

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Patent No. 11,969,333

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,969,333**

<i>Imperative Care v. Inari Medical</i> US Patent 11,969,333 Imperative Care Ex. 1003

TABLE OF CONTENTS

	Page No.
I. INTRODUCTION	1
A. Engagement	1
B. Experience and Qualifications	2
C. Topics of Opinions.....	4
D. Materials Considered	5
II. APPLICABLE LEGAL STANDARDS	5
A. Claim Construction	6
B. Anticipation	7
C. Obviousness	7
D. Person of Ordinary Skill in the Art.....	11
III. THE '333 PATENT.....	12
A. Summary of the '333 Patent	12
B. The Challenged Claims.....	21
C. Prosecution History.....	22
IV. CLAIM CONSTRUCTION	24
A. The Board's Institution Decisions from the '011 and '012 Patent IPRs.....	26
1. The '011 Patent IPR	26
2. The '012 Patent IPR	27

TABLE OF CONTENTS
(cont'd)

	Page No.
B. Construction of “Filament”	29
C. The Claims of the ’333 Patent Are Not Limited to “Flexible” Filaments	32
V. SUMMARY OF IPR GROUNDS	35
VI. GROUNDS 1A, 2A, 3A, 4A – LAUB, AKLOG, AND GARRISON	37
A. Claim 1	37
1. Preamble	37
2. Advancing Aspiration Catheter	53
3. Generating Vacuum Pressure With Valve In First Position	59
4. Moving The Valve From First Position To Second Position	67
5. Filter	68
B. Claim 2	72
1. Laub	72
2. Aklog	72
3. Garrison and Laub or Aklog	74
C. Claim 3	75
1. Laub	75
2. Aklog	75

TABLE OF CONTENTS (*cont'd*)

	Page No.
3. Garrison and Laub or Aklog.....	77
D. Claim 4.....	77
E. Claim 5.....	78
1. Laub.....	78
2. Aklog.....	80
3. Garrison.....	80
F. Claim 9.....	81
G. Claim 10.....	83
1. Garrison.....	83
2. Laub and Garrison.....	85
3. Aklog and Garrison.....	87
H. Claim 14.....	88
1. Laub.....	88
2. Aklog.....	89
3. Garrison.....	90
I. Claim 15.....	90
1. Laub.....	91
2. Aklog.....	91

TABLE OF CONTENTS **(cont'd)**

	Page No.
3. Garrison	92
J. Claim 16.....	93
1. Garrison	93
2. Laub and Aklog	95
K. Claim 18.....	97
1. Laub	98
2. Aklog	99
3. Garrison	100
L. Claim 19.....	101
M. Claims 20-24, 28-29, 33-35, 37-38.....	102
1. Laub	103
2. Aklog	103
3. Garrison and Laub or Aklog.....	104
VII. GROUNDS 1B, 2B, 3B, 4B – LAUB, AKLOG, AND GARRISON WITH GOFF	104
A. Claim 6.....	104
1. Laub	104
2. Aklog	106
3. Garrison	107

TABLE OF CONTENTS
(cont'd)

	Page No.
4. Goff.....	108
B. Claim 7.....	112
C. Claim 8.....	113
1. Laub.....	114
2. Aklog.....	115
3. Garrison.....	116
D. Claim 17.....	117
1. Garrison.....	117
2. Goff.....	117
E. Claims 25-27 and 36.....	118
VIII. GROUNDS 1C-1D, 2C-2D, 3C-3D, 4C-4D – LAUB, AKLOG, AND GARRISON WITH SCHAFER AND OPTIONALLY HARTLEY	119
A. Claim 11.....	119
1. Schaffer.....	120
2. Schaffer and Hartley.....	131
B. Claim 12.....	145
C. Claims 30-31.....	146
IX. SECONDARY CONSIDERATIONS.....	147

TABLE OF CONTENTS
(cont'd)

	Page No.
X. CONCLUSION	147

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,969,333 (“the ’333 patent”)
1002	’333 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. 2014/0276868 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. (“Lewis”)

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).

Table of Exhibits 2

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)

Table of Exhibits 3

Exhibit No.	Description
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)

Table of Exhibits 4

I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative Care”) to provide my opinion regarding the patentability of Claims 1-12, 14-31, and 33-38 of U.S. Patent No. 11,969,333 (“the ’333 patent”). For the reasons discussed herein, I have concluded that Claims 1-12, 14-31, and 33-38 of the ’333 patent are unpatentable because the prior art references render them obvious.

2. I understand that this Declaration supports Imperative Care’s Petition for the above-captioned *inter partes* review (“IPR”) of the ’333 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 ’333 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 resume, 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 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 '333 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 '333 patent;
- The level of ordinary skill in the art pertaining to the '333 patent;
- The teachings of the prior art; and
- Whether Claims 1-12, 14-31, and 33-38 of the '333 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 '333 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 '333 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, August 2018).

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 '333 patent, e.g., devices for aspirating unwanted material from a patient. 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 1-38 of the '333 patent would have been non-

obvious, as further explained in Section § IX (Heading: “Secondary Considerations”) below.

D. Person of Ordinary Skill in the Art

32. It is my understanding that when interpreting the claims of the ’333 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 ’333 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 '333 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 '333 PATENT

A. Summary of the '333 Patent

37. The '333 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 ('333 patent) at 4:17-4:33. The '333 patent explains that the system can treat various clots including pulmonary embolisms ("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 5:28-5:30.

catheter subsystem 100.” *Id.* at 6:57-6:60. “[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 7:33-7:41.

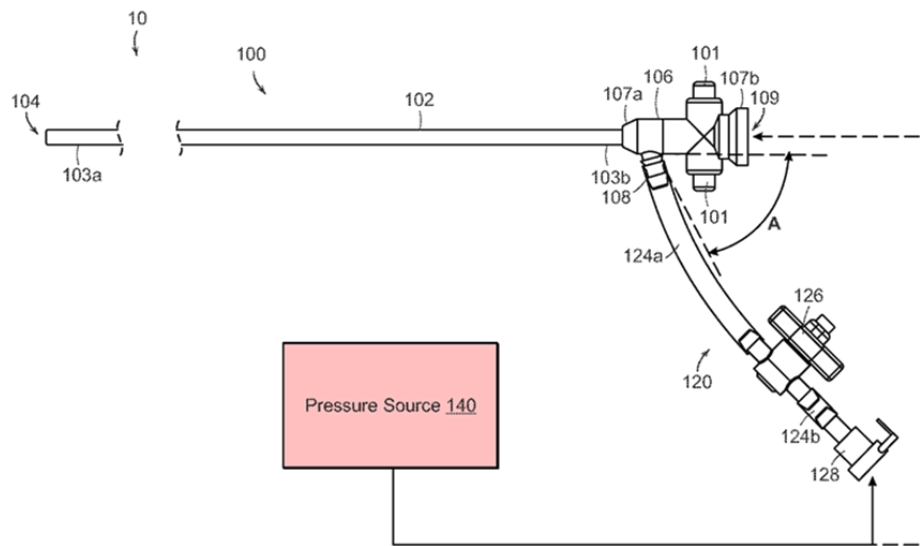


FIG. 1

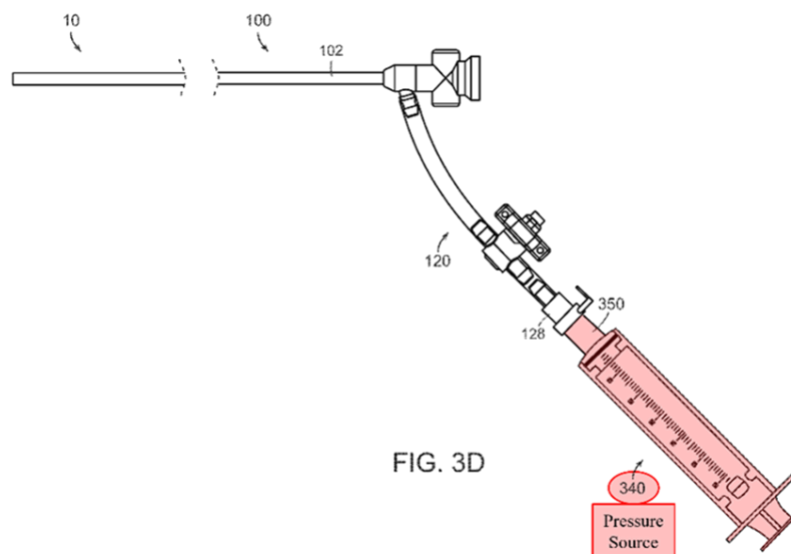


FIG. 3D

Id. at Figs. 1, 3D.

40. The '333 patent explains that the tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” *Id.* at 6:6-6:7. 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 6:6-6:23.

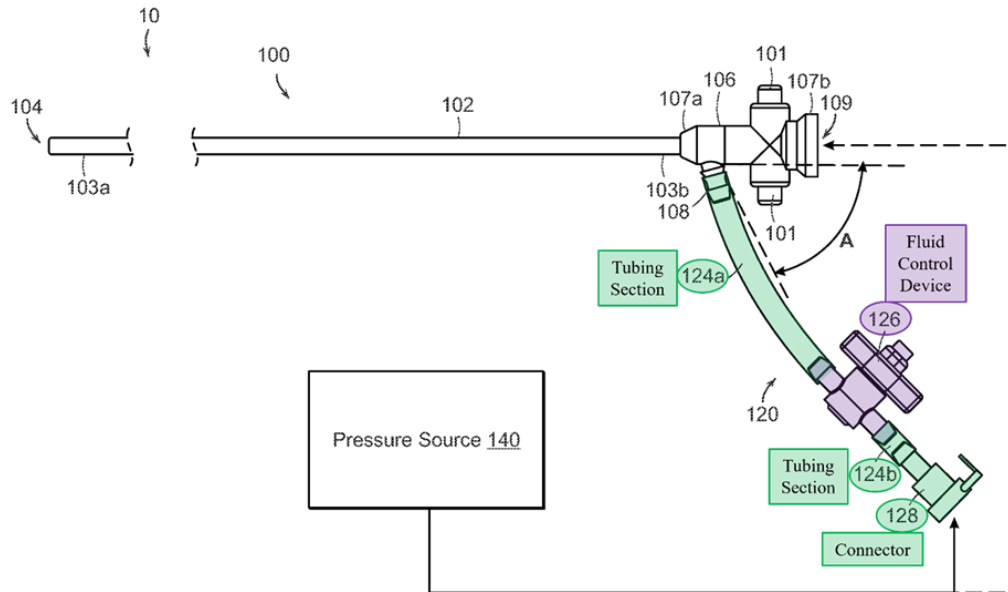
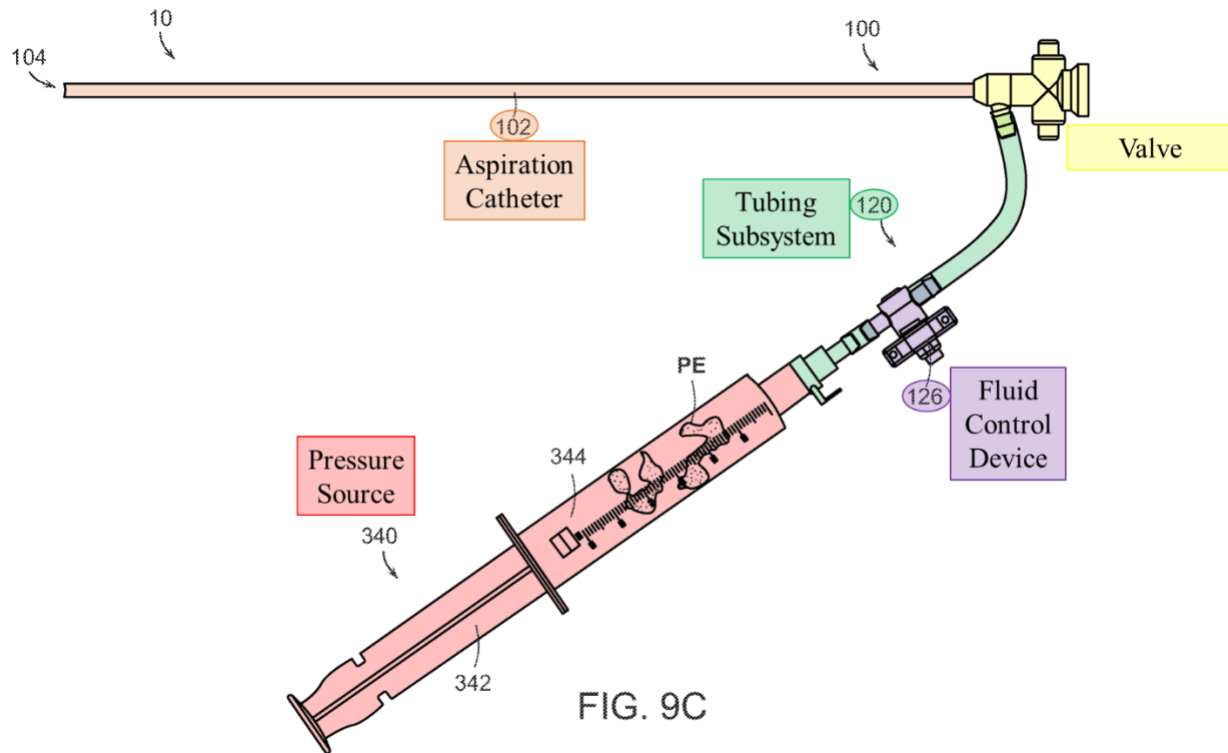


FIG. 1

Id. at Fig. 1.

41. The '333 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 6:62-6:66. 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 18:42-18:48. 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 7:1-7:8.



Id. at Fig. 9C. The '333 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 7:8-7:12.

42. The '333 patent also describes variations of the aspiration system described above. For example, the patent describes variations having a “pressure

source 1900” with a “secondary syringe 460” and a “canister 1940.” *Id.* at 31:5-27, Fig. 19. The “canister 1940 further includes a filter 1942,” which “separates the blood from the clot material within the canister 1940.” *Id.* at 31:28-29.

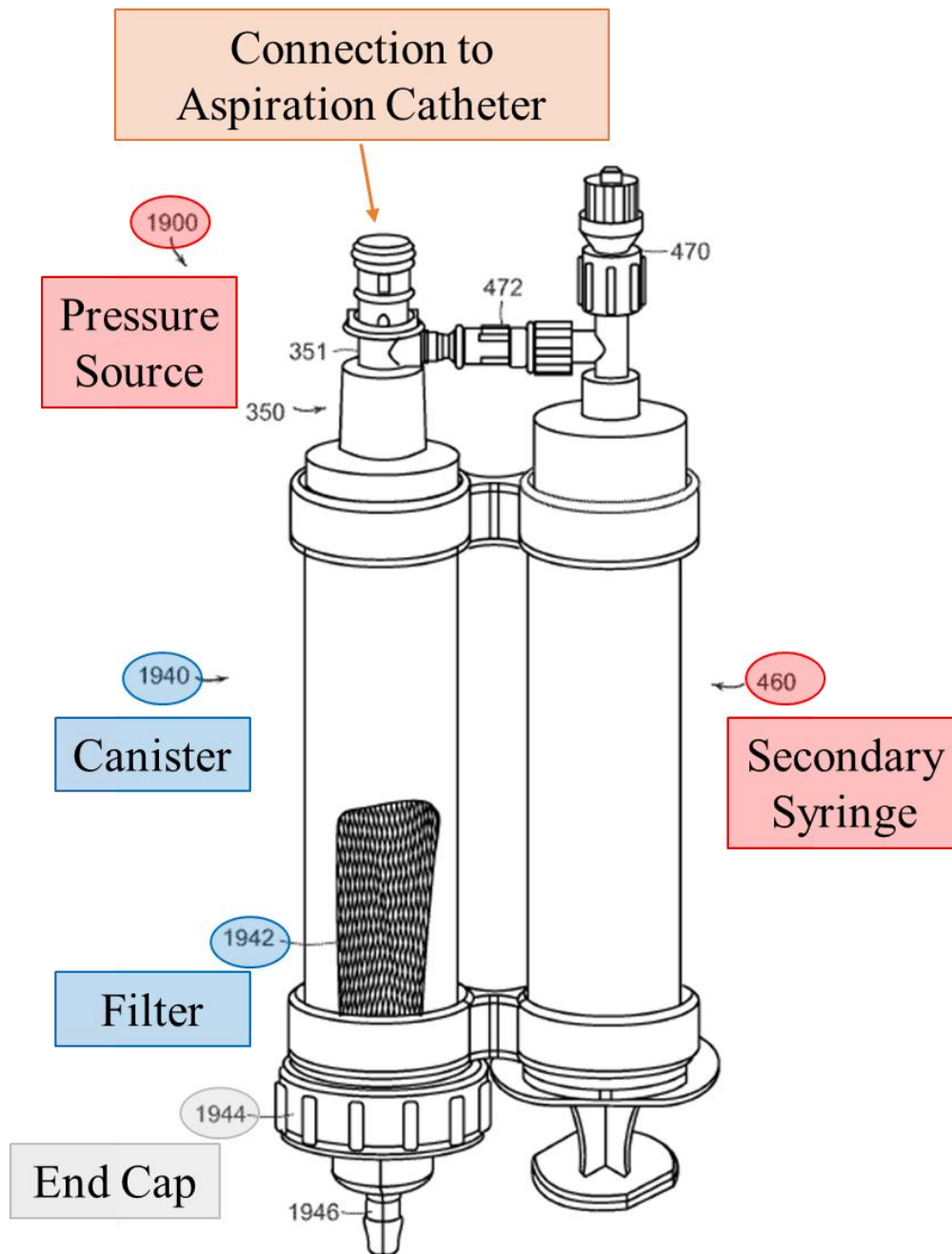
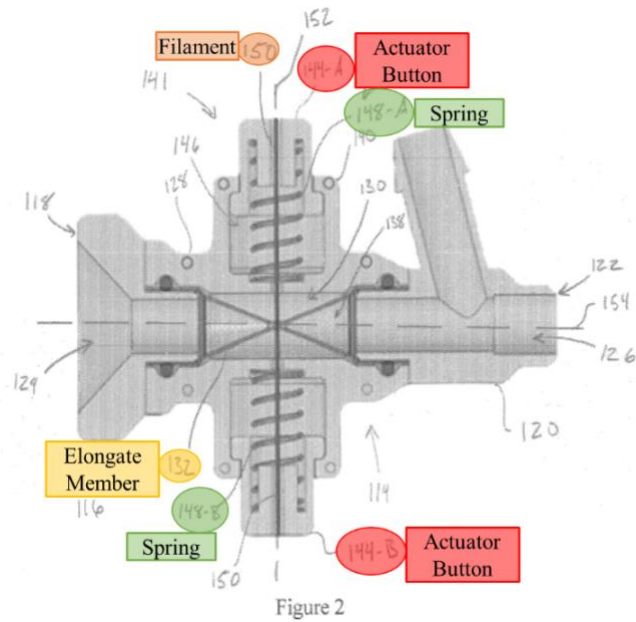


FIG. 19

Id. at Fig. 19.

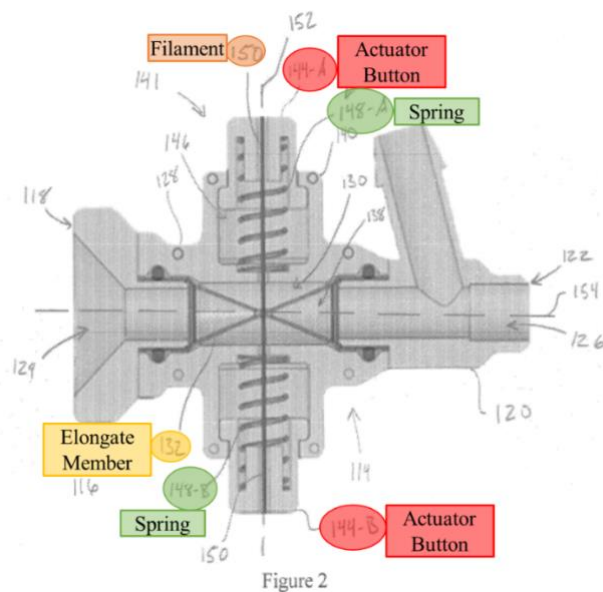
43. While the claims of the '333 patent recite aspects of a hemostasis valve, the '333 patent does not describe the structure of the hemostasis valve that can be included in valve 106. *See id.* at 5:30-54. But the '333 patent does state that “the valve 106 can be a valve of the type disclosed in U.S. 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 5:50-54. 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 ’333 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.

44. The ’519 Application describes a catheter and a hemostasis (or “garrote”) valve for use during minimally invasive intravascular procedures. Ex. 1021 (’519 Application) at [0033]. The hemostasis valve includes an “elongate member 132” extending through the interior of the valve housing 128. *Id.* at [0039]. The ’519 Application explains that the elongate member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132”:



Id. at [0039], Fig. 2.

45. 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., [0042-0043] at 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].

46. 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:

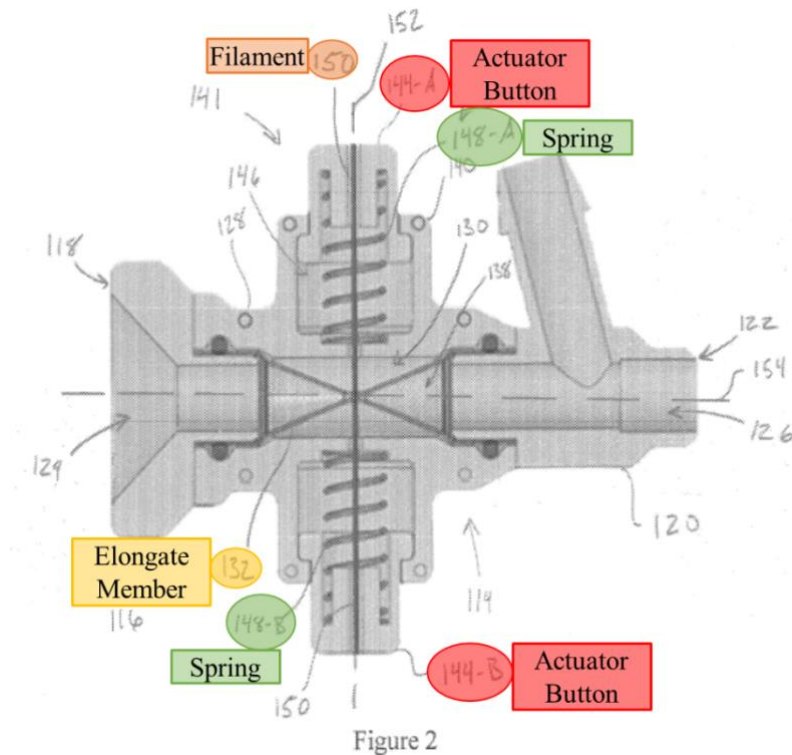


Figure 2

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:

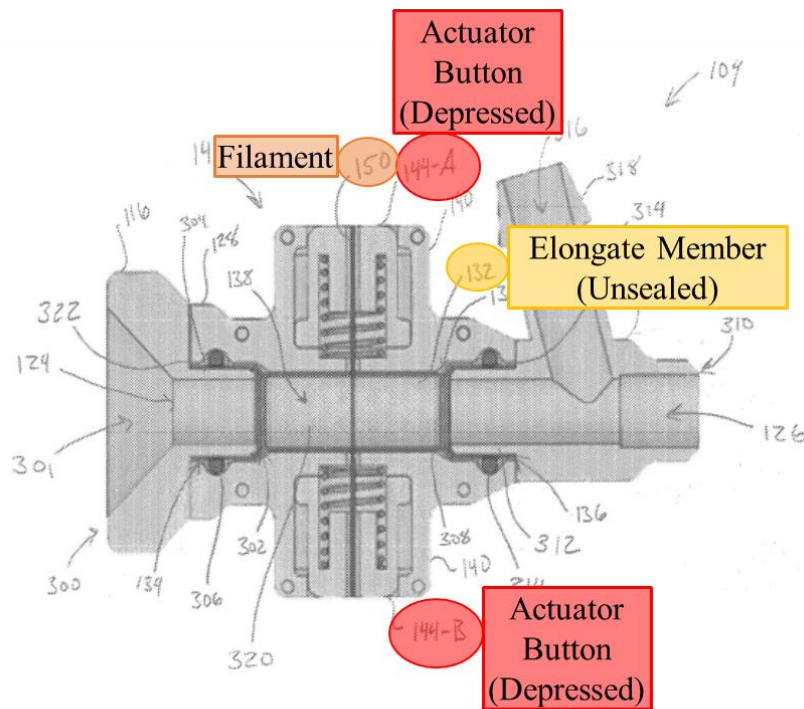


Figure 3

Id.

B. The Challenged Claims

47. The challenged claims include Claims 1-12, 14-31, and 33-38 of the '333 patent. Claim 1 is the only independent claim.

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

1. A method of treating a pulmonary embolism within a vasculature of a patient, the method comprising:

advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;

generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister; and

moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.

Ex. 1001 ('333 patent) at Claim 1.

C. Prosecution History

49. I have reviewed the '333 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action rejecting original claims 1-6, 11-14, 16-18, and 20-22 as obvious in view of US 2018/0064453 A1 ("Garrison II") (Ex. 1032) in combination with US 2005/0054995 A1 ("Barzell") (Ex. 1033) and US 8535283 B2 ("Heaton") (Ex. 1011). Ex. 1002 ('333 Prosecution History) at 156-173.

50. The Examiner found that Garrison II disclosed every limitation of the independent claim except: (1) “a filter positioned within the clot canister and configured to filter blood from clot material” and (2) “a flow path extending from the lumen of the aspiration catheter, through the clot canister, and to the aspiration source.” *Id.* at 157-159.¹ The Examiner found that Barzell discloses the claimed filter and that Heaton discloses the claimed flow path. *Id.* at 159-160. The Examiner found that Garrison, Barzell, and Heaton are all analogous references because they all “deal with an aspiration source configured to collect bodily fluids.” *Id.* at 159-160.

51. After the Examiner issued the non-final office action, Patent Owner conducted an interview with the Examiner, and then subsequently filed an amendment cancelling all previously pending claims and adding new claims 23-60 (which issued as claims 1-38 of the '333 patent). *Id.* at 98-100, 109-115. The

¹ Although the Garrison reference I discuss herein (Ex. 1006) and the Garrison II reference relied upon by the Examiner share a common inventor, they are not in the same patent family, and Garrison II does not disclose the embodiments from Garrison that are relied upon in the Petition, including the embodiments illustrated in Figures 33 and 34, which include a clot canister, a filter, and a flow path. *See infra* §VI.A.2.c.

amended claims recited methods of treating either pulmonary embolism or deep vein thrombosis. *Id.* at 109-115. According to the Examiner's summary of the interview, one of the inventors on the '333 patent, Dr. Tu, "discussed the differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis" during the interview. *Id.* at 99. In the Notice of Allowance, the Examiner appeared to rely on Patent Owner's representations regarding catheters used to treat pulmonary embolisms and deep vein thrombosis, stating that a person of ordinary skill in the art "would not have looked to use the Garrison device" to treat PE or DVT and that "the Device of Garrison would not be combinable with the device of Garrison [SIC] to teach a method of treating [PE] or [DVT]." *Id.*, at 46-47. The Examiner did not state any basis for this conclusion other than noting that "Garrison [II] specifically teaches the aspiration catheter being used for neurovascular procedures." *Id.* at 47.

