

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case IPR2024-01257
Patent No. 11,744,691

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,744,691**

IMPERATIVE Ex. 1003 IPR Petition - US 11,744,691

TABLE OF CONTENTS

Page No.

I. INTRODUCTION	1
A. Engagement	1
B. Experience and Qualifications	2
C. Topics of Opinions	5
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 '691 PATENT	13
A. Summary of the '691 Patent.....	13
B. The Challenged Claims	18
C. Prosecution History.....	19
IV. CLAIM CONSTRUCTION	23
V. SUMMARY OF IPR GROUNDS	26
VI. GROUNDS 1-8: GARRISON ALONE OR COMBINED WITH AKLOG, HARTLEY, AND/OR GOFF RENDERS CLAIMS 1-31 UNPATENTABLE	27
A. Independent Claim 1	33

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

	Page No.
1. Preamble [1]: “An aspiration system with accelerated response, comprising”	33
2. Limitation [1A]: “an aspiration pump in communication with a first chamber”	35
3. Limitation [1B]: “a coupled assembly including: an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube; a second chamber in between the aspiration pump and the aspiration catheter; and a hemostasis valve”	39
4. Limitation [1C]: “a user-actuable valve between the second chamber and the aspiration catheter”	43
5. Limitation [1D]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”	45
6. Limitation [1E]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”	47
B. Claim 2	50
C. Claim 3	52
D. Claim 4	58

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

	Page No.
1. Garrison	59
2. Garrison + Goff	63
E. Claim 5	67
F. Claim 6	68
G. Claim 7	70
1. Garrison	70
2. Garrison and Aklog.....	72
H. Claim 8	82
I. Claim 9	84
J. Claim 10	85
K. Claim 11	85
1. Garrison	85
2. Garrison + Goff	87
L. Claim 12	88
1. Garrison	89
2. Garrison + Goff	90
M. Claim 13	92
N. Independent Claim 14.....	94

TABLE OF CONTENTS

(cont'd)

	Page No.
1. Preamble [14]: “An aspiration system with accelerated response, comprising”	94
2. Limitation [14A]: “an aspiration pump in communication with a first chamber”	94
3. Limitation [14B]: “an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;”	94
4. Limitation [14C]: “a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter”	95
5. Limitation [14D]: “a user-actuatable valve between the second chamber and the aspiration catheter”	95
6. Limitation [14E]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”	96
7. Limitation [14F]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”	96
O. Claim 15	97
P. Claim 16	97

TABLE OF CONTENTS
(cont'd)

	Page No.
Q. Claim 17	97
R. Claim 18	98
S. Claim 19	98
T. Claim 20	98
U. Claim 21	99
V. Claim 22	100
W. Independent Claim 23	100
X. Claim 24	101
Y. Claim 25	102
Z. Claim 26	102
AA. Claim 27	103
BB. Independent Claim 28	103
CC. Claim 29	103
DD. Claim 30	104
EE. Claim 31	104
VII. SECONDARY CONSIDERATIONS	104
VIII. CONCLUSION	105

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,744,691 (“the ’691 patent”)
1002	’691 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 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 Treretola (“Treretola”)
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. 2005/0004534 A1 to Lockwood et al. (“Lockwood”)
1013	U.S. Patent Publication No. 2015/0352325 A1 to Quick et al. (“Quick”)
1014	U.S. Patent No. 5,938,645 to Gordon
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.

Exhibit No.	Description
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1021	U.S. Patent Application No. 16/117,519 (the “519 application”)
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.strokeaha.org (2005).

Table of Exhibits 2

I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative” or “Petitioner”) to provide my opinion regarding the patentability of Claims 1-31 of U.S. Patent No. 11,744,691 (“the ’691 patent”). For the reasons discussed herein, I have concluded that Claims 1-31 of the ’691 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Declaration supports Imperative’s Petition for the above-captioned *inter partes* review (“IPR”) of the ’691 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 ’691 patent, Inari Medical, Inc. (“Inari” or “Patent Owner”).

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

B. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the '691 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 '691 patent;
- The level of ordinary skill in the art pertaining to the '691 patent;
- The teachings of the prior art; and
- Whether Claims 1-31 of the '691 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 '691 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 '691 patent.

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

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

A. Claim Construction

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

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

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

B. Anticipation

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

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

C. Obviousness

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

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

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

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '691 patent, e.g., devices for aspirating unwanted material from a patient. My understanding of the field of the '691 patent is influenced by the prosecution history. I see that during prosecution the Examiner used patents describing aspiration devices for treating tissue wounds to reject the patent claims. I also see that the Patent Owner did not dispute the use of those patents or argue that such aspiration devices are not analogous art. The references are also

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

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

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

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

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

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

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

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

31. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that Claims 1-31 of the '691 patent would have been non-obvious, as further explained in Section § VII (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

32. It is my understanding that when interpreting the claims of the '691 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 '691 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 '691 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.

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 '691 PATENT

A. Summary of the '691 Patent

37. The '691 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 ('691 patent) at 4:17-4:33. The '691 patent explains that the system can treat various clots including PE, cerebral embolism, and 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 5:27-5:28.

38. The catheter subsystem also has a catheter 102 [orange below] “comprising an elongated shaft defining a lumen 104,” and a “valve 106” [yellow below] with a “lumen 109 extending therethrough.” *Id.* at 5:23-5:48. The '691 patent explains that the valve “is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106” when other components are inserted, such as “interventional devices” or “other aspiration catheters.” *Id.*

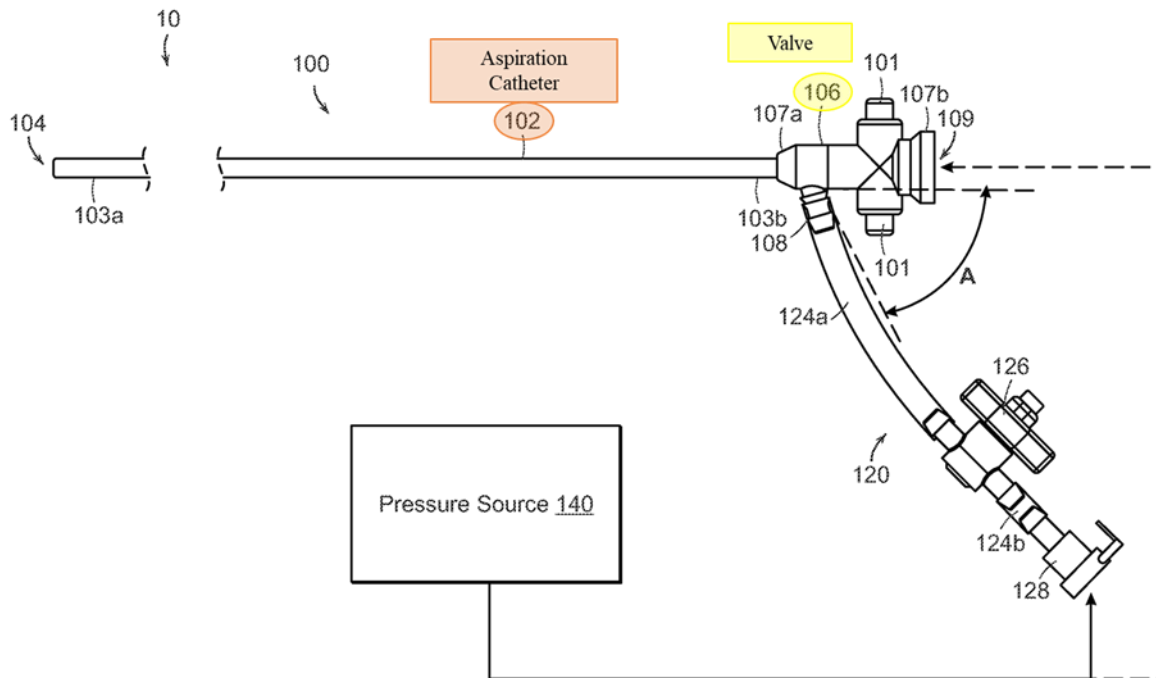


FIG. 1

Id. at Fig. 1.

39. The '691 patent discloses the pressure source [red below] is “configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 100.” *Id.* at 6:55-6:58. “[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 7:33-7:38.

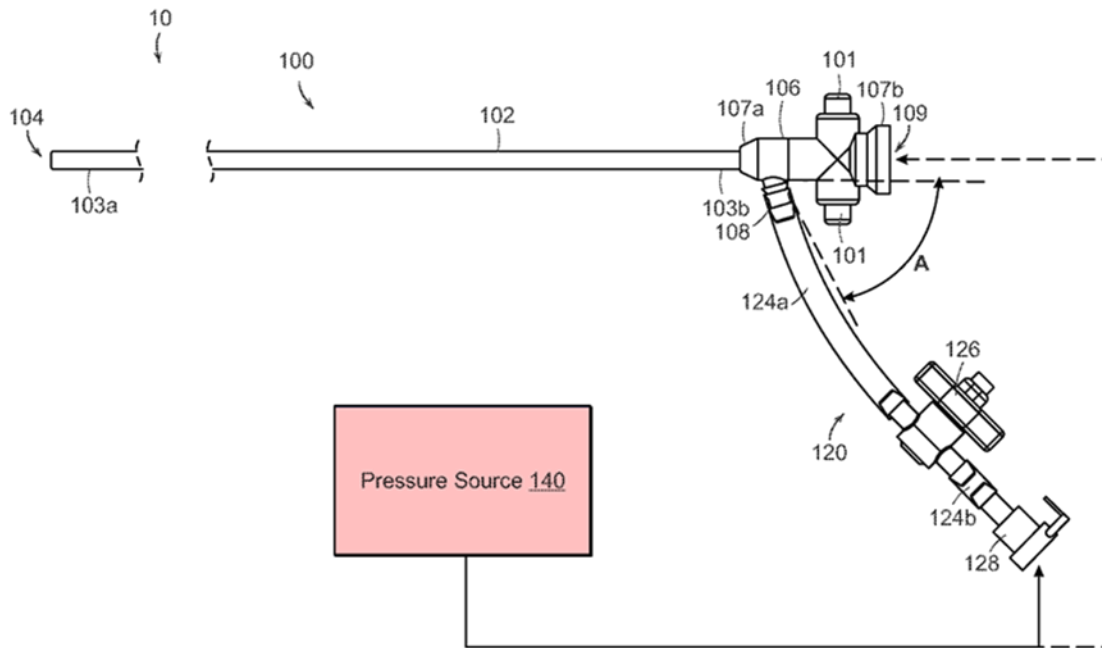


FIG. 1

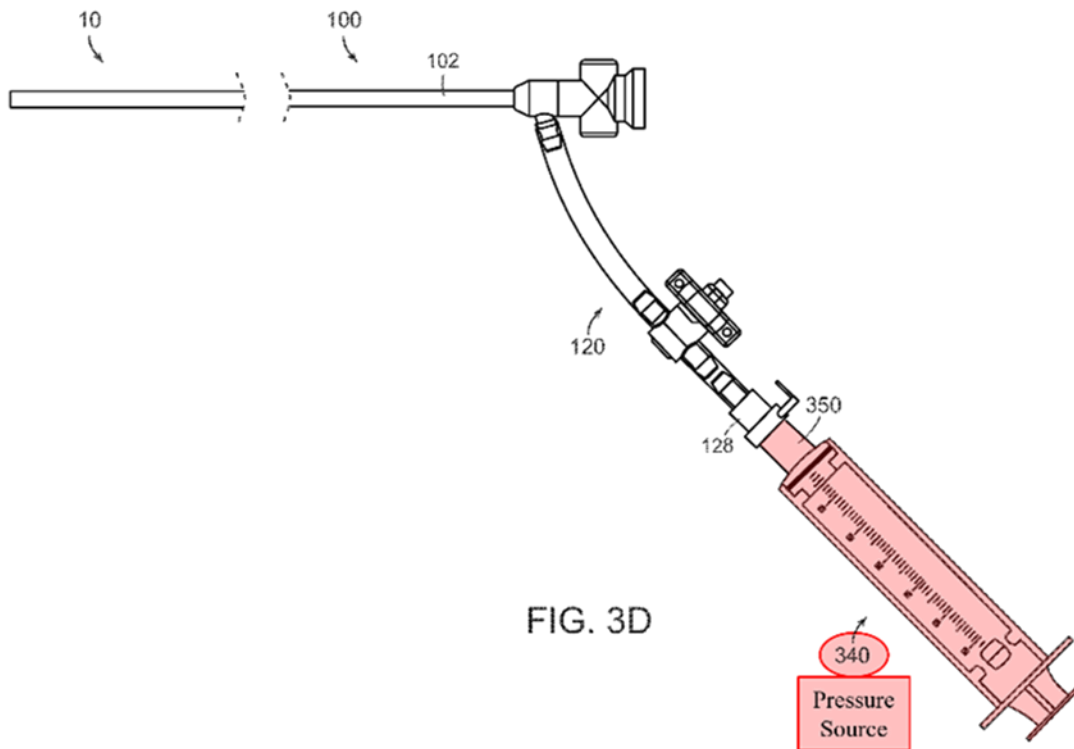


FIG. 3D

Id. at Figs. 1, 3D.

40. The '691 patent explains that the tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” *Id.* at 6:4-6:5. 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 6:4-6:21.

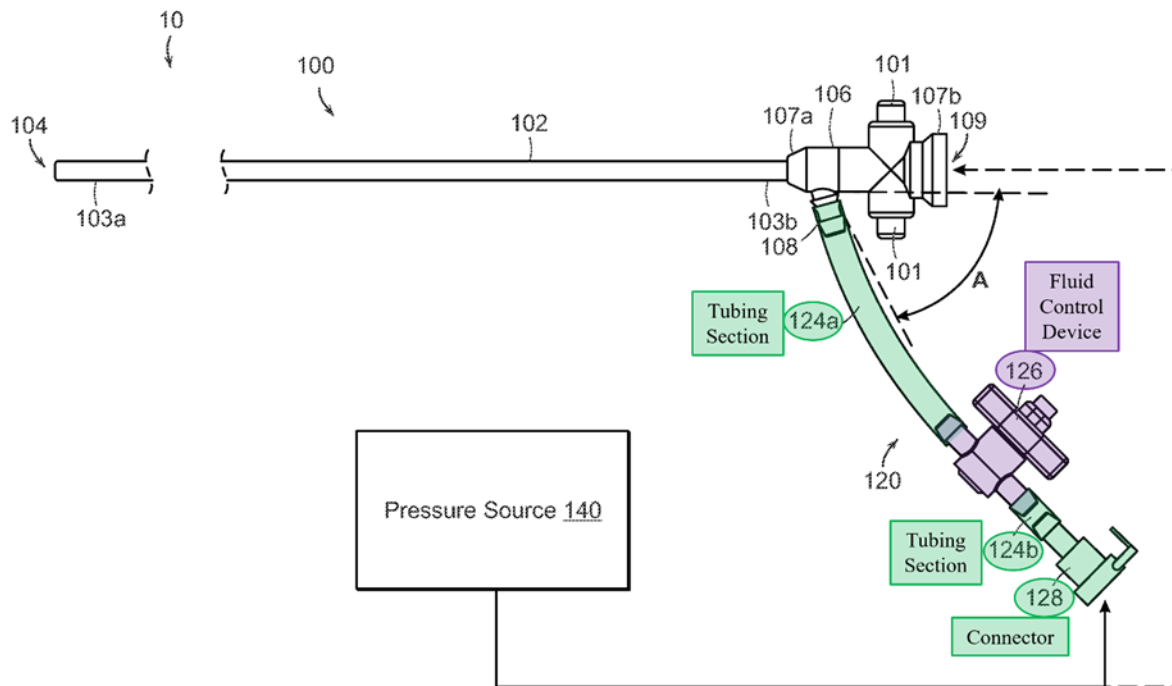
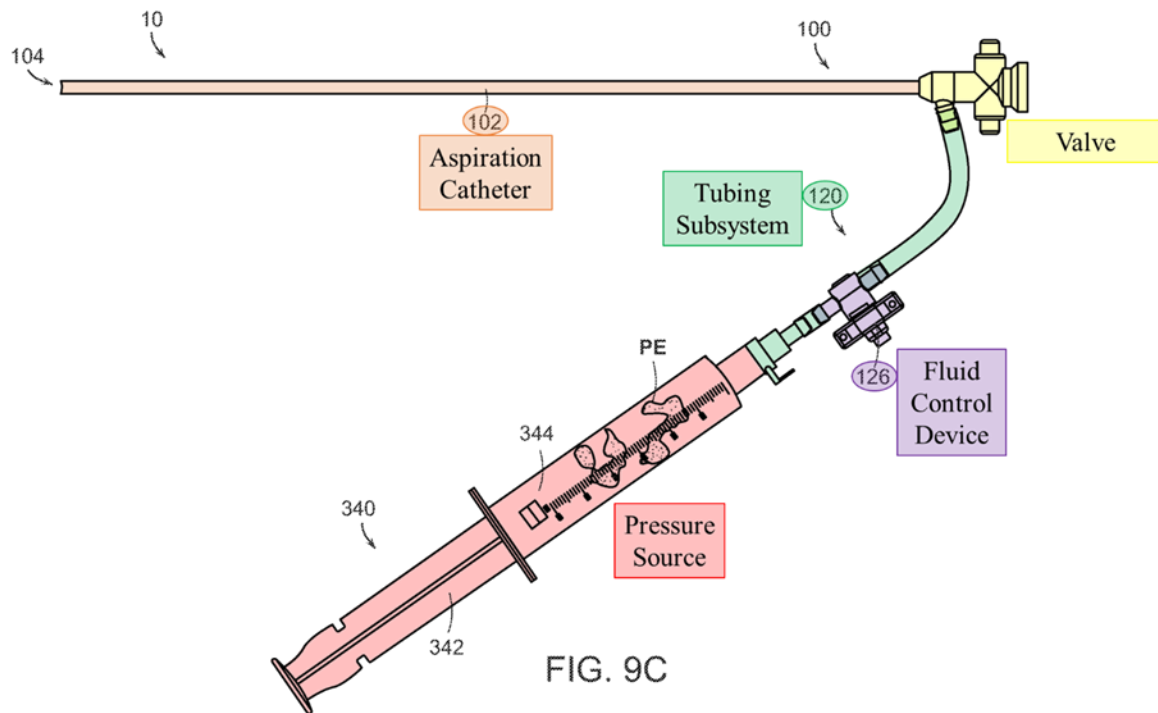


FIG. 1

Id. at Fig. 1.

