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 RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	**Description**
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.

	Petitioner's Exhibits
Exhibit	**Description**
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 Al ("Garrison II")
EX1033	US 2005/0054995 Al ("Barzell")

	Petitioner's Exhibits
Exhibit	**Description**
EX1034	Decision Granting Institution of *Inter Partes* Review for U.S. Patent No. 11,697,011 (Paper 7) in *Imperative Care, Inc. v. Inari Medical, Inc.,* IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
EX1035	Decision Granting Institution of *Inter Partes* Review for U.S. Patent No. 11,697,012 (Paper 6) in *Imperative Care, Inc. v. Inari Medical, Inc.,* 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 *Imperative Care, Inc. v. Inari Medical, Inc.,* 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 *Inari Medical, Inc. v. Imperative Care, Inc.,* 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 *Inari Medical, Inc. v. Imperative Care, Inc.,* 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
EX1044	Case Management & Scheduling Order (Dkt. #54) in *Inari Medical, Inc. v. Imperative Care, Inc.,* 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
EX1045	Decision Denying Institution of *Inter Partes* Review for U.S. Patent No. 11,744,691 (Paper 10) in *Imperative Care, Inc. v. Inari Medical, Inc.,* IPR2024-01257 (P.T.A.B. Feb. 7, 2025)

	Petitioner's Exhibits
Exhibit	**Description**
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 *Inari Medical, Inc. v. Imperative Care, Inc.,* 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
EX1048	Imperative Care's Notice of Motion and Motion to Stay Pending *Inter Partes* Review (Dkt. #100) in *Inari Medical, Inc. v. Imperative Care, Inc.,* 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 *Inari Medical, Inc. v. Imperative Care, Inc.,* 24-cv-03117-EKL (N.D. Cal.)
EX1054	Decision Denying Patent Owner's Request for Discretionary Denial (Paper 9) in *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR202-500289 (P.T.A.B. June 12, 2025)
EX1055	Decision Referring the Petition to the Board (Paper 9) in *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728 (P.T.A.B. July 31, 2025)
EX1056	Order Denying Motion for Preliminary Injunction (Dkt. #136) in *Inari Medical, Inc. v. Imperative Care, Inc.*, 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
EX1057	Joint Stipulation to Continue to Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference

	Petitioner's Exhibits
Exhibit	**Description**
	(Dkt. #139) in *Inari Medical, Inc. v. Imperative Care, Inc.*, 24-cv-03117-EKL (N.D. Cal.) (dated January 21, 2026)
EX1058	Order Granting Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference (Dkt. #140) in *Inari Medical, Inc. v. Imperative Care, Inc.*, 24-cv-03117-EKL (N.D. Cal.) (issued January 21, 2026)

	Patent Owner's Exhibits
Exhibit	**Description**
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. Stroke Vascular and Interventional Neurology, 4(4). https://doi.org/10.1161/svin.123.001177
EX2005	Order Granting in Part Motion to Stay, *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 5:24-cv-03117-EKL (N.D. Cal. Sept. 29, 2025), ECF No. 137
EX2006	Hearing Transcript, dated February 6, 2026
EX2007	*Reserved*
EX2008	Supplemental Declaration of Brian Brown
EX2009	Instructions for Use for Medtronic Bio-Bump™ BP-50, CBBP-50
EX2010	Instructions for Use for Maquet Getinge Group ROTAFLOW Centrifugal Pump
EX2011	40 Year Bio Pump Timeline
EX2012	OPERATING INSTRUCTIONS for the Pump Drive BVP-BP for centrifugal blood pump heads BP-50/BP-80 and SP-45
EX2013	Deposition Transcript of Troy L. Thornton (February 18, 2026)
EX2014	Deposition Transcript of Troy L. Thornton (February 19, 2026)
EX2015	Deposition Transcript of Aquilla S. Turk (February 25, 2026)

	Patent Owner's Exhibits
Exhibit	**Description**
EX2016	Declaration of Dr. Christopher S. Morris
EX2017	Redacted version of Declaration of Brian Brown, Inari Medical, Inc. v. Imperative Care, Inc., No. 5:24-cv-03117-EKL (N.D. Cal. July 24, 2024), ECF No. 24-2

I. INTRODUCTION

Petitioner has failed to demonstrate that any of Claims 1-8, 11-15, and 18-20 ("the Claims") of the '910 Patent are unpatentable.[1] Rather, as explained herein, the Claims are directed to innovations pioneered by patentee that are not disclosed or obvious in view of the prior art. During prosecution, 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'").

The '910 Patent is directed to improved clot treatment systems for removing clot material, specifically a pulmonary embolism (PE), from a blood vessel of a human patient. EX1001, 4:17-19; EX2008, ¶36. PE is a life-threatening condition that occurs when a clot becomes lodged in the pulmonary arteries (e.g., in the lungs),

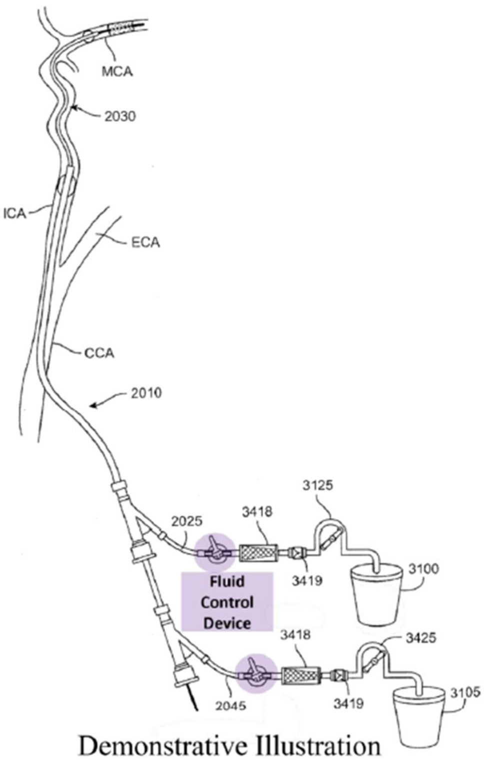
[1] The Petition does not assert that Claims 9-10 or 16-17 are unpatentable.

blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:57-67; EX2008, ¶32. The clot treatment systems of the '910 Patent generate and build up (i.e., 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; EX2008, ¶36.

That buildup and subsequent application of vacuum pressure to treat PE is a key feature of the Claims of the '910 Patent, which are directed to systems for removing a PE from the vasculature of a patient. 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"—one for each of a first and a second catheter; and Claim 11 recites a single "fluid control device" between a second catheter and a pressure source. EX2008, ¶72. Each of those pressure sources is "configured to generate vacuum pressure while" the respective fluid control device is in a "first position" in which the pressure source is fluidly disconnected from the respective catheter (i.e., closed). *Id.*

Petitioner relies on Garrison alone for disclosing the claimed buildup and release of vacuum pressure via a fluid control device by mixing and matching various embodiments shown in Figures 33 and 34 and described in paragraphs [0131]-[0135] of Garrison to allege that Garrison discloses those features of Claims

1 and 11, which it does not, ultimately arriving at a further undisclosed modification to Figure 33 of Garrison by adding two valves:



Demonstrative Illustration
Modified FIG. 33

Petition, pp.51, 71-72.

The Board preliminarily saw no "flaw in Petitioner's alleged mixing and matching of embodiments of Garrison." Institution Decision, p.32. Here, Patent Owner provides additional evidence that it would not have been obvious to mix and match those embodiments to arrive at Petitioner's modification to Garrison's Figure 33. Specifically, a POSA would not have made the modification because it would likely damage Garrison's pumps 3125/3425 and, in view of Petitioner's further modification of Garrison to upsize its catheters and treat PE, would damage blood that should be returned to the patient when treating PE.

Specifically, in Garrison's actual Figure 33 there are no fluid control devices that could cut off fluid flow to its pumps 3125/3425 to generate any vacuum pressure while the pumps 3125/3425 operate. EX2008, ¶74. And, in Figure 34 where Petitioner finds its purported "fluid control device," that device simply enables switching between one or both of the catheters connected to the single aspiration source 3430 via the valve, but Garrison has no disclosure of building up vacuum pressure with that valve closed. *Id*. at ¶75. The pumps in those embodiments are continuous pumps—specifically illustrated as peristaltic pumps but alternatively described as other "current sources of aspiration" like centrifugal pumps, and a POSA would understand such pumps are not suitable to operate against a closed valve. *Id*. at ¶78; EX1006, ¶[0135]. Laub and Aklog disclose the same types of pumps and Petitioner does not allege that those references disclose any fluid control device that is closed while vacuum is generated. EX1012, ¶[0041]; EX1005, 12:9-14.

None of Petitioner's references disclose a valve that is closed to generate vacuum pressure with the types of continuous pumps (e.g., peristaltic) shown in Figure 33 of Garrison, which is for good reason. Namely, a POSA would understand that in Petitioner's combination with their added valves closed while the pumps operate, fluid flow would be shut off to the pump such that the pump runs dry. EX2008, ¶¶79-82. That would damage the pump. *Id*. In fact, manuals for conventional continuous-operation blood pumps (like those of Garrison, Aklog, and Laub) at the time of the invention warned against operating those pumps in the absence of inlet flow for exactly those reasons. EX2009, pp.7-8 ("[d]o not operate the centrifugal blood pump … in the absence of flow … [t]he temperature within the pump could rise"); EX2012, pp.3 ("**IMPORTANT:** Pump heads must <u>never be run dry</u>! Danger of bearing damage!"), 5 ("⚠ **The pump head must not be running dry**."), 11; EX2010, pp.4-5. For that reason of likely pump damage, a POSA would not have found it obvious to have mixed and matched Garrison's various embodiments to arrive at Petitioner's modified Figure 33 including two valves that would be shut off when the pumps run. EX2008, ¶82.

And because, for good reason, none of those references disclose Petitioner's arrangement with a valve that is closed while vacuum pressure is built up with a continuous pump like in Garrison's Figure 33 (and Laub and Aklog), Petitioner relies on yet another disparate embodiment of Garrison briefly described in paragraph [0134] to purportedly show that buildup of vacuum pressure and to provide a motivation for adding the valves—"to enable the maximum level of aspiration." Petition, pp.37-39 & 54-57. But that disclosure in paragraph [0134] would not have taught a POSA to arrive Petitioner's modified Figure 33. EX2008,

¶83. In that embodiment, Garrison's syringe "is attached to the flow controller" without an intervening filter 3418, check valve 3419, or associated tubing in order to "enable the maximum level of aspiration in a rapid fashion." *Id.*; EX1006, ¶[0134]. Those structures in Petitioner's combination would introduce a dead volume that would lessen rather than "maximize" any level of aspiration if a syringe were substituted for the pumps 3125/3425 in Figure 33. EX2008, ¶¶83-84.