IV. CLAIM CONSTRUCTION

52. Claims 11-12 and 30-31 of the '333 patent require a hemostasis valve having "filament" and also require that decreasing and increasing tension on the filament opens and closes the hemostasis valve to fluid flow. 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 '333 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 '333 patent) would have understood the term “filament” in the claims of the '333 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

53. 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. If the Board decides that “filament” is limited to “flexible” filaments, that decision is relevant only to Inari’s arguments about Schaffer. The meaning of “filament” does not have any impact on my opinions regarding Schaffer in combination with Hartley because Inari has never disputed that Hartley describes “flexible” filaments. 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. 1023 ('012 Institution Decision) at 21, n.13. The Board also preliminarily found that a person of ordinary skill in the art would have found it

obvious to combine Hartley's filament with Schaffer's valve. Therefore, Schaffer in combination with Hartley renders the claimed "filament" obvious regardless of the construction of "filament."

A. The Board's Institution Decisions from the '011 and '012 Patent IPRs

54. I have reviewed the Board's Institution Decisions from the '011 patent and '012 patent IPRs. Below is a summary of the relevant portions relating to "filament."

1. The '011 Patent IPR

55. In the '011 patent IPR, I understand that the Institution Decision was Paper 7. In the Institution Decision, the Board found that it did not need to "expressly construe the term 'filament' in the manner urged by Petitioner." Ex. 1034 at 13 (Imperative Care was the Petitioner). However, the Board agreed with "Petitioner that a filament as claimed *encompasses* one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes." *Id.* (emphasis in original). The Board observed that the '011 patent "lists those structures explicitly, but suggests that those are only examples and, thus, the term 'filament' may be broader than those structures." *Id.* I agree with the Board that '011 patent identifies those structures as examples of "filament" and that additional structures could fall within the meaning of a filament. However, I understand that the Board needs to construe the terms only to the extent necessary to resolve the issues presented in the IPR. In this

IPR, I believe my construction of “filament” resolves the issues presented because the structures identified in the construction (e.g., threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes) are found in the prior art (as I explain below).

56. I see that the Board also addressed Patent Owner’s argument that “filament” should mean “a thin, flexible length of material formed by one or more strands of material.” The Board did not adopt Patent Owner’s construction. *Id.* at 15 (Inari was the Patent Owner). The Board observed that “the ’011 patent never uses the words ‘thin’ or ‘flexible’ to describe the ‘filament.’” *Id.* The Board also observed that “the words ‘thin’ and ‘flexible’ inject potential ambiguities as a relative term” because “flexibility and rigidity exist along a spectrum” *Id.*

57. I see the Board also addressed Patent Owner’s argument that the filament must be flexible to “circumferentially constrict” the lumen to create a seal. The Board stated, “Wanting for further explanation, however, is why two bights like shown in Figures 8-9 that cooperatively receive an elongate member in ‘encircled area 816’ cannot ‘circumferentially constrict’ the elongate member and lumen when pulled in opposite directions (810-812) even if those bights are substantially rigid.” Ex. 1034 at 18.

2. The ’012 Patent IPR

58. I see that the Board adopted a different preliminary construction of the term “filament” in the ’012 patent IPR. There, the Board found that the “claims, as

understood by the POSA, suggest that the filament must be flexible.” Ex. 1035 (’012 Patent Institution Decision) at 15. The Board focused on the specific language in the claims of the ’012 patent to reach this conclusion. The Board specifically focused on the limitations, “a first filament formed into a loop around the collapsible tubular sidewall” and that the “diameter of the valve lumen decreases in response to reducing a diameter of the loop.” *Id.* Additionally, the Board credited Patent Owner’s expert testimony that the loop must be flexible to have its diameter reduced. *Id.*

59. The Board also made a preliminary finding that the ’012 patent specification suggests that filaments that form loops are not the same as filaments that form bights. *Id.* at 18-19. The Board cited Patent Owner’s response to a restriction requirement as supporting an argument that the claims of the ’012 patent are limited to a filament that forms a loop, as shown in Figure 6, and not a filament that forms bights, as shown in Figures 8 and 9. *Id.* at 20.

60. The Board also addressed the interplay between the ’011 and ’012 patents. The Board said, “[t]here is no irreconcilable inconsistency” between its preliminary constructions in the ’011 and ’012 patent IPRs. *Id.* at 18. The Board explained that claim 1 of the ’011 patent “does not require that the ‘filament forms into a loop’ where the ‘diameter of the loop’ reduces when the end portions of the filament are pulled,” unlike the challenged claims in the ’012 patent. *Id.* Thus, the

Board found that “Claim 1 in the [’011 patent IPR] is arguably broader concerning the ‘filament’ and would purport to encompass, for example, both loop and bight embodiments.” *Id.*

B. Construction of “Filament”

61. 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.

62. 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.” Claims 11 and 30 of the ’333 patent require “decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.” While this language identifies some functions the filament must perform, the claim language does not identify the structures, material, or material properties that form a “filament.”

63. The specification of the ’333 patent does not provide any further guidance on the structures or materials that form a “filament.” The ’333 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 ’333 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.

64. The ’519 Application also explains that “the filament 150 can comprise multiple filaments and specifically, as shown in FIGS. 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

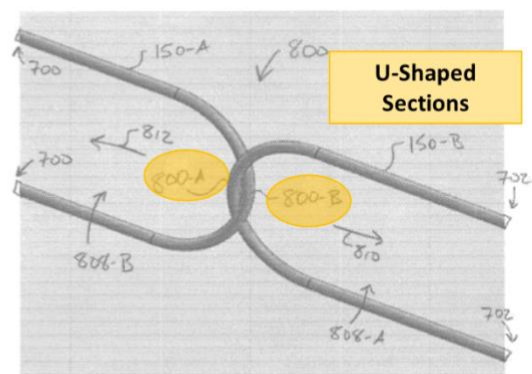


Figure 9

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).

65. 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 ’333 patent.

66. 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 ’333 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

C. The Claims of the ’333 Patent Are Not Limited to “Flexible” Filaments

67. I do not believe the claims of the ’333 patent should be limited to only “flexible” filaments. For clarity, I agree that the term “filament” in the ’333 patent encompasses “flexible” filaments. However, I do not see any language or descriptions in the patent that would limit the claims to only “flexible” filaments. Neither ’333 patent nor the ’591 application allegedly incorporated by reference into the ’333 patent use the word “flexible” to describe the filament. And neither the ’333 patent nor the ’591 application provides any criteria for flexibility that would help a person of ordinary skill in the art determine whether a specific material was “flexible.” While the ’591 application identifies some potential dimensions for the “filament(s),” the application states that those dimensions are exemplary, not mandatory. Because flexibility exists along a spectrum, I would not be able to tell whether a material was “flexible” enough to qualify as a filament based on the information in the ’333 patent or the ’591 application.

68. As summarized above, I am aware that the Board preliminarily construed “filament” in the claims of the ’012 patent to require *only* “flexible” filaments. However, I see some differences in the claims that I think impact the

Board's analysis.² The claims of the '012 patent require "a filament formed into a loop around the tubular sidewall" and that pulling on the first end of the filament results in "reducing a diameter of the lumen in response to reducing a diameter of the loop." The claims of the '333 patent do not include this limitation and do not require that the filament form a "loop" or that "that pulling on the first end of the filament results in "reducing a diameter of the lumen in response to reducing a diameter of the loop." Rather, the claims of the '333 patent merely require that adding and removing tension to the filament opens and closes the lumen of the valve to fluid flow.

69. Looking at the '591 application, I believe that the filaments in Figures 8 and 9 meet the claim limitations of the '333 patent because placing or removing tension on the filaments in Figures 8 and 9 would open and close the lumen of the valve to fluid flow. *See* Ex. 1021 ('519 application) at [00069]. Specifically, the '519 application specification explains movement of the constricting mechanism "decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814." *Id.*

70. I also see that the Board preliminarily limited the '012 patent claims to "flexible" filaments based, in part, on the '012 patent prosecution history. Ex. 1035

² I understand I will have the opportunity to address the Board's construction of filament in the '012 patent IPR.

at 19-20. However, the '333 patent prosecution is different and does not include any restriction requirement response like the one provided in the '012 patent. *See* Ex. 1002 (does not include restriction). Thus, the '333 patent prosecution history does not support a construction of “filament” that is limited only “flexible” filaments.

71. I also know that Patent Owner has obtained patent claims in related patents that specifically require a “flexible” filament. For example, Patent Owner’s U.S. Patent No. 12,109,384 includes claims reciting, “a first filament extending in a first loop around the tubular member, wherein the first filament *is flexible*.” Ex. 1036 at claim 1 (emphasis added). The claim further recites that the actuator can apply tension to the filament to “decrease the dimension of the first loop.” *Id.* I have been informed that each term in a claim has meaning. Therefore, the limitation that the filament is “flexible” in the '384 patent suggests that some filaments in the patent are not “flexible,” otherwise the words “is flexible” in the claims would be superfluous.

72. I also see in the '005 Patent IPR that Patent Owner has argued that the description of the embodiment in Figure 3 of the hemostasis valve patents requires a “flexible” filament. The specification of the '519 Application allegedly incorporated into the '333 patent states that when the buttons in the embodiment are depressed, “the filament 150 is loosened, thereby allowing the expansion of the

elongate member 132” Ex. 1021 (’519 Application) at [0050], Fig. 3. I see that Patent Owner tries to equate “loosened” with “flexible.” But, the word “loosened” is not synonymous with “flexible.” The term “loosen” in the dictionary submitted by Patent Owner means “to release from restraint.” Ex. 1037. The term “loosen” does not have any relationship to flexibility because many relatively inflexible items can be loosened, such as screws and u-bolts. The filaments in the embodiments in Figures 8 and 9 of the ’519 application are “loosened” to allow expansion of the elongate member, even if they are determined by the Board to be relatively inflexible. Therefore, I don’t see the use of “loosened” in the ’519 application to require only “flexible” filaments.

V. SUMMARY OF IPR GROUNDS

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

Ground		Reference(s)	35 U.S.C.	Challenged Claims
1	A	Laub + Garrison	§103	1-10, 13-29, 33-38
	B	Laub + Garrison + Goff	§103	6-8, 17, 25-27, 36
	C	Laub + Garrison + Schaffer	§103	11-12, 30-31
	D	Laub + Garrison + Schaffer + Hartley	§103	11-12, 30-31
2	A	Aklog + Garrison	§103	1-10, 13-29, 32-38
	B	Aklog + Garrison + Goff	§103	6-8, 17, 25-27, 36
	C	Aklog + Garrison + Schaffer	§103	11-12, 30-31
	D	Aklog + Garrison + Schaffer + Hartley	§103	11-12, 30-31
3	A	Garrison + Laub	§103	1-10, 13-29, 32-38
	B	Garrison + Laub + Goff	§103	6-8, 17, 25-27, 36
	C	Garrison + Laub + Schaffer	§103	11-12, 30-31
	D	Garrison + Laub + Schaffer + Hartley	§103	11-12, 30-31
4	A	Garrison + Aklog	§103	1-10, 13-29, 32-38
	B	Garrison + Aklog + Goff	§103	6-8, 17, 25-27, 36
	C	Garrison + Aklog + Schaffer	§103	11-12, 30-31
	D	Garrison + Aklog + Schaffer + Hartley	§103	11-12, 30-31

VI. GROUNDS 1A, 2A, 3A, 4A – LAUB, AKLOG, AND GARRISON

A. Claim 1

74. As I explain in detail below, a person of ordinary skill in the art would have found it obvious to incorporate Garrison’s valve and rapid aspiration procedures into Laub’s or Aklog’s aspiration systems that are designed to treat pulmonary embolisms. As I also explain in detail below, a person of ordinary skill in the art would have also found it obvious to 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 Laub or Aklog in combination with Garrison or Garrison in combination with Laub or Aklog.

1. Preamble

75. The preamble of Claim 1 recites: “A method of treating a pulmonary embolism within a vasculature of a patient.” If the Board finds that the preamble of Claim 1 is limiting, Laub and Aklog both disclose this limitation. In addition, Garrison in combination with Laub or Aklog renders this limitation obvious.

a. Laub

76. Laub discloses “a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” Ex.

1012 (Laub) at [0005]. Laub expressly discloses that its system may be used “to remove clots from patients suffering from or at risk of pulmonary embolisms.” *Id.* Laub also explains that its system includes “an aspiration catheter 200 configured to be inserted into the patient’s body (e.g., into a vein or artery) and aspirate blood and other material (e.g., thrombi).” *Id.* at [0024]. Given these disclosures, a person of ordinary skill in the art would have recognized that Laub describes, or at the very least renders obvious, a “method of treating a pulmonary embolism within a vasculature of a patient.”

b. Aklog

77. Aklog discloses aspiration systems and methods for aspirating clot material from different parts of a patient’s vasculature, including “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 (Aklog) at 7:32-37; *see also id.* at 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7. Aklog explains that an obstruction of the pulmonary arteries is “known as pulmonary embolism” and, as indicated by the quote above, Aklog’s aspiration system is intended to treat this condition. *Id.* at 2:20-32. Given these disclosures, a person of ordinary skill in the art would have recognized that Aklog describes, or at the very least renders obvious, a “method of treating a pulmonary embolism within a vasculature of a patient.”

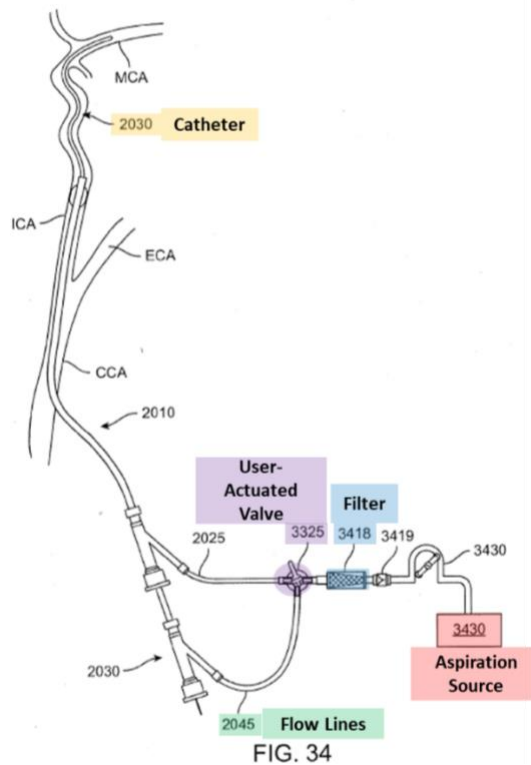
c. **Garrison and Aklog**

78. Garrison discloses an aspiration system for the “treatment of cerebral occlusions.” Ex. 1006 (Garrison) at [0002]. 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. 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. *Id.* 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.

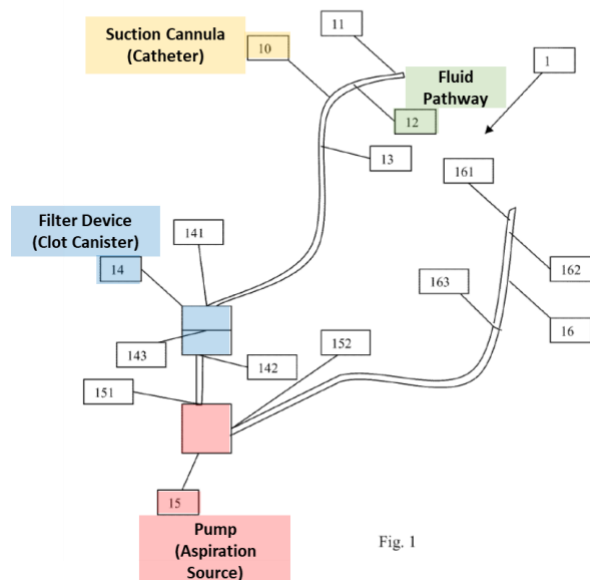
79. A person of ordinary skill in the art would have been further motivated to adapt Garrison’s system to be positioned proximate a pulmonary embolism and treat a pulmonary embolism because Aklog discloses that aspiration (like the aspiration disclosed in Garrison) can effectively remove the pulmonary 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



Aklog



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.

80. 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. 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. 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.

81. 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 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.

82. 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.

83. 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 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.

84. 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) Craido (Ex. 1017), which describes “[a] system for use in accessing and treating a ***carotid artery***” (*id.*, abstract (emphasis added)).

85. 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.

86. 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 [0001]; *see also id.*, [0011] (“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 (MY), 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 [0001] (emphasis added).

87. Even the challenged ’333 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 ’333 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 (’333 patent) at 4:51-58

(emphasis added). The '333 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 '333 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.)

88. 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.

d. Garrison and Laub

89. 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.

90. 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

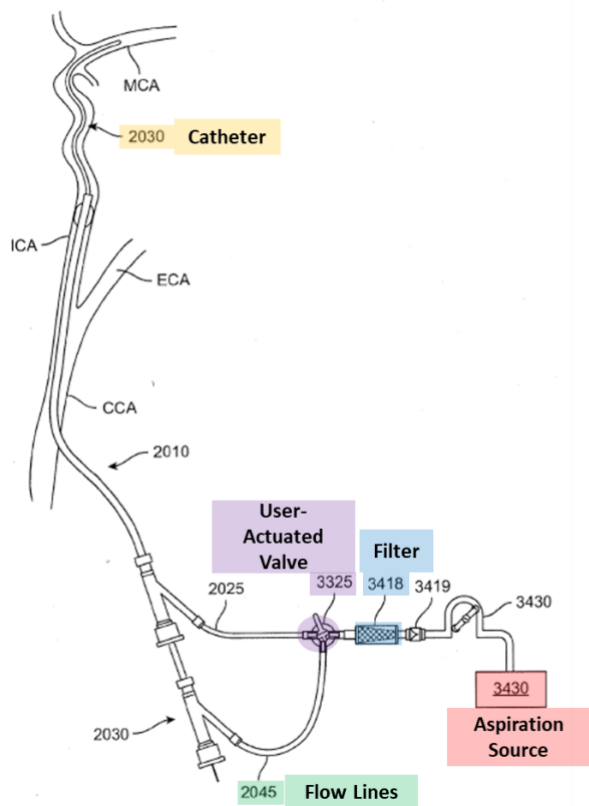


FIG. 34

Laub

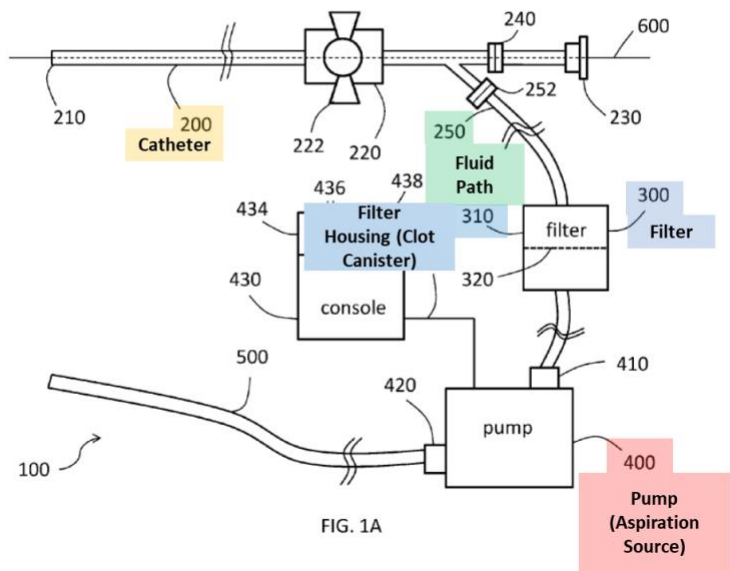


FIG. 1A

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.

91. 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.

92. 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* ¶82. 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.

93. 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.

94. 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.c. 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.*

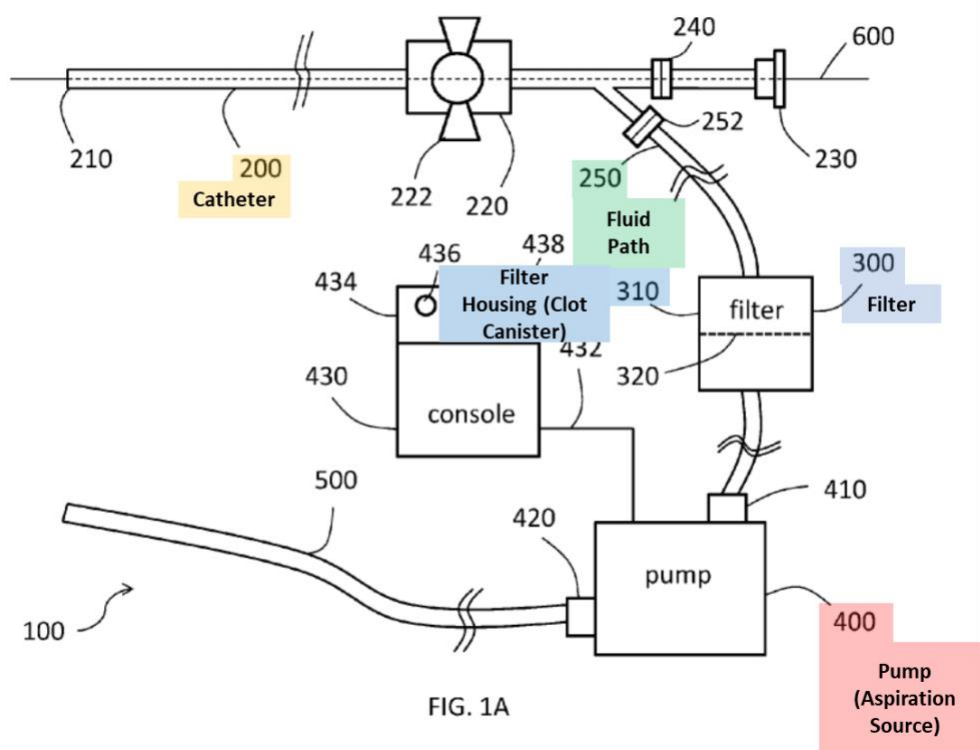
95. As I explained in the Garrison-Aklog ground, aspiration catheters primarily designed for treating cerebral occlusions, such as Garrison, are very closely related, and even interchangeable in some circumstances, to aspiration catheters for other parts of the vasculature. I have not seen any patents 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. Advancing Aspiration Catheter

96. Claim 1 next recites the method step of: "advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister." Laub and Aklog both disclose this limitation. In addition, Garrison in combination with Laub or Aklog renders this limitation obvious.

a. **Laub**

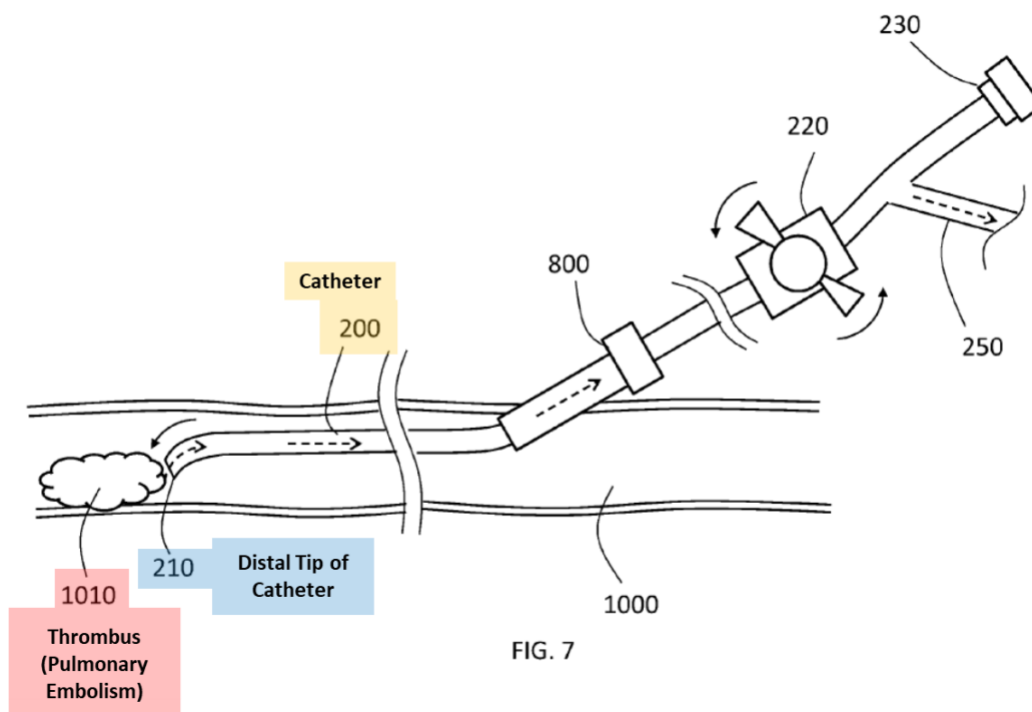
97. Laub discloses an aspiration system for treating pulmonary embolisms, and Laub's system includes an aspiration catheter 200 [orange], a fluid path 250 [green] that places the catheter in fluid communication with a pump 400 [red], and a filter [blue] positioned between the catheter and the pump:



Ex. 1012 (Laub) at [0024], [0039]-[0040], Fig. 1A. Laub explains that the filter 300 includes a housing 310 and that it “is configured to trap solid material received through aspiration catheter 200.” *Id.* at [0040]. Laub further explains that blood passes through a separator 320 in the filter, while solid materials (i.e., clots) are collected within the housing. *Id.* Given this disclosure, a person of ordinary skill

in the art would have recognized that Laub's filter housing 310 is a "clot canister," at least because it collects clot material aspirated from the patient. As illustrated above in Laub's Figure 1A, the aspiration catheter 200 is fluidly coupled along a fluid path 250 to the clot canister and a pump 400 that is located proximal to the filter.

