

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
Patent No. 11,974,910

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,974,910**

Imperative Care v. Inari Medical
U.S. Patent 11,974,910
Imperative Care Ex. 1003

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Exhibit No.	Description
1001	U.S. Patent No. 11,974,910 (“the ’910 patent”)
1002	’910 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. (“Heaton”)
1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.

Exhibit No.	Description
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1021	U.S. Patent Application No. 16/117,519 (the “519 application”)
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	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)
1025	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)
1026	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)
1027	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)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	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)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.strokeaha.org (2005).

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Exhibit No.	Description
1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1032	US 2018/0064453 A1 (“Garrison II”)
1033	US 2005/0054995 A1 (“Barzell”)
1034	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1035	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1036	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1037	Patent Owner’s Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) (“Indigo Aspiration System”)
1039	AXS Universal Aspiration Set Brochure (2017)
1040	VacLok Negative Pressure Syringe Brochure
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) (“Nikoubashman”)
1042	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025)
1043	Inari’s Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)

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1044	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1045	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)
1046	U.S. Patent No. 7,984,730 B2 to Ziv et al.
1047	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1048	Imperative Care's Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1049	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)
1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 Cardiovasc. Diagn. Ther. 599-611 (2016)
1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
1053	Claim Construction Expert Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

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I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative” or “Petitioner”) to provide my opinion regarding the patentability of Claims 1-8, 11-15, and 18-20 of U.S. Patent No. 11,974,910 (“the ’910 patent”). For the reasons discussed herein, I have concluded that Claims 1-8, 11-15, and 18-20 of the ’910 patent are unpatentable because the prior art references render them obvious.

2. I understand that this Declaration supports Imperative’s Petition for the above-captioned *inter partes* review (“IPR”) of the ’910 patent.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me. I also reserve the right to submit a rebuttal declaration in response to any expert declaration(s) submitted on behalf of the owner of the ’910 patent, Inari Medical, Inc. (“Inari” or “Patent Owner”).

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is included as Exhibit 1004.

6. I received a Bachelor of Science degree in Engineering Science, with Biomedical Engineering emphasis, in 1985 from Iowa State University. Since then, I have worked as an engineer, executive, and consultant in the medical device industry, particularly in the cardiovascular field. My work has included designing and developing numerous medical devices in the cardiovascular field, including catheters, percutaneous heart valve repair systems, stent grafts, and blood pumps.

7. Since 2015 I have worked as a consultant for various medical device companies, assisting the companies with early design, development, problem-solving, and intellectual property related matters.

8. Before my current consulting business, I was a Program Director for Abbott Ventures from June 2012 through December 2014. My work at Abbott Ventures focused on technical assessment and analysis of potential investments in both cardiovascular and non-cardiovascular medical device technologies.

9. In June 2000, I assumed the position of Director of Research and Development at Evalve, Inc., and in 2001 was promoted to Vice President of Research & Development. I served in that position until June 2012. While at

Evalve, I was responsible for managing all aspects of research and development for a percutaneous mitral valve repair system known as the MitraClip. The MitraClip system included three complex catheters and a permanent mechanical implant, and I led the research and development for all aspects of the product. The MitraClip product received FDA approval in 2013 and is currently available in over 30 countries.

10. From June 1995 through May 2000, I was a Project Manager at Prograft Medical Inc. While at Prograft, I was responsible for the development and commercial launch of a bifurcated, modular stent-graft used in the treatment of abdominal aortic aneurysms known as Excluder. I managed the overall project from its inception through initial commercialization, which involved designing and building initial prototypes, developing physician training materials, assisting with regulatory filings, providing physician training, and supporting physicians during five live case transmissions endovascular symposia.

11. From August 1989 through May 1995, I worked as a Project Group Leader and Senior Engineer for Advanced Cardiovascular Systems at Guidant. My work at Guidant focused on the design and development of percutaneous transluminal coronary angioplasty (PTCA) and perfusion catheters. I was responsible for catheter design, material selection, process development, performance testing, physician evaluation, and animal studies for an elliptical

coronary PTCA catheter that ultimately became the top-selling PTCA catheter in the United States.

12. From 1987 to 1989, I worked as a Manufacturing Engineer at Symbion, Inc. My work at Symbion included developing and improving manufacturing processes for class III medical devices, including a centrifugal blood pump.

13. From 1985 to 1987 I worked as a Process Engineer at Becton-Dickenson, Inc. My work at Becton-Dickenson included validating and implementing manufacturing processes for a thermodilution catheter and conducting cost saving and process improvements for central venous catheter products.

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the '910 patent.

C. Topics of Opinions

15. I offer opinions in this Declaration on the following general topics:

- The subject matter described and claimed in the '910 patent;
- The level of ordinary skill in the art pertaining to the '910 patent;
- The teachings of the prior art; and
- Whether claims 1-8, 11-15, and 18-20 of the '910 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

D. Materials Considered

16. In preparing this Declaration, I have considered the materials referenced in this Declaration and identified in the attached list of exhibits.

17. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '910 patent.

II. APPLICABLE LEGAL STANDARDS

18. I am a biomedical engineer by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training, and technical knowledge and experience to the evaluation of certain prior art with respect to the '910 patent.

19. Although I have had some prior exposure to patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of

patent law applicable in this matter, which I have used in arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

20. I understand that the first step in assessing the patentability of a patent claim is to understand the meaning of the words used in the claims. I understand this process of defining, or construing, the claim terms is generally referred to as claim construction. Generally speaking, I understand that I am to apply the ordinary and customary (i.e., plain and ordinary) meaning of each claim term as would have been understood by a person of ordinary skill in the art at the time of the invention, consistent with the specification and prosecution history.

21. I also understand that the patentee may act as its own lexicographer such that they may redefine a claim term to have a meaning that is different from the plain and ordinary meaning. I understand that when a patentee has acted as its own lexicographer, the patentee's definition should be applied instead of the plain and ordinary meaning that the term would have absent the redefinition. I understand that the patentee can redefine a claim term in either the specification or in statements made to the Patent Office during prosecution of the patent. I understand that the patentee's redefinition of a term does not need to be provided in express definitional format, but rather that the redefinition can be implied

through the disclosure of the specification or the patentee's statements during prosecution.

B. Anticipation

22. I understand that a patent claim is unpatentable if it is "anticipated" by a piece of prior art. I have been instructed that a claim is "anticipated" if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention (in this case, September 2017).

23. I understand that an element is "inherent in," and therefore taught by, the prior art, if it necessarily flows from the explicit disclosure of the prior art. The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed.

C. Obviousness

24. I understand that a patent claim may also be unpatentable if it is rendered "obvious" by the prior art. I have been instructed that a claim is "obvious" if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I understand

that in considering obviousness I must consider the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

25. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e., appropriate) prior art if it falls within the field of the inventor's endeavor. In addition, a reference is analogous prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '910 patent, e.g., devices for aspirating unwanted material from a patient. My understanding of the field of the '910 patent is influenced by the prosecution history. I see that during prosecution the Examiner used patents describing aspiration devices for treating tissue wounds to reject the patent claims. I also see that the Patent Owner did not dispute the use of those patents or argue that such aspiration devices are not analogous art. The references are also

pertinent to the problem the inventor was focused on, e.g., removing clots, emboli, and thrombi from a patient's blood vessel.

27. To assess the differences between prior art and the claimed subject matter, I have been instructed that the law requires the claimed invention to be considered as a whole. This "as a whole" assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

28. I am also informed that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include:

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;

- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

29. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

30. I have also been informed that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art

to arrive at the claimed invention and had a reasonable expectation of success in doing so.

31. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that Claims 1-8, 11-15, and 18-20 of the '910 patent would have been non-obvious, as further explained in Section § VIII (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

32. It is my understanding that when interpreting the claims of the '910 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the '910 patent is August 13, 2018. I have been informed that all of the references relied upon in this Declaration qualify as prior art under that priority date.

33. I am informed that the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. This is a person of ordinary creativity, not an automaton.

34. I am informed that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

35. Based on my review of the specification and claims of the '910 patent, it is my opinion that a person of ordinary skill in the art would have had 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.

36. I can make this assessment because during my career, I had experience assigning engineers to work on mechanical design projects, including projects to design catheters, sheaths, and related components such as hemostasis valves for use in cardiovascular procedures. For such projects, I would assign an engineer with the experience described above.

III. THE '910 PATENT

A. Summary of the '910 Patent

37. The '910 patent is titled “System for Treating Embolism and Associated Devices and Methods” and describes an aspiration system for intravascular removal of clot material. Ex. 1001 ('910 patent) at 4:17-33. The '910 patent explains that the system can treat various clots including pulmonary embolism (“PE”), cerebral embolism, and deep vein thrombosis (“DVT”). *Id.* at 4:51-4:58. The aspiration system includes an aspiration “assembly 10” having a “catheter subsystem 100”, “pressure source 140,” and “tubing subsystem 120.” *Id.* at 5:25-30.

38. The catheter subsystem also has a catheter 102 [orange below] “comprising an elongated shaft defining a lumen 104,” and a “valve 106” [yellow below] with a “lumen 109 extending therethrough.” *Id.* at 5:30-40. The '910 patent explains that the valve “is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106” when other components are inserted, such as “interventional devices” or “other aspiration catheters.” *Id.* at 5:41-50

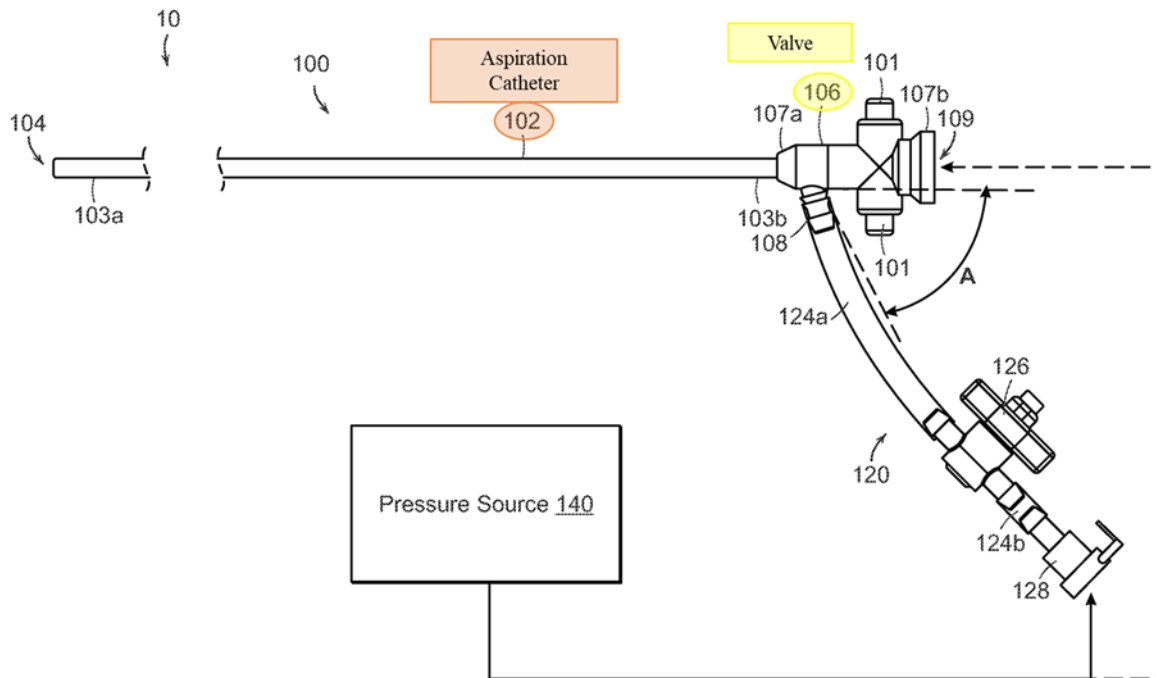


FIG. 1

Id. at Fig. 1.

39. The '910 patent discloses the pressure source [red below] is “configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 100.” *Id.* at 6:57-60. “[T]he 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 of the assembly 10 to generate and store a vacuum therein.” *Id.* at 7:36-41.

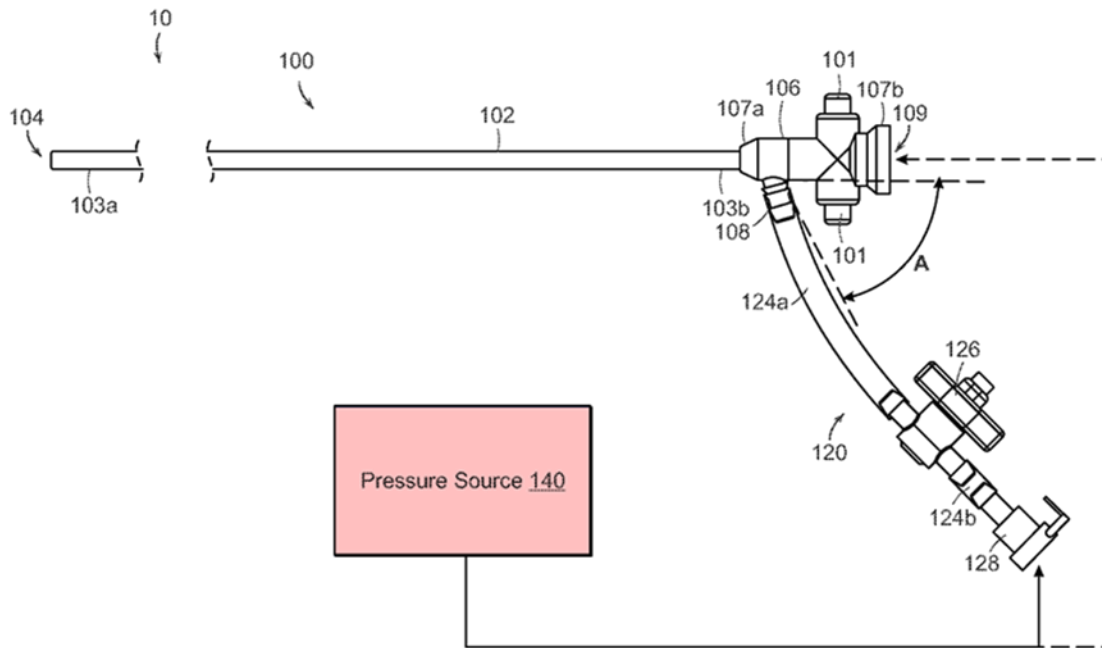


FIG. 1

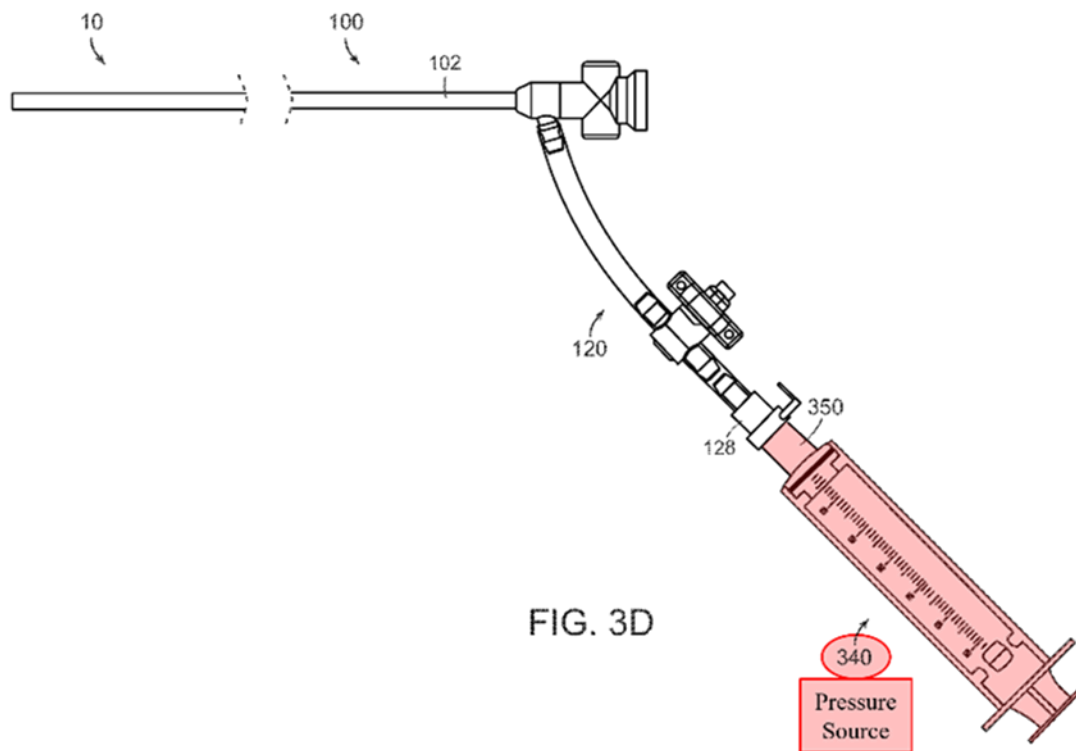


FIG. 3D

Id. at Figs. 1, 3D.

40. The '910 patent explains that the tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” *Id.* at 6:6-7. The tubing subsystem can include “one or more tubing sections 124,” [green] at least one “fluid control device 126” [purple] such a stopcock, and at least one “connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components.” *Id.* at 6:6-23.

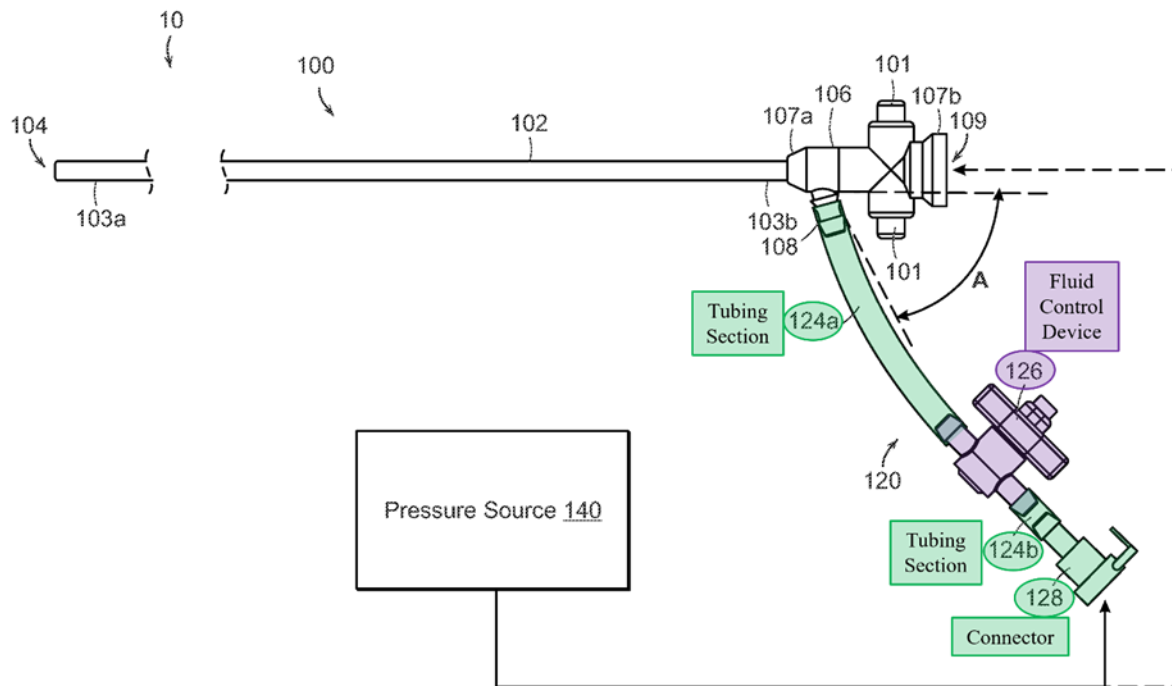
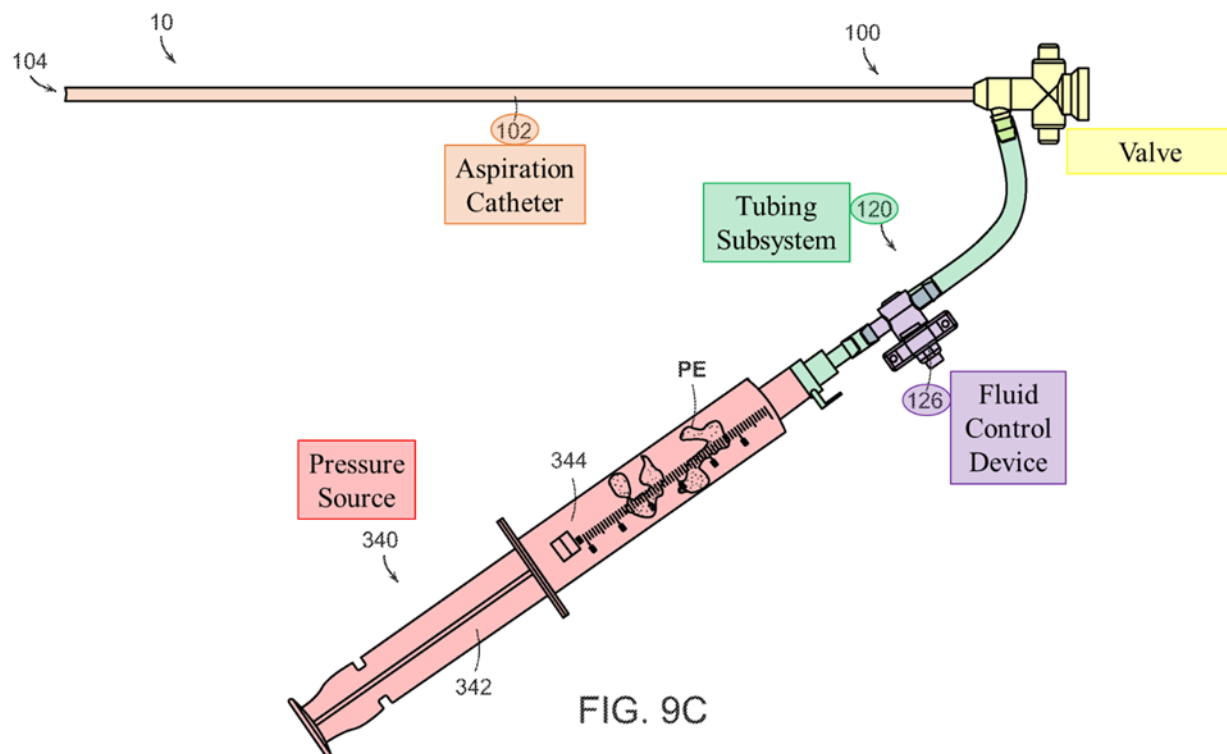


FIG. 1

Id. at Fig. 1.

