

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01025
U.S. Patent No. 11,974,910

PATENT OWNER'S PRELIMINARY RESPONSE

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EX1001	U.S. Patent No. 11,974,910 ("the '910 patent")
EX1002	'910 Patent Prosecution History
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog")
EX1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. ("Garrison")
EX1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. ("Goff")
EX1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley ("Hartley")
EX1009	U.S. Patent No. 6,776,770 B2 to Trerotola ("Trerotola")
EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. ("Heaton")
EX1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub ("Laub")
EX1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. ("Schaffer")
EX1014	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
EX1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1016	U.S. Patent No. 7,998,104 B2 to Chang ("Chang")
EX1017	U.S. Patent No. 8,157,760 B2 to Criado et al. ("Criado")
EX1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
EX1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.

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EX1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
EX1021	U.S. Patent Application No. 16/117,519 (the "519 application")
EX1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
EX1023	Resume of Dr. Aquilla Turk, III, D.O.
EX1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
EX1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
EX1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
EX1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
EX1028	April 24, 2024 Letter from Inari to Imperative Care
EX1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
EX1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
EX1031	U.S. Patent No. 9,980,813 B1 to Eller ("Eller")
EX1032	US 2018/0064453 A1 ("Garrison II")
EX1033	US 2005/0054995 A1 ("Barzell")

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EX1034	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
EX1035	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
EX1036	U.S. Patent No. 12,109,384 B2 to Merritt et al.
EX1037	Patent Owner's Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
EX1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) ("Indigo Aspiration System")
EX1039	AXS Universal Aspiration Set Brochure (2017)
EX1040	VacLok Negative Pressure Syringe Brochure
EX1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) ("Nikoubashman")
EX1042	Inari's Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24- cv-3117 (N.D. Cal.) (served February 7, 2025)
EX1043	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
EX1044	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
EX1045	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)

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EX1046	U.S. Patent No. 7,984,730 B2 to Ziv et al.
EX1047	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
EX1048	Imperative Care's Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
EX1049	Ahmed Pasha et al., Successful Management of Acute Massive Pulmonary Embolism Using Angiovac Suction Catheter Technique in a Hemodynamically Unstable Patient, 15 Cardiovasc. Revasc. Med. 240-243 (2014)
EX1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 Cardiovasc. Diagn. Ther. 599-611 (2016)
EX1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
EX1053	Claim Construction Expert Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

Patent Owner's Exhibits	
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EX2001	Notice of Allowance from U.S. Patent Application No. 18/329,450
EX2002	U.S. Patent Application Publication No. 2018/0042623 to Batiste ("Batiste")
EX2003	Declaration of Brian Brown
EX2004	Mirza, M., Kummer, K., Touchette, J., McCarthy, R., Rai, A., Brouwer, P., & Gilvarry, M. (2024). Variability in Intracranial vessel Diameters and Considerations for Neurovascular Models: A Systematic Review and Meta-Analysis. <i>Stroke Vascular and Interventional Neurology</i> , 4(4). https://doi.org/10.1161/svin.123.001177

I. INTRODUCTION

Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-8, 11-15, and 18-20 (“the Claims”) of the ’910 Patent are unpatentable.¹ As explained herein, the Claims are directed to innovations pioneered by patentee that are not disclosed or obvious in view of the prior art. The Patent Office agreed—expressly finding the Claims patentable over Petitioner’s primary reference Garrison in both the sole Office action and the Notice of Allowance explaining that it “would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.” EX1002, p.49; *see also id.* (“Garrison ... fails to teach a [‘]clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient’ and ‘wherein the second catheter has a size of 16 French or greater’”), p.377 (Garrison fails to disclose “‘a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source’”).

Specifically, the ’910 Patent is directed to improved clot treatment systems for removing clot material, and specifically pulmonary embolism (PE), from a blood vessel of a human patient. EX1001, 4:17-19; EX2003, ¶36. PE is a life-threatening condition that occurs when a clot becomes lodged in the arteries of the lungs,

¹ The Petition does not assert that Claims 9-10 and 16-17 are unpatentable.

blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:57-67; EX2003, ¶32. The clot treatment systems of the '910 Patent generate and build up (e.g., pre-charge) vacuum pressure before applying that vacuum pressure to an aspiration catheter positioned near a PE in a patient's blood vessel to generate large suction forces (and corresponding fluid flow velocities) needed to effectively aspirate and remove the PE from the patient. EX1001, 4:34-50; EX2003, ¶36. The suction forces generated and corresponding fluid flow velocities due to the pre-charged vacuum are greater than conventional systems allowing the systems to more effectively remove PE, even when the PE is strongly lodged or attached within the blood vessel (e.g., chronic PE). EX1001, 4:42-47, 10:14-27; EX2003, ¶36.

That buildup and subsequent application of vacuum pressure to treat PE is integral to the Claims of the '910 Patent, which are directed to systems for removing a PE from the vasculature of a patient. Specifically, the Claims recite “a first clot aspiration assembly” and “a second clot aspiration assembly.” EX1001, cls.1, 11. The “first clot aspiration assembly” includes “a first catheter” and “a first pressure source” to “generate vacuum pressure” in the first catheter, and the “second clot aspiration assembly” similarly includes “a second catheter” and a “second pressure source” to generate vacuum pressure in the second catheter. *Id.* The second catheter is “advanceable through the first catheter.” *Id.*

The second pressure source is connected to the second catheter via a “fluid control device” (for example, a stopcock or fluid control valve) that is closed when vacuum pressure is generated by the second pressure source and subsequently opened to apply the built-up (i.e., pre-charged) vacuum to the second catheter “to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.” *Id.* That is, the second clot aspiration assembly is arranged and operated to apply a pre-charged vacuum through the second catheter to remove the PE. The second catheter of the second clot aspiration assembly “has a size of 16 French or greater” (meaning that the first catheter through which the second catheter is advanced through must be larger). This facilitates high flow rates that more effectively aspirate the PE even when it is strongly adhered within the blood vessel. *Id.* at cl.1, cl.11, 9:36-10:27; EX2003, ¶39. In Claim 1, the first clot aspiration assembly is similarly connected to the first catheter via a “fluid control device” that is closed when vacuum pressure is generated by the first pressure source and subsequently opened to apply the built-up vacuum to the first catheter. *Id.* at cl.1.

Here, Petitioner relies on what it terms an “optimized” Garrison for disclosing all the features of independent Claims 1 and 11 except “for treating clot material comprising a pulmonary embolism” and wherein the second (e.g., inner telescoping) catheter “has a size of 16 French or greater.” But as explained below, Garrison does not disclose all the other claim limitations, and a POSA would not have modified

Garrison to arrive at the purported “optimized” version in the first instance, let alone to treat PE with a catheter having “a size of 16 French or greater” as claimed.

As the Petition recognizes, in contrast to the Claims of the '910 Patent, Garrison's clot treatment system is used “to remove cerebral clots [and] does not expressly mention PEs.” Petition, p.5. As such, Garrison discloses much smaller catheter sizes from the claimed 16 French catheter size, namely, “6 French” or “8 French” to access those cerebral clots. EX1006, ¶¶[0063], [0066].

Again as the Petition recognizes, there are many challenges when moving from smaller to larger catheters including that “a larger catheter ‘may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.’” Petition, p.33 (citing Aklog, EX1005, 7:23-26). So, the Petition continues, “Aklog explains that the solution to using larger catheters is to reinfuse the ‘fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient.’” *Id.* (citing EX1005, 7:47-52). Indeed, both Aklog and Laub disclose the need for blood return when treating PE with large bore catheters having high flow rates. EX1012, ¶[0045] (“Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.”); EX1005, 7:23-26 (“If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an

unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.”).

But, Garrison itself discloses that each of the embodiments of Garrison that Petitioner asserts a POSA would modify and combine to arrive at the purported “optimized” Garrison, are *incompatible* with that blood return. EX1006, ¶[0135] (“One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient.”). Specifically, Petitioner relies on an embodiment in Garrison where a syringe is connected directly to a flow controller to “enable the maximum level of aspiration.” Petition, pp.38-39; EX1006, ¶[0134]. But as explained above, Garrison discloses that that embodiment is not compatible with blood return—the blood is discarded rather than returned. EX1006, ¶[0135]. Accordingly, a POSA would not have modified Garrison in a manner inconsistent with blood return when combining Garrison with Aklog and Laub.

Moreover, Petitioner picks and chooses features of various embodiments in Garrison to manufacture its purported “optimized” system (Petitioner’s purported demonstrative illustration of Figure 33 showing two of the valves from Figure 34 incorporated into the system of Figure 33) that Garrison *does not disclose* and that is contrary to both Garrison and a system for “for treating clot material comprising

a pulmonary embolism” and wherein the second (e.g., inner) catheter “has a size of 16 French or greater,” which Petitioner admits is missing in Garrison.

Specifically, Garrison does not disclose or suggest the “first fluid control device” or the second “fluid control device” recited in independent Claim 1, or the “fluid control device” recited in independent Claim 11. So, Petitioner manufactures a “demonstrative illustration” not found in Garrison that modifies Garrison’s Figure 33 to import two valves that are each the same as the single valve shown in Figure 34. Petition, p.51; see also *id.* at p.72 (relying on the same demonstrative regarding independent Claim 11). But, a POSA would not have included valves in the system of Figure 33 at all, let alone the valve from Figure 34 in a system for treating PE with large-bore 16 French and larger catheters. In particular, doing so (1) would not provide increased control or function different from simply operating Garrison’s peristaltic pumps, (2) would provide dangerous flow paths for sucking air into the system through an unconnected port of the valves that could be reinfused into the patient to cause an air embolism, and (3) would not enable a “maximum level of aspiration.” EX2003, ¶¶71-88.

Similarly, Garrison does not disclose or suggest the buildup/subsequent release of vacuum pressure recited in Claims 1 and 11 (i.e., “[generating] vacuum pressure while the ... fluid control device is in the first position” and “wherein, upon movement of the ... fluid control device from the first position to the second

position, the vacuum pressure is applied to the ... catheter to generate suction at the distal portion of the ... catheter”). Instead, Petitioner relies on a different embodiment in Garrison where a syringe is connected directly to a flow controller to “enable the maximum level of aspiration.” As explained above, Garrison itself discloses that that embodiment and the other embodiments relied on by Petitioner are not compatible with blood return. EX1006, ¶¶[0135]. Accordingly, a POSA would not have modified Garrison in a manner inconsistent with blood return when “upsizing” Garrison in view of Aklog and Laub that both explain the importance of blood return.

Finally, a POSA would not have upsized Garrison’s catheters to “16 French or greater” as recited in independent Claims 1 and 11 because such a modification would render Garrison’s system inoperable for its intended purpose of treating a cerebrovascular clot, and more particularly, it would render Garrison unsuitable for treating clots in the middle cerebral artery as shown in, for example, Figures 33-34 of Garrison relied on by Petitioner. EX2003, ¶¶102-105. Put simply, when modified to have catheters at least twice as large and with four times or more cross-sectional area as Petitioner suggests, those catheters would be too large to fit into cerebral vessels and would damage those vessels if they were inserted therein. *Id.* That Petitioner’s proposed combination would render Garrison inoperable for its intended purpose is strong evidence of non-obviousness.

Accordingly, grounds 1-3 do not render Claims 1 or 11 obvious for the reasons set forth in detail below. Grounds 4-9 pertain only to additional limitations of the dependent claims, and fail for the same reasons as grounds 1-3. Petitioner has therefore failed to demonstrate that any of the Claims are unpatentable under any of grounds 1-9.

II. BACKGROUND

A. Overview of the '910 Patent

Patent Owner is the world's leading developer of aspiration-based mechanical thrombectomy devices that treat PE, and has pioneered the use of the systems claimed in the '910 Patent including large-bore telescoping catheter systems. For example, Patent Owner's FlowTrievers line of products that have been and are currently offered by Patent Owner to treat at-risk patients were the first FDA-approved aspiration-based mechanical thrombectomy systems for treating PE.²

The '910 Patent is directed to improved clot treatment systems for removing clot material, and specifically pulmonary embolism (PE), from a blood vessel of a human patient. EX1001, 4:17-19; EX2003, ¶36. PE is a common and particularly dangerous type of venous thromboembolism (VTE) caused by blood clot formation in the veins of the body that can migrate and cause occlusions in the lungs; VTE is,

²See <https://www.inarimedical.com/flowtriever-system>.

unfortunately, a leading cause of both death and disease worldwide. EX1001, 1:45-67; EX2003, ¶29. PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs, blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:57-67; EX2003, ¶32.

PE has traditionally been treated with drugs (thrombolytic agents) or invasive surgeries. EX1001, 2:1-33; EX2001, ¶33. However, those approaches have significant drawbacks. For example, thrombolytic agents do not always work, take hours or even days to be successful, can cause hemorrhage of the blood vessel, and cannot be used at all in many patients. EX1001, 2:26-32; EX2003, ¶¶33-35. Invasive surgical procedures involve exposing a patient to surgery and may be traumatic to the patient. EX1001, 2:9-11. Even today, most commercially available treatment systems do not use the type of aspiration described in the '910 Patent, instead employing a multitude of alternative solutions that have varying disadvantages. EX2001, ¶36.

The '910 Patent discloses various aspiration systems that generate and build up vacuum pressure before applying that vacuum pressure to an aspiration catheter positioned near clot material (e.g., PE) in a patient's blood vessel to generate large suction forces (and corresponding fluid flow velocities) to effectively aspirate and remove the clot material from the patient. EX1001, 4:34-50; EX2003, ¶36. The generated suction forces and corresponding fluid flow velocities are greater than

conventional systems allowing the aspiration system to more effectively remove the clot material, even when the clot material is strongly lodged or attached within the blood vessel in the instance of, for example, chronic PE. EX1001, 4:42-47, 10:14-27; EX2003, ¶36.