98. Laub explains that its system may be advanced through the patient's vasculature to remove PEs. Ex. 1012 (Laub) at [0005]. As illustrated in Laub's Figure 7 below, the distal tip 210 of Laub's catheter 200 is positioned proximate to the thrombus before removal:



Id. at [0046], Fig. 7.

b. Aklog

99. Aklog discloses an aspiration system for treating PEs, and Aklog's system includes a suction cannula 10 [orange] with a fluid pathway 12 [green] that fluidly connects the cannula to a filter [blue] and a pump [red] that is proximal to the filter:

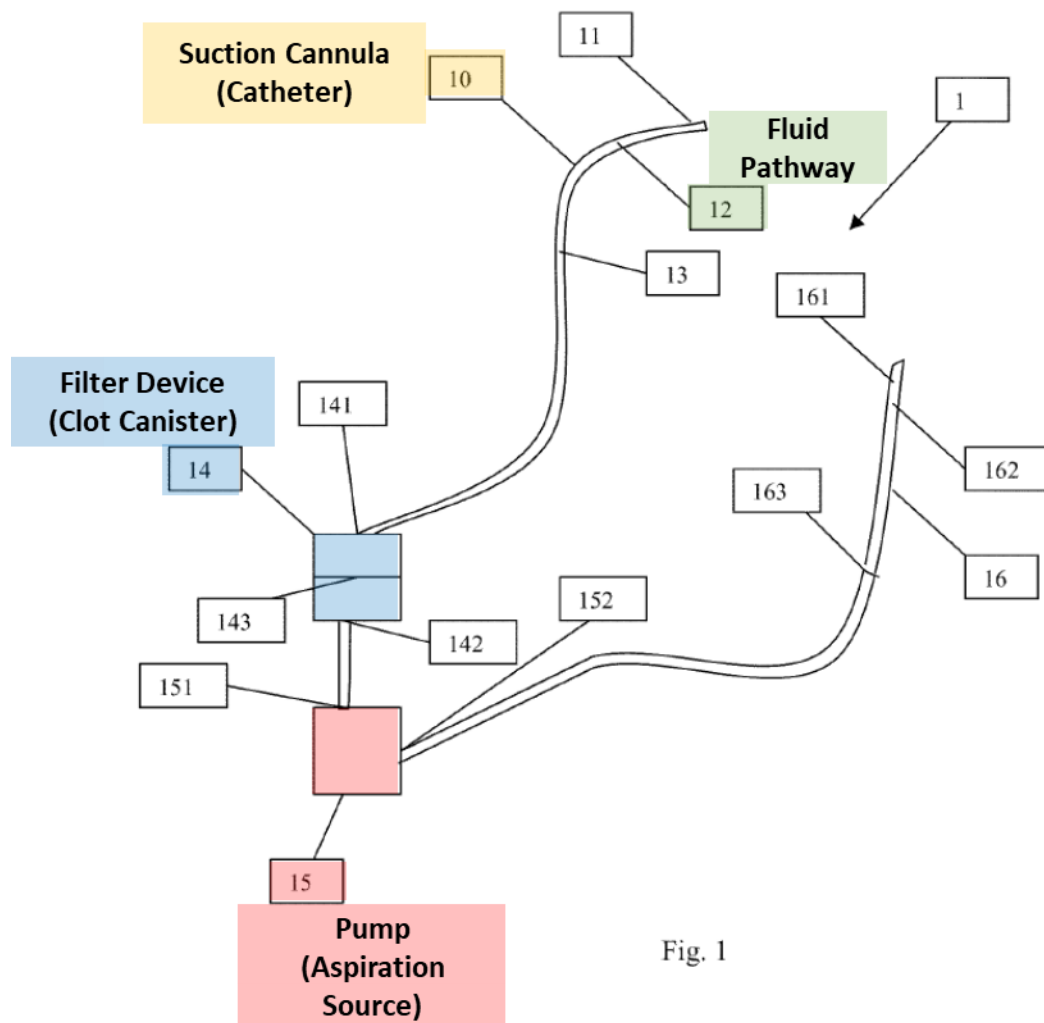


Fig. 1

Ex. 1005 (Aklog) 7:47-64, 11:24-35, 11:62-12:14, Fig. 1. Aklog discloses that the filter device 14 includes a permeable sheet or other filter material that allows

aspirated blood to flow through the filter while trapping solid material, such as aspirated clot material, within the filter. *Id.* at 11:24-61, 16:4-8. Given this disclosure, a person of ordinary skill in the art would have recognized that Aklog's filter device 400 is a "clot canister," at least because it collects clot material aspirated from the patient.

100. Aklog discloses that using its aspiration system to remove thrombus from a patient involves inserting the suction cannula into the patient's vasculature and advancing the cannula proximate to the clot material. Ex. 1005 (Aklog) at, 5:28-41, 11:62-65, 13:64-14:2, 16:27-53, 16:66-17:4. Aklog illustrates this in Figure 2C below:

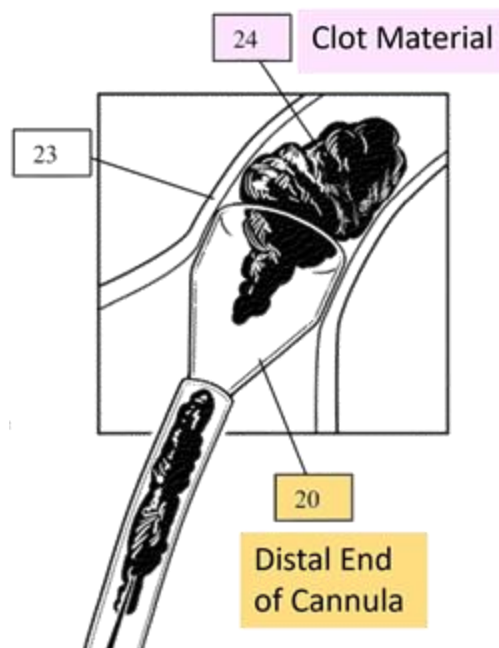


Fig. 2C

Id. at Fig. 2C; *see also id.* at Figs. 2D, 2H.

c. Garrison and Laub or Aklog

101. As I explained previously, Garrison discloses an aspiration system that is similar to the systems in Laub and Aklog. *Supra* §VI.A.1.c-d. Like Laub and Aklog, Garrison's system includes an aspiration catheter [orange] that is fluidly coupled along a fluid path [green dots] to a clot canister with a filter [blue] and an aspiration source (e.g., pump) [red] proximal to the clot canister:

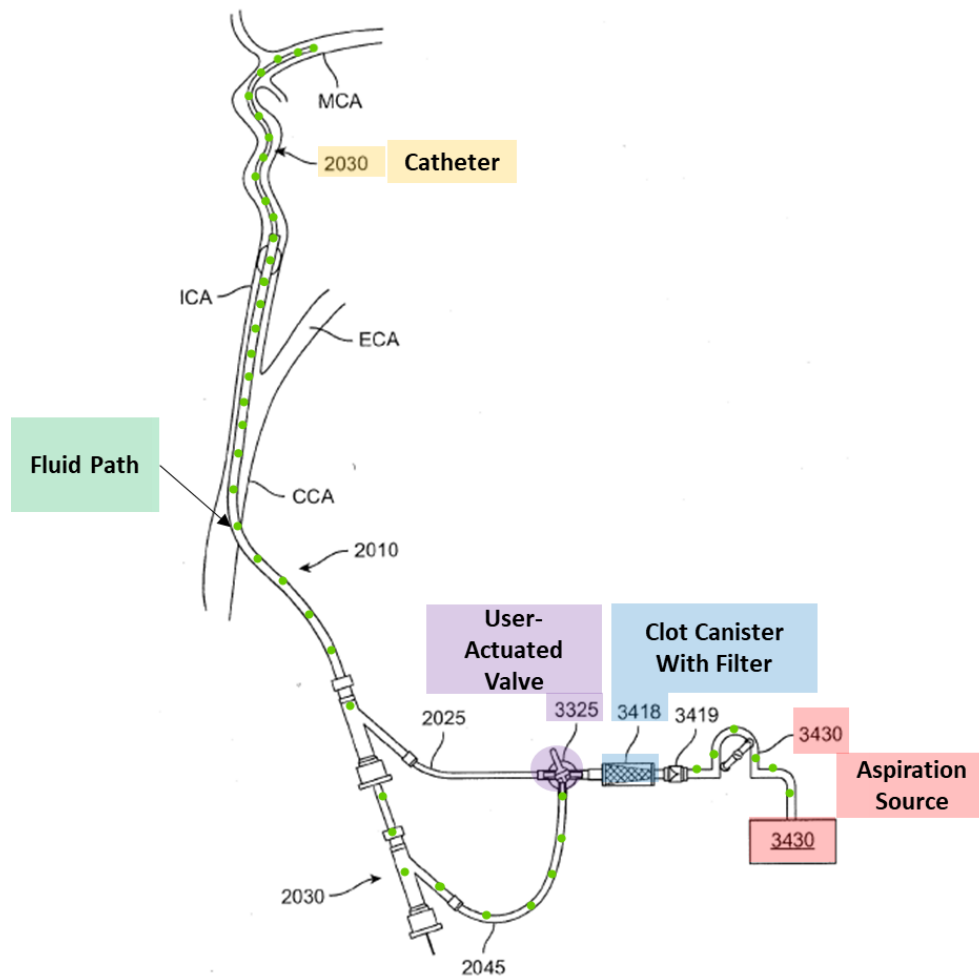


FIG. 34

Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134] (describing Figure 34 and related figures). Also like Laub and Aklog, Garrison discloses advancing its aspiration catheter through the patient's vasculature until the distal end portion of the catheter is proximate to the clot material. *Id.* at [0134].

102. A person of ordinary skill in the art would have found it obvious to modify and optimize Garrison's aspiration system to treat PE based on Laub or Aklog and their knowledge of the field for the reasons I explained previously. *Supra* § VI.A.1.c-d. A person of ordinary skill in the art would have recognized that when Garrison's system is used to treat PE, as taught by Laub and Aklog, the distal end of Garrison's catheter would be advanced proximate to the PE.

3. Generating Vacuum Pressure With Valve In First Position

103. Claim 1 next recites the method step of: "generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister." Garrison discloses this limitation. In addition, Laub or Aklog in combination with Garrison renders this limitation obvious.

a. Garrison

104. As I explained previously, Garrison's system includes an aspiration catheter [orange], an aspiration source (e.g., aspiration pump) [red], a filter [blue].

Supra §VI.A.1.c. Garrison’s system also includes a valve 3325 [purple] located along the fluid path between the filter and the aspiration catheter:

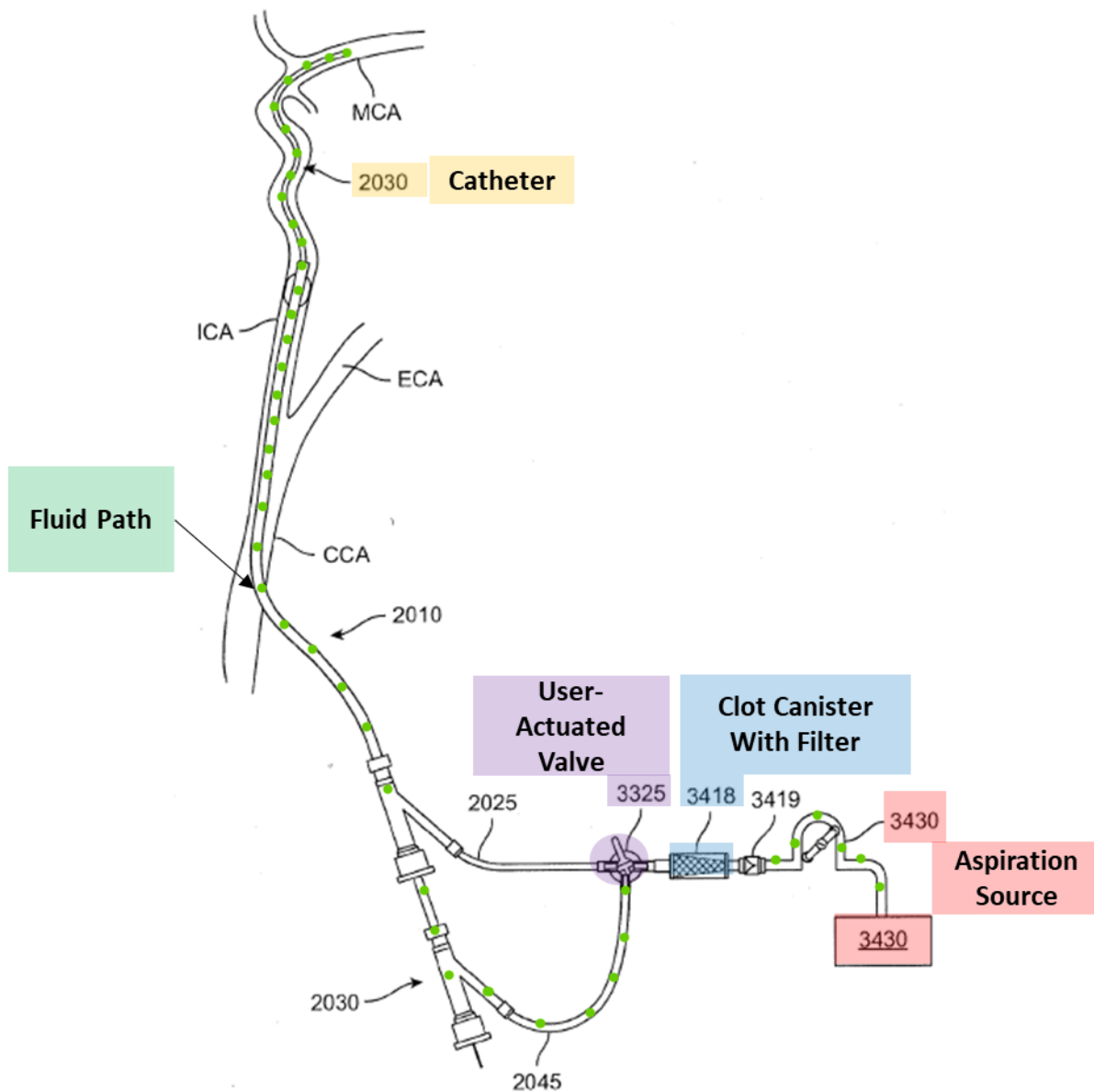


FIG. 34

Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134] (describing Figure 34 and related figures). Garrison explains that the “valve 3325 controls which device is connected to the aspiration source 3430.” *Id.* Garrison further discloses that “[t]he valve may

be a 3-way or 4-way stopcock” and “enable[s] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Garrison states 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).

105. 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 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, for example the stopcock 3325 in Figure 34 above, is distal to the filter, the vacuum pressure builds up within the filter canister via the pressure source when the valve is in the first (closed) position. *Id.* at Fig. 34. This particular example includes a flow controller for the valve and a syringe for the pressure source. However, as discussed above, Garrison discloses that the valve could also be a stopcock (*id.* at [0132]) and the aspiration source could also be an aspiration pump (*id.* at [0134]). Both the stopcock and aspiration pump could also generate the described rapid aspiration.

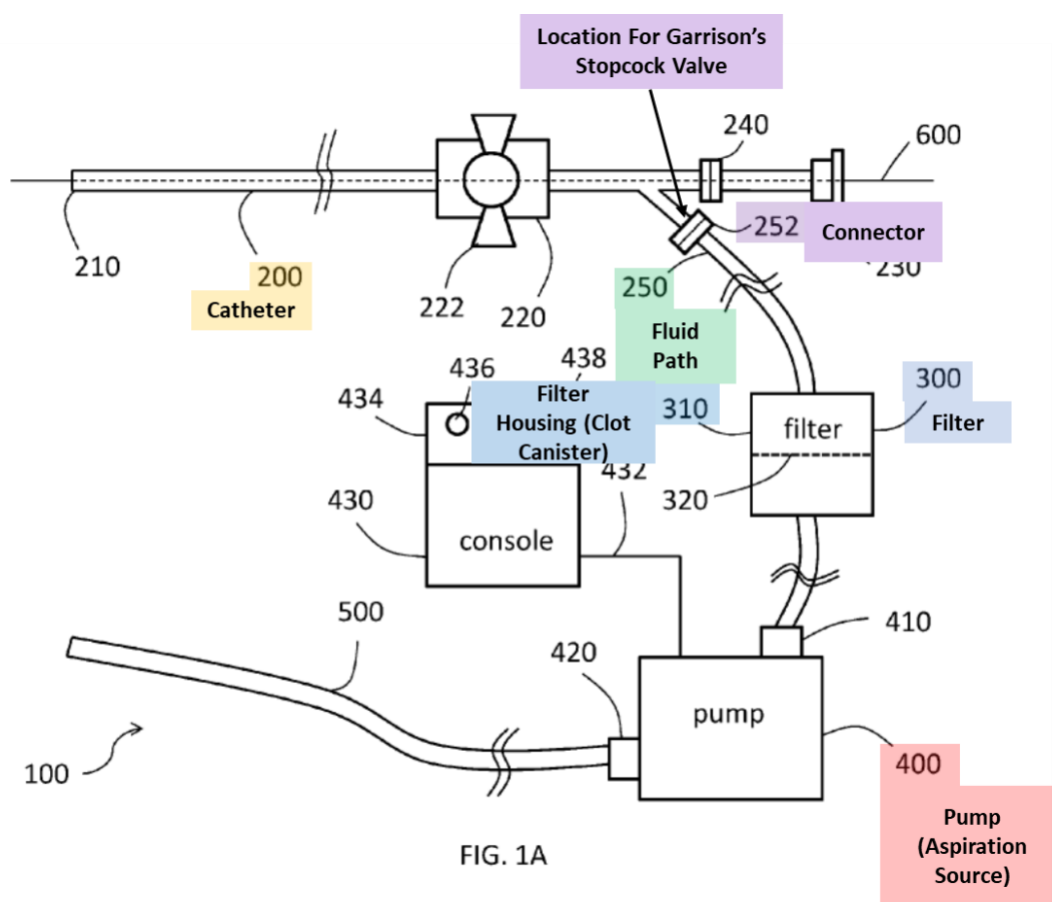
b. Laub and Garrison

106. A person of ordinary skill in the art would have been motivated to incorporate Garrison's valve 3325 and method of generating pressure while the valve is closed into Laub's aspiration system in order "enable the maximum level of aspiration in a rapid fashion with one user" as taught by Garrison. Ex. 1006 (Garrison) at [0134]. Given Garrison's descriptions of the benefits of its rapid aspiration procedures, a person of ordinary skill in the art would have recognized that Garrison's valve could maximize Laub's aspiration power to aspirate PE's more quickly. This would help Laub's system operate more quickly and effectively. In addition, combining Garrison's valve with Laub's aspiration system would have merely entailed combining known elements (Garrison's valve and Laub's system) according to known methods (positioning the valve between the catheter and filter along the flow path) to yield the predictable result of aspirating unwanted material from the patient's vasculature.

107. A person of ordinary skill in the art would have reasonably expected success in incorporating Garrison's valve and rapid aspiration technique into Laub's system. As I explained previously, Laub and Garrison describe similar aspiration systems that are inserted into a patient's vasculature in the same way to perform the same function – aspirating clot material. *Supra* §VI.A.1.c-d. Further, a stopcock valve is a simple mechanical structure that a person of ordinary skill in the art would

have used regularly as part of their job in 2018. A person of ordinary skill in the art would have had experience connecting and disconnecting stopcocks from a variety of medical systems at that time.

108. In addition, Laub's system includes a connector 252, which connects the aspiration catheter 200 to the fluid path 250 and "may allow detachment of fluid path 250 from aspiration catheter 200":



Ex. 1012 (Laub) at [0039], Fig. 1. A person of ordinary skill in the art would have recognized that a stopcock could be incorporated into Laub's system at the connector to help control the fluid flow. This is particularly true in view of

Garrison, which describes placing a stopcock at a similar location within Garrison's aspiration system (i.e., between the aspiration catheter and the filter) for the purpose of controlling fluid flow:

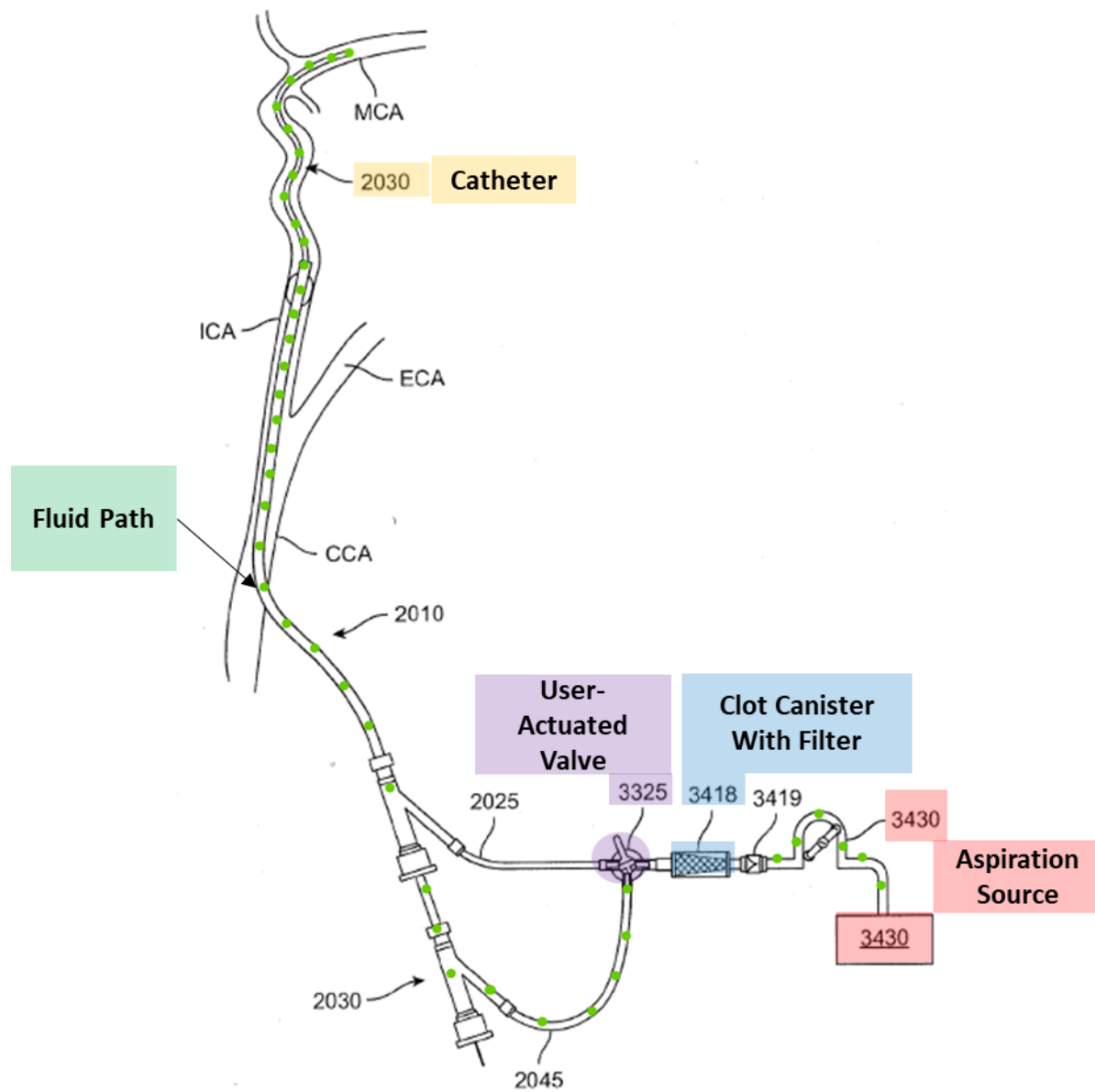


FIG. 34

Ex. 1006 (Garrison) at Fig. 34. A person of ordinary skill in the art would have

reasonably expected success in incorporating the stopcock at this location because Laub already includes the necessary connectors to incorporate the valve, and Garrison discloses that such an arrangement is beneficial for generating rapid suction.

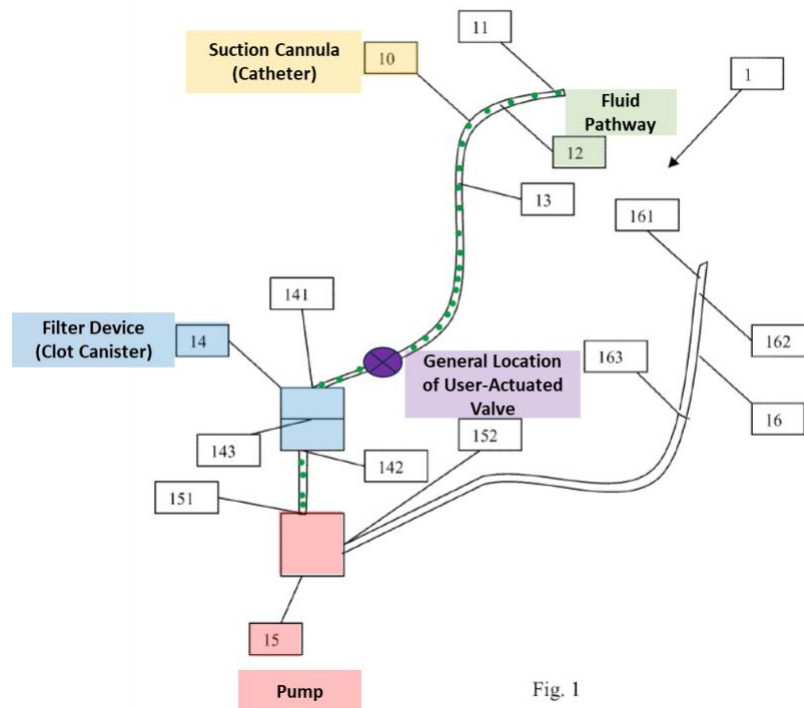
c. Aklog and Garrison

109. A person of ordinary skill in the art would have been motivated to incorporate Garrison's valve 3325 and method of generating pressure while the valve is closed into Aklog's aspiration system in order "enable the maximum level of aspiration in a rapid fashion with one user" as taught by Garrison. Ex. 1006 (Garrison) at [0134]. Given Garrison's descriptions of the benefits of its rapid aspiration procedures, a person of ordinary skill in the art would have recognized that Garrison's valve could maximize Aklog's aspiration power to aspirate PE's more quickly and potentially more effectively. This would help Aklog's system safer and more effective. In addition, combining Garrison's valve with Aklog's aspiration system would have merely entailed combining known elements (Garrison's valve and Aklog's system) according to known methods (positioning the valve between the catheter and filter along the flow path) to yield the predictable result of aspirating unwanted material from the patient's vasculature.

110. A person of ordinary skill in the art would have reasonably expected success in incorporating Garrison's valve and rapid aspiration technique into

Aklog's system. As I explained previously, Aklog and Garrison describe similar aspiration systems that are inserted into a patient's vasculature in the same way to perform the same function – aspirating clot material. *Supra* §VI.A.1.c. Further, a stopcock valve is a simple mechanical structure that a person of ordinary skill in the art would have used regularly as part of their job in 2018. A person of ordinary skill in the art would have had experience connecting and disconnecting stopcocks from a variety of medical systems at that time.

111. In addition, a person of ordinary skill in the art would have recognized that Garrison's valve (purple) could be incorporated into the flow path in Aklog's system between the distal end of the catheter and the filter/clot canister, similar to its placement in Garrison:



Ex. 1005 (Aklog) at Fig. 1. A person of ordinary skill in the art would have reasonably expected success in incorporating the stopcock at this location because Garrison discloses that such an arrangement is beneficial for generating rapid suction. Moreover, as I explained previously, stopcocks are simple, commonly used mechanical components that could have been easily connected to catheter tubing in Aklog's system via off-the-shelf connectors.

4. Moving The Valve From First Position To Second Position

112. Claim 1 next recites the method step of: “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister.” Garrison discloses this limitation. In addition, Laub or Aklog in combination with Garrison renders this limitation obvious.

113. As I discussed in the previous section, Garrison describes generating a vacuum pressure in the clot canister by closing the user-actuated valve (e.g., stopcock valve or flow controller). Once the user generates the vacuum pressure and positions the tip of the aspiration catheter near the occlusion, “the user may open the connection to the aspiration syringe” or other negative pressure source.