41. The '910 patent explains that a user “can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140).” *Id.* at 6:62-66. After pressure is generated, “the user can actuate (e.g.,

twist a handle of) the fluid control device 126 to open the fluid control device 126.” *Id.* at 18:44-48. Opening the fluid control device 126 will “fluidly connect the pressure source 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 to the lumen 104 of the catheter 102.” *Id.* at 7:3-8.



Id. at Fig. 9C. The ‘910 patent also explains that “[o]pening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102.” *Id.* at 7:8-12.

42. The ‘910 patent also describes variations of the aspiration system described above. For example, the ‘910 patent describes a variation with “a first

aspiration assembly 20 and a second aspiration assembly 30.” *Id.* at 20:60-62. The ’910 patent explains that “the first and second aspiration assemblies 20, 30 (“assemblies 20, 30”) can include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to FIGS. 1-10B.” *Id.* at 20:62-66. For example, the ’910 patent explains that the aspiration system includes a first aspiration assembly 20 having a “first catheter subsystem 1000[,]” “first pressure source 1040,” and “first tubing subsystem 1020.” *Id.* at 20:66-21:5. Similarly, the aspiration system includes a second aspiration assembly 30 having a “second catheter subsystem 1100,” “second pressure source 1140,” and “second tubing subsystem 1120.” *Id.* at 21:5-12.

43. The ’910 patent explains that the first tubing subsystem fluidly couples the first catheter subsystem 1000 to the first pressure source 1040 [red below], and the second tubing subsystem fluidly couples the second catheter subsystem 1100 to the second pressure source 1140 [red below]. *Id.* at 20:66-21:12. The first catheter subsystem also has a first catheter 1002 [orange below] comprising “an elongated shaft defining a lumen 1004,” a “valve 1006” [yellow below] with a “lumen 1009... extending therethrough,” and a “first fluid control device 1026” [purple below]. *Id.* at 21:13-23. The second catheter subsystem has a second catheter 1102 [orange below] defining a lumen 1104, and a second valve 1106 [yellow below] with a “lumen... 1109 extending therethrough,” and a

“second fluid control device 1126” [purple below]. *Id.* at 21:13-27. The first fluid control device 1026 is configured to “regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000”. *Id.* at 21:21-23. Likewise, the second fluid control device 1126 is configured to “regulate or control fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100”:

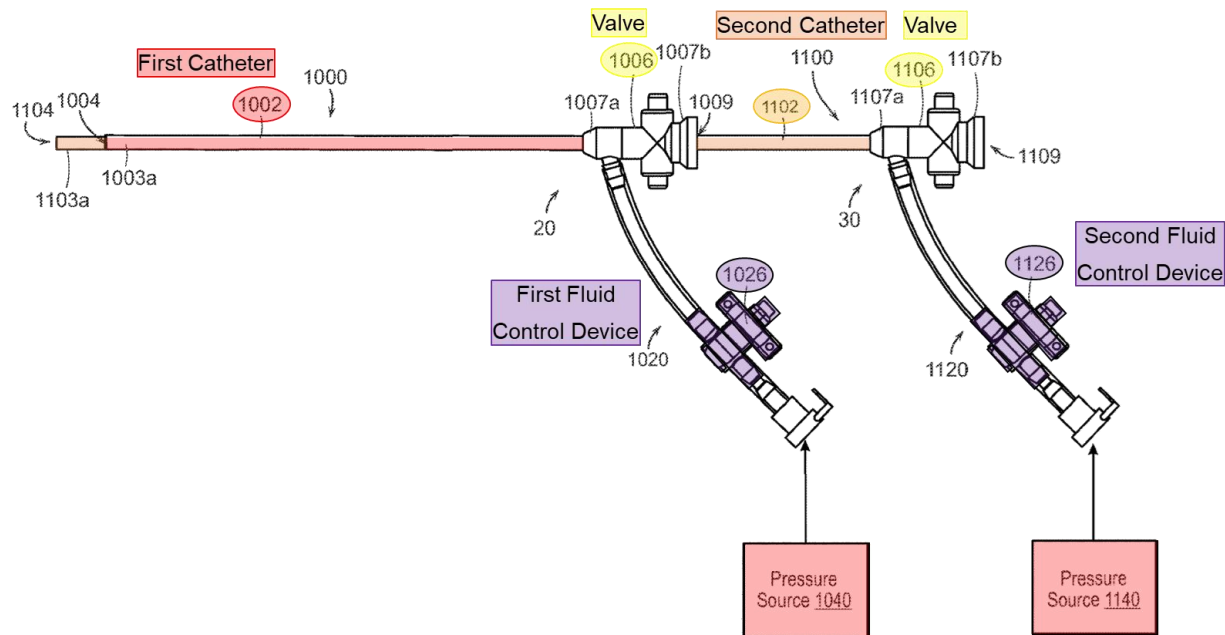


FIG. 11

Id. at 21:23-27, Fig. 11.

44. The '910 patent explains that the second catheter 1102 can be inserted through the “first valve 1006” and “can be telescoped through the lumen 1004 of the first catheter 1002”. *Id.* at 21:28-36. The second catheter 1102 can “have a size of 16 French or smaller” and the first catheter 1102 can “have a size

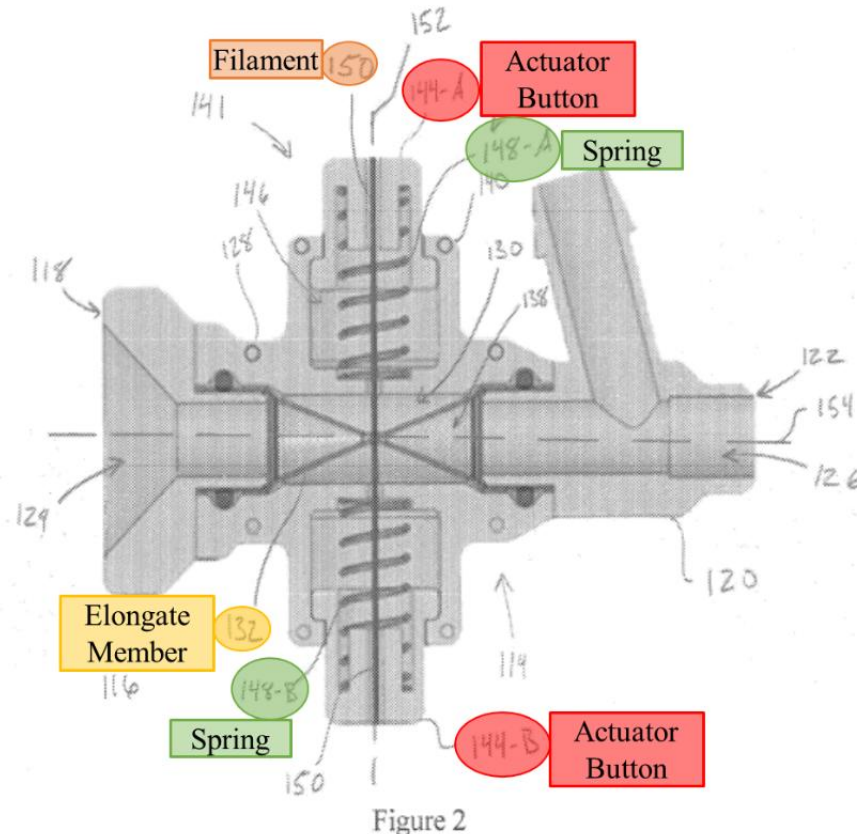
of 20 French or greater.” *Id.* at 21:36-40. The ’910 patent further explains that the first pressure source and second pressure source can “be activated to generate and store a vacuum” for subsequent application. *Id.* at 23:26-29. The first fluid control device 1026 can be opened “to generate suction at the distal portion 1003a of the first catheter 1002.” *Id.* at 23:48-52. Similarly, the second fluid control device 1126 can be opened “to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102.” *Id.* at 23:30-33.

45. While claims of the ’910 patent recite aspects of a hemostasis valve, the ’910 patent does not describe the structure of the hemostasis valve that can be included in valve 106. *Id.* at 5:54-56. But the ’910 patent does state that “the valve 106 can be a valve of the type disclosed in U.S. patent application Ser. No. 16/117,519, filed Aug. 30, 2018, and titled ‘HEMOSTASIS VALVES AND METHODS OF USE,’ which is incorporated herein by reference in its entirety.” *Id.* at 5:56-61. For ease of reference, I refer to U.S. patent application Ser. No. 16/117,519 as the “’519 Application” herein. I do not take any position on whether Patent Owner effectively incorporated the ’519 Application by reference in the ’910 patent, and none of my discussion of the ’519 Application should be construed as an admission or acknowledgement that the ’519 Application was effectively incorporated.

Id. at [0039], Fig. 2.

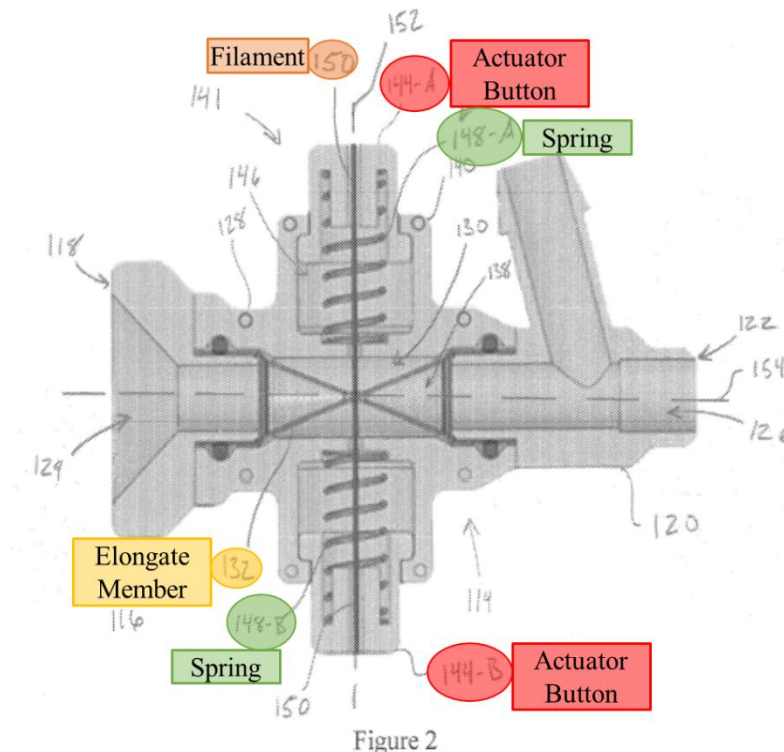


47. The '519 Application also discloses that the hemostasis valve can have a “constricting mechanism 141” that can “collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150.”



Id. at [0042-0043], Fig. 2. The constricting mechanism includes “an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132.” *Id.* The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” *Id.* at [0048].

48. The '519 Application also explains that the valve can include a “bias feature,” such as a spring, which biases the valve to either the closed (referred to as first) or open (referred to as second) position when no outside forces are being applied to the actuator button(s). *Id.* at [0045]. In Figure 2, the springs bias the valve toward the closed configuration:



Id. at Fig. 2. The '519 Application explains that when the actuator buttons are depressed by an outside force, the tension on the filament is loosened “thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.” *Id.* at [0050], Fig. 3. Figure 3 below depicts the valve in the second, opened position when the actuator buttons are depressed:

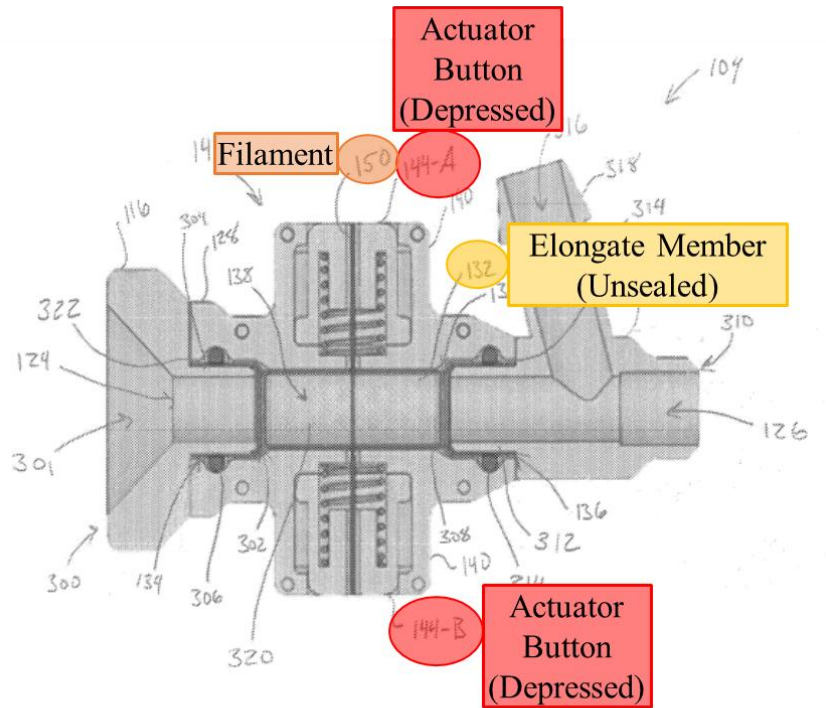


Figure 3

Id.

B. The Challenged Claims

49. The challenged claims include Claims 1-8, 11-15, and 18-20 of the '910 patent. The patent includes 2 independent claims (Claims 1 and 11).

50. Claim 1 is illustrative (but not representative) of some of the limitations in the challenged claims. Claim 1 states:

1. A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising:
 - a first clot aspiration assembly, including:
 - a first catheter;
 - a first pressure source; and
 - a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the

first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter, wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and

a second clot aspiration assembly, including:

- a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;
- a second pressure source; and
- a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter, wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

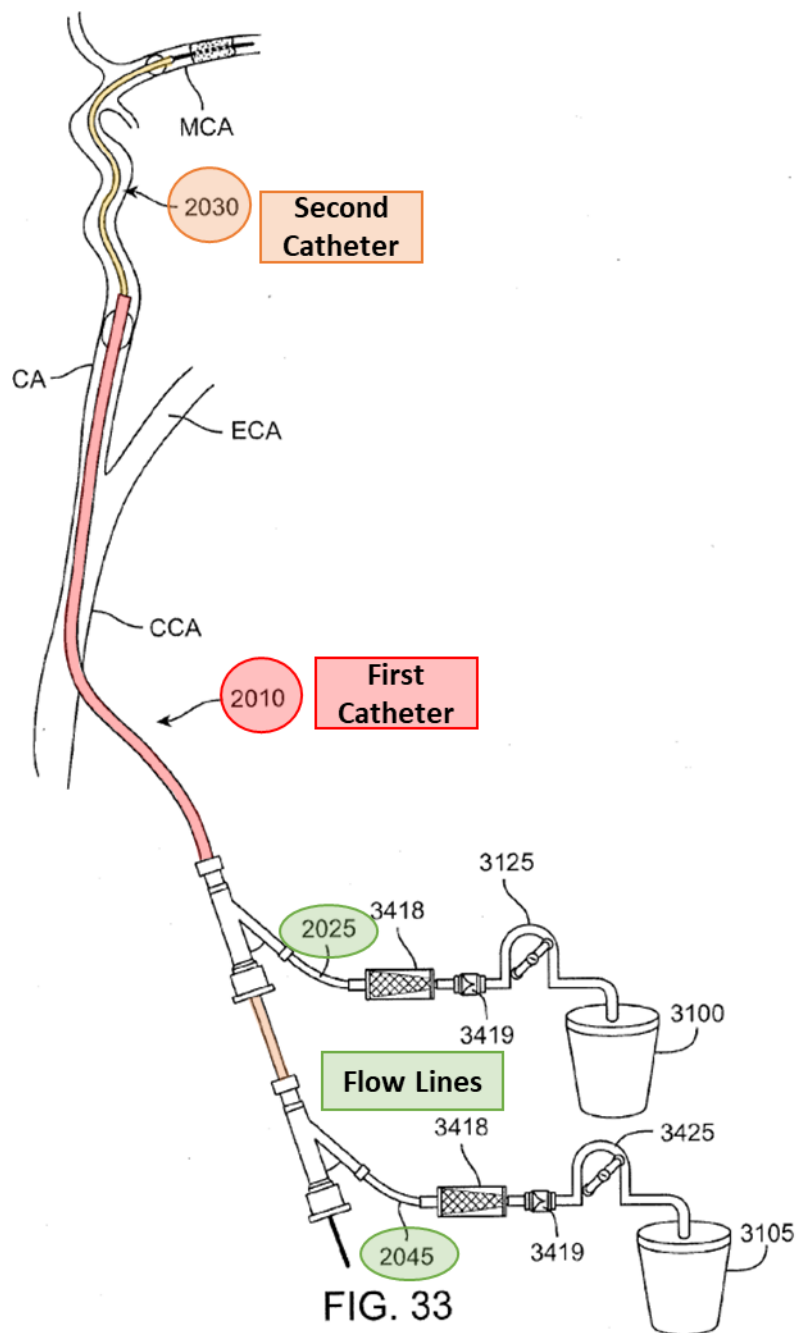
Ex. 1001 ('910 patent) at Claim 1.

C. **Prosecution History**

51. I have reviewed the '910 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action. Ex. 1002 at 373-382. The Examiner allowed then-pending claim 1 but noted that Garrison "teaches all of the limitations as discussed above" except for teaching a "second catheter advanceable through the first catheter." *Id.* at 377-378. The Examiner states:

Garrison (US 20150173782 A1) teaches all of the limitations as discussed above and Garrison further teaches a second clot aspiration assembly (second aspiration assembly connected to line (2045), see Figure 33), including: a second catheter (flow line (2045)); and a second pressure source (3425) configured to be fluidly coupled to the second catheter (see Figure 33) and to generate suction at a distal portion of the second catheter (aspiration source 3425) provides suction to the distal portion of the flow line (2045), see Figure 33). However, Garrison fails to teach a second catheter advanceable through the first catheter. The second catheter (2045) does not advance through the first catheter (2025), as shown in Figure 33. There is no reason to advance the second catheter through the first catheter of Garrison. Also Garrison does not explicitly disclose the flow lines (2025 and 2045) advancing through arterial access device (2010). It would be unreasonable to modify the flow lines to advance through the arterial access device (2010) because it would interfere with the thrombectomy device.

Id. I believe the Examiner was confused about Garrison. Items 2025 and 2045 in Garrison are "flow lines," not catheters as the Examiner states. Plus, Garrison expressly describes advancing the second catheter 2030 through the first catheter 2010.



Ex. 1006 (Garrison) at [0131], Fig. 33.

52. After the rejection, I see that the Patent Owner amended the claims to require a system “for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and to specify that the second catheter in the system

has a “size of 16 French or greater.” Ex. 1002 at 141-149. Patent Owner argued that the amended claims “are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related U.S. Patent Application No. 18/329,450 [“the ’450 application”], and specifically the Examiner’s comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that ‘Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art of Garrison.’” *Id.* at 147-148.

53. I reviewed the Summary referred to above and it does not specifically state why the Attorney and Examiner reached their agreement. Ex. 1052. The Summary merely adds that “Attorney and Examiner agree that the newly added method claims would be allowable for reciting the specific use in pulmonary embolism applications” and that “Dr. Tu discussed the differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis.” *Id.* I understand that Dr. Tu is a named inventor on the ’910 patent.

54. Following the amendment, the Examiner allowed the pending claims of the ’910 Patent. Ex. 1002 at 43-51. The Examiner found that Garrison teaches all the limitations of the claims as discussed in the previous Rejection except “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.” *Id.* at 49. The Examiner stated that the “clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism” and that “[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.” *Id.* The Examiner did not cite any evidence to support this conclusion. *Id.* For the reasons below, the Examiner erred in reaching this conclusion.

IV. CLAIM CONSTRUCTION

55. I understand that I should give the claim language its ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the earliest applicable priority date (August 2018) and in accordance with the specification and prosecution history. I have applied this standard in my analysis. I have not identified any other terms that require further construction by the Court to address the invalidity of independent claim 1.

