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Paper No. 20
Date: June 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner.

IPR2020-00133
Patent RE45,760 E

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Medtronic, Inc., and Medtronic Vascular, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 25–42, 44, and 47 of U.S. Patent No. RE45,760 E ("the '760 patent," Ex. 1201). Paper 1 ("Pet."). Teleflex Medical Devices S.A.R.L. ("Patent Owner") filed a Preliminary Response. Paper 10 ("Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply addressing its burden on secondary considerations and reduction to practice, and Patent Owner filed a Sur-Reply addressing Petitioner's burden on those issues. Paper 14; Paper 15. Also pursuant to our authorization, Petitioner filed another Reply (Paper 17), and Patent Owner filed another Sur-Reply (Paper 18) addressing the factors for discretionary denial under 35 U.S.C. § 314(a).

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2012). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has not satisfied its burden under § 314. Thus, we do not institute an *inter partes* review.

A. Real Parties in Interest

Petitioner identifies its real parties-in-interest as Medtronic, Inc. and Medtronic Vascular, Inc., and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies its real parties-in-interest as Teleflex Medical Devices S.A.R.L.; Vascular Solutions LLC; Arrow International, Inc.; and Teleflex LLC. Paper 4, 2. Patent Owner also notes that "Teleflex Incorporated is the ultimate parent of the entities listed above."

B. Related Matters

The ’760 patent is also at issue in IPR2020-00132 and IPR2020-00134. Paper 4, 2–3; Pet. 5. We instituted *inter partes* review in IPR2020-00132 on June 8, 2020. IPR2020-00132, Paper 22.

The parties indicate that the ’760 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 (D. Minn. filed July 2, 2019), and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017). Pet. 5; Paper 4, 2.

The ’760 patent is a reissue of U.S. Pat. No. 8,292,850 (“the ’850 patent). The ’850 patent was the subject of two previous *inter partes* reviews: IPR2014-00762, filed May 16, 2014, and terminated August 11, 2014 by way of joint motion to terminate, and IPR2014-00763, filed May 16, 2014, and terminated August 11, 2014, by way of joint motion to terminate. Pet. 5; Paper 4, 2–3. The ’850 patent was also at issue 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). *Id.*

C. The ’760 Patent

1. Specification

The subject matter claimed in the ’760 patent is directed to a device for use with a standard guide catheter. Ex. 1201, 13:36–17:13. Figures 1 and 5 of the ’760 patent, reproduced below, depict a coaxial guide catheter and a tapered inner catheter.

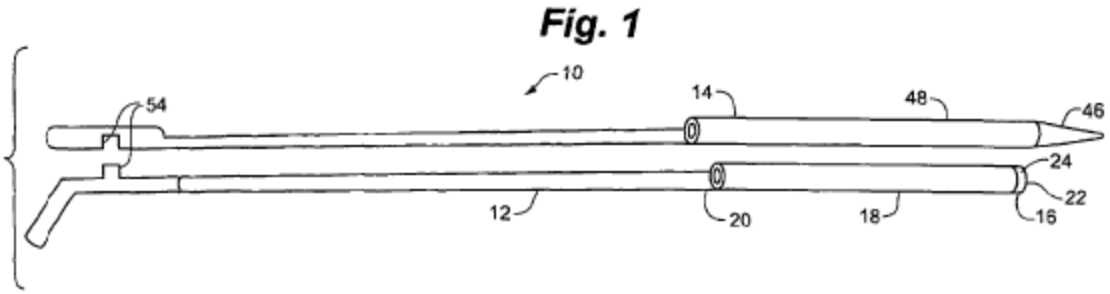


Figure 1 of the ’760 patent

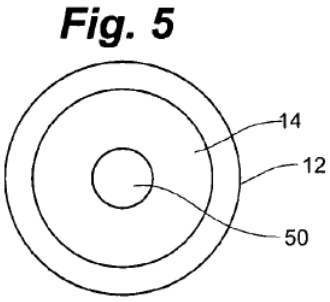


Figure 5 of the ’760 patent

As shown in Figures 1 and 5, above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 generally includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:40–41. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:44–45. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:45–46. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:49–50. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:22–23. Both tapered portion 46 and straight portion 48 are pierced by lumen 50. *Id.* at 7:23–24. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:27–29. Thus, tapered inner catheter 14 is keyed to coaxial guide catheter 12. *Id.* at 7:29–30.