Ex. 1006 at [0134], Fig. 34. Garrison discloses, “[t]his would enable the maximum level of aspiration in a rapid fashion with one user, something that is not currently possible with existing technologies.” *Id.* at [0134].

114. Thus, Garrison discloses a method of aspirating clot material that involves moving the valve from a first (closed) position to a second (open) position thereby applying vacuum pressure to the lumen of an aspiration catheter, which will aspirate the clot material through the aspiration catheter into the clot canister. Given Garrison’s disclosures, a person of ordinary skill in the art would have recognized that when Garrison’s system is used to treat PE, or when Garrison’s valve is incorporated into the PE aspiration systems in Laub or Aklog, moving the valve to the second position would cause at least a portion of the pulmonary embolism and blood to be aspirated into the clot canister.

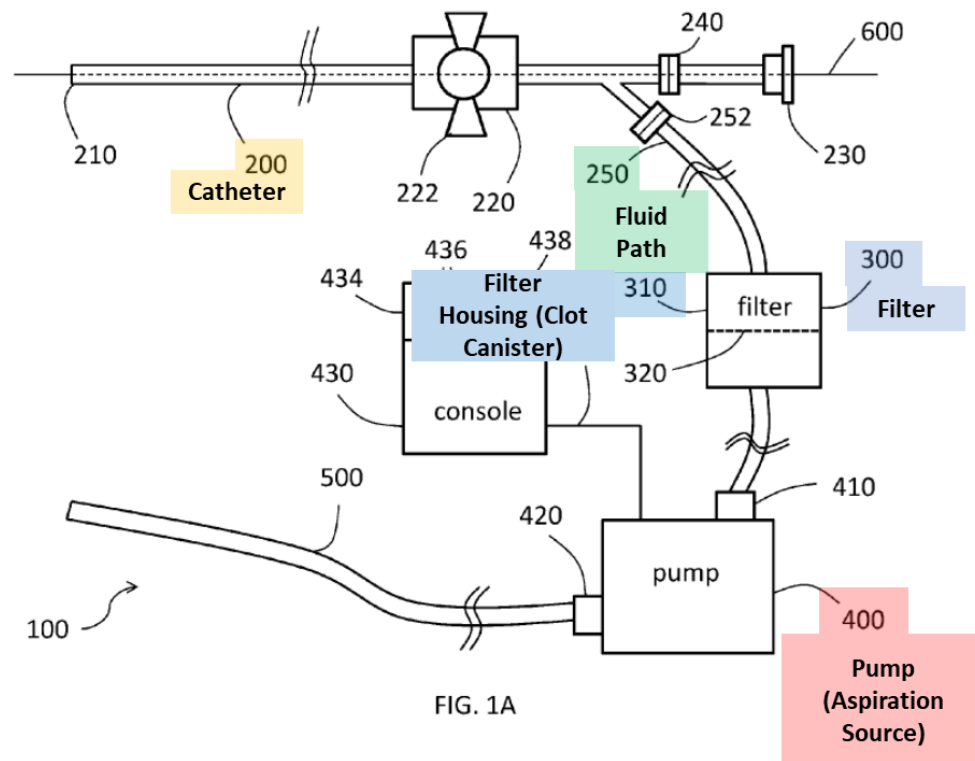
5. Filter

115. Claim 1 concludes with the following limitation: “wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.” Laub, Aklog, and Garrison each disclose this limitation.

a. Laub

116. Laub discloses an aspiration system for treating pulmonary embolisms, and Laub’s system includes an aspiration catheter 200 [orange], a fluid

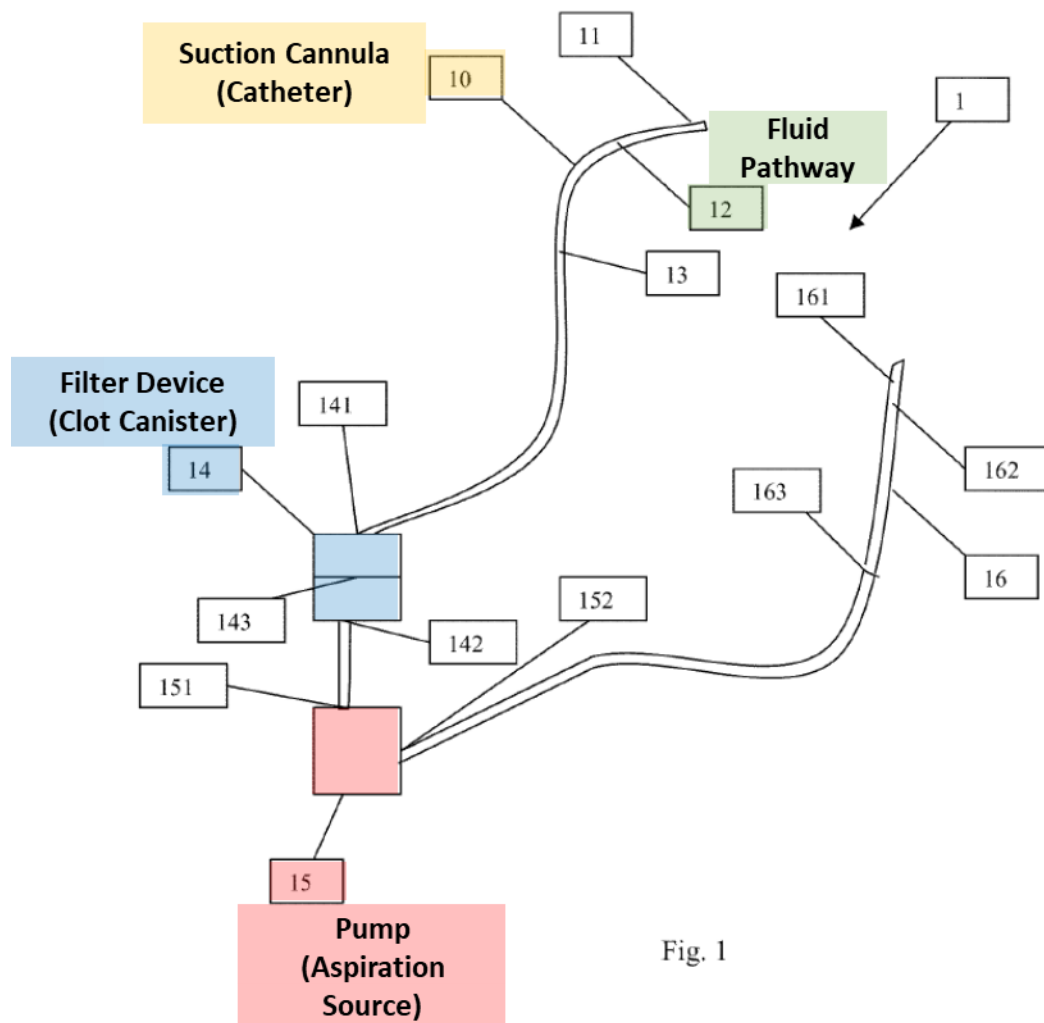
path 250 [green] that places the catheter in fluid communication with a pump 400 [red], and a filter [blue] positioned between the catheter and the pump:



Ex. 1012 (Laub) at [0024], [0039]-[0040], Fig. 1A. Laub explains that the filter 300 includes a housing 310 and that it “is configured to trap solid material received through aspiration catheter 200.” *Id.* at [0040]. Laub further explains that blood passes through a separator 320 in the filter, while solid materials (i.e., clots) are collected within the housing. *Id.* Accordingly, Laub’s filter housing (i.e., clot canister”) includes “a filter configured to filter the blood from the portion of the pulmonary embolism.”

b. Aklog

117. Aklog discloses an aspiration system for treating pulmonary embolisms, and Aklog's systems includes a suction cannula 10 [orange] with a fluid pathway 12 [green] that fluidly connects the cannula to a filter [blue] and a pump [red] that is proximal to the filter:



Ex. 1005 (Aklog) at 7:47-64, 11:24-35, 11:62-12:14, Fig. 1. Aklog discloses that the filter device 14 includes a permeable sheet or other filter material that allows

aspirated blood to flow through the filter while trapping solid material, such as aspirated clot material, within the filter. *Id.* at 11:24-61, 16:4-8. Accordingly, Aklog's filter device 14 (i.e., clot canister) includes "a filter configured to filter the blood from the portion of the pulmonary embolism."

c. Garrison

118. Garrison's aspiration system includes an aspiration catheter [orange] that is fluidly coupled along a fluid path [green dots] to a clot canister with a filter [blue] and an aspiration source (e.g., pump) [red] proximal to the clot canister:

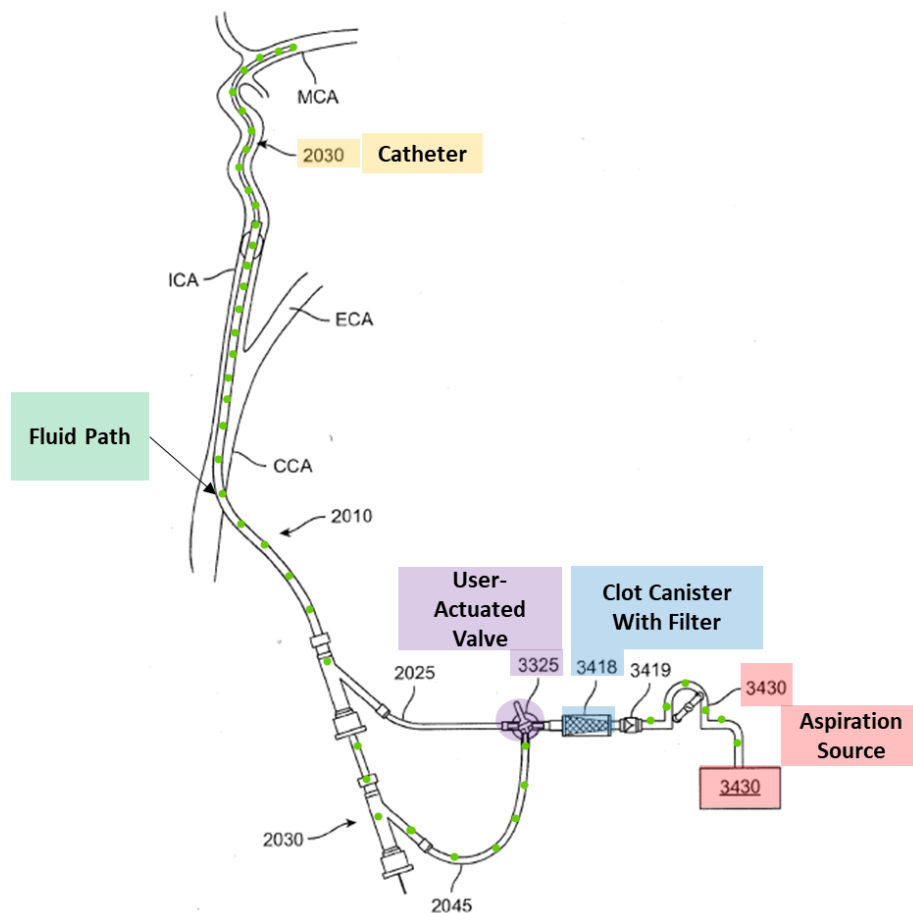


FIG. 34

Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134] (describing Figure 34 and related figures). Accordingly, Garrison's clot canister includes "a filter configured to filter the blood from" the aspirated clot material. When Garrison's system is used to treat PE, the filter would be "configured to filter the blood from the portion of the pulmonary embolism."

B. Claim 2

119. Claim 2 recites: "The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature." In my opinion, Claim 2 would have been obvious in view of (A) Laub or Aklog combined with Garrison and (B) Garrison combined with Laub or Aklog.

1. Laub

120. Laub discloses that "[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr." Ex. 1012 (Laub) at [0028]. Thus, Laub discloses this limitation.

2. Aklog

121. 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 11:13-15. 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 much larger than 16F:

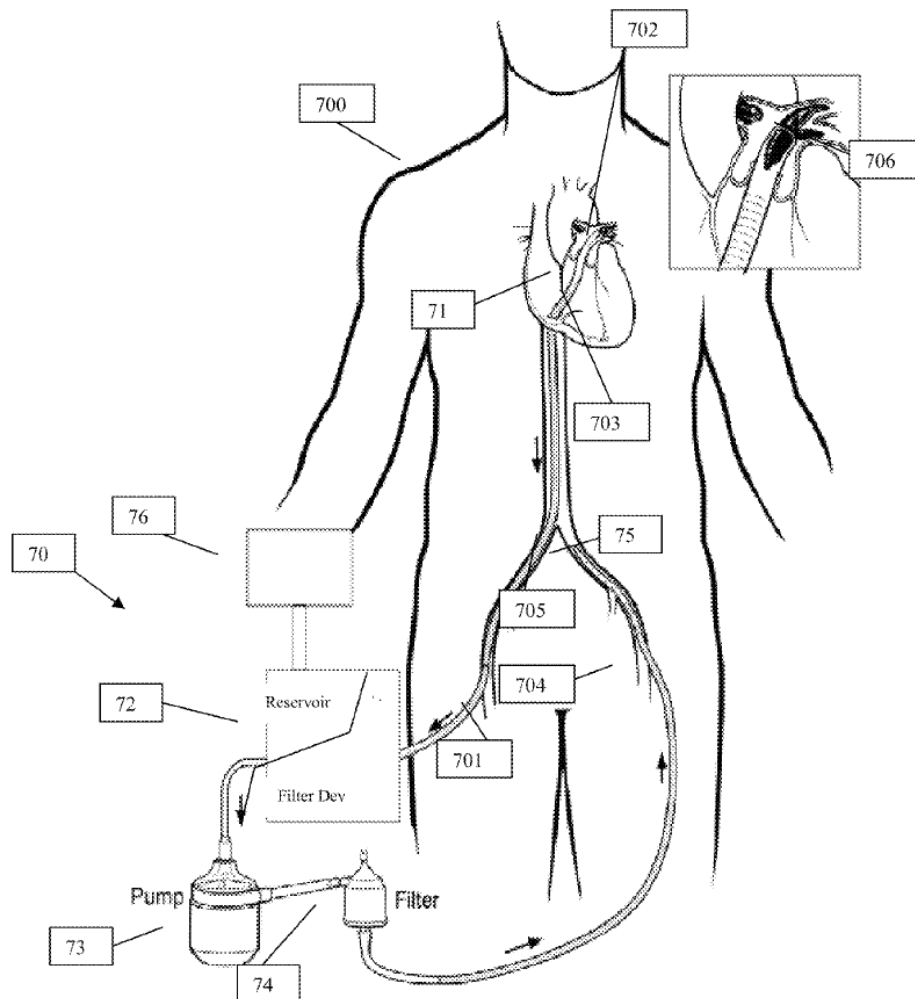


Fig. 7

Id. at Fig. 7. Thus, a person of ordinary skill in the art would have recognized that using a catheter measuring 16F or larger with Aklog's system would be reasonable given Aklog's disclosures.

122. 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).

123. Accordingly, given 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 a catheter of at least 16 Fr with Aklog's system, particularly when using the system to treat PE, and they would have reasonably expected success in doing so because Laub, and other references, confirm the effectiveness of such catheters.

3. Garrison and Laub or Aklog

124. Laub and Aklog disclose or render obvious aspirating PE with catheters having a size of 16 Fr. or greater for the reasons I explained in the two

preceding sections. *Supra* §§VI.B.1-2. 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.c-d.

C. Claim 3

125. Claim 3 recites: "The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature." In my opinion, Claim 3 would have been obvious in view of (A) Laub or Aklog combined with Garrison and (B) Garrison combined with Laub or Aklog.

1. Laub

126. Laub discloses that "[i]n some embodiments, aspiration catheter 200 has a French size of at least 20 Fr." Ex. 1012 (Laub) at [0028]. Thus, Laub discloses this limitation.

2. Aklog

127. A person of ordinary skill in the art would have been motivated to use a catheter of at least 20 Fr. with Aklog's system, particularly when using the system to treat PE, and they would have reasonably expected success in doing so for the same reasons explained previously for Claim 2. *Supra*, §VI.B.2. As I explained for Claim 2, there were several commercially available aspiration systems at that

time that were used to treat both PE and DVT and included catheters larger than 20 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). In addition, Aklog discloses that its catheter can be sized for medium and large vessels, and Figure 7 of Aklog depicts a large diameter catheter aspirating a large clot from the proximal portion of the pulmonary vasculature, which is typically much larger than 16F:

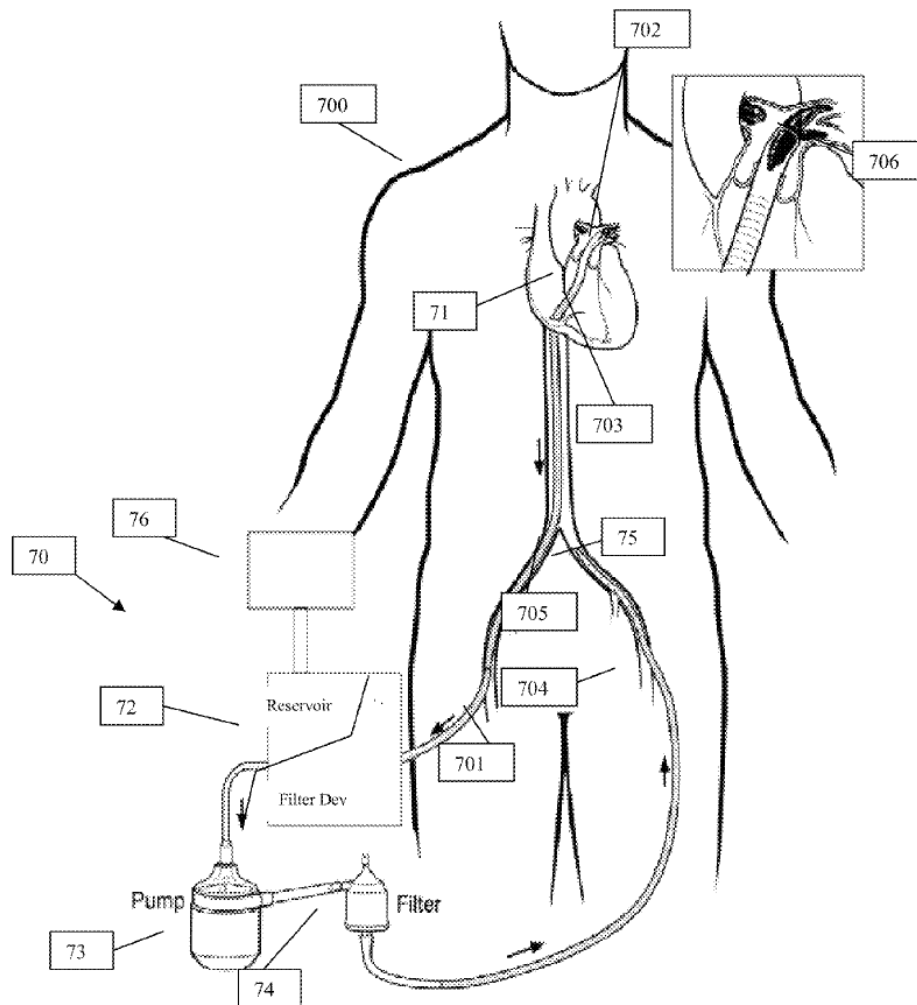


Fig. 7

Id. at Fig. 7. Thus, a person of ordinary skill in the art would have recognized that using a catheter measuring 16F or larger with Aklog's system would be reasonable given Aklog's disclosures. Thus, a catheter measuring 20F or larger would be reasonable.

3. Garrison and Laub or Aklog

128. Laub and Aklog disclose or render obvious aspirating PE with catheters having a size of 20 Fr. or greater for the reasons I explained in the two preceding sections. *Supra* §§VI.C.a-b. 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.c-d.

D. Claim 4

129. Claim 4 recites: "The method of claim 1 wherein advancing the aspiration catheter includes advancing the aspiration catheter such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism within a pulmonary artery of the patient." In my opinion, Claim 4 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

130. As I explained previously for Claim 1, Laub and Aklog each disclose systems and methods for aspirating PE, which involve advancing the distal portion

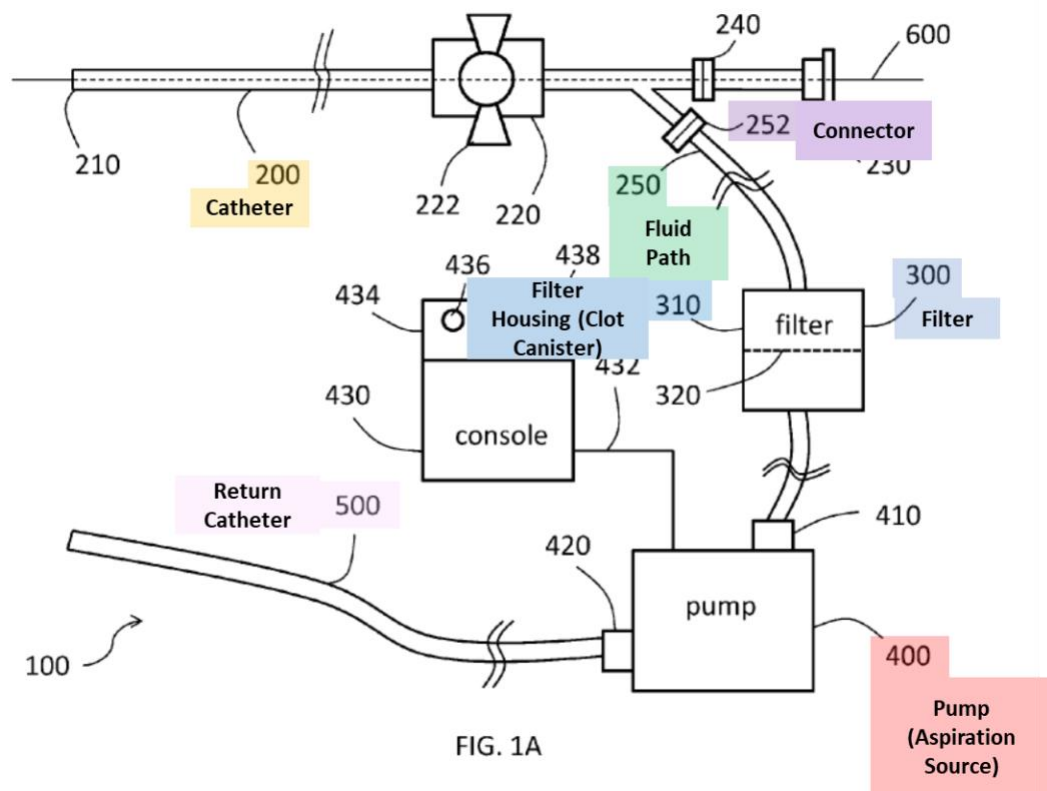
of an aspiration catheter proximate to the pulmonary embolism. *Supra* §VI.A.2.a-b. As I also explained for Claim 1, a person of ordinary skill in the art would have found it obvious to modify and optimize and use Garrison’s aspiration system to treat PE in view of Laub and Aklog, which would have involved advancing the distal portion of Garrison’s aspiration catheter proximate to the pulmonary embolism. *Supra* §VI.A.2.c. By definition, a pulmonary embolism is located within a patient’s pulmonary artery. Therefore, Laub or Aklog combined with Garrison and Garrison combined with Laub or Aklog renders Claim 4 obvious.

E. Claim 5

131. Claim 5 recites the “method of claim 1 wherein the method further comprises: receiving the filtered blood through a fluid outlet of the clot canister; and reintroducing the filtered blood into the vasculature of the patient.” In my opinion, Claim 4 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

1. Laub

132. Laub discloses that its aspiration system includes a “return catheter 500 for returning aspirated blood to the patient.” Ex. 1012 (Laub) at [0024]. Laub further discloses that a filter 300 is “positioned anywhere in fluid communication between the aspiration catheter 200 and return catheter 500”:



Id. at [0024], Fig. 1. Laub explains that the filter 300 includes a “housing 310 [i.e., clot canister] containing at least one separator 320 configured to separate the solid materials from the aspirated blood.” *Id.* at [0040]. Laub also discloses that “[b]lood which passes through separator 320 may then be suctioned through the remainder of fluid path 250 and into pump 400 through inlet port 410.” *Id.* Laub explains that the filtered blood suctioned into the pump is then reintroduced into the patient’s vasculature via return catheter 500. *Id.* at [0045].

133. Accordingly, Laub discloses “receiving the filtered blood through a fluid outlet of the clot canister; and reintroducing the filtered blood into the vasculature of the patient” as recited in Claim 5.

2. Aklog

134. Aklog discloses that its aspiration system includes a filter device 14 having an inlet 141 “through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10” and an outlet 142 “through which filtered fluid from within device 14 may be directed downstream of system 1.” Ex. 1005 (Aklog) at 11:24-31, Fig. 7. Aklog further discloses that its system includes a reinfusion cannula 16 “designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site.” *Id.* at 12:26-31.

135. Accordingly, Aklog discloses “receiving the filtered blood through a fluid outlet of the clot canister; and reintroducing the filtered blood into the vasculature of the patient” as recited in Claim 5.

3. Garrison

136. 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.” Ex. 1006 (Garrison) at [0136]-[0137]; *see also id.* at [0140]-[142], Fig. 38 (describing additional blood return systems). Garrison discloses that the device 3250 “may be connected to either or both the arterial access device 2010 and the catheter 2030.” *Id.* at [0136].

137. Accordingly, Garrison discloses “receiving the filtered blood through a fluid outlet of the clot canister; and reintroducing the filtered blood into the vasculature of the patient” as recited in Claim 5.

F. Claim 9

138. Claim 9 recites: “The method of claim 1 wherein the valve comprises a lever, and wherein moving the valve from the first position to the second position includes rotating the lever.” In my opinion, Claim 9 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

139. As explained previously for Claim 1, Garrison discloses a valve 3325 in fluid connection to the aspiration source that “may be a 3-way or 4-way stopcock” that “enable[s] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” Ex. 1006 (Garrison) at [0132]. Garrison’s stopcock valve includes a rotating lever to change the orientation of the valve and couple or decouple the pressure source from the catheters:

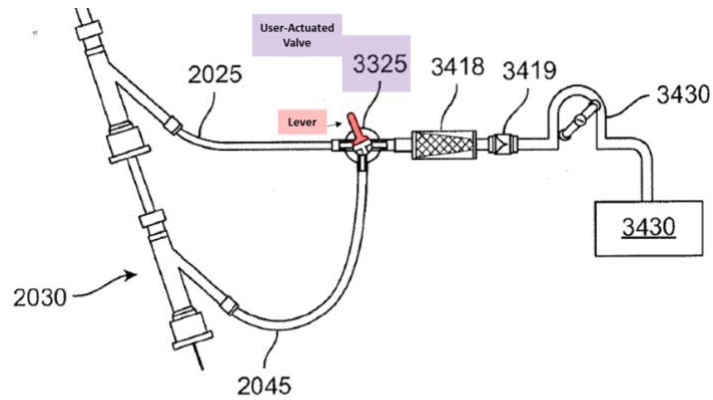


FIG. 34

Id. at [0132], Fig. 34. Stopcocks having a lever to rotate the stopcock were common in August 2018. For example, Figure 1 of U.S. Patent No. 7,984,730 (Ex. 1046) illustrates a stopcock that was common to the ones I used leading up to August 2018. As shown, the stopcock includes a rotatable lever with the word “OFF” written on it.