Such buildup and application of vacuum pressure is integral to the Claims of the '910 Patent, which are directed to clot treatment systems for removing a PE from the vasculature of a patient including a first clot aspiration assembly and a second clot aspiration assembly. EX1001, cls.1, 11. The first clot aspiration assembly includes a first catheter and a first pressure source for generating suction in (i.e., aspirating) the first catheter, and the second clot aspiration assembly similarly includes a second catheter and a second pressure source for generating suction in (i.e., aspirating) the second catheter. *Id.* The second catheter is advanceable (i.e., insertable) through the first catheter. *Id.* The second catheter has a distal portion that is positioned proximate the PE in the vasculature of the patient. *Id.*

The second pressure source is connected to the second catheter via a fluid control device (e.g., stopcock) that is closed while vacuum pressure is generated and built up by the second pressure source and subsequently opened to apply the built-up (i.e., pre-charged and stored) vacuum to the second catheter to aspirate blood and at least a portion of the PE into the second catheter and out of the patient. *Id.* That is, the second clot aspiration assembly is operated to apply a pre-charged vacuum

through the second catheter to effectively remove the PE. The second catheter of the second clot aspiration assembly has a size of 16 French or greater to, for example, facilitate high flow rates that effectively aspirate the PE even when it is strongly adhered within the blood vessel. *Id.* at cl.1, cl.11, 9:36-10:27; EX2003, ¶39. In Claim 1, the first clot aspiration assembly is similarly connected to the first catheter via another fluid control device that is closed when vacuum pressure is generated and built up by the first pressure source and subsequently opened to apply the built up vacuum to the first catheter. EX1001, cl.1.

Figure 11 of the '910 Patent illustrates an example of such a system for treating PE having a first clot aspiration assembly 20 and a second clot aspiration assembly 30 advanced through the first clot aspiration assembly 20:

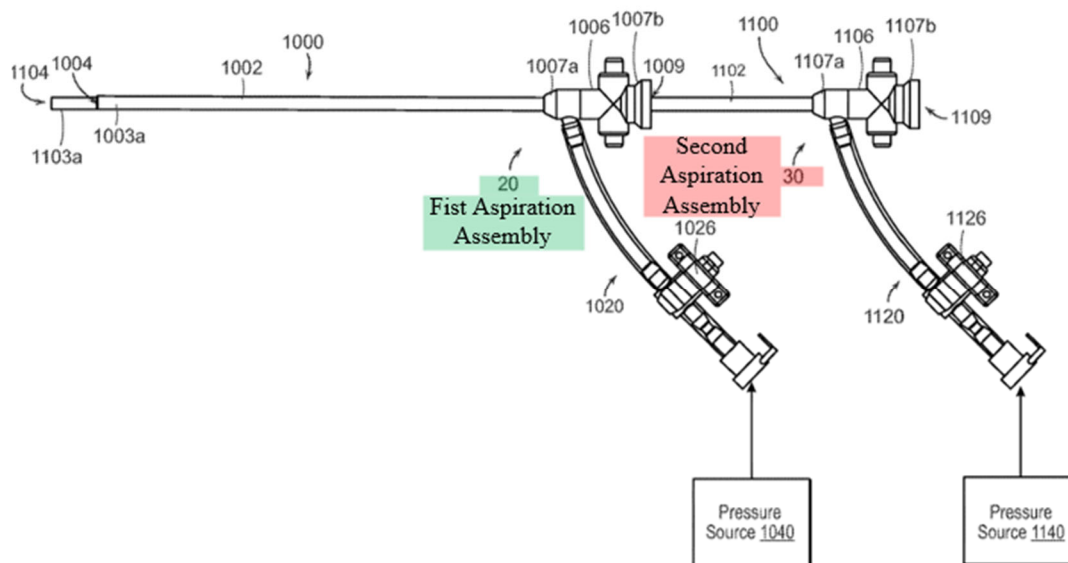


FIG. 11

EX2003, ¶40. The first clot aspiration assembly 20 includes a first catheter 1002 connected to a first pressure source 1040 via a first fluid control device 1026, and the second clot aspiration assembly 30 has a second catheter 1102 connected to a second pressure source 1140 via a second fluid control device 1126:

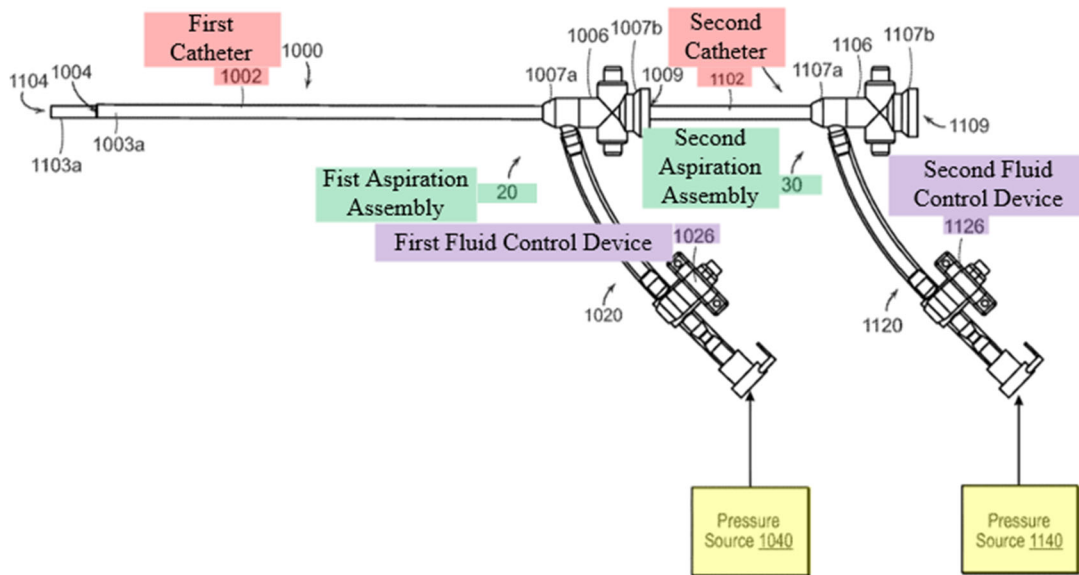


FIG. 11

Id.

As shown in Figure 13A of the '910 Patent, a distal portion 1103a of the second catheter 1102 is advanced through the first catheter 1002 and intravascularly positioned proximate to a PE:

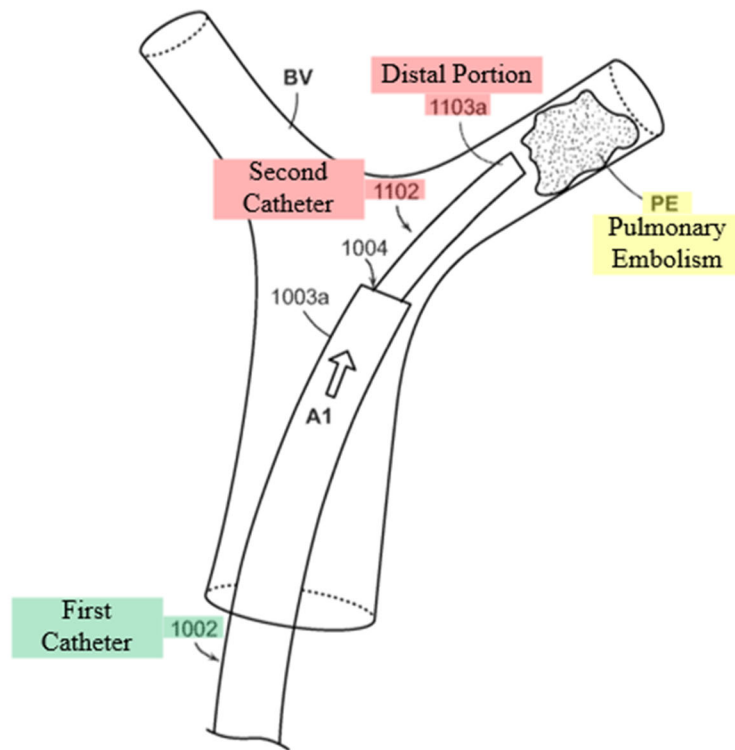


FIG. 13A

Id. at ¶41. The second pressure source 1140 is then activated to generate vacuum pressure while the second fluid control device 1126 is closed to “build-up or pre-charge a vacuum for subsequent application to the second catheter 1102.” EX1001, 23:21–29; EX2003, ¶41. That built-up vacuum pressure is then applied to the second catheter 1102 by opening the second fluid control device 1126 to aspirate at least a portion of the PE into the second catheter 1102 as shown in Figure 13B:

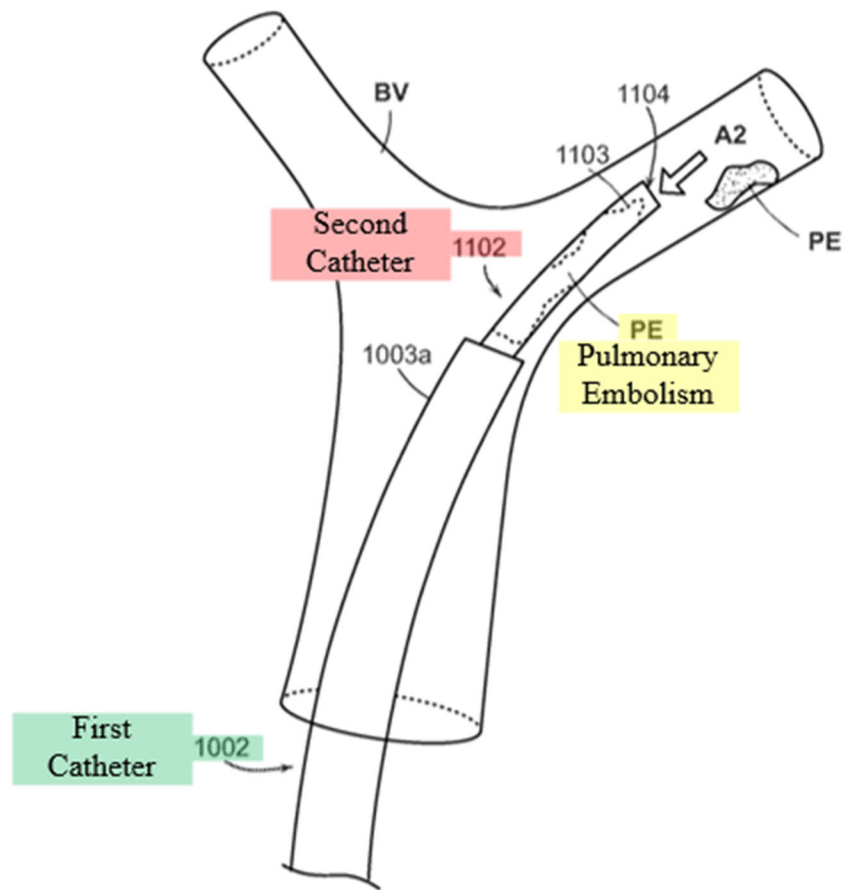


FIG. 13B

EX1001, 23:30-40; EX2003, ¶41. The '910 Patent explains that “pre-charging or storing the vacuum before applying the vacuum to the lumen 1104 of the second catheter 1102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 1103a of the second catheter 1102 compared to simply activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102.” EX1001, 23:40-47; EX2003, ¶41.

The first pressure source and second pressure source can either be a pump, or alternatively a different pressure source such as a syringe: “the pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user ... to generate and store a vacuum therein.” EX1001, 7:36-41; EX2003, ¶42.

B. Prosecution History

Garrison was the primary reference relied on by the Examiner during prosecution of the '910 Patent, and, after extensive consideration and analysis, the Examiner allowed independent Claims 1 and 11 over Garrison. For example, in the sole non-final Office action mailed November 6, 2023, the Examiner relied on Garrison to reject original independent claim 18 as anticipated under 35 U.S.C. § 102(a)(1). EX1002, p.375. In that same Office action, the Examiner found then-pending independent claims 1 and 11 (which matured into issued Claims 1 and 11 of the '910 Patent challenged here) to be allowable over Garrison because Garrison fails to disclose “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source’.” *Id.* at p.377.

In response to the Office action, Patent Owner canceled independent claim 18 and further distinguished Garrison by amending independent claims 1 and 11 to

narrow those allowed claims to clot treatment systems “for treating clot material comprising a pulmonary embolism” and wherein the second (e.g., inner) catheter “has a size of 16 French or greater” and “is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism.” *Id.* at pp.142-145. In the response, Patent Owner explained that:

[I]ndependent claims 1 and 11, as amended, are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related U.S. Patent Application No. 18/329,450, and specifically the Examiner's comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that “Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art Garrison.”

Id. at pp.147-148. That is, Patent Owner substantively addressed the disclosure of Garrison in a videoconference interview with the same Examiner in a related application claiming similar subject matter, and further narrowed the allowed claims by amendment based on discussions with the Examiner about Garrison.

Following that amendment, the Examiner agreed and further explained why the claims are patentable over Garrison in the Notice of Allowance:

Claims 1 and 11 are allowable for reciting, inter alia, “a clot treatment system for treating clot material comprising a pulmonary embolism in

the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”.

Garrison (US 20150173782 A1) ... fails to teach a [“]clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”. The clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms. There is no prior art that teaches all of the limitations. Therefore, claims 1 and 11 are allowable.

Id. at p.49.

Accordingly, Garrison—Petitioner’s primary reference—was considered and applied by the Examiner during prosecution, who expressly explained that Claims 1 and 11 were patentable over Garrison in both the sole Office action and in the Notice of Allowance.

Although Aklog itself was not cited in an information disclosure statement, Aklog’s parent (EX1019) was considered and includes disclosure that is identical to the only portions of Aklog relied upon in the Petition. EX1002, p.1123 (information disclosure statement identifying Aklog’s parent, EX1019). Aklog is a continuation-in-part of Aklog’s parent. EX1005, p.1. The only additional disclosure in Aklog over Aklog’s parent is found in column 18, line 56 to column 20, line 27 of Aklog. That

portion of Aklog describes using the system already disclosed in Aklog's parent to capture vegetative growths disrupted during another procedure, such as the removal of a pacemaker lead. That disclosure is not related to the claims of the '910 Patent and is not cited or relied upon in the Petition.

While Laub was not cited during prosecution, as explained below, Laub's system is substantively the same as Aklog and Aklog's parent.

C. Person of Ordinary Skill in the Art

Petitioner asserts that a POSA has "an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment." Petition, p.18. This is insufficient to qualify as a POSA. EX2003, ¶47. Nevertheless, Patent Owner applies Petitioner's definition herein as, even under this definition, Petitioner has failed to meet its burden.