56. I see that the term “filament” appears in some of the claims of the ’910 patent requiring a hemostasis valve (for example, Claim 7). I have offered a construction for “filament” in previous IPRs involving Patent Owner and Petitioner, including IPRs for U.S. Patent Nos. 11,697,011 and 11,697,012. I understand that the ’011 and ’012 patents have the same specification as the ’591

application that is allegedly incorporated by reference into the '910 patent. Consistent with my previous analysis, it is my opinion that a person of ordinary skill in the art in September 2017 (the earliest priority date of the '591 application) or August 2018 (the earliest priority date of the '910 patent) would have understood the term “filament” in the claims of the '910 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

57. In the previous IPRs, Patent Owner has argued that my construction of “filament” is incomplete because I did not limit the claims to “flexible” filaments. However, the debate about whether the term “filament” is limited to “flexible” filaments does not impact my views on unpatentability in this IPR. If the Board decides that “filament” is limited to “flexible” filaments, I have relied on the Hartley reference in this IPR, which discloses a “string.” Inari has never disputed that Hartley describes a “filament” or a “flexible” filament. As the Board preliminarily found in the Institution Decisions for the '011 and '012 Patents, Hartley includes a “filament,” regardless of whether the claims are limited to “flexible” filaments. The Board specifically found that Patent Owner “does not dispute that Hartley ... disclose[s] a flexible filament (e.g., flexible string or flexible wire).” Ex. 1035 ('012 Institution Decision) at 21, n.13. Therefore, the construction of “filament” is not critical to this IPR.

58. As explained above, I have previously construed “filament” in IPRs involving Patent Owner and Petitioner. Below, I substantially repeat the analysis I previously provided. I understand from counsel that the claim construction analysis should begin with the language of the claims.

59. I understand from counsel that the claim construction analysis should begin with the language of the claims. Here, the claims do not provide much information about the meaning of “filament.” Claim 7 of the ’910 patent requires “a filament extending at least partially around the tubular member.” This claim language does not identify the structures, material, or material properties that form a “filament.”

60. The specification of the ’910 patent does not provide any further guidance on the structures or materials that form a “filament.” The ’910 patent specification does not describe a hemostasis valve having a filament, and it does not use the word “filament” at all. However, the ’519 Application, which the ’910 patent states is incorporated by reference, does identify structures and materials that may form a “filament.” The ’519 Application discloses that the filament can be formed from a range of materials “including, for example, a polymer, a synthetic, and/or a metal.” Ex. 1021 (’519 Application) at [0047]. The ’519 Application also says that “the filament can comprise a single strand such as, for example, a monofilament, [or] the filament can comprise a plurality of strands that

can be, for example, twisted, woven, grouped, and/or fused to form the filament.”

Id. The '519 Application also states that “**the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.**” *Id.* (emphasis added). I have used this specific description of “filament” for my construction.

61. The '519 Application also explains that “the filament 150 can comprise multiple filaments and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B.” *Id.* at [0065]. Figure 7 illustrates an embodiment where the filament is comprised of multiple loops, and Figures 8 and 9 below illustrate embodiments where the filament is comprised of a “U-shaped section between the two ends of the filament 150” (i.e., a bight):

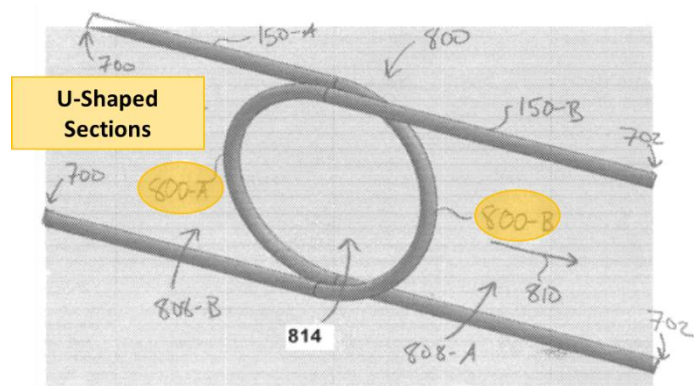


Figure 8

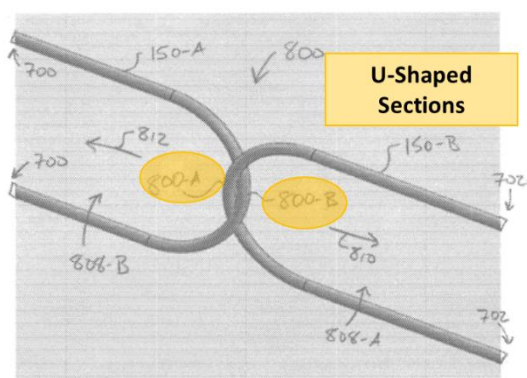


Figure 9

Id. at [0065]-[0067], Figs. 7-9. Focusing specifically on the embodiments having the “U-shaped section,” the '519 Application explains that the filaments can have “any desired cross-sectional shape.” *Id.* at [0067]-[0070]. The '519 Application

also identifies some exemplary dimensions for the filaments but does not specify any mandatory diameter, thickness, or cross-sectional dimensions for the filament. *Id.* at [0070]. The '519 Application also does not require the filament to have a specific amount of flexibility or hardness (or provide any guidance regarding those properties).

62. I understand that the prosecution history can also be relevant in construing patent claims because it can provide insight into how the applicant and the Patent Examiner understood the claims. However, neither the Examiner nor Patent Owner substantively discussed the “filament” limitation during prosecution of the '910 patent.

63. Thus, in view of the above analysis of the claim language, specification, and prosecution history, I believe that a person of ordinary skill in the art in September 2017 or August 2018 would have understood the term “filament” recited in the claims of the '910 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

V. SUMMARY OF IPR GROUNDS

64. I have identified the following grounds of unpatentability in this Declaration:

Ground	Claims Challenged	Basis	References
1	1-6, 8, 11-15, 18-20	35 U.S.C. § 103 (obviousness)	Garrison + Laub
2	1-6, 8, 11-15, 18-20	35 U.S.C. § 103 (obviousness)	Garrison + Aklog
3	1-6, 8, 11-15, 18-20	35 U.S.C. § 103 (obviousness)	Garrison + Laub + Aklog
4	6-7, 20	35 U.S.C. § 103 (obviousness)	Garrison + Laub + Hartley
5	6-7, 20	35 U.S.C. § 103 (obviousness)	Garrison + Aklog+ Hartley
6	6-7, 20	35 U.S.C. § 103 (obviousness)	Garrison + Laub + Aklog + Hartley
7	3, 12, 18	35 U.S.C. § 103 (obviousness)	Garrison + Laub + Pasha
8	3, 12, 18	35 U.S.C. § 103 (obviousness)	Garrison + Aklog + Pasha
9	3, 12, 18	35 U.S.C. § 103 (obviousness)	Garrison + Laub + Aklog + Pasha

VI. GROUNDS 1-3: GARRISON COMBINED WITH LAUB AND/OR AKLOG RENDERS CLAIMS 1-6, 8, 11-15, 18-20 UNPATENTABLE

A. Independent Claim 1

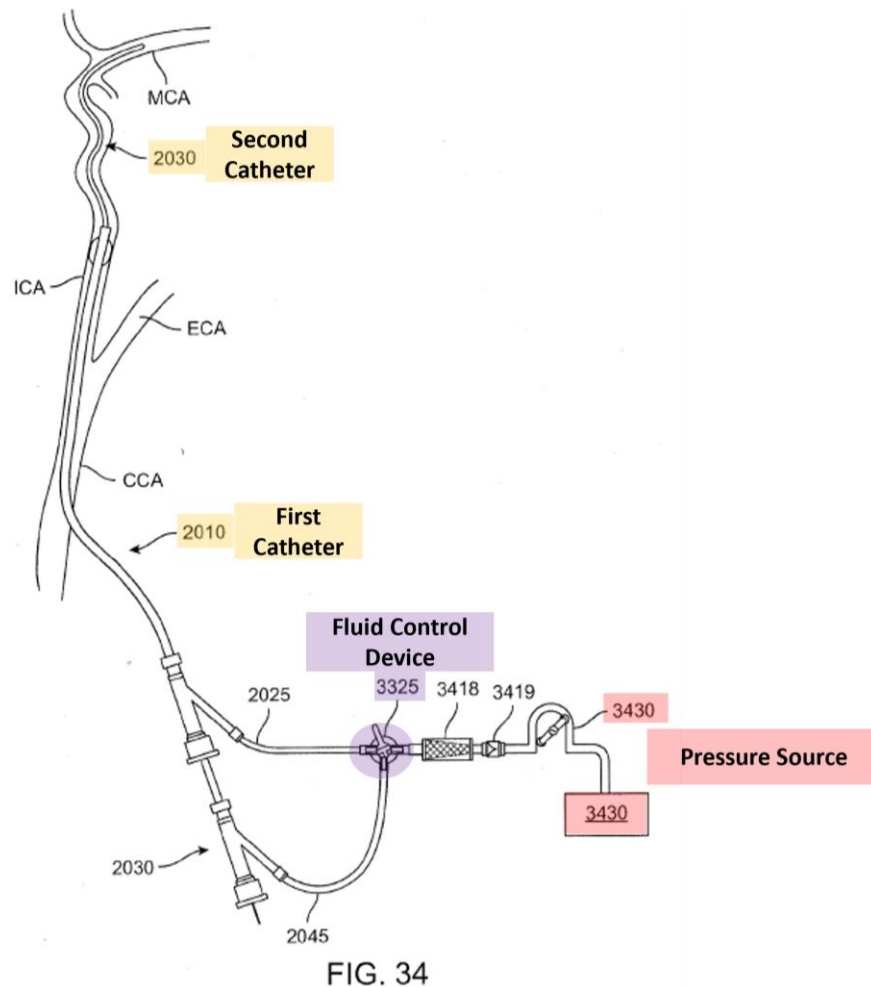
65. As I explain in detail below, a person of ordinary skill in the art would have found it obvious to use and, to the extent necessary, modify and optimize Garrison's aspiration system for use in treating pulmonary embolisms in view of Laub or Aklog. Accordingly, based on my review of the prior art, it is my

opinion that Claim 1 would have been obvious to a person of ordinary skill in the art in view of Garrison in combination with Laub and/or Aklog.

1. Preamble

66. The preamble of Claim 1 recites: “A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising.” If the Board finds that the preamble of Claim 1 is limiting, it is my opinion that Garrison renders this limitation obvious in combination with Laub and/or Aklog.

67. Garrison discloses an aspiration system for the “treatment of cerebral occlusions.” Ex. 1006 (Garrison) at [0002]. Garrison’s system includes a first and second catheter [orange], at least one pressure source (e.g., aspiration source) [red], and at least one fluid control device [purple]:



Id. at Fig. 34; *see also id.* at [0131]-[0134] (these portions of the specification describe Figure 34 and some of the related figures).

68. A person of ordinary skill in the art would have been motivated to use and, to the extent necessary, modify and optimize Garrison's aspiration system to treat pulmonary embolism based on Aklog and Laub.

a. Garrison and Aklog

69. Garrison's system is already designed to aspirate clots and Aklog explains that pulmonary embolisms are a harmful type of clot that can block blood

flow to the lungs and cause death. Ex. 1006 (Garrison) at [0002]; Ex. 1005 (Aklog) at 7:32-37. Aklog also 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).” Ex. 1005 at 7:32-37; *see also id.* at 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7. Thus, a person of ordinary skill in the art would have been motivated to use, and to the extent necessary, modify and optimize the existing and proven technology described in Garrison to treat similar conditions in other parts of the vasculature like PE.

70. A person of ordinary skill in the art would have been further motivated to adapt Garrison’s system to be positioned proximate a pulmonary embolism and treat a pulmonary embolism because Aklog discloses that aspiration (like the aspiration disclosed in Garrison) can effectively remove the pulmonary embolism. Ex. 1005 (Aklog) at 5:11-27. Moreover, the aspiration systems described in Garrison and Aklog are similarly configured. As illustrated below, both systems include an aspiration catheter [orange] that is positioned proximate to the clot material prior to aspiration, an aspiration source (e.g., aspiration pump) [red], a filter [blue], and a flow line [green] fluidly coupling the aspiration catheter to the filter and aspiration source:

Garrison

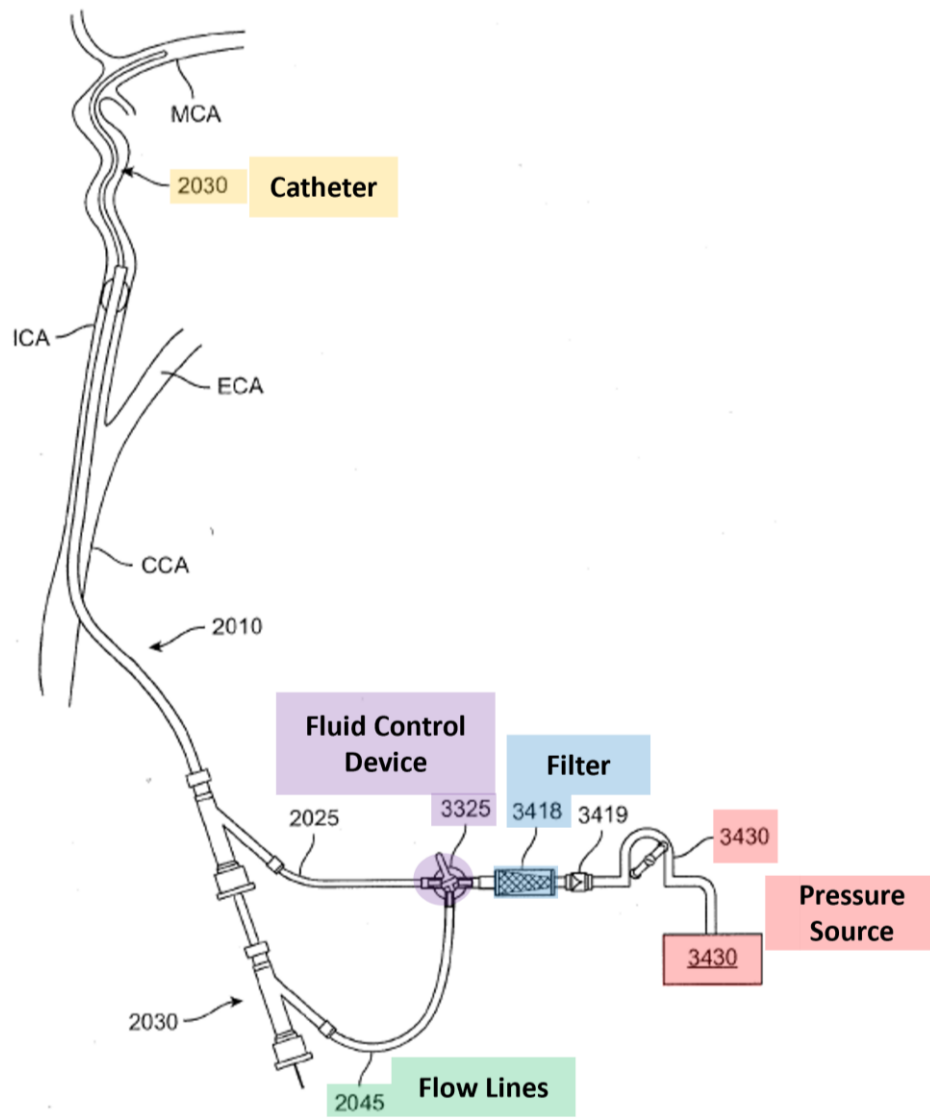


FIG. 34

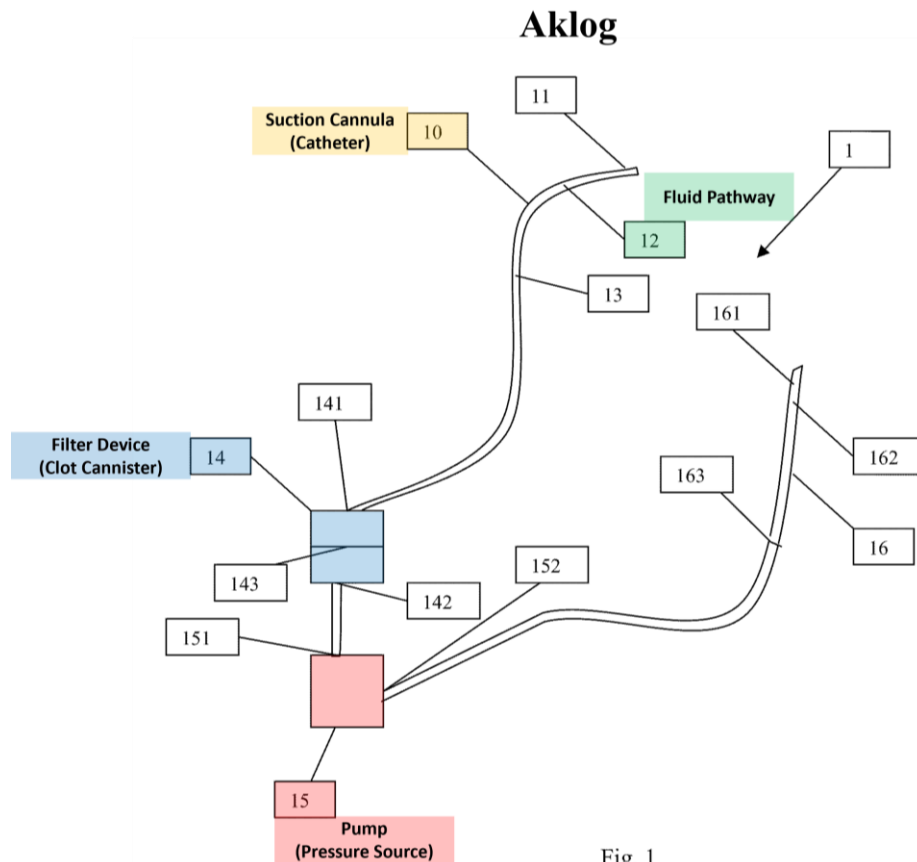


Fig. 1

Ex. 1006 (Garrison) at [0131]-[0134], Fig. 34; Ex. 1005 (Aklog) at 7:47-64, 11:24-35, 11:62-12:14, Fig. 1. Additionally, both systems are inserted into the patient in the same way (e.g., percutaneously through the femoral artery or vein). Ex. 1005 (Aklog) at 15:30-34 (describing insertion through “femoral vein, femoral artery or jugular vein); Ex. 1006 (Garrison) at [0048] (“Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches.”). A person of ordinary skill in the art would have reasonably expected success in adapting Garrison’s system to treat the conditions described in Aklog, including PE, based on the similar system configurations, insertion locations, and methods of treatment.

71. A person of ordinary skill in the art would have recognized that Garrison's system would not necessarily have needed any modification to treat pulmonary embolisms, especially those located more distally in the smaller pulmonary vessels. However, some simple modifications could optimize the system to treat pulmonary embolisms, depending on the specific location and size of the clot to be removed, such as increasing the size of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, and potentially adjusting the suction force and adjusting the catheter strength to resist the suction force. Aklog acknowledges that persons of ordinary skill in the art possessed the requisite knowledge to select the appropriate catheter size or adjust suction pressure. For example, while Aklog primarily describes treatments for medium and large vessels, Aklog discloses "that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired." Ex. 1005 (Aklog) at 7:43-46. Thus, Aklog presumes that a person of ordinary skill in the art possessed the requisite knowledge to make these simple sizing modifications and I agree with Aklog's presumption. In my own time overseeing engineers developing catheter-based medical devices, the engineers routinely optimized catheter size, flexibility, and torque as a standard part of the design process and would adapt catheters and other components for different sized vasculatures, depending on the location and

tortuosity of the target vessel. Even Garrison discloses a range of possible sheath and catheter sizes for its system, further demonstrating that the size of the catheter was not novel or unique. Ex. 1006 (Garrison) at [0063] (describing 6 and 8 French size sheaths); [0070] (describing 10 French size sheaths). Simply put, a person of ordinary skill in the art in August 2018 possessed the necessary knowledge to select an appropriate catheter size for a given application and integrate that catheter into an aspiration system.

72. Aklog also describes one challenge persons of ordinary skill in the art encountered in moving from smaller to larger aspiration catheters – a larger catheter “may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” Ex. 1005 (Aklog) at 7:23-26. 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.* at 7:47-52.

73. Garrison also describes the problem of aspirating excessive blood. Ex. 1006 (Garrison) at [0135]. To reduce blood loss, Garrison describes an “aspiration pump device 3250 which is configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” *Id.* at [0136]; *see also id.* at [0140], Fig. 38 (describing additional blood return

variations). Thus, Garrison already addresses the primary challenge a person of ordinary skill in the art would have encountered in enlarging Garrison's aspiration catheters to treat pulmonary embolisms. Consequently, it is my opinion that a person of ordinary skill in the art would have had a reasonable expectation of success in enlarging Garrisons' catheters to aspirate pulmonary embolisms.

74. As described above, it is my opinion that a person of ordinary skill in the art would have found it obvious to adapt Garrison's aspiration system to remove the clot materials identified in Aklog, including pulmonary embolisms, because the adaption would have been the predictable use of prior art elements (Garrison's system) according to their established functions (aspiration of clot material). Based on my experience in the field, I am aware that persons of ordinary skill in the art developing catheter-based medical devices in August 2018 regularly adapted innovations developed for one portion of the vasculature to treat another. For example, the references cited in this declaration illustrate the close relationship between clots and embolisms across the vasculature (e.g., pulmonary embolism, deep vein thrombosis ("DVT"), cerebral embolisms). Aklog explains, "DVT causes harm by (1) obstructing drainage of venous blood from the legs ... and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (**pulmonary embolism**) and across a opening between the chambers of the heart (patent foramen ovale) to the **brain (stroke)**, abdominal

organs or extremities.” Ex. 1005 (Aklog) at 2:13-19 (emphasis added). Thus, DVT can become a pulmonary embolism or cerebral embolism as it travels through the body. Consequently, a person of ordinary skill in the art developing treatments for clots in one part of the body would naturally consult innovations for treating clots in other parts of the body.

75. Garrison specifically suggests combining components with its aspiration systems that come from aspiration systems for treating other parts of the vasculature. For example, Garrison states that “it may be desirable to incorporate features on the arterial access sheath in order to minimize flow resistance through the insertable portion of the access sheath.” Ex. 1006 (Garrison) at [0070]. Garrison incorporates by reference two patents for this purpose: (1) Chang (Ex. 1016), which describes “a method for treating lesions in the **carotid artery** of a mammalian body (*id.*, abstract (emphasis added)), and (2) Criado (Ex. 1017), which describes “[a] system for use in accessing and treating a **carotid artery**” (*id.*, abstract (emphasis added)).