Accordingly, a POSA would not have mixed and matched Garrison's embodiments as Petitioner alleges. A POSA would not have added valves to Figure 33, much less used those valves to create built-up vacuum pressure with those valves closed as Petitioner alleges, because it would damage Garrison's continuous pumps (and Aklog's and Laub's). And a POSA would not have used a syringe in place of the continuous pumps in Petitioner's modified Figure 33 because that arrangement would lessen aspiration rather than "enable the maximum level of aspiration" due to the intervening structures that provide a significant dead volume. EX1006, ¶[0134]. Grounds 1-3 fail for those reasons.

Moreover, 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." Petition, p.25. But 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. EX2016, ¶¶70, 76-77.

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. 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] (not "returning the blood back to the patient … could quickly result in exsanguination of the patient."); EX1005, 7:23-26 ("such a [large] catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.").

But each of the embodiments (Figures 33-34 and paragraph [0134]) of Garrison that Petitioner asserts a POSA would have modified and combined to arrive at the purported "optimized" Garrison, is ***incompatible*** with that blood return. EX1006, ¶[0135]. And, Petitioner's proposed modification to Figure 33 adding valves and closing those valves while the pumps operate would further harm blood in Garrison's system if it were to be returned to a patient as taught by Laub/Aklog to treat PE. EX2008, ¶107. For example, the same conditions such as increased friction, overheating, etc., that act to damage the pump in a starvation state (i.e., no-inflow) as in Petitioner's purported combination would also act to damage blood already in the system. *Id*. at ¶107. Again, conventional continuous blood pumps, like the ones in Garrison, Laub, and Aklog, at the time of the invention, recognized that danger. EX2009, pg.7 ("in the absence of flow … [t]he temperature within the pump could rise and increased cellular damage may result."); EX2010, p.5 ("when clamping the tube: … turn the flow regulator to zero to prevent hemolysis."). Accordingly, a POSA would not have modified Garrison or combined Garrison with Aklog and Laub because it would have been inconsistent with the need for blood return. EX2016, ¶77.

A POSA would not have upsized Garrison's catheters to "16 French or greater" (by necessity the first, outer catheter must be larger than 16F to allow for the second, inner catheter to be advanced within it) as recited in independent Claims

1 and 11 because such a modification would render Garrison's system inoperable for its intended purpose of treating cerebrovascular clots, and more particularly, for treating clots in the middle cerebral artery as shown in, for example, Figures 33-34 of Garrison relied on by Petitioner. EX2008, ¶¶115-118. 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*. Petitioner's proposed combination would render Garrison inoperable for its intended purpose, so it would not have been obvious.

Finally, Patent Owner presents cross-examination testimony from Petitioner's purported experts demonstrating that Patent Owner's expert testimony supporting patentability should be credited over Petitioner's proffered testimony otherwise. First, Petitioner's primary expert, Mr. Thornton, has no experience in the field of the invention and thus would not qualify as a POSA, let alone as an expert here. And second, Petitioner's other purported expert, Dr. Turk, who is Petitioner's Chief Medical Officer and who holds "a lot" of Petitioner's stock, testified that he did not even read the '910 Patent, the Claims, or the asserted references Garrison, Aklog, and Laub. Dr. Turk also has no clinical experience treating pulmonary embolism. Petitioner's purported expert testimony should be given little or no weight. The

Petition's unsupported attorney argument fails to demonstrate unpatentability by a preponderance of the evidence.

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 thrombectomy devices that treat PE and has pioneered the use of the systems claimed in the '910 Patent, including systems with large-bore telescoping aspiration catheters. For example, Patent Owner's FlowTriever products 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; EX2008, ¶36. PE is a common and particularly dangerous type of venous thromboembolism (VTE) caused by blood clot formation

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[2]*See* https://www.inarimedical.com/flowtriever-system.

in the veins of the body that can migrate and cause occlusions in the lungs; VTE is, unfortunately, a leading cause of both death and disease worldwide. EX1001, 1:45-67; EX2008, ¶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; EX2008, ¶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, and cannot be used at all in many patients. EX1001, 2:26-32; EX2008, ¶¶33-35. Invasive surgical procedures may be traumatic to the patient. EX1001, 2:9-11.

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 a PE in a patient's blood vessel to generate the large suction forces (and corresponding fluid flow velocities) needed to effectively aspirate and remove the clot material from the patient. EX1001, 4:34-50; EX2008, ¶36. The generated forces and 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, such as in instances of chronic PE. EX1001, 4:42-47, 10:14-27; EX2008, ¶36.

The 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 through (i.e., insertable and moveable within) 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 remove at least a portion of the PE. The second catheter of the second clot aspiration assembly has a size of 16 French or greater, allowing for 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; EX2008, ¶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:

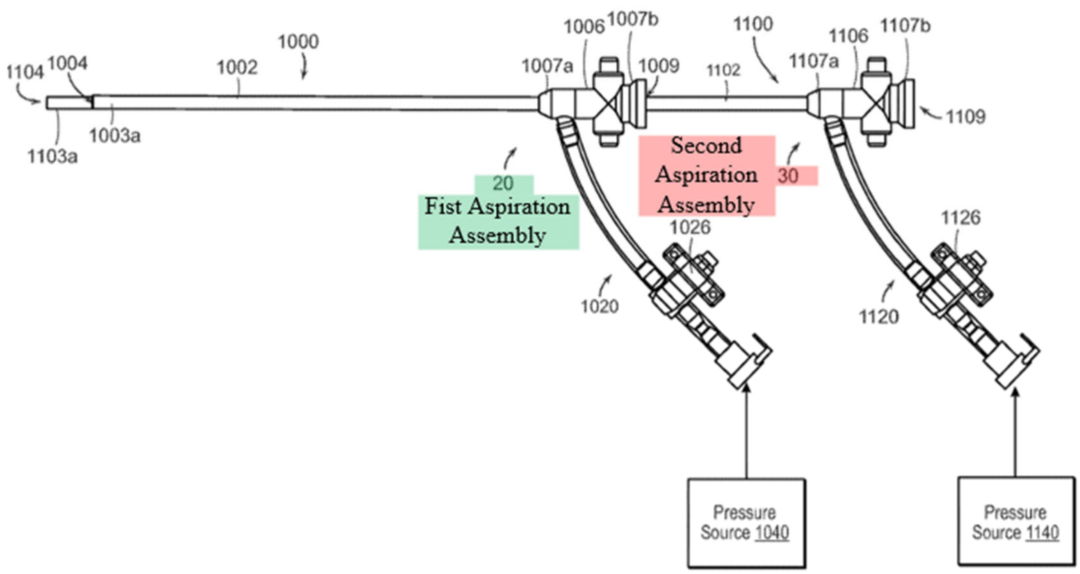


FIG. 11

EX2008, ¶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:

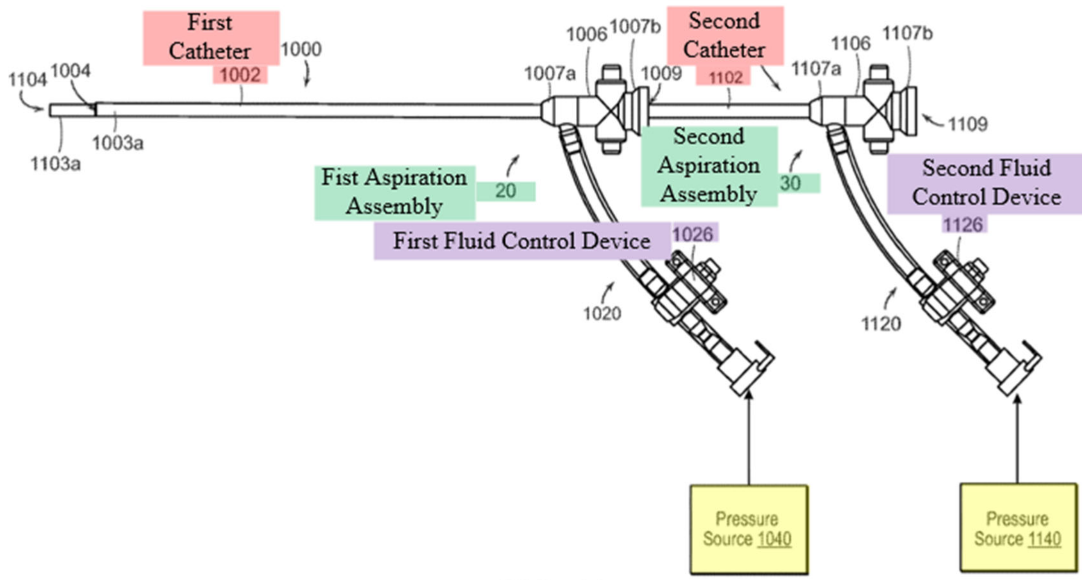


FIG. 11

Id.

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

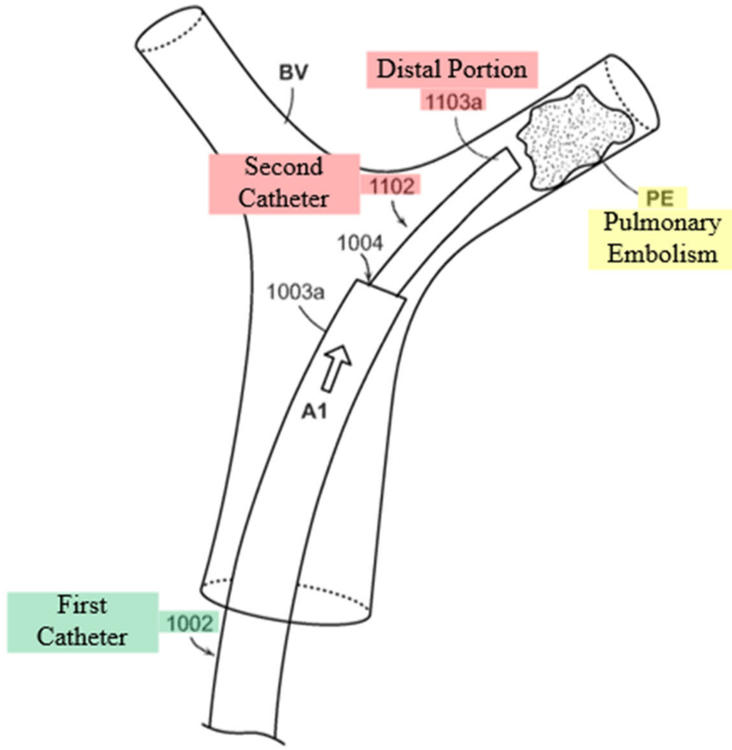


FIG. 13A

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; EX2008, ¶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:

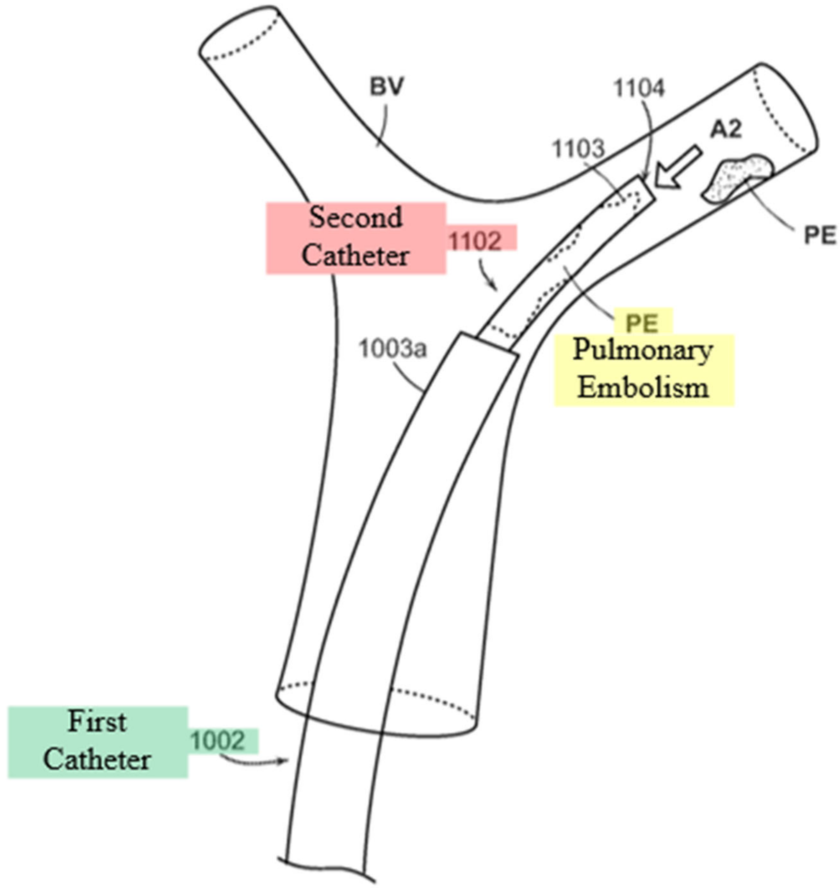


FIG. 13B

EX1001, 23:30-40; EX2008, ¶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) … compared to simply activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102." EX1001, 23:40-47; EX2008, ¶41.

The first pressure source and second 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; EX2008, ¶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 Office action mailed November 6, 2023, the Examiner relied on Garrison to reject original 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) 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 other words, Garrison failed to disclose telescoping aspiration catheters and generating and using stored aspiration via a fluid control device.

In response, 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 … positioned proximate to the pulmonary embolism." *Id*. at pp.142-145. Patent Owner explained that the amended claims were patentable over Garrison based on a discussion with the same Examiner about Garrison in the context of a related application (U.S. Patent Application No. 18/329,450) that claimed similar subject matter. *Id*. at pp.147-148. In other words, Patent Owner substantively addressed 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 were patentable over Garrison in the Notice of Allowance—e.g., that the "clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism." *Id*. at p.49. Accordingly, Garrison—Petitioner's primary reference—was already 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 (IDS), Aklog is a continuation-in-part of Aklog's parent (EX1019) which was considered during prosecution and includes identical disclosure to the only portions of Aklog relied upon in the Petition. EX1002, p.1123 (IDS identifying Aklog's parent, EX1019); EX1005, p.1. The only additional disclosure in Aklog over Aklog's parent is found in columns 18:56-20:27 of Aklog and is unrelated to the claims of the '910 Patent and is not cited or relied upon in the Petition. Although 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

A POSA as of August 13, 2018 (the earliest priority date of the '333 Patent) would have been (1) a person with a Bachelor of Science degree in engineering or an equivalent field, with two to four years of academic or industry experience in the mechanical thrombectomy industry or comparable industry experience who would, where necessary or desired, work or consult with others including a physician to develop thrombectomy devices; or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures, and who would, where necessary, work or consult with others including an engineer to develop such a medical device. EX2008, ¶47.

Petitioner's proposed definition of a POSA disregards the field of the invention of the '910 Patent and should be rejected. Specifically, Petitioner proposes that a POSA would have "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" without regard to the technology that is claimed. Petition, p.18.

First, there is no meaningful dispute regarding the field of the invention of the '910 Patent, namely, "systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient." EX1001, 1:23-26. Petitioner's purported expert, Mr. Thornton, agrees. Mr. Thornton testified that the field of the invention'910 Patent is "devices for aspirating unwanted material from a patient." EX2013, 21:25-22:12. He then confirmed that the recitation of "the present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient," is a reasonable description of the technical field of the'910 Patent and is the same in substance to his assertion that the field is "devices for aspirating unwanted material from a patient" set forth in his declaration (EX1003, ¶26). EX2013, 22:23-23:20.

Although Petitioner's proposed definition of a POSA includes a similar level of education, Petitioner's proposed POSA omits any experience in the field of the invention (or any field of invention). Instead, Petitioner asserts that only "catheter design experience" is necessary, proposing that a POSA has "2-4 years of catheter design experience." Petition, p.18. Petitioner's omission of experience in the field of the invention of the '910 Patent cannot be correct.

Moreover, Petitioner's purported expert, Mr. Thornton, has no experience in the field of the invention, which he characterizes as "devices for aspirating unwanted material from a patient" (EX1003, ¶26) or which the '910 Patent describes as "systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient." EX1001, 1:23-26. Specifically, Mr. Thornton testified:

> [Q.] Have you ever designed a catheter to aspirate emboli, blood clot, or a thrombus from a patient?
>
> [A.] No. The catheters that I developed, though, I would argue are more complex and have probably more design requirements than the single lumen aspiration catheters that are disclosed in these patents.
>
> [Q.] Have you ever designed any device intended to be used to aspirate a blood clot, thrombus, or emboli?
>
> [A.] No.
>
> [Q.] Have you ever designed any catheter intended to be used to aspirate a blood clot, thrombus, or emboli?
>
> [A.] I'll answer no again.

EX2013, 49:24-50:10.

And, while Petitioner proposes in its definition that a POSA, "where necessary, would have consulted with a physician" with appropriate experience in the field of the invention, Mr. Thornton testified that he did not do so in preparing his opinions, as follows:

> [Q.] And did you consult with any physician in preparing your declaration with respect to the '910 patent?
> [A.] No.
> [Q.] Did you rely on any statement from any physician in preparing your declaration with respect to the '910 patent?
> [MR. BARNES:] Object to the form.
> [THE WITNESS:] I don't believe so.

EX2013, 43:9-17.

Because Mr. Thornton himself has no experience in the field of the '910 Patent, he is not qualified as an expert here and his testimony should be afforded no weight.[3]

[3] Mr. Thornton's testimony should also be excluded from the record because he does not have the minimum experience required for a POSA in the field of the '333 Patent. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1377 (Fed. Cir. 2022).

D. The testimony of Petitioner's purported Experts should be afforded little or no weight.

Petitioner's purported expert testimony should be afforded little weight and should not be credited over the testimony of Patent Owner's experts, Brian Brown and Dr. Christopher S. Morris.

First as explained above, Petitioner's purported expert, Mr. Thornton, fails to qualify as a POSA, let alone as an expert, because he has no experience in the field of the invention of the '910 Patent. EX2013, 49:24-50:10. As such his testimony should be afforded no weight and should not be credited over the testimony of Patent Owner's experts.

Similarly, Petitioner's other purported expert Dr. Aquilla Turk's testimony should be afforded little weight and should not be credited over Patent Owner's experts. At deposition, Dr. Turk admitted that he did not review the '910 patent, including its claims. EX2015, 33:12-34:6 ("I don't typically review patents, it's not my – my area of strength."). He also stated that his declaration did not render an opinion regarding the patentability of the claims at issue here. *Id*. at 34:7-35:7. He further testified that in preparing his declaration, he did not read any of the primary references Garrison, Aklog, or Laub. *Id*. at 69:7-11. And, while the Claims are directed to systems for treating PE, Dr. Turk admitted at deposition that he has no experience treating PE. *Id*. at 23:14-16. ("Do you have experience in treating …

pulmonary embolisms? A. No."). He further expressly acknowledged that he is not an expert in treating PE. *Id*. at 95:2-4. Instead at best for Petitioner, Dr. Turk has been "in the room" for and watched "eight or nine at least[.]" *Id*. at 69:14-70:4 (referring to PE removal procedures). Dr. Turk's testimony is simply not relevant to the '910 Patent's claims for treating PE, the asserted references, or Petitioner's grounds here.

Dr. Turk is also biased. At deposition, Dr. Turk testified that he is Petitioner's Chief Medical Officer (CMO), receiving a compensation of $250K per year and that he has "a lot" of equity in Petitioner. *Id*. at 13:18-15:9. Patent Owner has sued Petitioner for patent infringement of the '910 patent. Paper 3, p.2. As such, Dr. Turk has a strong financial incentive in the success of Petitioner in general, and in particular, in the outcome of this IPR.

In direct contrast to Petitioner's purported experts, Patent Owner's experts are highly qualified to render testimony in this IPR, and that testimony should be credited over Petitioner's purported expert testimony. First, Brian Brown is qualified as an expert in the field of the '910 Patent and has extensive experience in designing devices in the actual field of the '910 Patent. EX2008, ¶¶7-16, 47. Similarly, Dr. Morris has decades of experience as a physician treating and teaching others to treat PE, the very condition treated by Petitioner's claimed systems. EX2016, ¶¶8-18.

E. 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 that focus on other aspects of the claims, and it is therefore not necessary to analyze that claim term for this proceeding. Patent Owner has proposed an express definition in other pending IPR proceedings.

F. 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 like the '910 Patent. EX1006, ¶[0002]; EX2008, ¶49. For example, Garrison's Figure 33 (annotated below) shows an arterial access device 2010 that provides access to the common carotid artery (CCA), through which a smaller catheter 2030 is inserted such that a distal tip of the catheter 2030 is positioned in the middle cerebral artery (MCA) to treat clot therein. EX1006, ¶[0131]; EX2008, ¶49. The catheters 2010/2030 are each connected to a flow line 2025/2045, which can be connected in series via tubing to a filter 3418, a check valve 3419, a source of aspiration 3125/3425 (a peristaltic pump), and a receptacle 3100/3105, respectively. *Id*.