D. Claim Construction

Petitioner proposes a claim construction for a single term, "filament," recited in dependent Claim 7. Petition, p.19. This claim construction issue is not germane to Patent Owner's arguments here, and it is therefore not necessary at this time to analyze that claim term. Patent Owner reserves the right to construe "filament" or

any other term according to its plain and ordinary meaning during the trial phase, if needed.³

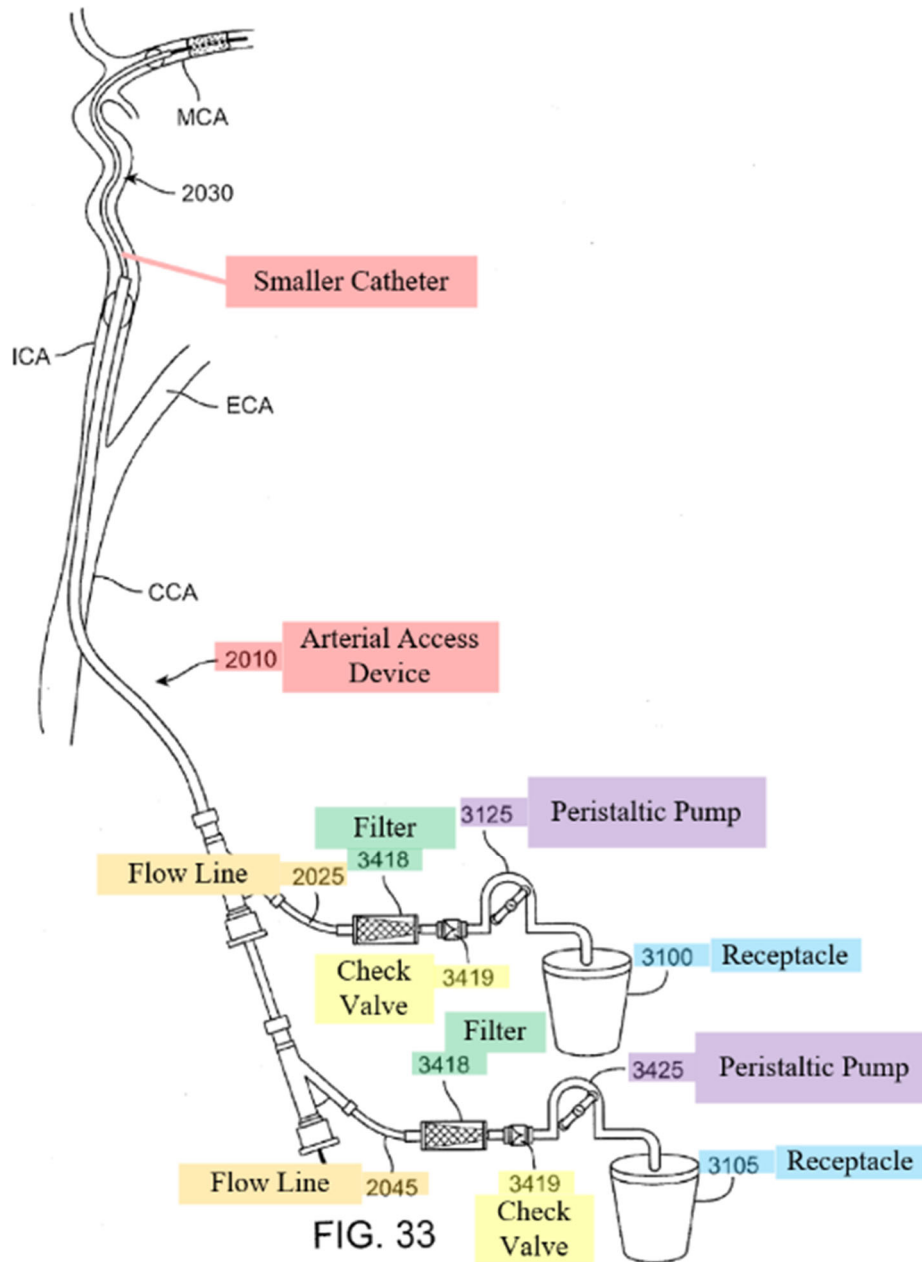
E. Petitioner's References

1. Garrison

Garrison is directed to systems for treating acute ischemic stroke caused by small cerebral clots in the cerebral arterial vasculature rather than, for example, treating large clots (e.g., PE) in the venous vasculature that is much larger in diameter than the cerebral vessels, as described in the '910 Patent. EX1006, ¶[0002]; EX2003, ¶49. For example, Figure 33 (annotated below) of Garrison shows an arterial access device 2010 that provides access to the common carotid artery (CCA), and a smaller catheter 2030 inserted (e.g., telescoped) through the arterial access device 2010 such that a distal tip of the catheter 2030 is positioned in the middle cerebral artery (MCA) where the clot to be treated is located. EX1006, ¶[0131]; EX2003, ¶49. The arterial access device 2010 is connected to a flow line 2025, which

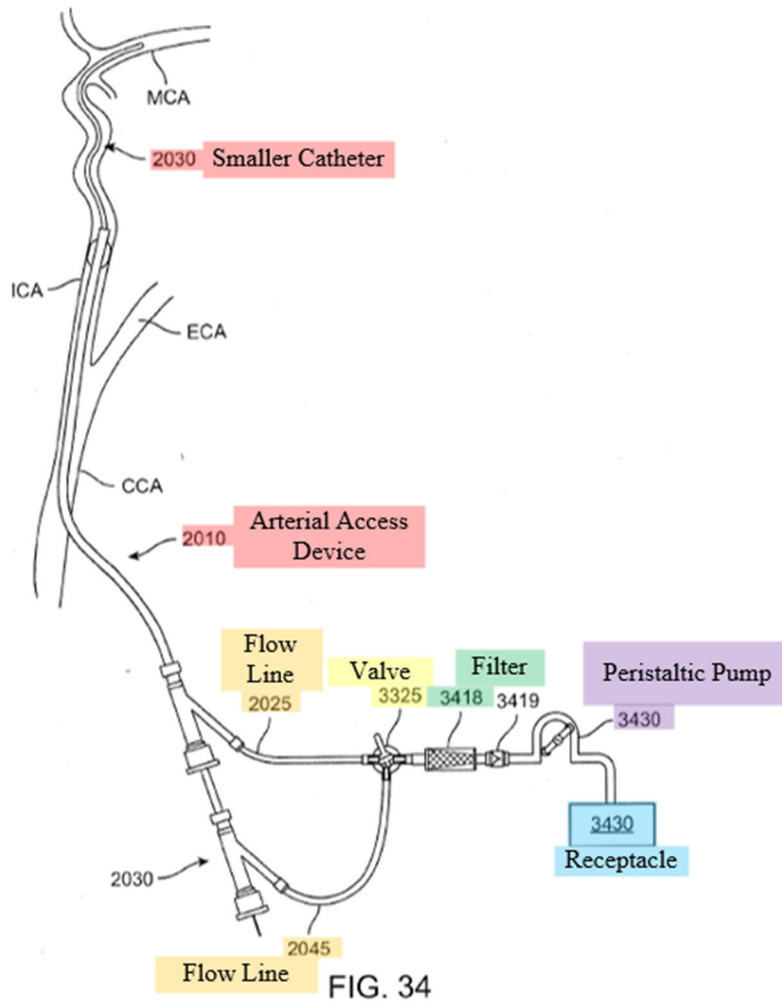
³ Petitioner has proposed the same construction for the term “filament” here as it did in IPR2025-00289 (Paper 10 for related U.S. Patent No. 11,554,005). The construction of the term there mattered to the arguments presented in opposition to the Petition there, so Patent Owner provided its views on the proper construction of this term in IPR2025-00289 (Paper 16).

can be connected in series to a filter 3418, a check valve 3419, a source of aspiration 3125 (a peristaltic pump), and a receptacle 3100, respectively. *Id.* The smaller inner catheter 2030 is similarly connected to a flow line 2045, a filter 3418, a check valve 3419, a source of aspiration 3425 (a peristaltic pump), and a receptacle 3105. *Id.*



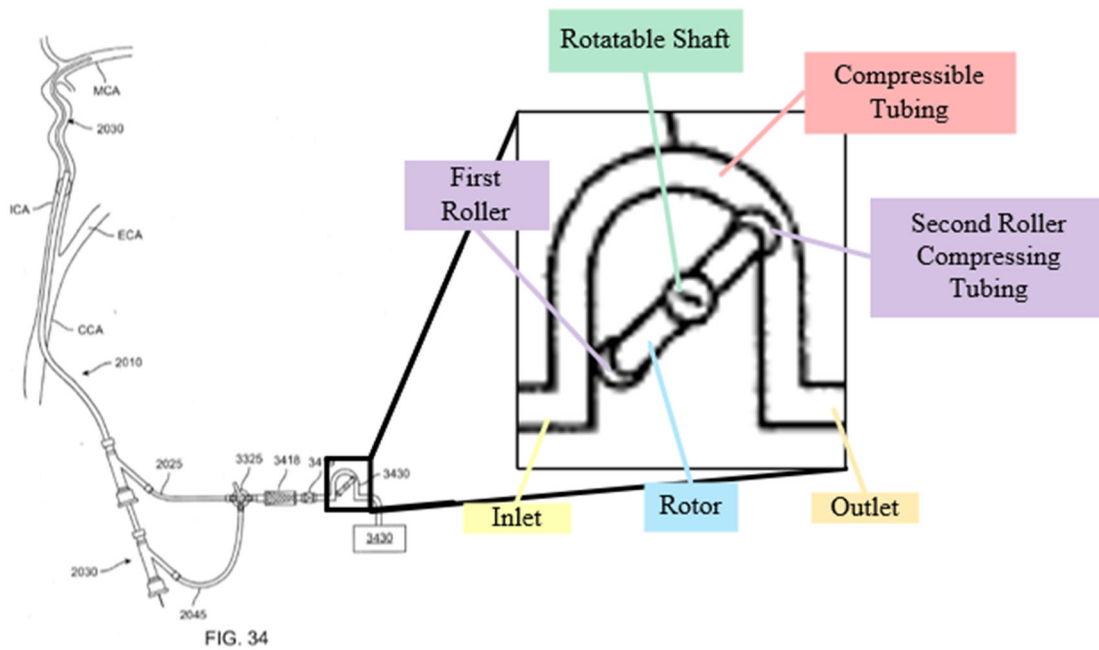
EX2003, ¶49. As can be seen above, Figure 33 does not include any fluid control device, flow controller, or valve in either flow path between the peristaltic pumps and connected catheter would allow for building up and then releasing vacuum pressure.

Figure 34 of Garrison (annotated below) shows a similar system in which “both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively.” *Id.* at ¶[0132]; EX2003, ¶50. A “valve 3325 controls which device is connected to the aspiration source 3430 [t]he valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Downstream of the aspiration source 3430 is a receptacle. EX2003, ¶50.



Id.

The aspiration sources 3125/3425 in Figures 33-34 are peristaltic pumps based on their depiction including compressible tubing and a rotatable shaft connected to a rotor that carries multiple rollers for compressing the tubing:



EX2003, ¶51. A POSA would understand that each of the peristaltic pumps are a positive displacement pump that operates by rotating the shaft to rotate the rotor such that the rollers compress and seal the tubing during passes along the length of the tubing, alternating the compression and relaxation of the tubing, and drawing content in and propelling product away from the pump to: (1) generate negative pressure to draw fluid through one or both of the flow lines 2025/2045 through the inlet of the pump, (2) transport the fluid through the pump, and (3) expel the fluid through the outlet of the pump for delivery to the receptacle 3430. *Id.*

Garrison discloses a different embodiment (“one embodiment”) of a syringe-based system in which “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position

by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure.” EX1006, ¶[0134]; EX2003, ¶53. When the syringe is used in that one embodiment, the syringe is attached directly to the flow controller (e.g., valve). EX2003, ¶53. Then, “[d]uring the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe ... [t]his would enable the maximum level of aspiration in a rapid fashion with one user.” EX1006, ¶[0134]. In that embodiment, the locking syringe is actuated with the connection to the flow line closed such that vacuum is generated in the syringe. EX2003, ¶53.

Garrison also discloses the drawbacks of the systems illustrated in Figures 33-34 and the different syringe embodiment disclosed (but not illustrated) in paragraph [0134], including that these embodiments are unsuitable for use with blood return:

One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient. In addition, pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells. Although it is possible to return blood from the external reservoir to the patient, the blood has been exposed to air or has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells. Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism.

EX1006, ¶[0135]. That is, when blood is pumped to a downstream receptacle as shown in Figures 33-34, or directly collected in a syringe as described in paragraph [0134], Garrison discloses that the blood is not suitable for reinfusion to the patient because the blood remains static and/or is exposed to air such that it can clot or the blood cells can otherwise be damaged. EX2003, ¶54.

To address that disadvantage, Garrison discloses a separate system in Figure 36 “which is configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” *Id.* at ¶[0136]. Figure 36 illustrates a pump device 3250 connected to either or both of the flow lines of the arterial access device or smaller inner catheter:

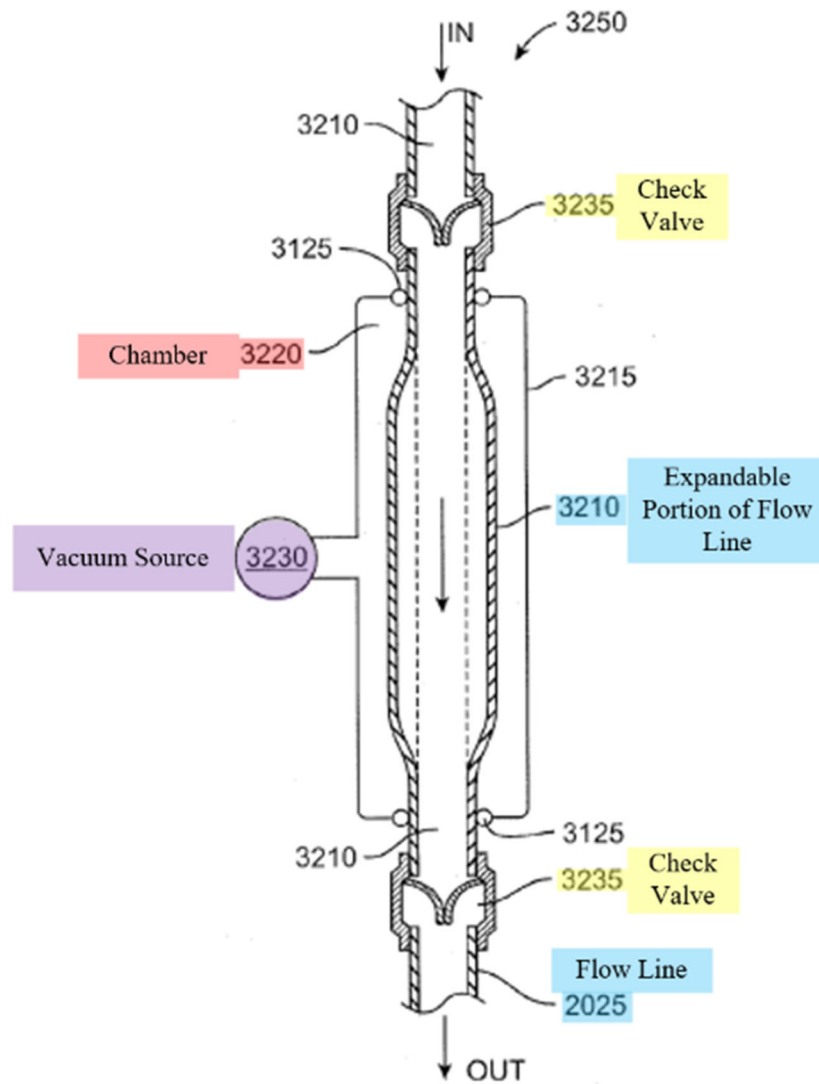


FIG. 36

EX1006, ¶[0136]; EX2003, ¶55.

