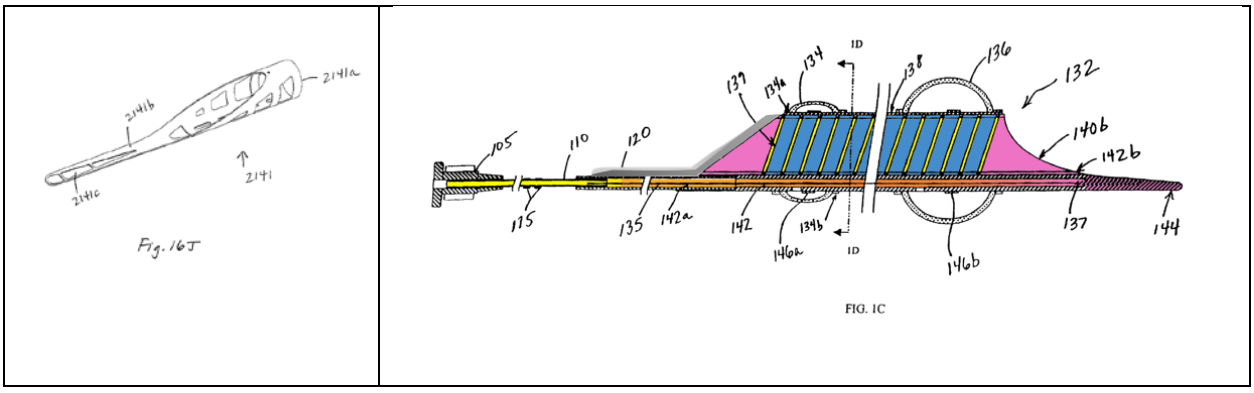
Ex-1208, Fig. 16J (annotation added).

Ressemann explicitly discloses support collar 2141 for use with evacuation sheath 2100. Ex-1208, 24:47-67, 22:38-42, 23:8-20. Specifically, the cylindrical portion of collar 2141a fits into the proximal opening of the evacuation lumen. *Id*. at 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*. at 24:59-67.

A POSITA would expect that support collar 2141 and evacuation assembly 100 (with evacuation head 132) are used together. Ex-1205, ¶¶ 183-184; Ex-1242,

¶¶ 76-87. The 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, ¶¶ 183-184; Ex-1242, ¶¶ 76-87. A POSITA would therefore envisage using the support collar 2141 with evacuation assembly 100. Ex-1205, ¶¶ 183-184; Ex-1242, ¶¶ 76-87; *see also Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (explaining that a reference will anticipate if a POSITA would "at once envisage the claimed arrangement or combination").

When support collar 2141 is added to the proximal opening of lumen 140 in the embodiment in Fig. 1, claim 26 is also disclosed. Ex-1205, ¶ 185. The distal end of the collar 2141a is inserted into the proximal opening of lumen 140, illustrated below, which adds a lining of a thin metallic material to the opening. Ex-1208, 24:55-67, 25:1-16. Ex-1205, ¶ 182.



Ex-1208, Fig. 16J (left); Fig. 1C (color, annotation and modification added (collar 2141 in gray)). Support collar 2141 extends the "side opening" a distance along the

longitudinal axis of the evacuation sheath assembly 100 such that the "side opening" is accessible from a longitudinal side that is transverse the longitudinal axis along the distance of the "side opening." Ex-1205, ¶ 182.

Because Ressemann's teachings regarding evacuation sheath 2100 anticipate claim 25, they also (in conjunction with Ressemann's teachings regarding support collar 2141) anticipate claim 26. This is for the same reasons as Ressemann's teachings regarding sheath 100 (in conjunction with support collar 2141) anticipate claim 26.

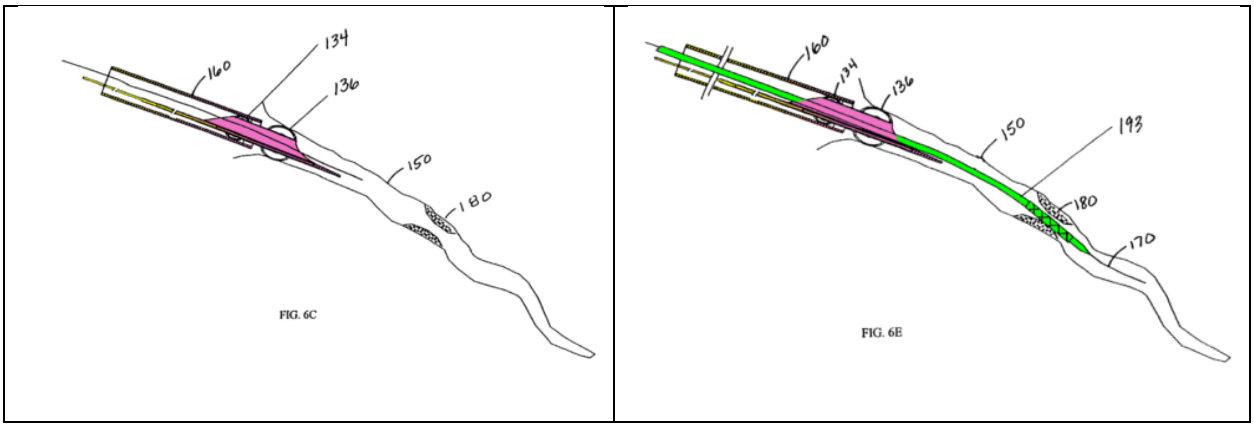
D. Claim 29: The method of claim 25, wherein providing the substantially rigid segment includes forming or obtaining a hypotube or a metal rail structure.

Ressemann discloses claim 29. Ex-1205, ¶ 186.

The substantially rigid segment of Ressemann's evacuation sheath, proximal shaft 110 and intermediate shaft 120, is a "metal" structure for the reasons discussed. *See supra* § VII ([25.c]).[12] The substantially rigid segment is also a "rail structure" (*see supra* § VI) because it may be used to facilitate delivery of evacuation sheath 100. As illustrated below, proximal shaft 110 and intermediate

[12] Because shaft 110 and 120 are also hollow tubes (Ex-1208, 10:36, 62-63), the "substantially rigid segment" is also a hypotube. Ex-1212 at 61 (Dkt. 36-2, ¶ 63, describing hypotubes).

shaft 120 facilitate the monorail or sliding rail delivery of sheath 100 through guiding catheter 160, so that the distal end of sheath 100 extends into the coronary vasculature.



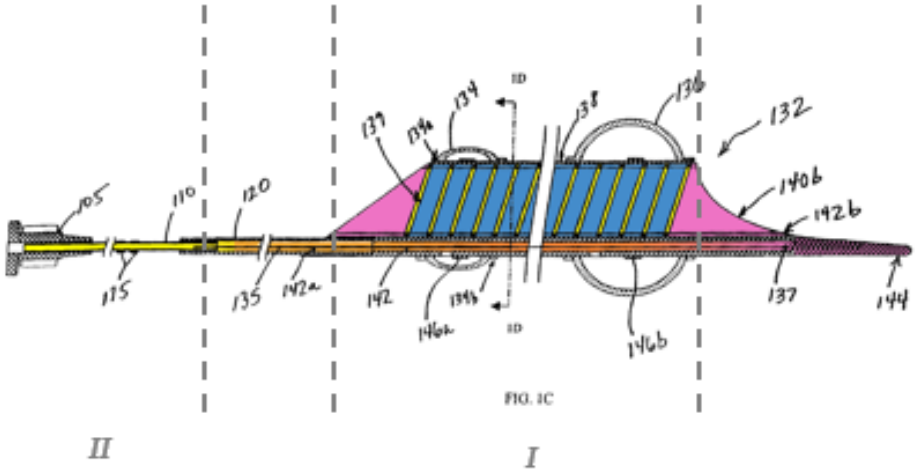
Id. at Fig. 6C (left), Fig. 6E (right) (color added).

E. Claim 30: The method of claim 25, wherein providing the substantially rigid segment and the reinforced segment includes, starting at the distal end portion of the reinforced segment and moving proximally toward the proximal end portion of the substantially rigid segment, forming or obtaining at least a first device portion having a first flexural modulus and a second device portion having a second flexural modulus, the second flexural modulus greater than the first flexural modulus.

Ressemann discloses claim 30, Ex-1205, ¶ 187, teaching that evacuation sheath 100 has a substantially rigid segment and a reinforced segment. *See supra* § VII ([25.b], [25.c]). Proximal shaft 110 is part of the "substantially rigid segment," is preferably made of stainless steel and is more rigid than shaft 120, as the latter must "allow navigation of the curves within the distal region of the guiding catheter, as are often present, particularly in cardiac related applications." Ex-1208,

11:6-10, 10:36-37; *see supra* § VII ([25.c]). Shaft 110 is a "second device portion having a second flexural modulus," (*II*). Ex-1205, ¶ 187; Ex-1242, ¶¶ 71-74.

The reinforced segment includes lumen 140, reinforcing coil 139, and a portion of distal shaft 130, which are made of mateials discussed above. *See supra* § VII ([25.a], [25.b]). The reinforced segment is a "first device portion having a first flexural modulus," (*I*). Ex-1205, ¶ 187; Ex-1242, ¶¶ 71-74.



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

As discussed for claim 25, given the differences in the materials that are used to form the second and first device portions, the flexural modulus of the second device portion (*II*) is necessarily greater than flexural modulus of the first device portion (*I*). Ex-1205, ¶ 187; Ex-1242, ¶ 74; *see also id.* at ¶¶ 30-37.

F. Claim 31: The method of claim 25, wherein providing the reinforced segment includes covering one or more braided or coiled metallic elements with the polymer.

Ressemann discloses claim 31, Ex-1205, ¶ 188. Ressemann teaches that the reinforced portion of multi-lumen tube 138 within the evacuation lumen 140 "may be formed around a coil 139 such that coil 139 is ***embedded*** within the multi-lumen tube 138." Ex-1208, 7:4-7 (emphasis added). Ressemann also discloses 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*. at 7:10-12. Thus, Ressemann discloses claim 31. Ex-1205, ¶ 188.