41. The '691 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 6:60-6:64. 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 18:41-18:45. 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 7:1-7:6.



Id. at Fig. 9C. The ‘691 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 7:6-7:10.

42. The ‘691 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 31:1-19, Fig. 19. The “canister 1940 further includes a filter 1942.” *Id.* at 31:20.

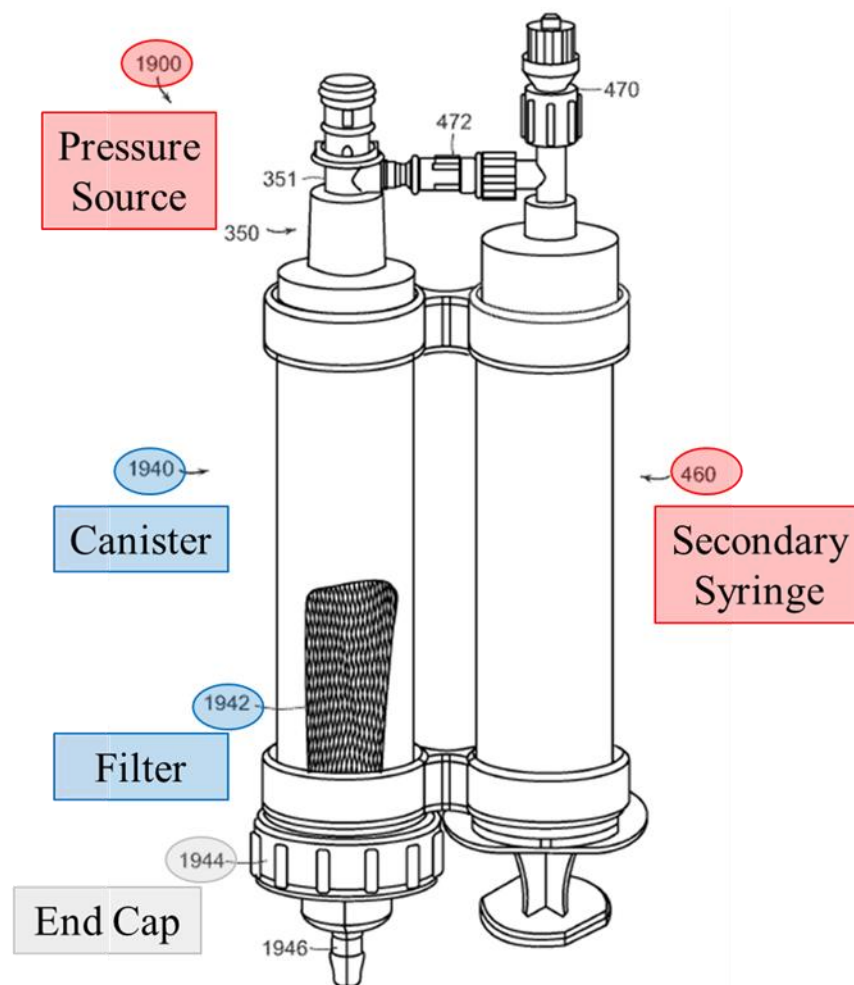


FIG. 19

Id. at Fig. 19. The canister 1940 also includes an end cap 1944 that can be unscrewed to access the filter. *Id.* at 31:20-42.

B. The Challenged Claims

43. The challenged claims include Claims 1-31 of the '691 patent. The patent includes 4 independent claims (Claims 1, 14, 23, 28).

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

1. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
a coupled assembly including:
 - an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
 - a second chamber in between the aspiration pump and the aspiration catheter; and
 - a hemostasis valve; and
- a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
- wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

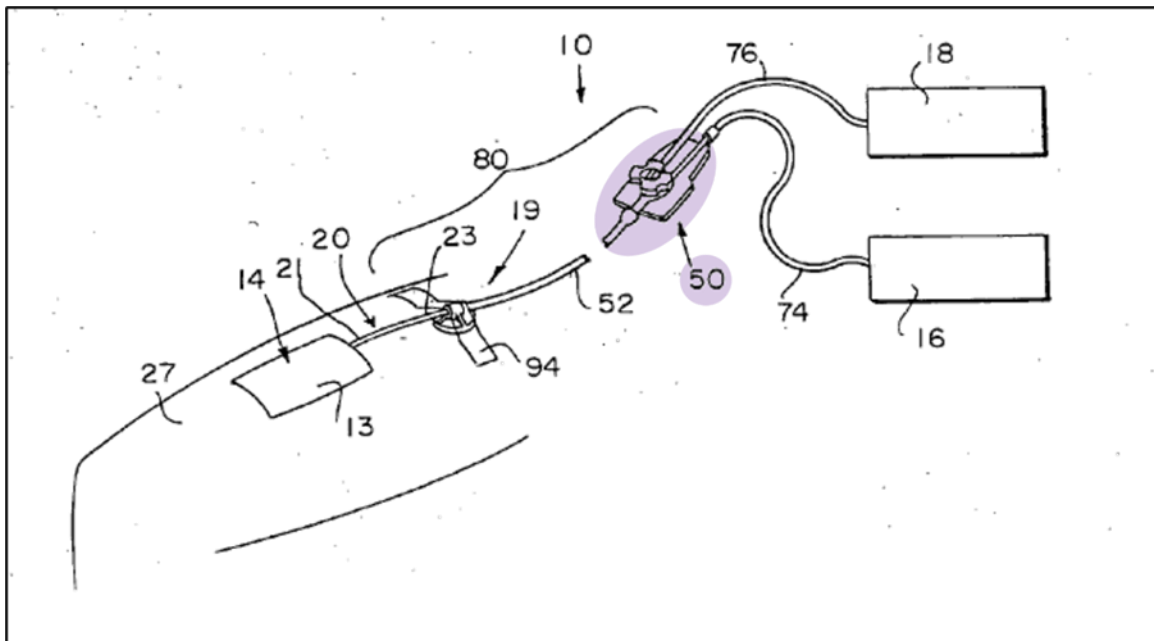
Ex. 1001 ('691 patent) at Claim 1.

C. Prosecution History

45. I have reviewed the '691 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action rejecting Inari's proposed claims. Ex. 1002 ('691 patent prosecution history excerpt) at 262. The Examiner rejected the independent claims for being obvious over U.S. Patent 8,535,283 (Ex. 1011, "Heaton") in view of U.S. Patent Publication 2005/0004534 (Ex. 1012, "Lockwood"). Both Heaton and Lockwood describe devices for treating wounds

on the skin surface. *See e.g.*, Ex. 1011 at 1:13-15 (“The present invention relates generally to the field of tissue treatment”); Ex. 1012 at [0001] (“The present disclosure relates to vacuum therapy wound treatment systems”).

46. The Examiner explained that Heaton disclosed all the elements of Inari’s Claim 1 except “a aspiration system comprising a user-actuable valve.” Ex. 1002 at 262. However, the Examiner found that Lockwood discloses “a user-actuable valve (stopcock or switch valve (50)) coupled to the single lumen tube (52).” *Id.* The item the Examiner identified as Lockwood’s valve is highlighted in purple below:



Ex. 1012 (Lockwood) at Fig. 1. The Examiner also found that it “would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the valve of the reduce pressure system of Heaton

and replace it with the user actuatable stopcock or switch valve, as taught by Lockwood.” Ex. 1002 at 262. The Examiner found many other claims obvious over Heaton and Lockwood in addition to Claim 1.

47. The Examiner also found some dependent claims obvious over Heaton modified by Lockwood in further view of US 20150352325 A1 (Ex. 1013, “Quick”). Ex. 1002 at 265-268. These additional claims required an aspiration catheter “configured to be intravascularly positioned within a blood vessel of a patient” proximate a pulmonary embolism (“PE”) or deep vein thrombosis (“DVT”). *Id.* The Examiner found that Quick disclosed catheters for treating PE or DVT and that it would have been obvious to modify the catheters in the wound treatment devices (e.g., Heaton and Lockwood) “to enable intravascular delivery of an interventional device to a treatment site in a blood vessel, as taught by Quick.” *Id.*

48. I see that the Examiner also found a few dependent claims would be allowable if they were re-written to include the limitations of the independent claim and the dependent claim. The allowable claims required “a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve” or “a second chamber is removably coupled between the aspiration pump and the catheter.” Ex. 1002 at 268-269. The Examiner stated that Heaton did not have a “coupled assembly” because Heaton’s second chamber “is configured to be

part of the first chamber” so “having the second chamber be part of another assembly that includes the aspiration catheter and a hemostasis valve would destroy the function of how Heaton operates.” *Id.* The Examiner also found that Heaton’s second chamber could not be “removably coupled between the aspiration pump and the catheter” because it was part of the pump. *Id.* The Examiner also found that Heaton did not mention a hemostasis valve. *Id.*

49. I see that Inari responded to the Examiner’s rejection by withdrawing the rejected claims and re-writing the allowable dependent claims to include the limitations of the independent claims. *Id.* at 244-254. I see that Inari also added new Claims 21-33, which included the claim elements the Examiner said were missing from the prior art (e.g., coupled assembly).

50. I see that the Examiner then allowed the rewritten and new claims. *Id.* at 51-52. The Examiner repeated the reasoning in the prior office action, namely that Heaton does not disclose “a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve” or mention a hemostasis valve. *Id.* The Examiner also repeated that Heaton does not disclose a second chamber “wherein the second chamber is removably coupled between the aspiration pump and the catheter.” *Id.*

51. The prior art I rely upon below discloses the limitations that the Examiner thought were missing from the prior art, including a “coupled

assembly,” a “hemostasis valve,” and a “second chamber” that is “removably coupled between the aspiration pump and the catheter.”

IV. CLAIM CONSTRUCTION

52. I provided a claim construction for the term “filament” in another IPR filed on U.S. Patent No. 11,697,011 (“’011 patent”) (IPR2024-01157). I see that the term “filament” appears in some of the claims of the ’691 patent requiring a hemostasis valve (for example, Claim 3). I have searched the ’691 patent and do not see the term “filament” used outside of the claims. I also do not see any description of a hemostasis having a filament. However, I see the ’691 patent discloses, “In some embodiments, the valve 106 can be a valve of the type disclosed in U.S. patent application Ser. No. 16/117,519, [“’519 application”] filed Aug. 30, 2018, and titled ‘HEMOSTASIS VALVES AND METHODS OF USE,’ which is incorporated herein by reference in its entirety.” Ex. 1001 (’691 patent) at 5:54-59. I do not have any opinion on whether the ’519 application has been effectively incorporated by reference into the ’691 patent. For the purposes of this declaration, I have assumed that the ’519 application is part of the ’691 patent.

53. I am informed that the ’519 application is a continuation of the ’011 patent that I analyzed in a previously filed IPR. I am also informed that the ’519 application has the same specification as U.S. Patent No. 11,697,011. Therefore,

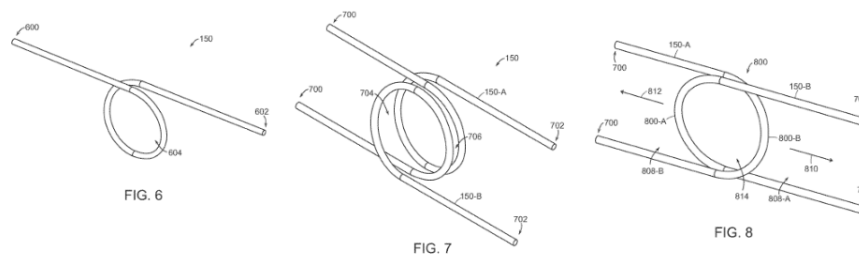
assuming the '519 application is part of the '691 patent, I believe that the term “filament” should have the same meaning in this IPR that it had in the '011 patent IPR. I therefore repeat my analysis from the '011 patent IPR with citations to the '519 application.

54. In my opinion, a person of ordinary skill in the art in August 2018 (the earliest possible priority date of the '691 patent) would have understood the term “filament” in the claims of the '691 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

55. I understand from counsel that the claim construction analysis should begin with the language of the claims themselves. The claims of the '691 patent do not provide much information about the meaning of “filament.” Claims 3 and 23 of the '691 patent recites there is “a filament extending at least partially around the tubular member.” Ex. 1001 ('691 patent) at Claim 1. Claims 3 and 23 go on to recite that the “filament is moveable between: (a) a first portion wherein the filament circumferentially constricts the lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially open the lumen.” *Id.* While this language identifies some features that the filament must have (e.g., a first portion and a second portion), the claim language does not identify the structures or materials that form a “filament.”

56. The specification of the '519 application does identify structures and materials that may form the “filament.” The 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 at [0047]. The application further provides 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 application states that “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” *Id.*

57. The 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 below 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):



Id. at [0065], Figs. 7-9.

58. 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. I do not see any specific mention of the “filament” in the prosecution history.

59. In view of the claim language, specification, and prosecution history discussed above, I believe that a person of ordinary skill in the art in August 2018 would have understood the term “filament” in Claims 3 and 23 to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

V. SUMMARY OF IPR GROUNDS

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

Ground	Claims Challenged	Basis	References
1	1-2, 5-6, 10-11, 13	35 U.S.C. § 102 (anticipation)	Garrison
2	1-2, 4-6, 9-20, 28-30	35 U.S.C. § 103 (obviousness)	Garrison
3	3, 23, 25-27	35 U.S.C. § 103 (obviousness)	Garrison + Hartley
4	4, 9, 11-12, 14-20, 28-30	35 U.S.C. § 103 (obviousness)	Garrison + Goff
5	7-8, 21-22, 31	35 U.S.C. § 103 (obviousness)	Garrison + Aklog
6	24	35 U.S.C. § 103 (obviousness)	Garrison + Aklog + Hartley
7	21-22, 31	35 U.S.C. § 103 (obviousness)	Garrison + Aklog + Goff
8	25-26	35 U.S.C. § 103 (obviousness)	Garrison + Hartley + Goff

**VI. GROUNDS 1-8: GARRISON ALONE OR COMBINED WITH
AKLOG, HARTLEY, AND/OR GOFF RENDERS CLAIMS 1-31
UNPATENTABLE**

61. Garrison describes an aspiration system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” Ex. 1006 (Garrison) at [0007]. As shown in Figure 34 below, Garrison describes an example of an aspiration system that has an aspiration catheter, an aspiration source (e.g., aspiration pump) having a first chamber, a second chamber having a filter, at least one hemostasis valve, and a user-actuated valve to provide an accelerated response.