76. Garrison also incorporates by reference several patents describing thrombectomy devices having aspiration catheters to remove thrombus. Ex. 1006 (Garrison) at [0144]. Many of these patents describe the use of aspiration catheters for parts of the vasculature outside of cerebral applications. For example, Garrison incorporates U.S. Patent No. 6,481,439, which describes

methods of treating blocked or occluded blood vessels. Ex. 1018 at 3:15-17. While the reference primarily focuses on the treatment of a “catastrophic blockage of a cerebral artery,” the patent states that the “present invention, however, will also be useful for treating acute blockages in other portions of the vasculature as well as for treating chronic occlusions in the cerebral, cardiac, peripheral, mesenteric, and other vasculature.” *Id.* at 3:28-39. Garrison also incorporates U.S. Patent No. 5,938,645, which discloses “a device adapted to break up and extract clots or thrombi which may form within the **coronary artery** comprising an improved percutaneous aspiration thrombectomy catheter system.” Ex. 1014 at 1:17-20 (emphasis added). Thus, Garrison demonstrates that persons of ordinary skill in the art readily borrowed innovations for one part of the vasculature for another.

77. Garrison is not an outlier. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady, a PCT patent application published in February 2018, describes “devices intended for removing acute blockages from blood vessels.” Ex. 1020 at 1:5; see *also id.*, 3:32-33 (“This invention improves the ability of a catheter to aspirate a clot fully”). Brady states, “The invention is particularly suited to removing clot from **cerebral arteries** in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction

(MI), and from pulmonary arteries in patients suffering from **pulmonary embolism** (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.” *Id.* at 1:13-17 (emphasis added).

78. Even the challenged '910 Patent acknowledges that POSITAs would have understood that aspiration systems for one part of the vasculature could be optimized for other portions of the vasculature. For example, the '910 patent states, “Although many of the embodiments are described below with respect to devices, systems, and methods for treating pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, **intravascular procedures for treating cerebral embolism**, intravascular procedures for treating deep vein thrombosis (DVT), etc).” Ex. 1001 ('910 patent) at 4:51-58 (emphasis added). The '910 patent does not identify any special reasons why its aspiration catheters can be used interchangeability across different parts of the vasculature while other aspiration catheters could not. Rather, the '910 patent admits a “person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to FIGS. 1-25.” *Id.* at 5:2-7.

79. Simply put, aspiration catheters primarily designed for treating cerebral occlusions, such as Garrison, are very closely related, and even interchangeable in some circumstances, to aspiration catheters for other parts of the vasculature. I have not seen any patents that describe cerebral occlusions as so different from other types of occlusions that an aspiration catheter designed to treat such occlusions would be irrelevant to other parts of the vasculature. Such statements would be inconsistent with my experience in developing catheters used to treat cardiovascular disease. For these reasons, it is my opinion that a person of ordinary skill in the art would have found it obvious to use Garrison's aspiration system to treat pulmonary embolism, with any necessary optimizations such as catheter upsizing, based on Aklog and the knowledge of a person of ordinary skill in the art.

b. Garrison and Laub

80. A person of ordinary skill in the art would have also been motivated to use and, to the extent necessary, modify and optimize Garrison's aspiration system to treat pulmonary embolism based on Laub. Garrison's system is already designed to aspirate clots and Laub explains that pulmonary embolisms are a harmful type of clot that can block blood flow to the lungs and cause death. Thus, a person of ordinary skill in the art would have been motivated to use, and to the

extent necessary, modify and optimize the existing and proven technology described in Garrison to treat similar conditions in other parts of the vasculature.

81. As in the Garrison-Aklog combination, a person of ordinary skill in the art would have been further motivated to adapt Garrison's system to be positioned proximate a pulmonary embolism and treat a pulmonary embolism because Laub discloses that aspiration (like the aspiration disclosed in Garrison) can effectively remove the pulmonary embolism. Ex. 1012 (Laub) at [0005]. Moreover, the aspiration systems described in Garrison and Laub are similarly configured. As illustrated below, both systems include an aspiration catheter [orange] that is positioned proximate to the clot material prior to aspiration, an aspiration source (e.g., aspiration pump) [red], a filter [blue], and a flow line [green] fluidly coupling the aspiration catheter to the filter and aspiration source:

Garrison

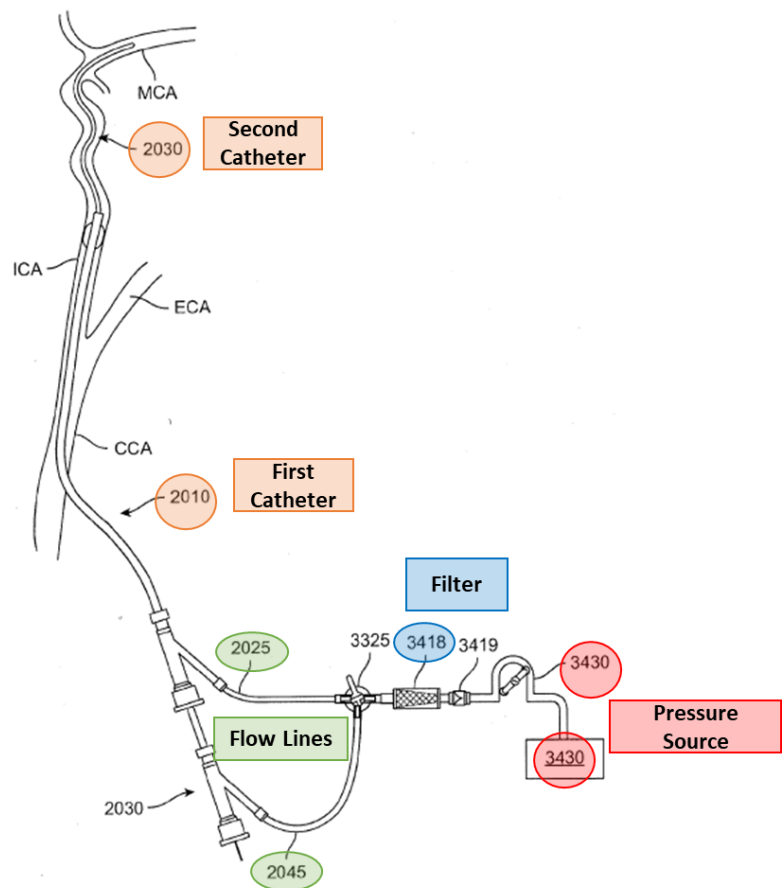


FIG. 34

Laub

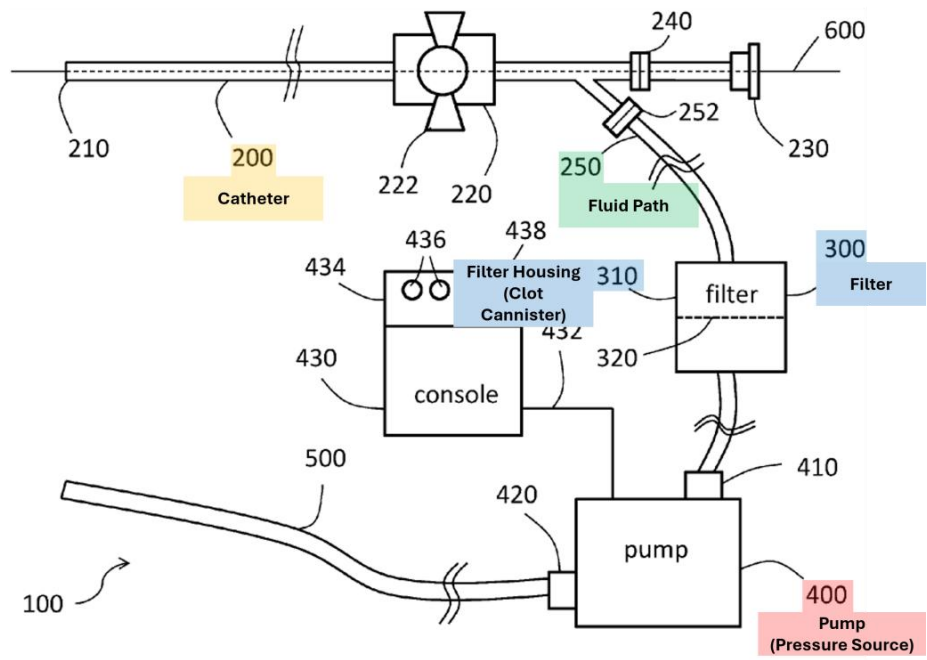


FIG. 1A

Ex. 1006 (Garrison) at [0131]-[0134], Fig. 34; Ex. 1012 (Laub) at [0024], [0039]-[0040], Fig. 1A. Additionally, the systems are inserted into the patient in the same way (e.g., through an artery or vein). Ex. 1012 (Laub) at [0024]-[0026] (describing that the catheter may be inserted into the patient's body via a vein or artery); Ex. 1006 (Garrison) at [0048] ("Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches."). A person of ordinary skill in the art would have reasonably expected success in adapting Garrison's system to treat the conditions described in Laub, including PE, based on the similar system configurations, insertion locations, and methods of treatment.

82. A person of ordinary skill in the art would have recognized that Garrison's system would not necessarily have needed any modification to treat pulmonary embolisms, especially emboli located in the distal end of the pulmonary vasculature. However, some simple modifications could optimize the system to treat pulmonary embolisms, depending on the specific location and size of the clot to be removed, such as increasing the size (i.e., diameter or French size) of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, potentially adjusting the suction force, and adjusting the catheter strength to resist the suction force. Laub reflects that persons of ordinary skill in the art possessed the requisite knowledge to make such

adjustments. For example, Laub discloses that its system can use aspiration catheters ranging from 5 to 20 Fr. and in some embodiments has a catheter equal to or greater than 10 Fr. “to allow for aspiration of large thrombi and/or other solid materials from the patient.” Ex. 1012 (Laub) at [0028]. Thus, Laub presumes that a person of ordinary skill in the art possessed the requisite knowledge to make these simple modifications and I agree with Laub’s presumption for the reasons provided in the Garrison-Aklog ground above.

83. In addition, Laub also discloses systems and methods for reintroducing aspirated blood into the patient to avoid excessive blood loss. Ex. 1012 (Laub) at [0040], [0045]. As I explained previously, Garrison also discloses reintroduction systems and procedures to avoid excessive blood loss. *Supra* ¶¶73-74. Thus, Garrison already addresses one of the primary challenges (excessive blood loss) a person of ordinary skill in the art would have encountered in enlarging Garrison’s aspiration catheters to treat pulmonary embolisms. Consequently, it is my opinion that a person of ordinary skill in the art would have had a reasonable expectation of success in adapting Garrisons’ catheters to aspirate pulmonary embolisms.

84. As described above, it is my opinion that a person of ordinary skill in the art would have found it obvious to adapt Garrison’s aspiration system to remove the clot materials identified in Laub, including pulmonary embolisms,

because the adaption would have been the predictable use of prior art elements (Garrison's system) according to their established functions (aspiration of clot material). Based on my experience in the field, I am aware that persons of ordinary skill in the art developing catheter-based medical devices in August 2018 regularly adapted innovations developed for one portion of the vasculature to treat another. For example, the references cited in this declaration illustrate the close relationship between clots and embolisms across the vasculature (e.g., pulmonary embolism, deep vein thrombosis ("DVT"), cerebral embolisms). This relationship is reflected in Laub, which recognizes that a thrombus can migrate to the vessels of the brain, causing stroke, or to the lungs, causing potentially fatal PE. Ex. 1012 (Laub) at [0004]. Consequently, a person of ordinary skill in the art developing treatments for clots in one part of the body would naturally consult innovations for treating clots in other parts of the body.

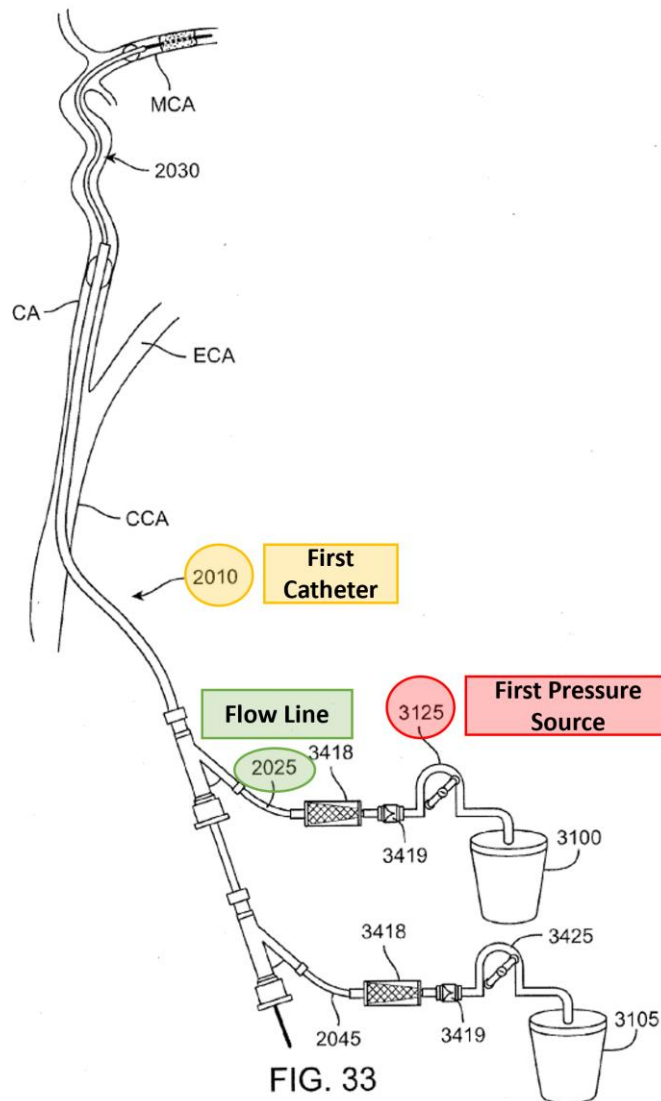
85. As I also explained in the Garrison-Aklog ground above, Garrison specifically suggests combining components with its aspiration systems that come from aspiration system for treating other parts of the vasculature. *Supra* §VI.A.1.a. Garrison also incorporates by reference several patents describing thrombectomy devices having aspiration catheters to remove thrombus. *Id.* Likewise, other prior art patents disclose aspiration systems intended for use across all portions of the vasculature, including the '333 Patent. *Id.*

86. As I explained in the Garrison-Aklog ground, aspiration catheters primarily designed for treating cerebral occlusions, such as Garrison, are very closely related, and even interchangeable in some circumstances, to aspiration catheters for other parts of the vasculature. I have not seen any patents that describe cerebral occlusions as so different from other types of occlusions that an aspiration catheter designed to treat such occlusions would be totally irrelevant to other parts of the vasculature. Such statements would be inconsistent with my experience in developing catheters used to treat cardiovascular disease. For these reasons, it is my opinion that a person of ordinary skill in the art would have found it obvious to use Garrison's aspiration system to treat pulmonary embolism, with any necessary modifications, based on Laub and the knowledge of a person of ordinary skill in the art.

2. First Clot Assembly

87. Claim 1 next recites: "a first clot aspiration assembly, including: a first catheter; a first pressure source." It is my opinion that Garrison discloses this limitation.

88. Garrison's aspiration system includes a first clot assembly including a first catheter 2010 [orange] configured for placement into fluid communication with a first aspiration source [red] by way of a flow line 2025 [green]:



Ex. 1006 (Garrison) at [0131], Fig. 33. While Garrison refers to catheter 2010 as an “arterial access device,” the device is a catheter because the device 2010 has a lumen that is fluidly coupled to a pressure source and aspirates blood and clot from the patient. *Id.* at [0131].

89. Garrison also states, “The active source of aspiration may be an **aspiration pump**, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” *Id.* at [0134] (emphasis added); see also *id.* at [0071]

(Garrison states, “The flow line 905 may also be connected to an aspiration source such as a pump or a syringe.”); [0172] (Garrison states, “Aspiration may be via a syringe, a pump, or other means as disclosed above.”). The listed sources of active aspiration are all “pressure source[s]” consistent with the term as used by ‘910 patent. Ex. 1001, 6:57-60.

3. First Fluid Control Device

90. Claim 1 next recites: “a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter.” It is my opinion that Garrison discloses this limitation.

91. In the previous section, I discussed Garrison’s Figure 33. Garrisons’ Figure 34 shows a variation of the system shown in Figure 33 (above) “whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively.” Ex. 1006 (Garrison) at [0132]. This aspiration system includes a “valve 3325” [purple] between the first catheter and the first pressure source:

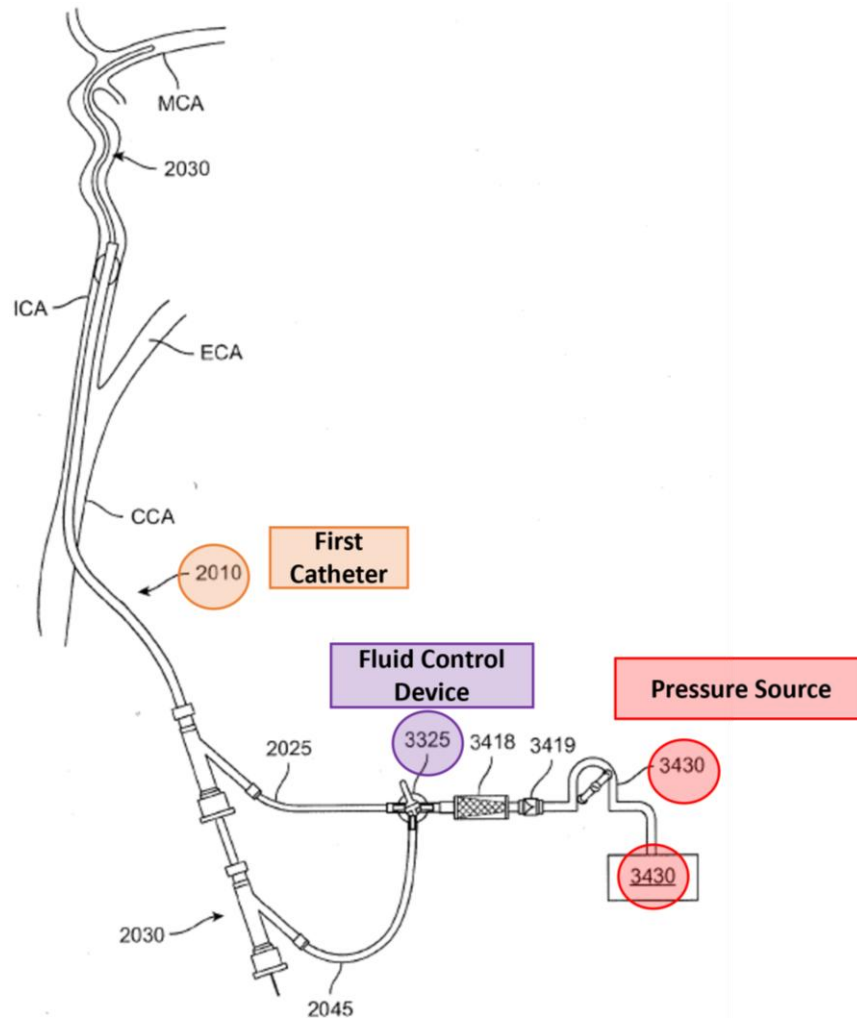


FIG. 34

Id. at [0132], Fig. 34. Garrison discloses that the “valve 3325 controls which device is connected to the aspiration source 3430.” *Id.* “The valve may be a 3-way or 4-way stopcock” and “enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Garrison discloses that the valve can also “be a flow controller with a simple actuation which selects the configuration as described above.” *Id.*; *see also id.* at [0133] (describing flow controller). Both the stopcock valve and flow controller

are fluid control devices. For example, Garrison discloses “the flow controller may include one or more control interfaces that a user may actuate to regulate which device is being aspirated[.]” *Id.* at [0133]. Similarly, a user exerts fluid control by turning the handle of the stopcock valve to open and close the valve.

92. Garrison also describes an embodiment in which “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure.” *Id.* at [0134]. Once the catheter is positioned near the thrombus, “the user may open the connection to the aspiration syringe.” *Id.* Garrison discloses that the valve could be a stopcock, *id.*, [0132], and the aspiration source could be an aspiration pump. *Id.*, [0134]. Thus, Garrison includes multiple disclosures of moving a fluid control device to fluidly disconnect a valve between the first catheter and first pressure source, then moving the fluid control device to a second position to fluidly connect the first catheter and first pressure source.

4. The First Pressure Source is Configured to Generate Vacuum Pressure

93. Claim 1 next recites: “wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first

catheter to generate suction at a distal portion of the first catheter.” It is my opinion that Garrison discloses this limitation.

94. As explained the previous section, Garrison describes an exemplary system in which “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure.” Ex. 1006 (Garrison) at [0134]. Once the catheter is positioned near the clot or thrombus, “the user may open the connection to the aspiration syringe” to “enable the maximum level of aspiration in a rapid fashion.” (*Id.*). Because the valve (e.g., stopcock 3325) is located between the pressure source and the catheter 2010, the movement of the valve to open and close the valve determines whether vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter. *Id.* at Fig. 34. While this embodiment specifically describes using a flow controller and syringe, Garrison discloses that the valve could be a stopcock, *id.* at [0132], and the aspiration source could be an aspiration pump. *Id.* at [0134].