G. Claim 36: The method of claim 25, wherein providing the flexible tip segment includes providing an atraumatic bumper formed of a polymer or an elastomeric material.

Ressemann discloses claim 36, Ex-1205, ¶ 189. Ressemann teaches that providing the flexible tip segment includes providing an atraumatic bumper formed of a polymer or an elastomeric material, which is the "soft distal tip portion 144" shown below. *See supra* § VII ([25.a]); Ex-1205, ¶ 189.

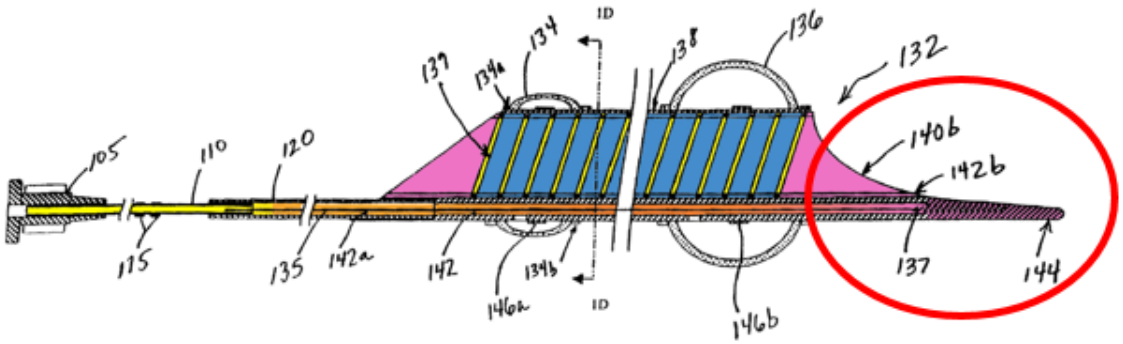


FIG. 1C

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

Ressemann teaches that tip 144 is made of a flexible polymer, such as a "low durometer polyurethane or Pebax." *Id*. at 11:24-25. The purpose of soft tip 144 is to allow the evacuation sheath to be placed "atraumatically into the blood vessel, even if the blood vessel exhibits tortuosity." *Id*. at 11:26-29; Ex-1205, ¶ 189.

H. Claim 38:

1. **[38.p] "A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:"**

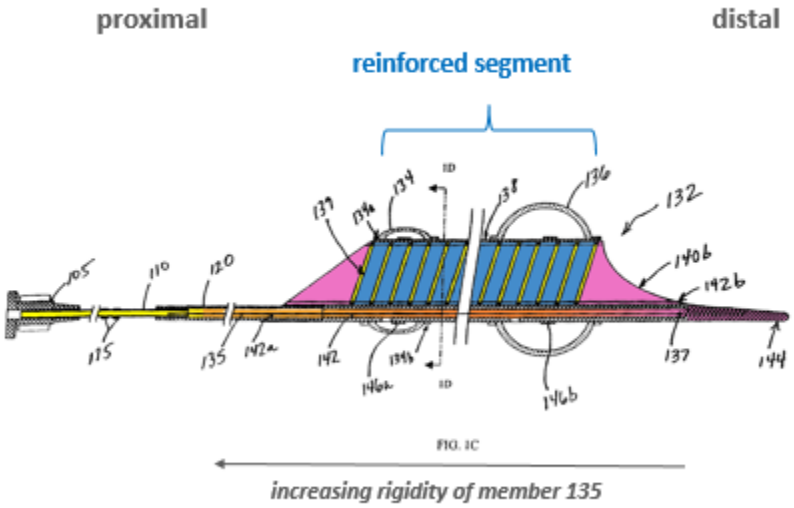
Ressemann discloses. *See supra* § VII ([25.pre]). Ex-1205, ¶ 190.

2. **[38.a] "providing a flexible tip segment having a lumen therethrough"**

Ressemann discloses. *See supra* § VII ([25.a]). Ex-1205, ¶ 191.

3. **[38.b] "providing a reinforced segment including one or more metallic elements covered with a polymer and having a lumen for coaxial alignment with the lumen of the flexible tip segment;"**

Ressemann discloses. Ex-1205, ¶ 192.



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

The "reinforced segment" illustrated above satisfies the requirements of 38.b for the same reasons that the "reinforced segment" of claim 25 satisfies the requirements of 25.b and 25.f.

4. **[38.c] "providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment"**

Ressemann discloses. *See supra* § VII ([25.c]). Ex-1205, ¶ 193.

5. **[38.d.i.] "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape"**

Ressemann discloses a side opening portion.

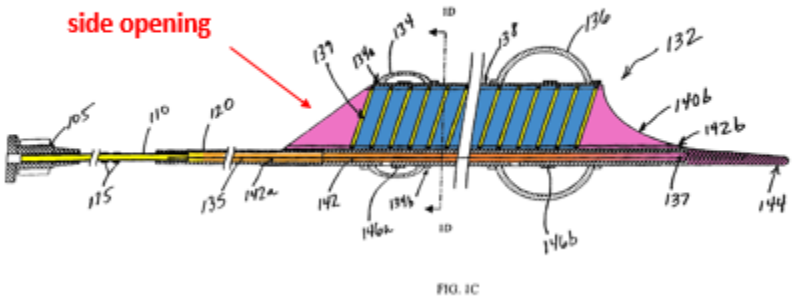


FIG. 1C

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

The side opening portion illustrated above satisfies the requirements of 38.d.i for the same reason the side opening portion discussed in claim 25 meets the requirements of 25.d. Ex-1205, ¶ 194.

6. **[38.d.ii] "the side opening portion extending for a distance along a longitudinal axis of the device such that the side opening is accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive a balloon catheter and stent; and"**

Ressemann discloses. *See supra* § VII (claim 26). Ex-1205, ¶ 195.

7. **[38.d.iii.] "arranging, in a proximal to distal direction, the substantially rigid segment, the side opening portion, the reinforced segment, and the flexible tip segment such that when the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter and the side opening portion is positioned within the continuous lumen of the guide catheter."**

Ressemann discloses. Ex-1205, ¶ 196.

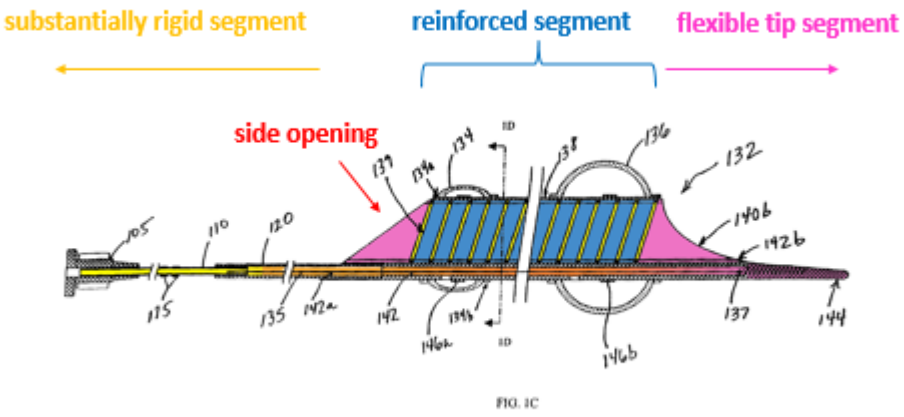
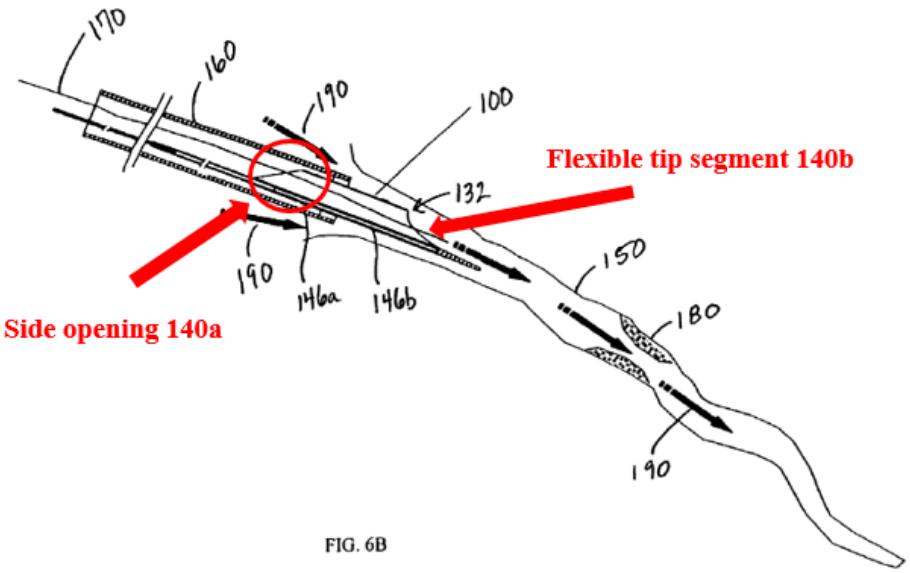


FIG. 1C

Ex-1208, Fig. 1C (color and annotation added); *see supra* § VII ([38.a]-[38.d.ii]); *see also* Ex-1208, 22:50-52, Figs. 16A-B.

Ressemann also teaches that when the "flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter and the side opening portion is positioned within the continuous lumen of

the guide catheter." *See supra* § VII ([25.g], claim 26); *see also* Ex-1208, 28:46-49.



Ex-1208, Fig. 6B (annotation added).

Apart from evacuation sheath assembly 100, addressed above, claim 38 is also anticipated by the disclosures related to evacuation sheath assembly 2100, for the same reasons that claim 25 is anticipated by evacuation sheath assembly 2100. Ex-1205, ¶ 197.