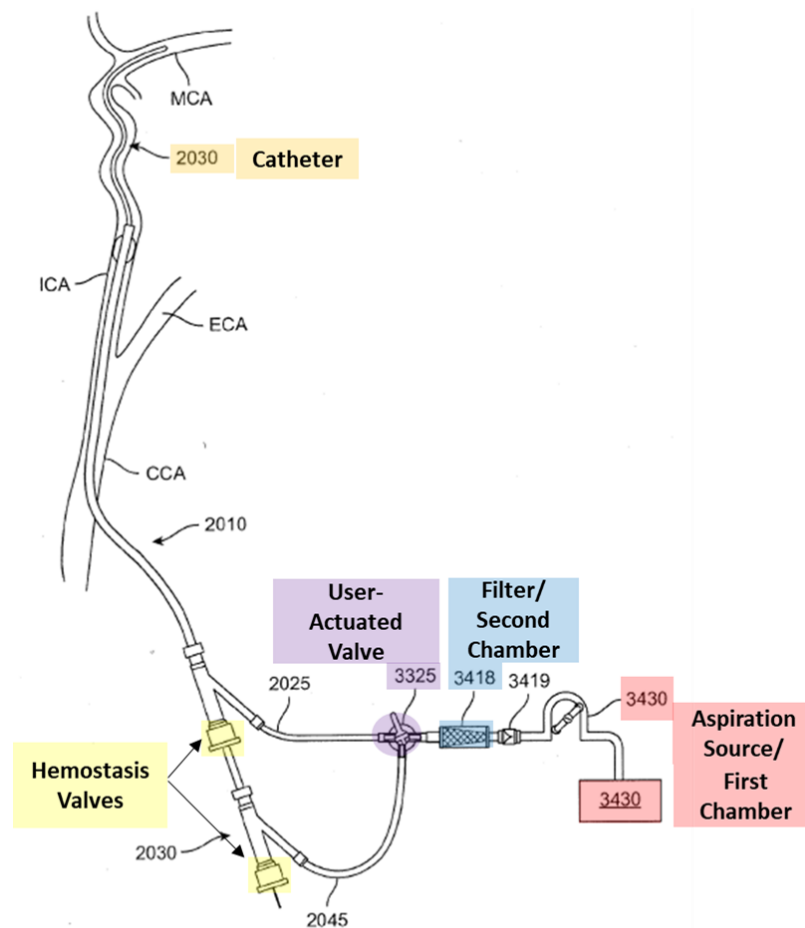
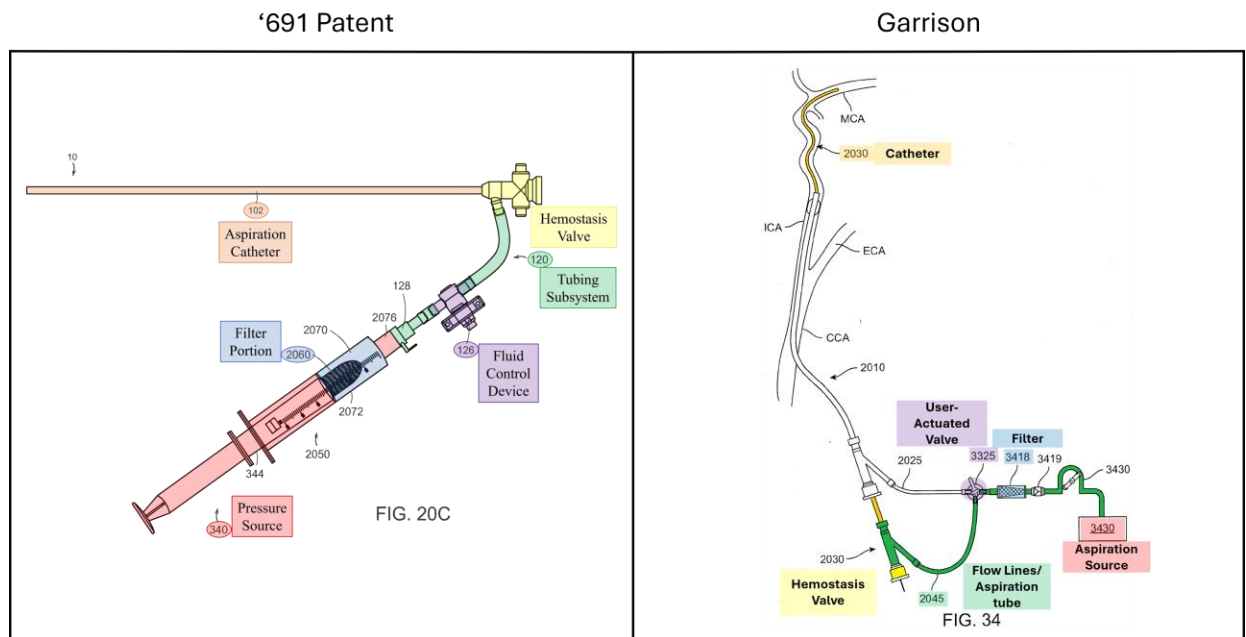


FIG. 34

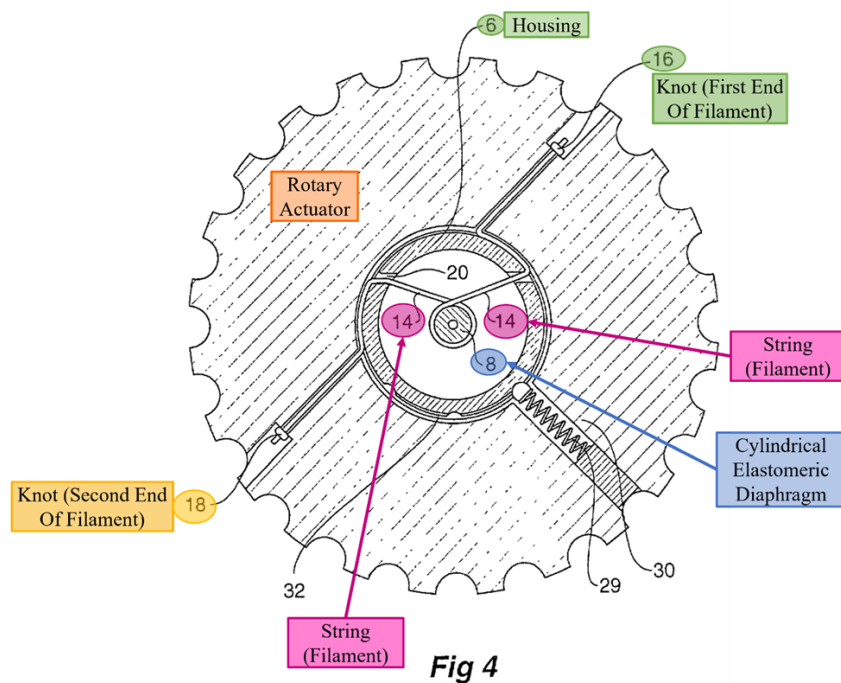
Id. at Fig. 34; *see also id.* at [0131]-[0134]. The example of Garrison’s aspiration system at least depicted in Figure 34 has the same components in the same arrangement as the system described and claimed in the ‘691 patent, which is apparent from the side-by-side comparison of Figure 20C of the ‘691 patent (left) and Figure 34 of Garrison (right):



Ex. 1001 (‘691 patent) at Fig. 20C (left); Ex. 1006 (Garrison) at Fig. 34 (right). Because Garrison discloses all of the components claimed in the ‘691 patent, it is my opinion that Garrison anticipates or renders obvious Claims 1-2, 4-6, 9-20, 28-30 of the ‘691 patent.

62. Garrison discloses a catheter having a hemostasis valve. Garrison explains that different types of hemostasis valves can be combined with the catheter, including, for example, “an adjustable-opening valve such as a Tuohy-

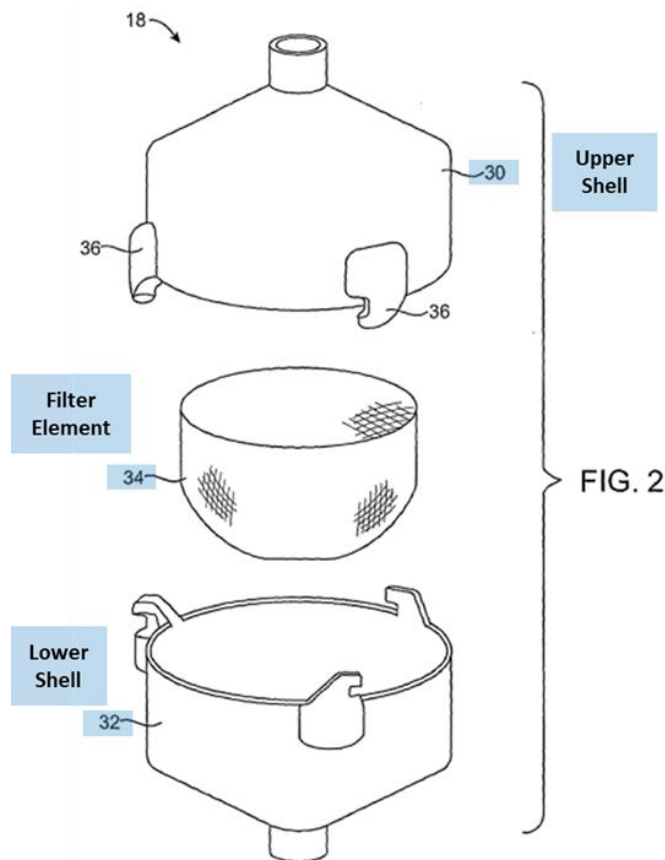
Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” Ex. 1006 (Garrison) at [0098]. Hartley discloses the structure of a type of rotating hemostasis valve. Hartley’s valve “can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” Ex. 1008 (Hartley) at [0003]. Hartley’s valve includes a tubular member and a filament extending at least partially around the tubular member to restrict the member and close the valve:



Ex. 1008 (Hartley), Fig. 4. Hartley explains that the valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”. *Id.* at [0031]. Hartley also explains that the “cylindrical diaphragm can be completely constricted to prevent fluid

Id. at 11:4-11, Fig. 7. Aklog also discloses ways to optimize aspiration systems for use in larger blood vessels to treat pulmonary embolisms and DVT, including, for example, returning the aspirated blood to the patient to reduce blood loss. *Id.* at 1:17-24. Further, 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. A person of ordinary skill in the art would have been motivated to position the distal end of Garrison’s aspiration catheter proximate a pulmonary embolism and, to the extent necessary, adapt Garrison’s aspiration system to treat pulmonary embolism. If the Board determines that Garrison alone does not expressly describe a catheter configured to be positioned near a pulmonary embolism or DVT, Aklog does.

64. Goff discloses an aspiration system having a filter housing 18 to “remove solid materials from the aspirate.” Ex. 1007 at [0011]. 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] (emphasis added).



65. Goff further discloses that the “housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.” *Id.* Goff’s stated intention to provide easy removal of the separated solids would have further motivated a person of ordinary skill in the art to removably couple Garrison’s filter to the aspiration system with removable connectors so that the physician could remove the filter and observe the clot material. If the Board determines that Garrison alone does not disclose a removable second chamber or filter, Goff does.

A. Independent Claim 1

66. Based on my review of the prior art, it is my opinion that Garrison (Ex. 1006) anticipates Claim 1 or renders Claim 1 obvious in combination with the knowledge of a person of ordinary skill in the art.

1. Preamble [1]: “An aspiration system with accelerated response, comprising”

67. The preamble of Claim 1 recites: “An aspiration system with accelerated response, comprising.” If the preamble is limiting, it is my opinion that Garrison discloses this limitation.

68. Garrison discloses an aspiration system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” Ex. 1006 at [0007]. Garrison’s system includes an aspiration catheter [orange], an aspiration source (e.g., aspiration pump) having a first chamber [red], a second chamber having a filter [blue], and at least one hemostasis valve [yellow]:

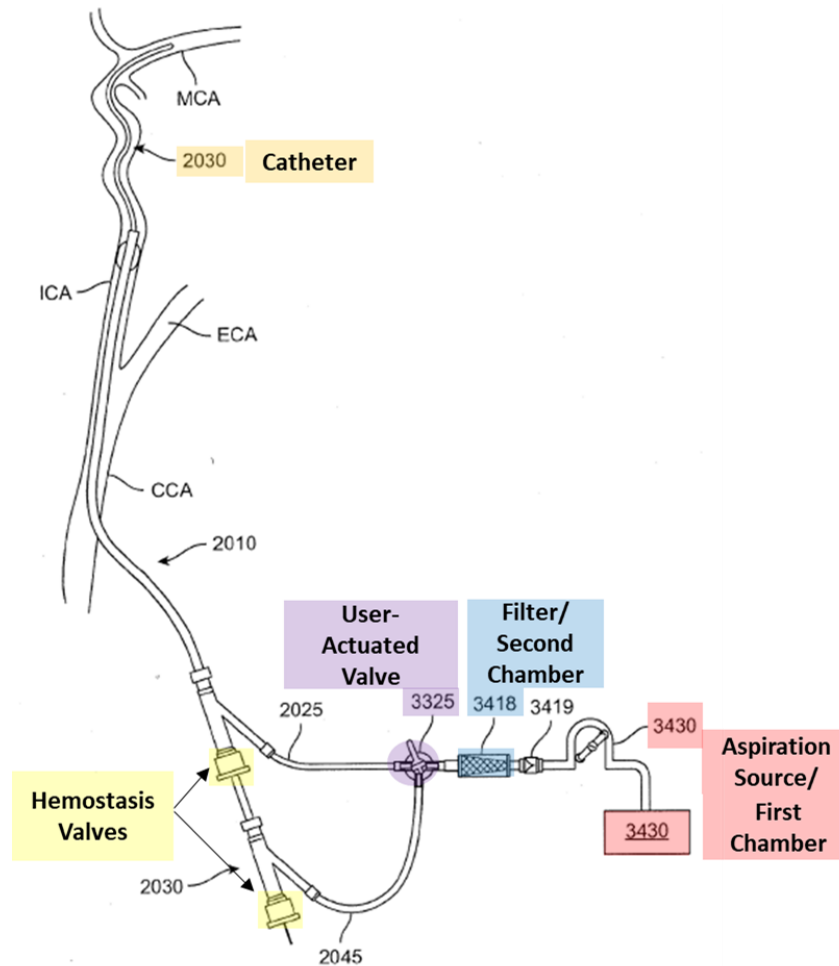


FIG. 34

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

69. Garrison also discloses aspiration with an accelerated response. As shown above, Garrison's system includes a user-actuated valve to provide an accelerated response [purple]. *Id.* Garrison discloses generating a negative pressure "while the connection [e.g., user-actuated valve] to the flow line is closed prior to the thrombectomy step of the procedure." *Id.* at [0134]. "During the procedure when the tip of the aspiration device ... is near or at the face of the

occlusion, the user may open the connection to the aspiration syringe.” *Id.* Garrison discloses that opening the user-actuated valve after generating the negative pressure “would enable the maximum level of aspiration in a ***rapid*** fashion with one user, something that is currently not possible with existing technologies.” *Id.* (emphasis added). Thus, Garrison discloses an aspiration system with accelerated response. *See also id.* at [0129] (Garrison discloses some testing results where an accelerated response was created by generating a negative pressure).

2. **Limitation [1A]: “an aspiration pump in communication with a first chamber”**

70. Claim 1 next recites: “an aspiration pump in communication with a first chamber.” It is my opinion that Garrison discloses this limitation.

71. Garrison’s aspiration system includes an aspiration source 3430 [red]:

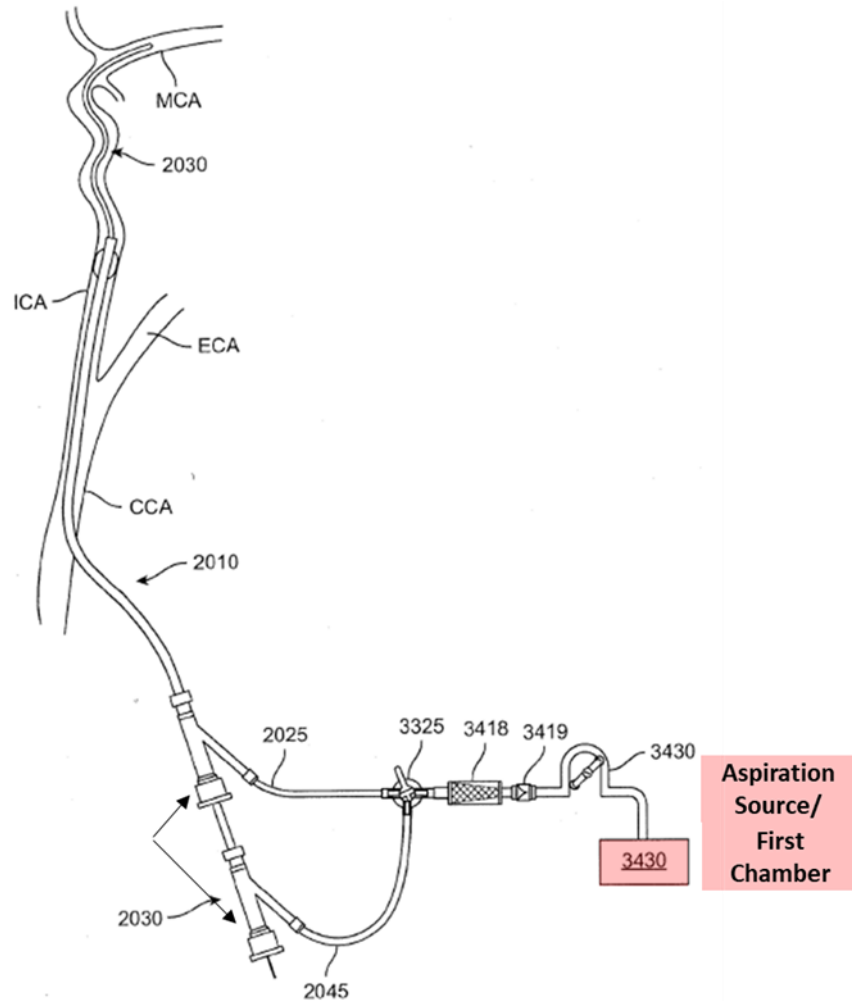
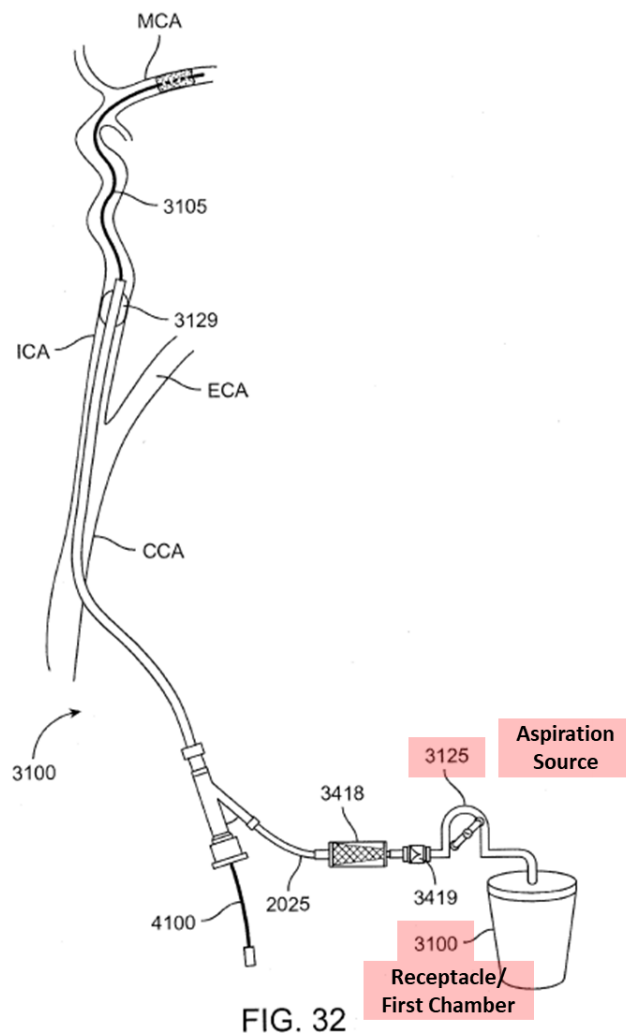


FIG. 34

Ex. 1006 at [0132], FIG. 34. Garrison states, “The active source of aspiration may be an **aspiration pump**, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” *Id.* at [0134] (emphasis added); *see also id.* at [0071] (Garrison states, “The flow line 905 may also be connected to an aspiration source such as a pump or a syringe.”); [0172] (Garrison states, “Aspiration may be via a syringe, a pump, or other means as disclosed above.”).