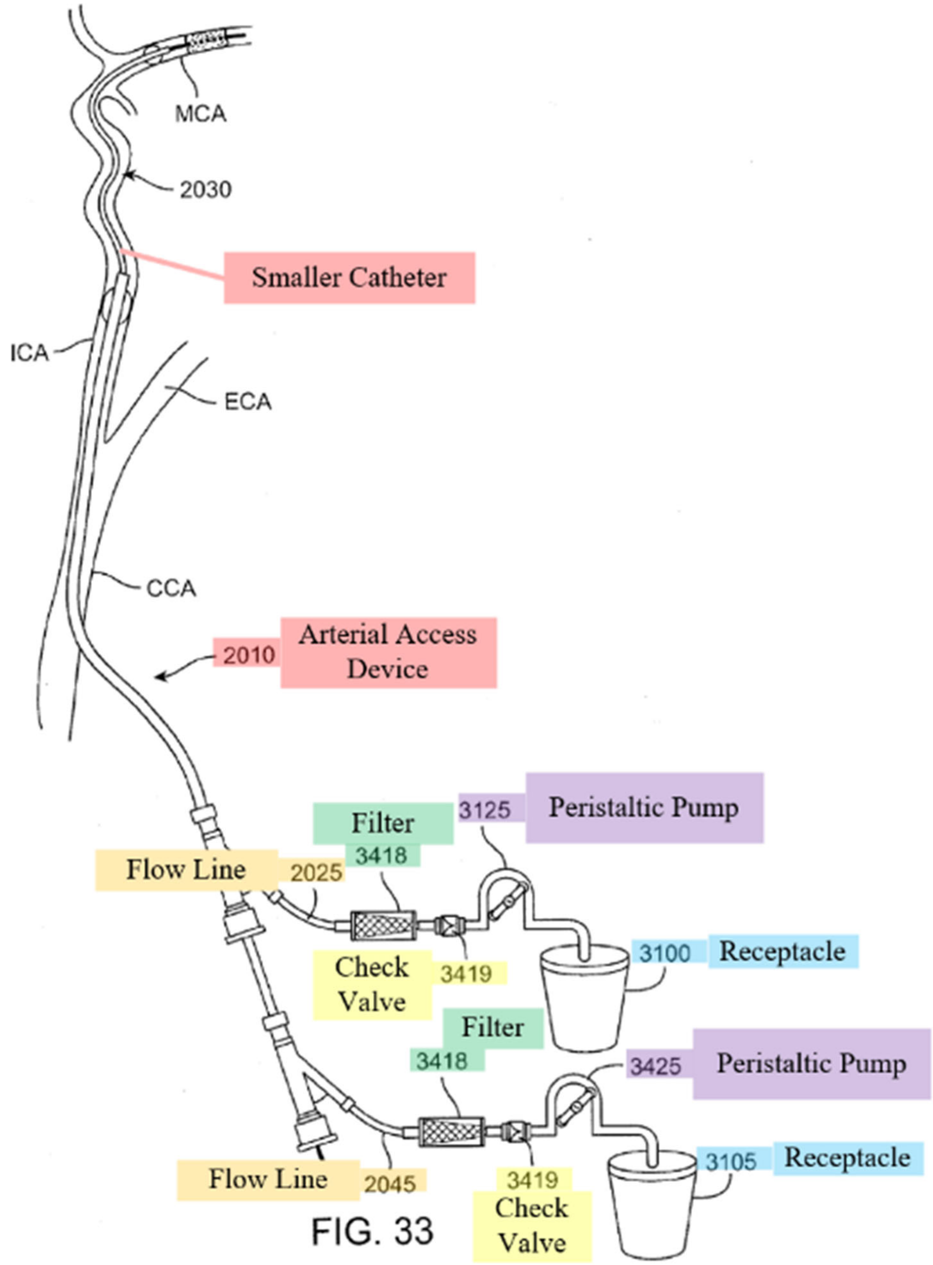


FIG. 33

EX2008, ¶49. As can be seen above, Figure 33 does not include any valve or fluid control device in either flow path between the pumps and connected catheter that could allow for building up and then releasing vacuum pressure.

Garrison's Figure 34 (annotated below) shows a similar system in which both catheters 2010/2030 are connected to the same aspiration source 3430 and receptacle. EX1006, ¶[0132]; EX2008, ¶50. A "valve 3325 controls which device is connected to the aspiration source 3430." *Id*.

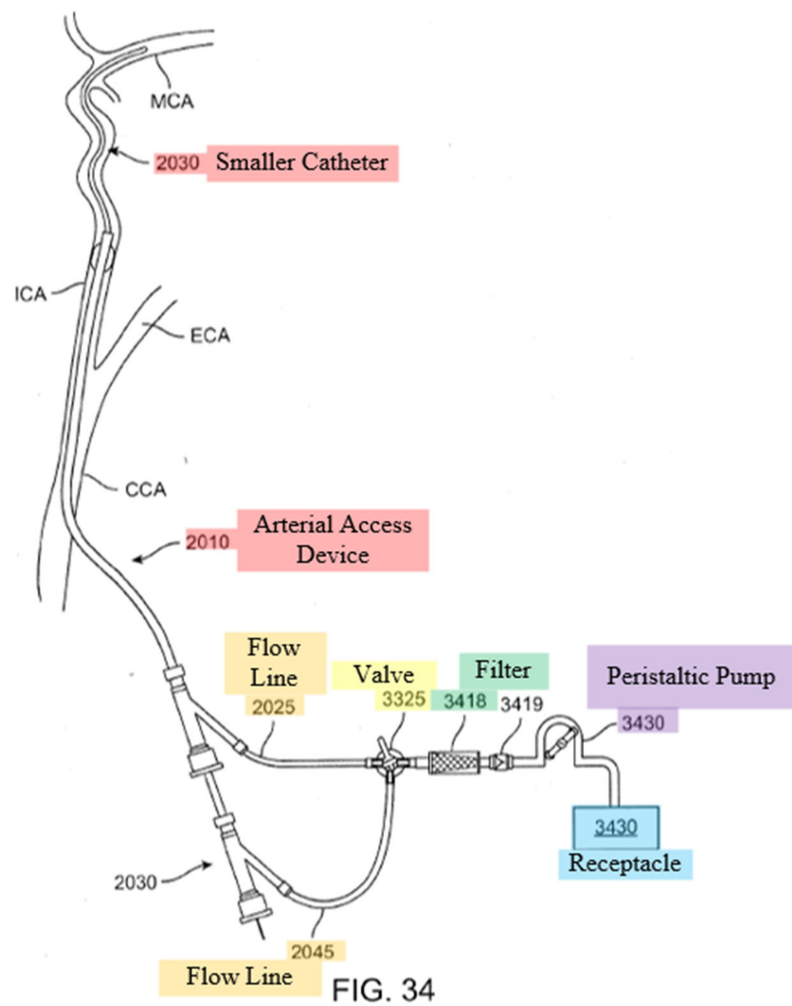


FIG. 34

Id.

The aspiration sources 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:

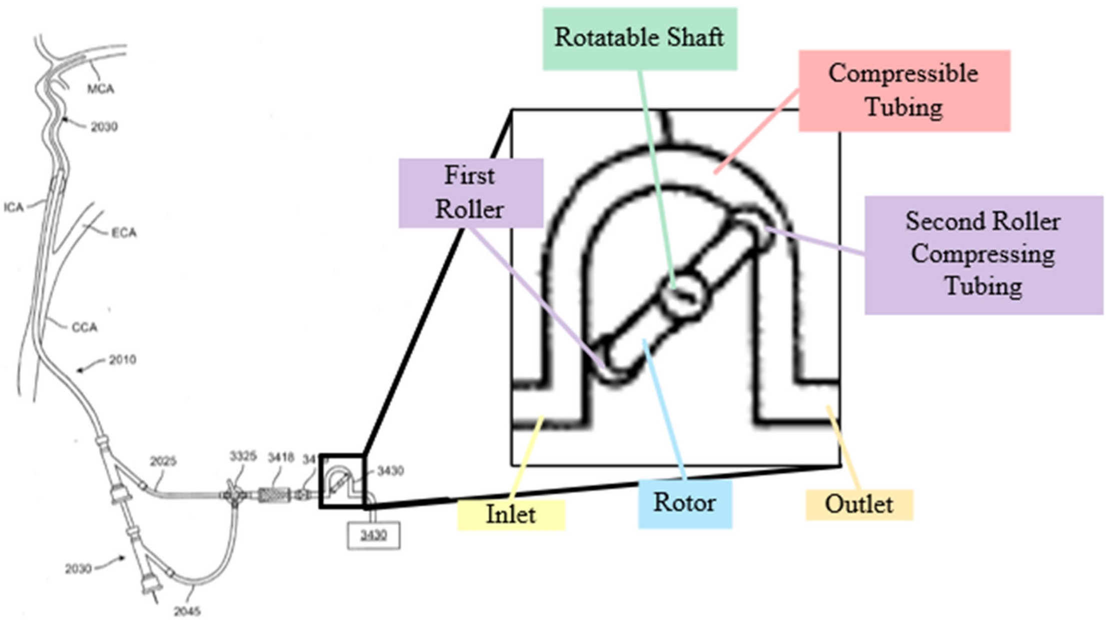


FIG. 34

EX2008, ¶51. A POSA would understand that such peristaltic pumps are a type of positive displacement pump. *Id.*

Garrison discloses a different embodiment of a syringe-based system in which "a locking 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]; EX2008, ¶53. In that embodiment, the syringe is attached directly to the flow controller (e.g., valve) rather than, for example, indirectly via a check valve and filter like the pumps shown in

Figures 33-34 to "enable the maximum level of aspiration" by reducing any dead volume between the syringe and the valve. EX2008, ¶53. Then, "[d]uring the procedure … 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 syringe is actuated with the connection to the flow line closed such that vacuum is generated in the syringe. EX2008, ¶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 because, for example, the blood is "exposed to air or has been static for a period of time" such that "there is a risk of thrombus formation or damage to the blood cells." EX1006, ¶[0135]; EX2008, ¶54. To address that disadvantage, Garrison discloses a separate, but incompatible, 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." EX1006, ¶¶[0136]-[0137]; EX2008, ¶¶55-56. The pump in Figure 36 is another type of positive displacement pump like a peristaltic pump, but that operates without rollers that compress tubing. EX2008, ¶56.

2. Laub

Laub discloses a "system for removing thrombi and other unwanted material from … [a] 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:

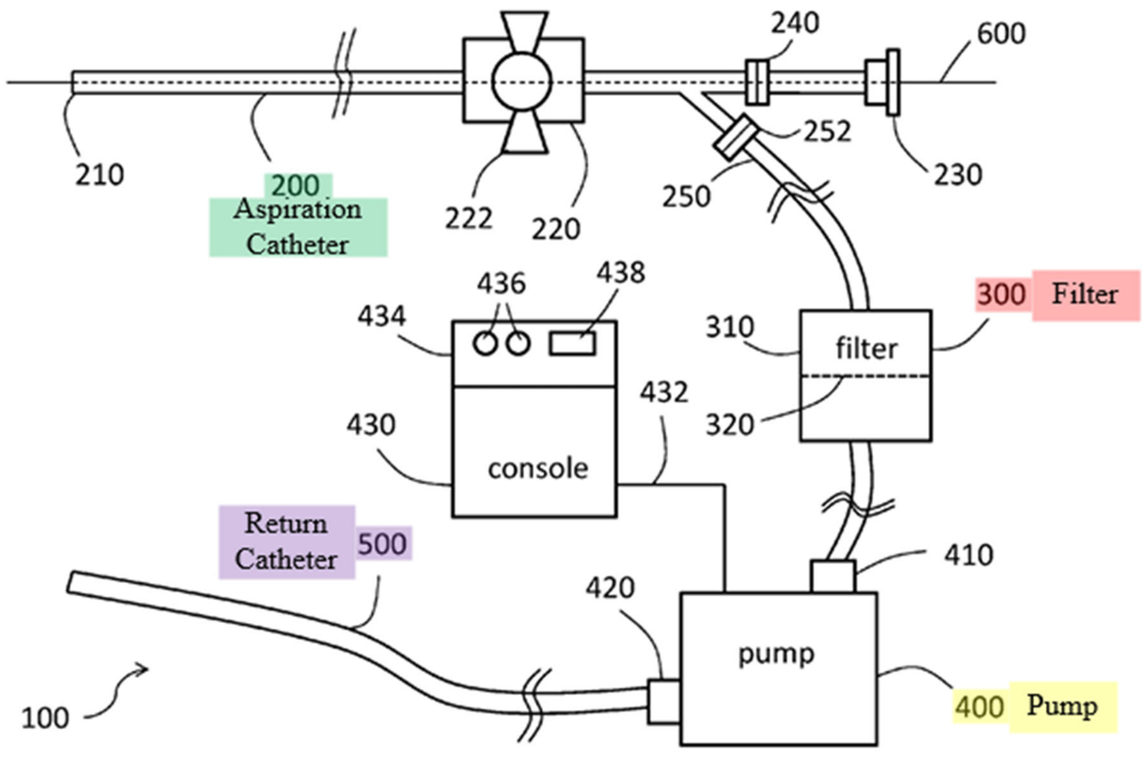


FIG. 1A

EX1012, ¶[0024]; EX2008, ¶57. The system includes no valve 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 into the patient. EX2008, ¶57. In other words, Laub does not generate a stored vacuum pressure. EX2008, ¶57. 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]; EX2008, ¶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. EX2008, ¶58; EX2016, ¶¶63, 71-74. 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: "[w]ithout returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient." EX1012, ¶[0045]. Thus, Laub assumes 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. EX2008, ¶59; EX2016, ¶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. EX2008, ¶59; EX2016, ¶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); EX2008, ¶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:

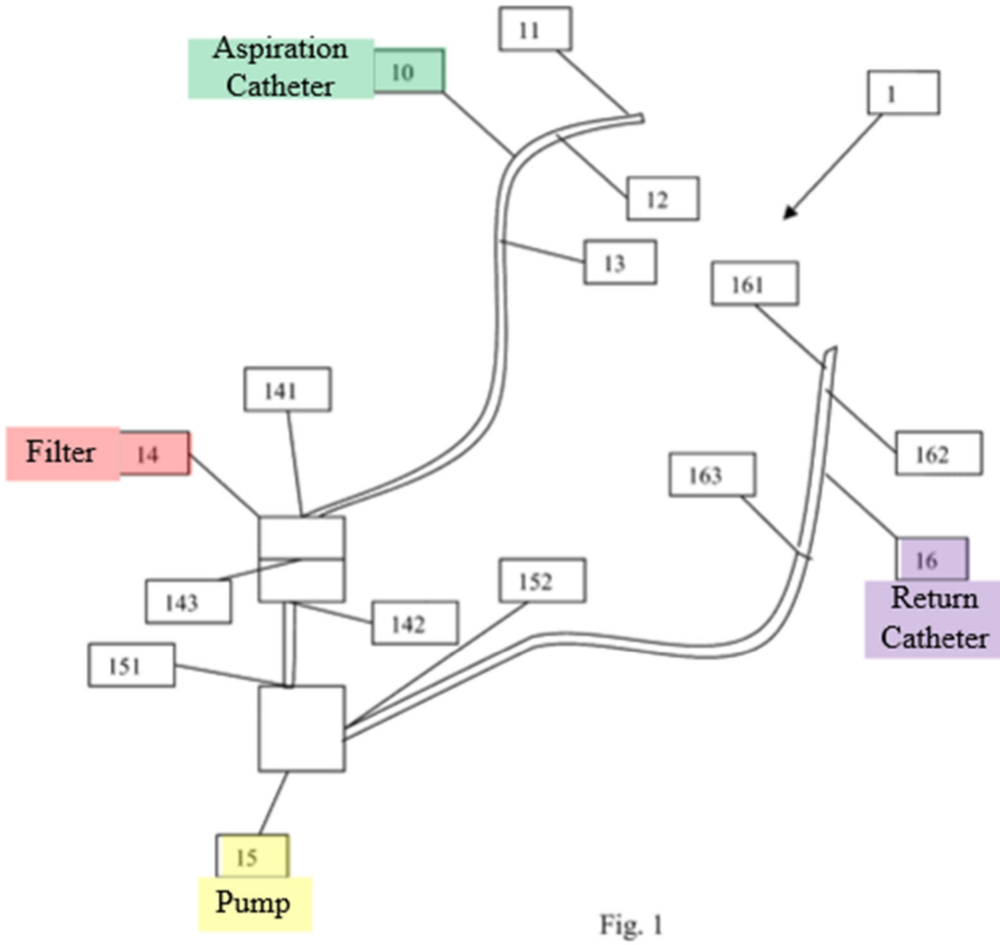


Fig. 1

EX2008, ¶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 also does not disclose any other mechanism for building up a stored vacuum pressure either, employing a continuous pump. EX2008, ¶60.

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 cm^3 of undesirable material substantially en bloc." *Id*. at 11:18-20. A POSA would understand that a clot of 10 cm^3 is much larger than neurovascular clots and more akin to the size of a PE. EX2008, ¶61. And, Aklog recognizes that its system "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; EX2008, ¶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. EX2008, ¶62; EX2016, ¶61. 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; EX2008, ¶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. EX2008, ¶62; EX2016, ¶61. 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 AKLOG (GROUND 2), OR GARRISON, LAUB, AND AKLOG (GROUND 3)

Petitioner fails to demonstrate that Claims 1-6, 8, 11-15, and 18-20 are obvious over Garrison in combination with Laub and/or Aklog. 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 do not disclose or render obvious multiple limitations of the Claims that go to the heart of the claimed invention. In particular, Petitioner picks and chooses features of various embodiments of Garrison to manufacture a purported system (Petitioner's purported demonstrative illustration of Figure 33 showing two of the valves from Figure 34 incorporated into Figure 33 that are used to build up vacuum pressure when closed) that Garrison ***does not disclose*** and that is contrary to Garrison's disclosure and that a POSA would not have constructed. *Infra*, §III.A. And, Petitioner admits that the requirements of "for treating … pulmonary embolism" and wherein the inner second catheter "has a size of 16 French or greater" are not found in Garrison. But 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 by inhibiting blood return. Finally, a POSA would not have radically increased the size of Garrison's smallest inner catheter to "16 French or greater" as required by Claims 1 and 11 because such a modification would render Garrison's system unsuitable for its intended purpose of treating cerebral clot. Such a large catheter would be too large to fit into the cerebral vessels Garrison's catheters are intended to be positioned in.

Accordingly, for those reasons and the reasons set forth below, independent Claims 1 and 11 (and the claims depending therefrom) are not rendered obvious by Garrison in combination with Laub and/or Aklog.

A. A POSA Would Not Have Mixed and Matched Garrison's Embodiment to Arrive at Petitioner's Purported Arrangement Adding Two Valves to Figure 33 of Garrison

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. EX2008, ¶72. These claims further require the "pre-charged" aspiration described in the '910 Patent in which vacuum is built up when a fluid control device is closed. *Id*. Specifically, 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, and Claim 11 recites a single "fluid control device" between a catheter and a pressure source. *Id*. Each of those pressure sources is "configured to generate vacuum pressure while" the respective fluid control device is in a "first position" in which the pressure source is fluidly disconnected from the respective catheter. *Id.*

Petitioner 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 it is contrary to Garrison's disclosure and combinations with Aklog and Laub. EX2008, ¶73; EX2016, ¶¶63-77. While the Board preliminarily saw no "flaw in Petitioner's alleged mixing and matching of embodiments of Garrison," Patent Owner submits new evidence herein to show that such mixing and matched is indeed flawed. Namely, a POSA would not have arrived at Petitioner's modified Figure 33 because that arrangement would lead to pump and blood damage if operated with Garrison's peristaltic (or like) pumps. *Id.*; Petition, pp.51, 53, 55.

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

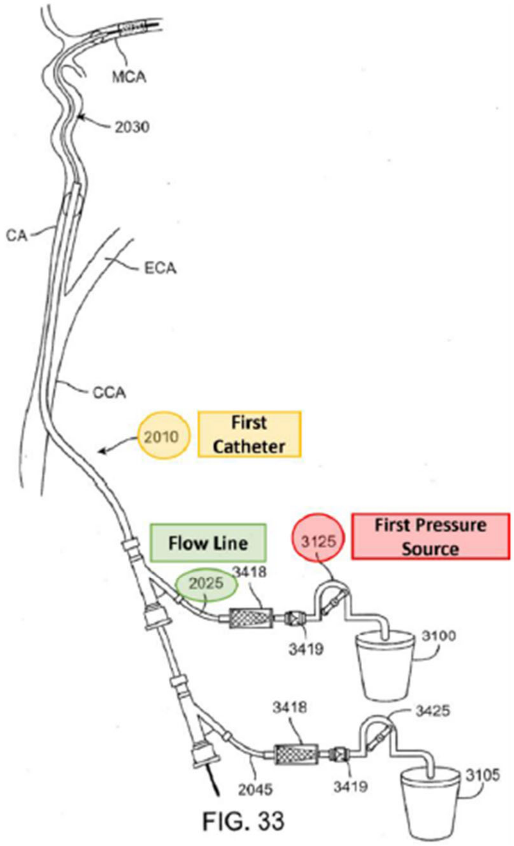


FIG. 33

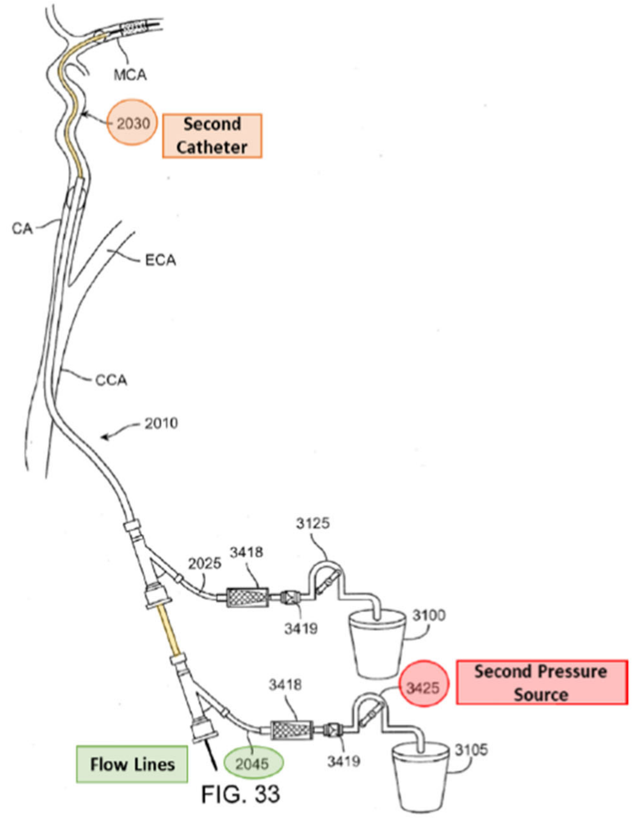


FIG. 33

Petition, pp.34-35, 39-42. But, in the embodiment of Figure 33, the first pressure source 3125 is fluidly connected to the catheter 2010 ***without*** any "first fluid control device" that "is movable between a "first position" and a "second position" as recited in independent Claim 1. EX1006, ¶[0131]; EX2008, ¶74. And, likewise, the second pressure source 3425 is fluidly connected to the second catheter 2030 ***without*** any "second fluid control device" that "is movable between a "first position" and a "second position" as recited in independent Claim 1 and similarly recited in independent Claim 11. *Id*. Therefore, Figure 33 of Garrison—the primary embodiment relied on by Petitioner—does not disclose any "fluid control device" as recited in the Claims. EX2008, ¶74. And, accordingly, that Figure 33 cannot disclose any pressure source that is "configured to generate vacuum pressure" when a fluid control device is closed as recited in the Claims of the '910 Patent—there is no fluid control device.