The chamber 3220 is connected to a vacuum source 3230, which is configured to generate (1) negative pressure in the chamber 3220 to cause the expandable portion 3210 of the flow line 2025 to expand to draw blood into the expandable portion 3210 through the upstream one-way check valve 3235 and (2) subsequent

normalized pressure in the chamber 3220 to permit the expandable portion 3210 to contract to expel blood from the expandable portion 3210 through the downstream one-way check valve 3235. EX1006, ¶¶[0136]-[0137]; EX2003, ¶56. Therefore, the pump device in Figure 36 operates to pull blood through an inlet and subsequently expel blood through an outlet continuously in real time. EX2003, ¶56.

2. Laub

Laub discloses a “system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” EX1012, ¶[0005]. The embodiment of Laub relied on by Petitioner is shown in Figure 1A annotated below and includes a single aspiration catheter 200 in fluid communication with a filter 300, a pump 400, and a return catheter 500:

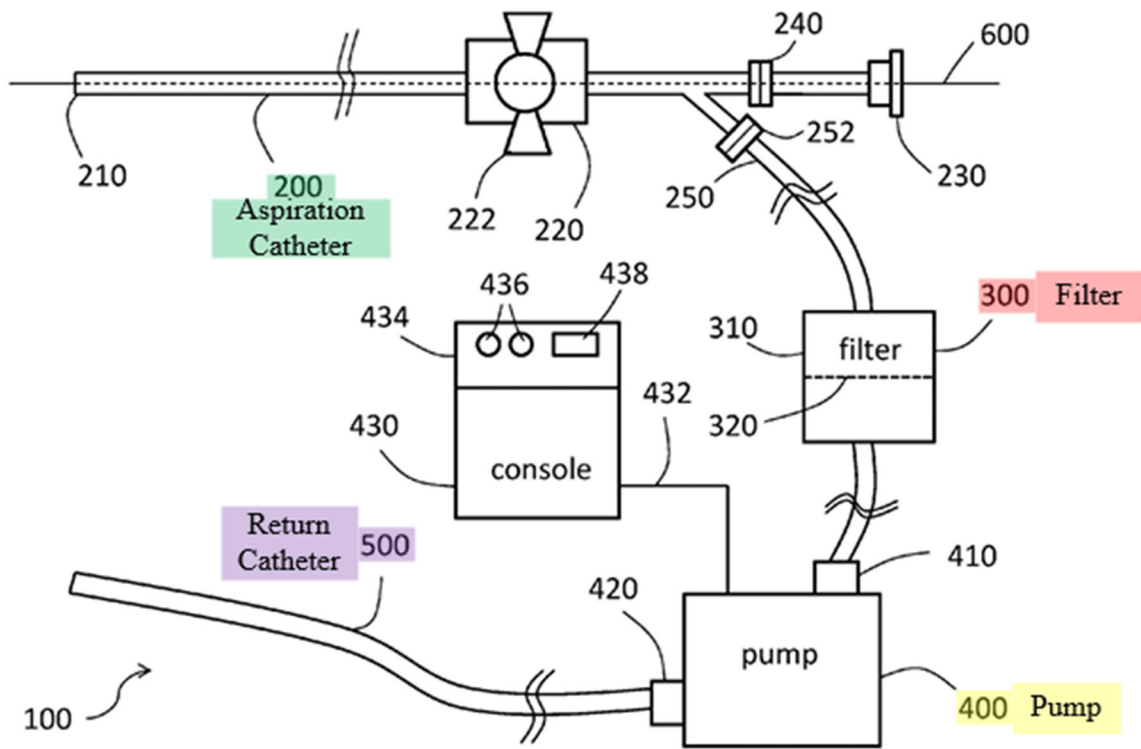


FIG. 1A

EX1012, ¶[0024]; EX2003, ¶57. The system includes no valve or fluid control device in the flow path and the pump 400 operates to continuously suction blood and thrombi through the aspiration catheter 200 and the filter 300 and then drive the filtered blood through the return catheter 500 back into the patient. *Id.* Accordingly, Laub discloses that “[i]n preferred embodiments, pump 400 is a centrifugal pump” while “[i]n other embodiments, pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art.” EX1012, ¶[0041]; EX2003, ¶57.

Laub discloses that the aspiration catheter 200 can have a wide range of sizes, but that “[i]n certain preferred embodiments, aspiration catheter has a French size of

equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid materials from the patient.” EX1012, ¶[0028]. A POSA would understand that a PE is a large clot. EX2003, ¶58. Laub also discloses a wide range of flow rates including flow rates up to 6 liters per minute. EX1012, ¶¶[0043]-[0044].

Because of those large flow rates enabled by a large catheter, Laub correctly recognizes the necessity of blood reinfusion: “Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.” EX1012, ¶[0045]. That is, Laub recognizes that when treating PE with large catheters as claimed in '910 Patent, the patient will bleed out and die or go into shock if the blood is not returned. EX2003, ¶59. Laub addresses that critical concern “[b]y returning the aspirated blood back to the patient ... allow[ing] for aspiration while minimizing the blood loss of the patient.” EX1012, ¶[0045]. Laub also discloses that “reinfusing the patient’s blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” *Id.* Accordingly, a POSA would understand that Laub’s system is intended to be operated to continuously aspirate (rather than build up and store vacuum pressure) and return blood at a high flow rate so that large clots, such as PE, can be removed. EX2003, ¶59. Laub discloses that its system would endanger the patient if blood were not returned. *Id.*

3. Aklog

A POSA would understand Aklog's system to be largely the same as Laub's, as Petitioner recognizes by stating that “[s]imilarly, Aklog discloses systems and methods for removing clot material from ‘the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches).’” Petition, pp.24-25 (emphasis added); EX2003, ¶60. Indeed, like Laub, the embodiments of Aklog relied on in the Petition shown in Figures 1, 6, and 7 of Aklog (Figure 1 annotated below) include an aspiration catheter (cannula) 10 in fluid communication with a filter device 14, a pump 15, and a reinfusion catheter (cannula) 16:

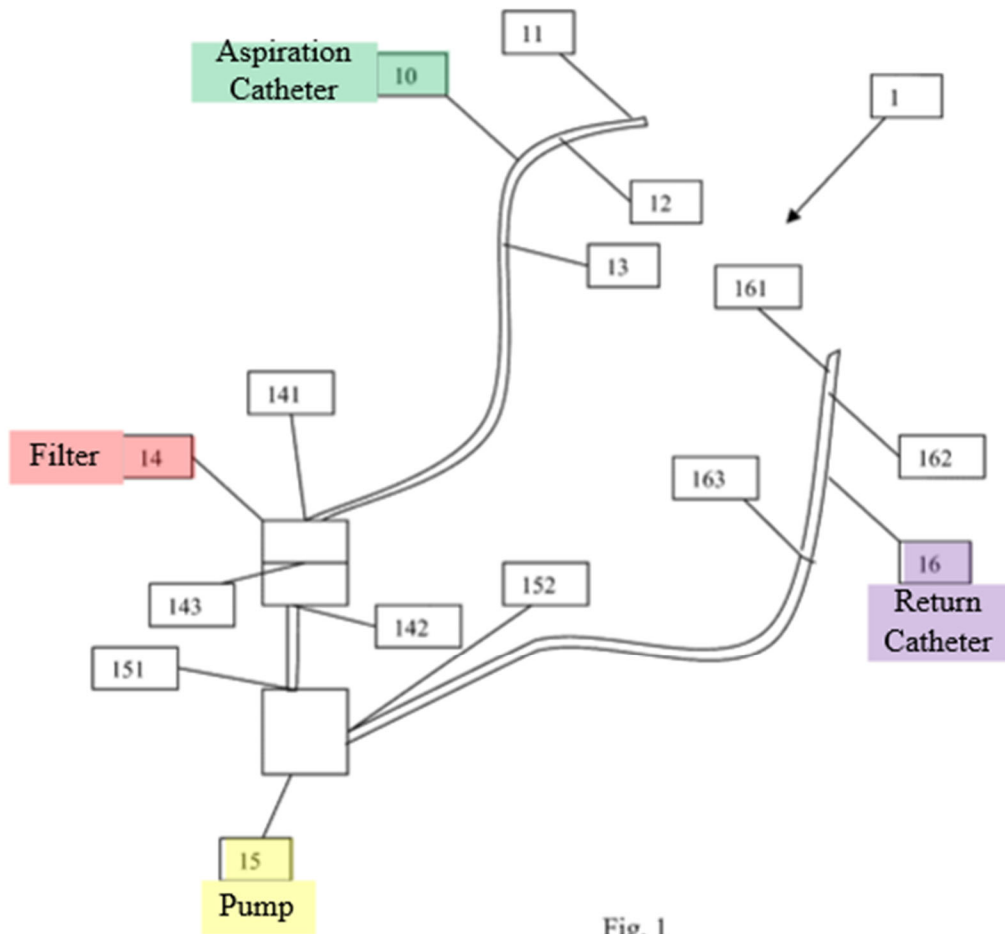


Fig. 1

EX2003, ¶60; EX1005, 11:24-12:34. Just like Laub, there is no valve or fluid control device in the flow path such that the pump 15 operates to suction blood and thrombi through the aspiration catheter 10 and the filter device 14 and then drive the filtered blood through the reinfusion catheter 16 into the patient. *Id.*

Aklog discloses that the aspiration catheter 10 “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel.” EX1005, 11:12-15. For example, the “suction cannula

10 may be designed to remove at least 10 cm³ of undesirable material substantially en bloc.” *Id.* at 11:18-20. A POSA would understand that a clot of 10 cm³ is much larger than neurovascular clots and more akin to the size of a PE. EX2003, ¶61. And, “[b]ecause the normal rate of blood flow through the heart and large blood vessels can be significant, suction cannula 11 and reinfusion cannula 16, when used around the heart and other large vessels, may displace a relatively large volume of fluid into and out of the patient's circulatory system.” EX1005, 19:57-62.

Given the large clots that Aklog is designed to treat, Aklog correctly recognizes that “[i]f the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” EX1005, 7:23-26; EX2003, ¶62. That is, the patient will be harmed due to excessive blood loss if the blood removed from the patient is not returned to the patient. EX2003, ¶62. To address this, Aklog’s system “simultaneously reinfuse[s] aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock.” EX1005, 5:19-23; EX2003, ¶62. Aklog further teaches that the “suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient.” EX1005, 6:9-11. Accordingly, like Laub, a POSA would understand that Aklog’s system is intended to be operated to continuously aspirate (rather than build

up and use stored pressure) and then return blood so that large clots can be removed. EX2003, ¶62. Aklog's system would endanger the patient if blood were not returned, and a POSA would understand the necessity of blood return based on Aklog's disclosure. *Id.*

III. CLAIMS 1-6, 8, 11-15, AND 18-20 ARE NOT RENDERED OBVIOUS BY ANY OF THE COMBINATIONS OF GARRISON AND LAUB (GROUND 1), GARRISON AND LAUB (GROUND 2), OR GARRISON, LAUB, AND AKLOG (GROUND 3)

Petitioner fails to demonstrate a reasonable likelihood that Claims 1-6, 8, 11-15, and 18-20 are obvious over Garrison in combination with Laub and/or Aklog. Indeed, those combinations do not disclose or render obvious multiple key limitations of the Claims.

In particular, Petitioner picks and chooses features of various embodiments to manufacture a purported system (Petitioner's purported demonstrative illustration of Figure 33 showing two of the valves from Figure 34 incorporated into the system of Figure 33) that Garrison *does not disclose* and that is contrary to Garrison's disclosure. Petitioner relies on Garrison for disclosing all the features of independent Claims 1 and 11 except that Petitioner admits that the requirements of "for treating clot material comprising a pulmonary embolism" and wherein the second (e.g., inner telescoping) catheter "has a size of 16 French or greater" and "is shaped to be intravascularly advanced through the vasculature of the patient such that the distal

portion of the second catheter is positioned proximate to the pulmonary embolism” are not found in Garrison. Moreover, each of Garrison, Aklog and Laub disclose that Petitioner's proposed modifications to Garrison are not compatible with and would not be combined with a 16 French catheter to treat PE as claimed.

First, Garrison does not disclose or suggest the “first fluid control device” and the “second fluid control device” recited in independent Claim 1, or the “fluid control device” recited in independent Claim 11. Because Garrison does not disclose such fluid control devices, particularly not in the embodiments that Petitioner relies on, Petitioner provides a demonstrative illustration of Figure 33 that is not found in Garrison that adds two of the single 3-way or 4-way stopcock 3325 shown in Figure 34 into the system of Figure 33. Petition, p.51; see also *id.* at p.72 (relying on the same demonstrative regarding independent Claim 11). But, a POSA would not have included those valves in the system of Figure 33 because doing so (1) would not provide any increased control or function different than simply operating Garrison's peristaltic pumps separately, (2) would provide dangerous flow paths for sucking air into the system through an unconnected port of the 3-way or 4-way stopcock that could be reinfused into the patient to cause an air embolism, and (3) would not enable a “maximum level of aspiration” because, unlike a syringe, a peristaltic pump's aspiration level is controlled by its operational speed rather than a fixed volume. EX2003, ¶¶71-88.