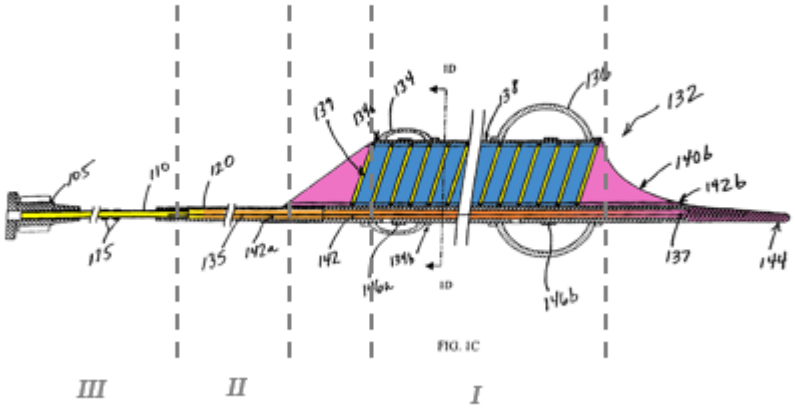
I. Claim 39: The method of claim 38, wherein providing the substantially rigid segment, defining the side opening, and providing the reinforced segment includes, starting at a distal end portion of the reinforced segment and moving proximally toward the proximal end portion of the substantially rigid segment, forming or obtaining at least a first device portion having a first flexural modulus, a second device portion having a second flexural modulus greater than the first flexural modulus, and a third device portion having a third flexural modulus greater than the second flexural modulus.

Ressemann discloses claim 39, Ex-1205, ¶ 198, teaching that evacuation sheath 100 has a substantially rigid segment and a reinforced segment. *See supra* § VII ([25.b]-[25.c], [38.b]-[38.c]).

Proximal shaft110 is part of the "substantially rigid segment," is preferably made of stainless steel and is more rigid than shaft 120, as the latter must "allow navigation of the curves within the distal region of the guiding catheter, as are often present, particularly in cardiac related applications." Ex-1208, 11:6-10; *see also id.* at 10:36-37; *see supra* § VII ([25.c]). Proximal shaft 110 is a "third device portion having a third flexural modulus." (*III*). Ex-1205, ¶ 198; Ex-1242, ¶¶ 71-73, 75.

Intermediate shaft 120 is also part of the "substantially rigid segment" and is "preferably formed of polyethylene or Pebax . . . or other suitable maerial exhibiting appropriate . . . flexibiltiy characteristics. Ex-1208, 10:63-11:1. Intermediate shaft 120 is a "second device portion having a second flexural modulus." (*II*). Ex-1205, ¶ 198; Ex-1242, ¶¶ 71-73, 75.

The reinforced segment includes lumen 140, reinforcing coil 139, and a portion of distal shaft 130, which are made of mateials discussed above. *See supra* § VII ([25.a]-[25.b], [38.a]-[38.b]). The reinforced segment is a "first device portion having a first flexural modulus," (*I*). Ex-1205, ¶ 198; Ex-1242, ¶¶ 71-73, 75.



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

As Dr. Brecker and Dr. Hillstead explain, and as discussed herein (claims 25, 38), given the differences in the materials that are used to form the third, second and first device portions, the flexural modulus of the third device portion (*III*) is necessarily greater than the flexural modulus of the second device portion (*II*), and the flexural modulus of the second device portion (*II*) is necessarily

greater than flexural modulus of the first device portion (*I*). Ex-1205, ¶ 198; Ex-1242, ¶ 75.

J. Claim 40: The method of claim 38, wherein defining the side opening portion includes providing an angled entrance into the lumen of the reinforced segment.

Ressemann discloses claim 40. Ex-1205, ¶ 199.

The proximal opening to evacuation lumen 140 is angled (arrow below).

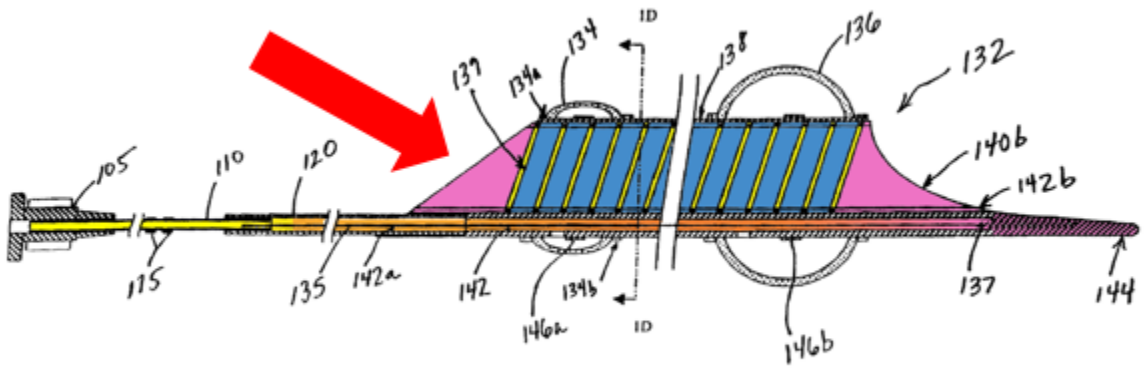


FIG. 1C

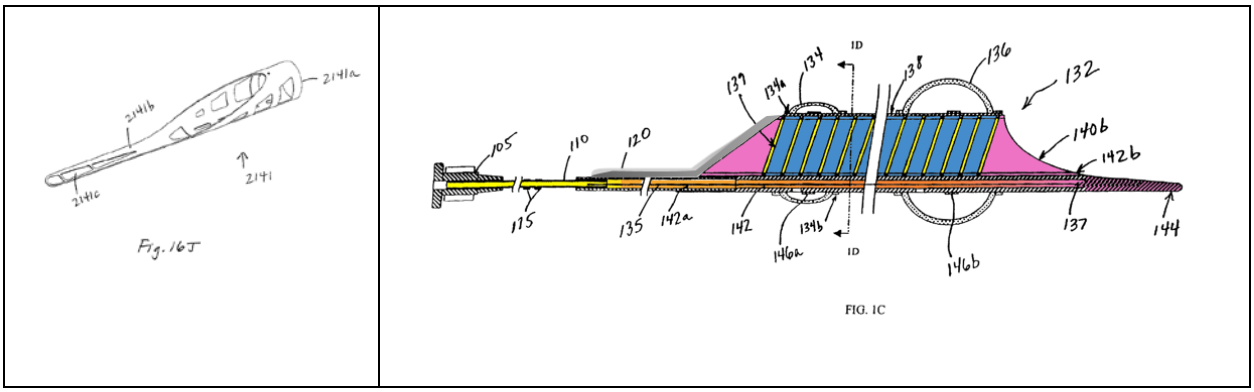
Ex-1208, Fig. 1C (color and annotation added).

The opening is an "entrance into the lumen of the reinforced segment," as Ressemann discloses that it is "preferably angled to . . . facilitate smoother passage of other therapeutic devices" through lumen 140. *Id*. at 6:52-57; *see also id.* at Figs. 6B-6E, 12:19-13:60; Fig. 16A, 24:33-41.

K. Claim 42: The method of claim 25, further comprising defining the side opening portion in the substantially rigid segment.

Ressemann discloses claim 42. Ex-1205, ¶¶ 200-206, teaching a support collar 2141. Ex-1208, Fig. 16J.

As shown below, the distal end of the collar 2141a is inserted into the proximal opening of lumen 140, which adds a lining of a thin metallic material to the opening. Ex-1208, 24:55-67, 25:1-16. Ex-1205, ¶¶ 200-201; Ex-1242, ¶¶ 76-85.



Ex-1208, Fig. 16J (left); Fig. 1C (color, annotation and modification added (collar 2141 in gray)).

While 2141a is the support collar's proximal end, tab 2141b is its distal end and facilitates attachment of the evacuation head and the intermediate shaft portion. *Id*. at 24:59-62, 27:59-67. Ex-1205, ¶ 202; Ex-1242, ¶ 84. Ressemann teaches that tab 2141b (and therefore the entirety of collar 2141, including circumferential portion 2141a) is attached to intermediate shaft 120, which is part

of Ressemann's "substantially rigid segment." *See supra* [25.c]. Ex-1205, ¶ 202; Ex-1242, ¶ 84.

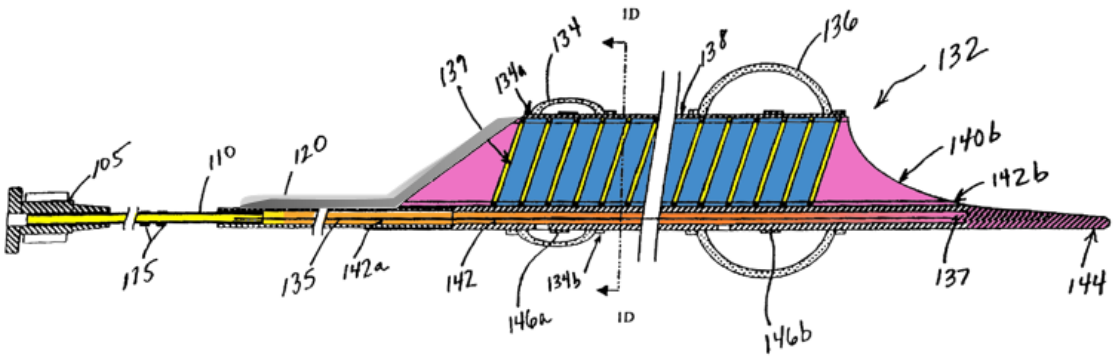


FIG. 1C

Ex-1208, Fig. 1C and reconstruction of Fig. 16J (color and annotation added (collar 2141 in gray)).

Like proximal and intermediate shaft portions (110, 120), collar 2141 is also "substantially rigid," because it is "rigid enough to allow the [evacuation sheath] to be advanced within the guide catheter." *See supra* § VI (construing "substantially rigid"); Ex-1208, 24:62-67 (explaining that collar 2141 provides hoop support for the evacuation lumen, and provides a flexibility transition between the proximal end of the evacuation head and the evacuation shaft). Ex-1205, ¶ 203.