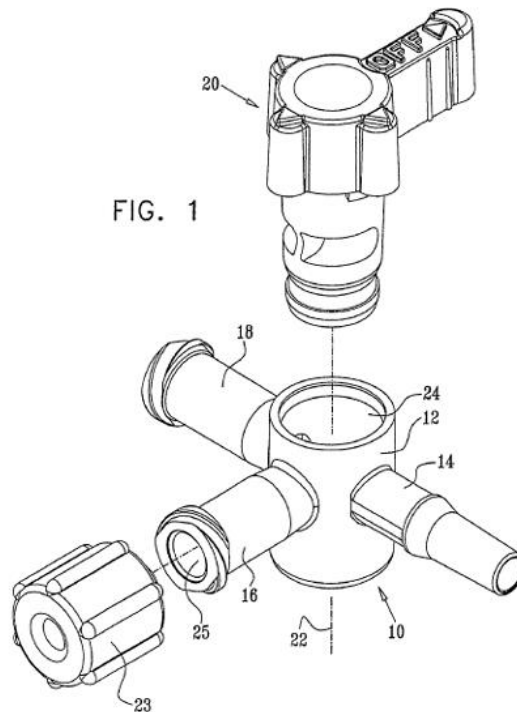


FIG. 1

I understand Garrison to be disclosing a stopcock that operated similar to the one above. Further, stopcocks like those disclosed in Garrison were commonly used in medical devices, and a person of ordinary skill in the art in 2018 would have been familiar with their use and construction.

G. Claim 10

140. Claim 10 recites: “The method of claim 1 wherein the method further comprises selectively providing fluid access to the lumen of the aspiration catheter via a hemostasis valve fluidly coupled to the aspiration catheter.” In my opinion, Claim 10 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

1. Garrison

141. As I explained for Claim 1, Garrison discloses a catheter 2030 [orange] having a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not pictured in Figure 34):

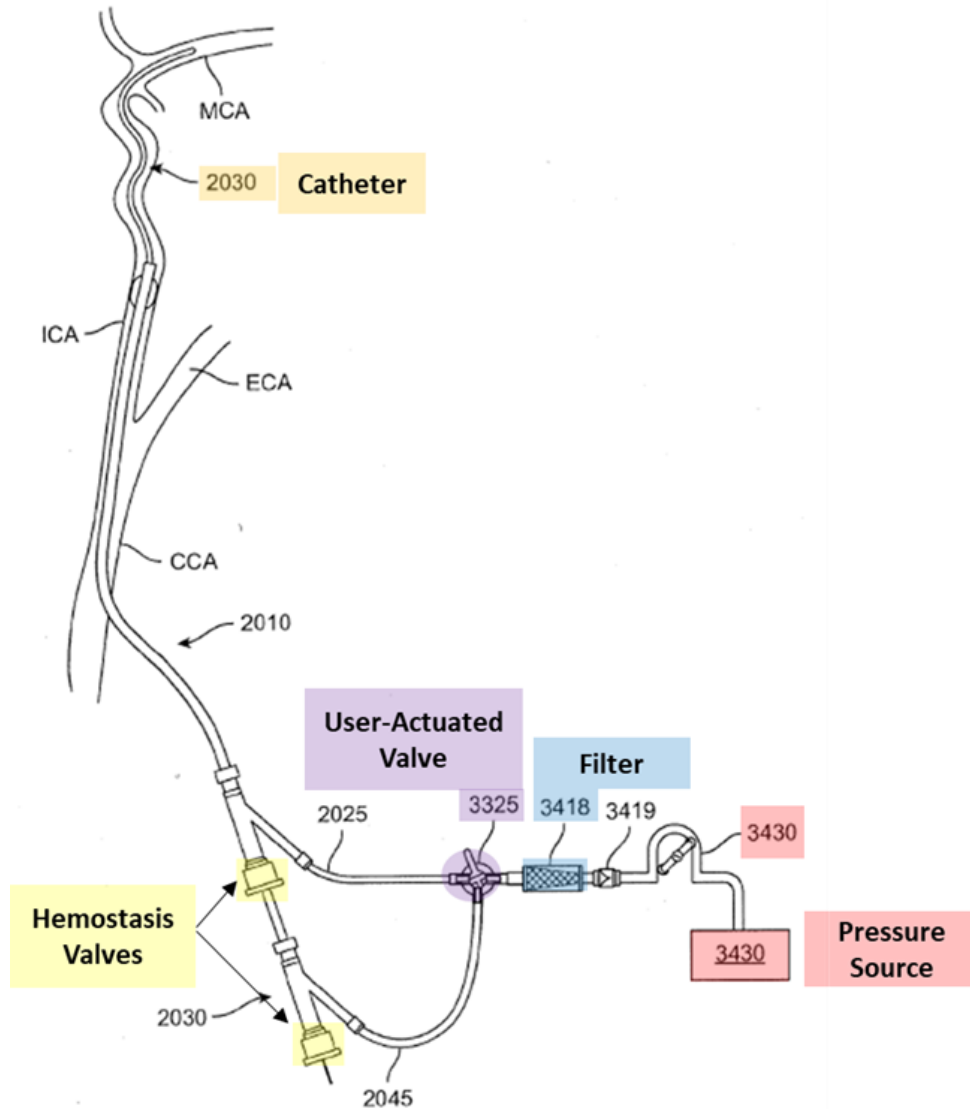


FIG. 34

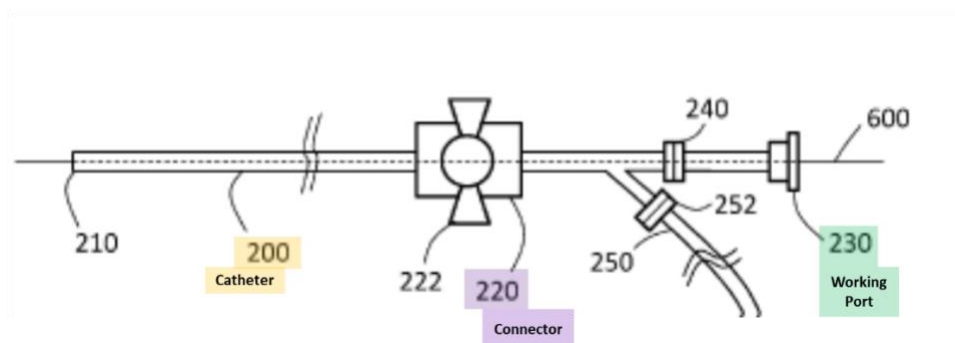
Ex. 1006 (Garrison) at [0098], Fig. 34. Garrison specifically states that “a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” *Id.* 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.” Ex. 1006 (Garrison) at [0098].

142. Figure 34 (above) does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figure 3 identifies 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. Accordingly, Garrison discloses the additional limitations of Claim 10.

2. Laub and Garrison

143. Laub discloses that its aspiration system may include a working port 230 that extends proximally from the controller 220 and “allows insertion of instruments into and/or through the lumen of aspiration catheter 200”:



Ex. 1012 (Laub) at [0035], Fig. 1A (excerpt). Laub explains that the working port may be “configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use,” such as by using a Tuohy-Borst adapter. *Id.* at [0036]. As demonstrated by Garrison above, a Tuohy-Borst adapter is a type of hemostasis valve. Laub further discloses that the “working port 230 may include a valve to close working port 230 when not in use.” *Id.* Thus, a person of ordinary skill in the art would have understood these disclosures in Laub to describe a hemostasis valve. Accordingly, Laub discloses selectively providing fluid access to the lumen of the aspiration catheter via a hemostasis valve fluidly coupled to the aspiration catheter.

144. Even if the Board concludes that Laub’s description of the working port does not constitute a “hemostasis valve,” it is my opinion that a person of ordinary skill in the art would have been motivated to use a hemostasis valve in Laub’s working port 230 in view of Garrison. As I explained previously, Garrison’s system includes a hemostasis valve that allows “introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” Ex. 1006 (Garrison) at [0098]. A person of ordinary skill in the art would have been motivated to use Garrison’s hemostasis valve in Laub’s working port 230 to create a fluid tight seal around any tools

inserted into the aspiration catheter to prevent or minimize blood loss during the procedure. As I explained previously for Claim 1, Laub and Garrison disclose similarly configured aspiration systems, and therefore a person of ordinary skill in the art would have reasonably expected success in incorporating Garrison's hemostasis valve into Laub's working port 230. This is particularly true given Laub's disclosure of the working port 230, which according to Laub, "may include a valve to close working port 230 when not in use." Ex. 1012 (Laub) at [0036].

3. Aklog and Garrison

145. Aklog discloses that its aspiration system may include "a port 51, as shown in FIG. 5, located at the proximal end 13 of cannula 10," which allows for introduction of additional devices, such as guidewires and catheters, into the lumen of the aspiration catheter during the clot removal procedure. Ex. 1005 (Aklog) at 11:4-7. Although Aklog does not expressly describe including a hemostasis valve within the port, a person of ordinary skill in the art would have been motivated to include a hemostasis valve, like Garrison's hemostasis valve, in Aklog's port 51 to prevent or minimize blood from leaking through the port 51 when a device is inserted. If Aklog's port did not include such a valve, blood would undesirably leak from the patient, via the port, into the operating room, something any person of ordinary skill in the art would have wanted to avoid. As I explained previously for Claim 1, Aklog and Garrison disclose similarly configured aspiration systems, and

particularly similar hubs/ports and the end of the catheters, and therefore a person of ordinary skill in the art would have reasonably expected success in incorporating Garrison's hemostasis valve into Aklog's port 51. *Supra* §VI.A.1.c.

H. Claim 14

146. Claim 14 recites: "The method of claim 1 wherein the method further comprises: positioning a clot treatment device within the lumen of the aspiration catheter; and engaging a portion of the pulmonary embolism with the clot treatment device thereby disrupting the pulmonary embolism." In my opinion, Claim 14 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

1. Laub

147. As I explained for Claim 10, Laub discloses that its system includes a working port 230 that "allows insertion of instruments into and/or through the lumen of aspiration catheter 200." Ex. 1012 [Laub] at [0035]. Laub discloses that the "other devices" can include "other wires, balloon catheters, diagnostic catheters, baskets, optical fibers, thrombolysis tools, needles, cutters, biopsy devices, and other surgical implements known in the art." *Id.* A person of ordinary skill in the art would have recognized that several of these "other devices" encompass clot treatment devices, including at least balloon catheters, thrombolysis tools, and biopsy devices, because the physician can use these devices to engage and disrupt

the clot material. For example, Aklog, described below, discloses a method of using a balloon catheter to engage and disrupt a clot. Similarly, the purpose of thrombolysis tools is to engage the clot and disperse medications around the clot to dissolve it. Biopsy devices would necessarily need to engage the clot and disrupt the clot in order to retrieve a biopsy or dislodge the clot.

2. Aklog

148. Aklog discloses that the lumen of its aspiration catheter can “accommodate other devices, such as other catheters or surgical instruments,” and Aklog explains that “[f]or example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material.” Ex. 1005 (Aklog) at 10:55-60. Aklog further discloses that when suction alone is insufficient to dislodge the clot material, a “balloon catheter can be inserted through the side port of suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material.” *Id.* at 18:38-43. Aklog explains that the balloon is then inflated and withdrawn into the aspiration catheter while suction is applied, which “can act to drag the undesirable material into the cannula 71.” *Id.* at 43-48.

149. Accordingly, Aklog discloses positioning a clot treatment device (i.e., device to “dislodge” material or balloon catheter) through the aspiration catheter and then engaging a PE with the treatment device to disrupt the embolism.

3. Garrison

150. Garrison discloses that its aspiration catheter can be used with “[m]echanical thrombectomy devices [such as] coil-tipped retrievers, stent retrievers, expandable cages, wire or filament loops, graspers, brushes, or the like.” Ex. 1006 (Garrison) at [0144]. Garrison also discloses an embodiment having “a separate thrombus disruption device with an expandable distal segment [that] is inserted into the catheter” and is then used to “break up the clot” material as it is being aspirated into the catheter during the procedure. *Id.* at [0125]. Garrison also explains that “[i]f the thrombus is too large or too strongly embedded into the vasculature such that it is not possible to remove the occlusion via aspiration alone, further steps are taken to remove the occlusion” such as deploying a “thrombectomy device 15 ... through the arterial access device to remove the clot.” *Id.* at [0165].

151. Accordingly, Garrison discloses positioning a clot treatment device (i.e., retriever or balloon catheter) through the aspiration catheter and then engaging a PE with the treatment device to disrupt the embolism.

I. Claim 15

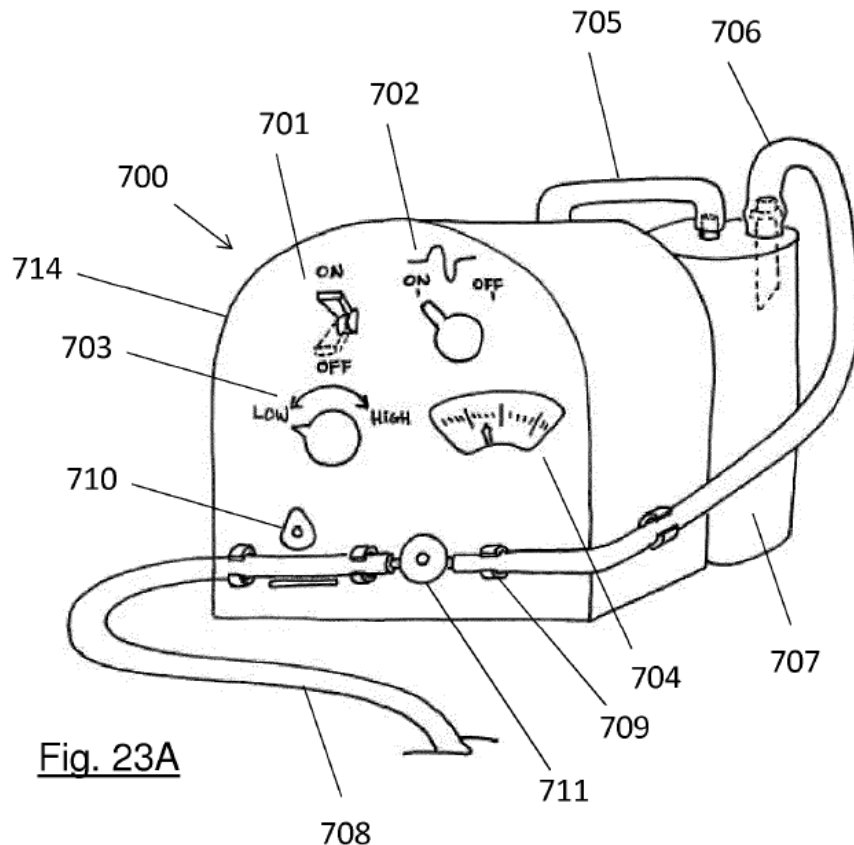
152. Claim 15 recites: “The method of claim 1 wherein the aspiration source is an electric pump.” In my opinion, Claim 15 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

1. Laub

153. Laub 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) [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, a person of ordinary skill in the art would have understood Laub to disclose using an electric pump.

2. Aklog

154. 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 11:62-12:14. 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 (Brady) at Fig. 23A. Therefore, a person of ordinary skill in the art would have understood that Aklog’s pump 15 may be an electric pump.

3. Garrison

155. 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] *see also id.* at [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

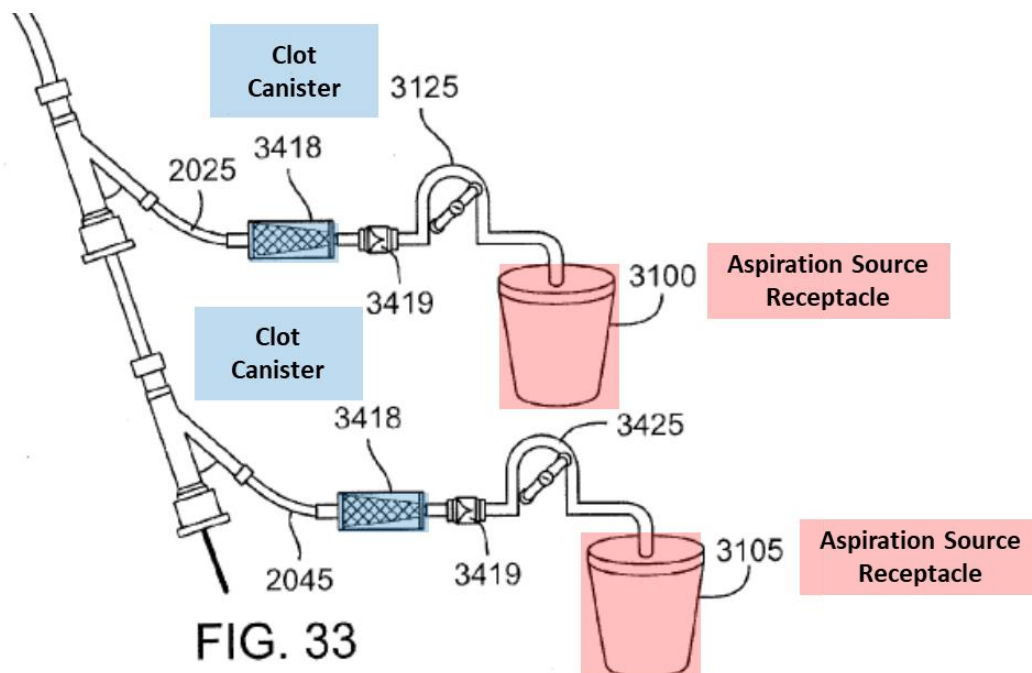
understood aspiration pumps to mean electric pumps. Further, as I explained in the preceding section for Aklog, a person of ordinary skill in the art would have known that commercially available aspiration pumps prior to August 2018 included electric pumps. *Supra* §VI.I.2.

J. Claim 16

156. Claim 16 recites: “The method of claim 1 wherein the clot canister has a first volume, and wherein the aspiration source has a second volume greater than the first volume.” In my opinion, Claim 16 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

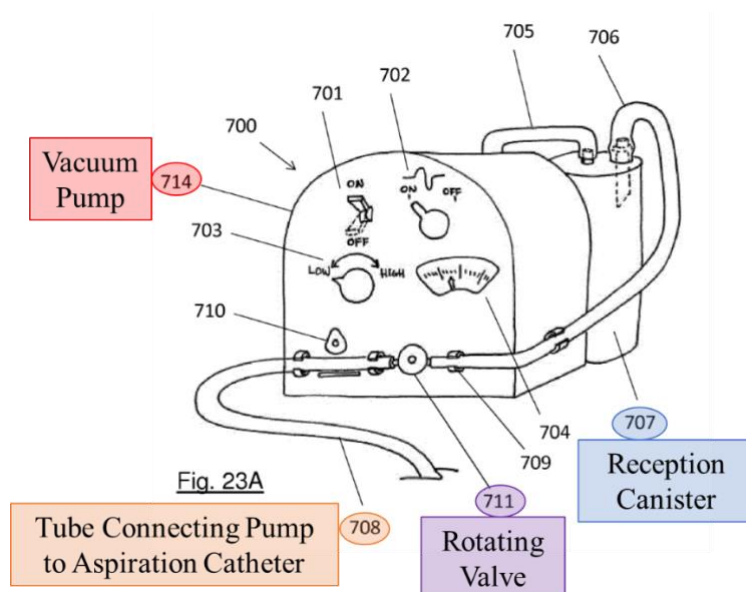
1. Garrison

157. As illustrated below, Figure 33 of Garrison discloses a clot canister 3418 having a first volume smaller than a second volume of the aspiration source:



Ex. 1006 (Garrison) at [0131]-[132], Figs. 33.

158. Figures 33 and 34 in Garrison appear to illustrate the aspiration source to include a peristaltic pump. *See id.* However, Garrison's disclosure does not limit the aspiration source to a peristaltic pump. Rather, Garrison broadly discloses that the aspiration source "may be "a syringe or other manual aspiration device, or an aspiration pump." *Id.* at [0072]. Accordingly, a person of ordinary skill in the art would have recognized that Garrison's system could use other types of aspiration pumps that were known in the art as the aspiration source besides peristaltic pumps. A person of ordinary skill in the art would have been familiar with many such pumps that would include a volume for collecting the aspirated blood. For example, Brady discloses an electric aspiration pump that includes a reception canister for collecting aspirated blood that has a significant volume:



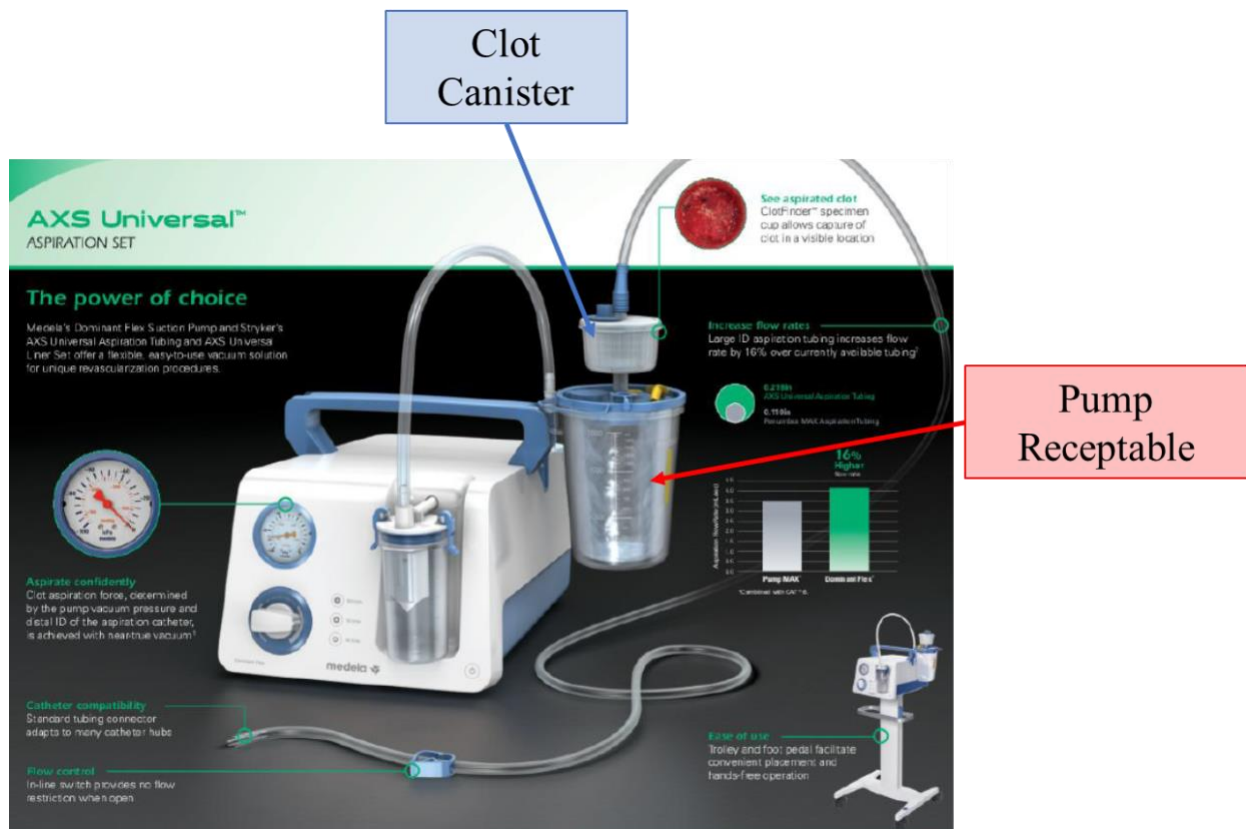
Ex. 1020 (Brady) at 21:16-22:24, Fig. 23A.

2. Laub and Aklog

159. A person of ordinary skill in the art would have had a binary choice – either select a clot canister having a volume larger than the pump volume or visa versa. A person of ordinary skill in the art would have found it obvious to try either, predictable configuration. The optimal configuration would be dictated by the anticipated amount of clot and blood being withdrawn from the patient. Laub discloses the use of pumps with its aspiration system that are capable of generating from 0 to -400mmHg of pressure and/or a flow rate of up to 5000mL/min. Ex. 1012 (Laub) at [0042]-[0043].) Aklog discloses that its system can be used with “any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood.” Ex. 1005 (Aklog) at 11:62-12:14. Most commercial pumps would aspirate larger amounts of blood than clot during a typical procedure, as demonstrated by Laub’s volumetric flow rate. Thus, a person of ordinary skill in the art would have found it obvious to use an aspiration source with Laub’s or Aklog’s systems that had a volume greater than the volume of Laub’s/Aklog’s clot canister to accommodate the volume of aspirated blood.

160. One example of a commercially available aspiration pump in August 2018 was the Penumbra Pump Max, which used a 1000mL canister. Ex. 1038 (Indigo Aspiration System). Another aspiration pump that was commercially

available in August 2018 was the Medela Dominant Flex Suction Pump, which used a 1500mL canister and could provide suction up to -95kPa (-712.558mmHg). Ex. 1039 (AXS Universal Aspiration Brochure). The AXS Universal Aspiration set that was used with the Medela pump included a clot canister that had a smaller volume than the pump canister:



See id. In addition, VacLok Negative Pressure syringes were commercially available prior to August 2018 at volumes up to 60mL. Ex. 1040 (VacLok Brochure); Ex. 1041 (Nikoubashman) at 906. Thus, aspiration sources with larger volumes than a clot canister used with the pump were not novel in August 2018.

161. A person of ordinary skill in the art would have found it obvious to use a clot canister in Laub's or Aklog's systems that had a volume that was smaller than the above volumes of commercially available aspiration sources, which ranged from 60-1500mL. A person of ordinary skill in the art would have recognized that the clot canister in Laub's and Aklog's systems does not require a large volume. Rather, the volume of the clot canister needs to only be large enough to filter and collect the aspirated clot material. A person of ordinary skill would recognize that the volume required to do so would typically be far less than the 60mL-1500mL volumes commonly used in commercially available aspiration sources in August 2018. For example, as I noted above, Aklog discloses that its system is designed to aspirate clot material of at least 10cm³, a significantly smaller volume than the 60-1500mL volumes for commercially available aspiration sources. Ex. 1005 (Aklog) at 11:18-20.

K. Claim 18

162. Claim 18 recites the "method of claim 1 wherein advancing the aspiration catheter comprises inserting through the vasculature an aspiration catheter having a size of 16 French or greater and an inner diameter, and wherein the fluid path from the aspiration catheter through the valve to the clot canister has a diameter that is the same as or greater than the inner diameter." In my opinion,

Laub or Aklog combined with Garrison, and Garrison combined with Laub or Aklog renders Claim 18 obvious.