Garrison also does not disclose or suggest the buildup and storage, and then subsequent release of vacuum pressure recited in Claims 1 and 11 (i.e., “[generating] vacuum pressure while the ... fluid control device is in the first position” and “wherein, upon movement of the ... fluid control device from the first position to the second position, the vacuum pressure is applied to the ... catheter to generate suction at the distal portion of the ... catheter”). Garrison discloses the buildup and storage and release of vacuum pressure using a syringe connected directly to a flow controller in a single embodiment described in paragraph [0134] to “enable the maximum level of aspiration.” EX1006, ¶[0134]. Petitioner relies on maximizing the level of aspiration for its purported motivation to import two valves from Figure 34 into Figure 33, close those valves to generate vacuum pressure, and open them to apply the vacuum pressure. Petition, pp.51, 53. That embodiment is different than the embodiment shown in Figure 33 relied on by Petitioner because it utilizes a syringe rather than a peristaltic pump, and the syringe is connected directly to a flow controller rather than indirectly via a filter and a check valve like the peristaltic pumps shown in Figure 33. EX2003, ¶83. And, the “maximum level of aspiration” for a peristaltic pump is achieved by increasing the operational speed of the peristaltic pump, rather than by evacuating a fixed volume as in a syringe to create a stored vacuum. *Id.* at ¶¶84-86.

A POSA also would not have used any of the embodiments of Garrison relied on by Petitioner (particularly its purported combination importing valves into Figure 33) to treat PE—even if the catheter were “upsized”—because as both Aklog and Laub recognize the importance of blood reintroduction to patient health and safety when treating large clots like PE with large catheters. In contrast, Garrison expressly discloses that the embodiments relied on by Petitioner to modify other Garrison embodiments are not suitable for blood reintroduction. EX1006, ¶¶0135; EX2003, ¶¶89-101.

Finally, a POSA would not have radically increased the size of Garrison's catheters to “16 French or greater” as required in independent Claims 1 and 11 (indeed, both claims require a first catheter that is larger than 16 French to allow the second catheter of 16 French or greater to telescope through the first catheter) because such a modification would render Garrison's system unsuitable for its intended purpose of treating cerebral clot, and more particularly, clot in the middle cerebral artery as shown in, for example, Figures 33-34 of Garrison relied on by Petitioner. EX2003, ¶¶102-105. Put simply, when increased to the size Petitioner suggests, Garrison's catheters would be too large to fit into the cerebral vessels they are intended to be positioned in. *Id.*

Accordingly, for those reasons and the reasons set forth below, independent Claims 1 and 11 are not rendered obvious by Garrison in combination with Laub

and/or Aklog. Dependent Claims 2-6 and 8 depend from independent Claim 1, and dependent Claims 12-15 and 18-20 depend from independent Claim 11. Therefore, those claims are also not rendered obvious by Garrison in combination with Laub and/or Aklog because they incorporate all the features of their respective independent Claims 1 or 11.

A. Garrison Does Not Disclose or Suggest the Buildup/Storage and Subsequent Release of Vacuum Pressure or the “Fluid Control Device[s]” that Enable that Buildup and Release as Recited in Independent Claims 1 and 11.

A claim is not obvious if a limitation of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding that asserted claims are not rendered obvious in view of the cited prior art because they do not supply the missing element for purposes of obviousness analysis). Moreover, to demonstrate obviousness, Petitioner must provide a reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); *see also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (“When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is ‘whether a ‘skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.’”).

Here, Petitioner's combinations of Garrison and Laub and/or Aklog do not disclose or render obvious multiple key limitations of the Claims. Independent Claims 1 and 11 are each directed to catheter systems for treating PE in which a second (inner) catheter of a second clot aspiration assembly is advanceable through a first (outer) catheter of a second clot aspiration assembly. EX2003, ¶71. These claims further require the "pre-charged" aspiration described in detail in the '910 Patent in which vacuum is built up when a fluid control device is in a first position to disconnect a pressure source from a catheter, then subsequently moved to a second position that fluidly connects the pressure source to the catheter such that the vacuum is applied to the catheter. *Id.* To effectuate that buildup, storage, and then release of vacuum pressure Claim 1 recites two fluid control devices, a "first fluid control device" and a "second fluid control device" each between a respective catheter and pressure source. Specifically, independent Claim 1 requires:

a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter,

wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and

wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and

a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and

wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

Independent Claim 11 similarly requires:

a fluid control device between the second catheter and the second pressure source, wherein the fluid control device is movable between (a) a first position in which the second pressure source is fluidly

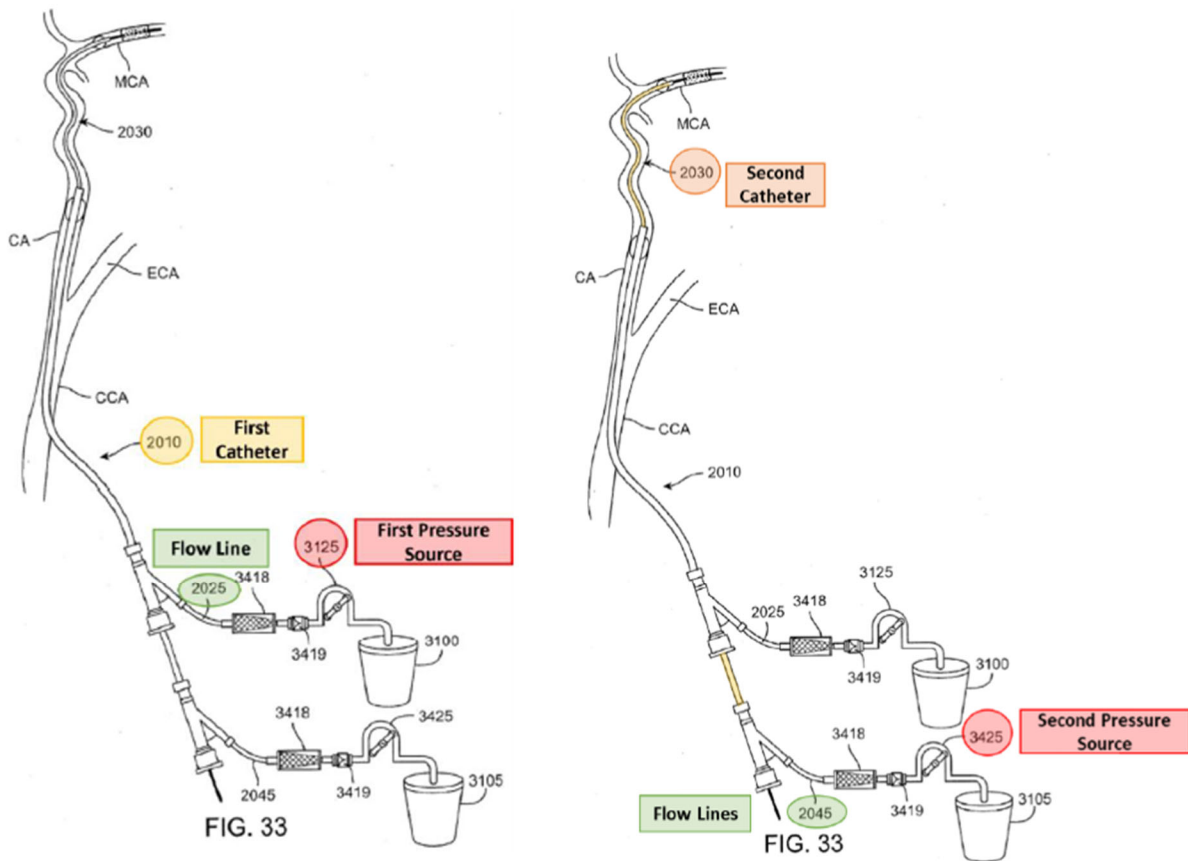
disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the fluid control device is in the first position, and

wherein, upon movement of the fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

Petitioner first mixes and matches features of various embodiments shown in Figures 33-34 and described in paragraphs [0131]-[0134] of Garrison to manufacture a purported system to allege that Garrison discloses the features of Claims 1 and 11. But, Garrison does not disclose that purported system and Petitioner's purported system is contrary to Garrison's disclosure and combinations with Aklog and Laub. EX2003, ¶72.

Petitioner first relies on Figure 33 of Garrison for allegedly disclosing the "first clot aspiration assembly" including a "first catheter" and a "first pressure source," and the "second clot aspiration assembly" including a "second catheter" a "second pressure source" as shown in their annotated Figures below:



Petition, pp.34-35, 39-42. But, in the embodiment of Figure 33, the first pressure source 3125 is fluidly connected to the first catheter 2010 (via a check valve 3419 and a filter 3418) *without* any “first fluid control device” that “is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter,” as recited in independent Claim 1. EX1006, ¶[0131]; EX2003, ¶73. And, likewise, the second pressure source 3425 is fluidly connected to the second catheter 2030 (via a check valve 3419 and a filter 3418) *without* any “second fluid control device is movable between (a) a first position in which the

second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,” as recited in independent Claim 1 and similarly recited in independent Claim 11. *Id.* Therefore, Figure 33 of Garrison—the primary embodiment of Garrison relied on by Petitioner—does not disclose any “fluid control device” as recited in the Claims. EX2003, ¶¶73-74.

Because Figure 33 does not disclose a “fluid control device,” Petitioner moves to a different embodiment shown in Figure 34 of Garrison to supply the missing fluid control device as shown in their annotations to Figure 34 below:

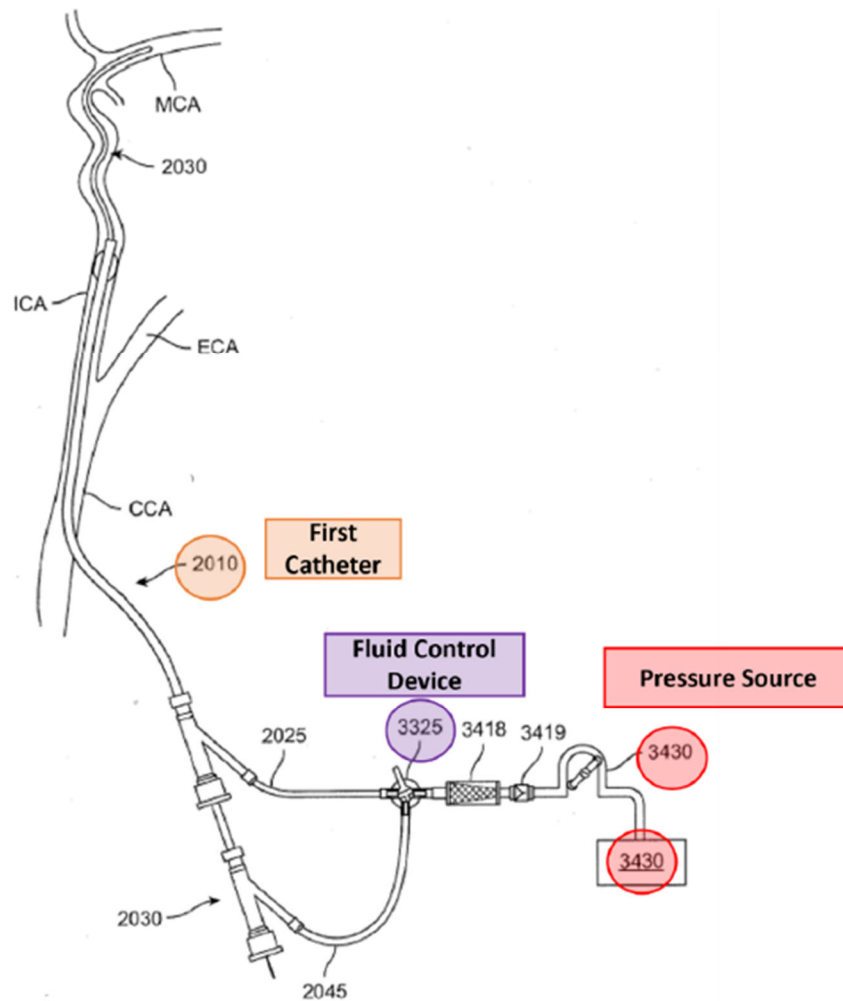
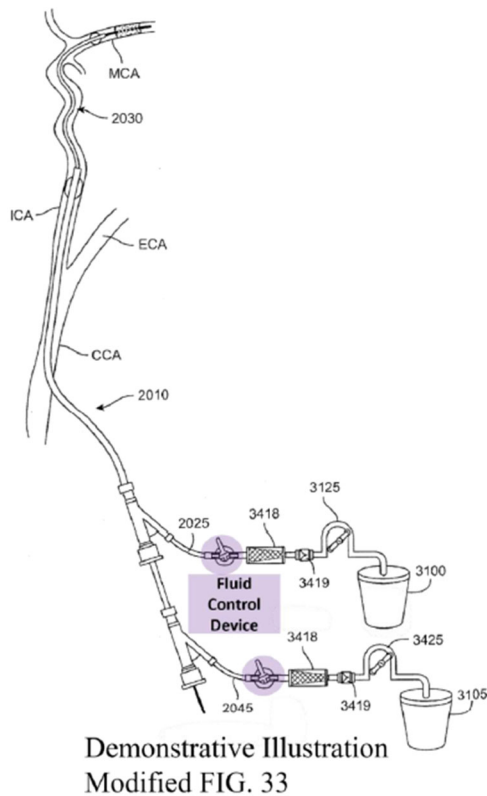


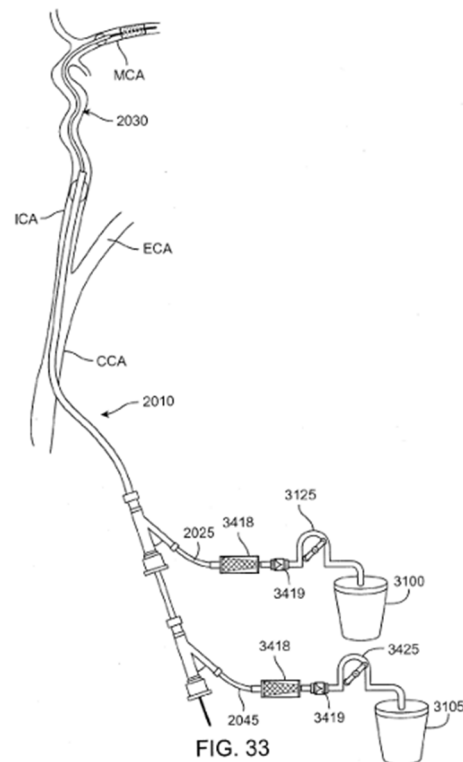
FIG. 34

Petition, pp.35-37, 49-54. In Figure 34 of Garrison, “both the arterial access device 2010 and the catheter 2030 are connected to the same aspiration source 3430” and the “valve 3325 controls which device is connected to the aspiration source 3430 ... [t]he valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” EX1006, ¶[0132]. The valve 3325 “may be a 3-way or 4-way stopcock” to enable those different connections. *Id.*

Finally, Petitioner creates a new demonstrative Figure *not found in Garrison* to allegedly show the features of independent Claims 1 and 11—first duplicating the valve shown in Figure 34 and then importing both new valves into Figure 33:



Petitioner's Demonstrative FIG. 33.