2. Illustrative Claim

Independent claim 25, reproduced below, is illustrative of the challenged claims.

25. A system, comprising:

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

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

the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and *a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter*, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein a material forming the segment defining the side opening is more rigid than the tubular structure.

Ex. 1201, 13:36–14:7 (emphasis added).

D. Evidence

Petitioner relies upon the following prior art references.

Ex. 1208, T. V. Ressemann et al., U.S. Patent No. 7,604,612 B2 (issued Oct. 20, 2009) ("Ressemann").

Ex. 1210, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63: 452-456 (2004) ("Takahashi").

Ex. 1225, Y. Kataishi et al., U.S. Patent Application Publication No. 2005/0015073 A1 (published Jan. 20, 2005) ("Kataishi").

Ex. 1250, C. D. Enger et al., U.S. Patent No. 5,980,486 (issued Nov. 9, 1999) ("Enger").

Petitioner also relies upon the Declarations of Dr. Stephen Brecker (Ex. 1205) and Richard A. Hillstead (Ex. 1242) to support its contentions.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 25–42, 44, and 47 would have been unpatentable on the following grounds.

Ground	Claim(s)	35 U.S.C. §[1]	References/Basis
1	25–42, 44, 47	103(a)	Ressemann, Takahashi, Knowledge of a POSITA
2	32	103(a)	Ressemann, Takahashi, Kataishi, Knowledge of a

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '760 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

Ground	Claim(s)	35 U.S.C. §[1]	References/Basis
			POSITA
3	32	103(a)	Ressemann, Takahashi, Enger, Knowledge of a POSITA

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for several claim terms, including the terms "concave track" and "flexural modulus." Pet. 14–16. Patent Owner responds to Petitioner's proposed constructions by asserting that "no specific construction of claim terms is necessary for the Board to deny the Petition in view of the deficiencies [Patent Owner] identifies" in this Preliminary Response." Prelim. Resp. 14.

At this stage of the proceeding, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Grounds 1–3: Obviousness over the Combination of Ressemann and Takahashi

Each of Petitioner's asserted obviousness grounds rely on the combination of Ressemann, Takahashi, and the knowledge of POSITA. Pet. 17–75. For the reasons set forth below, we determine that Petitioner has failed to demonstrate that the combination of Ressemann and Takahashi disclose the limitation of a "tubular structure defining a lumen coaxial . . . with the lumen of the guide catheter" as required by the challenged claims. Accordingly, we determine that the Petition fails to show a reasonable likelihood that claims 25–42, 44, and 47 would have been obvious.

a) Summary of the References Relied Upon

(1) Ressemann (Ex. 1208)

Ressemann is directed to an apparatus "used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels." Ex. 1208, 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