72. Garrison also discloses that the catheter assembly may include a receptacle (i.e., first chamber) to collect the aspirated blood and a source of aspiration that “may be separate or may be combined into a single device such as a syringe.” *Id.* at [0131], Figs. 32-33; *see also id.* at [0131] (Garrison states, “The aspiration source 3425 and delivery location may be combined into a single device such as a syringe.”).



Id. at Fig. 32.

73. For example, Garrison discloses an “aspiration pump device 3250” that may be connected to either or both the arterial access device 2010 and catheter 2030.” (*Id.*, [0136].) The pump device includes an “expandable portion 3210” to collect blood within “chamber 3220” before expelling the blood into a return line:

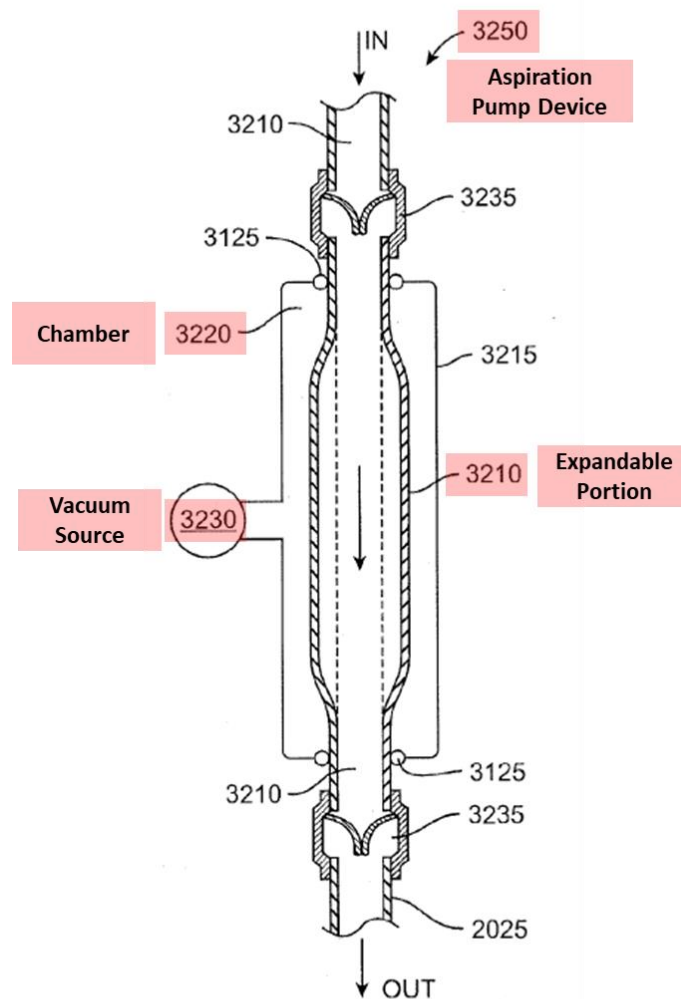


FIG. 36

Id. at [0136], Fig. 36; *see also id.* at [0134] (Garrison describes a hand-held aspirator that “contains a chamber with a plunger that is moved up and down with

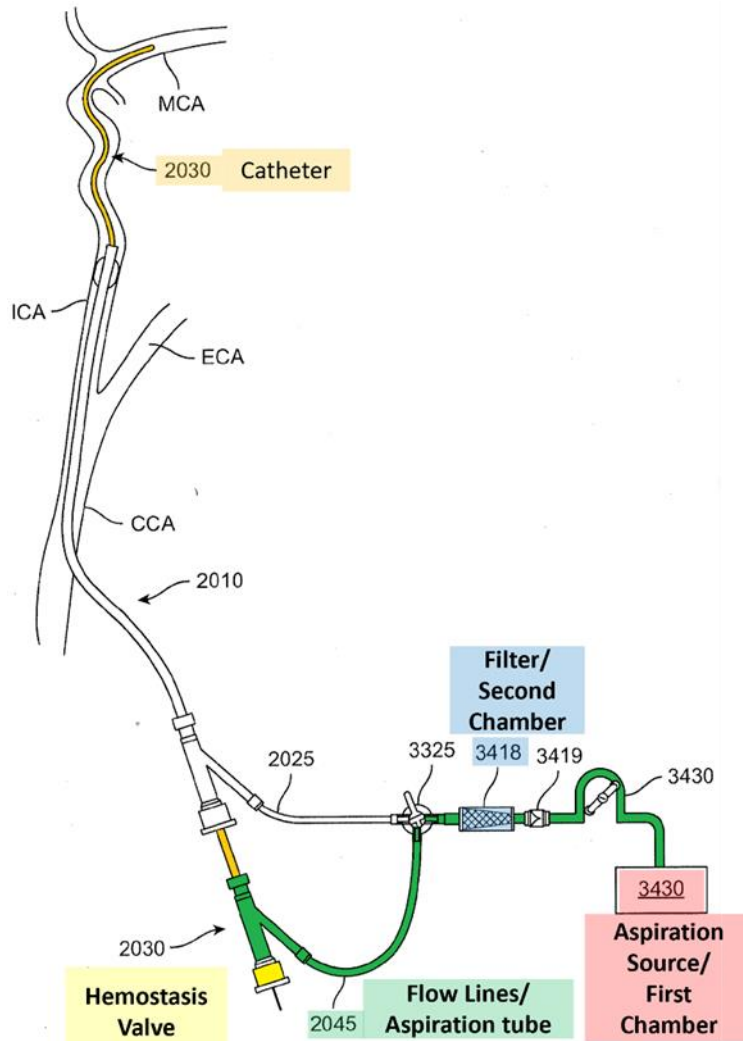
a single-handed actuator.”). Thus, Garrison discloses several examples of a “first chamber” as required by this claim limitation.

74. Also, as shown in the figures above, regardless of whether the receptacle/chamber is “separate” from the pump, or “combined into a single device” with the pump, the receptacle/chamber is “in communication” with the aspiration pump, as required by Claim 1.

3. **Limitation [1B]: “a coupled assembly including: an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube; a second chamber in between the aspiration pump and the aspiration catheter; and a hemostasis valve”**

75. Claim 1 next recites: “a coupled assembly including: an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube; a second chamber in between the aspiration pump and the aspiration catheter; and a hemostasis valve.” It is my opinion that Garrison discloses this limitation.

76. Garrison discloses a coupled assembly including an aspiration catheter [orange] configured for placement into fluid communication with a first chamber [red] by way of a flow line (i.e., aspiration tube) [green]:

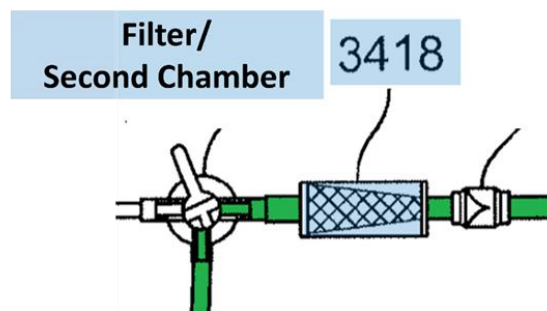


Ex. 1006 at Fig. 34; *see also id.* at [0132] (Garrison states, “both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source via flow lines 2024 and 2045, respectively”), Fig. 32.

77. Garrison's coupled assembly includes a second chamber having a filter [blue] between the aspiration pump [red] and the aspiration catheter [orange]. *Id.* at Fig. 34; *see also id.* at [0131] (Garrison discloses, "A filter 3418 and/or a check valve 3419 may also be coupled with the flow line 2045."). As

shown in Figure 34 above, the second chamber [blue] is coupled to the aspiration pump and catheter by the flow lines [green]. *Id.* The flow lines are an aspiration tube because suction from the pump is applied through the tubes and, because of the suction, aspirate is drawn through the tubes towards the first chamber.

78. The blown-up portion of Figure 34 below shows the chamber that surrounds the filter:

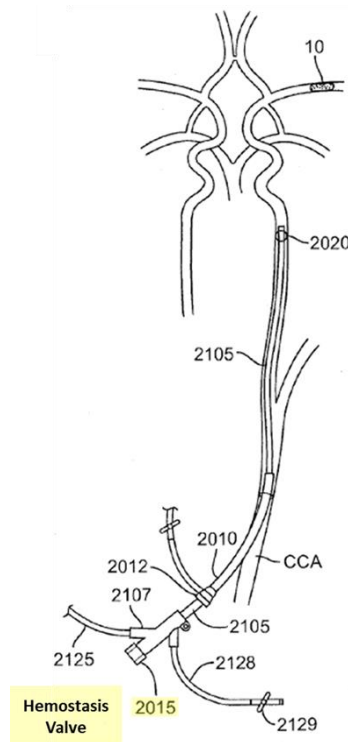


Ex. 1006 at Fig. 34 (excerpt). The chamber surrounding the filter is necessary for several reasons. First, blood passes through the filter. If a chamber did not surround the filter to collect the filtered blood, then the filtered blood would leak out of the system. Second, pressure must be maintained from the pump through the catheter to apply suction at the end of the catheter. If the filter were not surrounded by a sealed chamber, the system would lose pressure at the open filter, and it could not retrieve the clots. For these reasons, the filter must have a chamber surrounding it.

79. This limitation also requires a hemostasis valve. Garrison discloses that catheter 2030 [orange] can include a hemostasis valve [yellow] in its proximal

hub 2065 (item 2065 not pictured in Figure 34). Ex. 1006 at [0098]. Garrison specifically states, “The hemostasis valve may be integral to the catheter proximal adaptor” and, therefore, is part of the coupled assembly. *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 at [0098].

80. Figure 34 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”:

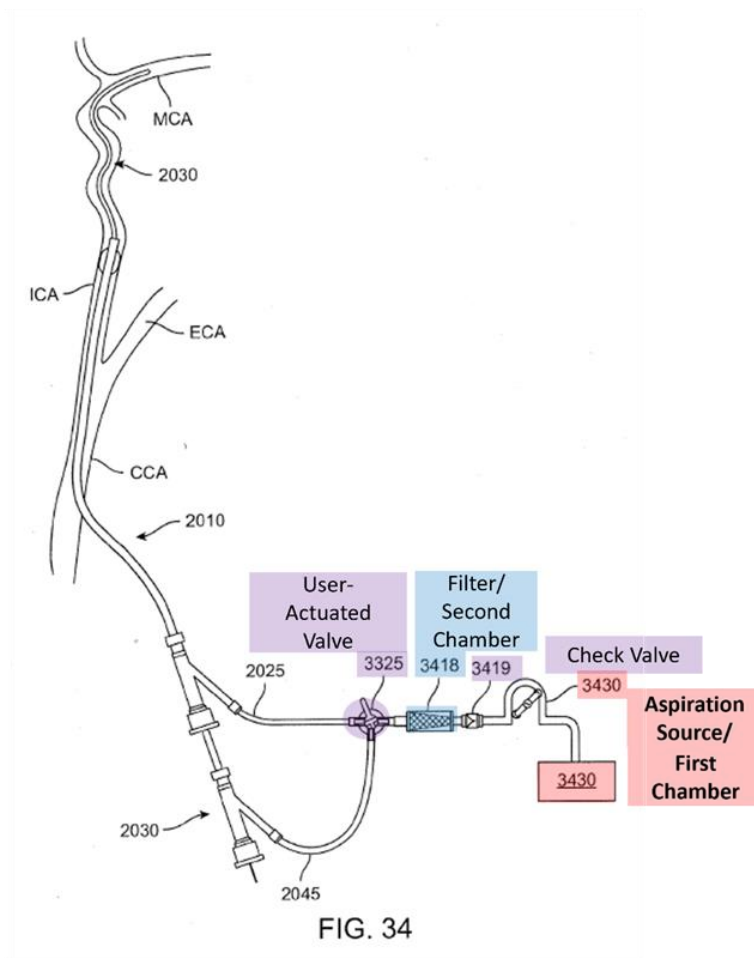


Id. at [0053] (emphasis added), Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (Garrison also explains that the arterial access device also has a hemostasis valve 2012). The location of the hemostasis valve in Figure 3 is the customary location for a hemostasis valve on a catheter. Thus, a person of ordinary skill in the art would have understood that catheter 2030's hemostasis valve in Figure 34 is located at the end of the proximal adaptor as shown in Figure 3.

4. **Limitation [1C]: “a user-actuable valve between the second chamber and the aspiration catheter”**

81. Claim 1 next recites: “a user-actuable valve between the second chamber and the aspiration catheter.” It is my opinion that Garrison discloses this limitation.

82. Garrison includes a “valve 3325” between the second chamber and aspiration catheter:



Ex. 1006 at [00132], Fig. 34. Garrison discloses that the “valve 3325 controls which device is connected to the aspiration source 3430.” *Id.* at [0132]. “The valve may be a 3-way or 4-way stopcock” and “enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Garrison discloses that the valve can also “be a flow controller with a simple actuation which selects the configuration as described above.” *Id.*; *see also id.* at [0133] (describing flow controller). Both the stopcock valve and flow controller are user-actuatable. For example, Garrison discloses

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

5. **Limitation [1D]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”**

83. Claim 1 next recites: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers.” It is my opinion that Garrison discloses this limitation.

84. 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.* (emphasis added). Because the valve, for example the stopcock 3325 in Figure 34 above, is distal to the first and second

chambers, the negative pressure is generated in both the first and second chambers. *Id.* at Fig. 34.

85. This particular example includes a flow controller for the valve and a syringe for the pressure source. However, as discussed in the previous section, 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.

86. Garrison also describes some tests that were run on different catheters. As part of the test, Garrison describes generating a negative pressure in a chamber and then releasing the negative pressure by opening a stopcock. Ex. 1006 at [0129], Figs. 56-57. The tested aspiration assemblies had a catheter and a syringe. *Id.* Garrison states:

The catheter and syringe were purged of air, the syringe was emptied, and ***then the stopcock was closed.*** The ***locking syringe was then pulled back*** the full 30 cc volume and locked in place. A timer was started when ***the stopcock was opened***, and the time was noted at 5 cc, 10 cc, 15 cc and 20 cc of extracted solution in they syringe.

Id. (emphasis added). By closing the stopcock before pulling back the syringe, the tester generated a negative pressure in the first chamber (i.e., the syringe chamber). The stopcock was then opened after the user generated the negative pressure to cause rapid aspiration. Thus, Garrison describes closing a valve to

generate negative pressure and opening the valve after the negative pressure is generated in multiple locations in the specification.

6. **Limitation [1E]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”**

87. Claim 1 next recites: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.” It is my opinion that Garrison discloses this limitation.