Unmodified FIG. 33.

Petition, p.51. While Claim 11 requires a single “fluid control device” in the second (inner) clot aspiration assembly, Petitioner relies on the same demonstrative to allege that Garrison discloses the features of that Claim. *Id.* at pp.71-72 (“a POSITA would have found it obvious to add the same valve 3325 from Garrison’s Figure 34 to the flow lines (2025, 2045) in the embodiment shown in Garrison’s Fig. 33”).

Accordingly, no embodiment of Garrison discloses the features of the Claims and, as set forth below, a POSA would not have modified Garrison to arrive at Petitioner's demonstrative illustration—just as the Patent Office already found, explaining in the sole Office action the allowability of Claims 1 and 11 over Garrison because Garrison fails to disclose “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source’.” EX1002, p.377.

First, Petitioner and its expert are incorrect that “incorporating two separate valves into the system [of Figure 33] with two separate pressure sources would have given physicians more flexibility when using the device” by, for example, enabling “the user [to] control these independent pressure sources separately.” Petition, p.52; EX1003, ¶115. No valves are needed in Figure 33 of Garrison to provide independent control of the pressure sources because the catheters are connected to different, independent pressure sources. EX2003, ¶76. In contrast, in Figure 34, because the arterial access device 2010 and the catheter 2030 are connected to the *same* pressure source 3430, the valve 3325 is needed to “enable[] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” EX1006, ¶[0132]. But, a POSA would understand that such control is not needed, and unnecessarily complicates control, when the catheters are connected to *separate* pressure sources as shown in Figure 33 because each pressure

source can be operated independently (e.g., turned off/on) to aspirate one catheter, the other catheter, both catheters, or neither catheter. EX2003, ¶76. Specifically:

1. *Aspiration enabled to “one device”*: The peristaltic pump 3125 can be turned off to cease aspiration of the first catheter 2010 and the peristaltic pump 3425 can be turned on to aspirate the second catheter 2030.
2. *Aspiration enabled to the “other device”*: The peristaltic pump 3125 can be turned on to aspirate the first catheter 2010 and the peristaltic pump 3425 can be turned off to cease aspiration of the second catheter 2030.
3. *Aspiration enabled to “both devices”*: The peristaltic pump 3125 can be turned on to aspirate the first catheter 2010 and the peristaltic pump 3425 can be turned on to aspirate the second catheter 2030.
4. *Aspiration enabled to “neither device”*: The peristaltic pump 3125 can be turned off to cease aspiration of the first catheter 2010 and the peristaltic pump 3425 can be turned off to cease aspiration of the second catheter 2030.

Id. In any event, neither the system in Figure 34 nor the modified Figure 33 have a fluid control device used to build up and store vacuum pressure with the valve closed before opening the stopcock to release that vacuum pressure, as required by the

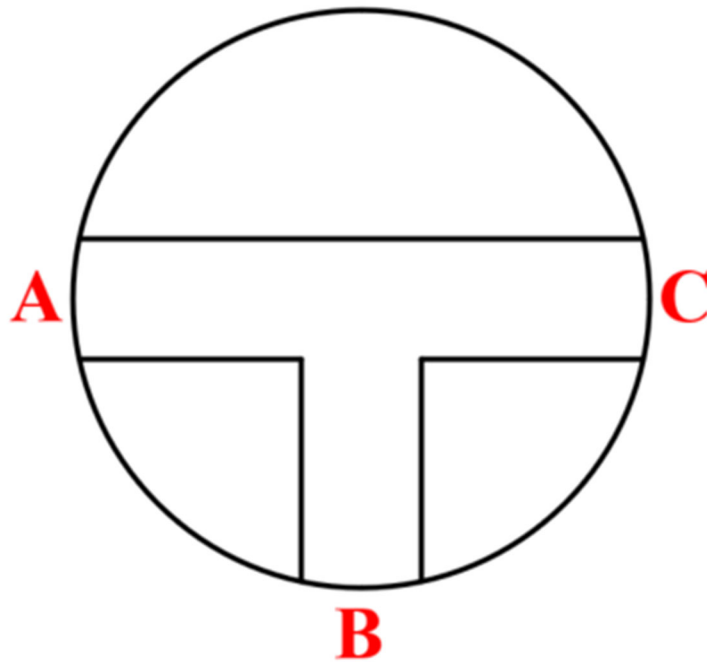
Claims. The valve only connects and disconnects a constant pressure source peristaltic pump rather than a source of built-up pressure. *Id.*

For the same reason, Petitioner and its expert are incorrect that “a POSITA would have been motivated to position the valve at this location based on the description in Figure 34 that positioning the valve here allows the physician to effectively control suction through the catheters.” Petition, p.52; EX1003, ¶114. That description in Figure 34 pertains to the embodiment where the catheters are connected to the same—not different—pressure sources and, again, the physician can “effectively control suction through the catheters” in Figure 33 by operating the independent pressure sources in Figure 33. EX2003, ¶77.

For the same reasons, Petitioner and its expert are also incorrect that “incorporating two separate valves into the system [of Figure 33] with two separate pressure sources would have given physicians more flexibility when using the device” by, for example, enabling “the user [to] control these independent pressure sources separately.” Petition, p.52; EX1003, ¶115. Again, the pressure sources in Figure 33 can be operated independently without the inclusion of the valves Petitioner invents, such that a POSA would not have been motivated to include those valves. EX2003, ¶78. Including the two additional valves would require an operator to operate two valves and two aspiration sources (i.e., turn on or off the aspiration

sources and also open/close the valves) to operate the system—needlessly complicating control and increasing the difficulty of the procedure. *Id.*

Moreover, in Petitioner's proposed combination, Petitioner alleges that "**the same valve 3325 (as shown in Figure 34)** [is] between each pressure source and catheter." Petition, p.51 (emphasis added). But a POSA would not have been motivated to include the 3-way or 4-way stopcock valve 3325 shown in Figure 34 (or the "flow controller "with the same functionality) in the system of Figure 33, let alone include two of them. *Id.* at ¶79. The 3-way or 4-way stopcock valve 3325 provides a controllable connection between three tubing sections and thus includes at least three different ports to connect to those tubing sections. *Id.* But, in Petitioner's combination, each valve is attached to only two tubes such that the 3-way or 4-way stopcock valve would have at least one port not connected to anything and open to the surrounding environment. *Id.* More specifically, Patent Owner's expert prepared the schematic below illustrating the different ports of the valve 3325 in Figure 34 based on its described functionality:



Id. at ¶80.

Port A connects to the flow line 2025 to the arterial access device 2010, port B connects to the flow line 2045 to the catheter 2030, and port C connects to the tubing to the filter 3418 and the aspiration source 3430. *Id.* When the valve “enable[s] one device ... to be connected to the aspiration source” as disclosed in Garrison, it connects only port A to port C to fluidly connect the aspiration source 3430 to the arterial access device 2010. EX1006, ¶[0132]; EX2003, ¶80. When the valve “enable[s] ... the other device ... to be connected to the aspiration source” it connects only port B to port C to fluidly connect the aspiration source 3430 to the catheter 2030. *Id.* When the valve “enable[s] ... both devices ... to be connected to the aspiration source” it connects both ports A and B to port C to fluidly connect the

aspiration source 3430 to the arterial access device 2010 and the catheter 2030. *Id.* When the valve “enable[s] ... neither device ... to be connected to the aspiration source” it connects neither port A nor port B to port C. *Id.*

In Petitioner's proposed arrangement one of port A or port B would not be connected to anything (because there are only two tubes connected to each valve in Petitioner's demonstrative illustration) and thus open to the surrounding environment. EX2003, ¶81. But, a POSA would not have included such a valve with an unconnected port in Garrison's system—let alone two of them—because it would complicate Garrison's system and second because it would potentially endanger the patient. *Id.* Specifically, if the valve were actuated to connect the non-connected port to the aspiration source, the system would needlessly suck air through the port and the aspiration source and drive it into the downstream receptacle. *Id.* This would occur in two states of the valve: when both ports A and B are connected to the aspiration source via port C, and when the unconnected one of ports A and B is individually connected to the aspiration source via port C. *Id.*

As explained in detail in §III.B. below, a POSA would also understand based on Petitioner's references that real-time blood return is important when treating PE using large catheters, and Petitioner asserts that a POSA would operate Garrison with “a blood return solution” that operates “in real time during the procedure” when “upsizing Garrisons' catheters to aspirate PEs.” Petition, p.33; EX1006, ¶[0135];

EX2003, ¶81. But, a POSA would understand the danger of potentially reinfusing air into the patient if Garrison's system in Figure 33 were modified to include two of the "same" valves 3425 shown in Figure 34 as Petitioner contends. Petition, p.51; EX2003, ¶81. Namely, if either of Petitioner's two valves 3425 were actuated to connect the pressure source to the unconnected port, air would be reinfused into the patient in real-time causing a dangerous and potentially deadly air embolism. EX2003, ¶81. For these reasons, a POSA would not have included the valve 3425 of Figure 34—let alone two of them—in Figure 33 as Petitioner asserts. *Id.*

Petitioner's other motivation to add two valves to Figure 33 of Garrison to "achieve 'the maximum level of aspiration in a rapid fashion'" is based on an incorrect understanding of Garrison and in fact demonstrates the opposite, namely, that the systems in Figures 33-34 do not use the buildup and subsequent release of pressure recited in the Claims. Petition, p.51; EX1003, ¶114; EX2003, ¶82. Garrison does not disclose building up vacuum pressure with a valve closed and then applying that vacuum pressure to a catheter with the systems of Figures 33-34 (i.e., "[generating] vacuum pressure while the ... fluid control device is in the first position" and "wherein, upon movement of the ... fluid control device from the first position to the second position, the vacuum pressure is applied to the ... catheter to generate suction at the distal portion of the ... catheter"). EX2003, ¶82.

Because of that deficiency, Petitioner relies on yet another different embodiment of Garrison described in paragraph [0134] to allegedly show the claimed buildup and release of pressure:

In one embodiment, a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user.

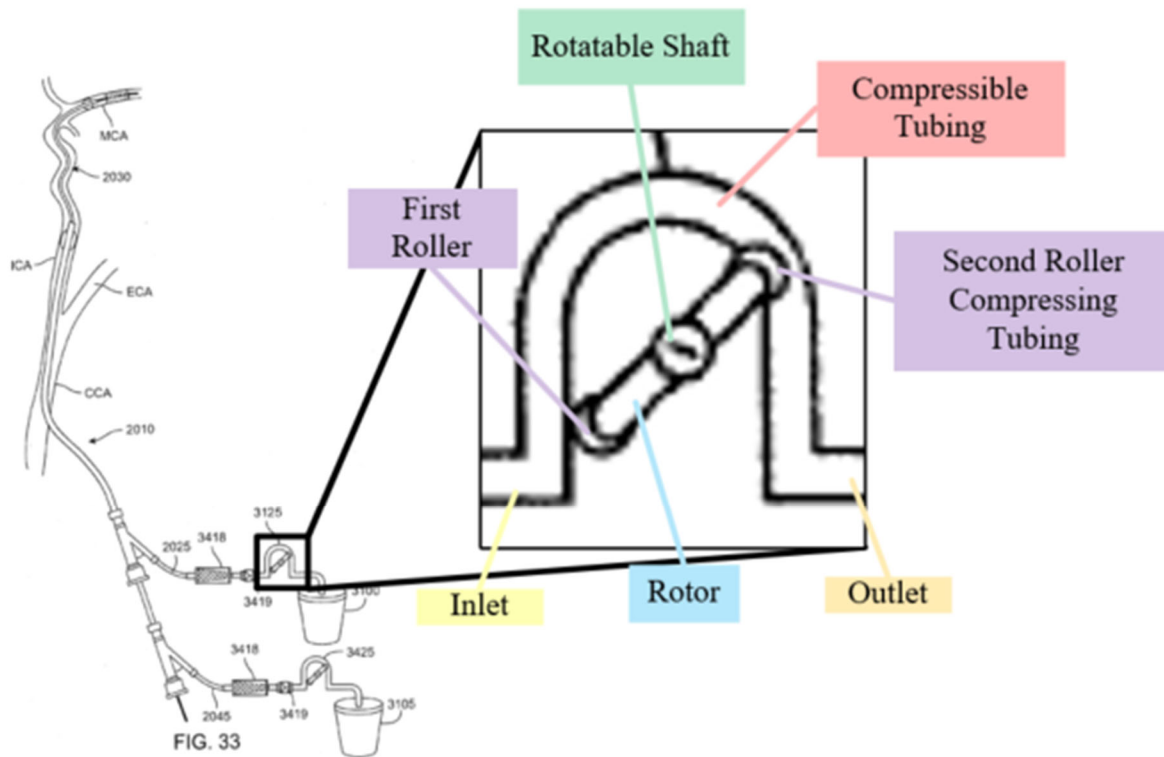
EX1006, ¶[0134]; Petition, pp.37-39, 54-57. Petitioner incorrectly concludes based on that disclosure that “Garrison includes multiple disclosures of closing a valve to generate vacuum pressure and opening the valve after the vacuum pressure is generated to cause suction at the distal end of a catheter.” *Id.* at p.39. But the disclosure in paragraph [0134] of Garrison relates to generating vacuum pressure with a *syringe* rather than with the *peristaltic pump* as shown in Figures 33-34, and further the syringe is “attached” directly to the flow controller rather than indirectly via a filter 3418 and a check valve 3419 like the peristaltic pumps in Figures 33-34. EX2003, ¶83. Accordingly, Garrison does not disclose generating vacuum pressure while any valve is closed using a peristaltic pump as shown in Figures 33-34 of

Garrison, let alone in the arrangement shown in Petitioner's demonstrative in which both a filter and a check valve are between the valve and the pressure source (peristaltic pump). *Id.*

Petitioner's assertion that a POSA would have included two of the valves from Figure 34 in Figure 33 of Garrison, closed those valves while generating vacuum pressure using the peristaltic pumps 3125/3425 in Figure 33, and subsequently opened those valves to apply vacuum pressure to "achieve 'the maximum level of aspiration in a rapid fashion'" ignores a fundamental difference between a syringe and a peristaltic pump. Petition, pp.51, 53; EX1003, ¶116; EX2003, ¶84. Namely, a POSA would understand the mechanism of generating vacuum with a syringe to comprise pulling back a plunger through a barrel. EX1006, ¶[0134]; EX2003, ¶84. A POSA would also understand that the barrel has a fixed volume and that volume sets and thus limits the "maximum level of aspiration." EX2003, ¶84. Therefore, when the "plunger is pulled back" with the flow controller closed as described in paragraph [0134] of Garrison, the maximum level of vacuum in the syringe is achieved because the full volume of the barrel is evacuated. *Id.*