Because Figure 33 does not disclose a "fluid control device" at all, 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:

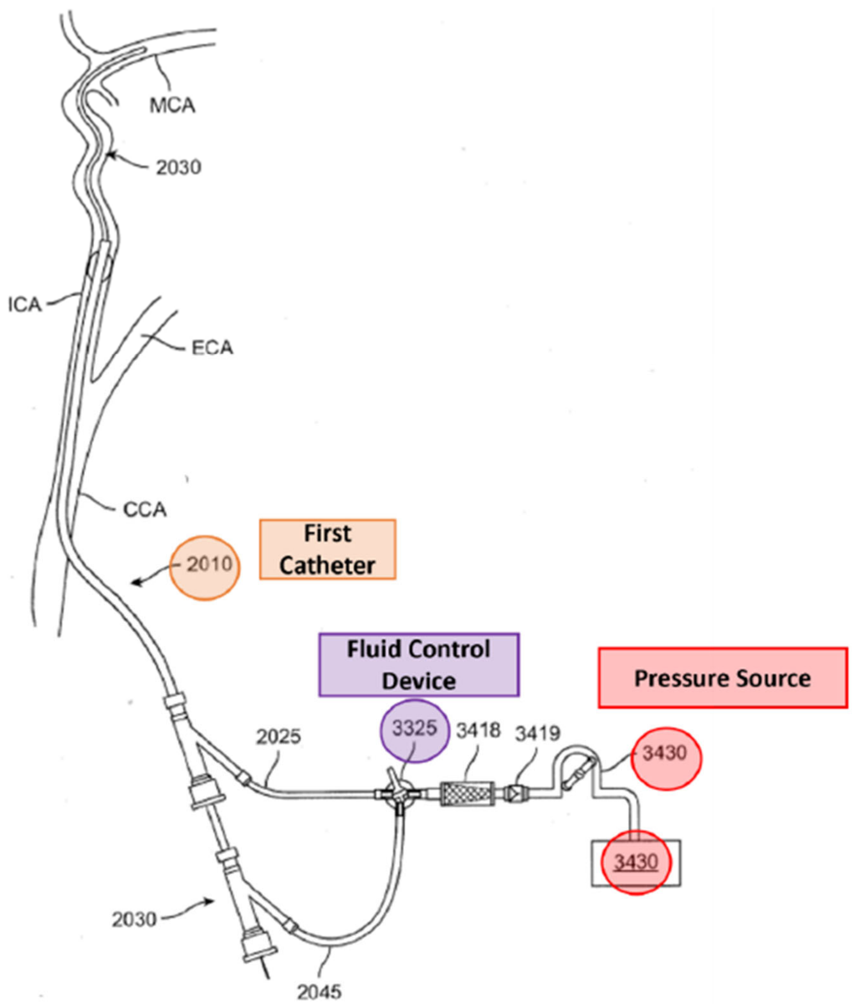
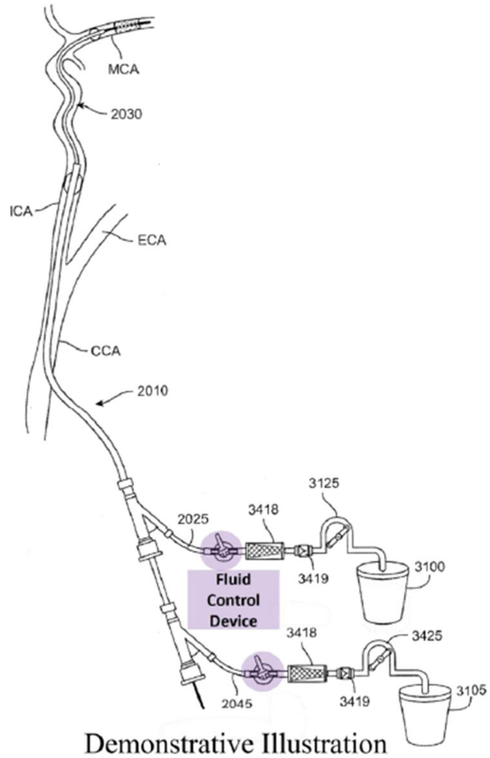
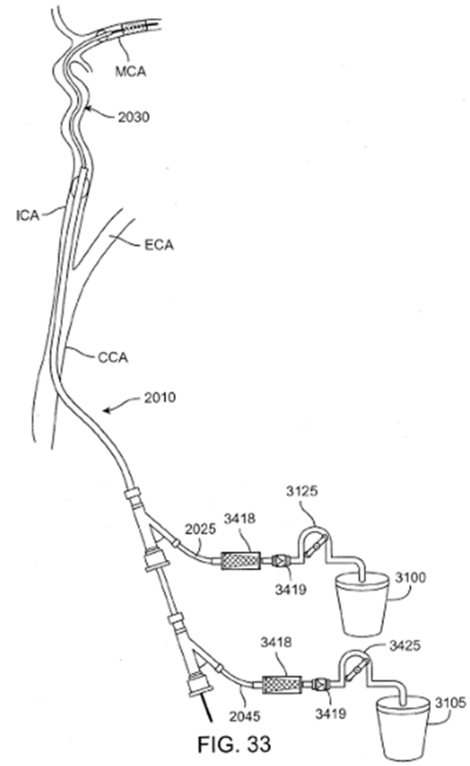


FIG. 34

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." EX1006, ¶[0132]. That is, both catheters 2010/2030 are connected to the same aspiration source 3430 (a pump), the valve 3325 is used to switch the connection of those catheters to the pump. EX2008, ¶75. Garrison does not disclose using any valve, such as the valve 3325, to build up vacuum pressure when the valve is closed, and a POSA would not have operated Garrison's system in such a manner because, as explained below, stopping inlet fluid flow to such a pump is warned and discouraged against as it could damage the pump and blood in Garrison's system. *Id*.

Next, 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.

Finally, because there is no disclosure in Garrison of using the valve 3325 in Figure 34 to build up vacuum pressure, Petitioner relies on yet a different embodiment of Garrison described in paragraph [0134] of Garrison to allegedly show the claimed buildup and release of vacuum pressure (but using a syringe rather than a pump):

> 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. But that disclosure of Garrison is for a syringe rather than a pump like in Petitioner's combination. And with that syringe, the "maximum level of aspiration" is achieved by directly connecting the syringe to the flow controller without any intervening filter 3418, check valve 3419, or tubing. EX2008, ¶78.

Accordingly, no embodiment of Garrison discloses the features of the Claims—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; EX2008, ¶78. Further, as set forth below, a POSA would not have mixed and matched Garrison's embodiment to arrive at Petitioner's demonstrative illustration for several reasons.

1. Petitioner's Proposed Modification to Figure 33 Would Likely Damage Garrison's Pumps

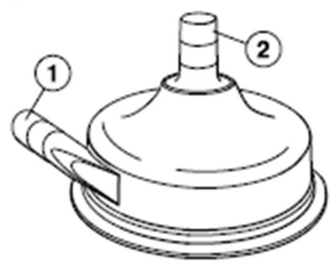
Garrison discloses various embodiments that utilize different aspiration sources, and in Figure 33 and 34 of Garrison, those aspiration sources are peristaltic pumps. EX2008, ¶78; *supra* §II.F.1. Garrison also discloses similar pumps like centrifugal pumps. EX1006, ¶[0135]; EX2008, ¶78. But, contrary to Petitioner's explanation for its modified Figure 33 of Garrison, a POSITA would not have configured or operated Garrison's system to generate a stored vacuum pressure using such pumps while those added valves were closed. Petition, pgs.54-55 & 37-38; EX2008, ¶78.

Namely, a POSA would understand that Garrison's peristaltic or centrifugal pumps are not intended to operate/run without fluid flow to their inlet as in Petitioner's modification to Figure 33. EX2008, ¶79. Rather a, POSA would have understood that running/operating a peristaltic pump (or any other centrifugal, rotary, or like pump as disclosed by Garrison (and Laub (EX1012, ¶[0041]) and Aklog (EX1005, 12:9-14)) with the fluid inlet (i.e., suction inlet) closed as in Petitioner's proposed combination would starve the pump of fluid, potentially damaging the pump. EX2008, ¶79. In particular, without fluid flowing through the pump, the pump would run dry, experience significantly increased friction and cavitation, and overheating, potentially leading to mechanical failure. *Id.* More specifically, with Garrison's added valves closed in Petitioner's purported combination, Garrison's pumps 3125/3425 would be unable to move fluid therethrough, thereby risking creating a vacuum that causes remaining fluid to boil and vaporize, destroying seals and bearings of the pump, while also cavitating and generating cavitation bubbles that could violently collapse within the pump and damage the pump. *Id*. Likewise, without fluid flowing to remove heat, the internal casing temperature of Garrison's pumps would rise rapidly due to friction caused by the components moving, leading to eventual failure. *Id*. And, without fluid lubricating the flow paths, the internal adjoining surfaces of Garrison's pumps could seize. *Id*.

A POSA would have readily understood for all the foregoing reasons that the Garrison's pumps would not be operated with a valve to the pump inlet closed shutting off fluid flow as Petitioner alleges. *Id*. at ¶80. It is for precisely that reason that a POSA would understand why neither Garrison, Laub, or Aklog disclose any such valve for use with their pumps. *Id*.

In agreement with that understanding, documentation for conventional blood pumps like those described in Garrison (and Laub and Aklog) cautioned and warned against operating those pumps without inlet fluid flow. Garrison describes the pumps in Figures 33-34 as conventional "current sources of aspiration." EX1006, ¶[0135]. One such blood pump at the time of the invention of the '910 Patent (a "current source of aspiration") that was commercially available was the Bio-Pump™ BP-50. *See*, e.g., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K852807 (showing 510(k) clearance from the U.S. Food and Drug Administration for the BP-50 pump September 30, 1985); EX2011, p.9 (showing Bio-Pump BP-50 innovations in 1985). Instructions for use for the BP-50 pump[4] describe the pump as a "centrifugal blood pump" having an inlet and outlet:

Figure 1. • Figura 1. • Figure 1.