88. As I discussed in the previous section, Garrison describes generating a negative pressure in the first and second chambers by closing the user-actuated valve (e.g., stopcock valve or flow controller). Once the user generates the negative 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] (emphasis added).

89. As shown in Figure 34, the system is closed so that blood and fluids aspirated through the catheter necessarily flow through the filter/second chamber and into the first chamber. Specifically, the blood aspirated through the catheter [orange] flows through the flow line 2045 [green] and into the second chamber housing the filter [blue]:

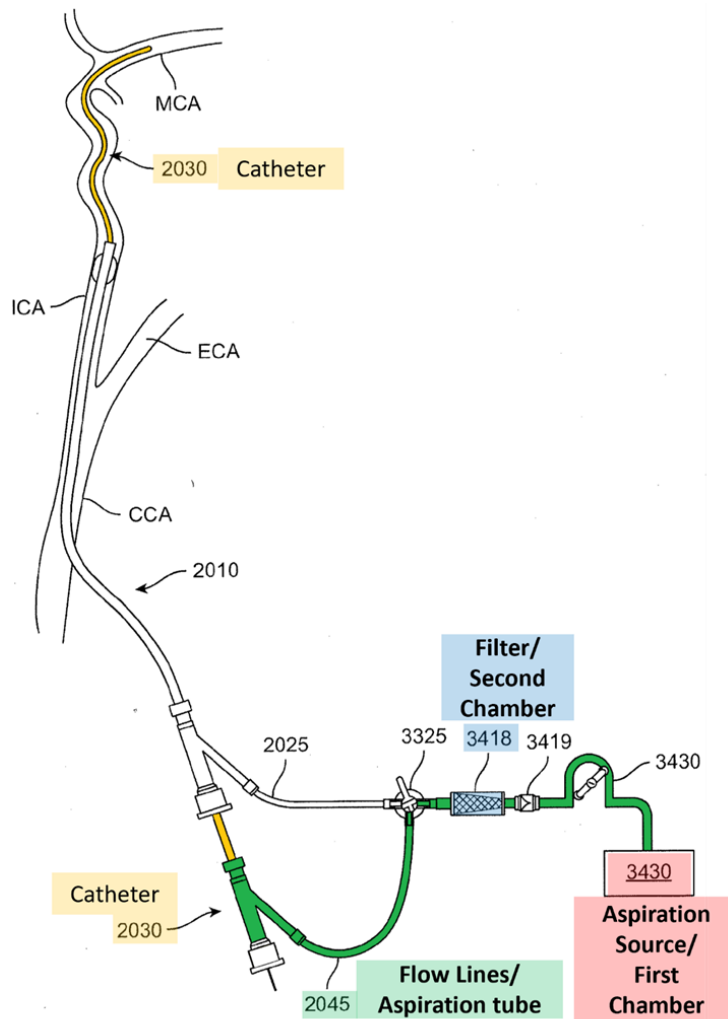


FIG. 34

Id. at Fig. 34; *see also id.* at [0132] (Garrison discloses the “arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow

lines 2025 and 2045, respectively”). The blood then passes through the remainder of the flow line [green] to the first chamber [red]. *Id.*

90. Moreover, when negative pressure is generated in the first and second chambers and the stopcock (or other valve) is initially opened, a rapid movement of blood from the second, filter chamber to the first chamber occurs. Thus, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

91. For all of these reasons, I believe that Garrison anticipates Claim 1. I also believe that Garrison renders Claim 1 obvious. All of the components required to generate negative pressure and rapid aspiration are described in Garrison, and Garrison expressly describes creating rapid aspiration by generating a negative pressure. Garrison presumes that a person of ordinary skill in the art would have understand how to interchange the components to adequately aspirate clot material. Garrison specifically explains:

Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination. Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be

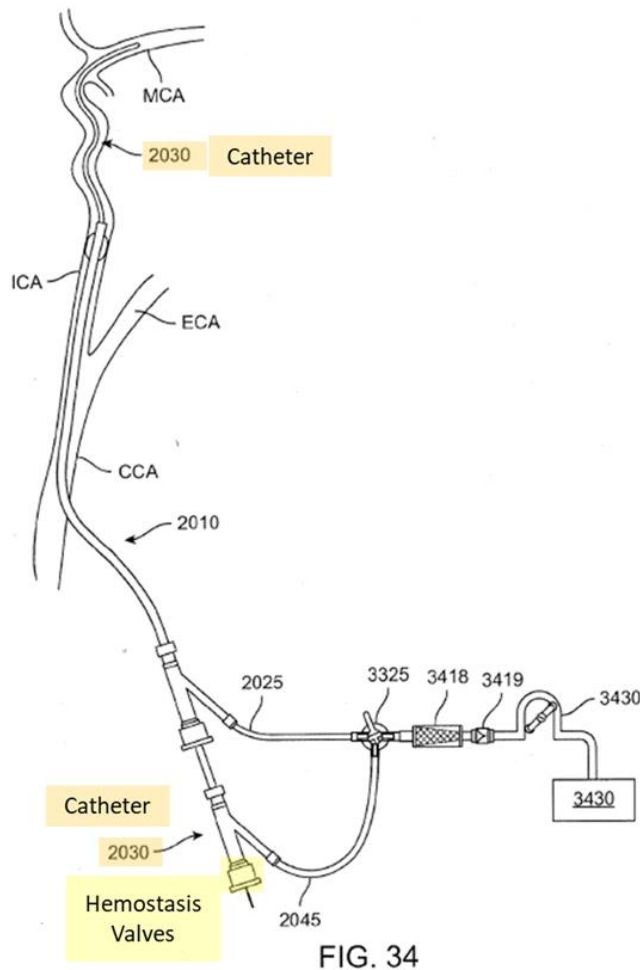
performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.”

Id. at [0175]. Based on my experience, Garrison is correct. A person of ordinary skill in the art would have been familiar with using different types of valves, such as stopcocks, catheters, tubing, and pressure sources and, because these simple devices are predictable, would have expected success in combining these components in different ways. For example, where Garrison specifically discloses an exemplary system that uses a syringe, a person of ordinary skill in the art would have recognized that other pressure sources could be used including, for example, an aspiration pump. Thus, if the Board determines that Garrison does not expressly disclose a limitation in Claim 1, Garrison renders the limitation and thus the claim obvious.

B. Claim 2

92. Claim 2 depends from Claim 1 and recites: “wherein the hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.” It is my opinion that Garrison discloses the additional limitations in Claim 2.

93. As I explained in Claim 1, Garrison discloses a catheter 2030 [orange] having a hemostasis valve [yellow]:



Ex. 1006 (Garrison) at Fig. 34.

94. Garrison states that catheter 2030 may “provide distal access for additional devices, localized fluid or contrast delivery, or localized aspiration at a location distal of the distal-most end of the arterial access device 2010.” *Id.* at [0054]. Garrison expressly discloses that a “second, smaller diameter catheter *may be inserted through the first catheter*” *Id.* (emphasis added). The physician inserts the second, smaller diameter catheter through the hemostasis valve attached to the first catheter because that is the only insertion point for the

second catheter and the purpose of the hemostasis valve is to seal the lumen when other devices are inserted. See Ex. 1006 at [0053] (Garrison explains that the catheter has “a hemostasis valve to allow introduction of devices while preventing or minimizing blood loss during the procedure”). Thus, the hemostasis valve directs the second catheter through the first catheter, as required by Claim 2.

C. Claim 3

95. Claim 3 depends from Claim 2 and recites: “wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter; and a filament extending at least partially around the tubular member, wherein the filament is moveable between (a) a first position wherein the filament circumferentially constricts a lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially open the lumen.” It is my opinion that Garrison combined with Hartley renders Claim 3 obvious.

96. As I recited in Claim 1, Garrison discloses a catheter 2030 having a hemostasis valve. Garrison explains that different types of hemostasis valves can be combined with the catheter, including, for example, “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” Ex. 1006 (Garrison) at [0098]. However, Garrison does not expressly describe the structure of the hemostasis valves. Hemostasis valves

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

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

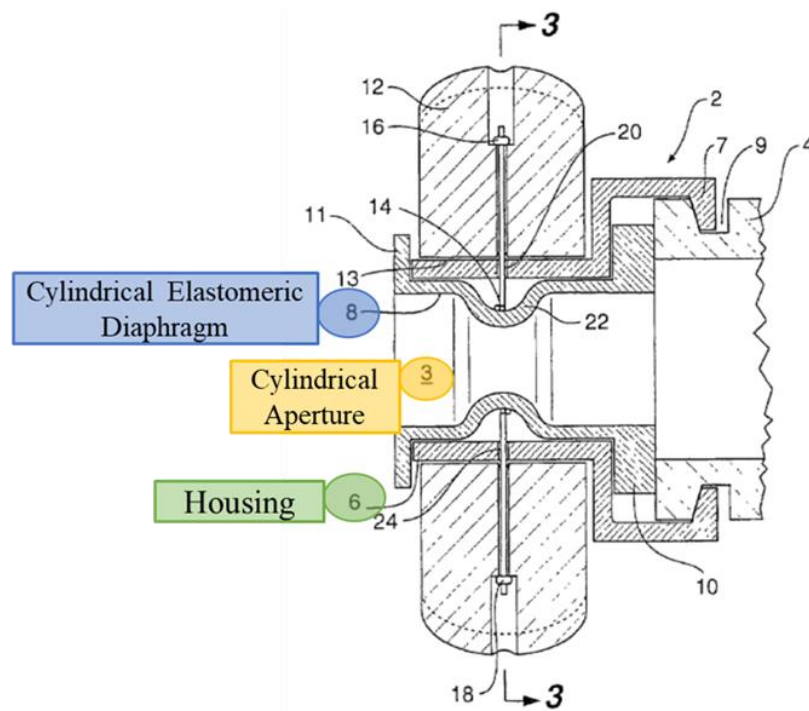
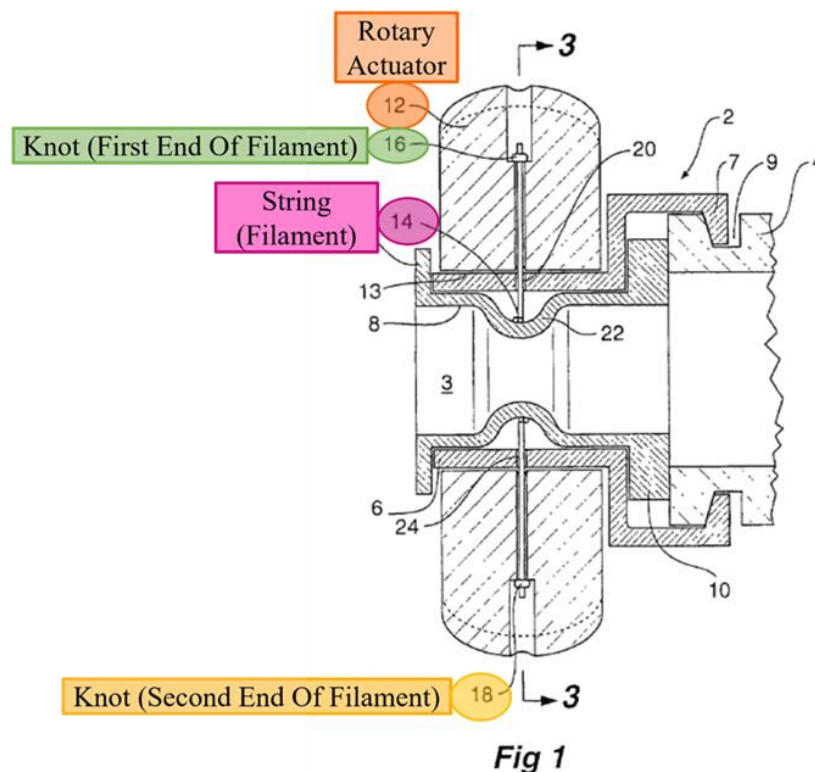


Fig 1

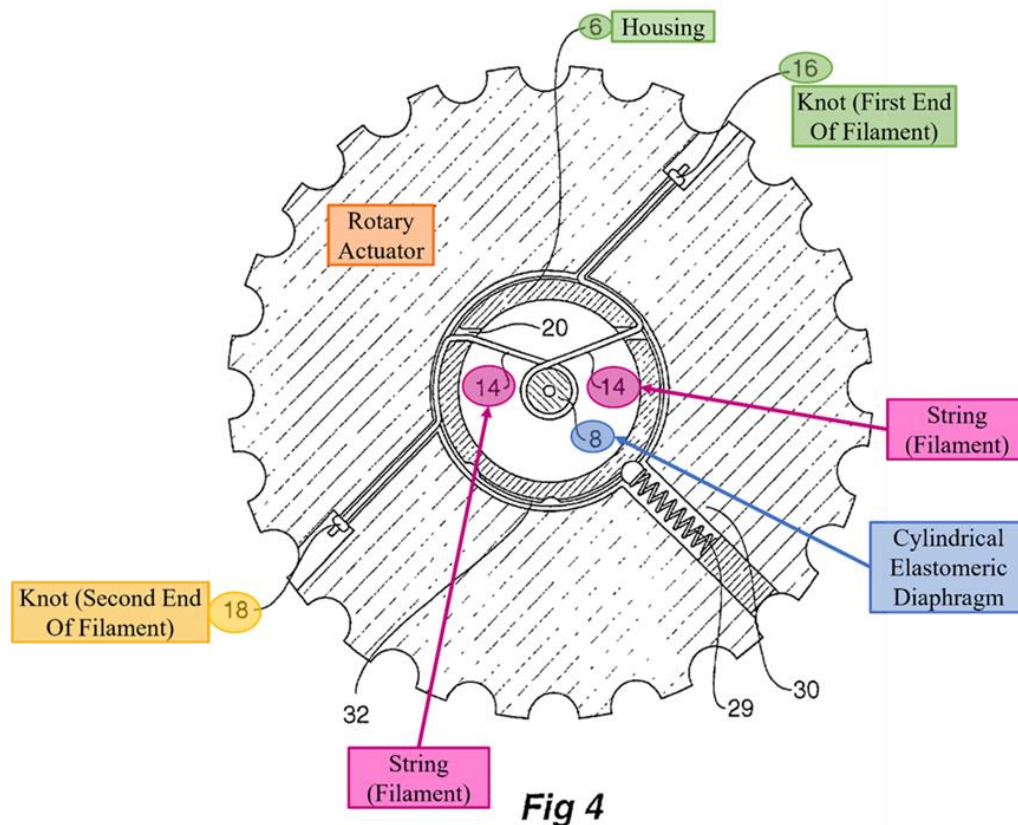
Id. at [0031], Fig. 1. Hartley also explains that the “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” *Id.* at [0006]. Based on this information, I believe that Hartley’s cylindrical diaphragm is “a tubular member defining a lumen configured to slidably receive the second catheter,” as required by Claim 3.

98. Hartley’s valve also includes a rotatory actuator 12 and a “string 14 ... mounted into the rotatory actuator”:



Id. at [0031], Fig. 1. Hartley’s string 14 is a filament because it includes, for example, one or more threads. My claim construction of “filament” is explained in the claim construction section above. *Supra* § IV (titled “Claim Construction”).

99. 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 at [0031], [0034], Fig. 4. This configuration corresponds to the “first position” required by Claim 3 because the filament circumferentially constricts the lumen (i.e., cylindrical elastomeric diaphragm) to create a seal around the second catheter. While Figure 4 above does not show a second catheter inserted through the valve, a person of ordinary skill in the art would have understood that the second catheter would be inserted through the valve. As explained above, Hartley expressly states that the “cylindrical diaphragm can be completely constricted to

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

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

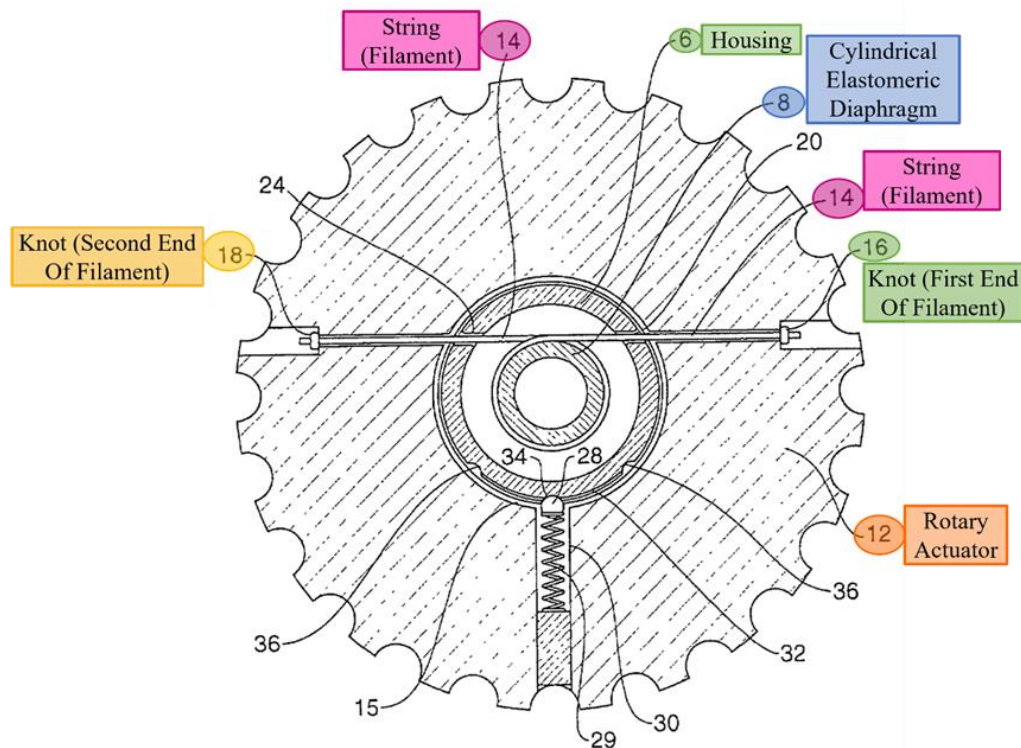


Fig 3

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

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

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

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

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

D. Claim 4

104. Claim 4 depends from Claim 1 and recites: “wherein the second chamber is removably carried by the assembly.” It is my opinion that Garrison renders this claim obvious alone or in combination with Goff.