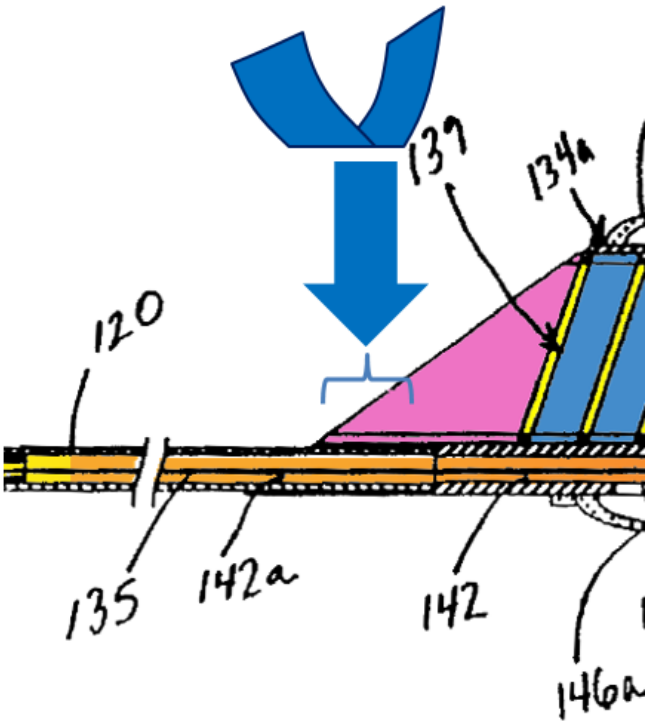
Thus, Ressemann teaches "defining the side opening portion in the substantially rigid segment." Ex-1205, ¶ 204.

As discuss in for claim 26, a POSITA would envisage using collar 2141 with evacuation assembly 100. Ex-1205, ¶ 205. When support collar 2141 is added to the proximal opening of lumen 140 in the embodiment in Fig. 1, claim 42 is disclosed for the reasons discussed above. *Id*.

In addition, claim 42 is anticipated by the disclosures related to evacuation sheath assembly 2100 based on the disclosures included above and the reasons stated in claim 25. Ex-1205, ¶ 206.

L. Claim 43: The method of claim 38, wherein defining the side opening portion includes forming a concave track.

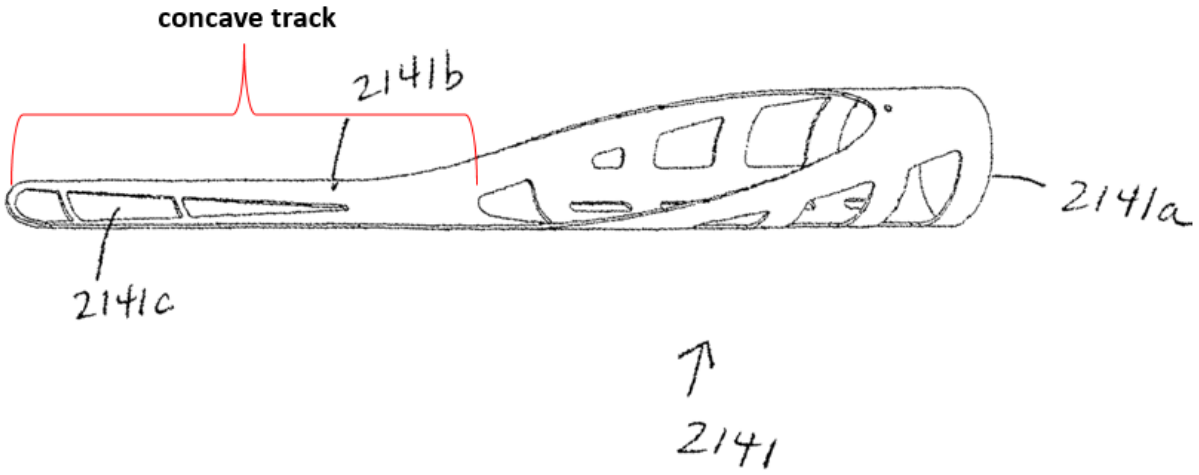
Ressemann discloses claim 43. Ex-1205, ¶¶ 207-208. Ressemann discloses that evacuation head includes a proximal side opening, 140a, which includes a portion that is not fully circumferential. Ex-1208, Figs. 1A, 1C; Ex-1205, ¶ 207; *see supra* § VI (defining "concave track.") The non-fully circumferential portion of side opening 140a forms a concave track. Ex-1208, Figs. 1A, 1C; Ex-1205, ¶ 207.



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

Additionally, Ressemann teaches a support collar. Ex-1208, Fig. 16J. A POSITA would envisage collar (2141) being used with the embodiments Ressemann teaches in Fig. 1. *See supra* claims 25, 42.

Like the non-fully circumferential portion of the proximal opening of lumen (140), the non-fully circumferential portion of collar 2141 forms a concave track.



Ex-1208, Fig. 16J (color and annotation added).

Thus, Ressemann discloses claim 43. Ex-1205, ¶¶ 207.

In addition, claim 43 is anticipated by the disclosures related to evacuation sheath assembly 2100 based on the disclosures included above and the reasons stated in claim 25. Ex-1205, ¶ 208.

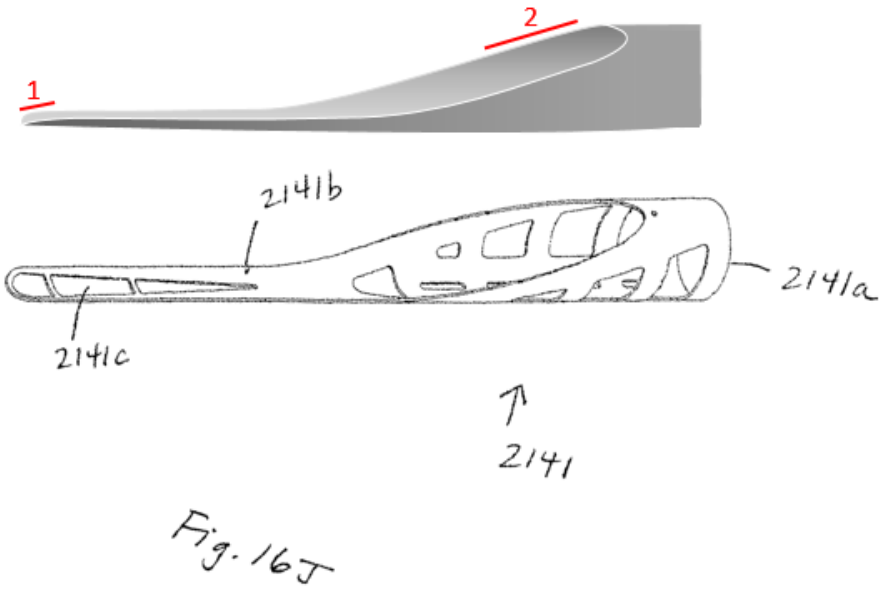
M. Claim 44: The method of claim 38, wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

Ressemann discloses claim 44. Ex-1205, ¶ 209-210.

As discussed for claims 26, 42 and 43, Ressemann discloses a metal collar 2141 that reinforces the proximal opening of the evacuation lumen 140 (or 2140). Collar 2141 discloses the side opening portion claimed in claim 44.

First, 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, ¶ 81. These inclined slopes are similar to what Patent Owner identifies in their infringement allegations in District Court. Ex-1205, ¶ 209; Ex-1242, ¶ 91; Ex-1275, 11.



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

Second, as Dr. Brecker and Dr. Hillstead explain (*see supra* § VII (claims 26, 42, and 43)), a POSITA would envisage using support collar 2141 with evacuation assembly 100. Ex-1208, Figs. 16J, Figs. 1A-1D.

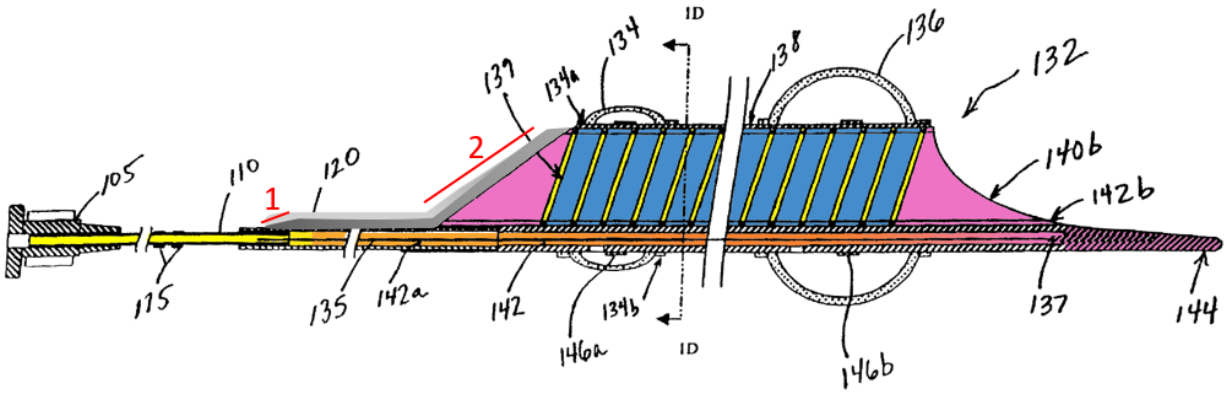


FIG. 1C

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

In addition, claim 44 is anticipated by the disclosures related to evacuation sheath assembly 2100 based on the disclosures included above and the reasons stated in claim 25. Ex-1205, ¶ 210.

N. Claim 45: The method of claim 38, wherein providing the substantially rigid segment, defining the side opening portion, providing the reinforced segment, and providing the flexible tip segment includes forming a device cross-sectional size and shape configured to be passed, at least in part, into the continuous lumen of the guide catheter.

Ressemann discloses claim 45. Ex-1205, ¶ 211. As discussed above, Ressemann's evacuation sheath includes a substantially rigid segment, a side opening portion, a reinforced segment, and a flexible tip segment. *See supra* § VII ([38.d.iii]). Ressemann also teaches that the evacuation sheath is of a "cross-sectional size and shape configured to be passed, at least in part, into the

continuous lumen of the guide catheter." *See supra* § VII ([25.g], claim 26, [38.d.iii]).

VIII. GROUND 2: RESSEMANN RENDERS CLAIMS 25, 26, 29-32, 35-40 AND 42-44 OBVIOUS IN VIEW OF THE COMMON KNOWLEDGE OF A POSITA.