EN 1 Outlet
2 Inlet

EX2009, pp.5-6. And, just like a POSA would understand based on the operation of such pumps, the instructions for use specifically warned and instructed users: (1) "[d]o not operate the centrifugal blood pump for more than 30 s in the absence of

[4] While these instructions are dated September 12, 2018—after the priority date of the '910 Patent—they reflect what a POSA would have understood of how the BP-50 pump, which was commercially available as early as 1985, should and should not be operated. EX2008, ¶80.

flow … [t]he temperature within the pump could rise," (2) "[a]ttach tubing in a manner that prevents kinks or restrictions that may alter flow," and (3) "[d]o not operate the centrifugal blood pump unprimed; damage to the internal components will occur." *Id.* at pp.7-8. Similar instructions for using the BP-50 pump (or like pumps such as the larger BP-80 version) likewise warn and emphasize that "**IMPORTANT:** Pump heads must never be run dry! Danger of bearing damage!" EX2012, p.3; *see also id.* at p.5 ("⚠ **The pump head must not be running dry**."), p.11 ("Operating the pump head dry may damage the rotor bearing"; "the internal seal … of the rotor bearing is endangered if … the pump head is operated dry").

Another commercially available blood pump at the time of the invention was the ROTAFLOW Centrifugal Pump from Maquet. EX2008, ¶81. And, like the instructions for the BP-50/BP-80 pumps, the instructions for use (dated June 2010) for the ROTAFLOW pump warned and instructed users: (1) "attach tubing in such a manner as to prevent kinks or any restrictions that may alter flow and (2) "[r]educe the pump speed to the minimum speed before clamping the tube, then turn the flow regulator to zero." EX2010, pp.4-5.

Accordingly, instructions for use for conventional blood pumps confirm that a POSA would have understood that adding valves to Garrison's Figure 33 and closing them to operate Garrison's pumps in Figure 33 without fluid flow therethrough (i.e., in the absence of flow, running dry, with restrictions, against a closed valve) as in Petitioner's proposed modification would likely damage those pumps. EX2008, ¶¶80-81. Therefore, a POSA would not have modified Garrison to include two different valves that could and would operate to close off fluid flow while those pumps run as in Petitioner's proposed combination shown in its demonstrative illustration of Figure 33. *Id*. at ¶82.

And, while Garrison discloses the different locking syringe embodiment in paragraph [0134], that embodiment would not have led a POSA to arrive at Petitioner's proposed modification of Figure 33 of Garrison. EX2008, ¶83. In particular, a syringe does not have continually moving parts like the continuous peristaltic pump in Figure 33 that can be damaged in the same manner when a valve is closed. And, while Garrison generally discloses that the aspiration source may be a pump or syringe, Petitioner does not specifically contend that the pumps in Figure 33 are anything other than peristaltic pumps as Garrison discloses. EX1006, ¶[0134].

Even so, a POSA would not have substituted a syringe for either of the aspiration sources 3125, 3425 in Figure 33 because it would lessen rather than maximize vacuum. EX2008, ¶83. For example, in the syringe embodiment of paragraph [0134], Garrison discloses that the syringe is "attached" directly to a flow controller rather than indirectly via a filter, check valve, and tubing like the pumps in Figure 3. EX1006, ¶[0134]. That arrangement "enables the maximum level of aspiration" because there is a minimal volume—i.e., no dead space—between the syringe and valve. *Id*.; EX2008, ¶83. In contrast, if a syringe were substituted for either pump in Petitioner's modified Figure 33, the filter, check valve, and tubing would provide a significant volume (i.e. dead space) between each of Garrison's syringes and Petitioner's added valves. *Id*. That extra volume decreases the maximum achievable vacuum pressure because removing the same volume of fluid (Garrison's syringe volume) from a larger volume (including the filter, check valve, and tubing) rather than a smaller volume (a direct connection to the flow controller as Garrison expressly teaches), results in less vacuum pressure. *Id*. Therefore, that arrangement would to "enable a maximum level of aspiration" as Garrison discloses and as Petitioner touts as its motivation to add the valves to Figure 33 in the first place. *Id*. at ¶84; EX1006, ¶[134]; Petition, pp.38, 51, 53, 55.

Taken altogether, a POSA would not have been motivated to arrive at the configuration shown in Petitioner's demonstrative illustration of Figure 33 of Garrison because closing Petitioner's valves added there to operate Garrison's peristaltic (or like) pumps 3125/3425 with those valves closed would damage the pumps. EX2008, ¶85. Even if aspiration power were momentarily increased by including a valve, a POSA still would not have included such a valve because any subsequent aspiration might be hindered by degradation of the pump from starvation of fluid to the pump. *Id*. And, a POSA would not have used a syringe like in paragraph [0134] of Garrison in the arrangement of Figure 33 with the "fluid control device … in the same position in modified Figure 33 [] (i.e., ***between the filter and the catheter***) as in Figure 34" (Petition, p.52; emphasis added) because that would significantly decrease the level of aspiration due to the intervening volume of the filter, check valve, and tubing—not enable the "maximum level of aspiration"—as Petitioner repeatedly touts as a motivation to combine. Petition, pp.38, 51, 53, 55; EX2008, ¶85.

2. Petitioner's Proposed Modification to Figure 33 Would Not Enable the Maximum Level of Aspiration

Petitioner's assertion that a POSITA would have included valves 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'" also ignores the fundamental difference between a syringe and a peristaltic pump regarding the maximum achievable level of vacuum. Petition, pgs.51, 53; EX1003, ¶116; EX2008, ¶86.

As set forth in §III.A.1., above, Garrison's only disclosure of building up pressure with a valve closed is the syringe embodiment in paragraph [0134]. A POSA would understand that vacuum pressure is generated in the syringe barrel when a plunger is withdrawn. EX1006, ¶[0134]; EX2008, ¶86. That barrel has a fixed volume, and that volume sets and thus limits the "maximum level of aspiration." EX2008, ¶86. Therefore, when the syringe plunger is withdrawn with the flow controller closed as described in paragraph [0134], the maximum level of vacuum in the syringe is achieved because the full barrel is evacuated. *Id*.

In contrast, peristaltic pumps like in Figure 33 of Garrison (and centrifugal and other positive displacement pumps) do not have a fixed volume that limits the "maximum level of aspiration"—instead operating to continuously shuttle fluid through a tube with a rotor. EX2008, ¶87. Accordingly, there is no fixed volume of the peristaltic pump that can be evacuated in the same manner as 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 moves 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 ¶88. 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 of including two valves that are purportedly closed and then opened to generate and then apply a stored vacuum. EX2008, ¶88. 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 ¶89.

3. Petitioner's Proposed Modification to Figure 33 Would Not Give Physicians More Flexibility

Petitioner is 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 to provide independent control of the aspiration sources because the catheters are connected to different, independent aspiration sources. EX2008, ¶90. In contrast, in Figure 34, because the catheters 2010/2030 are connected to the ***same*** pressure source 3430, the valve 3325 operates 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. EX2008, ¶90.

For the same reason, Petitioner is 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. EX2008, ¶91.

For the same reasons, Petitioner is 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—let alone to build pressure using those valves which Garrison does not disclose. EX2008, ¶91. 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*.

The Board preliminarily found these arguments unavailing because a POSA may "see a potential benefit in providing means to control each flow line (separate from, for example, directly turning the pressure sources on or off at the pressure source)." Institution Decision, p.33. But, a POSA would understand any such benefit to be significantly outweighed by the negative aspects of Petitioner's proposed configuration in which Garrison's continuous pumps shown in Figure 33 run dry without inlet flow—leading to pump damage. EX2008, ¶93.

For all the above reasons, 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 using those fluid control devices recited in both Claims.

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 this System as in Petitioner's Proposed Combination 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); s*ee also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023). 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 relied on by Petitioner are not suitable for blood reintroduction. EX2008, ¶99. Additionally, Petitioner's proposed combination adding valves to Figure 33 of Garrison would add further opportunity for blood damage when those pumps operate without fluid flow to their inlet ("run dry"). *Id*. 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 … 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.

As described in detail in §§II.F.2-3. above, both of Petitioner's references for treating PE using large catheters (Laub and Aklog) each disclose the criticality of blood return. EX2008, ¶¶100-105. For example, 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]; EX2008, ¶101.

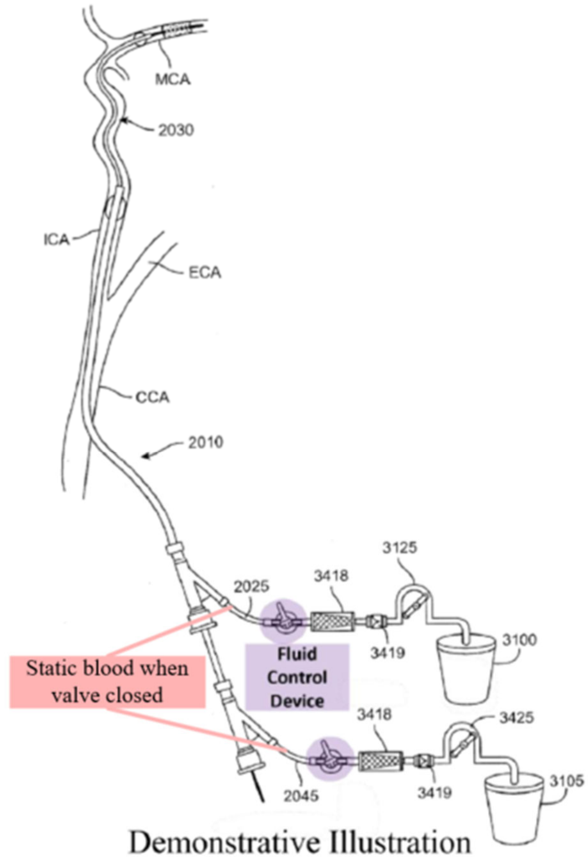
Likewise, Aklog recognizes the need for blood reinfusion: "[i]f the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient." EX1005, 7:23-26; EX2008, ¶104. Each reference accomplishes that critical blood return by continuously/simultaneously aspirating and reinfusing. EX1005, 5:19-23; EX1012, ¶[0045]; EX2008, ¶¶100, 104. Accordingly, a POSA would understand from Laub/Aklog that when using large catheters to treat PE, blood return is critical and that without blood return, such a system would endanger the patient. EX2008, ¶¶104-105.

Garrison, however, ***teaches against using blood return*** in Petitioner's purported combination because 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 because blood remains static and/or is exposed to air leading to thrombus formation or damage to red blood cells (e.g., hemolysis). EX1006, ¶[0135]; EX2008, ¶105. In Figures 33-34 relied on by Petitioner, blood is pumped to the external reservoirs 3100/3105/3430 where it remains "static" and is "exposed to air" such that it is not suitable for blood return. EX2008, ¶105. 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*. 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]; EX2008, ¶106.

Further yet, utilizing ***Petitioner's proposed modified Figure 33 of Garrison would additionally harm blood*** if it were to be returned as taught by Laub and Aklog to treat PE, in several ways. EX2008, ¶¶105-107. First, a POSA would understand that utilizing Garrison's pump(s) to generate vacuum pressure with Petitioner's added valves closed as in Petitioner's modified Figure 33 would further damage blood in the system for the same reasons it would damage Garrison's pumps. EX2008, ¶107. Specifically, as set forth above (§III.A.1.), closing a valve to Garrison's peristaltic pumps shown in Figure 33 and operating those pumps would damage those pumps due to pump starvation—i.e., no fluid flow through the fluid pump inlet. *Id*. A POSA would understand that such an operating state would damage the blood in Garrison's system such that it was even more unsuitable/unsafe for blood return. *Id*.