1. Garrison

105. As I recited in Claim 1, Garrison discloses a second chamber that houses a filter 3418 [blue]:

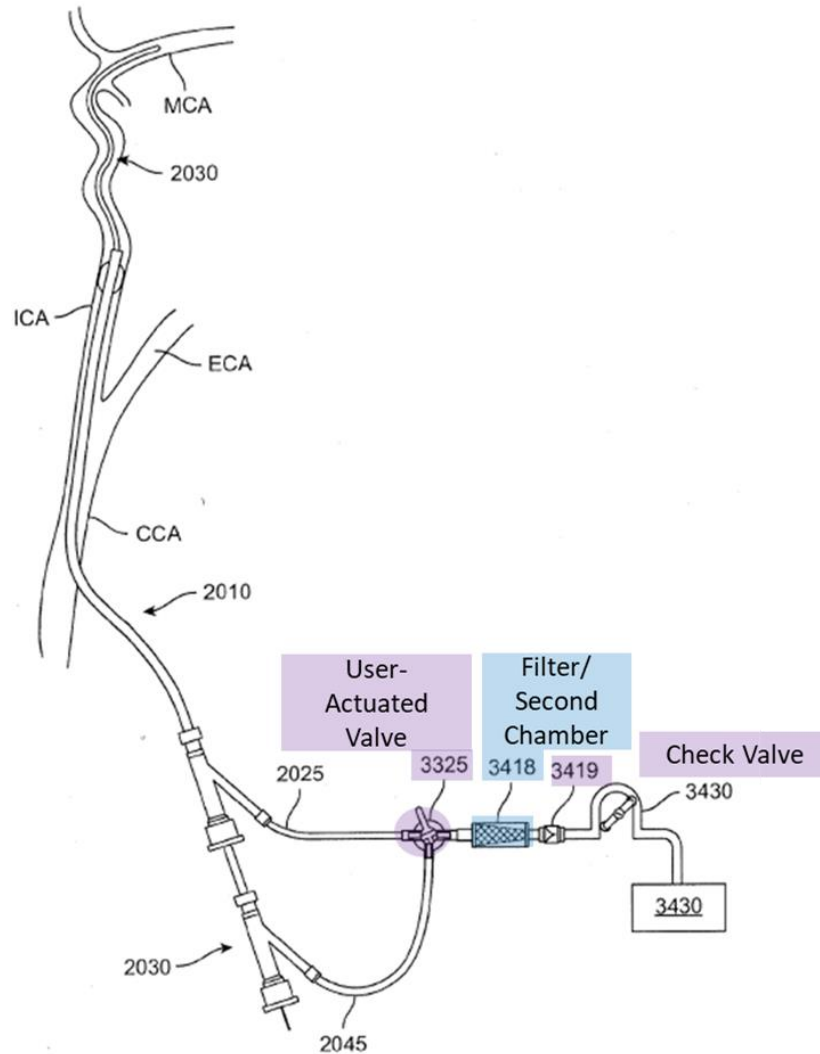


FIG. 34

Supra § VI.A.3 (titled “Limitation [1B]”). The filter (or second chamber) is positioned between the user-actuated valve 3325 (e.g., stopcock) and a check valve 3419. Ex. 1006 (Garrison) at [0131], Fig. 34. Garrison describes the stopcock, filter 3418, and check valve 3419 as optional components the user can

add or remove depending on the procedure. For example, Garrison discloses that a “filter 3418 and/or a check valve 3419 *may* be coupled with flow line 2025.” *Id.* at [0131] (emphasis added).

106. Garrison does not expressly describe how its filter is coupled to the tubing and other components. However, in August 2018, I believe a person of ordinary skill in the art would have found it obvious to couple the filter to the tubing and other components using conventional, removable connectors, such as Luer-type connectors (e.g., Luer slip and Luer lock) and barb connectors. In fact, several of the prior art references I rely on in this report describe these conventional, removable connectors and show that such connectors were widely known before August 2018. *See* Ex. 1006 (Garrison) at [0062], [0065], Fig. 11 (describing and picturing a stopcock with standard female connector); Ex. 1009 (Treretola) at 4:29-40 (describing the use of Luer type connectors for aspiration catheters); Ex. 1001 ('691 patent) at 7:61 (describing a “standard luer connector”), 33:24 (describing a “standard Luer or large bore connector”). In fact, Garrison incorporates by reference patents and publications that describe attaching catheter components using “a conventional Luer fitting” or improved types of Luer fittings. Ex. 1010 (U.S. Patent Publication No. 2010/0042118) at [0130]; *see also* Ex. 1014 (U.S. Patent No. 5,938,645) at 8:45, 8:63 (describing an “auxiliary Luer port”); Ex. 1015 (U.S. Patent Publication No. 2014/0296868) at [0056]-[0059]

(describing improvements to the “standardized ... locking Luer taper design”). Moreover, the ’691 patent acknowledges that Luer type and large bore connectors were known in the art through statements like, “e.g., a standard Luer or large bore connector.” Ex. 1001 (’691 patent) at 33:24; *see also id.* at 7:58-67 (referencing “a standard luer connector”); 34:25-28 (referencing “e.g., a standard Luer or large bore connector”).

107. In my opinion, a person of ordinary skill in the art would have been motivated to use conventional, removable connectors, such as Luer type connectors, to removably connect Garrison’s filter to the aspiration system for several reasons. First, conventional connectors, such as Luer type connectors, allowed physicians to add off-the-shelf components simply and quickly. In my experience, physicians preferred this flexibility because different procedures and patient conditions may require fewer or additional components, as suggested by the many configurations disclosed in Garrison. Based on my experience, I believe physicians would have been motivated to eliminate unnecessary components to avoid the additional cost and complexity caused by more components. I also believe physicians preferred components that had removable connectors that could be easily attached and removed.

108. Second, the conventional connectors available in August 2018 and before came in standard sizes that made them compatible with other catheter-

based medical components, such as tubing and valves. In my experience, physicians preferred this compatibility because it increased the options available to the physician during a procedure. Consequently, persons of ordinary skill in the art were motivated to include these standard connectors on devices where possible.

109. Third, physicians were familiar with the conventional connectors. In my experience, this familiarity meant physicians preferred the standard connectors, such as Luer type connectors, because they reduced the risk of complications and increased the speed for assembling the systems. This physician preference motivated persons of ordinary skill in the art to use conventional connectors. Moreover, persons of ordinary skill in the art would have reasonably expected success in using these conventional, removable connectors, such as Luer-type connectors, with Garrison's optional filter chamber because the connectors were simple, widely used, and predictable. If Garrison's filter included these conventional connectors, then the second chamber would be removably carried by the assembly.

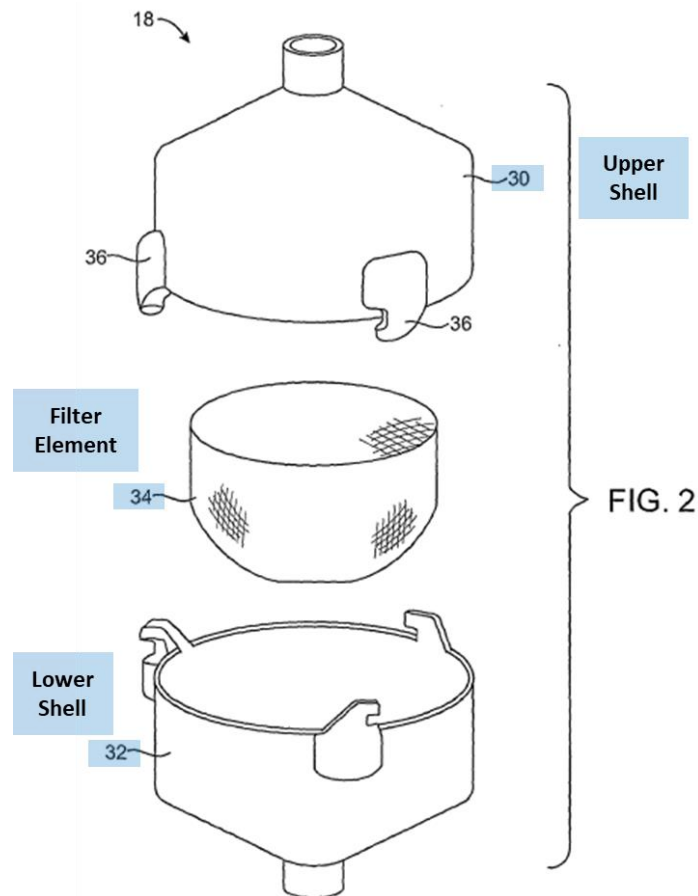
110. Fourth, it is my opinion that combining conventional, removable connectors with Garrison's filter would have merely entailed the combination of known elements (conventional connectors and filter) according to known methods

(coupling medical components with conventional connectors) to yield the predictable result of connecting medical components.

111. A person of ordinary skill in the art would have been motivated to include a removable filter chamber in Garrison's system so that the physician could empty the chamber and clean the filter. Garrison discloses a process for the physician to remove multiple occlusions with Garrison's aspiration system. For example, Garrison states, "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." Ex. 1006 (Garrison) at [0166]. A person of ordinary skill in the art would have recognized that removing multiple occlusions could clog the filter or fill the filter chamber. A person of ordinary skill in the art would have been motivated to removably couple the chamber to the system so that the chamber and/or filter could be cleaned. For these reasons, it is my opinion that Garrison alone renders Claim 4 obvious.

2. Garrison + Goff

112. I also believe that the combination of Garrison and Goff renders Claim 4 obvious. 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":



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].

114. Goff also discloses, “The housing will further have **conventional connectors** to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.” *Id.* at [0015] (emphasis added). As discussed in the prior section, conventional connectors in August 2018 included removable connectors, such as Luer-type connectors and barb connectors. Moreover, Goff expressly states that one advantage of its filter is to provide a

structure where “the separated solid materials be in a convenient structure or assembly to permit easy **removal** and observation.” Ex. 1007 at [0005]. Goff’s stated intention to provide easy removal of the separated solids would have further motivated a person of ordinary skill in the art to removably couple Garrison’s filter to the aspiration system with removable connectors so that the physician could remove the filter and observe the clot material.

115. Alternatively, it is my opinion that a person of ordinary skill in the art would have been motivated to use Goff’s removable filter in Garrison’s aspiration system. Goff’s filter is used for the same purpose as Garrison’s filter – filtering clots from aspirated blood. Ex. 1007 at [0001]. Goff’s filter is also positioned between the aspiration catheter and first chamber/pressure source, like Garrison’s filter. *Id.* at [0025]. Thus, the combination of Goff’s filter with Garrison’s system would have merely entailed the combination of known elements (filter and aspiration system) according to known methods (conventional connectors) to yield the predictable result of filtering aspirated blood.

116. Moreover, the similarities between the Goff and Garrison filters would have given a person of ordinary skill in the art a reasonable expectation of success that Goff’s filter could be incorporated into Garrison’s aspiration system. 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 Garrison's filter (or any aspiration filter). Ex. 1007 at [0011]. For these reasons, it is my opinion that Garrison in combination with Goff renders Claim 4 obvious.

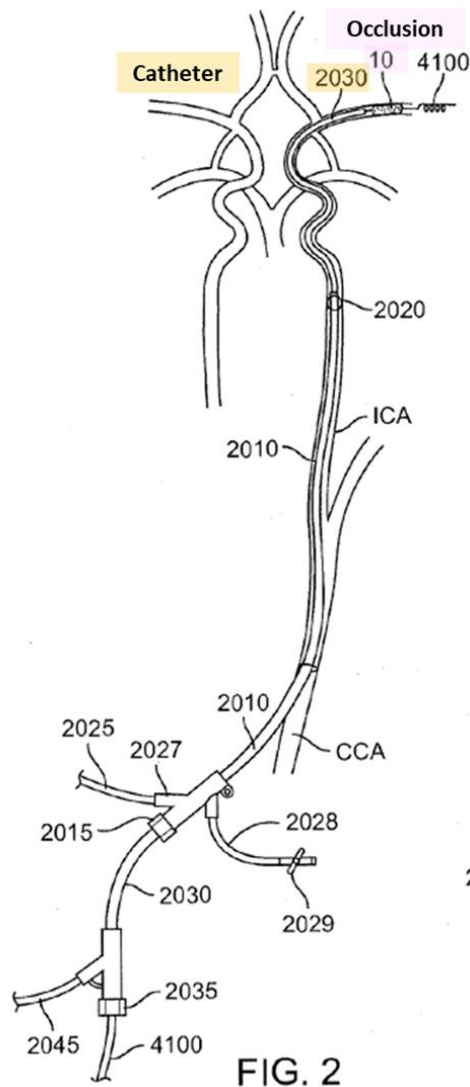
E. Claim 5

117. Claim 5 depends from Claim 1 and recites: "wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient." It is my opinion that Garrison discloses the additional limitations of Claim 5.

118. Garrison discloses a catheter that "has an external dimension that is sized and shaped for insertion into a blood vessel." Ex. 1006 (Garrison) at [0098]. Garrison also discloses that "the catheter may be used to aspirate an occlusion in the blood vessel." *Id.* at [0109]. Garrison illustrates aspiration catheters [orange] positioned intravascularly within the blood vessel of a patient, for example the catheter in Figure 34 extends through the CCA ("common carotid artery"), ICA ("internal carotid artery), and MCA ("middle cerebral artery").

120. Garrison discloses an aspiration catheter with an enlarged “distal-most tip or edge” that “forms an opening,” which may be “used to aspirate a clot in an artery.” Ex. 1006 at [0111]. Garrison states, “the catheter therefore may provide a larger suction force on the occlusion located near the tip.” *Id.*

121. In Figure 2, Garrison shows an aspiration catheter (catheter 2030, orange) with a distal end portion positioned proximate to clot material (thrombus 10, pink) within the blood vessel of the patient:



Id. at Fig. 2, [0050]-[0051]. For these reasons, it is my opinion that Garrison discloses the additional limitations of Claim 6.

G. Claim 7

122. Claim 7 depends from Claim 6 and recites: “wherein the clot material comprises a pulmonary embolism.” Even though this limitation does not define any particular physical attribute of the claimed system, it is my opinion that Garrison anticipates this claim or renders the claim obvious combined with Aklog.

1. Garrison

123. As I explained in Claim 6, Garrison’s aspiration catheter includes a distal end portion configured to be positioned proximate to clot material. While Garrison focuses on the “treatment of cerebral occlusions,” the distal end of Garrison’s catheter is ***configured to be*** positioned proximate other types of clots, including pulmonary embolisms and deep vein thrombosis. Garrison explains that cerebral occlusions are more difficult to treat than occlusions in larger vessels, which would include pulmonary embolisms and DVT, due to “special access challenges.” *Id.* at [0042]. Garrison explains that the “access route is long, often tortuous and may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications during the access portion of the procedure.” *Id.* Additionally, “the cerebral vessels are usually more delicate and prone to perforation than coronary or other

peripheral vasculature.” *Id.* To address these challenges, Garrison describes catheter with small diameters and enhanced flexibility. *Id.*; *see also id.* at [0109] (describing a “very flexible, kink resistant and collapse resistant catheter with a thin wall and large inner diameter”). Thus, while an aspiration catheter designed to treat pulmonary embolisms or DVT may not be configured to be positioned proximate a cerebral embolism due to its size or stiffness, a catheter designed to treat cerebral emboli **is** configured to be positioned proximate emboli in other parts of the vasculature, including pulmonary embolisms and DVT. Moreover, some overlap exists between the size of the vessels having a pulmonary embolism or DVT and a cerebral occlusion. For example, the MCA, ICA, and ECA can each have a similar diameter to some deep veins in the leg. A smaller diameter, more flexible catheter typically used to treat cerebral occlusions could be used effectively to treat pulmonary embolisms and DVT that are challenging to access or reside in smaller blood vessels of the lungs or legs.