In contrast, peristaltic pumps like those shown in Figure 33 of Garrison do not have a fixed volume that limits the "maximum level of aspiration" but instead include a rotor rotated by a shaft such that rollers compress and seal tubing,

alternating the compression and relaxation of the tubing to draw content into the pump through an inlet and propel that content away from the pump through an outlet:



EX2003, ¶85. Accordingly, there is no fixed volume of the peristaltic pump that can be evacuated in the same manner as the barrel of a syringe if a valve were included and closed to generate a “maximum level of aspiration” as Petitioner contends. *Id.* Instead, any “maximum level of aspiration” of a peristaltic pump is dictated by the speed of the pump—i.e., how quickly the rotor rotates to drive material through the pump. *Id.*

Petitioner’s secondary reference Laub confirms this by noting that in a system using a pump for treating large clots with large catheters, like the Claims of the ’910

Patent, the pump is controlled to control aspiration where continuous aspiration (i.e., without using a valve) maximizes the level of aspiration. *Id.* at ¶86. In particular, Laub discloses that in a system using a pump (like Garrison) including a peristaltic pump (EX1012, ¶[0041]), the pump is controlled to generate different negative pressures (*id.* at ¶[0042]) and flow rates (*id.* at ¶¶[0043]-[0044]). And, Laub discloses “reinfusing the patient’s blood *continuously* during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” *Id.* at ¶[0045] (emphasis added). That is, Laub discloses that to achieve the “maximum level of aspiration” with a peristaltic pump, the system is operated *continuously*—which is the opposite of Petitioner’s proposed modification to Garrison including two valves that are purportedly closed and then opened to generate vacuum. EX2003, ¶86. For those reasons, a POSA would not have included valves in Figure 33 of Garrison to achieve maximum aspiration using the peristaltic pumps in that embodiment and would have, instead, simply increased the operational speed of the peristaltic pumps or operated the system continuously. *Id.* In fact, a POSA would understand that adding the valves in Figure 33 of Garrison as Petitioner asserts would prevent continuous operation and minimize aspiration pressure based on Laub’s disclosure of maximized aspiration via continuous operation. *Id.* at ¶87.

And, as explained in further detail below in §III.B., in the context of the Claims—treating PE with large catheters—blood return is important to patient safety. Indeed, a POSA would further not have modified Garrison's system in Figure 33 to include two valves instead of no valves because doing so would increase stasis of the blood in the system (i.e., non-continuous aspiration) and further exacerbate the unsuitability of the blood to be returned to the patient. EX1006, ¶[0135]; EX2003, ¶87.

Accordingly, Garrison in combination with Laub and/or Aklog fail to disclose or render obvious the clot treatment systems of Claims 1 and 11 including the “first fluid control device” and the “second fluid control device” of Claim 1, the “fluid control device” of independent Claim 11, or the buildup and subsequent release of vacuum pressure recited in both Claims (i.e., “[generating] vacuum pressure while the ... fluid control device is in the first position” and “wherein, upon movement of the ... fluid control device from the first position to the second position, the vacuum pressure is applied to the ... catheter to generate suction at the distal portion of the ... catheter”).

B. A POSA Would Not Have Modified Garrison's System to Treat PE or to Include a Second Inner Catheter Having a "Size of 16 French or Greater" Because Petitioner's References Teach that Such a System Would Endanger the Patient

To demonstrate obviousness, Petitioner must provide a reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); see also *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) ("When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is 'whether a 'skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.'"). A POSA would not have been motivated to further modify Garrison to treat PE and upsize its inner catheter 2030 to a "size of 16 French or greater" because Petitioner's own references recognize the criticality of blood return to patient health and safety when treating PE using large catheters, and Garrison expressly discloses that the embodiments of Garrison relied on by Petitioner are not suitable for blood reintroduction. EX2003, ¶90. Thus, Petitioner has not met its burden of showing that a "skilled artisan would have been motivated to combine the teachings" of Garrison and Laub and/or Aklog. *Axonics*, 73 F.4th at 957.

Petitioner relies on Garrison for all the features of Claims 1 and 11 except "for treating clot material comprising a pulmonary embolism" and wherein the second

(e.g., inner telescoping) catheter “has a size of 16 French or greater” and “is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism.” For those limitations, Petitioner asserts that “[w]hile Garrison focuses on the ‘treatment of cerebral occlusions,’ a POSITA would have found it obvious to use and optimize Garrison’s clot treatment system to treat PE based on Laub or Aklog” and that a “POSITA would have found it obvious to upsize Garrison’s catheters from 8 French or 10 French to 16 French or greater based on Laub and Aklog.” Petition, pp.23-34, 42-48.

But, as described in detail in §II.E.2. above, Laub discloses a system for removing clots, including PE, from a patient including a pump 400 that operates to continuously suction blood and thrombi through an aspiration catheter 200 and a filter 300 and then drive the filtered blood through a return catheter 500 back into the patient:

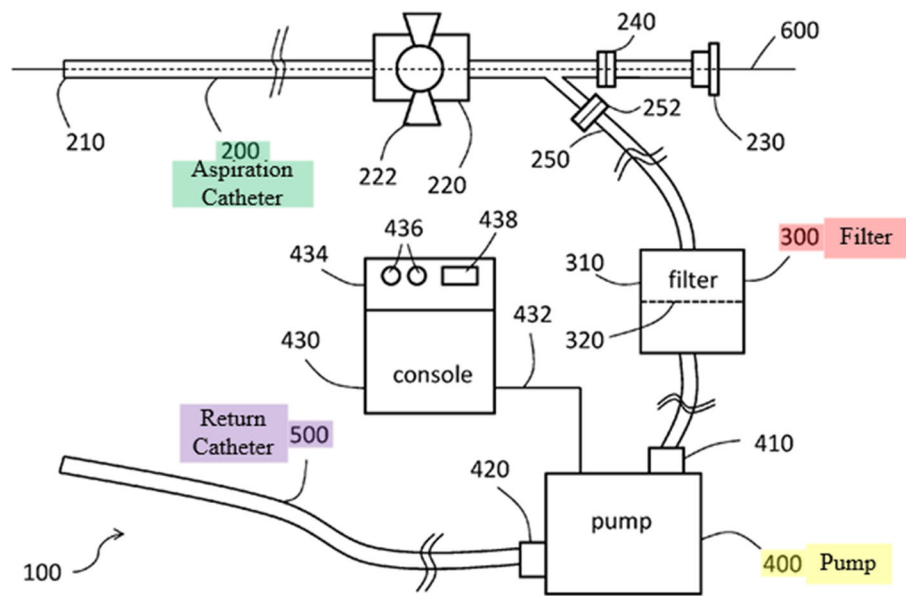


FIG. 1A

EX1012, ¶¶[0005], [0024]; EX2003, ¶91. To effectively treat PE and other large clots, Laub discloses a relatively large aspiration catheter (in “preferred embodiments, aspiration catheter has a French size of equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid materials from the patient”) and high aspiration flow rates (up to “6000 mL/min”). EX1012, ¶¶[0028], [0044]; EX2003, ¶91.

Because of the large aspiration flow rates enabled at least partially by utilizing a large catheter, Laub recognizes the need to reinfuse blood to the patient because of the large volume that is aspirated from the patient: “[w]ithout returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.” EX1012, ¶[0045]; EX2003, ¶92. That is, without returning blood to the patient, the patient will bleed out or go into shock, particularly with a constant

aspiration system, such as the peristaltic pumps relied on by Petitioner's asserted combinations. EX2003, ¶92. Accordingly, Laub discloses that "[b]y returning the aspirated blood back to the patient" Laub's system "allows for aspiration while minimizing the blood loss of the patient." EX1012, ¶[0045]; EX2003, ¶92. Accordingly, a POSA would understand from Laub that when using large catheters to treat PE, blood return is critical and that without it, such a system would endanger the patient. EX2003, ¶92.

As described in detail in §II.E.2. above, Aklog discloses a system that is very similar to Laub for removing large clots, that includes a pump 15 that operates to suction blood and thrombi through an aspiration catheter 10 and a filter device 14 and then drive the filtered blood through a reinfusion catheter 16 into the patient:

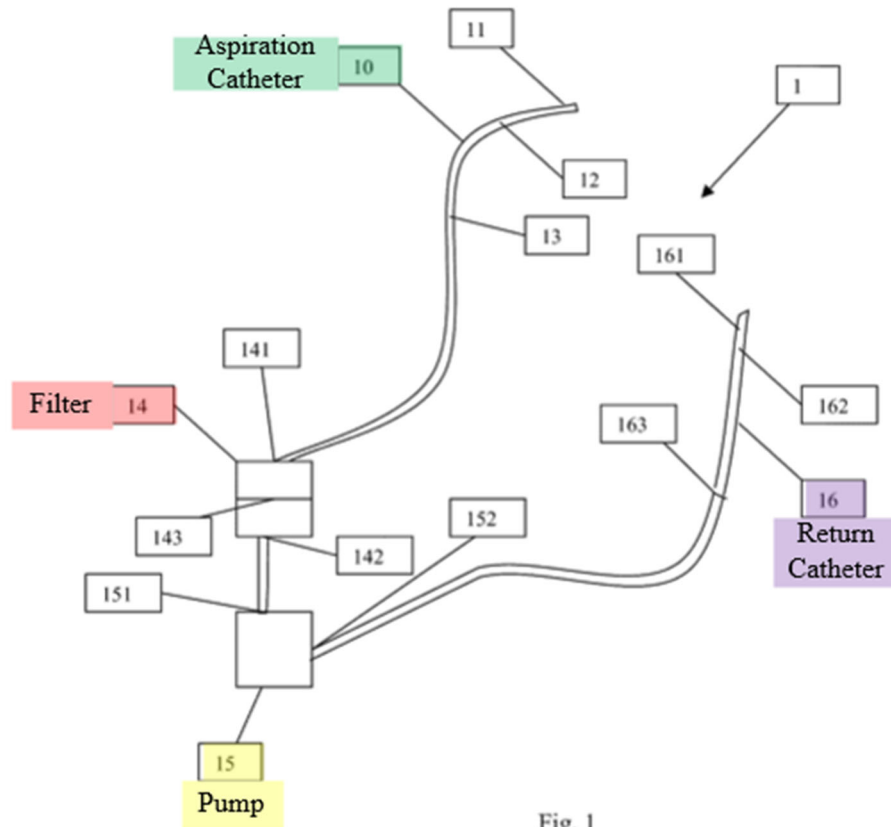


Fig. 1

EX1005, 11:24-12:34; EX2003, ¶93. To effectively treat PE and other large clots, Aklog discloses a relatively large aspiration catheter (“the suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially en bloc”) and high aspiration volumes/flow rates (“suction cannula 11 ... when used around the heart and other large vessels, may displace a relatively large volume of fluid into and out of the patient's circulatory system”). EX1005, 11:18-20, 19:57-62; EX2003, ¶94.

Because of those large aspiration volumes enabled at least partially by utilizing a large catheter, Aklog correctly recognizes the need for blood reinfusion:

“[i]f the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” EX1005, 7:23-26; EX2003, ¶95. That is, excessive blood removal using a large catheter, particularly with constant aspiration, will harm the patient. To address this, Aklog's system “simultaneously reinfuse[s] aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock.” EX1005, 5:19-23; EX2003, ¶95. Accordingly, a POSA would understand from Aklog, like Laub, that when using large catheters to treat PE, blood return is critical and that without blood return, such a system would endanger the patient. EX2003, ¶95.

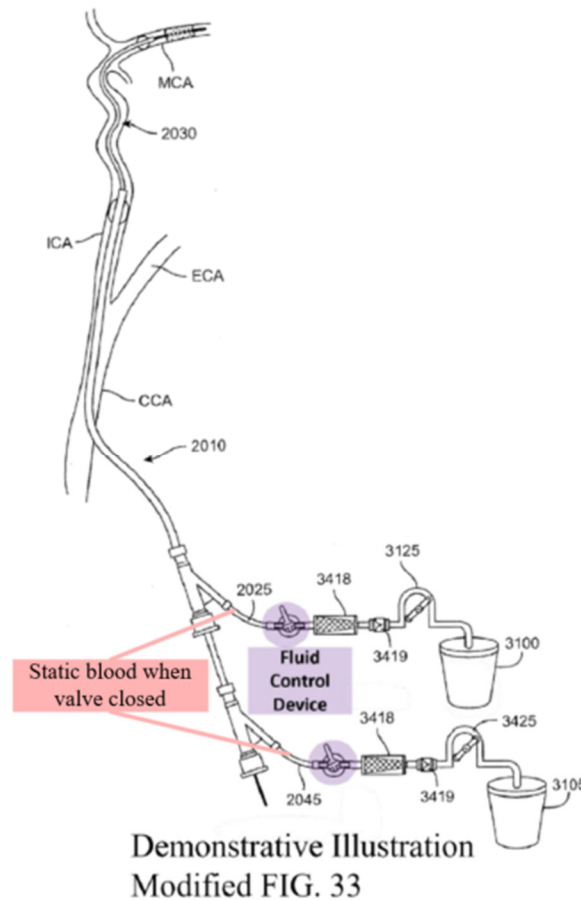
As such, both Laub and Aklog recognize the need to reintroduce aspirated blood to the patient when using large catheters to treat PE. But Garrison itself discloses that the very embodiments relied on by Petitioner in Figures 33-34 and paragraph [0134] (the syringe embodiment) are not suitable for returning blood:

One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient. In addition, pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells. Although it is possible to return blood from the external reservoir to the patient,

the blood has been exposed to air or has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells. Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism.

EX1006, ¶[0135]. In Figure 33 primarily relied on by Petitioner, blood is pumped to the receptacles 3100/3105 (“external reservoir[s]”) where it remains “static” and is “exposed to air” such that it is not suitable for blood return. EX2003, ¶96. In Figure 34 relied on by Petitioner for disclosing a “fluid control device,” blood is likewise pumped to the receptacle 3430 (an “external reservoir”) where it remains “static” and is “exposed to air” such that it is not suitable for blood return. *Id.* In the syringe embodiment disclosed in paragraph [0134], blood is aspirated into the syringe where it remains “static” such that it is not suitable for blood return. *Id.*

And, Petitioner's purported modification of Garrison—the addition of two valves to Figure 33 shown in its demonstrative illustration—would make that system *worse* for blood return by causing blood to remain static for longer when the valves are closed. *Id.* Specifically, when the valves are closed, blood would remain static within the flow lines 2025/2045 distal to the valves where it would not remain static in Garrison's unmodified system as shown in the annotations to Petitioner's demonstrative illustration:



Id.