95. Garrison also discusses testing different catheters by generating negative pressure in a pressure source and then releasing the negative pressure by opening a stopcock. Ex. 1006 (Garrison) at [0129], Figs. 56-57. Garrison states:

The catheter and syringe were purged of air, the syringe was emptied, and ***then the stopcock was closed.*** The ***locking syringe was then***

pulled back the full 30 cc volume and locked in place. A timer was started when ***the stopcock was opened***, and the time was noted at 5 cc, 10 cc, 15 cc and 20 cc of extracted solution in the syringe.

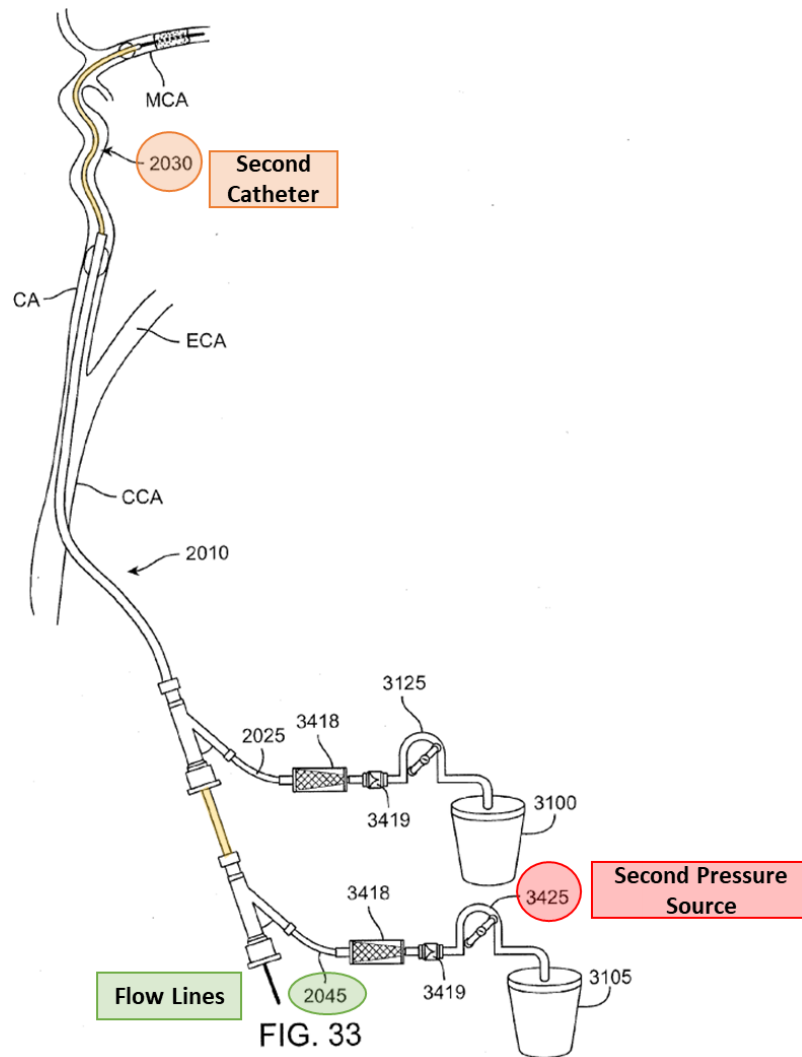
Id. (emphasis added). As described, the valve was closed while vacuum pressure was generated by the pressure source (i.e., syringe), and opened after vacuum pressure was generated. Moreover, when the valve was opened, the suction was applied to the distal end of the catheter, resulting in the “extracted solution.” Thus, Garrison includes multiple disclosures of closing a valve to generate vacuum pressure and opening the valve after the vacuum pressure is generated to cause suction at the distal end of a catheter.

5. Second Clot Aspiration Assembly

96. Claim 1 next recites: “a second clot aspiration assembly, including: a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism.” It is my opinion that Garrison in view of Laub and/or Aklog discloses this limitation.

97. Garrison’s aspiration system includes a second clot assembly including a second aspiration catheter 2030 [orange] configured for placement

into fluid communication with a second pressure source 3425 [red] by way of a flow line 2045 [green]:



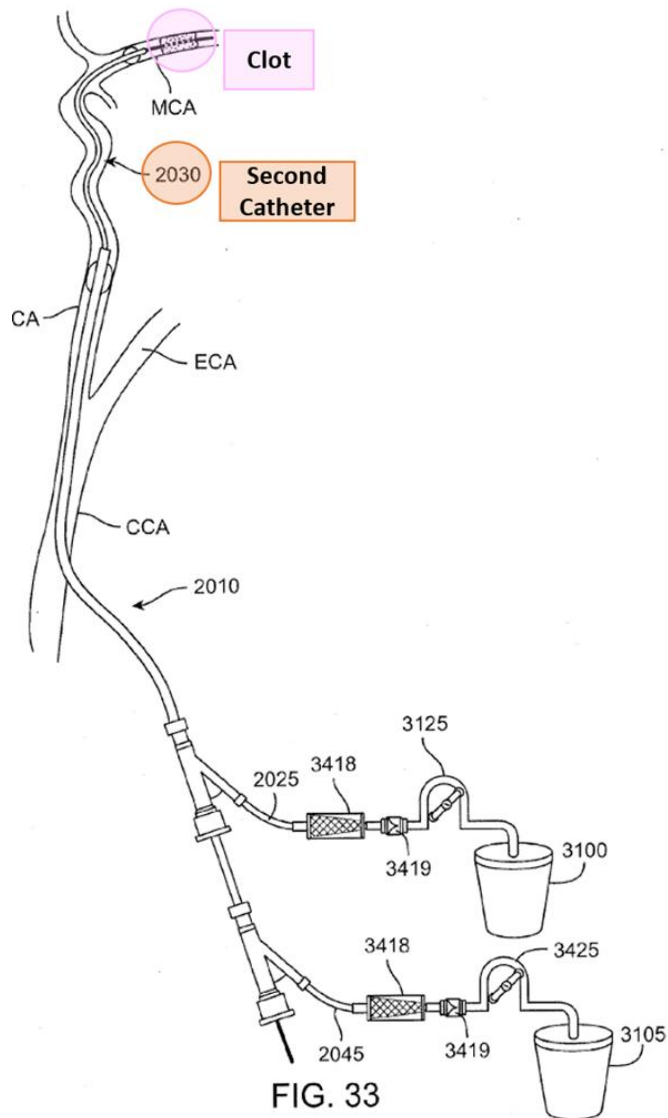
Ex. 1006 (Garrison) at [0131], Fig. 33. As shown in Figure 33 above, the second catheter 2030 is advanceable through the first catheter 2010 and is also advanced through the patient's vasculature (identified in the figure as the CCA and MCA). The Examiner was incorrect to conclude during prosecution that Garrison did not disclose a second catheter advanceable through a first catheter. I notice the

Examiner refers to the wrong item numbers in the office action. The Examiner stated:

However, Garrison fails to teach a second catheter advanceable through the first catheter. The second catheter (2045) does not advances through the first catheter (2025), as shown in Figure 33. There is no reason to advance the second catheter through the first catheter of Garrison. Also Garrison does not explicitly disclose the flow lines (2025 and 2045) advancing through arterial access device (2010) ... because it would interfere with the thrombectomy device.

Ex. 1002 at 377. But items 2025 and 2045 are not catheters. Items 2025 and 2045 are “flow lines.” Based on this description, it appears that the Examiner did not understand Garrison.

98. Garrison explains that its catheter 2030 may also “provide distal access for additional devices, localized fluid or contrast delivery, or localized aspiration at a location distal of the distal-most end of the arterial access device 2010.” Ex. 1006 (Garrison) at [0054]. In Figure 33, for example, the distal end of Garrison’s second catheter (catheter 2030, orange) extends beyond the end of the first catheter (catheter 2010) and is positioned proximate to clot material within the blood vessel of the patient:



Ex. 1006 (Garrison) at Fig. 33, [0131]. Garrison also describes variations of the aspiration catheter where the distal tip has been modified to provide enhanced aspiration, such as catheters with an enlarged “distal-most tip or edge.” *Id.*, [0111]. Thus, Garrison repeatedly discloses positioning the distal portion of the catheter proximate the clot material.

99. In my opinion, a person of ordinary skill in the art 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.

100. In the Litigation, I have opined that the '910 patent does not inform with reasonable certainty a person of ordinary skill in the art about the scope of the phrase "shaped to be intravascularly advanced." Ex. 1053 at 12-14. As I explained in my claim construction expert report, the claims do not explain what "shaped" means, and the specification does not use the phrase at all. I also note that the claims separately recite the size of the catheter (16 French or greater), so "shaped" does not mean sized, and the specification lacks other information that I would typically associate with the shape of a catheter (e.g., pre-set curves).

101. While I believe the claim term "shaped to be intravascularly advanced" is indefinite, Garrison, Laub, and Aklog illustrate catheter systems that are advanced through the patient's vasculature and, therefore, must be "shaped to be intravascularly advanced." I note that the illustrations in Garrison and Aklog particularly show the catheter tracking and conforming to the vasculature of the patient. Thus, while the boundaries of the term are uncertain, the prior art clearly meets the limitation.

a. Laub

102. Laub discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr.” Ex. 1012 (Laub) at [0028].

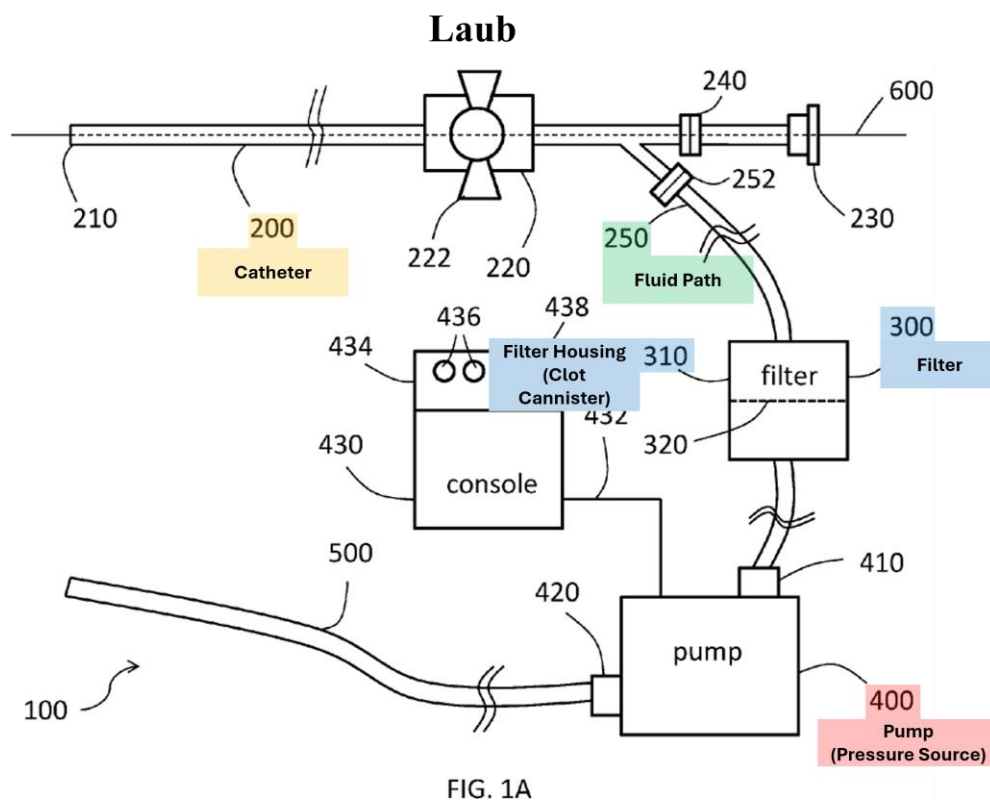


FIG. 1A

Id. at Fig. 1A.

b. Aklog

103. Aklog discloses that its “[c]annula ... 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.” Ex. 1005 (Aklog) at 11:12-14. Aklog further discloses that the “size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be

The diagram illustrates a medical system for blood filtration and perfusion. A patient's torso is shown with a heart (71) and major blood vessels. A catheter (703) is inserted into the heart. Another catheter (702) is inserted into the neck. A third catheter (706) is inserted into the arm. A fourth catheter (704) is inserted into the leg. A fifth catheter (701) is inserted into the leg. A sixth catheter (705) is inserted into the leg. A seventh catheter (704) is inserted into the leg. A reservoir (72) is connected to the system. A pump (73) is connected to the reservoir. A filter (74) is connected to the pump. A catheter (76) is connected to the reservoir. A catheter (70) is connected to the reservoir. A catheter (75) is connected to the leg. A catheter (705) is connected to the leg. A catheter (704) is connected to the leg. A catheter (701) is connected to the leg. A catheter (703) is connected to the heart. A catheter (702) is connected to the neck. A catheter (706) is connected to the arm. A catheter (704) is connected to the leg. A catheter (705) is connected to the leg. A catheter (701) is connected to the leg. A catheter (75) is connected to the leg. A catheter (76) is connected to the reservoir. A catheter (70) is connected to the reservoir. A pump (73) is connected to the reservoir. A filter (74) is connected to the pump. A catheter (703) is connected to the heart. A catheter (702) is connected to the neck. A catheter (706) is connected to the arm. A catheter (704) is connected to the leg. A catheter (705) is connected to the leg. A catheter (701) is connected to the leg. A catheter (75) is connected to the leg. A catheter (76) is connected to the reservoir. A catheter (70) is connected to the reservoir.

Id. at Fig. 7. Because Aklog explains that the catheter “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel,” a person of ordinary skill in the art would have understood Aklog to disclose using

catheters of 16F or larger, at least based on Figure 7 and the description in Aklog that the system can be used to treat pulmonary embolisms. *Id.* at 11:12-14.

c. Garrison and Laub or Aklog

104. A person of ordinary skill in the art would have been motivated to increase the size of Garrison's second catheter to 16F or greater based on Laub or Aklog because those references describe the successful use of larger catheters (16F or greater) to treat PE. As I explained the section above addressing the claim "Preamble" (*supra* §VI.A.1), a person of ordinary skill in the art would have had many motivations and reasonably expected success in using, or modifying and optimizing, Garrison's system to treat PE.

105. As I also discussed in the "Preamble" section above, persons of ordinary skill in the art would have recognized that optimizing Garrison's system to treat PE would have required, at most, simple modifications, ***such as increasing the size of the aspiration catheter*** (and related components), optimizing the flexibility and torque characteristics of the catheter, and potentially adjusting the suction force and adjusting the catheter strength to resist the suction force. *Supra* §VI.A.1. These types of catheter modifications, and specifically increasing the size of a catheter, was routine for medical device engineers. In fact, Laub acknowledges that persons of ordinary skill in the art possessed the requisite knowledge to optimize aspirations systems to use the appropriately sized catheter.

For example, Laub discloses embodiments where the “aspiration catheter 200 has a French size of at least 5 Fr”, and embodiments where “aspiration catheter 200 has a French size of at least 20 Fr”. Ex. 1012 (Laub) at [0028]. Laub presumes that persons of ordinary skill in the art would have possessed the requisite knowledge to select the correct catheter size for the particular application.

106. Similarly, Garrison discloses a range of possible sheath and catheter sizes for its system and also presumes that a person of ordinary skill in the art would have possessed the necessary knowledge to select the correct size for the particular application. *See, e.g.*, Ex. 1006 (Garrison) at [0063] (describing 6 and 8 French size sheaths); [0070] (describing 10 French size sheaths). Aklog also presumes that the person of ordinary skill in the art would be able to select the appropriately sized catheter, instructing that the catheter “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.” Ex. 1005 (Aklog) at 11:13-15.

107. These references are consistent with my own experiences in the medical field. Often, medical device companies will develop multiple sizes of catheters in a single product line over the life of the product. Companies develop multiple sizes because patient anatomy varies – what works in one patient may not work in another – and because companies are generally trying to optimize the product for the specific procedure over the life of the product. The routine

development of multiple sizes of catheter reflects how obvious it is to use catheters of different sizes with the same device.

108. In addition, using aspiration catheters having a size of 16 Fr. or greater to treat PE and DVT was well known prior to 2018, as evidenced by Laub above. Further, there were several commercially available aspiration systems at that time that were used to treat both PE and DVT and included catheters larger than 16 Fr. *See, e.g.*, Ex. 1049 (Pasha) at 241 (disclosing 26 Fr. AngioVac catheter used to treat PE); Ex. 1051 (Kohi) at 605-607, Table 3 (disclosing 22 Fr. AngioVac catheter used to treat DVT). And based on my experience, there is nothing unique about using a catheter 16F or larger. When I was involved in the development of the MitraClip device, which is a product that is implanted transfemorally and in a beating heart, we developed a Clip Delivery System that included a 16F Steerable Sleeve, which was advanced within a 24F steerable guiding catheter to help place the device. For all of these reasons, a person of ordinary skill in the art would have reasonably expected success in upsizing Garrison's catheters from 8F or 10F to 16F or larger.

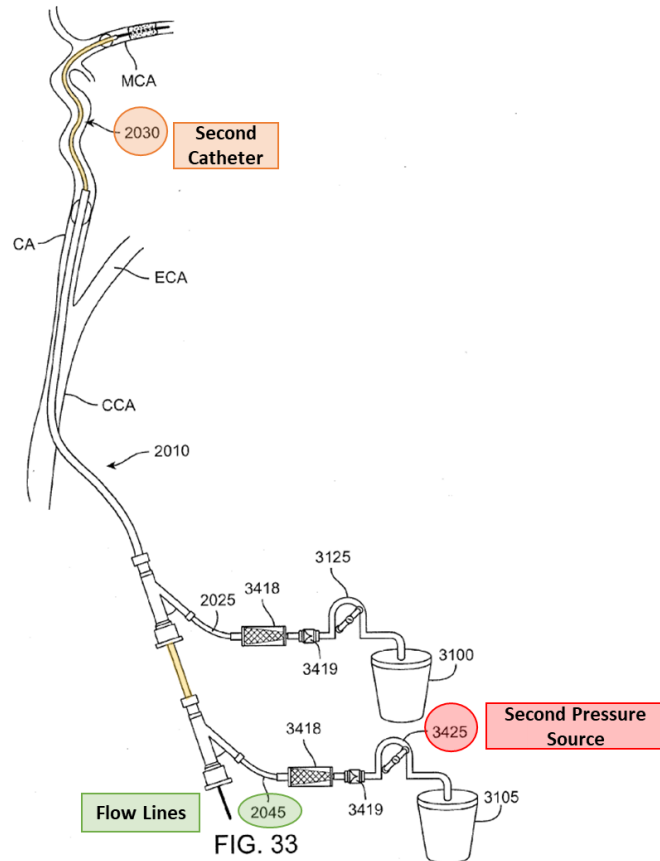
109. Additionally, for the reasons already explained in the "Preamble" section, a person of ordinary skill in the art would have found it obvious to position the distal end of Garrison's aspiration system proximate a pulmonary

embolism within the blood vessel of the patient based on Laub or Aklog and the knowledge of a person of ordinary skill in the art. *Supra* §VI.A.1

6. Second Pressure Source

110. Claim 1 next recites: “a second pressure source.” It is my opinion that Garrison discloses this limitation.

111. Garrison describes an embodiment in which the clot treatment system includes a second aspiration source 3425 [red]:



Ex. 1006 (Garrison) at [0131], Fig. 33. Garrison states, “the flow line 2045 of the catheter 2030 is additionally or alternately connected to a separate aspiration source 3425 and delivery location, such as receptable 3105.” *Id.* at [0131].

Garrison further explains that “the aspiration source 3425 and delivery location may be combined into a single device such as a syringe.” *Id.*

7. Second Fluid Control Device

112. Claim 1 next recites: “a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter.” It is my opinion that Garrison in combination with Laub or Aklog renders this limitation obvious.

113. Garrison’s aspiration system includes “valve 3325” as shown in Figure 34 between the first catheter and the first pressure source.