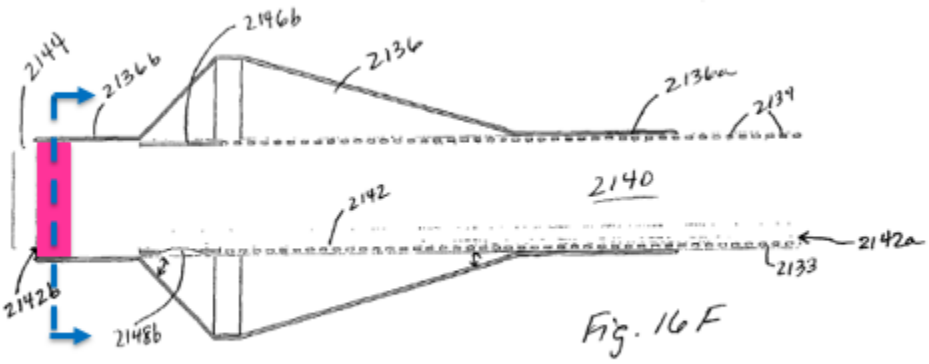
A. Claim 25

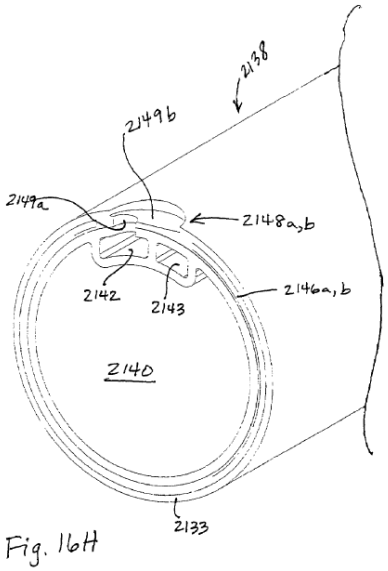
As discussed in §VII, Ressemann anticipates claim 25.

To the extent that Patent Owner asserts that 25.b requires that the ***entire*** flexible tip segment must have a lumen therethrough (which is not required by the claim), Ressemann renders claim 25 obvious. Ex-1205, ¶¶ 212-218.

Ressemann discloses that sheath assembly 2100, Ressemann includes an evacuation lumen 2140 within multi-lumen tube 2138. Ex-1208, 23:8-11. Evacuation lumen 2140 has the same function as evacuation lumen 140 discussed above, i.e. allowing passage of an interventional device. Ex-1208, 22:33-38 ("Many of the elements present in the previous embodiments are also shown in FIGS. 16A-16J and where those element are substantially the same, similar reference numerals have been used and no detailed description of the element has been provided."), 6:44-50, 23:8-15. Like multi-lumen tube 138, multi-lumen tube 2138 is made of "relatively flexible polymer, for example, a polyester blend such as Hytrel 6356. Hytrel 6356 has…a relatively high flexibility." Ex-1208, 22:53-58; Ex-1205, ¶¶ 214-215. At the distal end of multi-lumen tube 2138, i.e. the distal

opening of lumen 2140 (2140b) (shown in pink below), the cross-section (at the dashed blue line) has lumen extending therethrough the entire "flexible tip segment," just like that shown in Fig. 16H. Ex-1205, ¶ 215.





Ex-1208, Fig. 16F (above) (colored and annotated), 16H (below).

A POSITA would be motivated to modify evacuation assembly 100 to include the distal tip disclosed in embodiment 2100 because the "perpendicular tip is useful when the anatomy is such that an angled distal end would contact the

vessel wall in a way that would limit fluid flow through the evacuation lumen 2140." Ex-1208, 24:29-33; Ex-1205, ¶ 216.

Even if Ressemann was used solely as an extension catheter, a POSITA would be motivated to make the modification discussed above to avoid "sharp edges" on the child catheter. Ex-1254, 2:37-40 (teaching to include a "soft tip" that is "appropriately rounded to avoid sharp edges" on a child catheter); Ex-1205, ¶ 217; Ex-1242, ¶¶ 129-132. A POSITA would have had a reasonable expectation of success because modifying the tip of evacuation sheath 100 to have the soft, beveled tip 2144 of embodiment 2100 is nothing more than combining prior art elements according to known methods to yield predictable results. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

A POSITA would have a reasonable expectation of success in combining these embodiments as Ressemann discloses that many of the elements in the embodiments are the same. Ex-1208, 22:33-38; Ex-1205, ¶ 218. The manufacturing of a device with a distal end of multi-lumen tube 2138 would be easier than the angled distal end 140b. Ex-1242, ¶ 132. As such, the combination is known components used in a known way to achieve a predictable result of forming a device with tip that has lumen through a tube. Ex-1205, ¶ 218. Thus, claim 25 is obvious. *Id.*

B. Claims 26, 29-31

Ressemann either anticipates these claims, (*see supra* § VII) or renders them obvious because it renders claim 25 obvious and discloses the additional limitations set forth in claims 26 and 29-31. Ex-1205, ¶¶ 220-221.

To the extent that Patent Owner argues that a POSITA would not have envisaged using collar 2141 with evacuation sheath assembly 100, then it would have been obvious to use collar 2141 with assembly 100 for the reasons discussed above. *See supra* § VII (claim 26). Ex-1205, ¶¶ 182-185.

C. Claim 32: The method of claim 31, wherein a length of the one or more braided or coiled metallic elements is in a range of 20 centimeters to 30 centimeters.

As discussed in §VII, Ressemann anticipates claim 31, including disclosing a reinforced segment that includes one or more braided or coiled metallic elements covered with the polymer. *See supra* § VII (claims 25, 31). Ressemann also renders claim 32 obvious. Ex-1205, ¶¶ 222-224.

As illustrated below, coil 139 extends along the majority of the length of evacuation head 132.

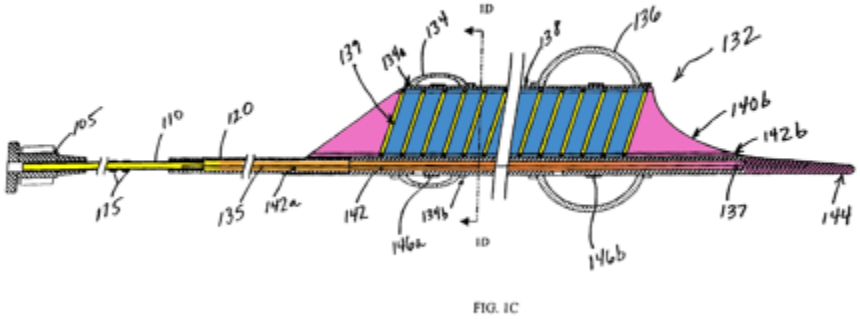


FIG. 1C

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

Ressemann teaches that the length of evacuation head 132 (in embodiment 100) is up to 20 cm in length, but also that the head's length is dependent on application. Ex-1208, 9:63-65, 10:11-12. Ressemann additionally teaches another embodiment, 2100, where the head may be up to 40 cm in length. *Id*. at 22:45-46.

A POSITA would be motivated to make evacuation head 132 longer for the following reason. By the time of the purported invention of the '379 patent, those working in the field appreciated that interventional cardiologists were attempting to treat "more challenging lesions than in the past" using PCI procedures. Ex-1236, pp. 2948-2949; Ex-1205, ¶ 223. And those in the field knew that in order to "maneuver [a catheter] through a tortuous path to [a] treatment site," the catheter must have "sufficient 'pushability' and 'torqueability' to allow the guiding catheter to be inserted percutaneously into a peripheral artery, moved and rotated in the vasculature to position the distal

end of the catheter at the desired site adjacent to a particular coronary artery." Ex-1246, 1:39-47.

But also that the catheter's "distal portion should have sufficient flexibility so that it can track over a guidewire and be maneuvered through a tortuous path to the treatment site." *Id*; 1:45-47; Ex-1205, ¶ 223. In particular, for a catheter to reach a "desired remote location in a bodily passageway, such as a small, tortuous artery," it was advantageous for the "less flexible section . . . [with] greater pushabiltiy . . . [to] comprise[] a substantial portion of the length of the catheter," while the more distal and more flexible portion could be up to 30 cm in length. Ex-1272, 2:24-25, 2:38-44.

As explained above, a POSITA would be aware that evacuation head 132 could be increased in length, up to 30-40 cm, to accommodate reaching lesions located in particularly tortuous vessels. Ex-1205, ¶ 224. And, in this instance, the longitudinal length of the reinforcing braid or coil would extend along the majority of that length, and therefore be in a range of 20 cm to 30 cm. Ex-1242, ¶ 92-97; Ex-1205, ¶ 224. *See also* Ex-1243, ¶¶ 38-48.

D. Claim 35: The method of claim 25, wherein providing one or both of the reinforced segment and the flexible tip segment includes lining the lumens thereof with polytetrafluoroethylene.

Ressemann renders claim 35 obvious. Ex-1205, ¶¶ 225.

Both the reinforced and flexible tip segments (*see supra* [25.a], [25.b]) include lumen 140. Ex-1208, 6:35-47. Ressemann teaches that lumen 140 is a tube that is "preferably made of a relatively flexible polymer such as low-density polyethylene, polyurethane, or low durometer Pebax(R) material," or of a "composite polymer and metal material or from other suitable biocompatible materials exhibiting appropriate flexibility. . . ." *Id.* at 6:37-42. Ressemann does not, however, specifically teach whether lumen 140 has a lining.