1. Laub

163. 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 further discloses that its system “includes a fluid path 250 that places aspiration catheter 200 in fluid communication with inlet port 410 of pump 400.” *Id.* at [0039]. Laub explains that the fluid path may be an elongate tube that is integral with or separable from the aspiration catheter. *Id.*

164. Laub does not expressly disclose the diameter of the fluid path. However, in my opinion, a person of ordinary skill in the art would have been motivated to use a tube for Laub’s fluid path having a diameter that is at least the same size or larger than the aspiration catheter. A person of ordinary skill in the art would have been motivated to do so to maximize the flow rate of aspirated blood through the fluid path. A person of ordinary skill would have recognized that if the flow path through the tube had a narrower diameter than the aspiration catheter, the downsizing from the aspiration catheter to the fluid path could restrict the flow rate through the fluid path and ultimately impact the suction at the end of the catheter. In addition, a person of ordinary skill in the art would have been further motivated to use tubing to connect the catheter to the clot canister and other portions of the

device having at least the same size as the catheter to avoid choke points within the system. A person of ordinary skill would have recognized that if the tubing had a smaller inner diameter than the aspiration catheter, then aspirated clot material might get stuck within and/or clog the tubing. This would render the system ineffective, and it could be easily avoided by using tubing for the flow path having the same or greater diameter as the aspiration catheter.

165. A person of ordinary skill in the art would have reasonably expected success in using tubing having an inner diameter at least as great as the inner diameter of the catheter. A primary objective of an aspiration system is to aspirate blood clot through the catheter and tubing to some sort of receptacle. If the inner diameter of the tubing is at least as large as the catheter, the user can be reasonably confident that aspirated clot can flow through the tubing to the receptacle without getting stuck. Further, the person of ordinary skill in the art had only two options – either the inner diameter of the tubing is larger or smaller than the catheter inner diameter. For all of the above reasons, a person of ordinary skill in the art would have found it obvious to try using tubing with an equal or larger inner diameter to that of the catheter.

2. Aklog

166. A person of ordinary skill in the art would have found it obvious to use an aspiration catheter having a diameter of at least 16Fr with Aklog's system for

the same reasons I explained previously for Claim 2. *Supra* §VI.B.2. Aklog discloses that its filter is in fluid communication with the aspiration catheter. Ex. 1005 (Aklog) 11:24-26. A person of ordinary skill in the art would have been motivated to use tubing to connect the aspiration catheter with the filter having at least the same or greater diameter as the aspiration catheter for the same reasons that I explained in the preceding section for Laub. *Supra* §VI.K.1.

3. Garrison

167. Laub and Aklog disclose or render obvious aspirating PE with catheters having a size 16 Fr. or greater. *Supra* §§VI.B.1-2. 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 for at least the reasons I explained previously for Claim 1. *Supra* §§VI.A.1.c-d. Garrison's filter is in fluid communication with the aspiration catheter. Ex. 1006 (Garrison) [0131]-[0134], Figs. 33-34. Garrison also discloses that "the connection to the flow line is optimized for aspiration of thrombus with flow lumens at least as large as the ID of the arterial access device 2010. *Id.* at [0059]. A person of ordinary skill in the art would have been motivated to use tubing to connect the aspiration catheter with the filter having at least the same or greater diameter as the aspiration catheter for the same reasons that I explained in the preceding section for Laub. *Supra* §VI.K.1.

L. Claim 19

168. Claim 19 recites the “method of claim 1 wherein the aspiration source has a volume of 60 cubic centimeters or greater.” In my opinion, Laub or Aklog combined with Garrison, and Garrison combined with Laub or Aklog renders Claim 19 obvious.

169. Laub discloses that its system can be used with pumps capable of generating from 0 to -400mmHg of pressure and/or a flow rate ranging from 100mL/min to 5000mL/min. Ex. 1012 (Laub) at [0042]-[0043]. Aklog discloses that its system can be used with “any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood.” Ex. 1005 (Aklog) at 11:62-12:14. Garrison discloses that aspiration for its system “may be done manually, with an aspiration pump, or with another aspiration source, or via the flow controller as described above.” Ex. 1006 (Garrison) at [0165]. Garrison further discloses that “[e]xamples of devices for active reverse flow are a syringe or other manual aspiration device, or an aspiration pump.” *Id.* at [0072]; *see also id.* at [0134].

170. Given the above disclosures of Laub, Aklog, and Garrison, as well as their knowledge of commercially available aspiration pump and syringes in August 2018, a person of ordinary skill in the art would have found it obvious to use an aspiration source with Laub’s, Aklog’s, or Garrison’s systems that had a volume of

60cc or greater. For example, a person of ordinary skill in the art would have understood that if a flow rate of 100mL/min was used (the lowest rate disclosed in Laub), an aspiration source volume of 60cc would be entirely filled after only roughly 35 seconds of aspiration. A person of ordinary skill in the art would have therefore been motivated to use a larger volume for the aspiration source to avoid filling the maximum volume so quickly. Also, as I explained previously for Claim 16, there were commercially available aspiration pumps and syringes prior to August 2018 having volumes ranging from 60-1500mL (i.e., 60-1500cc). *Supra* §VI.J.2. A person of ordinary skill in the art would have been motivated to use those commercially available pumps with Laub's, Aklog's, or Garrison's systems for the same reasons I explained for Claim 16.

M. Claims 20-24, 28-29, 33-35, 37-38

171. Claims 20-24, 28-29, 33-35, and 37-38 of the '333 patent are directed to a method of treating deep vein thrombosis instead of pulmonary embolism, but they otherwise recite the same method steps and limitations as Claims 1-5, 9-10, 14-16, and 18-19. In my opinion, Laub or Aklog combined with Garrison, and Garrison combined with Laub or Aklog renders Claims 20-24, 28-29, 33-35, and 37-38 obvious.

172. Both Laub and Aklog disclose that their aspiration systems can be used to treat DVT. Garrison combined with Laub or Aklog also renders the method of

treating DVT obvious. Laub, Aklog, and Garrison disclose or render obvious the remaining limitations of Claims 20-24, 28-29, 33-35, and 37-38 of the '333 Patent for the reasons I explained previously for Claims 1-5, 9-10, 14-16, and 18-19.

1. Laub

173. Laub states that its system is suitable for “removing thrombi and other unwanted material from the body of a patient, particularly from the patient's vasculature.” Ex. 1012 (Laub) at [0005]. Laub further states that its “aspiration catheter 200 may be positioned to aspirate blood from a patient's vein (e.g., right common femoral vein) during use.” *Id.* at [0025]. The right common femoral vein is a common location for DVT. Thus, a person of ordinary skill in the art would have recognized that aspirating clot material from a patient’s right common femoral vein is a method of treating DVT.

2. Aklog

174. Aklog discloses systems and methods for removing clot material from various parts of the patient’s vasculature, including “systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins).” Ex. 1005 (Aklog) at 7:32-37; *see also id.* at 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7. Aklog further discloses that its system can be used to remove material from, *inter alia*, the “deep veins of the pelvic, legs, arms or neck.” *Id.* at 15:38-45. Thus, Acklog discloses methods of treating DVT.

3. Garrison and Laub or Aklog

175. A person of ordinary skill in the art would have been motivated to adapt Garrison's aspiration system, with any necessary optimizations, to treat DVT in view of Laub and Aklog, and they would have reasonably expected success in doing so, for the same reasons I explained previously for Claim 1 and pulmonary embolisms. *Supra* §VI.A.1.c-d. Accordingly, Garrison in combination with Laub or Aklog renders Claims 20-24, 28-29, 33-35, and 37-38 obvious.

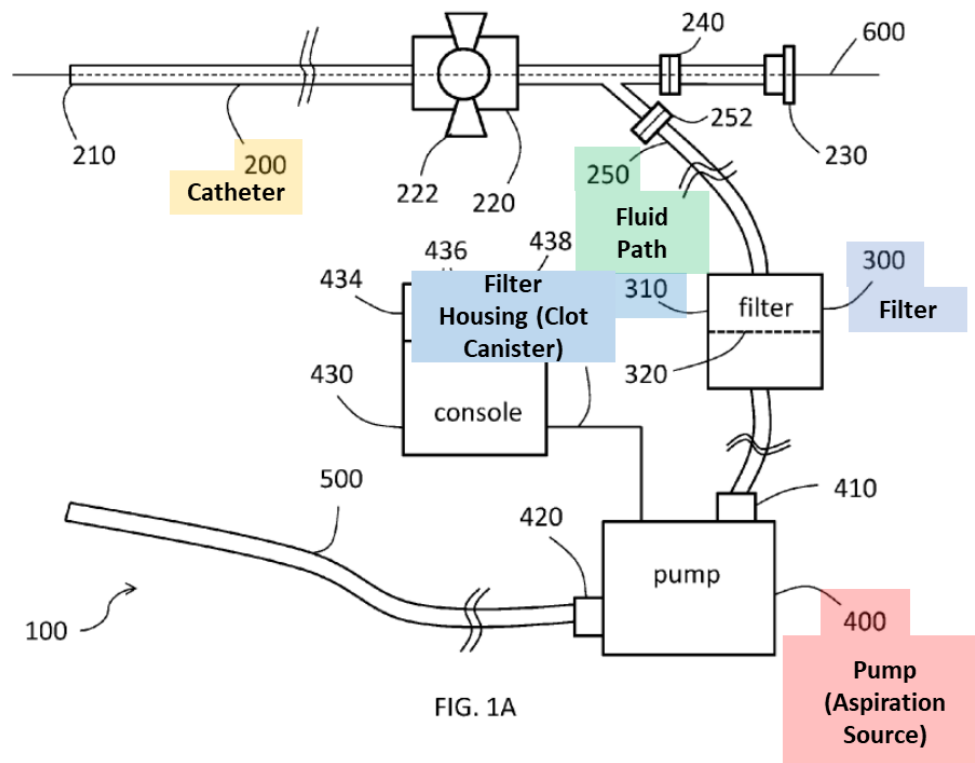
VII. GROUND 1B, 2B, 3B, 4B – LAUB, AKLOG, AND GARRISON WITH GOFF

A. Claim 6

176. Claim 6 recites the “method of claim 1 wherein the method further comprises removing the filter from within the clot canister.” In my opinion, Laub or Aklog combined with Garrison and Goff and Garrison combined with Laub or Aklog and Goff renders claim 6 obvious.

1. Laub

177. Laub discloses that its system includes a filter 300 with a housing 310 (clot canister) and a separator 320 (filter) “configured to separate the solid materials from the aspirated blood.”



Ex. 1012 (Laub) at [0040], Fig. 1A. Laub explains that the separator “may be a screen, mesh, membrane, etc.” *Id.* Laub further discloses that once aspirated blood passes through the filter, “the solid materials collected within housing 310 of filter 300 can then be subsequently disposed of or retrieved for additional analysis.” *Id.* at [0040]. Laub does not expressly disclose how the solid material is retrieved from the filter housing. But a person of ordinary skill in the art would have recognized that the filter housing must be opened to dispose of or retrieve the solid material.

2. Aklog

178. Aklog discloses that its aspiration system includes a filter device 14 (clot canister) with a permeable sheet 143 positioned within the device between the inlet and outlet ports:

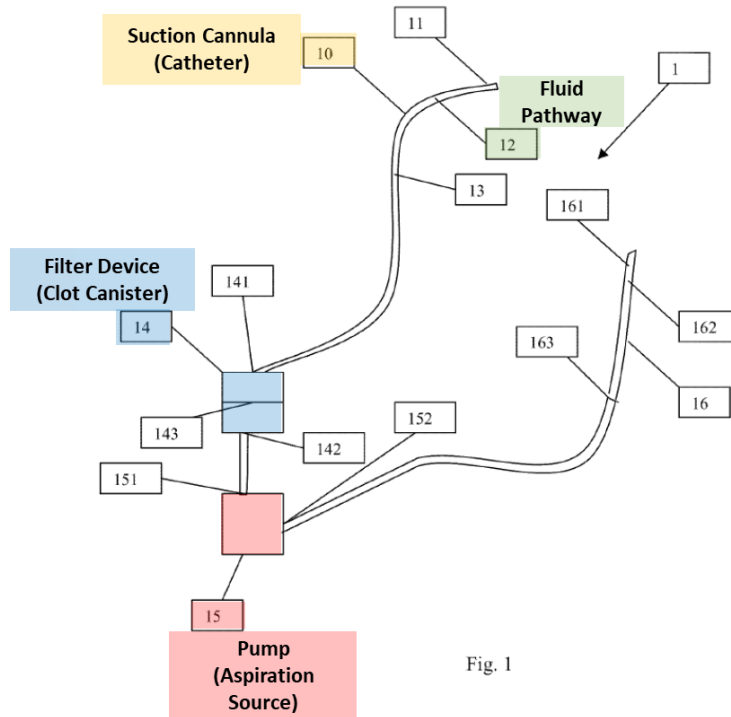


Fig. 1

Ex. 1005 (Aklog) at 11:24-35. Aklog explains that the permeable sheet may be “coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material.” *Id.* at 11:40-45. Aklog further states that “filter device 14 may be provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough.” *Id.* at 11:54-57.

3. Garrison

179. Garrison discloses a filter 3418 within a clot canister for removing unwanted material from the blood.

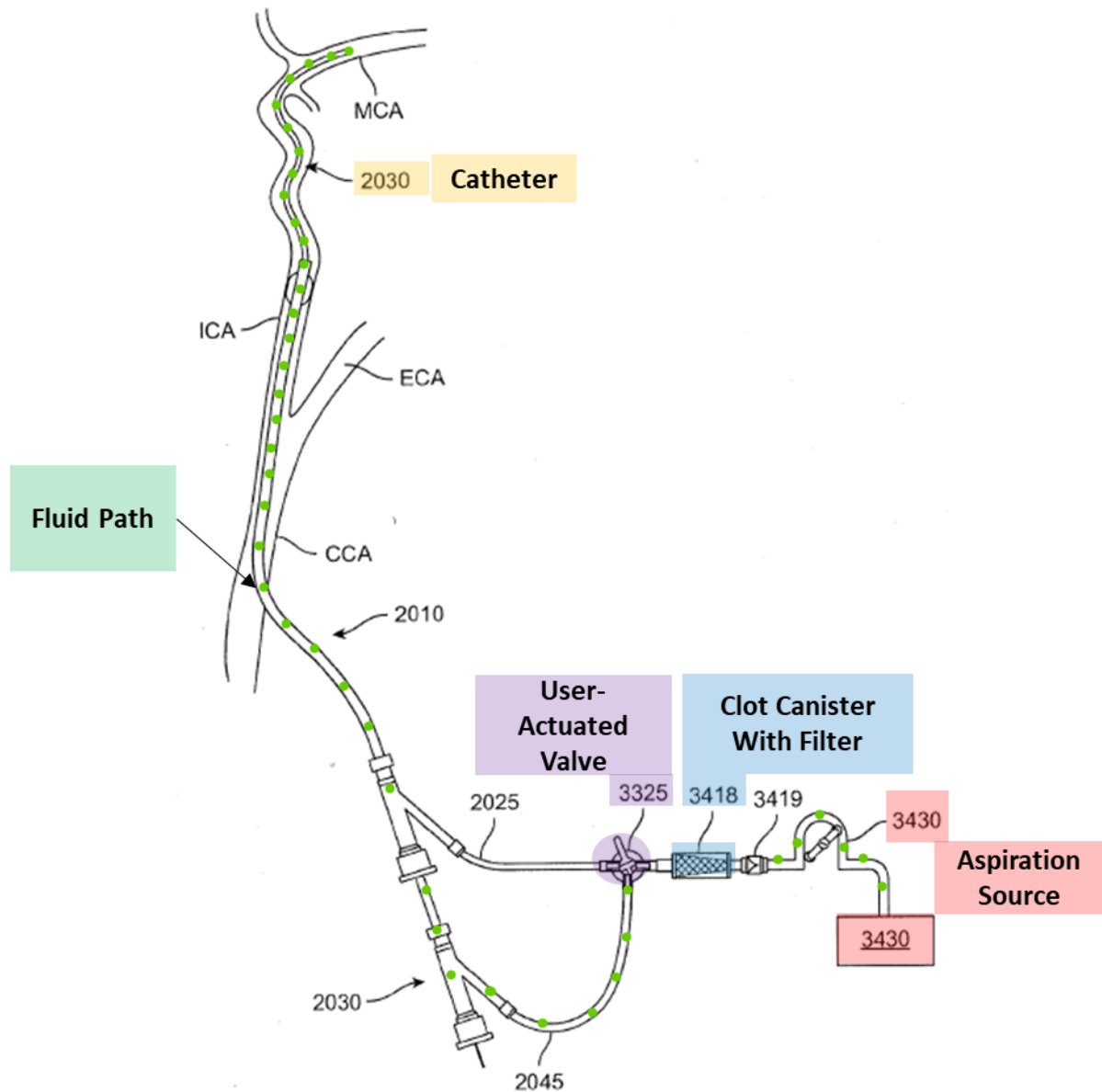


FIG. 34

Ex. 1006 (Garrison) at $[01\bar{3}1]$, Fig. 34.

4. Goff

180. Laub, Aklog, and Garrison do not expressly state that their filters are **removable** from their filter housing/canisters. However, in my opinion, a person of ordinary skill in the art in August 2018 would have found it obvious to include a removable filter in Laub's, Aklog's, and Garrison's systems based on Goff.

181. Goff is titled "methods and systems for filtering aspirated material." Ex. 1007 (Goff) at Title. Goff explains that its aspiration system includes a "filter housing 18 ... between the aspiration catheter 12 and the aspirate receptacle 14":

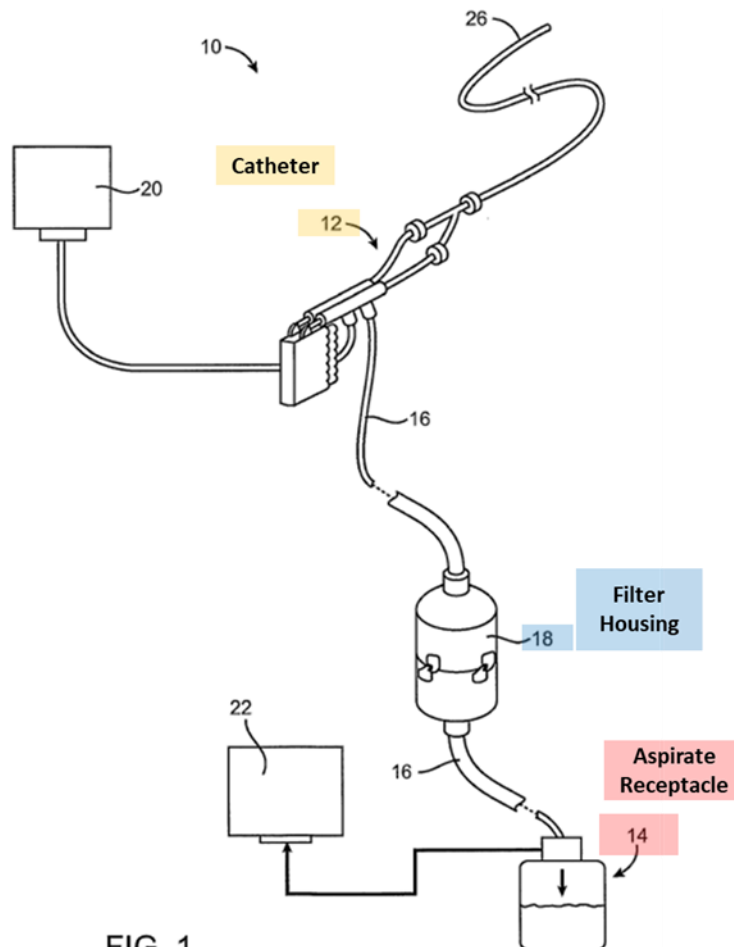
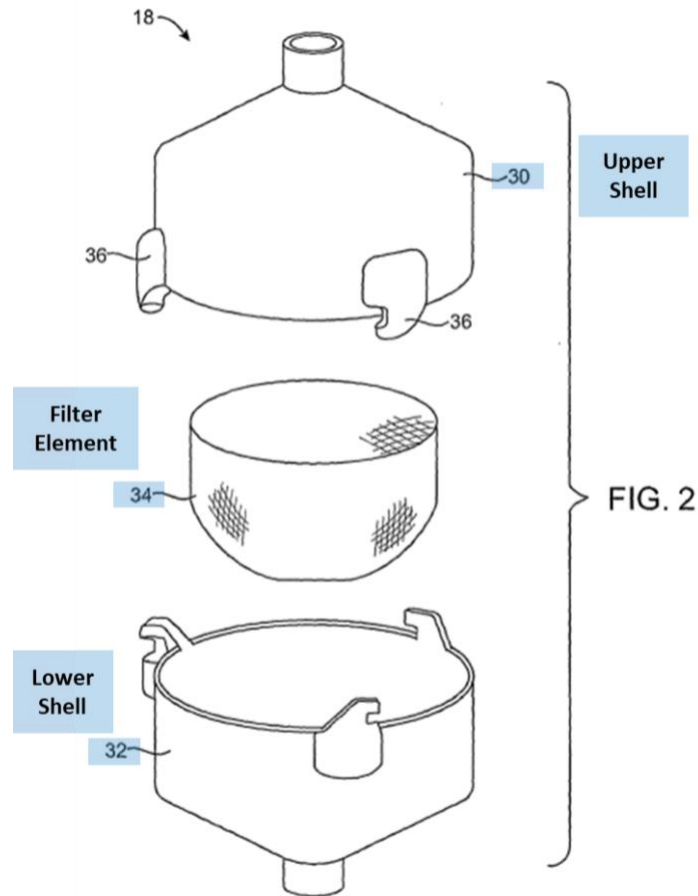


FIG. 1

Id. at [0025], Fig. 1.

182. Goff explains that the “filter assembly 18 typically comprises an upper shell 30, a lower shell 32, and a filter element 34 which may be disposed within the interior of the shells”:



Id. at [0025], Fig. 2. Goff also explains that “the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing.” *Id.* at [0015]. Goff discloses that its filter forms a structure allowing “the separated solid materials [to] be in a convenient structure or assembly to permit easy removal and observation.” *Id.* at [0005].

183. Goff would have motivated a person of ordinary skill in the art to include a removable filter in Laub's, Aklog's, or Garrison's systems so that the physician could retrieve samples, empty the housing, and clean or replace the filter. Even if the filter housings/clot canisters in Laub, Aklog, or Garrison were not already openable, Goff would have motivated a person of ordinary skill in the art to configure the filter housing/canister so that it could be opened to permit this removal or cleaning. Filter housings/canisters that could be unscrewed (left) or unclasp(ed) (right) were well known, as illustrated in Goff and Figures 7-9 of the Tretola reference below:

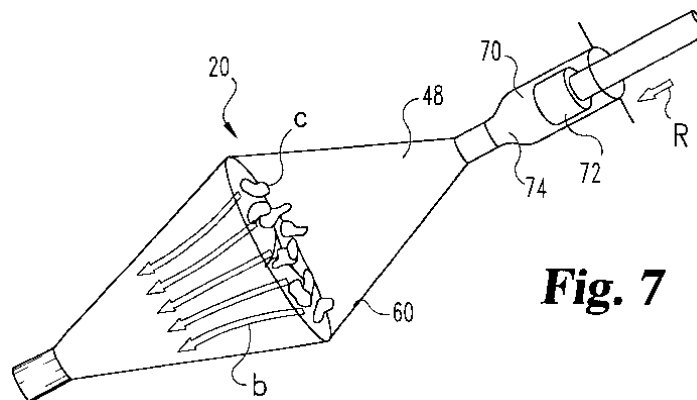


Fig. 7

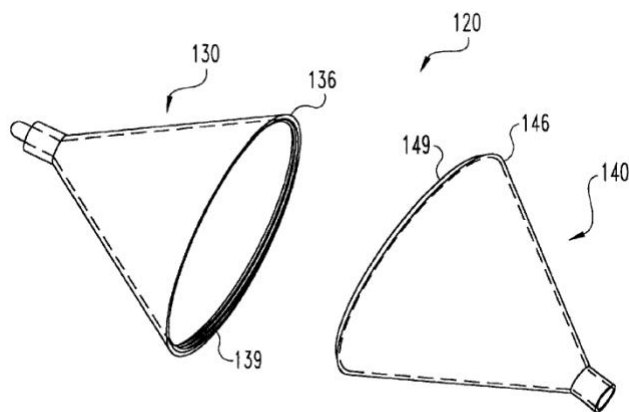


Fig. 8

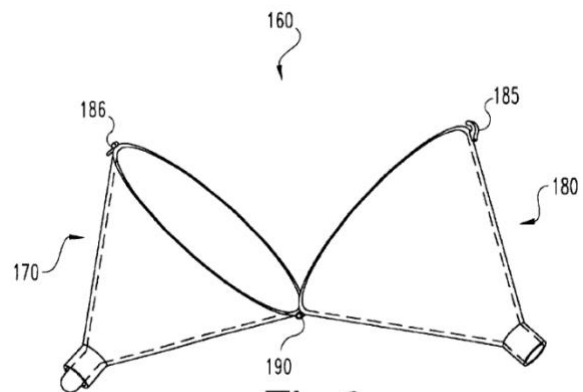


Fig. 9

Ex. 1009 (Tretola) at 5:65-6:10, Figs. 7-9. A person of ordinary skill in the art would have recognized that the parts needed to create a removable filter that could be used in Laub, Aklog, or Garrison would have been simple and predictable mechanical parts such as hinges, clips, interlocking tabs, or screw threads. These types of simple and predictable parts would have been well understood by a person of ordinary skill in the art in August 2018. Thus, a person of ordinary skill in the art would have reasonably expected success in designing Laub, Aklog, or Garrison to have a removable filter.

184. Alternatively, it is my opinion that a person of ordinary skill in the art would have been motivated to simply substitute Goff's removable filter for the filters in Laub, Aklog, or Garrison. Goff's filter is used for the same purpose as the filters in Laub, Aklog, and Garrison – filtering clots from aspirated blood. Ex. 1007 at [0001]. Goff's filter is also positioned between the aspiration catheter and the pressure source with standard medical tubing, like the filters in Laub, Aklog, and Garrison's. *Id.* at [0025]. Thus, substituting Goff's filter for Laub's, Aklog's, or Garrison's filter would have merely entailed the substitution of one known elements (Goff's filter) for another (Laub's, Aklog's, or Garrison's filter) to yield the predictable result of filtering aspirated blood.

185. Moreover, the similarities between the filters in Goff and Laub/Aklog/Garrison would have given a person of ordinary skill in the art a

reasonable expectation of success that Goff's filter could be incorporated into Laub's, Aklog's aspiration systems. For example, Goff discloses that its "filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff," the same requirement for Laub's, Aklog's, and Garrison's filter (or any aspiration filter). Ex. 1007 (Laub) at [0011].

186. For these reasons, it is my opinion that Laub or Aklog or Garrison in combination with Goff renders Claim 6 obvious.

B. Claim 7

187. Claim 7 recites: "The method of claim 1 wherein the method further comprises removing the portion of the pulmonary embolism from within the clot canister." In my opinion, Laub or Aklog combined with Garrison and Goff and Garrison combined with Laub or Aklog and Goff renders claim 7 obvious.