124. Garrison also discloses insertion techniques that could be used to position a catheter proximate a pulmonary embolism or DVT. For example, Garrison discloses using “transfemoral or transcarotid access approaches” to reach the targeted emboli. Ex. 1006 (Garrison) at [0048]. Similar procedures can be used to access the femoral vein to reach a pulmonary embolism or DVT. For example, the ’691 patent explains, “Access to the pulmonary vessels can be

achieve through the patient's vasculature, for example, via the femoral vein." Ex. 1001 at 17:7-8. Likewise, Aklog explains, "The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein." Ex. 1005 (Aklog) at 15:30-34. As explained above, Garrison discloses percutaneous access of the blood vessels. For these reasons, it is my opinion that Garrison discloses the limitations of Claim 7.

2. Garrison and Aklog

125. Claim 7 requires an aspiration system having a distal end portion of the catheter "configured to be positioned proximate" a pulmonary embolism. The claim does not recite a method of treating a pulmonary embolism. Thus, it is my opinion that Garrison discloses the limitations of Claim 7 for the reasons I provided in the prior section. However, if Claim 7 requires treating a pulmonary embolism, it is my opinion that a person of ordinary skill in the art would have found it obvious to position the distal end of Garrison's aspiration system (with any necessary modifications) proximate a pulmonary embolism within the blood vessel of the patient based on Aklog and the knowledge of a person of ordinary skill in the art.

126. Aklog discloses an aspiration system for removing clot material from different parts of the 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 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. A person of ordinary skill in the art would have been motivated to position the distal end of Garrison’s aspiration catheter proximate a pulmonary embolism and, to the extent necessary, adapt 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 adapt, the existing and proven technology described in Garrison to treat similar conditions in other parts of the vasculature.

127. 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. Like Garrison, Aklog's aspiration system includes a suction cannula 10 [orange] that is inserted into a patient's artery or vein until the end of the cannula is proximate the clot material, such as a pulmonary embolism. *Id.* at 5:28-41, 11:62-65, 13:64-14:2; *see also id.*, Fig. 2C, 7:8:20-44 (showing the cannula proximate a clot).

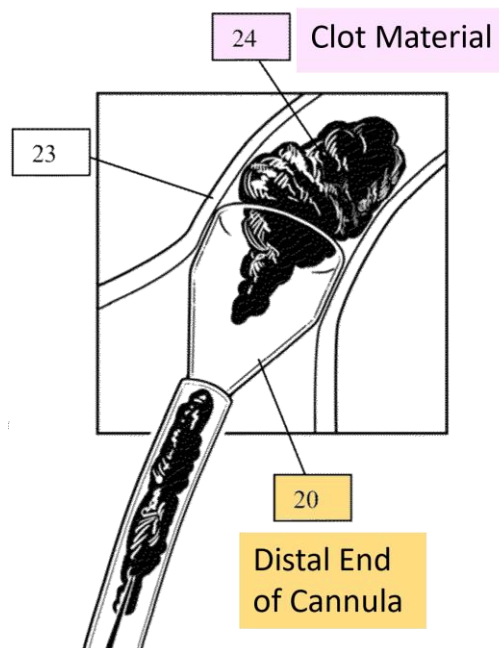


Fig. 2C

(*Id.*, Fig. 2C.) Also, like Garrison, the suction cannula is connected to a filter 14 [blue], a reservoir 61 [green], and a pump 15 [red] that provides “a sufficient suction force for removing the undesirable material from the site of interest.” *Id.*

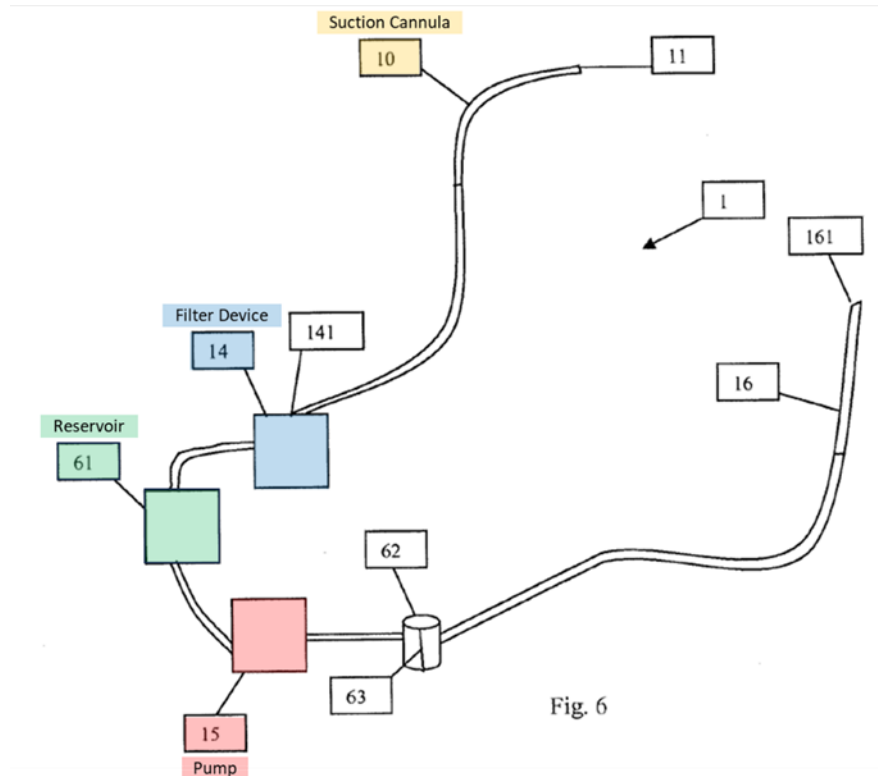


Fig. 6

Id. at Fig. 6-7.) Additionally, both systems are inserted into the patient in the same way (e.g., percutaneously through the femoral artery or vein). *Id.* 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.

128. 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, 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 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.

129. Aklog also describes one challenge person 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.

130. 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.

131. 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.

132. Garrison specifically suggests combining components with its aspiration systems that come from aspiration system 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)).

133. 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.

134. 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).

135. Even the challenged '691 Patent acknowledges that a person of ordinary skill in the art would have understood that aspiration systems for one part of the vasculature could be adapted for other portions of the vasculature. For example, the '691 patent explains, “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 at 4:41-58 (emphasis added). The '691 patent does not identify any reason why its aspiration catheters can be used interchangeability across different parts of the vasculature while other aspiration catheters would not. Rather, the '691 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 2:2-7.

136. 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 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 Aklog and the knowledge of a person of ordinary skill in the art.

H. Claim 8

137. Claim 8 depends from Claim 6 and recites: "wherein the clot material comprises a deep vein thrombus." Even though this limitation does not define any particular physical attribute of the claimed system, it is my opinion that Garrison anticipates this claim or renders it obvious combined with Aklog and the knowledge of a person of ordinary skill in the art.

138. In Claim 7, I explained that the distal end portion of Garrison's aspiration catheter is ***configured*** to be placed proximate cerebral occlusions, as well as other types of clot material including PE and DVT. I believe Garrison discloses the limitations of Claim 8 for the reasons I identified in Claim 7.

139. Moreover, Claim 8, like Claim 7, merely requires the distal end portion of the claimed catheter be "configured to be positioned proximate" a DVT

– the claim does not recite a method of treating a DVT. This is the reason Garrison discloses the limitations of Claim 8. However, if Claim 8 requires aspirating a DVT, it is my opinion a person of ordinary skill in the art would have found it obvious to position the distal end of Garrison’s aspiration system proximate a DVT within the blood vessel of the patient (with any necessary modifications) based on Aklog and the knowledge of a person of ordinary skill in the art.

140. As I explained in discussing Claim 7, Aklog discloses an aspiration system for removing clot material from different parts of the 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 (emphasis added). Aklog discloses that blood clots in the large veins of the legs and pelvis are “known as deep venous thrombosis (DVT)” and, as indicated by the quote above, Aklog’s aspiration system treats this condition. *Id.* at 2:7-19. It is my opinion that a person of ordinary skill in the art would have been motivated to position the distal end portion of Garrison’s catheter proximate a DVT, and to the extent necessary adapt Garrison’s system to treat DVT. Garrison’s system is already designed to aspirate clots and Aklog explains that DVT cause “swelling, ulcers, pain and infection” and lead to embolisms in other

parts of the body. *Id.* at 2:20-32. A person of ordinary skill in the art would have been motivated to adapt Garrison’s existing and proven aspiration technology to treat DVT, and expected success in doing so, for the same reasons such a person would have adapted Garrison’s system to treat pulmonary embolisms.

I. Claim 9

141. Claim 9 depends from Claim 1 and recites: “wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.” It is my opinion that Garrison renders Claim 9 obvious alone or in combination with Goff.

142. As I explained above concerning Claims 1 and 4, Garrison discloses a second chamber between the aspiration pump and aspiration catheter. *Supra* § VI.A.3 (titled “Limitation [1B]”) and § VI.D (titled “Claim 4”). For the reasons provided in Claim 4, a person of ordinary skill in the art would have found it obvious to removably couple Garrison’s second chamber (i.e., filter 3418) to the flow lines 2025/2045 and related components. *Supra* § VI.D (titled “Claim 4”).

143. Additionally, a person of ordinary skill in the art would have found it obvious to modify Garrison’s second chamber/filter to be removably coupled, or to use the removable chamber in Goff, for the reasons provided in Claim 4. *Supra* § VI.D (titled “Claim 4”).

J. Claim 10

144. Claim 10 depends from Claim 1 and recites: “further comprising a filter in the second chamber.” It is my opinion that Garrison discloses the limitation in Claim 10.

145. Garrison discloses a filter 3418, which may be coupled to the assembly with flow line 2025 and/or flow line 2045. Ex. 1001 at [0131]. As I explained in Claim 1 and as shown in FIG. 34, the filter 3418 is enclosed in a second chamber. *Supra* § VI.A.3 (titled “Limitation [1B]”).

K. Claim 11

146. Claim 11 depends from Claim 10 and recites: “wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” It is my opinion that Garrison anticipates this claim or renders it obvious alone or in combination with Goff.

1. Garrison

147. As I explained in Claim 1, Garrison discloses a filter 3418. Ex. 1006 at [0131]. However, Garrison does not expressly describe the filter construction and instead presumes a person of ordinary skill in the art would have possessed the knowledge to select an appropriate filter. A person of ordinary skill in the art would have recognized that Garrison’s filter must necessarily have a plurality of

pores to inhibit clot material from flowing through the valve. Afterall, the purpose of Garrison's filter is to remove clot material from the aspirated blood as it flows through the filter.

148. Even if Garrison's filter does not inherently disclose this limitation, it is my opinion that Garrison renders the limitation obvious in combination with the knowledge of a person of ordinary skill in the art. Conventional filters available in August 2018 (and well before) typically included pores sized to inhibit certain diameters of material from flowing through the filter. For example, Aklog describes a filter for its aspiration system having a "permeable sheet 143 positioned with the fluid flow" Ex. 1005 (Aklog) at 11:33-35. Aklog states that the "[p]ermeable sheet 143 ... may include a **plurality of pores** sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing undesirable material captured from the site of interest from moving downstream" *Id.* at 11:36-40. A person of ordinary skill in the art would have expected Garrison's aspiration system to have similar pores because the filters serve the same purpose. Additionally, a person of ordinary skill in the art implementing Garrison's aspiration system would have found it obvious to select pore sizes to remove clot material, as described in Aklog.

149. A person of ordinary skill in the art would have reasonably expected success in implementing a filter having a plurality of pores sized to inhibit clot

material from flowing therethrough because that is the purpose of Garrison's filter, and, generally speaking, any filter. See Ex. 1006 12:35-37 ("filtered fluid can be reinfused back into the body"). Further, filters were commonly used in medical devices in August 2018 and would have been well understood by persons of ordinary skill in the art such that they would have produced predictable results. In my experience developing cardiovascular devices, I am familiar with embolic filters, and in all cases, the filters had pores that were optimized by the engineering team to filter out the desired material. For these reasons, it is my opinion that Garrison discloses the limitations of Claim 11 or renders Claim 11 obvious.

2. Garrison + Goff

150. I am also of the opinion that Goff describes a filter that meets the limitations of Claim 11. I included a picture of Goff's filter in Claim 4. *Supra* § VI.D.2 (titled "Garrison + Goff"). Goff confirms that a person of ordinary skill in the art would have been familiar with filters, stating the "filter element may be any conventional filter element, such as paper, polymer, a woven filter membrane, a screen, or other porous member, or the like." Ex. 1007 at [0011]. Goff further explains, "The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff." *Id.* Goff provides examples of suitable pore sizes (e.g., "1 μm to 1000 μm "). *Id.*

151. A person of ordinary skill in the art would have been motivated to use Goff's pore sizes for Garrison's filter or, alternatively, use Goff's filter in Garrison, because Goff's pore sizes are suitable to "separate solid particles at a desired particle size cutoff" and "will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed." Ex. 1007 (Goff) at [0011]. Also, combining Goff's filter with Garrison's aspiration system would have merely entailed the combination of known elements (Goff's filter and Garrison's system) according to known methods (positioning the filter within a chamber in line with the system) to yield the predictable result of removing unwanted particles from the aspirated blood.

152. A person of ordinary skill in the art would have reasonably expected success in incorporating Goff's pore sizes, or Goff's filter, into Garrison because Goff's filter is used to filter emboli from blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art.

L. Claim 12

153. Claim 12 depends from Claim 10 and recites: "wherein the filter is removable from within the second chamber." It is my opinion that Garrison alone or in combination with Goff renders this claim obvious.

1. Garrison

154. As explained in Claim 1, Garrison discloses a filter 3418 within a second chamber but does not expressly state whether the filter is removable from the second chamber. Ex. 1006 at [0131], Fig. 34; *supra* § VI.A.3 (titled “Limitation [1B]”).

155. However, it is my opinion that a person of ordinary skill in the art would have found it obvious to configure Garrison’s second chamber so that the filter is removable. A person of ordinary skill in the art would have been motivated to make Garrison’s filter removable so that the filter could be easily replaced or cleaned then reinserted. As mentioned in Claim 4, Garrison discloses that a physician can use the system to remove multiple clots. Ex. 1006 at [0166]. A person of ordinary skill in the art would have recognized that multiple clots could clog the system and require cleaning or replacement of the filter. *Supra* § VI.D.2 (titled “Garrison + Goff”). For this reason, a person of ordinary skill in the art would have been motivated to configure the filter chamber so that it could be opened to permit removal or cleaning of the filter. The filters shown in the below examples from the prior art shows filter chambers that can be unscrewed (left) or unclasped (right). These references demonstrate that removable filters were well known in the art.

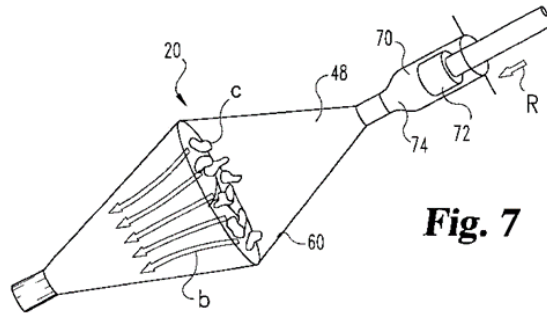


Fig. 7

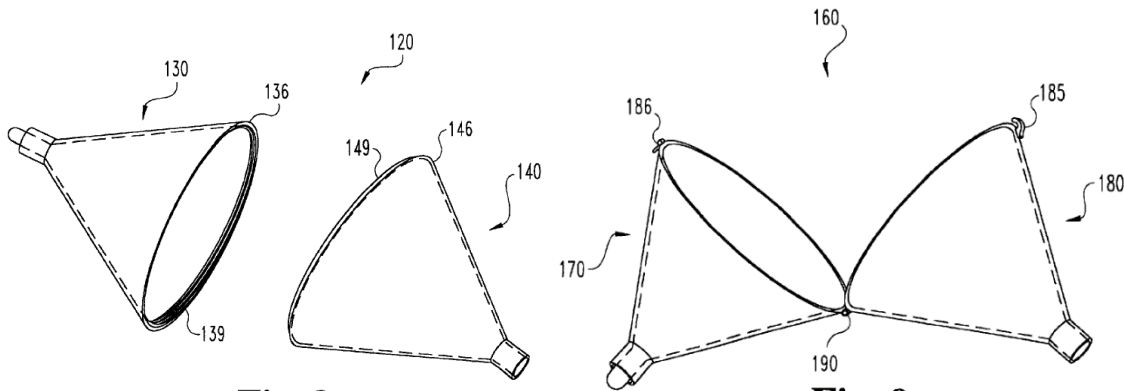


Fig. 8

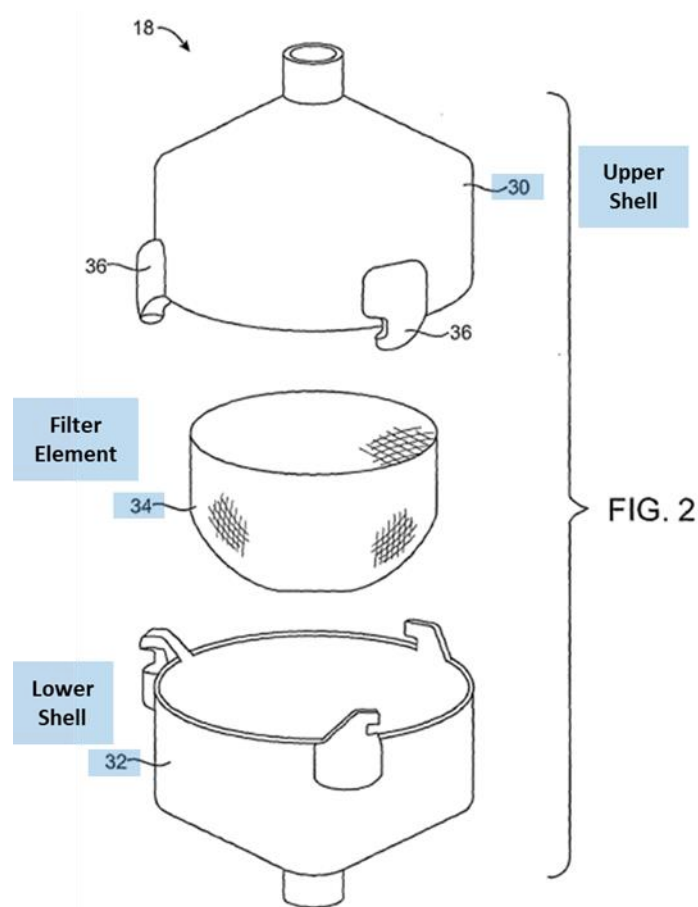
Fig. 9

Ex. 1009 (Treretola) at 5:65-6:10, Figs. 7-9; *see also* Ex. 1007 (Goff) at [0025] (describing a filter chamber that can be opened to remove the filter). A person of ordinary skill in the art would have reasonably expected success in incorporating such chambers into Garrison because the chambers involve simple and predictable mechanical parts (e.g., hinge, clip, interlocking tabs, or screw threads) that would have been well understood by persons of ordinary skill in the art.