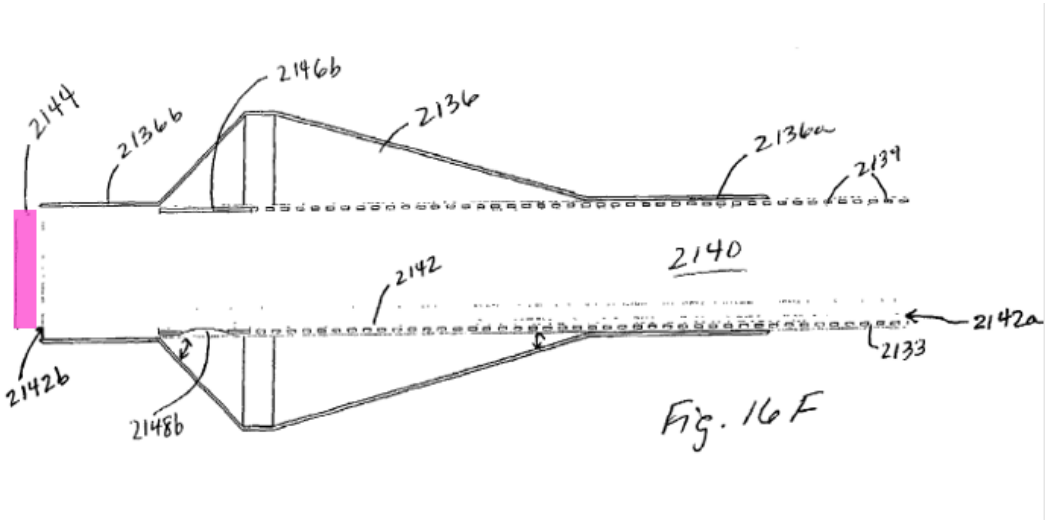
The lumens of catheters for coronary intervention were commonly lined with polytetrafluoroethylene. Ex-1205, ¶ 225; Ex-1242, ¶¶ 99; Ex-1215, 548 (explaining that guide catheters used for angioplasty are lined with Teflon to reduce friction); Ex-1276, 3:17-18 (describing guide catheters with "polytetrafluoroethylene (PTFE/Teflon) inner liner(s)").

Because Ressemann teaches using evacuation lumen 140 to deploy a balloon and stent catheter (Ex-1208, Figs. 6B-6E, 12:19-13:60), a POSITA would have been motivated to modify lumen 140 to include a PTFE liner, for the purpose of reducing friction when lumen 140 was used to deploy a therapeutic catheter. Ex-1205, ¶ 225; Ex-1242, ¶¶ 98-102. A POSITA would have a reasonable expectation of success because this combination was using known components in a known manner to achieve the predictable result of an extension catheter with lining a

lumen in the reinforced segment and/or the flexible tip segment with PTFE. Ex-1205, ¶ 225; Ex-1242, ¶ 102.

E. Claim 36

To the extent that Patent Owner asserts that "atraumatic bumper" must have lumen (which is not required by the claim), then Ressemann renders claim 36 obvious. Ex-1205, ¶¶ 226-229. Ressemann discloses an alternative embodiment wherein soft tip 2144 has a lumen. As shown below, tip 2144 has a lumen to allow passage of the interventional device through lumen 2140. Ex-1208, 23:8-15, Fig. 16F. Tip 2144 is formed from polyurethane. *Id*. at 24: 20-22.



Ex-1208, Fig. 16F (color and annotation added).

For the same reasons discussed above for claim 25, in regard to 25.b, a POSITA would be motivated to modify evacuation sheath assembly 100 to include tip 2144, and would have a reasonable expectation of success. A POSTIA would be motivated to combine these elements because catheters used to deliver therapy catheters typically included a "very soft material in the most distal 2 mm of the catheter to reduce the chance of vessel trauma." Ex-1215, 549; *see* Ex-1254, 2:37-40 (teaching to include a "soft tip" that is "appropriately rounded to avoid sharp edges" on a child catheter); Ex-1205, ¶¶ 227-229; Ex-1242, ¶ 129-132.

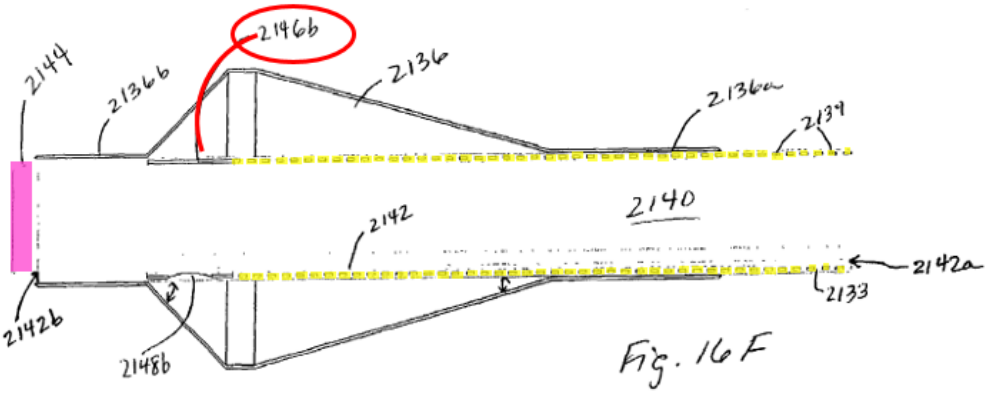
Including an atraumatic bumper at the tip of the tubular structure in the form of tip 2144 would simplify the manufacturing of the assembly because it would eliminate the step of having to secure tip 144 to the distal end of tube 138. Ex-1208, 11:20:22; Ex-1205, ¶ 229; Ex-1242, ¶ 132. Thus, Ressemann and the common knowledge of a POSITA render this claim obvious. Ex-1205, ¶ 229.

F. Claim 37: The method of claim 36, wherein providing the flexible tip segment includes covering a marker band with the polymer or the elastomeric material.

Ressemann renders claim 37 obvious. Ex-1205, ¶ 230. As discussed above, claim 36 is anticipated or rendered obvious.

Ressemann explicitly teaches placing a radiopaque marker band in the flexible tip segment in the 2100 embodiment. As illustrated below in Fig. 16F (color and annotation added), radiopaque marker bands are placed adjacent of and ***distal*** to

reinforcing coil 2139. Ex-1208, 23:55:-24:2. Ressemann also teaches that the coil and the marker band are coated with polyurethane, which is the same polymer used to form tip 2144, i.e. the "atraumatic bumper." *Id*. at 23:66-24:23.



Ex-1208, Fig. 16F (color and annotation added).

A POSITA would be motivated to modify the distal tip of evacuation sheath assembly 100 for the reasons discussed for claim 36. A POSITA would have retained the radiopaque marker band on the distal tip because those in the field appreciate that distal, radiopaque marker bands were necessary to allow detection of the distal end of a catheter via fluoroscopy. Ex-1209, 4:16-19; Ex-1205, ¶ 230.

G. 38-40, 42-43

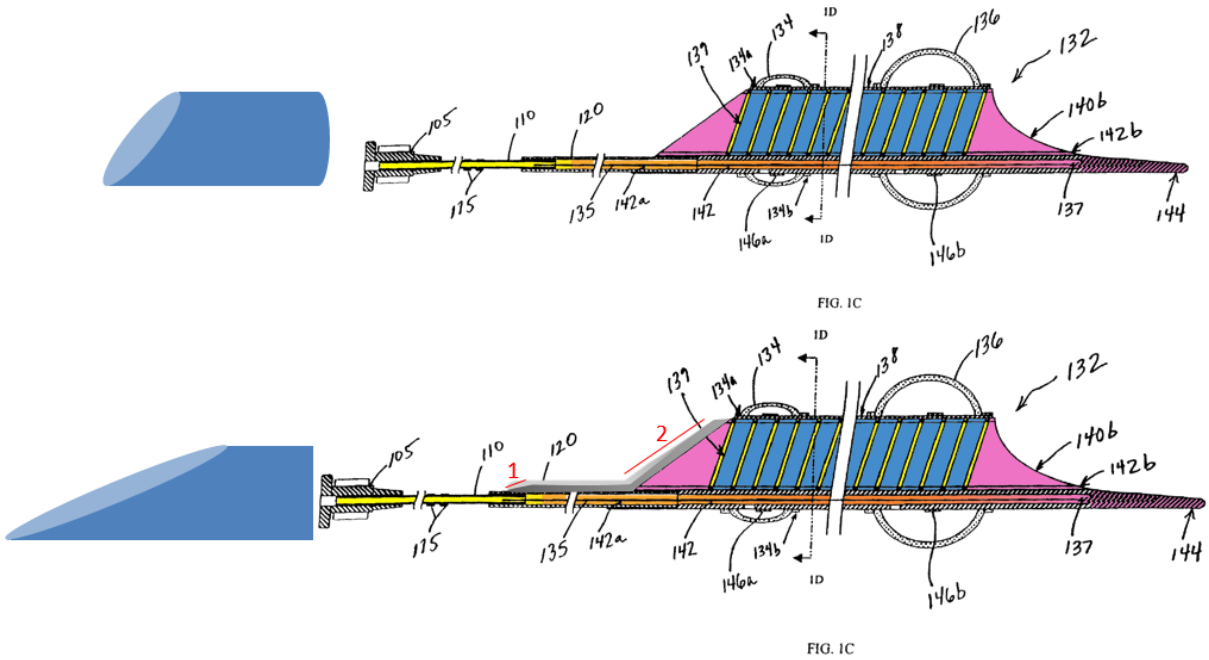
Ressemann either anticipates these claims (*see supra* § VII) or renders them obvious for the same reasons it renders claim 25 obvious (*see supra* § VIII (claim 25), and discloses the additional limitations set forth in claims 38, 39, 40, 42 and 43.

To the extent that Patent Owner argues that a POSITA would not have envisaged using collar 2141 with evacuation sheath assembly 100, then it would have been obvious to use collar 2141 with assembly 100 for the reasons discussed above. *See supra* § VII (claims 26, 42). Ex-1205, ¶¶ 232-233.

H. Claim 44

If not found to anticipate, Ressemann's evacuation assembly 100 in combination with support collar 2141 renders claim 44 obvious. As Ressemann explicitly teaches, the collar is beneficial for the reasons discussed. *See supra* § VII (claims 26, 42). Ex-1205, ¶¶ 234-236.

Additionally, modifying the proximal opening of evacuation lumen 140 to include support collar 2141 also increases the area entry for receiving a stent and balloon catheter. Ex-1205, ¶ 236; Ex-1242, ¶¶ 78, 88-90. The addition of the collar in the manufacturing process would be a routine task for a POSITA such that a POSITA would have a reasonable expectation of success in creating this combination. Ex-1205, ¶ 236; Ex-1242, ¶¶ 78, 88-90.