188. As I explained for Claim 6 above, Goff discloses a removable filter that allows for the clot material to be "easily observed and optionally removed from the aspiration circuit even while the aspiration protocol continues." Ex. 1007 (Goff) at [0007]; *supra* §VII.A.4. Goff states that the collected clot material "could be used to diagnose certain disease states or conditions." (*Id.*, [0033].) Laub similarly discloses that clot material may be retrieved from its filter for additional analysis. Ex. 1012 (Laub) at [0040].

189. It is my opinion that a person of ordinary skill in the art would have been motivated to remove the aspirated clot material (e.g., PE or DVT) from Laub's, Aklog's, and Garrison's filters (or Goff's filter if it were substituted for the existing filters) based on Goff's teachings that such removal allows for physicians to "diagnose certain disease states or conditions." Ex. 1007 (Goff) at [0033]. A person of ordinary skill in the art would have also been motivated to remove the aspirated clot material so the filter could be used again to extract additional clot material without becoming clogged.

C. Claim 8

190. Claim 8 depends from Claim 7 and recites the following additional method steps: (1) "after removing the portion of the pulmonary embolism from within the clot canister, positioning the filter within the clot canister"; (2) "repeating generating vacuum pressure within the clot canister via the aspiration source while the valve is in the first position"; and (3) "repeating moving the valve from the first position to the second position thereby applying the vacuum pressure to the lumen of the aspiration catheter to aspirate at least another portion of the pulmonary embolism and additional blood into the clot canister." In my opinion, Claim 8 would have been obvious in view of Laub or Aklog combined with Garrison or Garrison combined with Laub or Aklog.

1. Laub

191. Laub and Garrison render the limitations regarding the valve with a first position and second position obvious for the same reasons I explained previously for Claim 1. *Supra* §VI.A.3-4. Laub alone and combined with Goff renders the limitations of Claim 7 obvious for the reasons I explained above. *Supra* §VII.B.

192. After removing a first portion of the PE material from the clot canister, a person of ordinary skill in the art would have been motivated to repeat the aspiration steps taught by Laub and Garrison to remove a second portion of the PE if it remained in the patient's vasculature. A person of ordinary skill in the art would have known that if a portion of the PE was not removed from the patient, the remaining portion could lead to additional, serious health risks such as additional PE. *See, e.g.*, Ex. 1012 (Laub) at [0004]. Moreover, Garrison discloses that its aspiration system can be used for repeated aspiration of multiple different clots. *See e.g.*, Ex. 1006 (Garrison) at [0166] ("if a second 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"). Garrison's disclosure that its system can be used for repeated aspiration procedures would have provided a person of ordinary skill in the art with a reasonable expectation of success that the Laub's

system with Garrison's valve could be used for repeated aspiration of two portions of a PE.

2. Aklog

193. Aklog and Garrison render the limitations regarding the valve with a first position and second position obvious for the same reasons I explained previously for Claim 1. *Supra* §VI.A.3-4. Aklog alone and combined with Goff renders the limitations of Claim 7 obvious for the reasons I explained above. *Supra* §VII.B.

194. A person of ordinary skill in the art would have been motivated to repeat the aspiration steps taught by Aklog and Garrison to remove a second portion of the PE for the same reasons I explained in the preceding section for Laub. *Supra* §VII.C.1. In addition, Aklog discloses that its aspiration system may "be employed to remove a plurality of undesirable materials," including separate clots within the same or different vessels. Ex. 1005 (Aklog) at 18:7-13. Aklog explains that after the first clot material is removed, "the suction force may be deactivated" while the suction cannula is positioned to the location of the second clot. *Id.* at 18:13-20. Once in position, the suction force is reapplied until the second clot is removed. *Id.* Thus, Aklog's system is capable of applying repeated aspiration to retrieve multiple pieces of clot material from a patient's vasculature. A person of ordinary skill in

the art would have therefore reasonably expected success in using Aklog's system with Garrison's valve for repeated aspiration of two portions of a PE.

3. Garrison

195. Garrison combined with Laub or Aklog renders the limitations regarding the valve with a first position and second position obvious for the same reasons that I explained for Claim 1. *Supra* §VI.A.3-4. Garrison alone and combined with Goff renders the limitations of Claim 7 obvious for the reasons I explained above. *Supra* §VII.B.

196. A person of ordinary skill in the art would have been motivated to repeat the aspiration steps taught by Garrison to remove a second portion of the PE for the same reasons I explained above for Laub. *Supra* §VII.C.1. Moreover, Garrison discloses that its aspiration system can be used for repeated aspiration of multiple different clots. *See e.g.*, Ex. 1006 (Garrison) at [0166] ("if a second 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"). Garrison's disclosure that its system can be used for repeated aspiration procedures would have provided a person of ordinary skill in the art with a reasonable expectation of success that the Garrison's system could be used for repeated aspiration of two portions of a PE when combined with Laub or Aklog.

D. Claim 17

197. Claim 17 recites the “method of claim 1 wherein the filter has a generally tubular shape.” In my opinion, Laub or Aklog combined with Garrison and Goff and Garrison combined with Laub or Aklog and Goff renders Claim 17 obvious.

1. Garrison

198. Garrison’s filter 3418 has a generally tubular shape as illustrated in Figure 34:

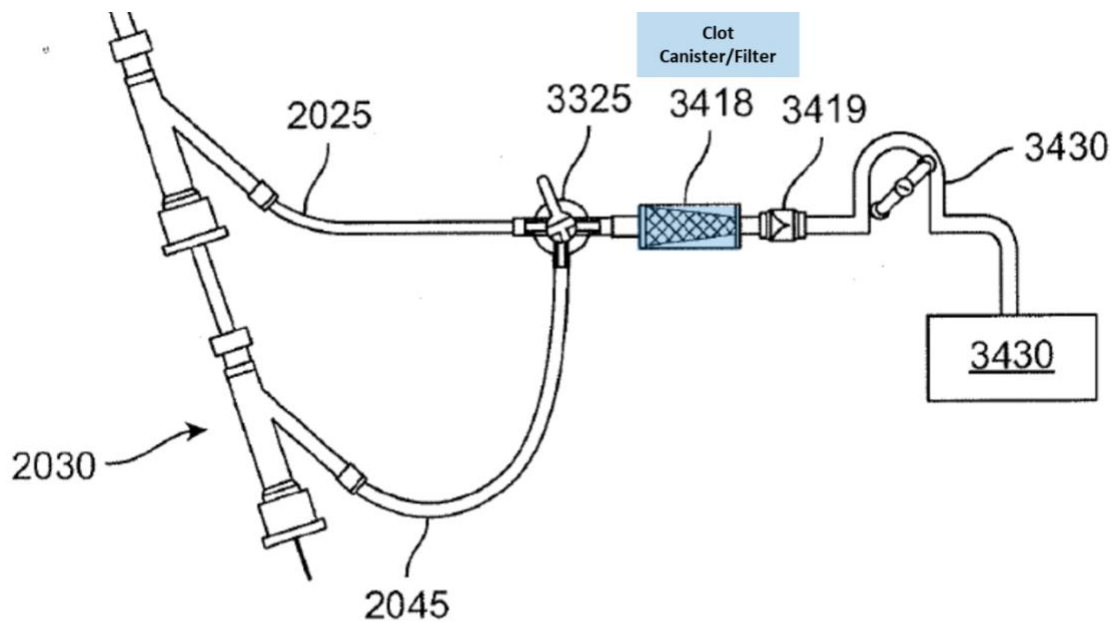
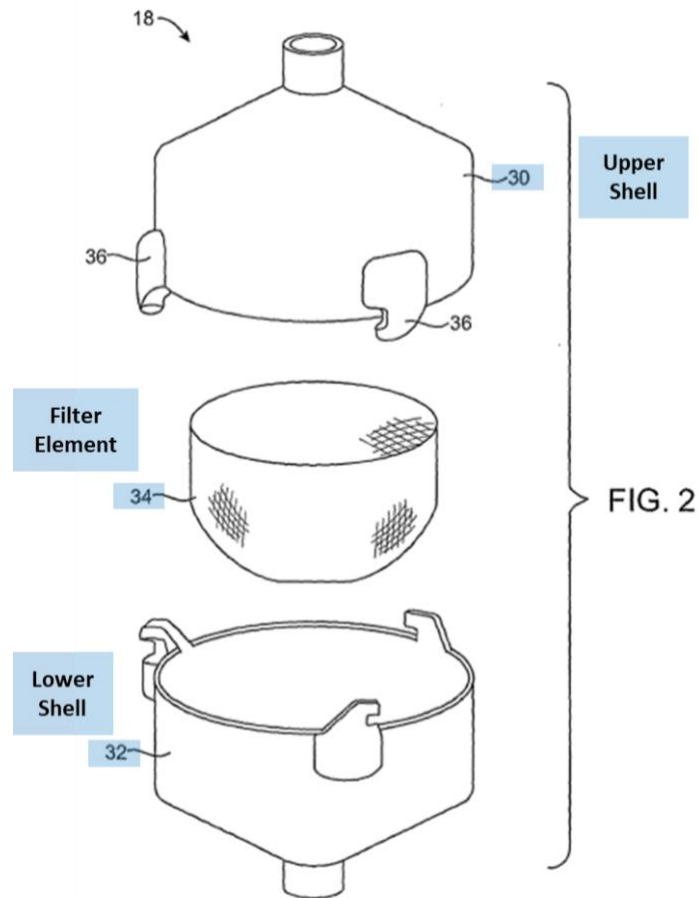


FIG. 34

Ex. 1006 (Garrison) Fig. 34.

2. Goff

199. Goff’s filter element 34 is tubular-shaped, and Goff’s filter housing 18 also forms a tubular shape:



Ex. 1007 (Goff) at [0015], [0025], Fig. 2. A person of ordinary skill in the art would have been motivated to substitute Goff's filter for the filter in Laub's, Aklog's, and Garrison's systems, and they would have reasonably expected success in doing so, for the same reasons I explained previously for Claim 6. *Supra* §VII.A.

E. Claims 25-27 and 36

200. Claims 25-27 and 36 repeat the limitations in Claims 6-7 and 17 with the exception that Claim 26 specifies that a portion of a DVT, as opposed to a PE, is removed from the filter. As I explained previously for in Claim 7, Goff discloses removing the clot material captured by the filter, regardless of the type of clot, and

a person of ordinary skill in the art would have been motivated to remove the captured portion of a PE or DVT in view of Goff.

201. Accordingly, it is my opinion that Laub or Aklog in combination with Garrison and Goff and Garrison with Laub or Aklog and Goff renders Claims 25-27 and 36 obvious for the reasons I previously explained for Claims 6-8 and 17.

Supra §§VII.A-D

VIII. GROUNDS 1C-1D, 2C-2D, 3C-3D, 4C-4D – LAUB, AKLOG, AND GARRISON WITH SCHAFFER AND OPTIONALLY HARTLEY

A. Claim 11

202. Claim 11 recites: “The method of claim 10 wherein selectively providing fluid access to the lumen of the aspiration catheter includes decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.” In my opinion, Claim 11 would have been obvious in view of Laub or Aklog in combination with Garrison and Schaffer and optionally Hartley. Claim 11 would also have been obvious in view of Garrison in combination with Laub or Aklog and Schaffer and optionally Hartley.

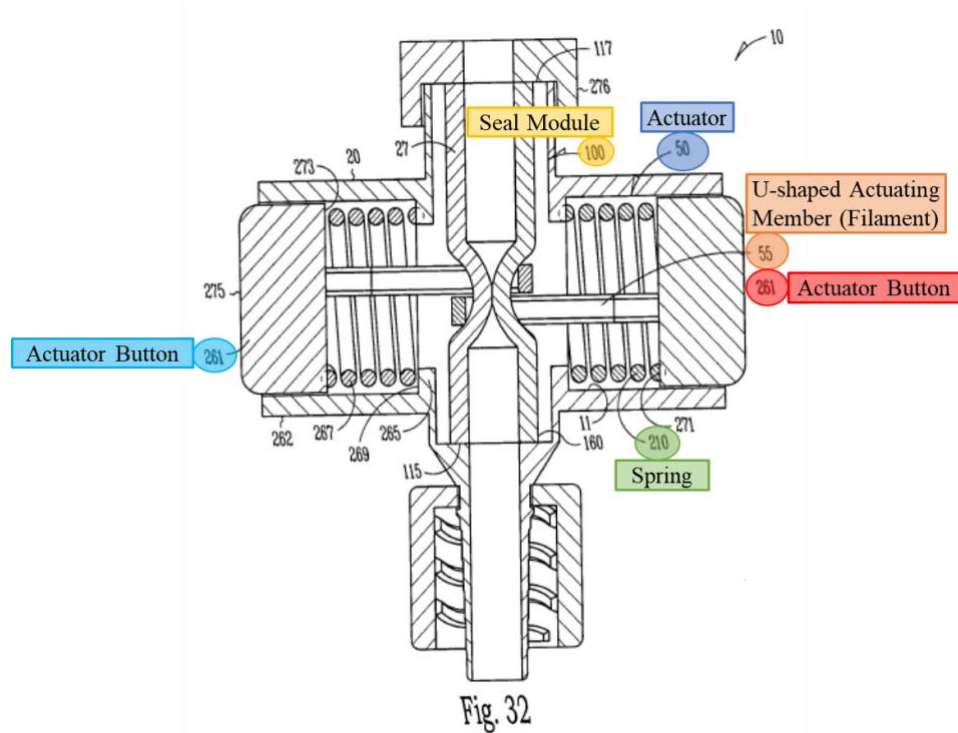
203. As I explained previously for Claim 10, Garrison discloses a hemostasis valve in its system that allows “introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” Ex. 1006 (Garrison) at [0098]; *supra* §VI.G.1.

As I also explained for Claim 10, Laub also discloses that its system can include a hemostasis valve, and a person of ordinary skill in the art would have been motivated to add Garrison's hemostasis valve to both Laub's and Aklog's systems. *Supra* §VI.G.2-3.

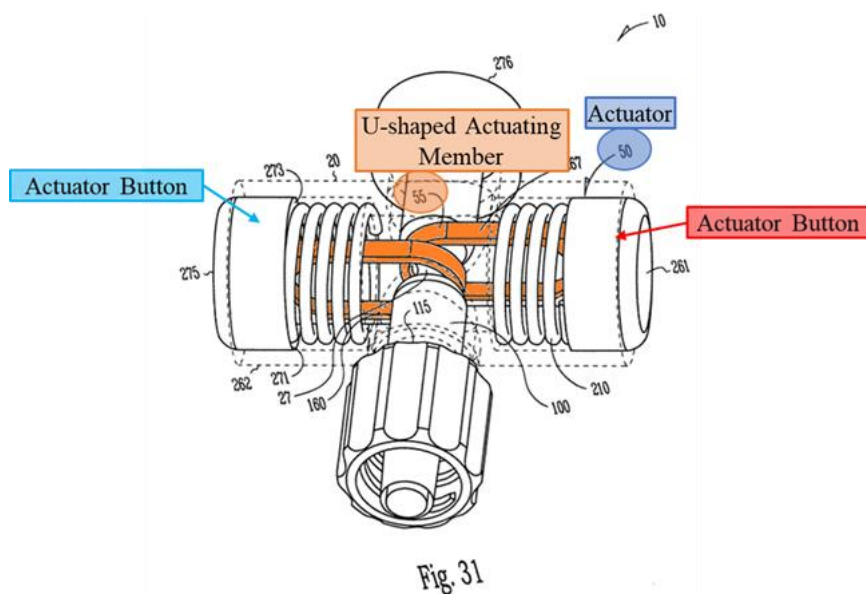
204. However, Laub, Aklog, and Garrison do not describe the details of their hemostasis valves and instead presume that a person of ordinary skill in the art would have been familiar with the available valves. As I describe in detail below, Schaffer and Hartley describe hemostasis valves that control the flow of fluid through a lumen by adjusting tension on a filament. In my opinion, a person of ordinary skill in the art in August 2018 would have found it obvious to use the hemostasis valves disclosed by Schaffer and Hartley in the aspiration systems of Laub, Aklog, or Garrison.

1. Schaffer

205. Schaffer discloses a hemostasis valve, depicted in Figures 31-34, that includes two circular actuators 50 that are “movable from a first position to a second position on opposing sides of the housing.” Ex. 1013 (Schaffer) at [0075]-[0076]. The actuators each include an actuator button 261 and a spring 210/267, as illustrated in Figure 32 below:



Id. at [0075]-[0076], Figs. 31-32. Schaffer's valve includes two actuating members, which may be U-shaped, that are coupled to the actuator buttons and constrict the valve when the buttons are undepressed:



Id. at [0076], Fig. 31.

206. Schaffer discloses a “filament,” as that term is claimed in the ’333 patent. I addressed the meaning of “filament” in the claim construction section above. *Supra* §IV. Schaffer does not describe the shape of the actuating members beyond stating that they are optionally U-shaped; however, Schaffer’s figures depict the actuating members as resembling a ribbon, flat wire, or tape, as described in the ’519 Application allegedly incorporated in the ’333 patent:

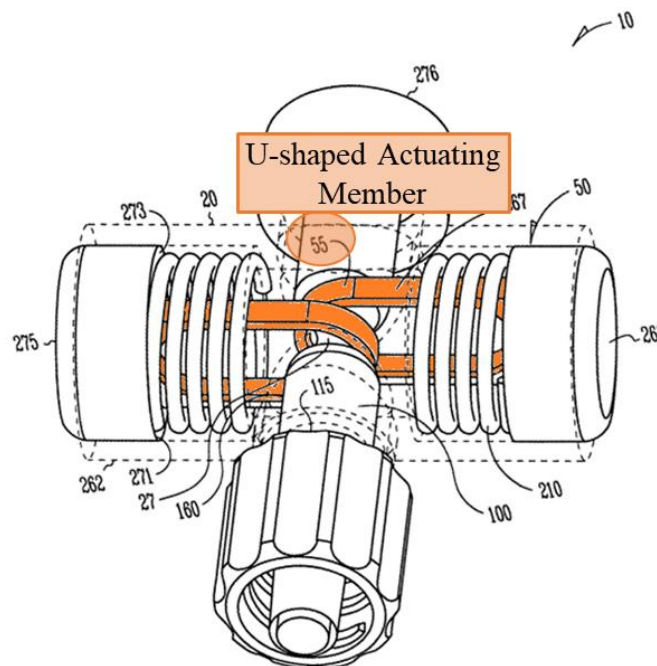


Fig. 31

Id. at Fig. 31; *see also id.* at Figs. 32-34.

207. I notice in related IPRs that Patent Owner characterizes Schaffer’s actuating members as “rigid.” Ex. 1034 (’011 patent Institution Decision) at 38; Ex. 1035 (’012 patent Institution Decision) at 32. However, Schaffer does not describe the actuating members as “rigid,” and does not provide any other

information that would suggest to a person of ordinary skill in the art that the actuating members are rigid, such as requirements for minimum or maximum dimensions or specific material properties. Thus, I see nothing in Schaffer that would require the actuating members to be “rigid.” To the contrary, a person of ordinary skill in the art would have understood that Schaffer’s U-shaped actuating members would have preferably been formed from a thin, flexible material. Such a material would have permitted the actuating members to conform, as much as possible, to the outer surface of the seal module and tool inserted through the valve. For example, not all tools inserted through the valve would have a circular profile. In those cases, U-shaped actuating members having some flexibility would better seal around the irregular shapes. A thin metallic or plastic flat wire, ribbon, or tape would have provided the flexibility required for the actuating members to best seal around tools of various shapes and sizes.

208. I also note that Patent Owner has argued that the actuating members in Schaffer are “rigid” based on the following description:

“The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum.”

Id. at [0082]. However, the description that a device is “made from machining” is not dispositive of whether the finished product is rigid or flexible. In the case of aluminum, for example, if enough material is removed during machining, then the

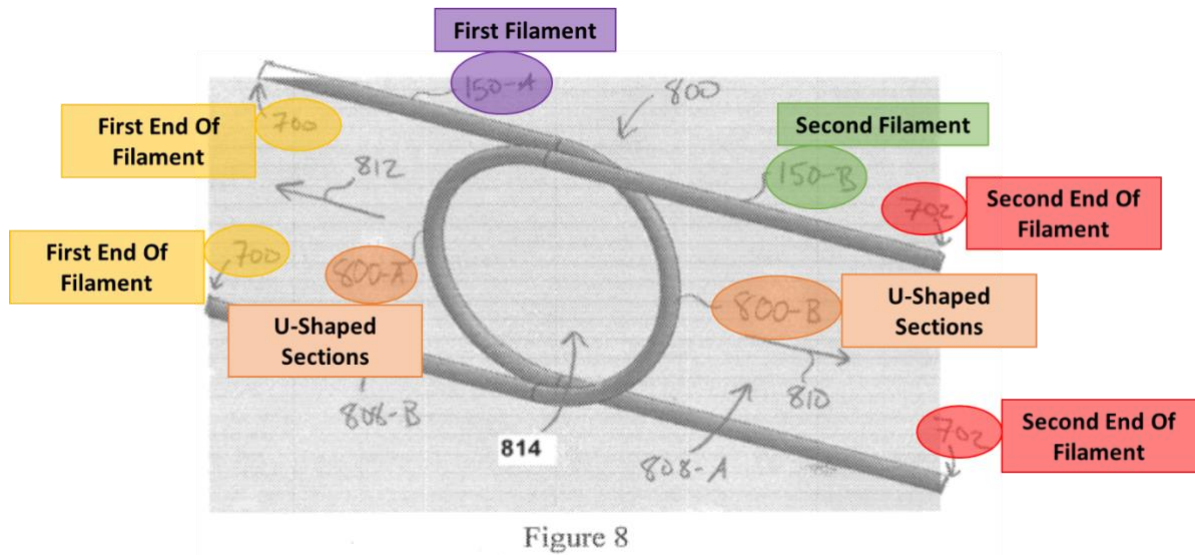
final product would not be rigid. Moreover, the description of “machining” the parts is just “one option.” A person of ordinary skill in the art would have known that the U-shaped actuating members could be made using a variety of common manufacturing techniques, including extrusion and drawing. In fact, in August 2018, a person of ordinary skill in the art could have simply purchased pre-made flat wire or plastic tapes or ribbons. Further, the actuating members in Schaffer would work if they were “flexible.” For example, if each U-shaped actuating member were formed of a small diameter wire similar to the material in a paper clip or a smaller diameter, the members would effectively collapse the tube. The members would also be flexible.

209. I note that in previous IPRs, Patent Owner has attempted to suggest that Schaffer’s actuating members behave differently from a filament because the patent says the members “forcibly disengage” the walls of the seal. I disagree. The description in Schaffer that the actuating members “forcibly disengage opposing outer walls of the seal module 100” does not mean that the actuating members do not remain in contact with the seal module. As shown in Figure 34 above, the actuating members are still in contact with the seal module 100 even after being forcibly disengaged. Rather, the term “forcibly disengage” refers to the act of applying force to the buttons to release the tension created by the actuating members on the seal module, which in turn allows the seal module “to retract to an

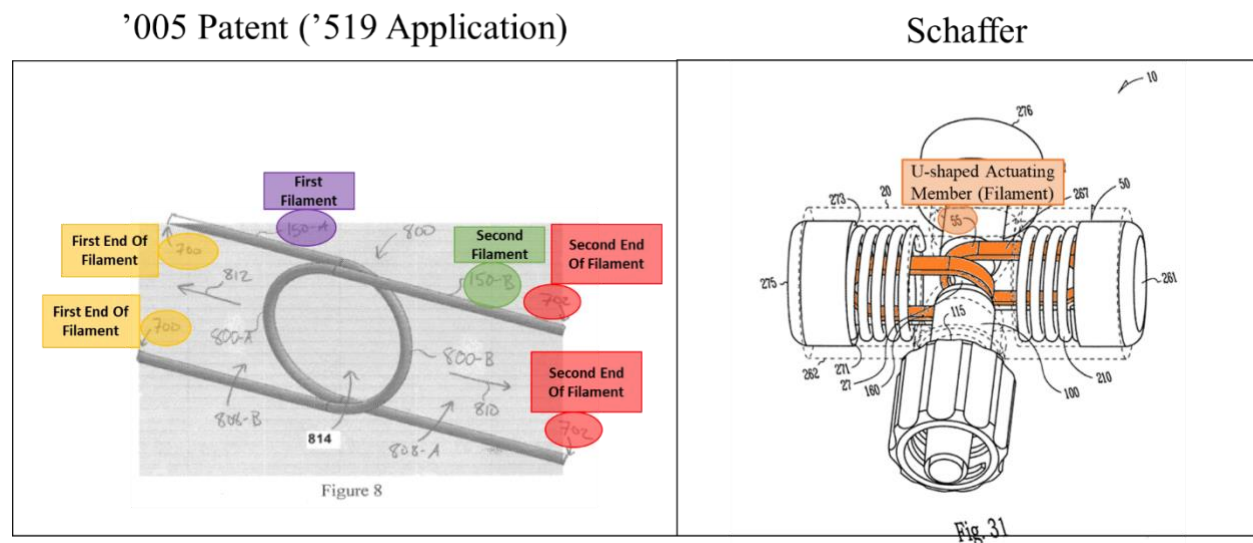
uncollapsed configuration where gases and fluids can pass therethrough.” Ex. 1013 (Schaffer) at [0077], Fig. 34. Schaffer’s actuating members move in opposition directions when force is applied to the buttons, allowing the seal module/tubular member to retract to an uncollapsed configuration, the exact same way that the ’333 patent’s filament does.

210. However, even if the Board determines that Schaffer’s actuating members were relatively rigid, a person of ordinary skill in the art would have found it obvious to use “flexible” materials to form the actuating members. A person of ordinary skill in the art would have been motivated to use a thin, flexible material so that the actuating members could conform as much as possible to the outer surface of the seal module and the tool inserted therethrough. Not all tools have a circular profile so using more flexible actuating members allows the members to more closely conform to the tools. As discussed in the sections addressing Hartley, a person of ordinary skill in the art would have reasonably expected flexible materials, like a string or wire, to work in Schaffer’s device.