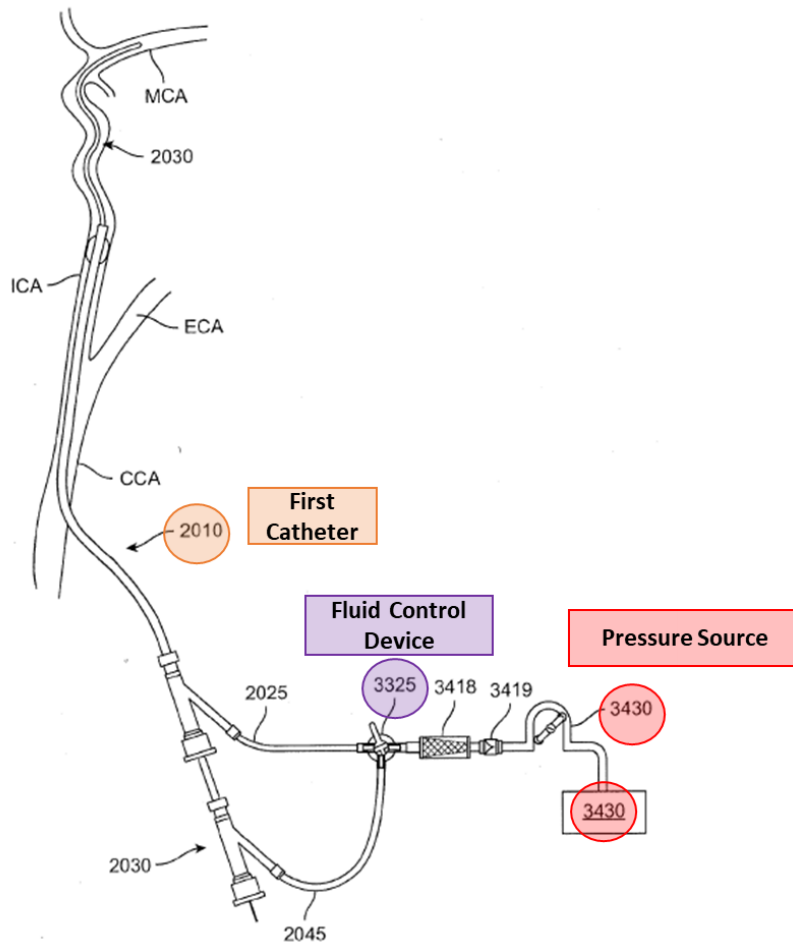
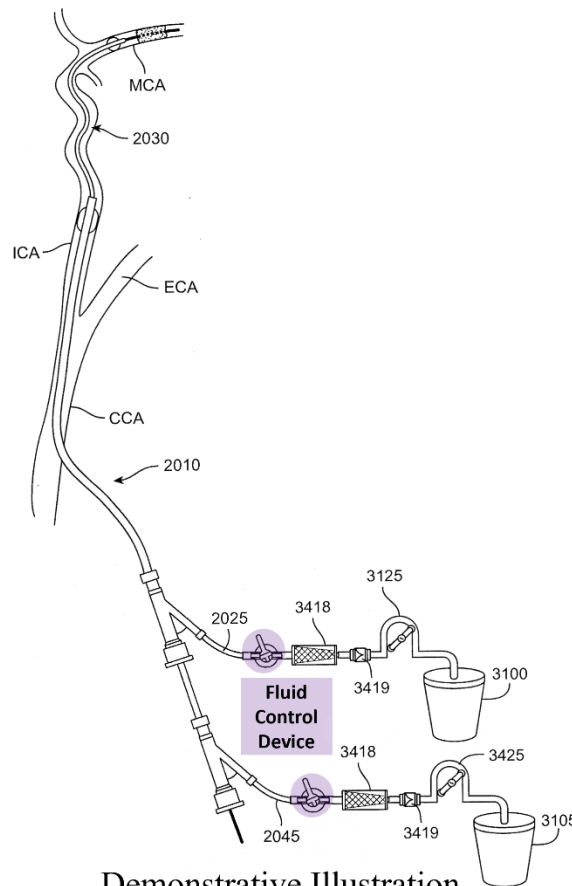


FIG. 34

Id. at [0132], Fig. 34. The valve is a fluid control device for the reasons previously provided. *Supra* §VI.A.3. While Figure 34 illustrates a single fluid control device (stopcock valve 3325) between the pressure source and catheters, Garrison explains that the flow control elements, such as valve 3325, can be used with all the catheters and flow lines described in the embodiments. *See e.g.*, Ex. 1006 at [0130] (“Described herein are aspiration and flow control elements configured to be used with an arterial access device, a guide catheter, and/or a catheter of the disclosed system.”).

114. A person of ordinary skill in the art using the embodiment in Figure 33 would have found it obvious, and been motivated, to add the same valve 3325 (as shown in Figure 34) between each pressure source and catheter so that the user could control the flow of suction to the catheter and achieve “the maximum level of aspiration in a rapid fashion”:¹



Demonstrative Illustration
Modified FIG. 33

Ex. 1006 (Garrison) at [0134], Fig. 33 (Modified to include a second “fluid control device” colored purple to each flow line)). The above demonstrative

¹ This image reflects a demonstrative prepared by Imperative Care. All modifications to the figure have been made by Imperative Care.

shows the potential location for both fluid control devices. Notably, the fluid control device is in the same position in modified Figure 33 above (i.e., between the filter and the catheter) as in Figure 34. A person of ordinary skill in the art 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.

115. Further, incorporating two separate valves into the system with two separate pressure sources would have given physicians more flexibility when using the device. For example, the pressure sources could be different types of pressure sources, such as a syringe and pump, that could have provided different amounts and different types (e.g., continuous vs short burst) of suction. The pressure sources could have also provided different suction strengths. By incorporating two fluid control devices (e.g., stopcocks) in the device, the user could control these independent pressure sources separately.

116. A person of ordinary skill in the art would have reasonably expected success in connecting two fluid control valves (e.g., stopcocks) to the system, as demonstrated in modified Figure 33 above, because Garrison already discloses that such a valve is useful in controlling the flow of pressure to the catheters. Likewise, Garrison discloses that positioning the valve between the filter and catheter provides effective control.

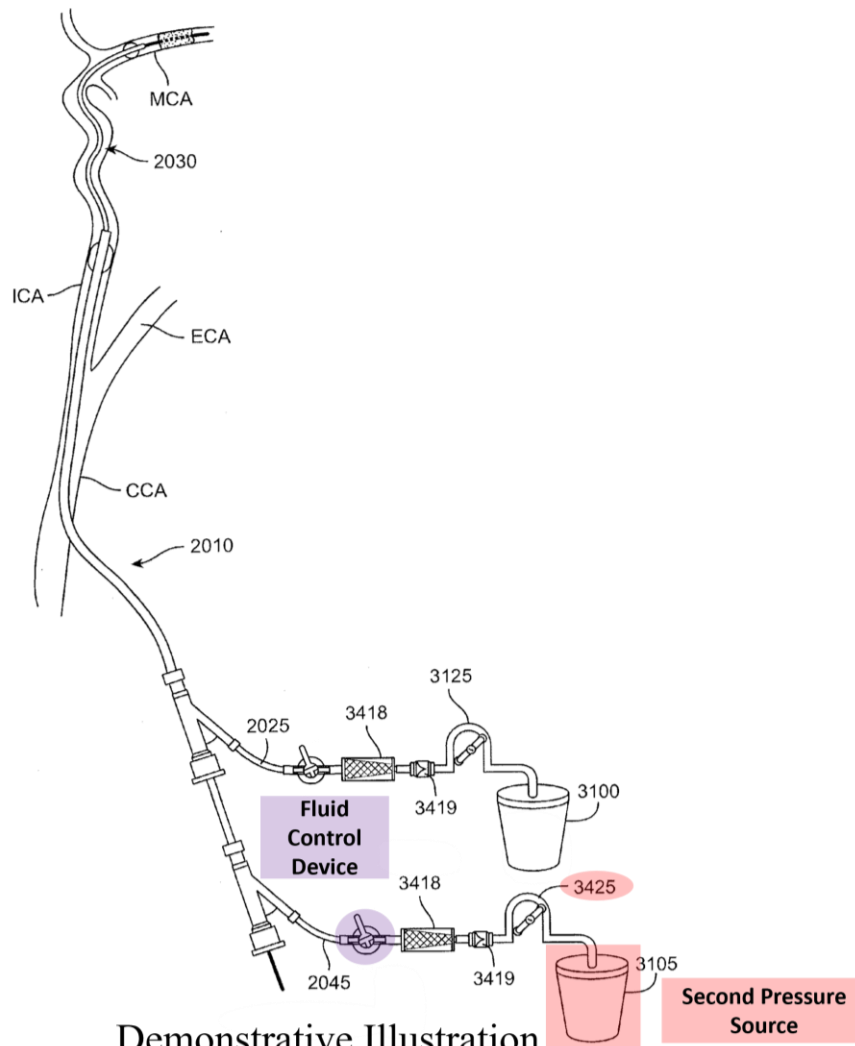
117. Further, connecting two valves to the tubing shown in Figure 33 would have been a simple modification. In August 2018, a person of ordinary skill in the art would have found it obvious to couple the fluid control devices to the tubing and other components using conventional connectors, such as Luer-type connectors (e.g., Luer slip and Luer lock) and barb connectors. Ex. 1006 (Garrison) at [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); Ex. 1001 at 7:61 (describing a “standard luer connector”), 33:24 (describing a “standard Luer or large bore connector”). In fact, Garrison incorporates by reference patents and publications that describe attaching catheter components using “a conventional luer fitting” or improvements to such fittings. Ex. 1010 at [0130]; *see also* Ex. 1014 at 8:45, 8:63 (describing an “auxiliary Luer port”); Ex. 1015 at [0056]-[0059] (describing improvements to the “standardized ... locking Luer taper design”).

118. Additionally, if the fluid control device were the same as the device in Figure 34 (e.g., a stopcock), then the second fluid control device would be movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter for the same reasons previously provided. *Supra* §VI.A.3.

8. The Second Pressure Source is Configured to Generate Vacuum Pressure

119. Claim 1 next recites: “wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position.” Garrison in combination with Laub or Aklog renders this limitation.

120. As explained above, Garrison describes a pressure source that is configured to generate vacuum pressure while a fluid control device is in the first position. *Supra* §VI.A.4. This configuration is mostly notably described at paragraph [0134] of Garrison and with reference to Figure 34. A person of ordinary skill in the art would have found it obvious, and been motivated, to use this same procedure with a second fluid control device:



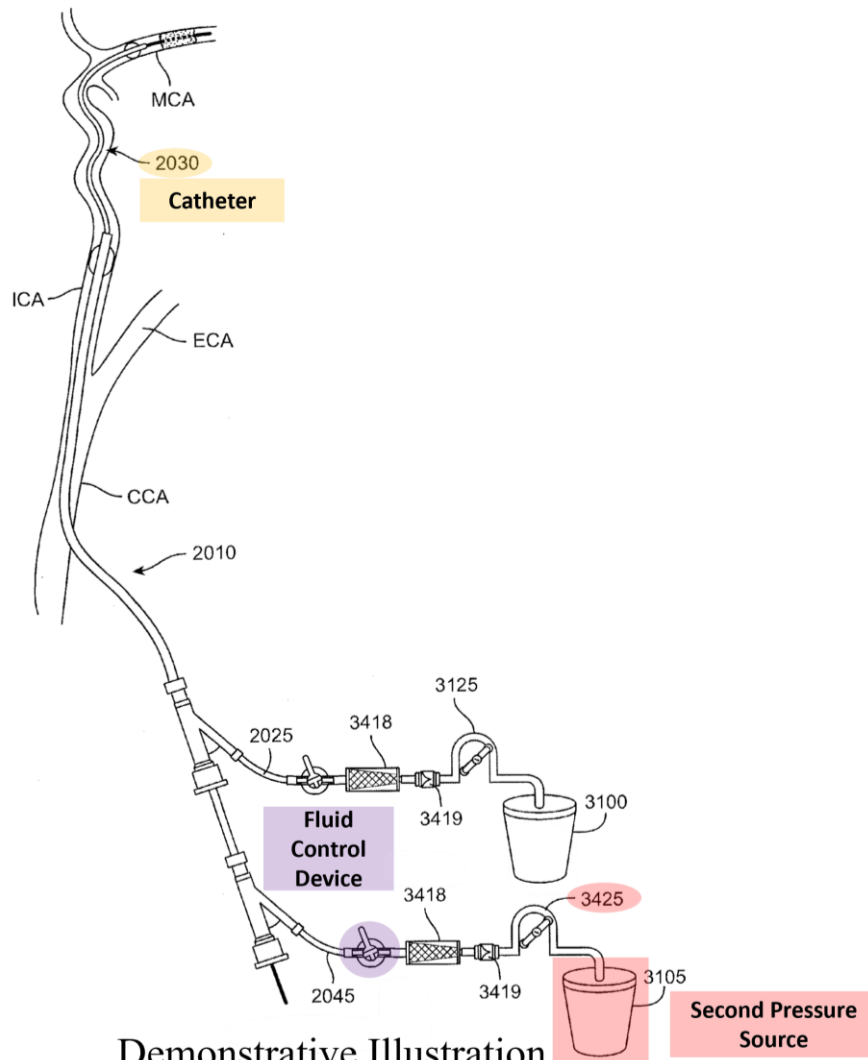
Demonstrative Illustration
Modified FIG. 33

Supra §VI. A.4; Ex. 1006 (Garrison) at Fig. 33 (Modified). Garrison explains that closing the fluid control device while the pressure source generates vacuum and then opening the fluid control device when the catheter is positioned near the clot “would enable the maximum level of aspiration in a rapid fashion with one user[.]” Ex. 1006 (Garrison) at [0134]. Both the fluid control devices shown in modified Figure 33 above are configured to have this capability.

9. The Vacuum Pressure is Applied

121. Claim 1 next recites: “wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.” Garrison in combination with Laub and/or Aklog renders this limitation obvious.

122. As I explained in the prior section, Garrison discloses a fluid control device that can be moved from a first position to a second position. When that happens, the built-up vacuum pressure is applied to the catheter to generate suction at the distal portion of the catheter to aspirate blood and clot. *Supra* §§VI.A.4, 8; Ex. 1006 (Garrison) at [0134], Figs. 33-34. If the fluid control device disclosed in Figure 34 were incorporated into both flow lines in the embodiment in Figure 33, moving either of the fluid control devices to the second position would have had this same impact:



Demonstrative Illustration
Modified FIG. 33

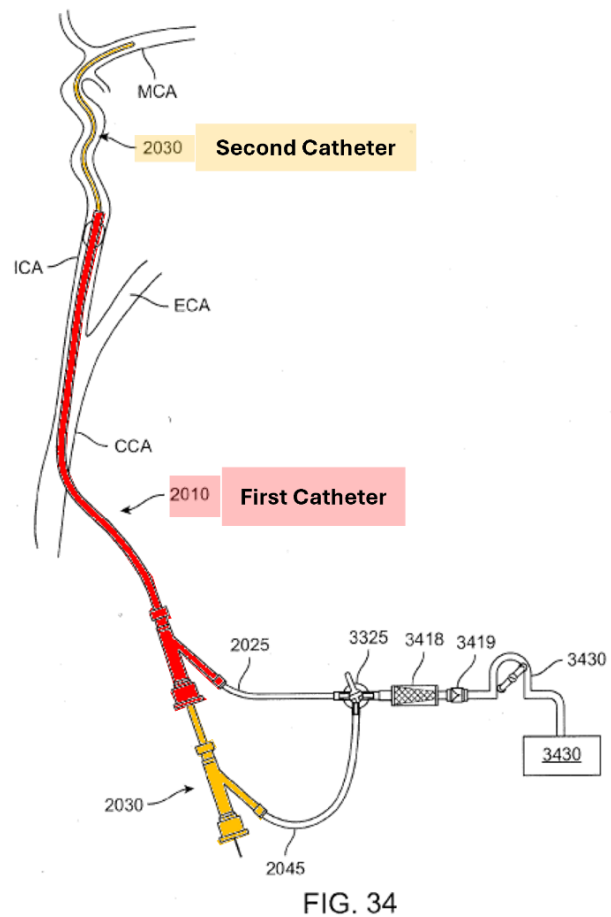
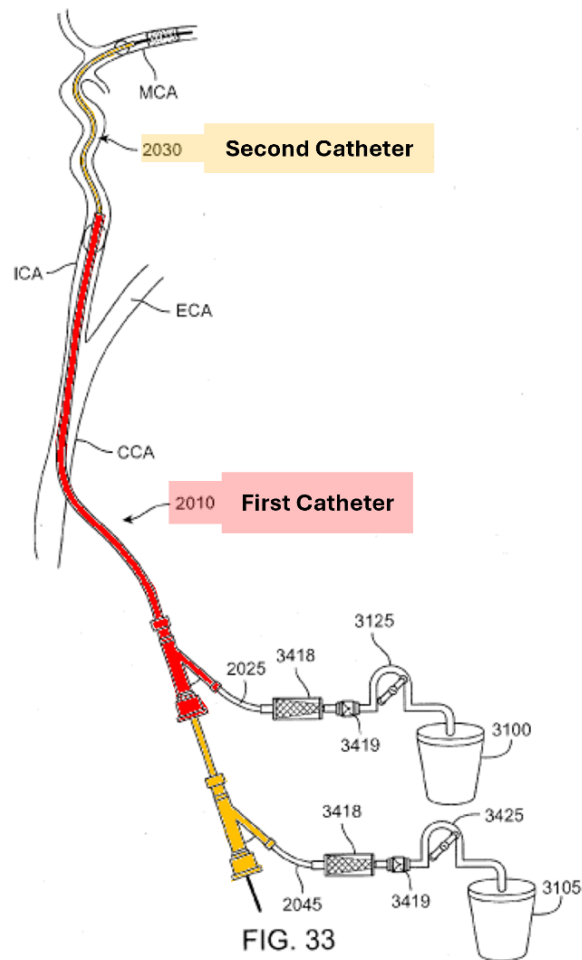
Supra §VI. A.5; Ex. 1006 (Garrison) at Fig. 33 (Modified).

123. As discussed above, Garrison's aspiration catheter includes a distal end portion configured to be positioned proximate to clot material. If Garrison's system were used, or optimized, to treat pulmonary embolisms, the distal end of the second catheter would be positioned so as to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

B. Claim 2

124. Claim 2 depends from Claim 1 and recites: “wherein the first catheter has a first length, and wherein the second catheter has a second length longer than the first length.” It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 2 obvious.

125. Garrison discloses that “[if] the catheter is unable to reach the treatment site, or if a secondary more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site.” Ex. 1006 (Garrison) at [0166]. Garrison illustrates a second catheter that has a length longer than the length of the first catheter in multiple embodiments, including the embodiments in Figures 33 and 34:



Id. at Figs. 33-34.

C. **Claim 3**

126. Claim 3 depends from Claim 1 and recites: “wherein the first catheter has a size of 24 French, and wherein the size of the the [sic] second catheter has [sic] is 16 French.” It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 3 obvious.

127. Laub discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr.” Ex. 1012 (Laub) at [0028]. Laub also

discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of **at least** 20 Fr.” *Id.* (emphasis added.)

128. Aklog discloses that its “[c]annula ... 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.” Ex. 1005 (Aklog) at 11:12-14. Aklog further discloses that the “size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation,” and it explains that the cannula may have a sufficient size “to remove at least 10 cm³ of undesirable material substantially en bloc.” *Id.* at 11:15-20. Figure 7 of Aklog also depicts a large diameter catheter aspirating a large clot from the proximal portion of the pulmonary vasculature, which is typically larger than 24F:

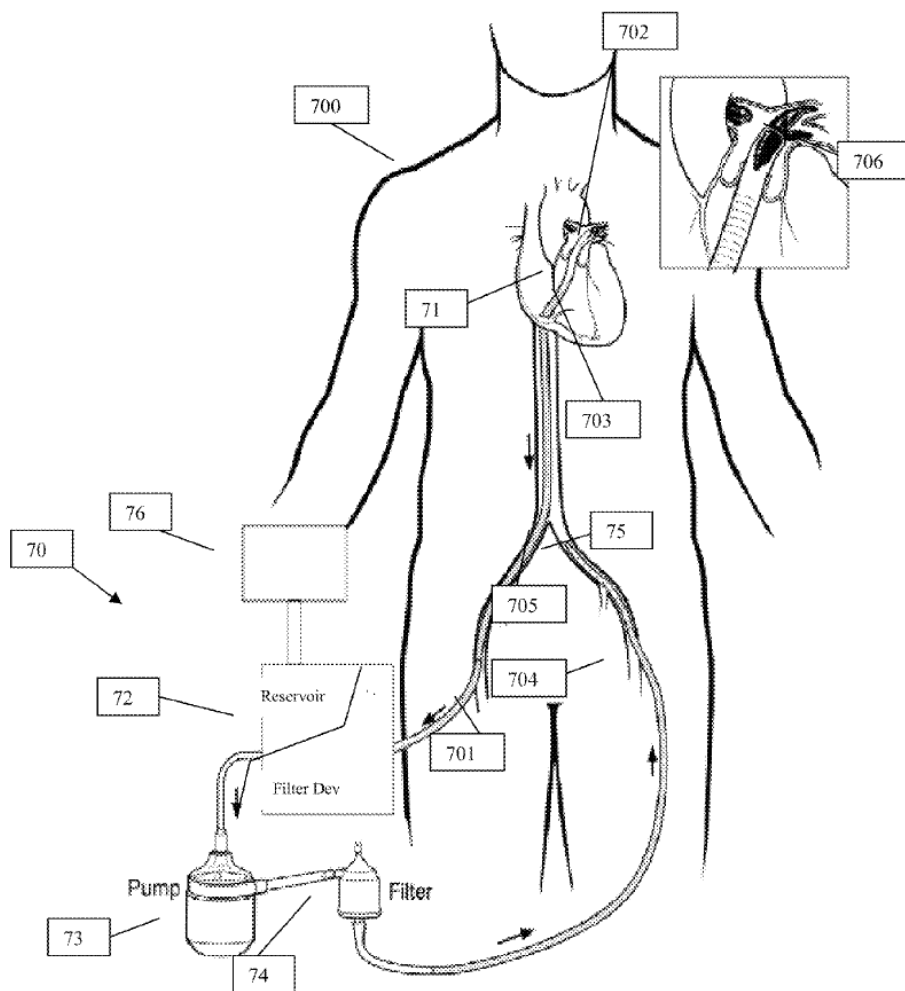


Fig. 7

Id. at Fig. 7. Because Aklog explains that the catheter “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel,” a person of ordinary skill in the art would have understood Aklog to disclose using catheters of 24F or larger, at least based on Figure 7 and the description in Aklog that the system can be used to treat pulmonary embolisms. *Id.* at 11:12-14.

129. Further, as I explained in claim 1, using aspiration catheters having a size of 16 Fr. or 24 Fr to treat PE and DVT was well known prior to 2018, as evidenced by Laub above. There were several commercially available aspiration

systems at that time that were used to treat both PE and DVT that included catheters larger than 16 and even 24 Fr. See, e.g., Ex. 1049 (Pasha) at 241 (disclosing 26 Fr. Angiovac catheter used to treat PE); Ex. 1051 (Kohi) at 604-607, Table 3 (disclosing 22 Fr. Angiovac catheter used to treat DVT).