Namely, the same conditions such as increased friction, overheating, etc., that act to damage the pump in a starvation (i.e., no-inflow) state as in Petitioner's purported combination would also act to damage blood already in the system. *Id*. at ¶108. For example, a POSA would understand that heating blood or repeatedly contacting that blood could lead to blood damage. *Id*. Indeed, the instructions for use for the BP-50 pump specifically warned that "in the absence of flow … [t]he temperature within the pump could rise and ***increased cellular damage*** may result." EX2009, pg.7 (emphasis added). Likewise, the instructions for use for the ROTAFLOW pump instructed the user to cease flow when the inlet tube was clamped to prevent hemolysis (destruction of red blood cells): "when clamping the tube: … turn the flow regulator to zero ***to prevent hemolysis***." EX2010, pg.5 (emphasis added). Those instructions confirm that a POSA would have understood that operating Garrison's pumps 3125/3425 with Petitioner's added valves closed as in Petitioner's proposed modification to Figure 33 would further damage blood in that system. EX2008, ¶108.

Second, Petitioner's purported modification of Garrison would also make that system ***worse*** for blood return by causing blood to remain static for longer when the valves are closed. *Id*. at ¶105. Specifically, with the valves 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:



Demonstrative Illustration
Modified FIG. 33

Id. Garrison expressly cautions against stasis of blood when trying to reintroduce it. EX1006, ¶[0135].

For all those reasons, 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 (1) Garrison discloses that the embodiments relied on by Petitioner are not suitable for blood return and (2) a POSA would understand Petitioner's modification to Garrison's Figure 33 to further harm blood. Petition, pp.23-34, 42-48; EX2008, ¶106. 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. EX2008, ¶106.

Moreover, a POSA would not have had a reasonable expectation of success in treating PE when making Petitioner's proposed combination and thus would not have done so, particularly in view of the numerous possible negative effects from the proposed combination. EX2016, ¶¶63-77. First, a POSA would not have reasonably expected to create catheters of 16 French or larger and that are of sufficient size, strength, and maneuverability that could also perform the claimed methods could have reliably reached the locations necessary to treat PE without unacceptable risk to harming the patient. EX2016, ¶76, 84-85. And second, "a POSA would not have expected a quick burst of pre-charged vacuum as provided by the current claims could so effectively remove the clot material associated with a PE." EX2016, ¶¶84-85. As such a POSA would not have been motived to modify and combine the references as claimed. EX2016, ¶70.

The Board preliminarily found that Patent Owner's arguments in its Preliminary Response regarding blood return did "not undermine Petitioner's challenge at this stage" based on a number of preliminary observations (1)-(5).

Institution Decision, pgs.37-38. Patent Owner, however, respectfully submits that a POSA would not have found it obvious—and in fact would have found it disadvantageous and dangerous—to duplicate Garrison's valve 3325 and add those valves to Figure 33 to build up vacuum pressure as proposed by Petitioner. EX2008, ¶109.

More specifically, the Board's preliminary observation (1) that Garrison teaches an embodiment in Figure 36 that is compatible with blood return actually reinforces that a POSA would not have added a valve—let alone two valves—to Figure 33 of Garrison as proposed by Petitioner. Institution Decision, p.37; EX2008, ¶110. Indeed, Garrison expressly contrasts the embodiments relied on by Petitioner (Figures 33-34 and paragraph [0134]) that are unsuitable for blood return with the embodiment 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." EX1006, ¶[0136] (emphasis added). So, just like Laub and Aklog, Garrison's embodiment in Figure 36 that is suitable for blood return operates to continuously return blood without any intervening valve that is closed to generate vacuum. EX2008, ¶110. A POSA would not have operated the pump in Figure 36 of Garrison—a positive displacement pump—with the inlet clamped to starve the pump of fluid flow for the same reasons discussed above. *Id.* A POSA would understand such systems to be incompatible with the challenged Claims including 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 and harm blood return. *Id*.

Regarding the Board's preliminary observation (2) that Laub and Aklog "teach that aspirated blood (including blood aspirated with conventional pumps, like centrifugal or peristaltic pumps) can safely be returned to the patient," neither those references nor Garrison disclose that blood can safely be returned in a system like Petitioner's proposed modification to Figure 33—and a POSA would understand it would not be for all the reasons described above. Institution Decision, pg.38; EX2008, ¶111. Similarly, regarding the Board's preliminary observation (3), even if Laub and Aklog can run "intermittently," a POSA would understand that intermittent operation does not mean using a valve to shut off fluid flow and build vacuum pressure while those pumps operate. Institution Decision, pg.38; EX2008, ¶112. Instead, intermittent operation simply means turning the pump on at different times with the pump inlet and outlet ***unobstructed*** to prevent pump starvation. EX2008, ¶112.

Likewise, regarding the Board's preliminary observation (4), a POSA would not have added valves to Figure 33 of Garrison and operated that modified system to build up pressure as alleged by Petitioner to provide any "rapid burst of suction pressure" based on the potential for pump and blood damage. Institution Decision, pg.38; EX2008, ¶113. Finally, regarding the Board's preliminary observation (5) that "the valve closure and vacuum generation would seem to be a temporary step to enable a rapid burst of suction—***without blood being withdrawn from the patient*** during this brief window," a POSA would understand that it is precisely because blood or other fluid is not being withdrawn while the pump operates in Petitioner's proposed combination that pump/blood damage would occur. *Id*. (emphasis added).

C. A POSA Would Also Not Have Modified Garrison to Include Any Catheter Having a "Size of 16 French or Greater" or to Treat PE 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.'"); s*ee 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; EX2008, ¶¶115-118.

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. EX2008, ¶115; EX1006, ¶[0063] ("6 French sheath size"; "8 French sheath size").

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

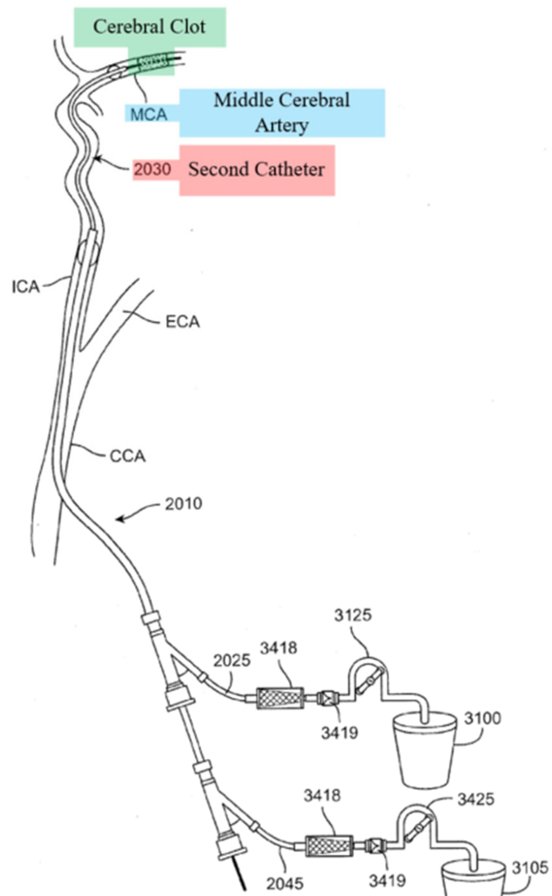


FIG. 33

EX2008, ¶116. 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 ± .42 mm. EX2004, pp.5-7; EX2008, ¶116. A 16 French catheter size translates to a 5.1 mm catheter size (1 French equals ~1/3 mm as French is a measurement of the circumference of a catheter in millimeters such that 1 French =

(1 mm) / (π)) which is substantially ~200% greater than the mean vessel diameter of the MCA. EX2008, ¶116. 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 differently, 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. EX2008, ¶116.

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. EX2008, ¶117. 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). EX2008, ¶117.

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 ¶116. 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 ¶118.

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, for example, that "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." 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. UNEXPECTED RESULTS

When a combination of known elements according to their established functions yields more than predictable results it is nonobvious. *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1309 (Fed. Cir. 2010). When unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared to the closest prior art. *Millennium Pharmaceuticals, Inc. v.* Sandoz*, Inc.*, 862 F.3d 1356, 1368 (Fed. Cir. 2017). "Unexpected results are useful to show the improved properties provided by the claimed invention are much greater than would have been predicted." *Leo Pharma Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013).

Here, the closest prior art is the Garrison, Aklog, and Laub references and the closest comparable prior art device is the AngioVac device, which is similar to the Aklog reference. EX2016, ¶81. A POSA would not have expected that a quick burst of pre-charged vacuum as provided in the methods of Claims 1 and 20 "could so effectively remove the clot material, particularly in view of the difficulty in mechanically removing clot material using other methods and systems…." *Id*. at ¶¶84-85. But, "the ability to remove a clot when treating PE or DVT (particularly with catheters of 16 French or greater) greatly exceeded any expectation of POSA at the time and thus was surprising and unexpected." *Id*. at ¶85. As Dr. Morris explains, Inari's Flowtriever systems practice the steps of claims 1 and 20 that generate pre-charged vacuum and release to treat PE and that provide unexpected results when treating PE. EX2016, ¶78-80. Specifically, Dr. Morris testified that when he first used the Flowtriever in the claimed manner, he "was personally surprised that the generation of a quick burst of vacuum and rapid pressure equalization could so effectively remove a clot when treating a PE, oftentimes removing the clot intact." EX2016, ¶84. Dr. Morris further testified that "a POSA would not have expected a quick burst of pre-charged vacuum as provided by the current claims could so effectively remove the clot material, particularly in view of the difficulty in mechanically removing clot material using other methods and systems, including the AngioVac system." *Id*., ¶¶84-85.

Accordingly, regardless of whether a POSA would have been motived to combine Garrison, Aklog, and/or Laub as claimed, the surprising and unexpected ability of the claimed methods to remove a clot when treating PE or DVT that "greatly exceeded" any predicted result demonstrates that the claims are not obvious over the prior art.

V. GROUNDS 4-9: THE COMBINATIONS OF GARRISON AND LAUB AND/OR AKLOG FURTHER IN VIEW OF HARTLEY OR PASHA DO 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.

VI. CONCLUSION

Petitioner failed to establish by a preponderance of evidence that the Claims of the '910 Patent are unpatentable. Accordingly, for each of the above reasons, Patent Owner respectfully requests that the Board find all the Claims patentable.

Respectfully submitted,

Dated: March 12, 2026

By: / Joseph P. Hamilton /
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph P. Hamilton, certify that **PATENT OWNER'S RESPONSE** contains 13,916 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: March 12, 2026

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on March 12, 2026, a copy of **PATENT OWNER'S RESPONSE and EXHIBITS 2008-2017 were** served upon the below-listed counsel by electronic mail:

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