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

Thus, Ressemann renders obvious claim 44. Ex-1205, ¶ 234-236.

IX. GROUND 3: RESSEMANN RENDERS CLAIMS 33 AND 34 OBVIOUS IN VIEW OF TAKAHASHI AND KNOWLEDGE OF POSITA.

A. Takahashi

Takahashi et al. ("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 pre-AIA §102(b) and post-AIA §102(a)(1). Ex-1278, ¶¶ 43-52.

Takahashi is cited in the Background of the '379 patent, but was not the basis of an Examiner rejection during prosecution of either the '379 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. 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 about a 1 French difference in inner diameters. Ex-1205, ¶¶ 163-166; *see also id.* at ¶¶ 81-84.

B. Claim 33: The method of claim 25, wherein providing the reinforced segment includes forming or obtaining a reinforced segment including a lumen having a uniform inner diameter that is about one French smaller than an inner diameter of the continuous lumen of the guide catheter.

Ressemann renders claim 33 obvious in view of Takahashi and the common knowledge of a POSITA. Ex-1205, ¶¶ 237-247.

Ressemann teaches a reinforced segment with a lumen, as discussed for claim 25. *See supra* §§ VII, VIII. Ressemann also discloses that the lumen has a “uniform inner diameter.” First, no taper is shown in the tubular structures that form the evacuation lumen in evacuation assemblies 100 or 2100. *See* Ex-1208, Figs. 1A, 1C, 16A, 16F. Second, Ressemann reports a *single* diameter for the evacuation lumen. *Id*. at 10:17-21 (reporting an evacuation lumen of 0.061 inches for assembly 100).

Ressemann does not, however, teach that the lumen of the tubular structure is "about one French smaller than an inner diameter of the continuous lumen of the guide catheter." Ressemann explains that evacuation lumen 140 has a diameter of 0.061 inches, which is 1.54 mm. Ex-1208, 10:17-18; Ex-1205, ¶ 237. 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; Ex-1205, ¶ 238. 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, ¶ 238.

Takahashi, however, discloses a lumen of a guide extension catheter that is "about one French smaller than an inner diameter of the continuous lumen of the 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 .012 inches, or 0.30 mm, which is about 1 Fr. Ex-1205, ¶ 238; Ex-1262, 545.

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 about one French, and a POSITA would have been capable of

achieving such a difference with a reasonable expectation of success. Ex-1205, ¶¶ 239-246.

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*. at 6:25-34; *see also id.* at 23:8-20. By the time of the alleged invention of the '379 patent, a POSITA had the motivation to modify the evacuation assembly of Ressemann to remove the sealing balloons. Ex-1205, ¶¶ 239-241. Ressemann could be modified for use solely as an extension catheter, and not as an aspiration catheter. Ex-1205, ¶ 239; Ex-1242, ¶¶ 124-128.

First, the use of extension catheters—with guide catheter—was known in the art. 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, ¶ 128. 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, ¶ 244; Ex-1242, ¶ 128. 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, ¶¶ 240, 244. This is desirable because bleeding is easier to control and patients are immediately ambulatory. Ex-1215, 91-92; Ex-1205, ¶ 241.

Moreover, a POSITA had the motivation to choose a guide catheter such that the inner diameter of the modified Ressemann assembly 100 was "about one French 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 "about one French 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, ¶¶ 237-247.

C. Claim 34: The method of claim 33, wherein the lumen of the reinforced segment is greater than or equal to 0.056 inches and the continuous lumen of the guide catheter is greater than or equal to 0.070 inches.

As discussed for claim 33, a POSITA had the motivation to combine the teachings of Ressemann with Takahashi, as well as a reasonable expectation of success.

For example, Takahashi teaches an inner, Heartrail catheter with an inner diameter of 0.059 inches. Ex-1210, 452. This is greater than or equal to 0.056

inches. Similarly, Takahashi teaches a guide catheter with an inner diameter of 0.071 inches. *Id*. This is greater than or equal to 0.070 inches. Claim 34 is rendered obvious by Ressemann in view of Takahashi. Ex-1205, ¶ 248.

X. GROUND 4: RESSEMANN IN VIEW OF KATAISHI RENDERS CLAIM 44 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 ’379 patent (and its previous iteration, the ’850 patent), Kataishi was neither disclosed by Patent Owner, nor cited by the Examiner. Exs-1201, 1202, 1203.

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*. at 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*. at Abstract, [0026-0027], Fig. 10), which corresponds to loading a thrombus into the catheter’s distal end.

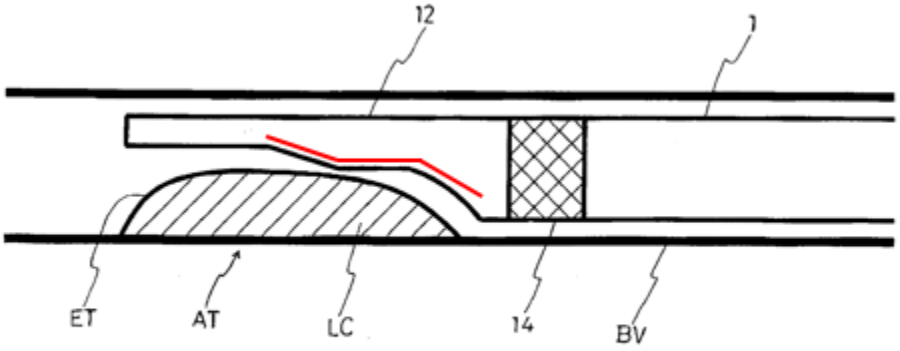


Fig. 10

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*. at [0010]. The catheter tip is shown below.

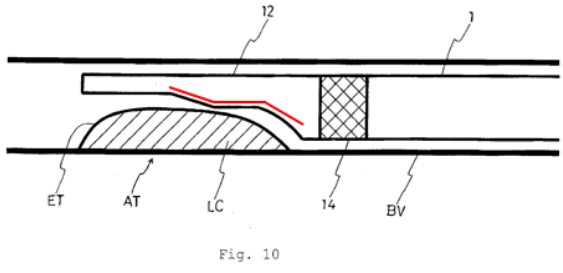


Fig. 10

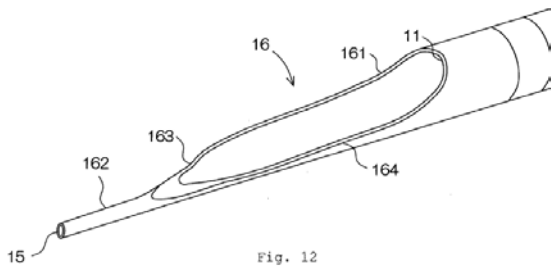


Fig. 12

Ex-1225, Fig. 10 (left, annotation added), Fig. 12 (right).

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 defin[es] an angle with the longitudinal axis of the catheter." *Id*. at [0027]. Ex-1205, ¶¶ 113-117, 153-157.

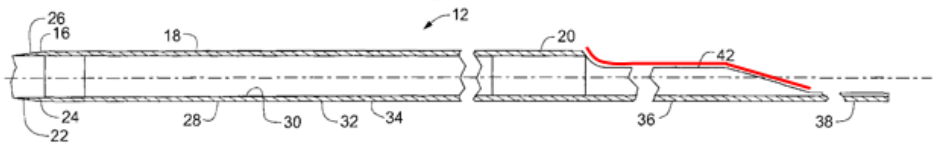
B. Claim 44: The method of claim 38, wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region.

As discussed in §§ VII and VIII, Ressemann anticipates claim 44 or renders it obvious. Ressemann also renders claim 44 obvious in view of Kataishi. Ex-1205, ¶¶ 249-256.

In an attempt to support claim 27 in a related patent, patentee represented to the Examiner that Fig. 4 of the '379 patent showed two different inclined slopes in the side opening.

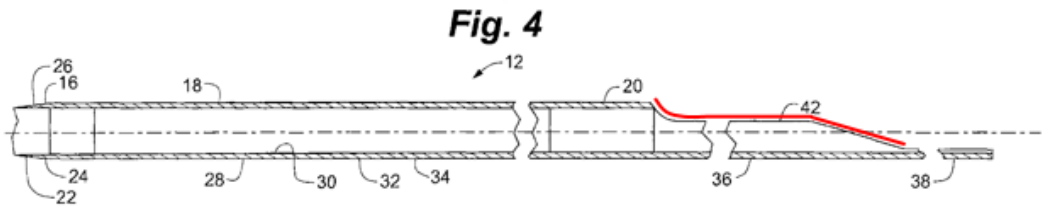
'379 Patent

Fig. 4



Ex-1203 at 31 (12/30/15 Preliminary Amendment at 24) (annotation added).

Of course, the disclosure in the '379 patent is no different than what was disclosed in Kataishi.



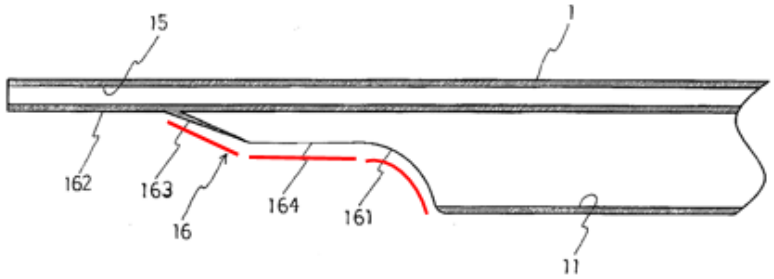


Fig. 2

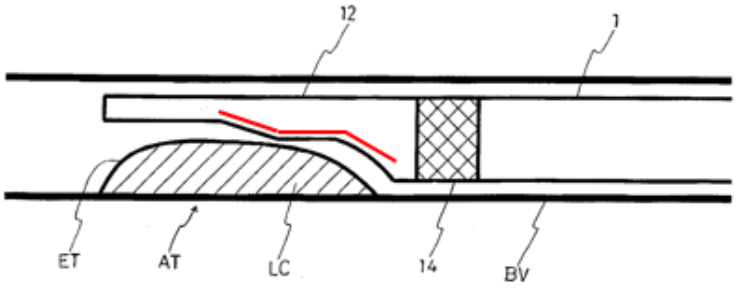


Fig. 10

Compare Ex-1201, Fig. 4 (color added), *with* Ex-1225, Figs. 2, 10; (color added). Ex-1205, ¶ 249; Ex-1242, ¶¶ 116-117; *see also id.* at ¶¶ 49-56.