130. Accordingly, given Laub's or Aklog's disclosures and the knowledge of a person of ordinary skill in the art regarding the treatment of PE and known systems used for doing so in August 2018, a person of ordinary skill in the art would have been motivated to use catheters of at least 16 Fr and 24 Fr in Garrison's system to treat PE. Also, there were a finite number of large catheter sizes that could be used to aspirate large blood vessels (~16 French to 26 French). A POSITA would have found it obvious to try any of these finite, predictable options. The person of ordinary skill in the art would have reasonably expected success in doing so because Laub, Aklog, and other references, confirm the effectiveness of catheters measuring at least 16F or at least 24F for treating PE.

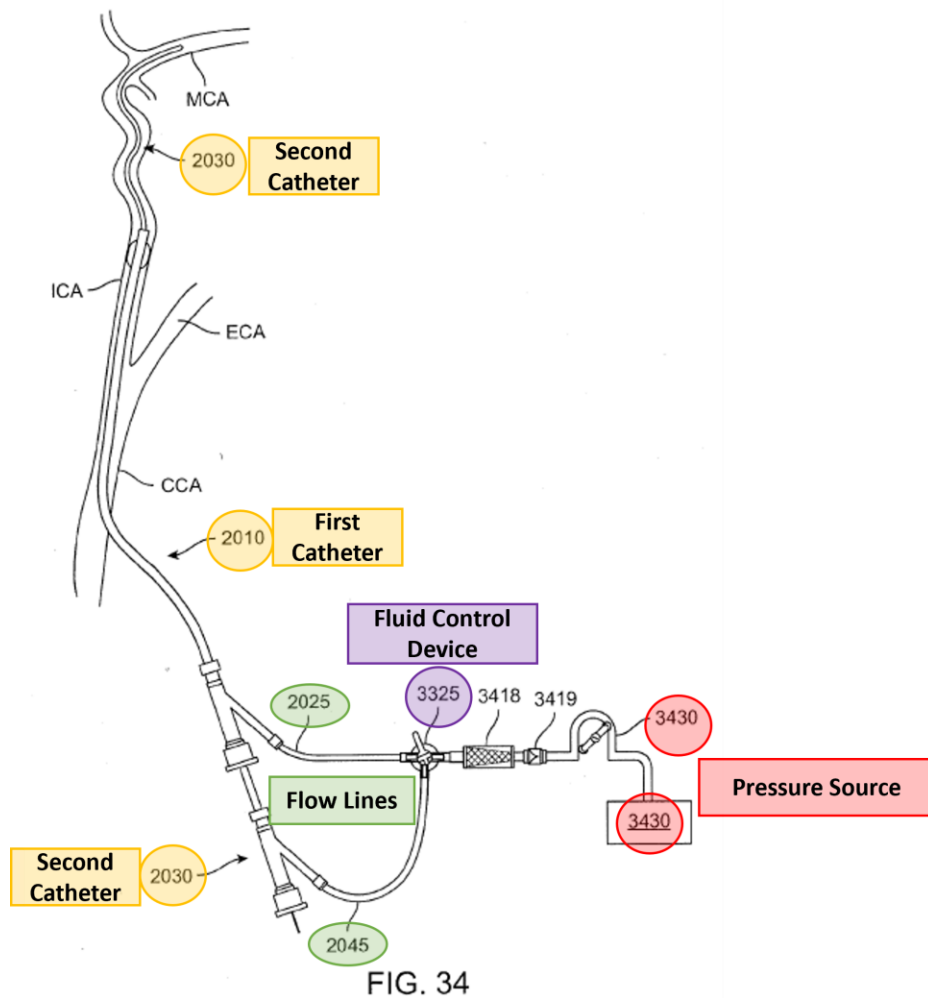
131. A person of ordinary skill in the art would have been motivated to use the catheters of Laub or Aklog with Garrison's system to treat PE at least for the reasons I explained previously for Claim 1. *Supra* §VI. A.1.

D. Claim 4

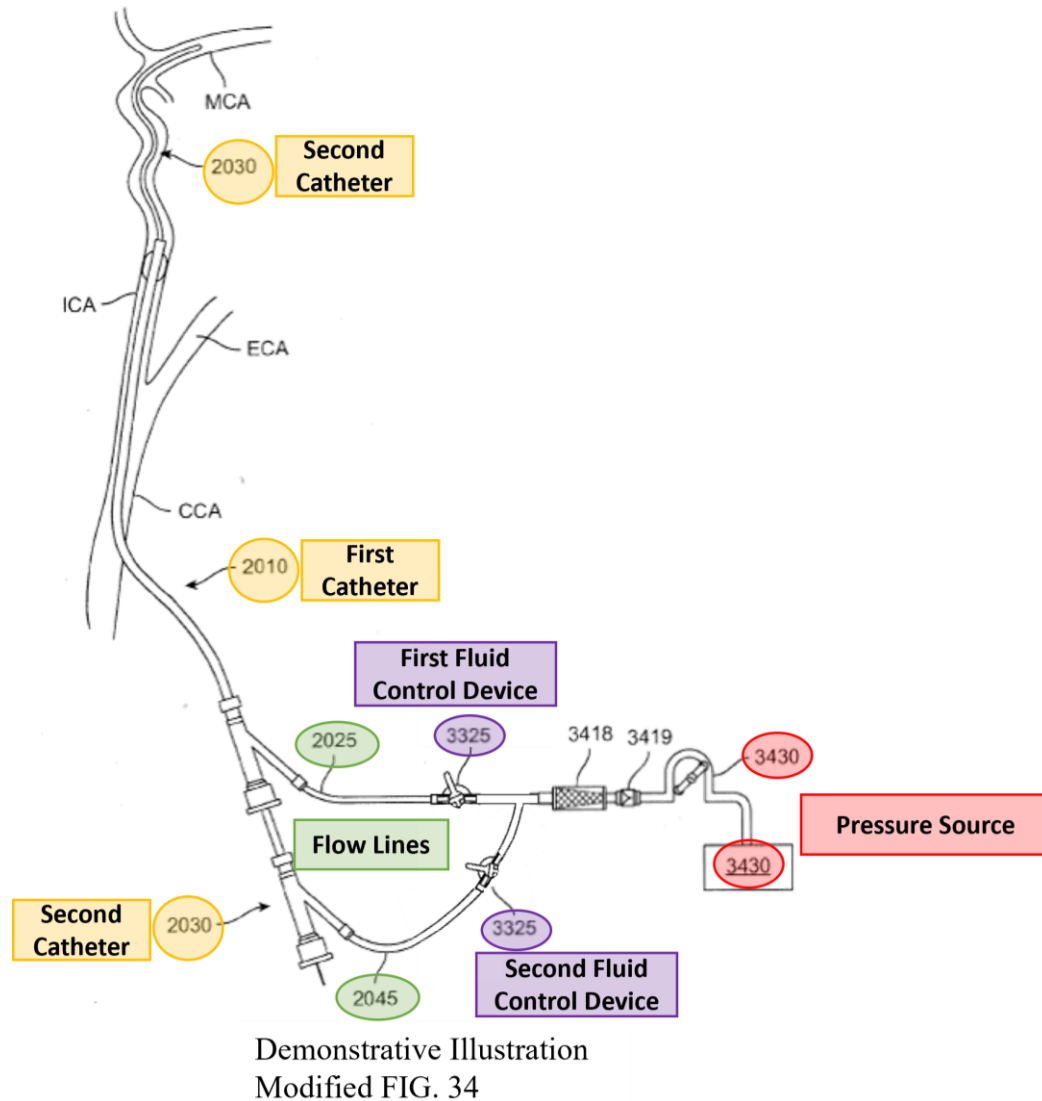
132. Claim 4 depends from Claim 1 and recites: "wherein the first pressure source is the same as the second pressure source." It is my opinion that

Garrison in view of Laub and/or Aklog renders Claim 4 obvious for at least the reasons I explained previously for Claim 1. *Supra* §VI. A.6.

133. As explained above, Garrison discloses an embodiment “whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively”:



Ex. 1006 (Garrison) at [0132], Fig. 34. A person with ordinary skill in the art would have found it obvious to use two valves 3325 with the embodiment shown in Fig. 34 so that the physician could separately apply pressure to both catheters²:



Supra §VI.A.7; Ex. 1006 (Garrison) at Fig. 34 (Modified to include a second fluid control device).

² This image reflects a demonstrative prepared by Imperative Care. All modifications to the figure have been made by Imperative Care.

134. While Figure 34 already may include a three-way stopcock to allow the physician to separately control the flow of fluid through both flow lines, a person of ordinary skill in the art would have been motivated to try using a separate, two-way fluid control device on each individual flow line. While a three-way stopcock is a convenient tool, it does increase the risk that the user inadvertently applies pressure to the wrong flow line at the wrong time. For example, the user may wish to apply negative pressure to only flow line 2025, but accidentally turn the three-way stopcock in the wrong direction resulting in the application of pressure to flow line 2045 (and ultimately the second catheter). By using individual two-way stopcocks on each line, the risk of inadvertently applying pressure to the wrong flow line is decreased.

135. A person of ordinary skill in the art would have expected success in using two fluid control devices in the embodiment in Figure 34 for several reasons. First, Garrison already describes using such a stopcock to maximize fluid flow to the catheter. Second, stopcocks are simple mechanical structures that were used with many medical devices in 2018. A person of ordinary skill in the art would have been intimately familiar with these devices and would have had experience connecting and disconnecting them from medical tubing, such as flow lines 2025 and 2045. As I described previously, Garrison incorporates patents describing standard connectors for stopcocks. *Supra* §VI.A.6. Ultimately, the

combination of a second fluid control device with the system in Figure 34 would have been nothing more than the combination of prior art elements (stopcock and tubing) according to known methods (positioning the stopcock between the filter and catheter using standard connectors) to yield predictable results (controlling the application of suction to the catheter).

E. Claim 5

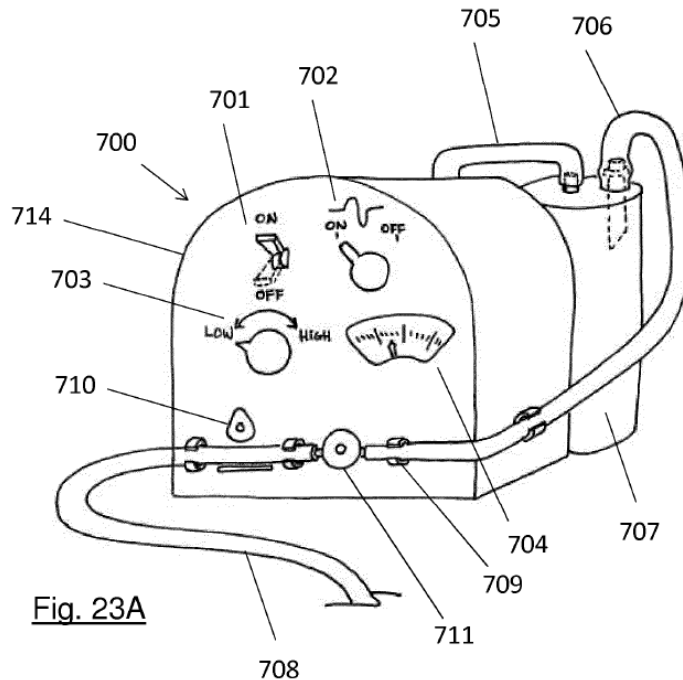
136. Claim 5 depends from Claim 1 and recites: “wherein the first pressure source and the second pressure source comprise an electric pump.” It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 5 obvious.

137. Garrison discloses that aspiration for its system “may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” Ex. 1006 (Garrison) at [00134], *see also id.* at [0165]. Garrison also discloses using “a syringe or other manual aspiration device, or an aspiration pump.” *Id.* at [0072]; *see also id.* at [0134], [0071] (“an aspiration source such as a pump or a syringe”). Because Garrison distinguishes between “manual aspiration devices” and “aspiration pumps,” a person of ordinary skill in the art would have understood aspiration pumps to mean electric pumps.

138. Laub also discloses that its aspiration system includes a pump 400, and Laub explains that the pump 400 may be a centrifugal pump, a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art. Ex. 1012

(Laub) at [0041]. Laub also states that the pump 400 “may be controlled by a console” connected to the pump via either a “hard-wired electrical pathway” or a wireless connection. *Id.* Thus, if the Board determines that Garrison does not expressly disclose an electric pump, a person of ordinary skill in the art would have found it obvious to use one of Laub’s electric pumps with Garrison to provide continuous suction.

139. Aklog discloses that its system can include a pump 15 that is “designed to generate negative pressure ... to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest.” Ex. 1005 (Aklog) at 11:62-65. The pump 15 “may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood.” *Id.* at 12:10-14. There were several commercially available electronic pumps designed and used for clot aspiration systems prior to August 2018. *See, e.g.*, Ex. 1038 (Indigo Aspiration System); Ex. 1039 (AXS Universal Aspiration Brochure). Likewise, many prior art patents and applications described electric pumps for aspiration system, such as Brady:

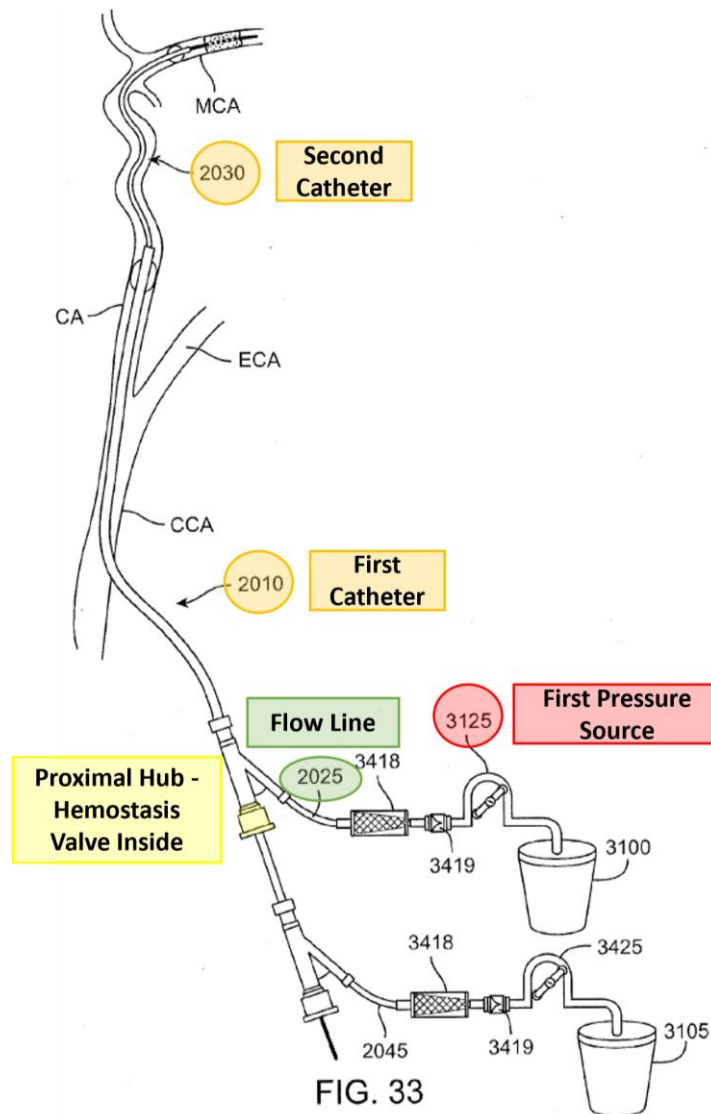


Ex. 1020 at Fig. 23A. Therefore, if the Board determines that Garrison does not expressly disclose an electric pump, a person of ordinary skill in the art would have found it obvious to combine Aklog and a commercially available electric pump with Garrison.

F. Claim 6

140. Claim 6 depends from Claim 1 and recites: “wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.” It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 6 obvious.

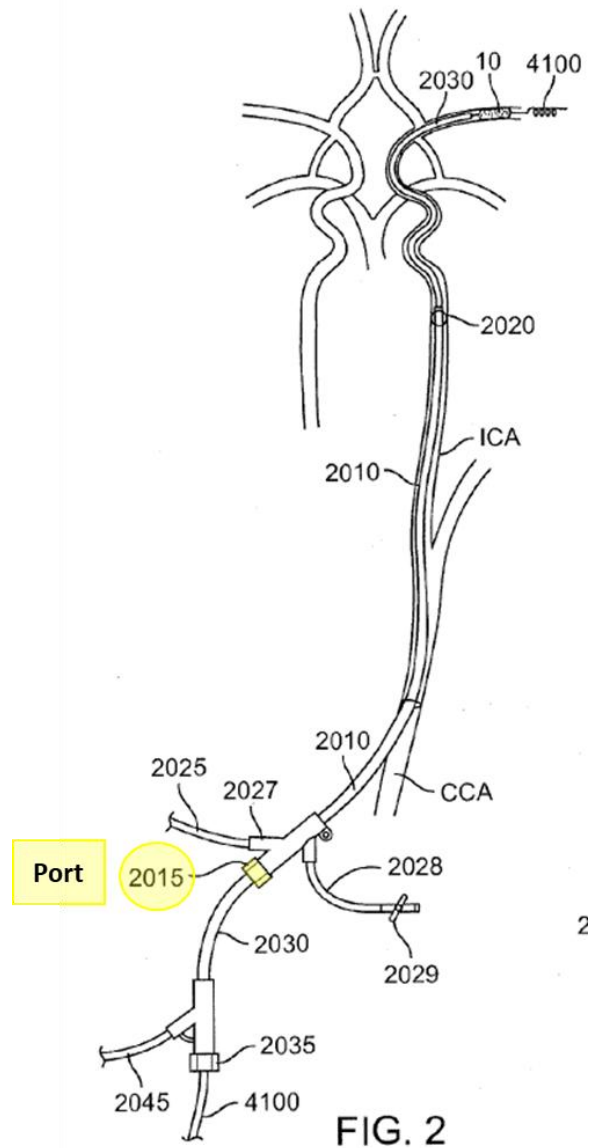
141. Garrison discloses a first catheter 2010 [orange] having a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not pictured in Figure 34):



Ex. 1006 (Garrison) at [0098], Fig. 33. Garrison specifically states that “a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” *Id.* at [0098]. Garrison also discloses that “the hemostasis valve may be integral to the catheter proximal adaptor.” *Id.* Garrison further discloses that the hemostasis valve can take many configurations, including “an adjustable-opening valve such

as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” *Id.*

142. Figure 34 (above) does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figures 2 and 3 identify a “proximal adaptor having a proximal port 2015 **with a hemostasis valve** to allow introduction of devices while preventing or minimizing blood loss during the procedure.” *Id.* at [0053] (emphasis added), Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (Garrison also explains that the arterial access device also has a hemostasis valve 2012). The location of the hemostasis valve in Figure 3 is the customary location for a hemostasis valve on a catheter.



Id. at Fig. 2. Accordingly, Garrison discloses the additional limitations of Claim 6.

G. Claim 8

143. Claim 8 depends from Claim 1 and recites: “wherein the first fluid control device is user actuatable to move between the first position and the second positions of the first fluid control device, and wherein the second fluid control

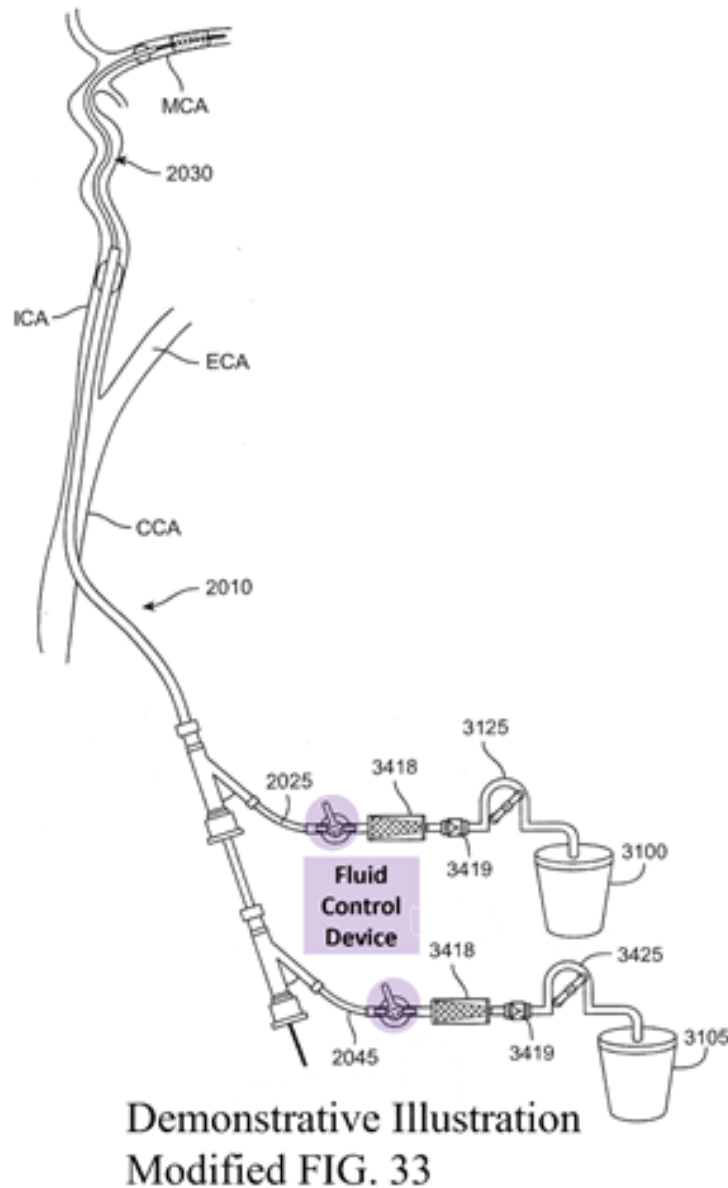
device is user actuatable to move between the first positoin [sic] and the second position of the second fluid control device.” It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 8 obvious for the reasons I explained for Claim 1. *Supra* §§VI. A.3; VI. A.7VI. C (titled “First Fluid Control Device”; “Second Fluid Control Device”). Notably, a stopcock is a user actuatable type of valve.