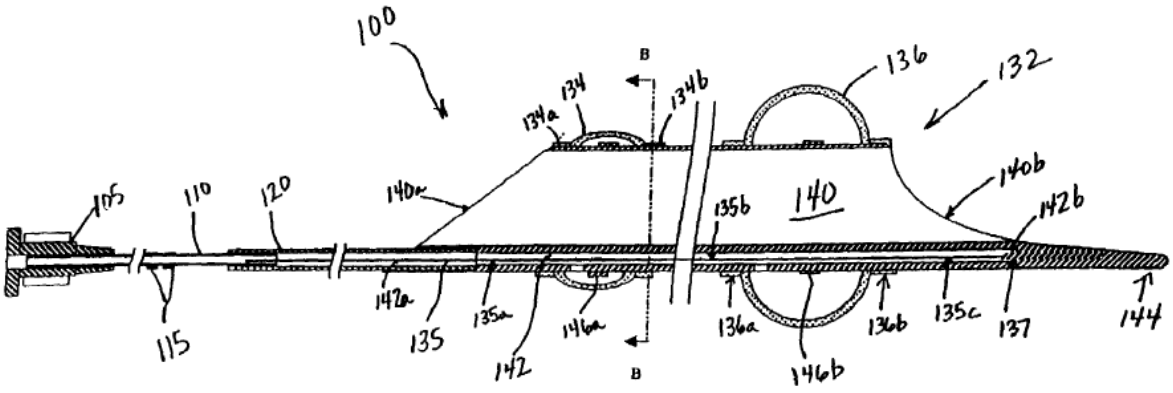


FIG. 1A

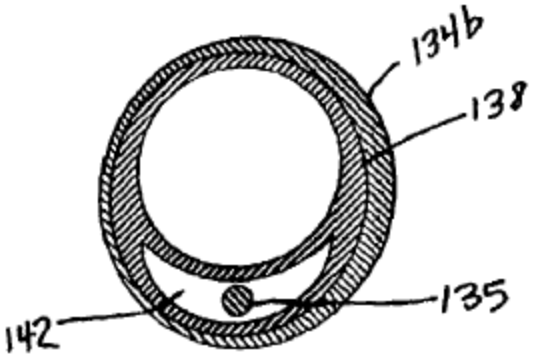


FIG. 1B

Figure 1A is a cross-sectional view of a partial length evacuation sheath. *Id.* at 3:16–18. Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B-1B of Figure 1A. *Id.* at 3:19–20.

Figure 1A depicts evacuation sheath assembly 100, which "is sized to fit inside a guide catheter" and be advanced "into a blood vessel to treat a stenosis." *Id.* at 6:18–24, Fig. 5A. Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35. Evacuation head 132 includes multi-lumen tube 138 having evacuation lumen 140 and inflation lumen 142 and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and "is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters." *Id.* at 6:44–47. Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, "[t]he larger area of

the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly." *Id.* at 6:58–60.

Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, "is located co-axially in the inflation lumen 142," and extends to soft tip 144. *Id.* at 11:30–39. Inflation lumen 142, having open proximal end 142a and closed distal end 142b, is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64.

In use, a guiding catheter is directed to a blood vessel and then a coronary guide wire is advanced to a location just proximal to the distal tip of the guiding catheter. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

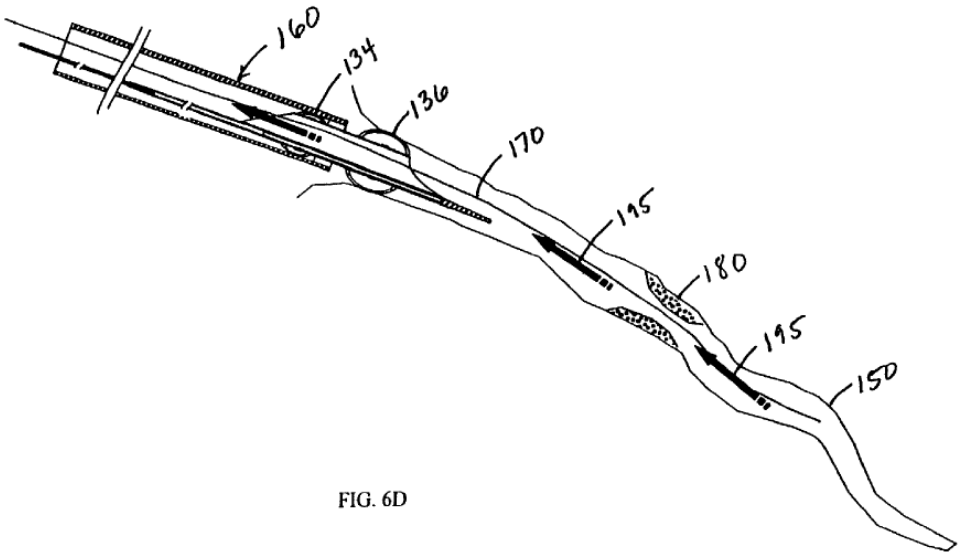


FIG. 6D

Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. Guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, "[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber." *Id.* at 13:43–44.

(2) Takahashi (Ex. 1210)

Takahashi is a journal article entitled "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter." Ex. 1210. It bears a copyright date of 2004. *Id.* at 5. Takahashi discloses a "five-in-six" system wherein a 5 French guiding catheter is inserted into a 6 French guiding catheter to provide increased backup support. *Id.* at 452. In this system, the 5 French catheter is 120 cm in length, whereas the 6 French catheter is 100 cm in length. *Id.* According to Takahashi, the soft end portion of the 5 French catheter "can easily negotiate the tortuous coronary artery with minimal damage and then it can be inserted more deeply into the artery." *Id*.

b) Discussion

To support its position, Petitioner directs our attention to the foregoing discourses of Ressemann and Takahashi and provides a detailed claim analysis addressing how each element of independent claim 25 is disclosed by the combination of references. Pet. 17–40 (citing *generally* Exs. 1205 and 1242).