2. **Garrison + Goff**

156. It is my opinion that Garrison in combination with Goff also renders this claim obvious. As I explained above with respect to Claim 4, Goff's "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”:



Ex. 1007 at [0025], Fig. 2. Goff also states, “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] (emphasis added). It is my opinion that a person of ordinary skill in the art would have been motivated to use Goff’s filter in Garrison’s aspiration system because it would have permitted to physician to clean or replace a clogged filter. *See supra* § VI.D (titled “Claim 4”) (describing motivation to combine Garrison and Goff).

Goff also explains, “The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff,” which a person of ordinary skill in the art would have recognized would be useful in Garrison’s system. Ex. 1007 at [0011]. Further, it is my opinion that combining Goff’s filter with Garrison’s aspiration system would have merely entailed the combination of known elements (Goff’s filter and Garrison’s system) according to known methods (positioning the filter within a chamber in line with the system) to yield the predictable result of removing unwanted particles from the aspirated blood.

157. It is my opinion that a person of ordinary skill in the art would have reasonably expected success in incorporating Goff’s removable filter into Garrison because Goff’s filter is used to filter blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art. For these reasons, it is my opinion that Garrison in combination with Goff renders Claim 12 obvious.

M. Claim 13

158. Claim 13 depends from Claim 1 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” It is my opinion that Garrison discloses this limitation.

159. Garrison discloses a second chamber that houses filter 3418, which is fluidically coupled in serial to the first chamber in the aspiration source with flow line 2025 and/or flow line 2045 [green]. Ex. 1006 at [0131], Fig. 34.

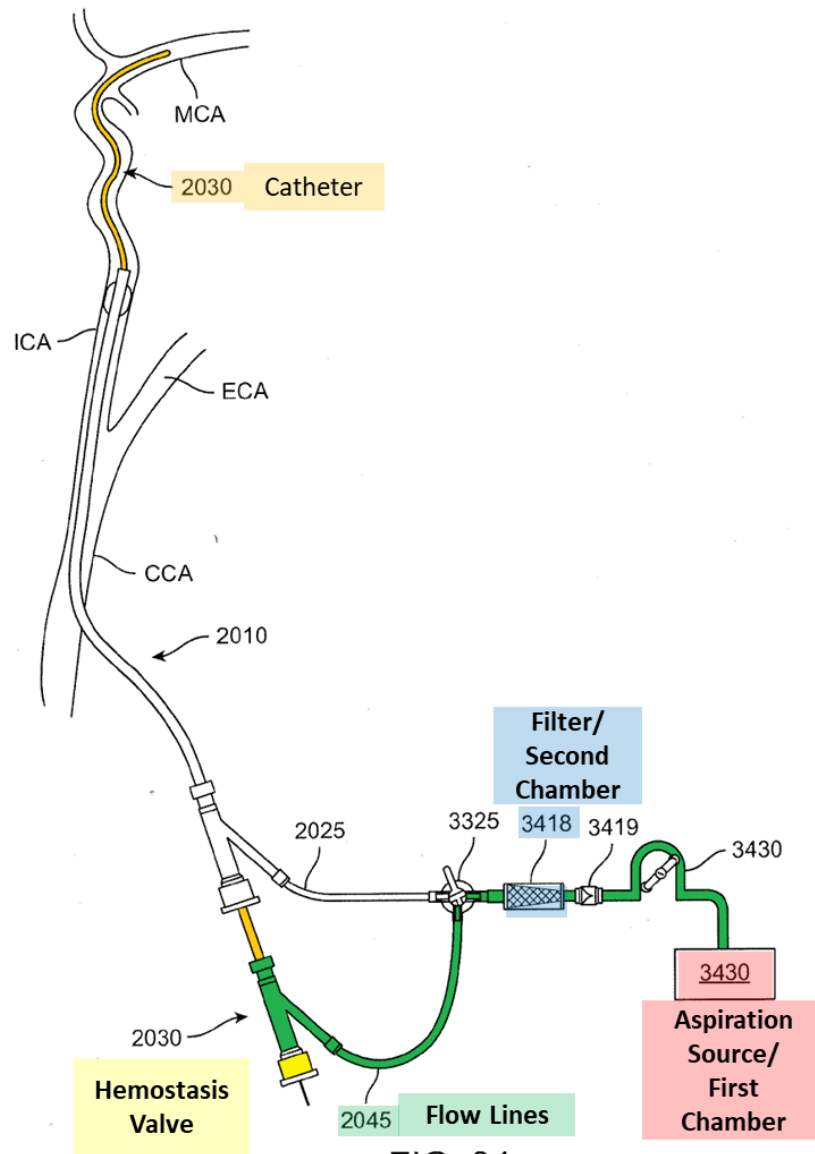


FIG. 34

Ex. 1006 at Fig. 34; *see also* Fig. 32 (shows receptacle fluidly coupled in serial with second chamber). For these reasons, Garrison discloses the limitations in Claim 13.

N. **Independent Claim 14**

160. Claim 14 combines the limitations of Claim 1 and Claim 9 (*see* Limitation [14C] below for the combination of Claim 9). Thus, it is my opinion that Claim 14 is rendered obvious by Garrison alone or in combination with Goff for the reasons explained in Claims 1 and 9.

1. **Preamble [14]: “An aspiration system with accelerated response, comprising”**

161. The preamble of Claim 14 recites: “An aspiration system with accelerated response, comprising.” This same preamble also appears in Claim 1. If the preamble is limiting, Garrison discloses this limitation for the reasons I provided in Claim 1. *Supra* § VI.A.1 (titled “Preamble [1]”).

2. **Limitation [14A]: “an aspiration pump in communication with a first chamber”**

162. Claim 14 next recites: “an aspiration pump in communication with a first chamber.” This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons I provided in Claim 1. *Supra* § VI.A.2 (titled “Limitation [1A]”).

3. **Limitation [14B]: “an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;”**

163. Claim 14 next recites: “an aspiration catheter configured for placement into fluid communication with the first chamber by way of an

aspiration tube.” This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons I provide in Claim 1. *Supra* § VI.A.3 (titled “Limitation [1B]”).

4. **Limitation [14C]: “a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter”**

164. Claim 14 next recites: “a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.” This limitation combines limitations from Claim 1 and Claim 9. Garrison renders this limitation obvious alone or in combination with Goff for the reasons I provided in Claims 1 and 9. *Supra* § VI.A.3 (titled “Limitation [1B]”), § VI.D (titled “Claim 4”), § VI.I (titled “Claim 9”).

5. **Limitation [14D]: “a user-actuatable valve between the second chamber and the aspiration catheter”**

165. Claim 14 next recites: “a user-actuatable valve between the second chamber and the aspiration catheter.” This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons I provide in Claim 1. *Supra* § VI.A.4 (titled “Limitation [1C]”).

6. **Limitation [14E]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”**

166. Claim 14 next recites: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers.” This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons I provide in Claim 1. *Supra* § VI.A.5 (titled “Limitation [1D]”).

7. **Limitation [14F]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”**

167. Claim 14 next recites: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.” This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons I provided in Claim 1. *Supra* § VI.A.6 (titled “Limitation [1E]”).

O. Claim 15

168. Claim 15 depends from Claim 14 and recites: “further comprising a filter in the second chamber.” This is the same limitation found in Claim 10, and it is my opinion that Garrison discloses the limitation for the reasons I provided in Claim 10. *Supra* § VI.J (titled “Claim 10”).

P. Claim 16

169. Claim 16 depends from Claim 15 and recites: “wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” This is the same limitation found in Claim 11, and it is my opinion that Garrison discloses the limitation or renders the limitation obvious alone or in combination with Goff for the reasons I provided in Claim 11. *Supra* § VI.K (titled “Claim 11”).

Q. Claim 17

170. Claim 17 depends from Claim 15 and recites: “wherein the filter is removable from within the second chamber.” This is the same limitation found in Claim 12, and it is my opinion that Garrison renders the limitation obvious alone or in combination with Goff for the reasons I provided in Claim 12. *Supra* § VI.L (titled “Claim 12”).

R. Claim 18

171. Claim 18 depends from Claim 14 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This is the same limitation found in Claim 13, and it is my opinion that Garrison discloses the limitation for the reasons I provided in Claim 13. *Supra* § VI.M (titled “Claim 13”).

S. Claim 19

172. Claim 19 depends from Claim 14 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.” This is the same limitation found in Claim 5, and it is my opinion that Garrison discloses the limitation for the reasons I provided in Claim 5. *Supra* § VI.E (titled “Claim 5”).

T. Claim 20

173. Claim 20 depends from Claim 19 and recites: “wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.” This is the same limitation found in Claim 6, and it is my opinion that Garrison discloses the limitation for the reasons I provided in Claim 6. *Supra* § VI.F (titled “Claim 6”).

U. Claim 21

174. Claim 21 depends from Claim 20 and recites: “wherein the clot material comprises a pulmonary embolism.” This is the same limitation found in Claim 7. It is my opinion that Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons I provided in Claim 7. *Supra* § VI.G (titled “Claim 7”).

175. Further, the modification of Garrison’s system to include Goff’s removable filter chamber and/or removable filter would not impact the positioning of Garrison’s catheter proximate a pulmonary embolism or DVT, or Garrison’s further adaptation to treat pulmonary embolisms or DVT. Goff discloses that its removable filter is appropriate for filtering unwanted material from fluids aspirated from many different parts of the body. Ex. 1007 (Goff) at [0008] (“The fluid may be aspirated from a variety of hollow body organs and other structures, including blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile, ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like.”). Likewise, Goff discloses that the filter can have a range of pore sizes depending on the application and can be used to filter aspirated blood. *Id.* at [0008], [0011]. Thus, Goff would be appropriate for treating clots removed from all portions of the vasculature, including pulmonary embolisms and DVT.

V. Claim 22

176. Claim 22 depends from Claim 20 and recites: “wherein the clot material comprises a deep vein thrombus.” This is the same limitation found in Claim 8. It is my opinion that Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claim 8. *Supra* § VI.H (titled “Claim 8”).

W. Independent Claim 23

177. Independent Claim 23 combines the limitations of Claims 1-3 with one modification. Claim 23 requires “fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter,” which is different from the limitation in Claim 1 (“fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”). However, this change does not meaningfully differentiate Claims 1 and 23. When the physician opens the user-actuated valve after building up negative pressure in the first and second chambers, the system causes a rapid decrease in pressure in the aspiration catheter because the material in the catheter is being suctioned into the first and second chambers. This rapid decrease in pressure causes the rapid aspiration of clot material through the catheter. Thus, Garrison combined with Hartley renders Claim 23 obvious for the reasons provided in Claims 1-3. *Supra* §§ VI.A-C.

X. Claim 24

178. Claim 24 depends from Claim 23 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or deep vein thrombus.” Claim 24 combines the limitations of Claims 5-6 and 7 or 8. It is my opinion that Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claims 5-8. *Supra* §§ VI.E-H.

179. Also, it is my opinion that the modification of Garrison’s system to include Hartley’s hemostasis valve would not impact Garrison’s further adaptation to treat pulmonary embolisms or DVT. Hartley generally describes a hemostasis valve for use with “medical devices” to “prevent loss of blood or other fluid.” Ex. 1008 at [0002]-[0003]. Hartley is not limited to medical devices for use in a particular part of the anatomy. Thus, Hartley would be appropriate for aspiration catheters for use in all portions of the vasculature, including catheters for treating pulmonary embolisms and DVT.

Y. Claim 25

180. Claim 25 depends from Claim 23 and recites: “wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.” This is the same limitation in Claim 9, and it is my opinion that Garrison renders this limitation obvious alone or in combination with Goff for the reasons provided in Claim 9. *Supra* §§VI.D (titled “Claim 4”), VI.I (titled “Claim 9”).

181. Further, it would have been obvious for a person of ordinary skill in the art to have used Goff’s removable filter with Hartley’s hemostasis valve in an aspiration catheter. As explained above, Goff and Hartley both describe devices for use in a range of medical procedures and across all portions of the vasculature. Thus, Hartley would be appropriate for aspiration systems that also incorporate Goff’s removable filter.

Z. Claim 26

182. Claim 26 depends from Claim 23 and recites: “further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.” This claim combines the limitations of Claims 10 and 12, and it is my opinion that Garrison alone or in combination with Goff renders this claim obvious for the reasons I provided in Claims 10 and 12. *Supra* §§VI.J (titled “Claim 10”), VI.L (titled “Claim 12”).

AA. Claim 27

183. Claim 27 depends from Claim 23 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This limitation also appears in Claim 13, and it is my opinion that Garrison discloses this limitation for the reasons provided in Claim 13. *Supra* §VI.M (titled “Claim 13”).

BB. Independent Claim 28

184. Claim 28 combines the limitations of Claims 1 and 9, as well as the last limitation of Claim 23 requiring “fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.” It is my opinion that Claim 28 is rendered obvious by Garrison alone or in combination with Goff for the reasons I provided in Claims 1, 9, and 23. *Supra* §§VI.A (titled “Claim 1), VI.I (titled “Claim 9”), VI.W (titled “Claim 23”).

CC. Claim 29

185. Claim 29 depends from Claim 28 and recites: “further comprising a filter in the second chamber, wherein the filter is removable from the second chamber.” This claim combines the limitations of Claims 10 and 12, and it is my opinion that Garrison alone or in combination with Goff renders this claim obvious for the reasons I provided in Claims 10 and 12. *Supra* §§VI.J (titled “Claim 10”), VI.L (titled “Claim 12”).

DD. Claim 30

186. Claim 30 depends from Claim 28 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This limitation also appears in Claim 13, and it is my opinion that Garrison discloses this limitation for the reasons provided in Claim 13. *Supra* §VI.M (titled “Claim 13”).

EE. Claim 31

187. Claim 31 depends from Claim 28 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or deep vein thrombus.” Claim 31 combines the limitations of Claims 5-6 and 7 or 8. It is my opinion that Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claims 5-6 and 7 or 8. *Supra* §§VI.E-H.

VII. SECONDARY CONSIDERATIONS

188. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '691 patent.

189. Further, because the devices claimed in the '691 patent are not new, and were invented long before August 2018, I am not aware of any long-felt need

in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

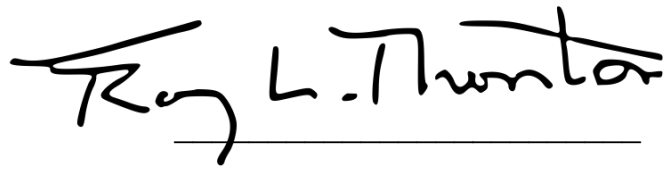
VIII. CONCLUSION

190. For the foregoing reasons, it is my opinion that Claims 1-31 of the '691 patent are not patentable because they would have been anticipated by or 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.

191. 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.

192. 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 July 18, 2024 in Glen Ellen, CA.

A handwritten signature in black ink, reading "Troy L. Thornton". The signature is written in a cursive style with a horizontal line underneath the name.

Troy Thornton