211. As I explained in section III.A (Heading: “Summary of the ’333 Patent”) above, the ’519 Application also discloses that the “**the filament 150** can comprise multiple filaments,” including two filaments that have “a U-shaped section between the two ends of the filament 150,” as shown in Figure 8 from the ’519 Application:



Ex. 1021 ('519 Application) at 12:61-13:16, Fig. 8 (emphasis added). Schaffer's U-shaped actuating members have the same arrangement as that disclosed in Figure 8 of the '519 Application:



Ex. 1021 ('519 Application) at Fig. 8 (left); Ex. 1013 (Schaffer) at Fig. 31 (right). The '519 Application's explanation that the two U-shaped filaments are "*the filament 150*" confirms that Schaffer's U-shaped actuating members collectively

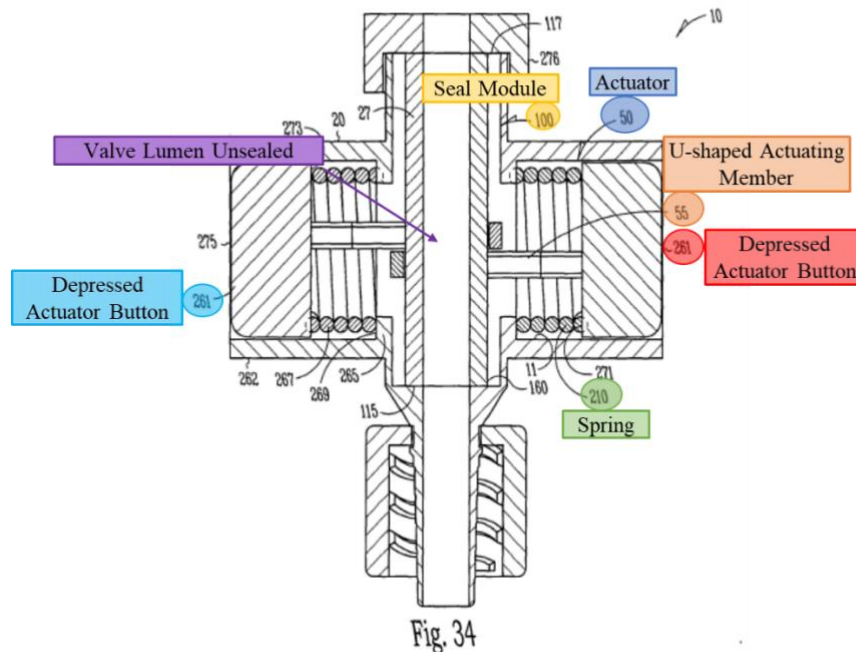
constitute “a filament” as claimed in the ’333 patent. *See* Ex. 1021 (’519 Application) at [0064] (“With reference now to FIGS. 6 through 9, different embodiments and/or configurations of the filament 150 are shown.”), [0065]-[0070], Figs. 6-9.

212. Schaffer’s hemostasis valve functions by increasing tension on the actuating members (i.e., filament) to close the valve to fluid flow and decreasing tension on the actuating members (i.e., filament) to open the valve. Schaffer discloses that in a first position, the U-shaped actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” Ex. 1013 (Schaffer) at [0077]. This position is depicted in Figure 32, which shows that the central lumen is completely constricted and sealed in the first position:

Fig. 32

- 128 -

Second Position – Actuator Buttons Depressed



Id. at [0077], Fig. 34.

213. In my opinion, a person of ordinary skill in the art would have been motivated, and found it obvious, to use Schaffer’s valve (with or without Hartley’s string) with Laub’s, Aklog’s, or Garrison’s aspiration systems for several reasons.

214. First, Schaffer discloses that its hemostasis valve is intended “for use with catheters” and provides “a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” Ex. 1013 (Schaffer) at [0002], [0008]. Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle, or fiber.” *Id.* at [0056], [0074]. Thus, Schaffer’s valve would allow for tools to be inserted through Laub’s working port 230, Aklog’s port 51, or

Garrison's proximal hub/adaptor 2065, as disclosed in those references, while preventing blood from leaking through the ports during the procedure.

215. Second, a person of ordinary skill in the art would have recognized that Schaffer's hemostasis valve could simplify the operation of Laub's, Aklog's, and Garrison's systems. For example, Schaffer's springs bias the valve to the closed position when no pressure is applied to the buttons, which would eliminate the need for the operator to manually seal or close the valve during a procedure. This feature could make the procedure simpler for the physician and save time during the procedure. A person of ordinary skill in the art would have therefore been motivated to implement Schaffer's valve in Laub's, Aklog's, or Garrison's systems to achieve this benefit.

216. Third, combining Schaffer's valve with the aspiration catheters in Laub, Aklog, or Garrison would merely entail the combination of known elements (Schaffer's valve and the aspiration catheter) according to known methods (attaching the valve to Laub's working port 230 or Aklog's port 51 or Garrison's proximal hub/adaptor 2065). This combination would yield the predictable result of preventing or minimizing blood loss and preventing the introduction of air into the catheter. Combining known elements in such a predictable fashion would have been well within the level of ordinary skill in the art in August 2018.

217. Fourth, a person of ordinary skill in the art in August 2018 had a finite number of predictable hemostasis valves to choose, including Schaffer's valve. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Laub's, Aklog's, or Garrison's systems. Moreover, the known valves, including Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. I cannot see any technical reason that a person of ordinary skill in the art would not have been able to attach Schaffer's valve to the aspiration catheters in Laub, Aklog, or Garrison. For this additional reason, a person of ordinary skill in the art would have reasonably expected success in combining any of the known valves with Laub, Aklog, or Garrison.

2. Schaffer and Hartley

218. Hartley discloses a fluid control valve that "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 [0004]. As shown in Figure 1 below, Hartley's valve includes a cylindrical valve housing that houses a "cylindrical elastomeric diaphragm," and a rotary actuator mounted onto the housing:

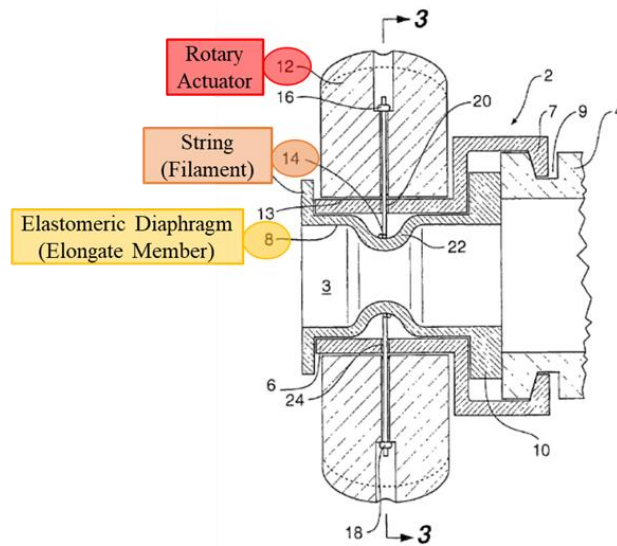


Fig 1

Ex. 1008 (Hartley) at [0031], Fig. 1. Hartley's valve also includes a "flexible member," referred to as a "string" in the Detailed Description section, that is "mounted into the rotary actuator. *Id.* at [0005], [0031]. Hartley discloses that the flexible member "may be a string, suture or band or other suitable material." *Id.* at [0017]. Hartley's flexible member is therefore a "filament" as disclosed in the '519 Application and claimed in the '333 patent because a "string" is made of at least one or more threads, lines, or cords. *See* Ex. 1021('519 Application) at [0047] (disclosing that the filament can constitute "one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape").

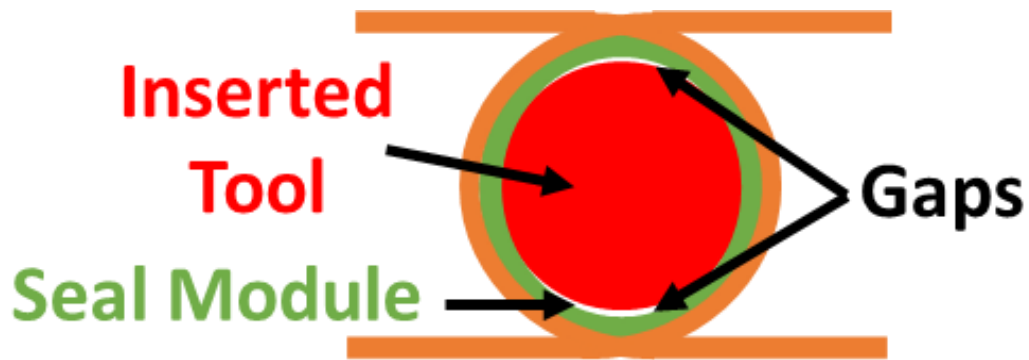
219. Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." Ex. 1008 (Hartley) at [0031], [0034], Fig. 4. Thus, Hartley's valve closes the lumen to fluid

flow by increasing tension on the filament and opens to the lumen to fluid flow by relaxing the tension. Hartley also discloses that its valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” *Id.* at [0037]. A person of ordinary skill in the art would have understood that Hartley’s ability to seal over a range of devices and to self seal when no device is passed through the valve is an important benefit for a hemostasis valve used during intravascular procedures, and it is important to minimize blood loss when a tool is inserted through the valve and before/after the tool is inserted. *See, e.g.,* Ex. 1013 (Schaffer) at [0008] (recognizing that “what is needed is a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”).

220. A person of ordinary skill in the art would have found it obvious, and been motivated to, substitute Hartley’s string/flexible member for Schaffer’s U-shaped actuating members for several reasons. First, a person of ordinary skill in the art would have been motivated by Hartley’s disclosure that its valve with the string can “close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” Ex. 1008 (Hartley) at [0037]. A person of ordinary skill in the art would have known that multiple tools of varying sizes and shapes could be required for a medical procedure, so Hartley’s ability to seal around a range of diameters/shapes would have been beneficial. A person of

ordinary skill in the art would have also recognized that a hemostasis valve should seal and prevent leakage of fluid even when no tool is inserted through the valve, such as at the beginning or end of a medical procedure. Thus, Hartley's stated ability of its string to completely close the lumen when no tool is inserted would have also been a valuable benefit to a person of ordinary skill.

221. Second, a person of ordinary skill in the art would have recognized that Hartley's flexible string may better seal the valve than Schaffer's metallic/plastic U-shaped actuating members depending on the precise dimensions, materials, and mechanical properties of the actuating members. Hartley's flexible string may better conform to varying diameters or shapes of tools inserted into the valve than Schaffer's U-shaped actuating members. For example, as I discussed above, not all tools will have a round profile and Hartley's flexible string may better conform to the tool than the U-shaped actuating members. A person of ordinary skill in the art would have recognized that if Schaffer's U-shaped actuating members were not sufficiently flexible and conformable to form a perfect seal for a wide range of tools, small gaps could form between the tool and the valve's lumen, as illustrated in the graphic below:



However, Hartley’s string encircles and, depending on the materials, may conform to the size and shape of a wider range of tools used with the valve. This ability to accommodate more tools would have been a highly desirable feature to a person of ordinary skill in August 2018.

222. I note in related proceedings that Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer’s valve with Hartley’s string because Schaffer would not result in gaps. Patent Owner Preliminary Response re: ’011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024); Patent Owner Preliminary Response re: ’012 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2025-00156, Paper 5 at 43-44 (P.T.A.B. Feb. 25, 2025). However, even Schaffer recognizes it may not form a complete seal with the “gelatinous” and “sticky” valves identified by Patent Owner, stating the valves form a “*nearly* fluid/gas tight seal.” Ex. 1013 (Schaffer) at [0059]. Further, Patent Owner argues that Schaffer’s “gelatinous” or “sticky” valve has “selfclosing” properties so it would not form any gaps. Patent Owner Preliminary Response re: ’011 patent filed

in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 29 (P.T.A.B. Oct. 29, 2024). But the portion of Schaffer that refers to a “sticky” or “gelatinous” substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a “sticky” or “gelatinous” substance having a specific “shore hardness.” Ex. 1013 (Schaffer) at [0059]. Schaffer discloses many other materials that would not be “sticky” or “gelatinous” that could make up that same portion of the valve, such as modified vinyl, silicone, or polyurethane. *Id.* Nothing in Schaffer suggests that the third valve portion must be made with a “sticky” or “gelatinous” substance. Additionally, Schaffer makes clear that the valves in Figures 31-34 do not require the third portion stating: “The seal module 100 is formed of one or more seal members, as discussed above.” *Id.* at [0075]. Further, a person of ordinary skill in the art would have recognized that the “sticky” or “gelatinous” materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must “retract to an uncollapsed configuration” when the tension on the module is released by the actuating members. A seal module made of the “sticky” or “gelatinous” materials would not easily return to its uncollapsed configuration.

223. Third, the combination of Hartley’s string and Schaffer’s valve would have merely entailed the substitution of one known element (Hartley’s string) for another (Schaffer’s U-shaped actuating members) and would have yielded the

predictable results of constricting the central lumen of Schaffer's valve to form a seal. I do not see any significant technical challenges that a person of ordinary skill would have confronted in substituting Hartley's string for Schaffer's U-shaped actuating members, and I believe that the substitution would have been well within the level of ordinary skill in August 2018.

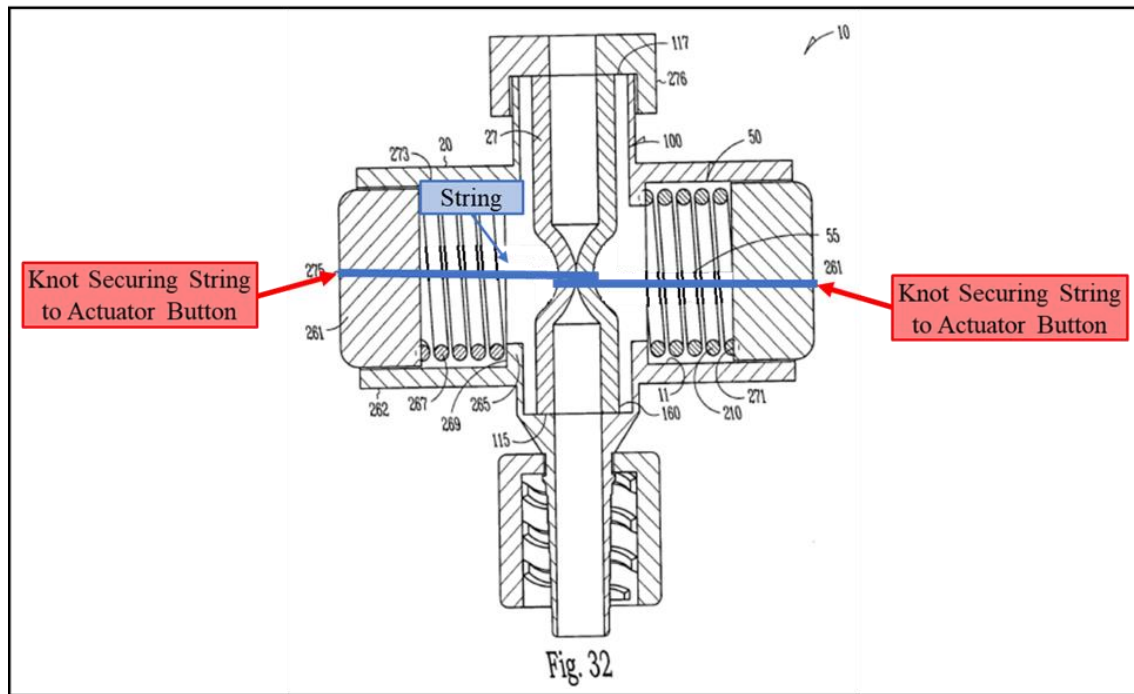
224. I note in related proceedings that Patent Owner argues that a person of ordinary skill in the art would not have combined Hartley's string with Schaffer's valve because the combination would compromise Schaffer's "ease of manufacturing and durability." Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 33 (P.T.A.B. Oct. 29, 2024). Notably, however, Schaffer does not claim to be easy to manufacture or durable. Further, as I explained during my deposition in the Litigation, Hartley's string would not have made Schaffer's valve so much more difficult to manufacture that it would have discouraged a person of ordinary skill in the art from making the combination. A person of ordinary skill in the art would have known of many ways to assemble the valve with the string. For example, a tapered fixture could be used to introduce a folded/collapsed seal module through the looped strings that are already attached to the buttons. Alternatively, the seal module could be positioned in the valve before the strings were looped around the module and connected to the buttons. Fundamentally, Schaffer's valve uses simple,

predictable components and a person of skill would have had ample training and experience to manufacture the valve using Hartley's strings. I note that neither the '333 patent nor the '519 application describes any special manufacturing procedures that would be needed to assemble a valve having a relatively flexible filament. Moreover, I see no basis for Patent Owner's argument that Hartley's strings would "weaken the valve's durability." Hartley uses the strings for the same purpose they would be used in Schaffer's valve and does not identify any issues with durability. Based on the teachings in Schaffer, a person of ordinary skill in the art would reasonably expect success in using Hartley's string in Schaffer's valve.

225. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1013 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a hemostasis valve to create a seal in August 2018. Hartley and Schaffer disclose two such methods – Hartley's single string and Schaffer's two U-shaped actuating members formed from metal or plastic. As I discuss in the following section, Eller discloses a third option: one or more wire members. A person of ordinary skill in the art in August 2018 would have found it obvious to select from these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

226. A person of ordinary skill in the art would have had reasonably expected success in substituting Hartley's string for Schaffer's U-shaped actuating members for multiple reasons. First, Hartley teaches a simple method for attaching its string to an actuator – a knot at the terminal ends of the string. Ex. 1008 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that this same method could be used to attach Hartley's string to each of Schaffer's actuator buttons. For example, small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole on the opposite buttons and knotted on the other side. This would have been a very simple modification, and a person of ordinary skill in the art would have been fully capable of implementing it in August 2018. The demonstrative illustration that I provide below depicts a basic diagram of how this modification could be achieved. As shown, the first end of the string would be secured to the first actuator button (first actuator member), the string would loop at least once around the lumen of Schaffer's valve, and then the second end of the string would be secured to the second actuator button (second actuator member) on the opposite side of the valve:

Demonstrative Illustration Schaffer + Hartley's String



227. Second, a person of ordinary skill in the art would have recognized that Hartley's string and Schaffer's U-shaped actuating members use similar mechanisms to compress and seal the central lumen of the valves, and therefore no additional modifications of Schaffer's valve would be necessary when implementing Hartley's string. Hartley's string seals the valve in response to rotation of the actuator, which causes "the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted" as shown in Figures 3 (relaxed) and 4 (constricted):

directions to constrict and compress the central lumen of the valve. *See* Ex. 1013 (Schaffer) at [0077], Ex. 1008 (Hartley) at [0031]. Moreover, both Hartley and Schaffer disclose a seal module/cylindrical diaphragm that is resilient and can resume its open position when tension is removed by pressing the buttons. For example, Schaffer discloses that its seal module is formed of a “resilient material” that will “retract to an uncollapsed configuration” when the compressive forces are removed. Ex. 1013 (Schaffer) at [0003], [0077]. Similarly, Hartley discloses that “the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens.” Ex. 1008 (Hartley) at [0008].

228. In view of the similarities between the operation of Hartley and Schaffer’s valves, a person of ordinary skill in the art would have expected Hartley’s string to serve as a reasonable, if not superior, substitute for the U-shaped actuating members. In a first position, Schaffer’s undepressed actuator buttons would cause the “string 14 [attached to the buttons] to be pulled in both directions at once.” *See* Ex. 1013 (Schaffer) at [0077]; Ex. 1008 (Hartley) at [0031]. This would cause the string to constrict and collapse the lumen of Schaffer’s containment structure, sealing the valve. If Schaffer’s springs did not initially exert sufficient force to pull the string of Hartley to constrict the valve, a person of ordinary skill in the art would have reasonably expected success in adjusting the spring strength to

exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. Springs are simple, predictable mechanical devices that would have been well understood by a person of ordinary skill in the art in August 2018.

229. When Schaffer's actuator buttons are depressed and moved to the second position, the compressive forces from the springs would be relaxed, relieving the tension on the string, and causing the string to loosen around the central lumen so that the lumen at least partially opens. *See* Ex. 1013 (Schaffer) at [0077]; Ex. 1008 (Hartley) at [0031]. Schaffer discloses that the seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1013 (Schaffer) at [0054]. Thus, a person of ordinary skill in the art would have expected that Schaffer's lumen would have the resilience to return to its open configuration when the actuator buttons are pressed inwardly, and the tension on the string is released such that "no compressive force [] is applied" to the lumen." *Id.*

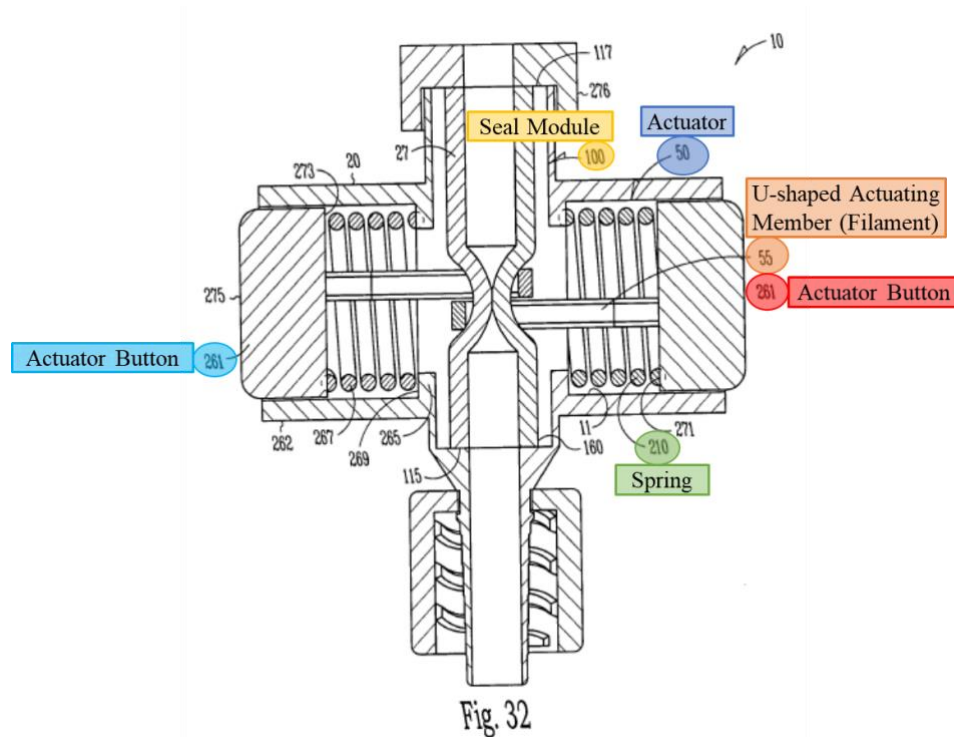
230. Moreover, if the person of ordinary skill found that the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, the person of skill would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. There were a range of suitable materials

disclosed in the prior art for forming the lumen of a hemostasis valve. For example, Schaffer discloses that the materials for the lumen can include “modified vinyl, silicone, polyurethane or a combination thereof,” as well as modifications of those materials with “waxes and/or oils or un-cross-linked modifiers.” Ex. 1013 (Schaffer) at [0081]. Hartley discloses that “[p]referably the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens” and further discloses that “[i]n a preferred form the cylindrical diaphragm of the valve may be constructed from a elastomeric material such as silicone rubber.” Ex. 1008 (Hartley) at [0008], [0016]. Eller discloses a variety of sleeves made from “NuSil MED-4755, NuSil MED-4765, and NuSil MED-4014.” Ex. 1031 (Eller) at 36:27-60. The components referred to as the “seal module” in Schaffer, the “cylindrical diaphragm” in Hartley, and the “sleeve” in Eller all correspond to the portion of the hemostasis valve that forms the central lumen of the valve. *See* Ex. 1013 (Schaffer) at [0049], [0051], [0054], [0075]; Ex. 1008 (Hartley) at [0031]; Ex. 1031 (Eller) at 11:60-64. Thus, the prior art would have provided a person of ordinary skill with a range of suitable options for selecting a suitable lumen material that was both deformable and possessed the resilience to return to its open state when constricting force is removed.

B. Claim 12

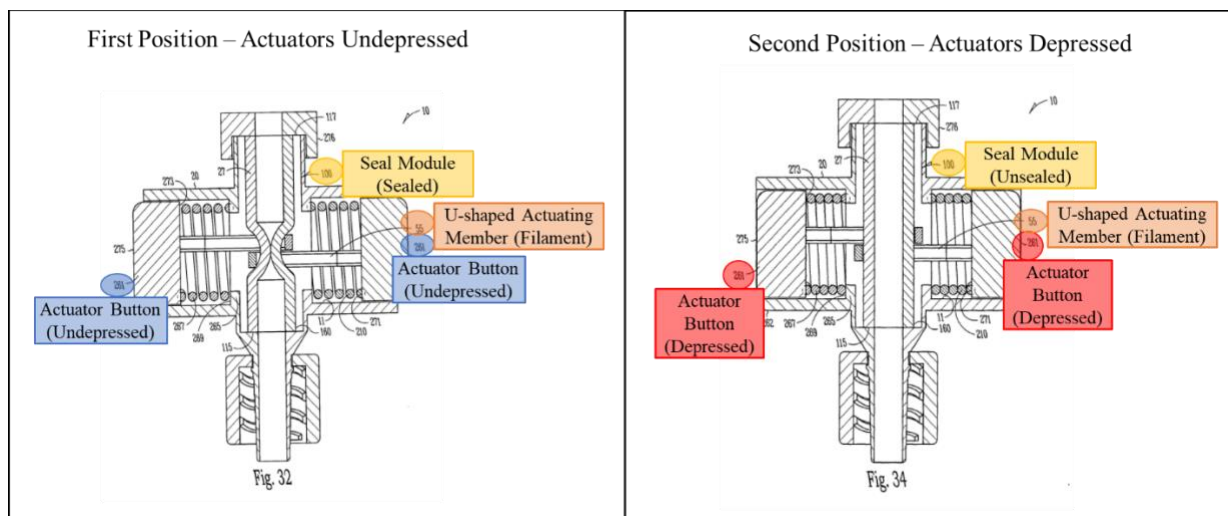
231. Claim 12 recites: “The method of claim 11 wherein decreasing the tension on the filament includes depressing a button coupled to the hemostasis valve.” In my opinion, Claim 12 would have been obvious in view of Laub or Aklog in combination with Garrison and Schaffer and optionally Hartley. Claim 12 would also have been obvious in view of Garrison in combination with Laub or Aklog and Schaffer and optionally Hartley.

232. Schaffer’s hemostasis valve, depicted in Figures 31-34, includes two spring-loaded actuator buttons 261 that are “movable from a first position to a second position on opposing sides of the housing:



Ex. 1013 (Schaffer) at [0075]-[0076], Figs. 31-32. Schaffer’s actuator buttons are

undepressed when the valve is in the first (closed) position and depressed when the valve is in the second (open) position, as illustrated in Figures 32 and 34:



Id. at [0077], Figs. 32, 34. A person of ordinary skill in the art would have been motivated to combine Schaffer's valve with Laub's, Aklog's, or Garrison's aspiration system systems, and they would have reasonably expected success in doing so, for the same reasons I explained previously for Claim 11. *Supra* §VIII.A.

C. Claims 30-31

233. Claims 30-31 of the '333 patent recite a method of treating deep vein thrombosis instead of pulmonary embolism, but they otherwise recite the same method steps and limitations as Claims 11-12. Therefore, claims 30-31 are obvious for the same reasons that I explained previously for Claims 11-12. *Supra* §§VIII.A-B.

IX. SECONDARY CONSIDERATIONS

234. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '333 patent.

235. The methods and devices claimed in the '333 patent are not new, and were invented long before August 2018. Therefore, 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. Many aspiration systems were available on the market by August 2018, and many of those systems were used to perform the conventional method steps with the conventional components recited in the claims of the '333 patent. *See, e.g., supra* §VI.A (discussing Laub, Aklog, and Garrison).

236. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

X. CONCLUSION

237. For the foregoing reasons, it is my opinion that Claims 1-12, 14-31, and 33-38 of the '333 patent are not patentable because they are anticipated by or 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.

238. 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.

239. 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 16, 2025 in Glen Ellen, CA.

troy thornton

Troy Thornton