In particular, Petitioner directs our attention to the following annotated Figure 1A of Ressemann:

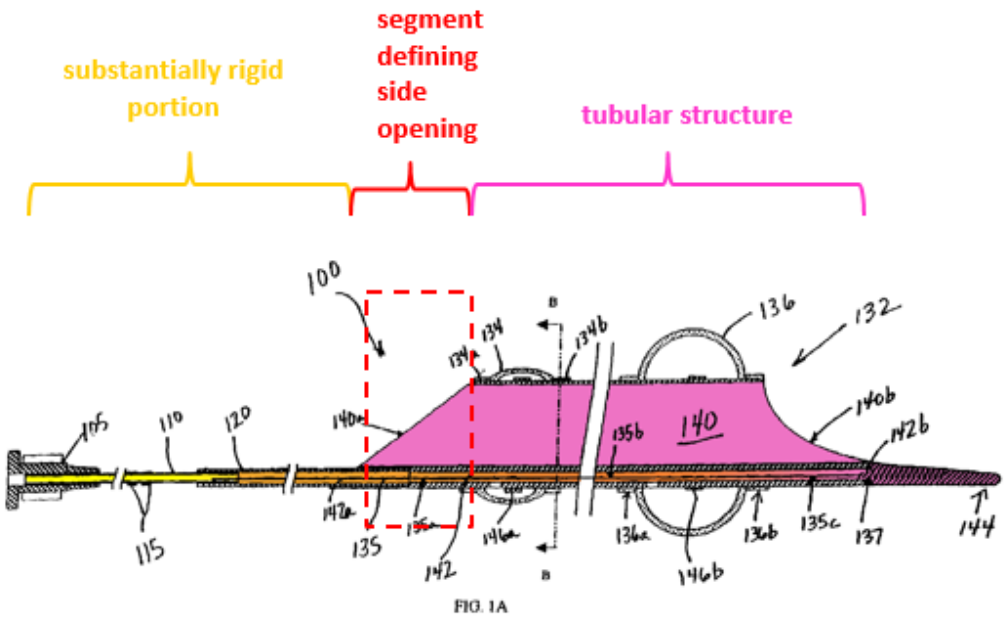


FIG. 1A

Pet. 25; Ex. 1208, Fig. 1A (color and annotations added by Petitioner). As discussed above, Figure 1A is a cross-sectional view of a partial length evacuation sheath disclosed by Ressemann. *Id.* at 3:16–18. With reference to the figure above, Petitioner contends that "Ressemann teaches a guide catheter 160 that is used with an evacuation sheath assembly 100 sized to fit therein." Pet. 21 (citing Ex. 1208, Abstract, 6:18–24, 28:26–29). Petitioner contends that sheath assembly (100) includes proximal shaft (110) and intermediate shaft (120) and that "shaft (110) and shaft (120) are sufficiently rigid to allow evacuation sheath (100) to be advanced within the guide catheter." *Id.* at 25 (citing Ex. 1208, Figs. 1A, 6A–F; Ex. 1205 ¶ 164). Petitioner further contends as follows:

> Ressemann discloses a segment defining a side opening, shown above in a dotted red box. That segment is a portion of evacuation head 132. It includes 140a, which is the proximal opening to the evacuation lumen 140. [Ex. 1208,] 6:35-60.

> Because head 132 includes distal shaft 130, *id*.[] 10:31–35, the segment defining a side opening also includes the portion of shaft 130 that is adjacent 140a.
>
> Distal to opening 140a is a tubular structure, "multi-lumen tube 138," which defines evacuation lumen 140. *Id*., 6:35-47. The claimed "tubular structure" is the portion of the evacuation lumen 140 that is distal to 140a. 9 Ex. 1205, ¶ 164.

Id. at 25–26 (footnote omitted). Thus, with respect to the requirement for a "guide extension catheter" including a "tubular structure defining a lumen coaxial . . . with the lumen of the guide catheter," Petitioner relies on the disclosure of Ressemann's evacuation lumen 140 and contends that "lumen (140) is coaxial and in fluid communication with the lumen of the guiding catheter (160)." Pet. 26–27 (citing Ex. 1205 ¶ 164).