A POSITA had the motivation to modify the proximal opening of Ressemann's evacuation head so that it was configured to include two different inclined slopes and a non-inclined region 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. Moreover, Ressemann and Kataishi are directed at using a guide catheter and a therapy catheter, such as a balloon catheter, to remove occlusions. Ex-1208, Abstract; Ex-1225, Abstract; Ex-1205, ¶¶ 250-251.

A POSITA had the motivation to modify the proximal end of Ressemann's evacuation head because a POSITA would understand that the evacuation head was configured to receive a stent and balloon catheter. Ex-1208, 6:25-34; Ex-1205, ¶ 252.

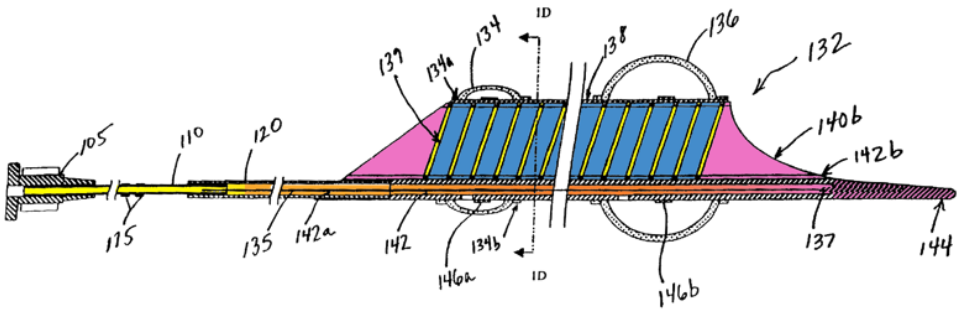


FIG. 1C

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. 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, ¶¶ 49-56, 103-115. As such, POSITA would be motivated to apply Kataishi's distal opening structure to the proximal opening of Ressemann for the reasons set forth below. Ex-1205, ¶ 253.

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, ¶ 254; Ex-1242, ¶ 111. 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); Ex-1205, ¶ 254; Ex-1242, ¶ 111.

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, ¶ 255; Ex-1242, ¶ 114. 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 two different inclined slopes for side opening 140a in order to minimize

kinking and thus improve the crossability of the device by avoiding drag on the inside of the guide catheter. *Id*. at Ex-1242, ¶ 112-114.

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, ¶¶ 115; 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 catheter with the two-inclined side opening disclosed in Kataishi. Ex-1205, ¶ 256. Thus, claim 44 is obvious.

XI. GROUND 5: RESSEMANN RENDERS CLAIM 44 OBVIOUS IN VIEW OF 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)(1), and was not cited or considered during prosecution of the '850 patent. Ex-1202. It is cited on the face of the '379 patent, but was not discussed during prosecution.[13] Ex-1201, 1203. Enger discloses a balloon catheter for use in a

[13] 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-

coronary artery. Ex-1250, Abstract. Ex-1205, ¶¶ 158-162; Ex-1242, ¶¶ 57, 58.

B. Claim 44:

As discussed in §§ VII, VIII, and X, Ressemann anticipates claim 44 or renders it obvious. Ressemann also renders claim 44 obvious in view of Enger. Ex-1205, ¶ 257.

Like Ressemann, Enger is directed to a catheter system for treating occluded coronary arteries. *See supra* § VII; Ex-1250, Abstract, 1:13-15. Like Ressemann's evacuation sheath, Enger's angioplasty catheter is inserted through a guide catheter and into the coronary artery. Ex-1250, 3:25-27. And, like Ressemann's evacuation sheath, Enger's angioplasty catheter is designed to reach deep into the coronary vasculature. *Id*. at 3:9-12.

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

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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).

portion of the catheter that did not have guidewire support tended to "buckle" within the guide catheter. *Id*. at 2:31-38. This would result in friction between the angioplasty catheter and the guide catheter, impairing the ability to deliver the therapy. *Id*. at 2:38-49.

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*. at 4:66-5:11.

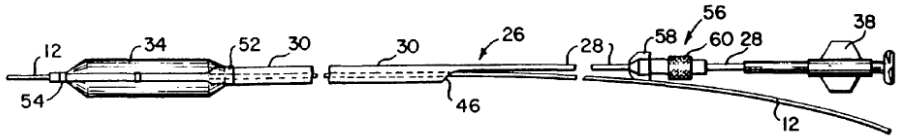


Fig. 1

Id. at Fig. 1.

The catheter is designed to have a short, distally located guidewire lumen incorporated into both the intermediate and distal catheter segments. *Id*. at 3:9-10, 5:34-40.

The proximal opening to the guidewire lumen has at least two inclined slopes.[14]

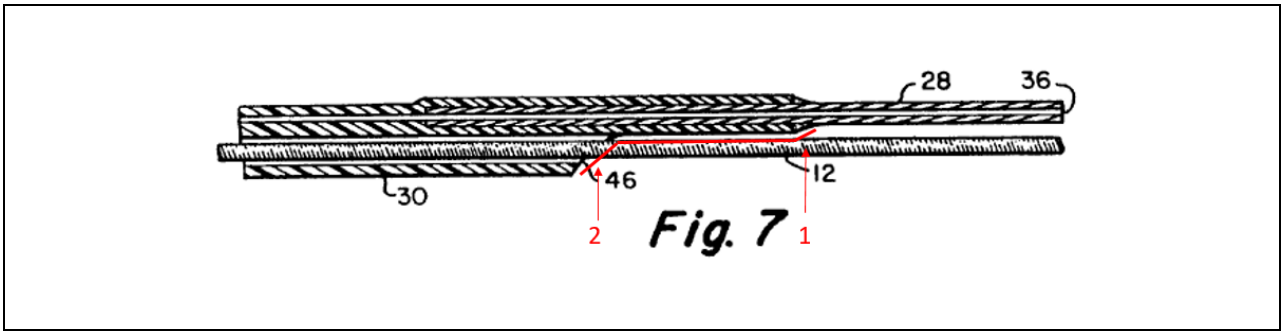


Fig. 7

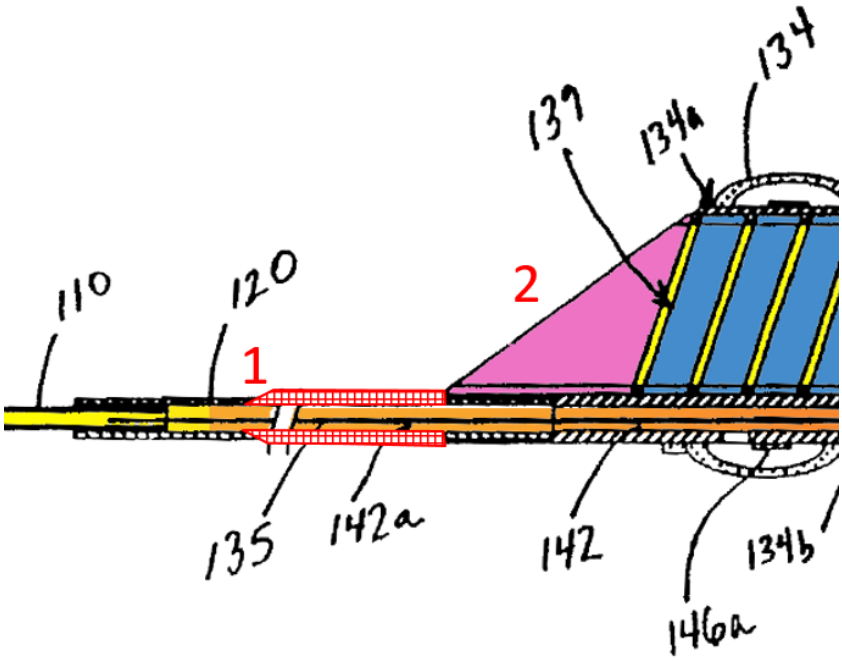
Ex-1250, Fig. 7 (color and annotation added).

Enger's incline #1 functions as a start of an incline to the entry port located at incline #2. This incline functions to guide the interventional device (in this case a guidewire) into its designated lumen. A POSITA would be motivated to provide a first incline to function as an "on-ramp" to guide interventional devices such as a stent and balloon catheter into Ressemann's lumen 140. Ex-1205, ¶ 257.

[14] 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*. at 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*. at 3:25-29.

The first incline of Enger is formed from an inclined polymer collar that grips the pushrod of Enger. Ex-1242, ¶ 121. POSITA would have a reasonable expectation of success in combining these two as a POSITA would understand that the first incline of Enger could be incorporated into Ressemann's evacuation lumen 140 by using a similarly inclined polymer collar to grip wire-like pushrod 25. Ex-1205, ¶ 257; Ex-1242, ¶ 121; *see also id.* at ¶¶ 118-123.

This would result in a two-incline opening as shown schematically in modified Figure 1C of Ressemann. Ex-1205, ¶ 257; Ex-1242, ¶ 121.



Ex-1208, Fig. 1C (annotated and modified).

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

XIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request institution of a trial under 37 C.F.R. Part 42 and cancellation/invalidation of the claims 25-26, 29-45 of the '379 patent as unpatentable under 35 U.S.C. §§ 102 or 103.

XV. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 600615 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

RESPECTFULLY SUBMITTED,

ROBINS KAPLAN LLP

Date: November 12, 2019

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WORD COUNT CERTIFICATION

I hereby certify that this Petition complies with the word count limit, and contains 13,556 words, excluding any Mandatory Notices. I further certify that, in preparation of this Corrected Petition, I used Microsoft Word, Version 2010, and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the word count.

Dated: November 12, 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 12, 2019, by Federal Express mail to the USPTO correspondence address of record listed below:

Paul Onderick
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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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