H. Independent Claim 11

144. Claim 11 recites the same limitations as Claim 1 except that claim 11 recites that the first pressure source is configured to be fluidly “coupled” to the first catheter instead of fluidly “connected” to the first catheter, and does not require a first fluid control device between the first catheter and the first pressure source. Thus, it is my opinion that Claim 11 is rendered obvious by Garrison in view of Laub and/or Aklog at least for the reasons explained in Claim 1 *Supra* §VI. A.

145. As I explained in claim 1, Garrison’s first pressure source is fluidly connected to the first catheter. The first pressure source is also fluidly coupled to the first catheter for the same reasons, namely that fluid can flow from the catheter through the flow lines to the first pressure source and the associated receptacle.

146. As explained in claim 1, a person of ordinary skill in the art would have found it obvious to add the valve 3325 from Figure 34 to one or both of the flow lines 2025 and 2045 in the embodiment shown in Figure 33³:



³ This image reflects a demonstrative prepared by Imperative Care. All modifications to the figure have been made by Imperative Care.

Ex. 1006 (Garrison) at Fig. 33 (Modified to include a second “fluid control device” colored purple to each flow line)). The fluid control device would beneficially allow the physician to independently control the flow of pressure to one or both of the catheters, and would have motivated a person of ordinary skill in the art to make this modification with a reasonable expectation of success. *Supra* §VI.A.6. For example, the user may want to provide continuous suction through the first catheter, while providing a rapid burst of aspiration through the second catheter, as described by Garrison. Ex. 1006 (Garrison) at [0134]. Thus, Garrison renders this limitation obvious.

I. Claim 12

147. Claim 12 depends from Claim 11 and recites: “wherein the first catheter has a size of 24 French, and wherein the size of the the [sic] second catheter is 16 French.” This is the same limitation found in Claim 3, and it is my opinion that Garrison in view of Laub and/or Aklog renders Claim 12 obvious for the reasons I provided in Claim 3. *Supra* §VI. C (titled “Claim 3”).

J. Claim 13

148. Claim 13 depends from Claim 11 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claim 4, and it is my opinion that Garrison in view of Laub

and/or Aklog renders Claim 13 obvious for the reasons I provided in Claim 4. *Supra* §VI. D (titled “Claim 4”).

K. Claim 14

149. Claim 14 depends from Claim 11 and recites: “wherein the first pressure source and the second pressure source comprise an electric pump.” This is the same limitation found in Claim 5, and it is my opinion that Garrison in view of Laub and/or Aklog renders Claim 14 obvious for the reasons I provided in Claim 5. *Supra* §VI. E (titled “Claim 5”).

L. Claim 15

150. Claim 15 depends from Claim 11 and recites: “wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.” This is the same limitation found in Claim 6, and it is my opinion that Garrison in view of Laub and/or Aklog renders Claim 15 obvious for the reasons I provided in Claim 6. *Supra* §VI. F (titled “Claim 6”).

M. Claim 18

151. Claim 18 depends from Claim 11 and recites: “wherein the first catheter has a size of 24 French, wherein the size of the second catheter is 16 French, and wherein the first pressure source and the second pressure source comprise an electric pump.” These are the same limitations found in Claims 3 and 5 and again in Claims 12 and 14, and it is my opinion that Garrison in view of

Laub and/or Aklog renders Claim 18 obvious for the reasons I provide in Claims 3 and 5. *Supra* §§VI. C; VI. E (titled “Claim 3”; “Claim 5”).

N. Claim 19

152. Claim 19 depends from Claim 15 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claim 4, and again in Claim 13, and it is my opinion that Garrison in view of Laub and/or Aklog renders Claim 19 obvious for the reasons I provided in Claim 4. *Supra* §VI. D (titled “Claim 4”).

O. Claim 20

153. Claim 20 depends from Claim 7 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claim 4, again in Claim 13, and again in Claim 19. It is my opinion that Garrison in view of Laub and/or Aklog renders Claim 20 obvious for the reasons I provided in Claim 4. *Supra* §VI. D (titled “Claim 4”).

VII. GROUNDS 4-6: GARRISON COMBINED WITH LAUB, AKLOG, AND/OR HARTLEY RENDERS CLAIMS 6-7, 20 UNPATENTABLE

A. Claim 6

154. Claim 6 depends from Claim 1 and recites: “wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.” For the reasons explained below (titled “Claim 7”), persons with ordinary skill in the art would have been motivated, and found it obvious, to

use Hartley's hemostasis valve as the hemostasis valve on Garrison's catheters. *Infra* §VII. B (titled "Claim 7"). Thus, it is my opinion that Garrison in view of Laub and/or Aklog and Hartley renders Claim 6 obvious.

B. Claim 7

155. Claim 7 depends from Claim 6 and recites: "wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter; and a filament extending at least partially around the tubular member, wherein the filament is moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially open the lumen." It is my opinion that Garrison in view of Laub and/or Aklog and Hartley renders Claim 7 obvious.

156. Garrison discloses catheters 2010 and 2030 having a hemostasis valve in the hub or port at the end of the catheter. *Supra* §VI.F. Garrison explains that different types of hemostasis valves can be combined with the catheter, including, for example, "an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)" or "a passive seal hemostasis valve." Ex. 1006 (Garrison) at [0098]. However, Garrison does not expressly describe the structure of the hemostasis valves usable with its system. Hemostasis valves were ubiquitous in the art and persons of ordinary skill would have been familiar with

such valves. I presume Garrison did not expressly describe the structure of the hemostasis valves because persons of ordinary skill in the art were already familiar with such structures.

157. Hartley discloses a type of rotating hemostasis valve. Hartley's valve "can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve." Ex. 1008 (Hartley) at [0003]. Hartley explains that the valve includes a "cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough":

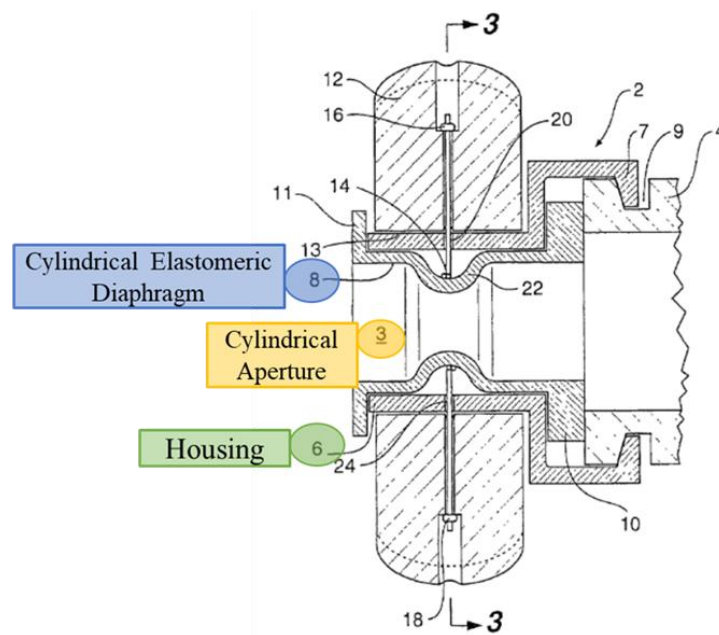
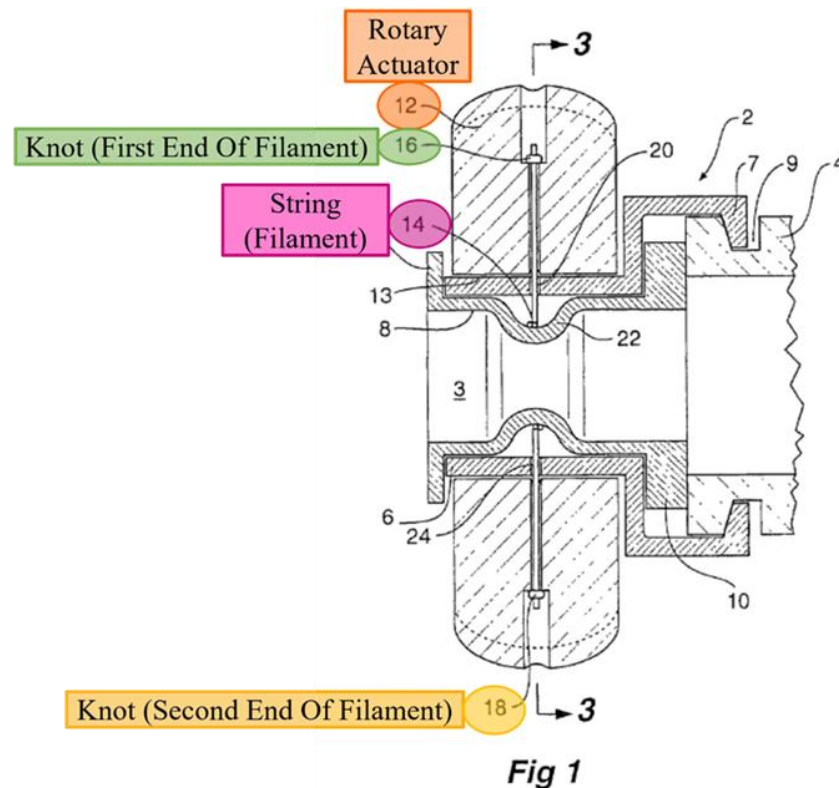


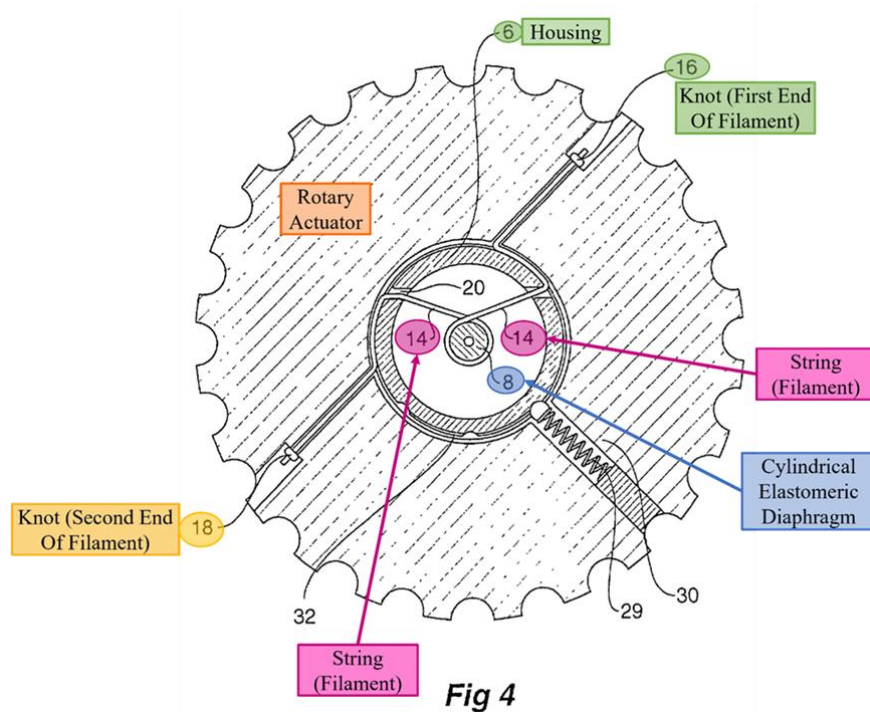
Fig 1

Id. at [0031], Fig. 1. Hartley also explains that the "cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a

catheter, passed through the valve.” *Id.* at [0006]. Based on this information, I believe that Hartley’s cylindrical diaphragm is “a tubular member defining a lumen configured to slidably receive the second catheter,” as required by Claim 7.



159. Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted”:



Ex. 1008 (Hartley) at [0031], [0034], Fig. 4. This configuration corresponds to the “first position” required by Claim 7 because the filament circumferentially constricts the lumen (i.e., cylindrical elastomeric diaphragm) to create a seal around the second catheter. While Figure 4 above does not show a second catheter inserted through the valve, a person of ordinary skill in the art would have understood that the second catheter would be inserted through the valve. As explained above, Hartley expressly states that the “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be

constricted to the extent that it closes *around an instrument, for instance a catheter*, passed through the valve.” *Id.* at [0006] (emphasis added).

160. Hartley also discloses that “[r]otation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3”:

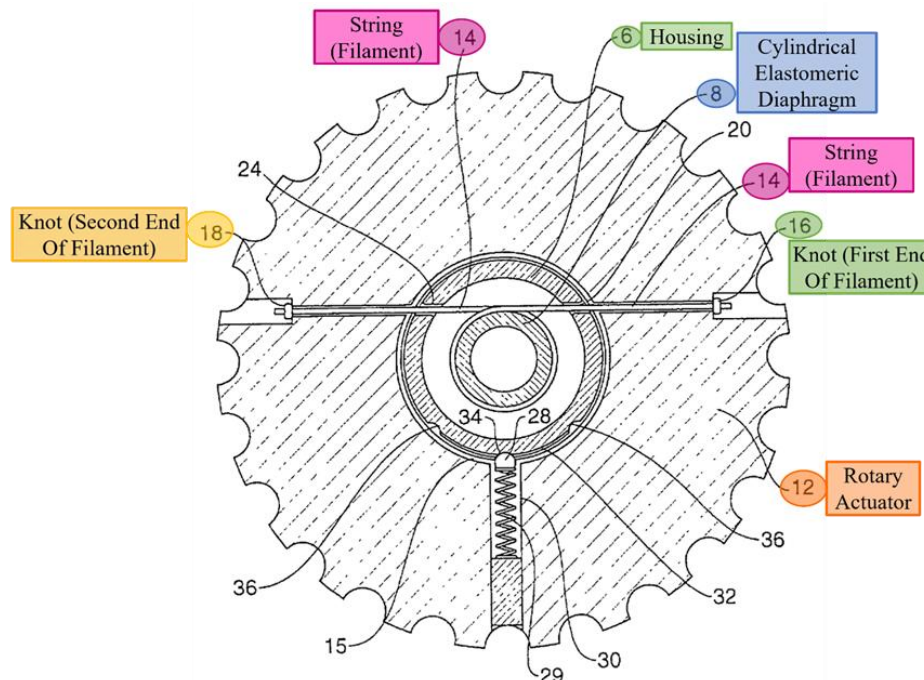


Fig 3

Ex. 1008 (Hartley) at [0034], Fig. 3. This configuration corresponds to the “second position” required by Claim 7 because the filament has been moved to at least partially open the lumen.

161. It is my opinion that a person of ordinary skill in the art would have been motivated to combine Hartley’s hemostasis valve with Garrison’s catheters

2010 and 2030 for several reasons and would have reasonably expected success in doing so. First, Garrison expressly discloses that Garrison's catheters 2010 and 2030 can be combined with a "rotating hemostasis valve." Ex. 1006 (Garrison) at [0098]. Hartley discloses a type of rotating hemostasis valve and, therefore, I believe a person of ordinary skill in the art would have been motivated to combine, and reasonably expected success in combining, Hartley's valve with Garrison based on this suggestion.

162. Second, I believe that combining Hartley's valve with Garrison's catheters 2010 and 2030 would have merely entailed the combination of known elements (Hartley's hemostasis valve and Garrison's catheters 2010 and 2030) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub) to yield the predictable result of reducing leakage through the valve. Ex. 1006 (Garrison) at [0098]. As I mentioned above, catheters having hemostasis valves were ubiquitous in the art before August 2018, as was the procedure to combine a hemostasis valve with a catheter. A person of ordinary skill in the art would have encountered various types of stasis valves during their education and career and would have been familiar with how the valves operate. The valves, like the valve described in Hartley, are simple mechanical structures that operate in a predictable manner. I

do not see anything novel in August 2018 about combining a hemostasis valve to a catheter.

163. Third, a person of ordinary skill in the art in August 2018 had a finite number of predictable hemostasis valves to select when trying to seal a catheter. The prior art I discuss above, such as Garrison and Hartley, reference some of the known hemostasis valves, including an “adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV),” Hartley’s specific rotating valve, or “a passive seal hemostasis valve.” Ex. 1006 (Garrison) at [0098]. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Garrison’s catheters 2010 and 2030. Moreover, as discussed above, the known hemostasis valves, including Hartley’s rotating hemostasis valve, were simple mechanical structures that operate in a predictable way. For this additional reason, it is my opinion that a person of ordinary skill in the art would have reasonably expected success in combining any of the known valves with Garrison’s catheters 2010 and 2030.

164. Thus, it is my opinion that Hartley would have been appropriate for aspiration catheters for use in all portions of the vasculature, including catheters for treating pulmonary embolisms and DVT. Hartley does not restrict its hemostasis valve to any particular size and, therefore, a person of ordinary skill in the art would have understood that the hemostasis valve could be used with

catheters measuring 16F or 24F. In fact, Hartley discloses that the valve could also be used for access ports in laparoscopic catheters (or trocars), which can commonly be up to 10 or 12mm in diameter (i.e., 30F-36F), well above 24F. Ex. 1008 at [0021].

C. Claim 20

165. Claim 20 depends from Claim 7 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claim 4, again in Claim 13, and again in Claim 19. The use of the Hartley’s valve would not impact whether the system uses two pressure sources or uses the same pressure source. Thus, it is my opinion that Garrison in view of Laub and/or Aklog renders Claim 20 obvious for the reasons I provided in Claim 4. *Supra* §VI. D (titled “Claim 4”).

VIII. GROUNDS 7-9: GARRISON COMBINED WITH LAUB AND/OR AKLOG AND PASHA

A. Claim 3

166. It is also my opinion that Garrison in view of Laub and/or Aklog and additionally Pasha renders claim 3 obvious. If the Board determines that Laub and Aklog do not disclose using a first catheter measuring 24F, a person of ordinary skill in the art would have found it obvious to optimize Garrison’s system to use a 24F first catheter based on Pasha. Pasha is an article published in 2014 that describes the treatment of a patient suffering from a “pulmonary

embolus extending into right and left pulmonary arteries as well as lobar arteries.” Ex. 1049 (Pasha) at 240-241. The physicians determined the patient was not a candidate for thrombolytics or surgery. *Id.* at 241. Therefore, the physicians treated the patient’s pulmonary embolism using “a 26-French Angiovac catheter” using suction created by the catheter. *Id.*; *see also id.* (“The embolus was partially removed by suction.”). The article explains that the “Angiovac system consists of Angiovac circuit, an extracorporeal bypass tubing system and Anigovac cannula, which is intended for venous drainage during extracorporeal bypass.” *Id.* at 242. The physicians concluded that “off-label use of Angiovac suction catheter devices provides a novel technique to remove large emboli effectively as an alternative method to other catheter-based devices.” *Id.*

167. The decision by these physicians to use the Angiovac system for this patient confirms my earlier testimony that physicians and persons of ordinary skill in the art possessed the requisite knowledge to select the appropriately sized catheter for a particular procedure. There is nothing novel or nonobvious about selecting one catheter size over another – such selections are routine. Pasha discloses the successful use of catheter even larger than 24F to treat pulmonary embolism. This disclosure would have motivated persons of ordinary skill in the art to adapt Garrison’s system to use a first catheter of at least 24F to treat pulmonary embolisms. Moreover, the successful results experienced by the

physicians in using such a catheter would have given persons of ordinary skill in the art a reasonable expectation of success.

168. Further, Laub discloses using catheters of 16F to treat pulmonary embolisms, and Aklog also discloses using larger catheters to treat such embolisms. A person of ordinary skill in the art would have found it obvious to use a first catheter measuring 24F and a second catheter measuring 16F that could telescope (i.e., be advanced) through the first catheter. Laub specifically discloses that a catheter measuring 16F can successfully treat pulmonary embolisms. Moreover, Garrison discloses the benefits of using telescoping catheters to treat patients suffering from blood clots. *See e.g.*, Ex. 1006 (Garrison) at [0054]. Thus, the use of a 16F catheter in a telescoping configuration with a 24F catheter would have been nothing more than the combination of prior art elements (two known catheters) according to known methods (telescoping) to yield predictable results (aspirating pulmonary embolisms).

169. Further, as I explained above, a person of ordinary skill in the art would have been familiar with using catheters ranging from 16F to 24F in a telescoping fashion. *Supra* §VI.A.5. In my own experience, the Mitraclip device I developed well before 2018 included a 24F guiding catheter and had two other catheters that telescoped through that guiding catheter. The ubiquitous of telescoping catheters in the medical device field to deliver all manner of devices,

including stents and heart valves, would have given a person of ordinary skill in the art a reasonable expectation of success in using 16F and 24F catheters to treat a pulmonary embolism.

B. Claims 12 and 18

170. Claims 12 and 18 depend from Claim 11 and recite the same limitations found in Claims 3 and 5. Therefore, it is my opinion that Garrison in view of Laub and/or Aklog renders Claims 12 and 18 obvious for the reasons I provide in Claims 3 and 5. *Supra* §§VI. C; VI. E (titled “Claim 3”; “Claim 5”).

IX. SECONDARY CONSIDERATIONS

171. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '910 patent.

172. Further, because the devices claimed in the '910 patent are not new, and were invented long before August 2018, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

X. CONCLUSION

173. For the foregoing reasons, it is my opinion that Claims 1-8, 11-15, and 18-20 of the '910 patent are not patentable because they would have been obvious in view of the prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged claimed inventions.

174. I reserve the right to supplement my opinions in the future to address or respond to any arguments that Patent Owner may raise, as well as new information, including, but not limited to, any claim constructions advanced by Patent Owner or adopted by the Board in the Institution Decision, and respond to any alleged secondary considerations as they become available to me.

175. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on May 19, 2025 in San Francisco, CA.

troy thornton

Troy Thornton