Patent Owner contends that Petitioner's assertion that lumen (140) is coaxial and in fluid communication with the lumen of the guiding catheter (160) is incorrect. Prelim. Resp. 26 (citing Pet. 26–27; Ex. 1205, ¶ 164). In contrast, Patent Owner contends that Ressemann's evacuation lumen 140 is part of a multi-lumen tube consisting of offset lumens. *Id.* at 26–27. To that point, Patent Owner directs our attention to, *inter alia*, annotated Figure 1B and an annotated portion of Figure 6C, both reproduced below. *Id.* at 27.

Fig. 6C

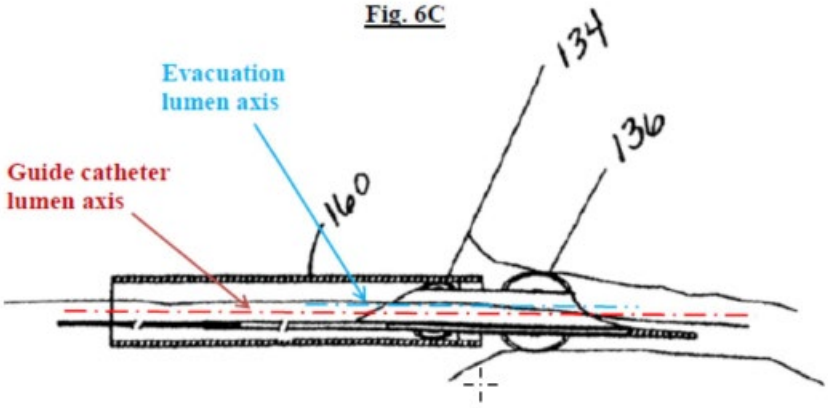
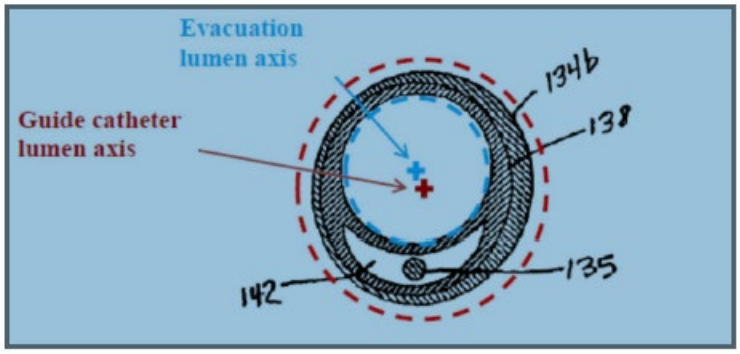


Fig. 1B



Ressemann discloses that Figure 6C is a "cross-sectional view[] of the partial length evacuation sheath of FIGS. 1A and 1B as employed in a method according to one aspect of the present invention." Ex. 1208, 3:59–61. Ressemann discloses that "FIG. 1B is a cross-sectional view of the partial length evacuation sheath taken along line 1B-1B of FIG. 1A." *Id.* at 3:19–20 (color and annotations added by Patent Owner).

According to Patent Owner, "Figures 1B and 6C show that the longitudinal axis of Ressemann's evacuation lumen 140 is offset from that of the guide catheter 160." Prelim. Resp. 27. Thus, according to Patent Owner, Ressemann "does not disclose 'a tubular structure defining a lumen *coaxial* . . . with the lumen of the guide catheter,' as recited by claim 25." *Id.* at 27–28.

Having considered the parties positions and evidence of record, summarized above, we are persuaded by Patent Owner's arguments that the Petition fails to sufficiently establish that Ressemann discloses "a tubular structure defining a lumen coaxial . . . with the lumen of the guide catheter" as required recited by claim 25 and dependent claims thereto. In particular, we are persuaded that Ressemann discloses that evacuation lumen 140 is offset from that of the guide catheter 160, and thus the lumen of the evacuation lumen 140 is not disclosed as being coaxial to the lumen of the guide catheter 160. The Petition fails to sufficiently account for that difference identified by Patent Owner.

In view of the above, we determine that Petitioner has not established a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 25–42, 44, and 47 based on the combination of Ressemann and Takahashi. Consequently, each of Petitioner's Grounds 1–3 fail.

III. CONCLUSION

Petitioner has failed to establish a reasonable likelihood of prevailing in demonstrating that claims 25–42, 44, and 47 would have been obvious over the combinations of prior art set forth in the asserted grounds.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no trial is instituted.

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