Accordingly, a POSA would understand that in each embodiment of Garrison relied on by Petitioner the aspirated blood is not suitable for blood return and should be “discarded at the end of the procedure” as Garrison discloses. EX1006, ¶[0135]; EX2003, ¶97. For that reason, a POSA would not have “found it obvious to use and optimize Garrison’s clot treatment system to treat PE based on Laub or Aklog” or “found it obvious to upsize Garrison’s catheters from 8 French or 10 French to 16 French or greater based on Laub and Aklog” because both of those references

emphasize the critical nature of blood return when treating PE using large catheters—and Garrison discloses that the embodiments relied on by Petitioner are not suitable for blood return. Petition, pp.23-34, 42-48; EX2003, ¶97. As such, a POSA would not have optimized Garrison's system in a manner not disclosed by Garrison and in a manner discouraged by Garrison and both Laub and Aklog. EX2003, ¶97.

After Garrison discloses the blood return deficiencies of the embodiments relied on by Petitioner, Garrison discloses a different embodiment in Figure 36 configured to address blood return: “[it] is configured not to harm blood cells and which may be configured to return blood to the central venous system *in real time* during the procedure, so there is no reservoir in which the blood remains static.” EX1006, ¶[0136] (emphasis added). Figure 36 of Garrison illustrates a pump device 3250 connected to either or both of the flow lines of the arterial access device or smaller inner catheter and having a chamber 3220 connected to a vacuum source 3230, which is configured to generate (1) negative pressure in the chamber 3220 to cause the expandable portion 3210 of the flow line 2025 to expand to draw blood into the expandable portion 3210 through the upstream one-way check valve 3235 and (2) subsequent normalized pressure in the chamber 3220 to permit the expandable portion 3210 to contract to expel blood from the expandable portion 3210 through the downstream one-way check valve 3235:

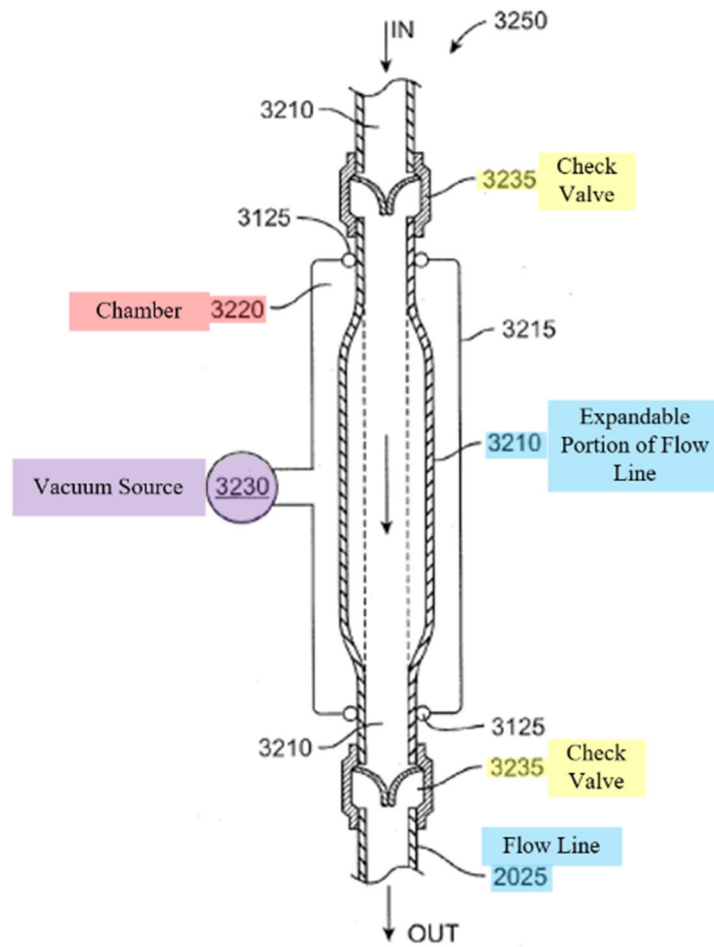


FIG. 36

EX2003, ¶98; EX1006, ¶¶[0136]-[0137]. That is, in this different embodiment of Garrison, the pump device operates to “return blood to the central venous system in real time” by operating the vacuum source so as to oscillate the expandable portion between the expanded and retracted states to, together with the one-way check valves, thereby drive fluid through the flow line. *Id.*

A POSA would understand that the pump device in Figure 36 is intended to be used in a system without any “fluid control device” unlike in Petitioner’s

demonstrative illustration, because blood is continuously aspirated and returned in *real time* to prevent the blood from remaining static. EX2003, ¶99. Blood return would not be continuous/real time and blood would remain static if a “fluid control device” were included in the system and closed when vacuum was generated, as recited in Claims 1 and 11 of the '910 Patent.

Indeed, the system Garrison discloses in Figure 36 is akin to the systems of Laub and Aklog, which also disclose the continuous nature of aspiration/blood return. EX2003, ¶100. For example, Laub discloses that “reinfusing the patient’s blood *continuously* during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” EX1012, ¶[0045] (emphasis added). And, Aklog’s system “*simultaneously* reinfuse[s] aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock.” EX1005, 5:19-23 (emphasis added). Thus, each of Garrison, Laub, and Aklog disclose continuous aspiration and reinfusion when blood is returned to the patient. EX2003, ¶100. A POSA would understand such systems to be incompatible with the Claims of the '910 Patent reciting the treatment of PE, a “16 French or greater” inner catheter, and the “fluid control device[s]” that enable vacuum pressure to be generated “while the ... fluid

control device is in the first position” inhibiting fluid flow therethrough because the fluid control device would prevent continuous reinfusion and aspiration.

Petitioner simply asserts that “Garrison already accounts for one challenge POSITAs encountered when moving from smaller to larger aspiration catheters – a larger catheter ‘may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient’” based on the embodiment in Figure 36 of Garrison. Petition, p.33. But, Petitioner does not assert or explain why any aspect of that embodiment would be combined with the Garrison embodiments. To the contrary, the embodiment of Figure 36 is fundamentally different than the embodiments in Figures 33-34 and paragraph [0134] of Garrison relied on by Petitioner where blood is unsuitable to be returned, and a POSA would understand the embodiment in Figure 36 not to include any “fluid control device” as recited in Claims 1 and 11 to enable continuous aspiration and reinfusion. EX2003, ¶101.

C. A POSA Would Also Not Have Modified Garrison to Include Any Catheter Having a “Size of 16 French or Greater” Because Such a Modification Would Prevent Garrison’s System from Being Positioned in the Cerebral Vasculature

When a proposed modification/combination would render the prior art inoperable for its intended purpose it counsels “strongly against obviousness.” *See Medtronic, Inc. v. Teleflex Innovations*, 69 F.4th 1341, 1349-50 (Fed. Cir. 2023) (cleaned up) (affirming PTAB finding of nonobviousness where the prior art

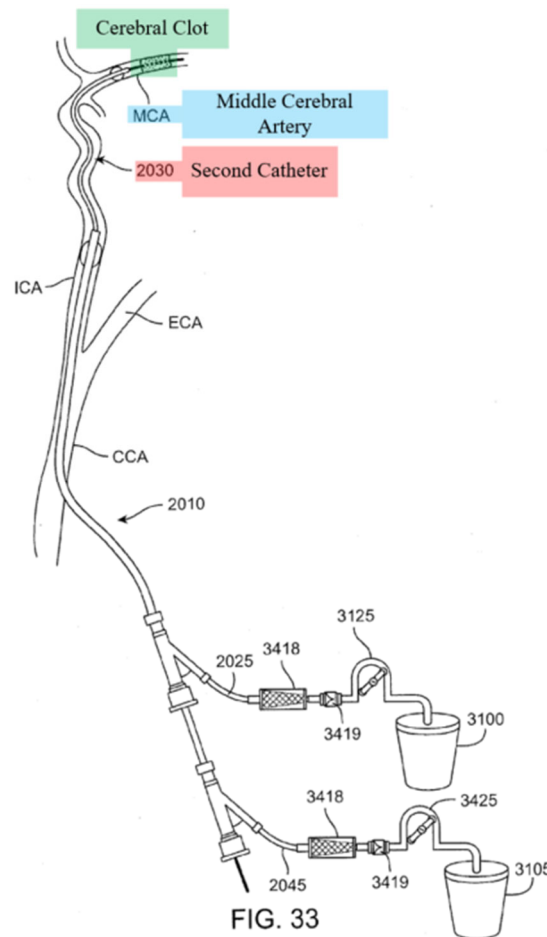
reference's "entire premise" was to provide embolic protection using sealing balloons and that [Petitioner's] "extensive" modifications would eliminate "the capability of [the prior art's] aspiration catheter to act as an aspiration catheter."); *see also Plas-Pak Indus. V. Sulzer MixPak AG*, 600 Fed.App'x. 755, 760 (Fed. Cir. 2015) (affirming non-obviousness where the prior art combinations would render the prior art reference "inoperable for its intended purpose[.]").

Here, a POSA would not "have found it obvious to upsize Garrison's catheters from 8 French or 10 French to 16 French or greater based on Laub and Aklog" because doing so would render Garrison unsuitable for its express purpose of treating cerebral clots. Petition, p.42; EX2003, ¶¶102-105.

As Petitioner explains, "Garrison focuses on the 'treatment of cerebral occlusions.'" Petition, p.24. Indeed, Garrison discloses "methods and systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions." EX1006, ¶[0002]. Because the cerebral vasculature is much smaller than the vasculature accessed to treat pulmonary embolism, Garrison discloses catheters much smaller than 16 French, such as 6 or 8 French. EX2003, ¶102; *See id.* at ¶[0063] ("In an embodiment, the sheath body 222 can have an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size. In another embodiment, the sheath body 222 has an inner diameter of

about 0.113” and an outer diameter of about 0.13”, corresponding to an 8 French sheath size.”).

In Figures 33-34 of Garrison relied on by Petitioner, the inner catheter 2030 is positioned in the middle cerebral artery (MCA) to treat a cerebral clot therein:



EX2003, ¶103. A POSA would understand that upsizing the catheter 2030 to have a size of “16 French or greater” as recited in Claims 1 and 11 would render Garrison’s system completely unsuitable for its intended purpose of treating clots in the MCA because neither of Garrison’s catheters (inner and outer) would fit in the cerebral

vasculature. *Id.* For example, a POSA would understand the mean diameter of the MCA to be $2.55 \pm .42$ mm. EX2004, pp.5-7; EX2003, ¶103. A 16 French catheter size translates to a 5.1 mm catheter size (1 French equals $\sim 1/3$ mm as French is a measurement of the circumference of a catheter in millimeters such that 1 French = $(1 \text{ mm}) / (\pi)$) which is substantially $\sim 200\%$ greater than the mean vessel diameter of the MCA. EX2003, ¶103. Accordingly, if the catheter 2030 were “16 French or greater” in size as Petitioner proposes, the catheter would be unable to fit into the MCA. *Id.*; see also EX2004, p.2 (noting that if the MCA was close to the size of the catheter “the catheter may have struggled to fit appropriately within the vessel”). Put another way, upsizing Garrison’s catheter from 8 French or smaller to 16 French or greater would massively increase the cross-sectional area of the catheter by four times. EX2003, ¶103.

Similarly, with a 16 French or greater inner catheter, a POSA would understand that the outer “first catheter” through which the inner catheter is advanced must be even larger to allow the inner catheter to fit through it. EX2003, ¶104. In Figures 33-34 of Garrison, the arterial access device 2010 (which Petitioner alleges is the “first catheter”) is positioned in the internal carotid artery (ICA). *Id.* The largest mean diameter of the ICA is 4.74 ± 0.64 mm. EX2004, pp.5-6. But even assuming a minimal 1 French size difference between the catheters, if the arterial

access device 2010 were upsized to 17 French (5.4 mm) it would not fit in the ICA (5.4 mm > 4.74 ± 0.64 mm). EX2003, ¶104.

In both scenarios, a POSA would understand that advancing such an over-sized catheter could damage the vasculature (e.g., perforate the vessels), and a POSA would not have used such an inappropriately large catheter. *Id.* at ¶103. Accordingly, a POSA would not have upsized the catheter 2030 of Garrison (and correspondingly the arterial access system 2010 through which the catheter 2030 is advanced) because such a modification would render Garrison's system unsuitable for its intended purpose of treating cerebral clot, and more particularly, clot in the MCA. *Id.* at ¶105.

Indeed, the Examiner of the '910 Patent understood that Garrison is not suited for treating PE and would not be modified to do so, explaining in the Notice of Allowance:

Claims 1 and 11 are allowable for reciting, inter alia, “a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”.

Garrison (US 20150173782 A1) ... fails to teach a [“]clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”. The clot treatment device of Garrison is

configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms. There is no prior art that teaches all of the limitations. Therefore, claims 1 and 11 are allowable.

EX1002, p.49. That is, the Examiner correctly found that it would be unreasonable to modify Garrison to include a 16 French catheter or to treat PE—exactly opposite to Petitioner's contentions now.

IV. GROUNDS 4-9: THE COMBINATIONS OF GARRISON AND LAUB AND/OR AKLOG FURTHER IN VIEW OF HARTLEY OR PASHA AKLOG DOES NOT RENDER OBVIOUS ANY OF CLAIMS 3, 6-7, 12, 18, OR 20

As set forth in §III above, independent Claims 1 and 11 are not rendered obvious by Garrison in combination with Laub and/or Aklog. Dependent Claims 3 and 6-7 depend from independent Claim 1, and dependent Claims 12, 18, and 20 depend from independent Claim 11. Petitioner does not allege that Hartley (grounds 3-6; Claims 6-7 and 20) or Pasha (grounds 7-9; Claims 3, 12, and 18) disclose any of the features of independent Claims 1 or 11. Therefore, those dependent Claims are also not rendered obvious by Garrison in combination with Laub and/or Aklog and further in view of Hartley (grounds 4-6) or Pasha (grounds 7-9) because they incorporate all the features of their respective independent Claims 1 or 11.

V. CONCLUSION

For all the above reasons, Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: Sept. 16, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770
Lead Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 13,841 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: Sept. 16, 2025

By: / Joseph P. Hamilton / _____
Joseph Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on September 16, 2025, a copy of **PATENT OWNER'S PRELIMINARY RESPONSE** was served upon the below-listed counsel by electronic mail:

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